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111TH CONGRESS
1st Session

HOUSE OF REPRESENTATIVES

REPT. 111–299
Part 1

AMERICA'S AFFORDABLE HEALTH CHOICES ACT OF 2009

R E P O R T

OF THE

COMMITTEE ON ENERGY AND COMMERCE

ON

H.R. 3200

together with

DISSENTING VIEWS

OCTOBER 14, 2009.—Ordered to be printed

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AMERICA'S AFFORDABLE HEALTH CHOICES ACT OF 2009

OCTOBER 14, 2009.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. WAXMAN, from the Committee on Energy and Commerce, submitted the following

R E P O R T

together with

DISSENTING VIEWS

[To accompany H.R. 3200]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 3200) to provide affordable, quality health care for all Americans and reduce the growth in health care spending, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

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AMENDMENT

The amendment is as follows:

Strike all after the enacting clause (other than sections 321 and 322, title IV of division A, subtitle A of title I of division B, and title VIII of division B) and insert the following:

SECTION 1. SHORT TITLE; TABLE OF DIVISIONS, TITLES, AND SUBTITLES.

(a) SHORT TITLE.—This Act may be cited as the "America's Affordable Health Choices Act of 2009".

(b) TABLE OF DIVISIONS, TITLES, AND SUBTITLES.—This Act is divided into divisions, titles, and subtitles as follows:

DIVISION A—AFFORDABLE HEALTH CARE CHOICES

TITLE I—PROTECTIONS AND STANDARDS FOR QUALIFIED HEALTH BENEFITS PLANS
Subtitle A—General Standards
Subtitle B—Standards Guaranteeing Access to Affordable Coverage
Subtitle C—Standards Guaranteeing Access to Essential Benefits
Subtitle D—Additional Consumer Protections
Subtitle E—Governance
Subtitle F—Relation to Other Requirements; Miscellaneous
Subtitle G—Early Investments
TITLE II—HEALTH INSURANCE EXCHANGE AND RELATED PROVISIONS
Subtitle A—Health Insurance Exchange
Subtitle B—Public Health Insurance Option
Subtitle C—Individual Affordability Credits
Subtitle D—Health Insurance Cooperatives
TITLE III—SHARED RESPONSIBILITY
Subtitle A—Individual Responsibility
Subtitle B—Employer Responsibility
TITLE IV—AMENDMENTS TO INTERNAL REVENUE CODE OF 1986
Subtitle A—Shared Responsibility
Subtitle B—Credit for Small Business Employee Health Coverage Expenses
Subtitle C—Disclosures To Carry Out Health Insurance Exchange Subsidies
Subtitle D—Other Revenue Provisions

DIVISION B—MEDICARE AND MEDICAID IMPROVEMENTS

TITLE I—IMPROVING HEALTH CARE VALUE
Subtitle A—Provisions Related to Medicare Part A
Subtitle B—Provisions Related to Medicare Part B
Subtitle C—Provisions Related to Medicare Parts A and B
Subtitle D—Medicare Advantage Reforms
Subtitle E—Improvements to Medicare Part D
Subtitle F—Medicare Rural Access Protections
TITLE II—MEDICARE BENEFICIARY IMPROVEMENTS
Subtitle A—Improving and Simplifying Financial Assistance for Low Income Medicare Beneficiaries
Subtitle B—Reducing Health Disparities
Subtitle C—Miscellaneous Improvements
TITLE III—PROMOTING PRIMARY CARE, MENTAL HEALTH SERVICES, AND COORDINATED CARE
TITLE IV—QUALITY
Subtitle A—Comparative Effectiveness Research
Subtitle B—Nursing Home Transparency
Subtitle C—Quality Measurements
Subtitle D—Physician Payments Sunshine Provision
Subtitle E—Public Reporting on Health Care-Associated Infections
TITLE V—MEDICARE GRADUATE MEDICAL EDUCATION
TITLE VI—PROGRAM INTEGRITY
Subtitle A—Increased Funding To Fight Waste, Fraud, and Abuse
Subtitle B—Enhanced Penalties for Fraud and Abuse
Subtitle C—Enhanced Program and Provider Protections
Subtitle D—Access to Information Needed To Prevent Fraud, Waste, and Abuse
TITLE VII—MEDICAID AND CHIP
Subtitle A—Medicaid and Health Reform
Subtitle B—Prevention
Subtitle C—Access
Subtitle D—Coverage
Subtitle E—Financing
Subtitle F—Waste, Fraud, and Abuse
Subtitle G—Payments to the Territories
Subtitle H—Miscellaneous
TITLE VIII—REVENUE-RELATED PROVISIONS
TITLE IX—MISCELLANEOUS PROVISIONS

DIVISION C—PUBLIC HEALTH AND WORKFORCE DEVELOPMENT

TITLE I—COMMUNITY HEALTH CENTERS
TITLE II—WORKFORCE
Subtitle A—Primary Care Workforce
Subtitle B—Nursing Workforce
Subtitle C—Public Health Workforce

Subtitle D—Adapting Workforce to Evolving Health System Needs
TITLE III—PREVENTION AND WELLNESS
TITLE IV—QUALITY AND SURVEILLANCE
TITLE V—OTHER PROVISIONS
Subtitle A—Drug Discount for Rural and Other Hospitals
Subtitle B—Programs
Subtitle C—Food and Drug Administration
Subtitle D—Community Living Assistance Services and Supports
Subtitle E—Miscellaneous

DIVISION A—AFFORDABLE HEALTH CARE CHOICES

SEC. 100. PURPOSE; TABLE OF CONTENTS OF DIVISION; GENERAL DEFINITIONS.

(a) PURPOSE.—

(1) IN GENERAL.—The purpose of this division is to provide affordable, quality health care for all Americans and reduce the growth in health care spending.

(2) BUILDING ON CURRENT SYSTEM.—This division achieves this purpose by building on what works in today's health care system, while repairing the aspects that are broken.

(3) INSURANCE REFORMS.—This division—

(A) enacts strong insurance market reforms;

(B) creates a new Health Insurance Exchange, with a public health insurance option alongside private plans and cooperatives under subtitle D of title II;

(C) includes sliding scale affordability credits; and

(D) initiates shared responsibility among workers, employers, and the government;

so that all Americans have coverage of essential health benefits.

(4) HEALTH DELIVERY REFORM.—This division institutes health delivery system reforms both to increase quality and to reduce growth in health spending so that health care becomes more affordable for businesses, families, and government.

(b) TABLE OF CONTENTS OF DIVISION.—The table of contents of this division is as follows:

Sec. 100. Purpose; table of contents of division; general definitions.

TITLE I—PROTECTIONS AND STANDARDS FOR QUALIFIED HEALTH BENEFITS PLANS

Subtitle A—General Standards

Sec. 101. Requirements reforming health insurance marketplace.
Sec. 102. Protecting the choice to keep current coverage.

Subtitle B—Standards Guaranteeing Access to Affordable Coverage

Sec. 111. Prohibiting preexisting condition exclusions.
Sec. 112. Guaranteed issue and renewal for insured plans.
Sec. 113. Insurance rating rules.
Sec. 114. Nondiscrimination in benefits; parity in mental health and substance abuse disorder benefits.
Sec. 115. Ensuring adequacy of provider networks.
Sec. 116. Ensuring value and lower premiums.

Subtitle C—Standards Guaranteeing Access to Essential Benefits

Sec. 121. Coverage of essential benefits package.
Sec. 122. Essential benefits package defined.
Sec. 123. Health Benefits Advisory Committee.
Sec. 124. Process for adoption of recommendations; adoption of benefit standards.
Sec. 125. Prohibition of discrimination in health care services based on religious or spiritual content.

Subtitle D—Additional Consumer Protections

Sec. 131. Requiring fair marketing practices by health insurers.
Sec. 132. Requiring fair grievance and appeals mechanisms.
Sec. 133. Requiring information transparency and plan disclosure.
Sec. 134. Application to qualified health benefits plans not offered through the Health Insurance Exchange.
Sec. 135. Timely payment of claims.
Sec. 136. Standardized rules for coordination and subrogation of benefits.
Sec. 137. Application of administrative simplification.
Sec. 138. Information on end-of-life planning.
Sec. 139. Utilization review activities.
Sec. 139A. Internal appeals procedures.
Sec. 139B. External appeals procedures.

Subtitle E—Governance

Sec. 141. Health Choices Administration; Health Choices Commissioner.
Sec. 142. Duties and authority of Commissioner.
Sec. 143. Consultation and coordination.
Sec. 144. Health Insurance Ombudsman.

Subtitle F—Relation to Other Requirements; Miscellaneous

Sec. 151. Relation to other requirements.
Sec. 152. Prohibiting discrimination in health care.
Sec. 153. Whistleblower protection.
Sec. 154. Construction regarding collective bargaining.
Sec. 155. Severability.
Sec. 156. Application of State and Federal laws regarding abortion.
Sec. 157. Non-discrimination on abortion and respect for rights of conscience.

Subtitle G—Early Investments

Sec. 161. Ensuring value and lower premiums.
Sec. 162. Ending health insurance rescission abuse.
Sec. 163. Ending health insurance denials and delays of necessary treatment for children with deformities.
Sec. 164. Administrative simplification.
Sec. 165. Expansion of electronic transactions in medicare.
Sec. 166. Reinsurance program for retirees.
Sec. 167. Limitations on preexisting condition exclusions in group health plans and health insurance coverage in the group and individual markets in advance of applicability of new prohibition of preexisting condition exclusions.

TITLE II—HEALTH INSURANCE EXCHANGE AND RELATED PROVISIONS

Subtitle A—Health Insurance Exchange

Sec. 201. Establishment of Health Insurance Exchange; outline of duties; definitions.
Sec. 202. Exchange-eligible individuals and employers.
Sec. 203. Benefits package levels.
Sec. 204. Contracts for the offering of Exchange-participating health benefits plans.
Sec. 205. Outreach and enrollment of Exchange-eligible individuals and employers in Exchange-participating health benefits plans.
Sec. 206. Other functions.
Sec. 207. Health Insurance Exchange Trust Fund.
Sec. 208. Optional operation of State-based health insurance exchanges.
Sec. 209. Limitation on premium increases under Exchange-participating health benefits plans.

Subtitle B—Public Health Insurance Option

Sec. 221. Establishment and administration of a public health insurance option as an Exchange-qualified health benefits plan.
Sec. 222. Premiums and financing.
Sec. 223. Negotiated payment rates for items and services.
Sec. 224. Modernized payment initiatives and delivery system reform.
Sec. 225. Provider participation.
Sec. 226. Application of fraud and abuse provisions.
Sec. 227. Application of HIPAA insurance requirements.
Sec. 228. Application of health information privacy, security, and electronic transaction requirements.
Sec. 229. Enrollment in public health insurance option is voluntary.

Subtitle C—Individual Affordability Credits

Sec. 241. Availability through Health Insurance Exchange.
Sec. 242. Affordable credit eligible individual.
Sec. 243. Affordable premium credit.
Sec. 244. Affordability cost-sharing credit.
Sec. 245. Income determinations.
Sec. 246. No Federal payment for undocumented aliens.

Subtitle D—Health Insurance Cooperatives

Sec. 251. Establishment.
Sec. 252. Start-up and solvency grants and loans.
Sec. 253. Definitions.

TITLE III—SHARED RESPONSIBILITY

Subtitle A—Individual Responsibility

Sec. 301. Individual responsibility.

Subtitle B—Employer Responsibility

PART 1—HEALTH COVERAGE PARTICIPATION REQUIREMENTS

Sec. 311. Health coverage participation requirements.
Sec. 312. Employer responsibility to contribute towards employee and dependent coverage.
Sec. 313. Employer contributions in lieu of coverage.
Sec. 314. Authority related to improper steering.

PART 2—SATISFACTION OF HEALTH COVERAGE PARTICIPATION REQUIREMENTS

Sec. 321. Satisfaction of health coverage participation requirements under the Employee Retirement Income Security Act of 1974.
Sec. 322. Satisfaction of health coverage participation requirements under the Internal Revenue Code of 1986.
Sec. 323. Satisfaction of health coverage participation requirements under the Public Health Service Act.
Sec. 324. Additional rules relating to health coverage participation requirements.

TITLE IV—AMENDMENTS TO INTERNAL REVENUE CODE OF 1986

Subtitle A—Shared Responsibility

PART 1—INDIVIDUAL RESPONSIBILITY

Sec. 401. Tax on individuals without acceptable health care coverage.

PART 2—EMPLOYER RESPONSIBILITY

Sec. 411. Election to satisfy health coverage participation requirements.
Sec. 412. Responsibilities of nonelecting employers.

Subtitle B—Credit for Small Business Employee Health Coverage Expenses

Sec. 421. Credit for small business employee health coverage expenses.

Subtitle C—Disclosures To Carry Out Health Insurance Exchange Subsidies

Sec. 431. Disclosures to carry out health insurance exchange subsidies.

Subtitle D—Other Revenue Provisions

PART 1—GENERAL PROVISIONS

Sec. 441. Surcharge on high income individuals.
Sec. 442. Delay in application of worldwide allocation of interest.

PART 2—PREVENTION OF TAX AVOIDANCE

Sec. 451. Limitation on treaty benefits for certain deductible payments.
Sec. 452. Codification of economic substance doctrine.
Sec. 453. Penalties for underpayments.

(c) GENERAL DEFINITIONS.—Except as otherwise provided, in this division:

(1) ACCEPTABLE COVERAGE.—The term "acceptable coverage" has the meaning given such term in section 202(d)(2).

(2) BASIC PLAN.—The term "basic plan" has the meaning given such term in section 203(c).

(3) COMMISSIONER.—The term "Commissioner" means the Health Choices Commissioner established under section 141.

(4) COST-SHARING.—The term "cost-sharing" includes deductibles, coinsurance, copayments, and similar charges but does not include premiums or any network payment differential for covered services or spending for non-covered services.

(5) DEPENDENT.—The term "dependent" has the meaning given such term by the Commissioner and includes a spouse.

(6) EMPLOYMENT-BASED HEALTH PLAN.—The term "employment-based health plan"—

(A) means a group health plan (as defined in section 733(a)(1) of the Employee Retirement Income Security Act of 1974); and

(B) includes such a plan that is the following:

(i) FEDERAL, STATE, AND TRIBAL GOVERNMENTAL PLANS.—A governmental plan (as defined in section 3(32) of the Employee Retirement Income Security Act of 1974), including a health benefits plan offered under chapter 89 of title 5, United States Code.

(ii) CHURCH PLANS.—A church plan (as defined in section 3(33) of the Employee Retirement Income Security Act of 1974).

(7) ENHANCED PLAN.—The term "enhanced plan" has the meaning given such term in section 203(c).

(8) ESSENTIAL BENEFITS PACKAGE.—The term "essential benefits package" is defined in section 122(a).

(9) FAMILY.—The term "family" means an individual and includes the individual's dependents.

(10) FEDERAL POVERTY LEVEL; FPL.—The terms "Federal poverty level" and "FPL" have the meaning given the term "poverty line" in section 673(2) of the Community Services Block Grant Act (42 U.S.C. 9902(2)), including any revision required by such section.

(11) HEALTH BENEFITS PLAN.—The terms "health benefits plan" means health insurance coverage and an employment-based health plan and includes the public health insurance option and cooperatives under subtitle D of title II.

(12) HEALTH INSURANCE COVERAGE; HEALTH INSURANCE ISSUER.—The terms "health insurance coverage" and "health insurance issuer" have the meanings given such terms in section 2791 of the Public Health Service Act.

(13) HEALTH INSURANCE EXCHANGE.—The term "Health Insurance Exchange" means the Health Insurance Exchange established under section 201.

(14) MEDICAID.—The term "Medicaid" means a State plan under title XIX of the Social Security Act (whether or not the plan is operating under a waiver under section 1115 of such Act).

(15) MEDICARE.—The term "Medicare" means the health insurance programs under title XVIII of the Social Security Act.

(16) PLAN SPONSOR.—The term "plan sponsor" has the meaning given such term in section 3(16)(B) of the Employee Retirement Income Security Act of 1974.

(17) PLAN YEAR.—The term "plan year" means—

(A) with respect to an employment-based health plan, a plan year as specified under such plan; or

(B) with respect to a health benefits plan other than an employment-based health plan, a 12-month period as specified by the Commissioner.

(18) PREMIUM PLAN; PREMIUM-PLUS PLAN.—The terms "premium plan" and "premium-plus plan" have the meanings given such terms in section 203(c).

(19) QHBP OFFERING ENTITY.—The terms "QHBP offering entity" means, with respect to a health benefits plan that is—

(A) a group health plan (as defined, subject to subsection (d), in section 733(a)(1) of the Employee Retirement Income Security Act of 1974), the plan sponsor in relation to such group health plan, except that, in the case of a plan maintained jointly by 1 or more employers and 1 or more employee organizations and with respect to which an employer is the primary source of financing, such term means such employer;

(B) health insurance coverage, the health insurance issuer offering the coverage, including a cooperative under subtitle D of title II;

(C) the public health insurance option, the Secretary of Health and Human Services;

(D) a non-Federal governmental plan (as defined in section 2791(d) of the Public Health Service Act), the State or political subdivision of a State (or agency or instrumentality of such State or subdivision) which establishes or maintains such plan; or

(E) a Federal governmental plan (as defined in section 2791(d) of the Public Health Service Act), the appropriate Federal official.

(20) QUALIFIED HEALTH BENEFITS PLAN.—The term "qualified health benefits plan" means a health benefits plan that meets the requirements for such a plan under title I and includes the public health insurance option and cooperatives under subtitle D of title II.

(21) PUBLIC HEALTH INSURANCE OPTION.—The term "public health insurance option" means the public health insurance option as provided under subtitle B of title II.

(22) SERVICE AREA; PREMIUM RATING AREA.—The terms "service area" and "premium rating area" mean with respect to health insurance coverage—

(A) offered other than through the Health Insurance Exchange, such an area as established by the QHBP offering entity of such coverage in accordance with applicable State law; and

(B) offered through the Health Insurance Exchange, such an area as established by such entity in accordance with applicable State law and applicable rules of the Commissioner for Exchange-participating health benefits plans.

(23) STATE.—The term "State" means the 50 States and the District of Columbia.

(24) STATE MEDICAID AGENCY.—The term "State Medicaid agency" means, with respect to a Medicaid plan, the single State agency responsible for administering such plan under title XIX of the Social Security Act.

(25) Y1, Y2, ETC..—The terms "Y1" , "Y2", "Y3", "Y4", "Y5", and similar subsequently numbered terms, mean 2013 and subsequent years, respectively.

TITLE I—PROTECTIONS AND STANDARDS FOR QUALIFIED HEALTH BENEFITS PLANS

Subtitle A—General Standards

SEC. 101. REQUIREMENTS REFORMING HEALTH INSURANCE MARKETPLACE.

(a) PURPOSE.—The purpose of this title is to establish standards to ensure that new health insurance coverage and employment-based health plans that are offered meet standards guaranteeing access to affordable coverage, essential benefits, and other consumer protections.

(b) REQUIREMENTS FOR QUALIFIED HEALTH BENEFITS PLANS.—On or after the first day of Y1, a health benefits plan shall not be a qualified health benefits plan under this division unless the plan meets the applicable requirements of the following subtitles for the type of plan and plan year involved:

(1) Subtitle B (relating to affordable coverage).

(2) Subtitle C (relating to essential benefits).

(3) Subtitle D (relating to consumer protection).

(c) TERMINOLOGY.—In this division:

(1) ENROLLMENT IN EMPLOYMENT-BASED HEALTH PLANS.—An individual shall be treated as being "enrolled" in an employment-based health plan if the indi-

vidual is a participant or beneficiary (as such terms are defined in section 3(7) and 3(8), respectively, of the Employee Retirement Income Security Act of 1974) in such plan.

(2) INDIVIDUAL AND GROUP HEALTH INSURANCE COVERAGE.—The terms "individual health insurance coverage" and "group health insurance coverage" mean health insurance coverage offered in the individual market or large or small group market, respectively, as defined in section 2791 of the Public Health Service Act.

SEC. 102. PROTECTING THE CHOICE TO KEEP CURRENT COVERAGE.

(a) GRANDFATHERED HEALTH INSURANCE COVERAGE DEFINED.—Subject to the succeeding provisions of this section, for purposes of establishing acceptable coverage under this division, the term "grandfathered health insurance coverage" means individual health insurance coverage that is offered and in force and effect before the first day of Y1 if the following conditions are met:

(1) LIMITATION ON NEW ENROLLMENT.—

(A) IN GENERAL.—Except as provided in this paragraph, the individual health insurance issuer offering such coverage does not enroll any individual in such coverage if the first effective date of coverage is on or after the first day of Y1.

(B) DEPENDENT COVERAGE PERMITTED.—Subparagraph (A) shall not affect the subsequent enrollment of a dependent of an individual who is covered as of such first day.

(2) LIMITATION ON CHANGES IN TERMS OR CONDITIONS.—Subject to paragraph (3) and except as required by law, the issuer does not change any of its terms or conditions, including benefits and cost-sharing, from those in effect as of the day before the first day of Y1.

(3) RESTRICTIONS ON PREMIUM INCREASES.—The issuer cannot vary the percentage increase in the premium for a risk group of enrollees in specific grandfathered health insurance coverage without changing the premium for all enrollees in the same risk group at the same rate, as specified by the Commissioner.

(b) GRACE PERIOD FOR CURRENT EMPLOYMENT-BASED HEALTH PLANS.—

(1) GRACE PERIOD.—

(A) IN GENERAL.—The Commissioner shall establish a grace period whereby, for plan years beginning after the end of the 5-year period beginning with Y1, an employment-based health plan in operation as of the day before the first day of Y1 must meet the same requirements as apply to a qualified health benefits plan under section 101, including the essential benefit package requirement under section 121.

(B) EXCEPTION FOR LIMITED BENEFITS PLANS.—Subparagraph (A) shall not apply to an employment-based health plan in which the coverage consists only of one or more of the following:

(i) Any coverage described in section 3001(a)(1)(B)(ii)(IV) of division B of the American Recovery and Reinvestment Act of 2009 (PL 111–5).

(ii) Excepted benefits (as defined in section 733(c) of the Employee Retirement Income Security Act of 1974), including coverage under a specified disease or illness policy described in paragraph (3)(A) of such section.

(iii) Such other limited benefits as the Commissioner may specify.

In no case shall an employment-based health plan in which the coverage consists only of one or more of the coverage or benefits described in clauses (i) through (iii) be treated as acceptable coverage under this division

(2) TRANSITIONAL TREATMENT AS ACCEPTABLE COVERAGE.—During the grace period specified in paragraph (1)(A), an employment-based health plan that is described in such paragraph shall be treated as acceptable coverage under this division.

(c) LIMITATION ON INDIVIDUAL HEALTH INSURANCE COVERAGE.—

(1) IN GENERAL.—Individual health insurance coverage that is not grandfathered health insurance coverage under subsection (a) may only be offered on or after the first day of Y1 as an Exchange-participating health benefits plan.

(2) SEPARATE, EXCEPTED COVERAGE PERMITTED.—Excepted benefits (as defined in section 2791(c) of the Public Health Service Act) are not included within the definition of health insurance coverage. Nothing in paragraph (1) shall prevent the offering, other than through the Health Insurance Exchange, of excepted benefits so long as it is offered and priced separately from health insurance coverage.

(3) STAND-ALONE DENTAL AND VISION COVERAGE PERMITTED.—Nothing in this division shall be construed—

(A) to prevent the offering of a stand-alone plans that offer coverage of excepted benefits described in section 2791(c)(2)(A) of the Public Health Service Act (relating to limited scope dental or vision benefits)for individuals and families from a State licensed dental and vision carrier; or

(B) as applying requirements for a qualified health benefits plan to such stand-alone plans that is offered and priced separately from a qualified health benefits plan.

Subtitle B—Standards Guaranteeing Access to Affordable Coverage

SEC. 111. PROHIBITING PREEXISTING CONDITION EXCLUSIONS.

A qualified health benefits plan may not impose any preexisting condition exclusion (as defined in section 2701(b)(1)(A) of the Public Health Service Act) or otherwise impose any limit or condition on the coverage under the plan with respect to an individual or dependent based on any health status-related factors (as defined in section 2791(d)(9) of the Public Health Service Act) in relation to the individual or dependent.

SEC. 112. GUARANTEED ISSUE AND RENEWAL FOR INSURED PLANS.

The requirements of sections 2711 (other than subsections (c) and (e)) and 2712 (other than paragraphs (3), and (6) of subsection (b) and subsection (e)) of the Public Health Service Act, relating to guaranteed availability and renewability of health insurance coverage, shall apply to individuals and employers in all individual and group health insurance coverage, whether offered to individuals or employers through the Health Insurance Exchange, through any employment-based health plan, or otherwise, and shall apply to the public health insurance option, in the same manner as such sections apply to employers and health insurance coverage offered in the small group market, except that such section 2712(b)(1) shall apply only if, before nonrenewal or discontinuation of coverage, the issuer has provided the enrollee with notice of non-payment of premiums and there is a grace period during which the enrollee has an opportunity to correct such nonpayment. Rescissions of such coverage shall be prohibited except in cases of fraud as defined in sections 2712(b)(2) of such Act.

SEC. 113. INSURANCE RATING RULES.

(a) IN GENERAL.—The premium rate charged for an insured qualified health benefits plan and for coverage under the public health insurance option may not vary except as follows:

(1) LIMITED AGE VARIATION PERMITTED.—By age (within such age categories as the Commissioner shall specify) so long as the ratio of the highest such premium to the lowest such premium does not exceed the ratio of 2 to 1.

(2) BY AREA.—By premium rating area (as permitted by State insurance regulators or, in the case of Exchange-participating health benefits plans, as specified by the Commissioner in consultation with such regulators).

(3) BY FAMILY ENROLLMENT.—By family enrollment (such as variations within categories and compositions of families) so long as the ratio of the premium for family enrollment (or enrollments) to the premium for individual enrollment is uniform, as specified under State law and consistent with rules of the Commissioner.

(b) ACTUARIAL VALUE OF OPTIONAL SERVICE COVERAGE.—

(1) IN GENERAL.—The Commissioner shall estimate the basic per enrollee, per month cost, determined on an average actuarial basis, for including coverage under a basic plan of the services described in section 122(d)(4)(A).

(2) CONSIDERATIONS.—In making such estimate the Commissioner—

(A) may take into account the impact on overall costs of the inclusion of such coverage, but may not take into account any cost reduction estimated to result from such services, including prenatal care, delivery, or postnatal care;

(B) shall estimate such costs as if such coverage were included for the entire population covered; and

(C) may not estimate such a cost at less than $1 per enrollee, per month.

(c) STUDY AND REPORTS.—

(1) STUDY.—The Commissioner, in coordination with the Secretary of Health and Human Services and the Secretary of Labor, shall conduct a study of the

large group insured and self-insured employer health care markets. Such study shall examine the following:

(A) The types of employers by key characteristics, including size, that purchase insured products versus those that self-insure.

(B) The similarities and differences between typical insured and self-insured health plans.

(C) The financial solvency and capital reserve levels of employers that self-insure by employer size.

(D) The risk of self-insured employers not being able to pay obligations or otherwise becoming financially insolvent.

(E) The extent to which rating rules are likely to cause adverse selection in the large group market or to encourage small and mid size employers to self-insure

(2) REPORTS.—Not later than 18 months after the date of the enactment of this Act, the Commissioner shall submit to Congress and the applicable agencies a report on the study conducted under paragraph (1). Such report shall include any recommendations the Commissioner deems appropriate to ensure that the law does not provide incentives for small and mid-size employers to self-insure or create adverse selection in the risk pools of large group insurers and self-insured employers. Not later than 18 months after the first day of Y1, the Commissioner shall submit to Congress and the applicable agencies an updated report on such study, including updates on such recommendations.

SEC. 114. NONDISCRIMINATION IN BENEFITS; PARITY IN MENTAL HEALTH AND SUBSTANCE ABUSE DISORDER BENEFITS.

(a) NONDISCRIMINATION IN BENEFITS.—A qualified health benefits plan (including the public health insurance option) shall comply with standards established by the Commissioner to prohibit discrimination in health benefits or benefit structures for qualifying health benefits plans, building from sections 702 of Employee Retirement Income Security Act of 1974, 2702 of the Public Health Service Act, and section 9802 of the Internal Revenue Code of 1986.

(b) PARITY IN MENTAL HEALTH AND SUBSTANCE ABUSE DISORDER BENEFITS.—To the extent such provisions are not superceded by or inconsistent with subtitle C, the provisions of section 2705 (other than subsections (a)(1), (a)(2), and (c)) of section 2705 of the Public Health Service Act shall apply to a qualified health benefits plan, regardless of whether it is offered in the individual or group market, in the same manner as such provisions apply to health insurance coverage offered in the large group market.

SEC. 115. ENSURING ADEQUACY OF PROVIDER NETWORKS.

(a) IN GENERAL.—A qualified health benefits plan (including the public health insurance option) that uses a provider network for items and services shall meet such standards respecting provider networks as the Commissioner may establish to assure the adequacy of such networks in ensuring enrollee access to such items and services and transparency in the cost-sharing differentials between in-network coverage and out-of-network coverage.

(b) PROVIDER NETWORK DEFINED.—In this division, the term "provider network" means the providers with respect to which covered benefits, treatments, and services are available under a health benefits plan.

SEC. 116. ENSURING VALUE AND LOWER PREMIUMS.

(a) IN GENERAL.—A qualified health benefits plan shall meet a medical loss ratio as defined by the Commissioner. For any plan year in which the qualified health benefits plan does not meet such medical loss ratio, QHBP offering entity shall provide in a manner specified by the Commissioner for rebates to enrollees of payment sufficient to meet such loss ratio.

(b) BUILDING ON INTERIM RULES.—In implementing subsection (a), the Commissioner shall build on the definition and methodology developed by the Secretary of Health and Human Services under the amendments made by section 161 for determining how to calculate the medical loss ratio. Such methodology shall be set at the highest level medical loss ratio possible that is designed to ensure adequate participation by QHBP offering entities, competition in the health insurance market in and out of the Health Insurance Exchange, and value for consumers so that their premiums are used for services.

Subtitle C—Standards Guaranteeing Access to Essential Benefits

SEC. 121. COVERAGE OF ESSENTIAL BENEFITS PACKAGE.

(a) IN GENERAL.—A qualified health benefits plan shall provide coverage that at least meets the benefit standards adopted under section 124 for the essential benefits package described in section 122 for the plan year involved.

(b) CHOICE OF COVERAGE.—

(1) NON-EXCHANGE-PARTICIPATING HEALTH BENEFITS PLANS.—In the case of a qualified health benefits plan that is not an Exchange-participating health benefits plan, such plan may offer such coverage in addition to the essential benefits package as the QHBP offering entity may specify.

(2) EXCHANGE-PARTICIPATING HEALTH BENEFITS PLANS.—In the case of an Exchange-participating health benefits plan, such plan is required under section 203 to provide specified levels of benefits and, in the case of a plan offering a premium-plus level of benefits, provide additional benefits.

(3) CONTINUATION OF OFFERING OF SEPARATE EXCEPTED BENEFITS COVERAGE.—Nothing in this division shall be construed as affecting the offering of health benefits in the form of excepted benefits (described in section 102(b)(1)(B)(ii)) if such benefits are offered under a separate policy, contract, or certificate of insurance.

(c) NO RESTRICTIONS ON COVERAGE UNRELATED TO CLINICAL APPROPRIATENESS.—A qualified health benefits plan may not impose any restriction (other than cost-sharing) unrelated to clinical appropriateness on the coverage of the health care items and services.

SEC. 122. ESSENTIAL BENEFITS PACKAGE DEFINED.

(a) IN GENERAL.—In this division, the term "essential benefits package" means health benefits coverage, consistent with standards adopted under section 124 to ensure the provision of quality health care and financial security, that—

(1) provides payment for the items and services described in subsection (b) in accordance with generally accepted standards of medical or other appropriate clinical or professional practice;

(2) limits cost-sharing for such covered health care items and services in accordance with such benefit standards, consistent with subsection (c);

(3) does not impose any annual or lifetime limit on the coverage of covered health care items and services;

(4) complies with section 115(a) (relating to network adequacy); and

(5) is equivalent, as certified by Office of the Actuary of the Centers for Medicare & Medicaid Services, to the average prevailing employer-sponsored coverage.

(b) MINIMUM SERVICES TO BE COVERED.—Subject to subsection (d), the items and services described in this subsection are the following:

(1) Hospitalization.

(2) Outpatient hospital and outpatient clinic services, including emergency department services.

(3) Professional services of physicians and other health professionals.

(4) Such services, equipment, and supplies incident to the services of a physician's or a health professional's delivery of care in institutional settings, physician offices, patients' homes or place of residence, or other settings, as appropriate.

(5) Prescription drugs.

(6) Rehabilitative and habilitative services.

(7) Mental health and substance use disorder services, including behavioral health treatments.

(8) Preventive services, including those services recommended with a grade of A or B by the Task Force on Clinical Preventive Services and those vaccines recommended for use by the Director of the Centers for Disease Control and Prevention.

(9) Maternity care.

(10) Well baby and well child care; treatment of a congenital or developmental deformity, disease, or injury; and oral health, vision, and hearing services, equipment, and supplies at least for children under 21 years of age.

(c) REQUIREMENTS RELATING TO COST-SHARING AND MINIMUM ACTUARIAL VALUE.—

(1) NO COST-SHARING FOR PREVENTIVE SERVICES.—There shall be no cost-sharing under the essential benefits package for preventive items and services (as specified under the benefit standards), including well baby and well child care.

(2) ANNUAL LIMITATION.—

(A) ANNUAL LIMITATION.—The cost-sharing incurred under the essential benefits package with respect to an individual (or family) for a year does not exceed the applicable level specified in subparagraph (B).

(B) APPLICABLE LEVEL.—The applicable level specified in this subparagraph for Y1 is $5,000 for an individual and $10,000 for a family. Such levels shall be increased (rounded to the nearest $100) for each subsequent year by the annual percentage increase in the Consumer Price Index (United States city average) applicable to such year.

(C) USE OF COPAYMENTS.—In establishing cost-sharing levels for basic, enhanced, and premium plans under this subsection, the Secretary shall, to the maximum extent possible, use only copayments and not coinsurance.

(3) MINIMUM ACTUARIAL VALUE.—

(A) IN GENERAL.—The cost-sharing under the essential benefits package shall be designed to provide a level of coverage that is designed to provide benefits that are actuarially equivalent to approximately 70 percent of the full actuarial value of the benefits provided under the reference benefits package described in subparagraph (B).

(B) REFERENCE BENEFITS PACKAGE DESCRIBED.—The reference benefits package described in this subparagraph is the essential benefits package if there were no cost-sharing imposed.

(d) ABORTION COVERAGE PROHIBITED AS PART OF MINIMUM BENEFITS PACKAGE.—

(1) PROHIBITION OF REQUIRED COVERAGE.—The Health Benefits Advisory Committee may not recommend under section 123(b) and the Secretary may not adopt in standards under section 124(b), the services described in paragraph (4)(A) or (4)(B) as part of the essential benefits package and the Commissioner may not require such services for qualified health benefits plans to participate in the Health Insurance Exchange.

(2) VOLUNTARY CHOICE OF COVERAGE BY PLAN.—In the case of a qualified health benefits plan, the plan is not required (or prohibited) under this Act from providing coverage of services described in paragraph (4)(A) or (4)(B) and the QHBP offering entity shall determine whether such coverage is provided.

(3) COVERAGE UNDER PUBLIC HEALTH INSURANCE OPTION.—The public health insurance option shall provide coverage for services described in paragraph (4)(B). Nothing in this Act shall be construed as preventing the public health insurance option from providing for or prohibiting coverage of services described in paragraph (4)(A).

(4) ABORTION SERVICES.—

(A) ABORTIONS FOR WHICH PUBLIC FUNDING IS PROHIBITED.—The services described in this subparagraph are abortions for which the expenditure of Federal funds appropriated for the Department of Health and Human Services is not permitted, based on the law as in effect as of the date that is 6 months before the beginning of the plan year involved.

(B) ABORTIONS FOR WHICH PUBLIC FUNDING IS ALLOWED.—The services described in this subparagraph are abortions for which the expenditure of Federal funds appropriated for the Department of Health and Human Services is permitted, based on the law as in effect as of the date that is 6 months before the beginning of the plan year involved.

(e) STAND-ALONE COVERAGE.—

(1) NO APPLICATION TO ADULT COVERAGE.—Nothing in this subtitle shall be construed as requiring an individual who is 21 years of age or older to be provided stand-alone dental-only or vision-only coverage.

(2) TREATMENT OF COMBINED COVERAGE.—The combination of stand-alone coverage described in paragraph (1) and a qualified health benefits plan without coverage of such oral and vision services shall be treated as satisfying the essential benefits package under this division.

SEC. 123. HEALTH BENEFITS ADVISORY COMMITTEE.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—There is established a private-public advisory committee which shall be a panel of medical and other experts to be known as the Health Benefits Advisory Committee to recommend covered benefits and essential, enhanced, and premium plans.

(2) CHAIR.—The Surgeon General shall be a member and the chair of the Health Benefits Advisory Committee.

(3) MEMBERSHIP.—The Health Benefits Advisory Committee shall be composed of the following members, in addition to the Surgeon General:

(A) 9 members who are not Federal employees or officers and who are appointed by the President.

(B) 9 members who are not Federal employees or officers and who are appointed by the Comptroller General of the United States in a manner similar to the manner in which the Comptroller General appoints members to the Medicare Payment Advisory Commission under section 1805(c) of the Social Security Act.

(C) Such even number of members (not to exceed 8) who are Federal employees and officers, as the President may appoint.

Such initial appointments shall be made not later than 60 days after the date of the enactment of this Act.

(4) TERMS.—Each member of the Health Benefits Advisory Committee shall serve a 3-year term on the Committee, except that the terms of the initial members shall be adjusted in order to provide for a staggered term of appointment for all such members.

(5) PARTICIPATION.—The membership of the Health Benefits Advisory Committee shall at least reflect providers, consumer representatives, employers, labor, health insurance issuers, experts in health care financing and delivery, experts in racial and ethnic disparities, experts in care for those with disabilities, representatives of relevant governmental agencies. and at least one practicing physician or other health professional and an expert on children's health and shall represent a balance among various sectors of the health care system so that no single sector unduly influences the recommendations of such Committee. Not less than 25 percent of the members of the Committee shall be practicing health care practitioners who, as of the date of their appointment, practice in a rural area and who have practiced in a rural area for at least the 5-year period preceding such date.

(b) DUTIES.—

(1) RECOMMENDATIONS ON BENEFIT STANDARDS.—The Health Benefits Advisory Committee shall recommend to the Secretary of Health and Human Services (in this subtitle referred to as the "Secretary") benefit standards (as defined in paragraph (4)), and periodic updates to such standards. In developing such recommendations, the Committee shall take into account innovation in health care and consider how such standards could reduce health disparities.

(2) DEADLINE.—The Health Benefits Advisory Committee shall recommend initial benefit standards to the Secretary not later than 1 year after the date of the enactment of this Act.

(3) PUBLIC INPUT.—The Health Benefits Advisory Committee shall allow for public input as a part of developing recommendations under this subsection.

(4) BENEFIT STANDARDS DEFINED.—In this subtitle, the term "benefit standards" means standards respecting—

(A) the essential benefits package described in section 122, including categories of covered treatments, items and services within benefit classes, and cost-sharing consistent with subsection (d) of such section; and

(B) the cost-sharing levels for enhanced plans and premium plans (as provided under section 203(c)) consistent with paragraph (5).

(5) LEVELS OF COST-SHARING FOR ENHANCED AND PREMIUM PLANS.—

(A) ENHANCED PLAN.—The level of cost-sharing for enhanced plans shall be designed so that such plans have benefits that are actuarially equivalent to approximately 85 percent of the actuarial value of the benefits provided under the reference benefits package described in section 122(c)(3)(B).

(B) PREMIUM PLAN.—The level of cost-sharing for premium plans shall be designed so that such plans have benefits that are actuarially equivalent to approximately 95 percent of the actuarial value of the benefits provided under the reference benefits package described in section 122(c)(3)(B).

(c) OPERATIONS.—

(1) PER DIEM PAY.—Each member of the Health Benefits Advisory Committee shall receive travel expenses, including per diem in accordance with applicable provisions under subchapter I of chapter 57 of title 5, United States Code, and shall otherwise serve without additional pay.

(2) MEMBERS NOT TREATED AS FEDERAL EMPLOYEES.—Members of the Health Benefits Advisory Committee shall not be considered employees of the Federal government solely by reason of any service on the Committee.

(3) APPLICATION OF FACA.—The Federal Advisory Committee Act (5 U.S.C. App.), other than section 14, shall apply to the Health Benefits Advisory Committee.

(d) PUBLICATION.—The Secretary shall provide for publication in the Federal Register and the posting on the Internet website of the Department of Health and Human Services of all recommendations made by the Health Benefits Advisory Committee under this section.

SEC. 124. PROCESS FOR ADOPTION OF RECOMMENDATIONS; ADOPTION OF BENEFIT STANDARDS.

(a) PROCESS FOR ADOPTION OF RECOMMENDATIONS.—

(1) REVIEW OF RECOMMENDED STANDARDS.—Not later than 45 days after the date of receipt of benefit standards recommended under section 123 (including such standards as modified under paragraph (2)(B)), the Secretary shall review such standards and shall determine whether to propose adoption of such standards as a package.

(2) DETERMINATION TO ADOPT STANDARDS.—If the Secretary determines—

(A) to propose adoption of benefit standards so recommended as a package, the Secretary shall, by regulation under section 553 of title 5, United States Code, propose adoption such standards; or

(B) not to propose adoption of such standards as a package, the Secretary shall notify the Health Benefits Advisory Committee in writing of such determination and the reasons for not proposing the adoption of such recommendation and provide the Committee with a further opportunity to modify its previous recommendations and submit new recommendations to the Secretary on a timely basis.

(3) CONTINGENCY.—If, because of the application of paragraph (2)(B), the Secretary would otherwise be unable to propose initial adoption of such recommended standards by the deadline specified in subsection (b)(1), the Secretary shall, by regulation under section 553 of title 5, United States Code, propose adoption of initial benefit standards by such deadline.

(4) PUBLICATION.—The Secretary shall provide for publication in the Federal Register of all determinations made by the Secretary under this subsection.

(b) ADOPTION OF STANDARDS.—

(1) INITIAL STANDARDS.—Not later than 18 months after the date of the enactment of this Act, the Secretary shall, through the rulemaking process consistent with subsection (a), adopt an initial set of benefit standards.

(2) PERIODIC UPDATING STANDARDS.—Under subsection (a), the Secretary shall provide for the periodic updating of the benefit standards previously adopted under this section.

(3) REQUIREMENT.—The Secretary may not adopt any benefit standards for an essential benefits package or for level of cost-sharing that are inconsistent with the requirements for such a package or level under sections 122 (including subsection (d)) and 123(b)(5).

SEC. 125. PROHIBITION OF DISCRIMINATION IN HEALTH CARE SERVICES BASED ON RELIGIOUS OR SPIRITUAL CONTENT.

Neither the Commissioner nor any health insurance issuer offering health insurance coverage through the Health Insurance Exchange shall discriminate in approving or covering a health care service on the basis of its religious or spiritual content if expenditures for such a health care service are allowable as a deduction under section 213(d) of the Internal Revenue Code of 1986, as in effect on January 1, 2009.

Subtitle D—Additional Consumer Protections

SEC. 131. REQUIRING FAIR MARKETING PRACTICES BY HEALTH INSURERS.

The Commissioner shall establish uniform marketing standards that all insured QHBP offering entities shall meet.

SEC. 132. REQUIRING FAIR GRIEVANCE AND APPEALS MECHANISMS.

A QHBP offering entity shall provide for timely grievance and appeals mechanisms as the Commissioner shall establish consistent with sections 139 through 139B.

SEC. 133. REQUIRING INFORMATION TRANSPARENCY AND PLAN DISCLOSURE.

(a) ACCURATE AND TIMELY DISCLOSURE.—

(1) IN GENERAL.—A qualified health benefits plan (including the public health insurance option) shall comply with standards established by the Commissioner for the accurate and timely disclosure of plan documents, plan terms and conditions, claims payment policies and practices, periodic financial disclosure, data on enrollment, data on disenrollment, data on the number of claims denials, data on rating practices, information on cost-sharing and payments with respect to any out-of-network coverage, and other information as determined appropriate by the Commissioner. The Commissioner shall require that such disclosure be provided in plain language.

(2) PLAIN LANGUAGE.—In this subsection, the term "plain language" means language that the intended audience, including individuals with limited English

proficiency, can readily understand and use because that language is clean, concise, well-organized, and follows other best practices of plain language writing.

(3) GUIDANCE.—The Commissioner shall develop and issue guidance on best practices of plain language writing.

(b) CONTRACTING REIMBURSEMENT.—A qualified health benefits plan (including the public health insurance option) shall comply with standards established by the Commissioner to ensure transparency to each health care provider relating to reimbursement arrangements between such plan and such provider.

(c) ADVANCE NOTICE OF PLAN CHANGES.—A change in a qualified health benefits plan (including the public health insurance option) shall not be made without such reasonable and timely advance notice to enrollees of such change.

(d) PHARMACY BENEFIT MANAGERS TRANSPARENCY REQUIREMENTS.—

(1) IN GENERAL.—Notwithstanding any other provision of law, a qualified health benefits plan shall enter into a contract with a pharmacy benefit managers (in this subsection referred to as a "PBM") to manage the prescription drug coverage provided under such plan, or to control the costs of such prescription drug coverage, only if as a condition of such contract the PBM is required to provide at least annually to the Commissioner and to the QHBP offering entity offering such plan the following information:

(A) Information on the volume of prescriptions under the contract that are filled via mail order and at retail pharmacies.

(B) An estimate of aggregate average payments under the contract, per prescription (weighted by prescription volume), made to mail order and retail pharmacists, and the average amount, per prescription, that the PBM was paid by the plan for prescriptions filled at mail order and retail pharmacists.

(C) An estimate of the aggregate average payment per prescription (weighted by prescription volume) under the contract received from pharmaceutical manufacturers, including all rebates, discounts, prices concessions, or administrative, and other payments from pharmaceutical manufacturers, and a description of the types of payments, and the amount of these payments that were shared with the plan, and a description of the percentage of prescriptions for which the PBM received such payments.

(D) Information on the overall percentage of generic drugs dispensed under the contract at retail and mail order pharmacies, and the percentage of cases in which a generic drug is dispensed when available.

(E) Information on the percentage and number of cases under the contract in which individuals were switched from a prescribed drug that was less expensive to a drug that was more expensive, the rationale for these switches, and a description of the PBM policies governing such switches.

(2) CONFIDENTIALITY OF INFORMATION.—Notwithstanding any other provision of law, information disclosed by a PBM to the Commissioner or a QHBP offering entity under this subsection is confidential and shall not be disclosed by the Commissioner or the QHBP offering entity in a form which discloses the identity of a specific PBM or prices charged by such PBM or a specific retailer, manufacturer, or wholesaler, except—

(A) as the Commissioner determines to be necessary to carry out this subsection;

(B) to permit the Comptroller General to review the information provided;

(C) to permit the Director of the Congressional Budget Office to review the information provided; and

(D) to permit the Commissioner to disclose industry-wide aggregate or average information to be used in assessing the overall impact of PBMs on prescription drug prices and spending.

SEC. 134. APPLICATION TO QUALIFIED HEALTH BENEFITS PLANS NOT OFFERED THROUGH THE HEALTH INSURANCE EXCHANGE.

The requirements of the previous provisions of this subtitle shall apply to qualified health benefits plans that are not being offered through the Health Insurance Exchange only to the extent specified by the Commissioner.

SEC. 135. TIMELY PAYMENT OF CLAIMS.

A QHBP offering entity shall comply with the requirements of section 1857(f) of the Social Security Act with respect to a qualified health benefits plan it offers in the same manner an Medicare Advantage organization is required to comply with such requirements with respect to a Medicare Advantage plan it offers under part C of Medicare.

SEC. 136. STANDARDIZED RULES FOR COORDINATION AND SUBROGATION OF BENEFITS.

The Commissioner shall establish standards for the coordination and subrogation of benefits and reimbursement of payments in cases involving individuals and multiple plan coverage.

SEC. 137. APPLICATION OF ADMINISTRATIVE SIMPLIFICATION.

A QHBP offering entity is required to comply with standards for electronic financial and administrative transactions under section 1173A of the Social Security Act and the operating rules under section 1173B of such Act, as added by section 163(a).

SEC. 138. INFORMATION ON END-OF-LIFE PLANNING.

(a) IN GENERAL.—The QHBP offering entity —

(1) shall provide for the dissemination of information related to end-of-life planning to individuals seeking enrollment in Exchange-participating health benefits plans offered through the Exchange;

(2) shall present such individuals with—

(A) the option to establish advanced directives and physician's orders for life sustaining treatment according to the laws of the State in which the individual resides; and

(B) information related to other planning tools; and

(3) shall not promote suicide, assisted suicide, or the active hastening of death.

The information presented under paragraph (2) shall not presume the withdrawal of treatment and shall include end-of-life planning information that includes options to maintain all or most medical interventions.

(b) CONSTRUCTION.— Nothing in this section shall be construed—

(1) to require an individual to complete an advanced directive or a physician's order for life sustaining treatment or other end-of-life planning document;

(2) to require an individual to consent to restrictions on the amount, duration, or scope of medical benefits otherwise covered under a qualified health benefits plan; or

(3) to encourage the hastening of death or the promotion of assisted suicide.

(c) ADVANCED DIRECTIVE DEFINED.—In this section, the term "advanced directive" includes a living will, a comfort care order, or a durable power of attorney for health care

(d) PROHIBITION ON THE PROMOTION OF ASSISTED SUICIDE.—

(1) IN GENERAL.—Subject to paragraph (3), information provided to meet the requirements of subsection (a)(2) shall not include advanced directives or other planning tools that list or describe as an option suicide, assisted suicide or the intentional hastening of death regardless of legality.

(2) CONSTRUCTION.—Nothing in paragraph (1) shall be construed to apply to or affect any option to—

(A) the withhold or withdraw of medical treatment or medical care;

(B) withhold or withdraw of nutrition or hydration; and

(C) provide palliative or hospice care or use an item, good, benefit, or service furnished for the purpose of alleviating pain or discomfort, even if such use may increase the risk of death, so long as such item, good, benefit, or service is not also furnished for the purpose of causing, or the purpose of assisting in causing, death, for any reason.

(3) EXEMPTION.—The requirements of subsection (a) shall not apply to any State that as of August 1, 2009, requires the inclusion of information prohibited in such paragraph in advanced directives or other planning tools.

SEC. 139. UTILIZATION REVIEW ACTIVITIES.

(a) COMPLIANCE WITH REQUIREMENTS.—

(1) IN GENERAL.—A qualified health benefits plan, and a QHBP offering entity that offers such plan, shall conduct utilization review activities in connection with the provision of benefits under such plan only in accordance with a utilization review program that meets the requirements of this section.

(2) USE OF OUTSIDE AGENTS.—Nothing in this section shall be construed as preventing a qualified health benefits plan or QHBP offering entity from arranging through a contract or otherwise for persons or entities to conduct utilization review activities on behalf of the plan entity, so long as such activities are conducted in accordance with a utilization review program that meets the requirements of this section.

(3) UTILIZATION REVIEW DEFINED.—For purposes of this section, the terms "utilization review" and "utilization review activities" mean procedures used to monitor or evaluate the use or coverage, clinical necessity, appropriateness, efficacy, or efficiency of health care services, procedures or settings, and includes

prospective review, concurrent review, second opinions, case management, discharge planning, or retrospective review.

(b) WRITTEN POLICIES AND CRITERIA.—

(1) WRITTEN POLICIES.—A utilization review program shall be conducted consistent with written policies and procedures that govern all aspects of the program.

(2) USE OF WRITTEN CRITERIA.—

(A) IN GENERAL.—Such a program shall utilize written clinical review criteria developed with input from a range of appropriate actively practicing health care professionals, as determined by the plan, pursuant to the program. Such criteria shall include written clinical review criteria that are based on valid clinical evidence where available and that are directed specifically at meeting the needs of at-risk populations and covered individuals with chronic conditions or severe illnesses, including gender-specific criteria and pediatric-specific criteria where available and appropriate.

(B) CONTINUING USE OF STANDARDS IN RETROSPECTIVE REVIEW.—If a health care service has been specifically pre-authorized or approved for an enrollee under such a program, the program shall not, pursuant to retrospective review, revise or modify the specific standards, criteria, or procedures used for the utilization review for procedures, treatment, and services delivered to the enrollee during the same course of treatment.

(C) REVIEW OF SAMPLE OF CLAIMS DENIALS.—Such a program shall provide for an evaluation of the clinical appropriateness of at least a sample of denials of claims for benefits.

(c) CONDUCT OF PROGRAM ACTIVITIES.—

(1) ADMINISTRATION BY HEALTH CARE PROFESSIONALS.—A utilization review program shall be administered by qualified health care professionals who shall oversee review decisions.

(2) USE OF QUALIFIED, INDEPENDENT PERSONNEL.—

(A) IN GENERAL.—A utilization review program shall provide for the conduct of utilization review activities only through personnel who are qualified and have received appropriate training in the conduct of such activities under the program.

(B) PROHIBITION OF CONTINGENT COMPENSATION ARRANGEMENTS.—Such a program shall not, with respect to utilization review activities, permit or provide compensation or anything of value to its employees, agents, or contractors in a manner that encourages denials of claims for benefits.

(C) PROHIBITION OF CONFLICTS.—Such a program shall not permit a health care professional who is providing health care services to an individual to perform utilization review activities in connection with the health care services being provided to the individual.

(3) ACCESSIBILITY OF REVIEW.—Such a program shall provide that appropriate personnel performing utilization review activities under the program, including the utilization review administrator, are reasonably accessible by toll-free telephone during normal business hours to discuss patient care and allow response to telephone requests, and that appropriate provision is made to receive and respond promptly to calls received during other hours.

(4) LIMITS ON FREQUENCY.—Such a program shall not provide for the performance of utilization review activities with respect to a class of services furnished to an individual more frequently than is reasonably required to assess whether the services under review are medically necessary or appropriate.

(d) DEADLINE FOR DETERMINATIONS.—

(1) PRIOR AUTHORIZATION SERVICES.—

(A) IN GENERAL.—Except as provided in paragraph (2), in the case of a utilization review activity involving the prior authorization of health care items and services for an individual, the utilization review program shall make a determination concerning such authorization, and provide notice of the determination to the individual or the individual's designee and the individual's health care provider by telephone and in printed form, as soon as possible in accordance with the medical exigencies of the case, and in no event later than the deadline specified in subparagraph (B).

(B) DEADLINE.—

(i) IN GENERAL.—Subject to clauses (ii), (iii), and (iv), the deadline specified in this subparagraph is 14 days after the date of receipt of the request for prior authorization, but in no event later than 3 business days after the date of receipt of information that is reasonably necessary to make such determination.

(ii) EXTENSION PERMITTED WHERE NOTICE OF ADDITIONAL INFORMATION REQUIRED.—If a utilization review program—

(I) receives a request for a prior authorization;

(II) determines that additional information is necessary to complete the review and make the determination on the request; and

(III) notifies the requester, not later than 5 business days after the date of receiving the request, of the need for such specified additional information;

the deadline specified in this subparagraph is 14 days after the date the program receives the specified additional information, but in no case later than 28 days after the date of receipt of the request for the prior authorization. This clause shall not apply if the deadline is specified in clause (iii).

(iii) EXPEDITED CASES.—In the case of a situation described in section 139A(c)(1)(A), the deadline specified in this subparagraph is 72 hours after the time of the request for prior authorization.

(iv) EXCEPTION FOR EMERGENCY SERVICES.—No prior approval shall be required in the case of emergency services provided by a hospital.

(2) ONGOING CARE.—

(A) CONCURRENT REVIEW.—

(i) IN GENERAL.—Subject to subparagraph (B), in the case of a concurrent review of ongoing care (including hospitalization), which results in a termination or reduction of such care, the plan must provide by telephone and in printed form notice of the concurrent review determination to the individual or the individual's designee and the individual's health care provider as soon as possible in accordance with the medical exigencies of the case, and in no event later than 1 business day after the date of receipt of information that is reasonably necessary to make such determination, with sufficient time prior to the termination or reduction to allow for an appeal under section 139A(c)(1)(A) to be completed before the termination or reduction takes effect.

(ii) CONTENTS OF NOTICE.—Such notice shall include, with respect to ongoing health care items and services, the number of ongoing services approved, the new total of approved services, the date of onset of services, and the next review date, if any, as well as a statement of the individual″s rights to further appeal.

(B) EXCEPTION.—Subparagraph (A) shall not be interpreted as requiring plans or issuers to provide coverage of care that would exceed the coverage limitations for such care.

(3) PREVIOUSLY PROVIDED SERVICES.—In the case of a utilization review activity involving retrospective review of health care services previously provided for an individual, the utilization review program shall make a determination concerning such services, and provide notice of the determination to the individual or the individual's designee and the individual's health care provider by telephone and in printed form, within 30 days of the date of receipt of information that is reasonably necessary to make such determination, but in no case later than 60 days after the date of receipt of the claim for benefits.

(4) FAILURE TO MEET DEADLINE.—In a case in which a qualified health benefits plan or QHBP offering entity fails to make a determination on a claim for benefit under paragraph (1), (2)(A), or (3) by the applicable deadline established under the respective paragraph, the failure shall be treated under this subtitle as a denial of the claim as of the date of the deadline.

(e) NOTICE OF DENIALS OF CLAIMS FOR BENEFITS.—

(1) IN GENERAL.—Notice of a denial of claims for benefits under a utilization review program shall be provided in printed form and written in a manner calculated to be understood by the participant, beneficiary, or enrollee and shall include—

(A) the reasons for the denial (including the clinical rationale);

(B) instructions on how to initiate an appeal under section 139A; and

(C) notice of the availability, upon request of the individual (or the individual″s designee) of the clinical review criteria relied upon to make such denial.

(2) SPECIFICATION OF ANY ADDITIONAL INFORMATION.—Such a notice shall also specify what (if any) additional necessary information must be provided to, or obtained by, the person making the denial in order to make a decision on such an appeal.

(f) CLAIM FOR BENEFITS AND DENIAL OF CLAIM FOR BENEFITS DEFINED.—For purposes of this subtitle:

(1) CLAIM FOR BENEFITS.—The term "claim for benefits" means any request for coverage (including authorization of coverage), for eligibility, or for payment in whole or in part, for an item or service under a qualified health benefits plan.

(2) DENIAL OF CLAIM FOR BENEFITS.—The term "denial" means, with respect to a claim for benefits, means a denial, or a failure to act on a timely basis upon, in whole or in part, the claim for benefits and includes a failure to provide benefits (including items and services) required to be provided under this title.

SEC. 139A. INTERNAL APPEALS PROCEDURES.

(a) RIGHT OF REVIEW.—

(1) IN GENERAL.—Each qualified health benefits plan, and each QHBP offering entity offering such plan—

(A) shall provide adequate notice in writing to any participant or beneficiary under such plan, or enrollee under such coverage, whose claim for benefits under the plan has been denied (within the meaning of section 139(f)(2)), setting forth the specific reasons for such denial of claim for benefits and rights to any further review or appeal, written in a manner calculated to be understood by the participant, beneficiary, or enrollee; and

(B) shall afford such a participant, beneficiary, or enrollee (and any provider or other person acting on behalf of such an individual with the individual″s consent or without such consent if the individual is medically unable to provide such consent) who is dissatisfied with such a denial of claim for benefits a reasonable opportunity (of not less than 180 days) to request and obtain a full and fair review by a named fiduciary (with respect to such plan) or named appropriate individual (with respect to such coverage) of the decision denying the claim.

(2) TREATMENT OF ORAL REQUESTS.—The request for review under paragraph (1)(B) may be made orally, but, in the case of an oral request, shall be followed by a request in writing.

(b) INTERNAL REVIEW PROCESS.—

(1) CONDUCT OF REVIEW.—

(A) IN GENERAL.—A review of a denial of claim under this section shall be made by an individual who—

(i) in a case involving medical judgment, shall be a physician or, in the case of limited scope coverage (as defined in subparagraph (B), shall be an appropriate specialist;

(ii) has been selected by the plan or entity; and

(iii) did not make the initial denial in the internally appealable decision.

(B) LIMITED SCOPE COVERAGE DEFINED.—For purposes of subparagraph (A), the term "limited scope coverage" means a qualified health benefits plan the only benefits under which are for benefits described in section 2791(c)(2)(A) of the Public Health Service Act (42 U.S.C. 300gg-91(c)(2)).

(2) TIME LIMITS FOR INTERNAL REVIEWS.—

(A) IN GENERAL.—Having received such a request for review of a denial of claim, the QHBP offering entity offering a qualified health benefits plan, in accordance with the medical exigencies of the case but not later than the deadline specified in subparagraph (B), complete the review on the denial and transmit to the participant, beneficiary, enrollee, or other person involved a decision that affirms, reverses, or modifies the denial. If the decision does not reverse the denial, the plan or issuer shall transmit, in printed form, a notice that sets forth the grounds for such decision and that includes a description of rights to any further appeal. Such decision shall be treated as the final decision of the plan. Failure to issue such a decision by such deadline shall be treated as a final decision affirming the denial of claim.

(B) DEADLINE.—

(i) IN GENERAL.—Subject to clauses (ii) and (iii), the deadline specified in this subparagraph is 14 days after the date of receipt of the request for internal review.

(ii) EXTENSION PERMITTED WHERE NOTICE OF ADDITIONAL INFORMATION REQUIRED.—If a qualified health benefits plan of QHBP offering entity—

(I) receives a request for internal review,

(II) determines that additional information is necessary to complete the review and make the determination on the request, and

(III) notifies the requester, not later than 5 business days after the date of receiving the request, of the need for such specified additional information,

the deadline specified in this subparagraph is 14 days after the date the plan or entity receives the specified additional information, but in no case later than 28 days after the date of receipt of the request for

the internal review. This clause shall not apply if the deadline is specified in clause (iii).

(iii) EXPEDITED CASES.—In the case of a situation described in subsection (c)(1)(A), the deadline specified in this subparagraph is 72 hours after the time of the request for review.

(c) EXPEDITED REVIEW PROCESS.—

(1) IN GENERAL.—A qualified health benefits plan, and a QHBP offering entity, shall establish procedures in writing for the expedited consideration of requests for review under subsection (b) in situations—

(A) in which, as determined by the plan or issuer or as certified in writing by a treating health care professional, the application of the normal timeframe for making a determination could seriously jeopardize the life or health of the participant, beneficiary, or enrollee or such an individual″s ability to regain maximum function; or

(B) described in section 139(d)(2) (relating to requests for continuation of ongoing care which would otherwise be reduced or terminated).

(2) PROCESS.—Under such procedures—

(A) the request for expedited review may be submitted orally or in writing by an individual or provider who is otherwise entitled to request the review;

(B) all necessary information, including the plan's or entity's decision, shall be transmitted between the plan or issuer and the requester by telephone, facsimile, or other similarly expeditious available method; and

(C) the plan or issuer shall expedite the review in the case of any of the situations described in subparagraph (A) or (B) of paragraph (1).

(3) DEADLINE FOR DECISION.—The decision on the expedited review must be made and communicated to the parties as soon as possible in accordance with the medical exigencies of the case, and in no event later than 72 hours after the time of receipt of the request for expedited review, except that in a case described in paragraph (1)(B), the decision must be made before the end of the approved period of care.

(d) WAIVER OF PROCESS.—A plan or entity may waive its rights for an internal review under subsection (b). In such case the participant, beneficiary, or enrollee involved (and any designee or provider involved) shall be relieved of any obligation to complete the review involved and may, at the option of such participant, beneficiary, enrollee, designee, or provider, proceed directly to seek further appeal through any applicable external appeals process.

SEC. 139B. EXTERNAL APPEALS PROCEDURES.

(a) RIGHT TO EXTERNAL APPEAL.—

(1) IN GENERAL.—A qualified health benefits plan, and a QHBP offering entity, shall provide for an external appeals process that meets the requirements of this section in the case of an externally appealable decision described in paragraph (2), for which a timely appeal is made either by the plan or entity or by the participant, beneficiary, or enrollee (and any provider or other person acting on behalf of such an individual with the individual's consent or without such consent if such an individual is medically unable to provide such consent). The appropriate Secretary shall establish standards to carry out such requirements.

(2) EXTERNALLY APPEALABLE DECISION DEFINED.—

(A) IN GENERAL.—For purposes of this section, the term "externally appealable decision" means a denial of claim for benefits (as defined in section 139(f)(2))—

(i) that is based in whole or in part on a decision that the item or service is not medically necessary or appropriate or is investigational or experimental; or

(ii) in which the decision as to whether a benefit is covered involves a medical judgment.

(B) INCLUSION.—Such term also includes a failure to meet an applicable deadline for internal review under section 139A.

(C) EXCLUSIONS.—Such term does not include—

(i) specific exclusions or express limitations on the amount, duration, or scope of coverage that do not involve medical judgment; or

(ii) a decision regarding whether an individual is a participant, beneficiary, or enrollee under the plan.

(3) EXHAUSTION OF INTERNAL REVIEW PROCESS.—Except as provided under section 139A(d), a plan or entity may condition the use of an external appeal process in the case of an externally appealable decision upon a final decision in an internal review under section 140, but only if the decision is made in a timely basis consistent with the deadlines provided under this subtitle.

(4) FILING FEE REQUIREMENT.—

(A) IN GENERAL.—Subject to subparagraph (B), a plan or entity may condition the use of an external appeal process upon payment to the plan or entity of a filing fee that does not exceed $25.

(B) EXCEPTION FOR INDIGENCY.—The plan or issuer may not require payment of the filing fee in the case of an individual participant, beneficiary, or enrollee who certifies (in a form and manner specified in guidelines established by the Secretary of Health and Human Services) that the individual is indigent (as defined in such guidelines).

(C) REFUNDING FEE IN CASE OF SUCCESSFUL APPEALS.—The plan or entity shall refund payment of the filing fee under this paragraph if the recommendation of the external appeal entity is to reverse or modify the denial of a claim for benefits which is the subject of the appeal.

(b) GENERAL ELEMENTS OF EXTERNAL APPEALS PROCESS.—

(1) CONTRACT WITH QUALIFIED EXTERNAL APPEAL ENTITY.—

(A) CONTRACT REQUIREMENT.—Except as provided in subparagraph (D), the external appeal process under this section of a plan or entity shall be conducted under a contract between the plan or issuer and one or more qualified external appeal entities (as defined in subsection (c)).

(B) LIMITATION ON PLAN OR ISSUER SELECTION.—The applicable authority shall implement procedures—

(i) to assure that the selection process among qualified external appeal entities will not create any incentives for external appeal entities to make a decision in a biased manner, and

(ii) for auditing a sample of decisions by such entities to assure that no such decisions are made in a biased manner.

(C) OTHER TERMS AND CONDITIONS.—The terms and conditions of a contract under this paragraph shall be consistent with the standards the appropriate Secretary shall establish to assure there is no real or apparent conflict of interest in the conduct of external appeal activities. Such contract shall provide that all costs of the process (except those incurred by the participant, beneficiary, enrollee, or treating professional in support of the appeal) shall be paid by the plan or entity, and not by the participant, beneficiary, or enrollee. The previous sentence shall not be construed as applying to the imposition of a filing fee under subsection (a)(4).

(D) STATE AUTHORITY WITH RESPECT TO QUALIFIED EXTERNAL APPEAL ENTITY FOR HEALTH INSURANCE ISSUERS.—With respect to QHBP offering entities offering qualified health benefits plans in a State, the State may provide for external review activities to be conducted by a qualified external appeal entity that is designated by the State or that is selected by the State in a manner determined by the State to assure an unbiased determination.

(2) ELEMENTS OF PROCESS.—An external appeal process shall be conducted consistent with standards established by the appropriate Secretary that include at least the following:

(A) FAIR AND DE NOVO DETERMINATION.—The process shall provide for a fair, de novo determination. However, nothing in this paragraph shall be construed as providing for coverage of items and services for which benefits are specifically excluded under the plan.

(B) STANDARD OF REVIEW.—An external appeal entity shall determine whether the plan's or issuer's decision is in accordance with the medical needs of the patient involved (as determined by the entity) taking into account, as of the time of the entity's determination, the patient's medical condition and any relevant and reliable evidence the entity obtains under subparagraph (D). If the entity determines the decision is in accordance with such needs, the entity shall affirm the decision and to the extent that the entity determines the decision is not in accordance with such needs, the entity shall reverse or modify the decision.

(C) CONSIDERATION OF PLAN OR COVERAGE DEFINITIONS.—In making such determination, the external appeal entity shall consider (but not be bound by) any language in the plan or coverage document relating to the definitions of the terms medical necessity, medically necessary or appropriate, or experimental, investigational, or related terms.

(D) EVIDENCE.—

(i) IN GENERAL.—An external appeal entity shall include, among the evidence taken into consideration—

(I) the decision made by the plan or QHBP offering entity upon internal review under section 140 and any guidelines or standards used by the plan or QHBP offering entity in reaching such decision;

(II) any personal health and medical information supplied with respect to the individual whose denial of claim for benefits has been appealed; and

(III) the opinion of the individual's treating physician or health care professional.

(ii) ADDITIONAL EVIDENCE.—Such external appeal entity may also take into consideration but not be limited to the following evidence (to the extent available):

(I) The results of studies that meet professionally recognized standards of validity and replicability or that have been published in peer-reviewed journals.

(II) The results of professional consensus conferences conducted or financed in whole or in part by one or more government agencies.

(III) Practice and treatment guidelines prepared or financed in whole or in part by government agencies.

(IV) Government-issued coverage and treatment policies.

(V) Community standard of care and generally accepted principles of professional medical practice.

(VI) To the extent that the entity determines it to be free of any conflict of interest, the opinions of individuals who are qualified as experts in one or more fields of health care which are directly related to the matters under appeal.

(VII) To the extent that the entity determines it to be free of any conflict of interest, the results of peer reviews conducted by the plan involved.

(E) DETERMINATION CONCERNING EXTERNALLY APPEALABLE DECISIONS.—A qualified external appeal entity shall determine—

(i) whether a denial of claim for benefits is an externally appealable decision (within the meaning of subsection (a)(2));

(ii) whether an externally appealable decision involves an expedited appeal; and

(iii) for purposes of initiating an external review, whether the internal review process has been completed.

(F) OPPORTUNITY TO SUBMIT EVIDENCE.—Each party to an externally appealable decision may submit evidence related to the issues in dispute.

(G) PROVISION OF INFORMATION.—The plan or issuer involved shall provide timely access to the external appeal entity to information and to provisions of the plan relating to the matter of the externally appealable decision, as determined by the entity.

(H) TIMELY DECISIONS.—A determination by the external appeal entity on the decision shall—

(i) be made orally or in writing and, if it is made orally, shall be supplied to the parties in writing as soon as possible;

(ii) be made in accordance with the medical exigencies of the case involved, but in no event later than 21 days after the date (or, in the case of an expedited appeal, 72 hours after the time) of requesting an external appeal of the decision;

(iii) state, in layperson's language, the basis for the determination, including, if relevant, any basis in the terms or conditions of the plan; and

(iv) inform the participant, beneficiary, or enrollee of the individual's rights (including any limitation on such rights) to seek further review by the courts (or other process) of the external appeal determination.

(I) COMPLIANCE WITH DETERMINATION.—If the external appeal entity reverses or modifies the denial of a claim for benefits, the plan shall—

(i) upon the receipt of the determination, authorize benefits in accordance with such determination;

(ii) take such actions as may be necessary to provide benefits (including items or services) in a timely manner consistent with such determination; and

(iii) submit information to the entity documenting compliance with the entity's determination and this subparagraph.

(c) QUALIFICATIONS OF EXTERNAL APPEAL ENTITIES.—

(1) IN GENERAL.—For purposes of this section, the term "qualified external appeal entity" means, in relation to a plan or issuer, an entity that is certified under paragraph (2) as meeting the following requirements:

(A) The entity meets the independence requirements of paragraph (3).

(B) The entity conducts external appeal activities through a panel of not fewer than 3 clinical peers.

(C) The entity has sufficient medical, legal, and other expertise and sufficient staffing to conduct external appeal activities for the plan on a timely basis consistent with subsection (b)(2)(G).

(D) The entity meets such other requirements as the appropriate Secretary may impose.

(2) INITIAL CERTIFICATION OF EXTERNAL APPEAL ENTITIES.—

(A) IN GENERAL.—In order to be treated as a qualified external appeal entity with respect to—

(i) a qualified health benefits plan that is a group health plan, the entity must be certified (and, in accordance with subparagraph (B), periodically recertified) as meeting the requirements of paragraph (1)—

(I) by the Secretary of Labor;

(II) under a process recognized or approved by the Secretary of Labor; or

(III) to the extent provided in subparagraph (C)(i), by a qualified private standard-setting organization (certified under such subparagraph); or

(ii) a QHBP offering entity that is a health insurance issuer operating in a State, the qualified external appeal entity must be certified (and, in accordance with subparagraph (B), periodically recertified) as meeting such requirements—

(I) by the applicable State authority (or under a process recognized or approved by such authority); or

(II) if the State has not established a certification and recertification process for such entities, by the Secretary of Health and Human Services, under a process recognized or approved by such Secretary, or to the extent provided in subparagraph (C)(ii), by a qualified private standard-setting organization (certified under such subparagraph).

(B) RECERTIFICATION PROCESS.—The appropriate Secretary shall develop standards for the recertification of external appeal entities. Such standards shall include a review of—

(i) the number of cases reviewed;

(ii) a summary of the disposition of those cases;

(iii) the length of time in making determinations on those cases;

(iv) updated information of what was required to be submitted as a condition of certification for the entity's performance of external appeal activities; and

(v) such information as may be necessary to assure the independence of the entity from the plans or issuers for which external appeal activities are being conducted.

(C) CERTIFICATION OF QUALIFIED PRIVATE STANDARD-SETTING ORGANIZATIONS.—

(i) FOR EXTERNAL REVIEWS OF GROUP HEALTH PLANS.—For purposes of subparagraph (A)(i)(III), the Secretary of Labor may provide for a process for certification (and periodic recertification) of qualified private standard-setting organizations which provide for certification of external review entities. Such an organization shall only be certified if the organization does not certify an external review entity unless it meets standards required for certification of such an entity by such Secretary under subparagraph (A)(i)(I).

(ii) FOR EXTERNAL REVIEWS OF HEALTH INSURANCE ISSUERS.—For purposes of subparagraph (A)(ii)(II), the Secretary of Health and Human Services may provide for a process for certification (and periodic recertification) of qualified private standard-setting organizations which provide for certification of external review entities. Such an organization shall only be certified if the organization does not certify an external review entity unless it meets standards required for certification of such an entity by such Secretary under subparagraph (A)(ii)(II).

(3) INDEPENDENCE REQUIREMENTS.—

(A) IN GENERAL.—A clinical peer or other entity meets the independence requirements of this paragraph if—

(i) the peer or entity does not have a familial, financial, or professional relationship with any related party;

(ii) any compensation received by such peer or entity in connection with the external review is reasonable and not contingent on any decision rendered by the peer or entity;

(iii) except as provided in paragraph (4), the plan and the issuer have no recourse against the peer or entity in connection with the external review; and

(iv) the peer or entity does not otherwise have a conflict of interest with a related party as determined under any regulations which the Secretary may prescribe.

(B) RELATED PARTY.—For purposes of this paragraph, the term "related party" means—

(i) with respect to—

(I) a qualified health benefits plan that is a group health plan, the plan or QHBP offering entity of such plan; or

(II) a qualified health benefits plan that is individual health insurance coverage, the health insurance issuer offering such coverage, or any plan sponsor, fiduciary, officer, director, or management employee of such plan or issuer;

(ii) the health care professional that provided the health care involved in the coverage decision;

(iii) the institution at which the health care involved in the coverage decision is provided;

(iv) the manufacturer of any drug or other item that was included in the health care involved in the coverage decision; or

(v) any other party determined under any regulations which the Secretary may prescribe to have a substantial interest in the coverage decision.

(4) LIMITATION ON LIABILITY OF REVIEWERS.—No qualified external appeal entity having a contract with a qualified health benefits plan under this part and no person who is employed by any such entity or who furnishes professional services to such entity, shall be held by reason of the performance of any duty, function, or activity required or authorized pursuant to this section, to have violated any criminal law, or to be civilly liable under any law of the United States or of any State (or political subdivision thereof) if due care was exercised in the performance of such duty, function, or activity and there was no actual malice or gross misconduct in the performance of such duty, function, or activity.

(d) EXTERNAL APPEAL DETERMINATION BINDING ON PLAN.—The determination by an external appeal entity under this section is binding on the plan involved in the determination.

(e) PENALTIES AGAINST AUTHORIZED OFFICIALS FOR REFUSING TO AUTHORIZE THE DETERMINATION OF AN EXTERNAL REVIEW ENTITY.—

(1) MONETARY PENALTIES.—In any case in which the determination of an external review entity is not followed by a qualified health benefits plan, any person who, acting in the capacity of authorizing the benefit, causes such refusal may, in the discretion in a court of competent jurisdiction, be liable to an aggrieved participant, beneficiary, or enrollee for a civil penalty in an amount of up to $1,000 a day from the date on which the determination was transmitted to the plan by the external review entity until the date the refusal to provide the benefit is corrected.

(2) CEASE AND DESIST ORDER AND ORDER OF ATTORNEY'S FEES.—In any action described in paragraph (1) brought by a participant, beneficiary, or enrollee with respect to a qualified health benefits plan, in which a plaintiff alleges that a person referred to in such paragraph has taken an action resulting in a refusal of a benefit determined by an external appeal entity in violation of such terms of the plan, coverage, or this subtitle, or has failed to take an action for which such person is responsible under the plan or this title and which is necessary under the plan or coverage for authorizing a benefit, the court shall cause to be served on the defendant an order requiring the defendant—

(A) to cease and desist from the alleged action or failure to act; and

(B) to pay to the plaintiff a reasonable attorney's fee and other reasonable costs relating to the prosecution of the action on the charges on which the plaintiff prevails.

(3) ADDITIONAL CIVIL PENALTIES.—

(A) IN GENERAL.—In addition to any penalty imposed under paragraph (1) or (2), the appropriate Secretary may assess a civil penalty against a person acting in the capacity of authorizing a benefit determined by an external review entity for one or more qualified health benefits plans, for—

(i) any pattern or practice of repeated refusal to authorize a benefit determined by an external appeal entity in violation of the terms of such a plan, or this title; or

(ii) any pattern or practice of repeated violations of the requirements of this section with respect to such plan or plans.

(B) STANDARD OF PROOF AND AMOUNT OF PENALTY.—Such penalty shall be payable only upon proof by clear and convincing evidence of such pattern or practice and shall be in an amount not to exceed the lesser of—

(i) 25 percent of the aggregate value of benefits shown by the appropriate Secretary to have not been provided, or unlawfully delayed, in violation of this section under such pattern or practice, or

(ii) $500,000.

(4) REMOVAL AND DISQUALIFICATION.—Any person acting in the capacity of authorizing benefits who has engaged in any such pattern or practice described in paragraph (3)(A) with respect to a plan or coverage, upon the petition of the appropriate Secretary, may be removed by the court from such position, and from any other involvement, with respect to such a plan or coverage, and may be precluded from returning to any such position or involvement for a period determined by the court.

(f) PROTECTION OF LEGAL RIGHTS.—Nothing in this subtitle shall be construed as altering or eliminating any cause of action or legal rights or remedies of participants, beneficiaries, enrollees, and others under State or Federal law (including sections 502 and 503 of the Employee Retirement Income Security Act of 1974), including the right to file judicial actions to enforce actions.

(g) APPLICATION TO ALL ACCEPTABLE COVERAGE.—The provisions of this section shall apply with respect to all acceptable coverage in the same manner as such provisions apply with respect to qualified health benefits plans under this section.

Subtitle E—Governance

SEC. 141. HEALTH CHOICES ADMINISTRATION; HEALTH CHOICES COMMISSIONER.

(a) IN GENERAL.—There is hereby established, as an independent agency in the executive branch of the Government, a Health Choices Administration (in this division referred to as the "Administration").

(b) COMMISSIONER.—

(1) IN GENERAL.—The Administration shall be headed by a Health Choices Commissioner (in this division referred to as the "Commissioner") who shall be appointed by the President, by and with the advice and consent of the Senate.

(2) COMPENSATION; ETC.—The provisions of paragraphs (2), (5), and (7) of subsection (a) (relating to compensation, terms, general powers, rulemaking, and delegation) of section 702 of the Social Security Act (42 U.S.C. 902) shall apply to the Commissioner and the Administration in the same manner as such provisions apply to the Commissioner of Social Security and the Social Security Administration.

SEC. 142. DUTIES AND AUTHORITY OF COMMISSIONER.

(a) DUTIES.—The Commissioner is responsible for carrying out the following functions under this division:

(1) QUALIFIED PLAN STANDARDS.—The establishment of qualified health benefits plan standards under this title, including the enforcement of such standards in coordination with State insurance regulators and the Secretaries of Labor and the Treasury.

(2) HEALTH INSURANCE EXCHANGE.—The establishment and operation of a Health Insurance Exchange under subtitle A of title II.

(3) INDIVIDUAL AFFORDABILITY CREDITS.—The administration of individual affordability credits under subtitle C of title II, including determination of eligibility for such credits.

(4) ADDITIONAL FUNCTIONS.—Such additional functions as may be specified in this division.

(b) PROMOTING ACCOUNTABILITY.—

(1) IN GENERAL.—The Commissioner shall undertake activities in accordance with this subtitle to promote accountability of QHBP offering entities in meeting Federal health insurance requirements, regardless of whether such accountability is with respect to qualified health benefits plans offered through the Health Insurance Exchange or outside of such Exchange.

(2) COMPLIANCE EXAMINATION AND AUDITS.—

(A) IN GENERAL.—The commissioner shall, in coordination with States, conduct audits of qualified health benefits plan compliance with Federal requirements. Such audits may include random compliance audits and targeted audits in response to complaints or other suspected non-compliance.

(B) RECOUPMENT OF COSTS IN CONNECTION WITH EXAMINATION AND AUDITS.—The Commissioner is authorized to recoup from qualified health ben-

efits plans reimbursement for the costs of such examinations and audit of such QHBP offering entities.

(c) DATA COLLECTION.—The Commissioner shall collect data for purposes of carrying out the Commissioner's duties, including for purposes of promoting quality and value, protecting consumers, and addressing disparities in health and health care and may share such data with the Secretary of Health and Human Services.

(d) SANCTIONS AUTHORITY.—

(1) IN GENERAL.—In the case that the Commissioner determines that a QHBP offering entity violates a requirement of this title, the Commissioner may, in coordination with State insurance regulators and the Secretary of Labor, provide, in addition to any other remedies authorized by law, for any of the remedies described in paragraph (2).

(2) REMEDIES.—The remedies described in this paragraph, with respect to a qualified health benefits plan offered by a QHBP offering entity, are—

(A) civil money penalties of not more than the amount that would be applicable under similar circumstances for similar violations under section 1857(g) of the Social Security Act;

(B) suspension of enrollment of individuals under such plan after the date the Commissioner notifies the entity of a determination under paragraph (1) and until the Commissioner is satisfied that the basis for such determination has been corrected and is not likely to recur;

(C) in the case of an Exchange-participating health benefits plan, suspension of payment to the entity under the Health Insurance Exchange for individuals enrolled in such plan after the date the Commissioner notifies the entity of a determination under paragraph (1) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur; or

(D) working with State insurance regulators to terminate plans for repeated failure by the offering entity to meet the requirements of this title.

(e) STANDARD DEFINITIONS OF INSURANCE AND MEDICAL TERMS.—The Commissioner shall provide for the development of standards for the definitions of terms used in health insurance coverage, including insurance-related terms.

(f) EFFICIENCY IN ADMINISTRATION.—The Commissioner shall issue regulations for the effective and efficient administration of the Health Insurance Exchange and affordability credits under subtitle C, including, with respect to the determination of eligibility for affordability credits, the use of personnel who are employed in accordance with the requirements of title 5, United States Code, to carry out the duties of the Commissioner or, in the case of sections 208 and 241(b)(2), the use of State personnel who are employed in accordance with standards prescribed by the Office of Personnel Management pursuant to section 208 of the Intergovernmental Personnel Act of 1970 (42 U.S.C. 4728).

SEC. 143. CONSULTATION AND COORDINATION.

(a) CONSULTATION.—In carrying out the Commissioner's duties under this division, the Commissioner, as appropriate, shall consult with at least with the following:

(1) The National Association of Insurance Commissioners, State attorneys general, and State insurance regulators, including concerning the standards for insured qualified health benefits plans under this title and enforcement of such standards.

(2) Appropriate State agencies, specifically concerning the administration of individual affordability credits under subtitle C of title II and the offering of Exchange-participating health benefits plans, to Medicaid eligible individuals under subtitle A of such title.

(3) Other appropriate Federal agencies.

(4) Indian tribes and tribal organizations.

(5) The National Association of Insurance Commissioners for purposes of using model guidelines established by such association for purposes of subtitles B and D.

(b) COORDINATION.—

(1) IN GENERAL.—In carrying out the functions of the Commissioner, including with respect to the enforcement of the provisions of this division, the Commissioner shall work in coordination with existing Federal and State entities to the maximum extent feasible consistent with this division and in a manner that prevents conflicts of interest in duties and ensures effective enforcement.

(2) UNIFORM STANDARDS.—The Commissioner, in coordination with such entities, shall seek to achieve uniform standards that adequately protect consumers in a manner that does not unreasonably affect employers and insurers.

SEC. 144. HEALTH INSURANCE OMBUDSMAN.

(a) IN GENERAL.—The Commissioner shall appoint within the Health Choices Administration a Qualified Health Benefits Plan Ombudsman who shall have expertise and experience in the fields of health care and education of (and assistance to) individuals.

(b) DUTIES.—The Qualified Health Benefits Plan Ombudsman shall, in a linguistically appropriate manner—

(1) receive complaints, grievances, and requests for information submitted by individuals;

(2) provide assistance with respect to complaints, grievances, and requests referred to in paragraph (1), including—

(A) helping individuals determine the relevant information needed to seek an appeal of a decision or determination;

(B) assistance to such individuals with any problems arising from disenrollment from such a plan;

(C) assistance to such individuals in choosing a qualified health benefits plan in which to enroll; and

(D) assistance to such individuals in presenting information under subtitle C (relating to affordability credits); and

(3) submit annual reports to Congress and the Commissioner that describe the activities of the Ombudsman and that include such recommendations for improvement in the administration of this division as the Ombudsman determines appropriate. The Ombudsman shall not serve as an advocate for any increases in payments or new coverage of services, but may identify issues and problems in payment or coverage policies.

Subtitle F—Relation to Other Requirements; Miscellaneous

SEC. 151. RELATION TO OTHER REQUIREMENTS.

(a) COVERAGE NOT OFFERED THROUGH EXCHANGE.—

(1) IN GENERAL.—In the case of health insurance coverage not offered through the Health Insurance Exchange (whether or not offered in connection with an employment-based health plan), and in the case of employment-based health plans, the requirements of this title do not supercede any requirements applicable under titles XXII and XXVII of the Public Health Service Act, parts 6 and 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, or State law, except insofar as such requirements prevent the application of a requirement of this division, as determined by the Commissioner.

(2) CONSTRUCTION.—Nothing in paragraph (1) shall be construed as affecting the application of section 514 of the Employee Retirement Income Security Act of 1974.

(b) COVERAGE OFFERED THROUGH EXCHANGE.—

(1) IN GENERAL.—In the case of health insurance coverage offered through the Health Insurance Exchange—

(A) the requirements of this title do not supercede any requirements (including requirements relating to genetic information nondiscrimination and mental health) applicable under title XXVII of the Public Health Service Act or under State law, except insofar as such requirements prevent the application of a requirement of this division, as determined by the Commissioner; and

(B) individual rights and remedies under State laws shall apply.

(2) CONSTRUCTION.—In the case of coverage described in paragraph (1), nothing in such paragraph shall be construed as preventing the application of rights and remedies under State laws with respect to any requirement referred to in paragraph (1)(A).

SEC. 152. PROHIBITING DISCRIMINATION IN HEALTH CARE.

(a) IN GENERAL.—Except as otherwise explicitly permitted by this Act and by subsequent regulations consistent with this Act, all health care and related services (including insurance coverage and public health activities) covered by this Act shall be provided without regard to personal characteristics extraneous to the provision of high quality health care or related services.

(b) IMPLEMENTATION.—To implement the requirement set forth in subsection (a), the Secretary of Health and Human Services shall, not later than 18 months after the date of the enactment of this Act, promulgate such regulations as are necessary or appropriate to insure that all health care and related services (including insur-

ance coverage and public health activities) covered by this Act are provided (whether directly or through contractual, licensing, or other arrangements) without regard to personal characteristics extraneous to the provision of high quality health care or related services.

SEC. 153. WHISTLEBLOWER PROTECTION.

(a) RETALIATION PROHIBITED.—No employer may discharge any employee or otherwise discriminate against any employee with respect to his compensation, terms, conditions, or other privileges of employment because the employee (or any person acting pursuant to a request of the employee)—

(1) provided, caused to be provided, or is about to provide or cause to be provided to the employer, the Federal Government, or the attorney general of a State information relating to any violation of, or any act or omission the employee reasonably believes to be a violation of any provision of this Act or any order, rule, or regulation promulgated under this Act;

(2) testified or is about to testify in a proceeding concerning such violation;

(3) assisted or participated or is about to assist or participate in such a proceeding; or

(4) objected to, or refused to participate in, any activity, policy, practice, or assigned task that the employee (or other such person) reasonably believed to be in violation of any provision of this Act or any order, rule, or regulation promulgated under this Act.

(b) ENFORCEMENT ACTION.—An employee covered by this section who alleges discrimination by an employer in violation of subsection (a) may bring an action governed by the rules, procedures, legal burdens of proof, and remedies set forth in section 40(b) of the Consumer Product Safety Act (15 U.S.C. 2087(b)).

(c) EMPLOYER DEFINED.—As used in this section, the term "employer" means any person (including one or more individuals, partnerships, associations, corporations, trusts, professional membership organization including a certification, disciplinary, or other professional body, unincorporated organizations, nongovernmental organizations, or trustees) engaged in profit or nonprofit business or industry whose activities are governed by this Act, and any agent, contractor, subcontractor, grantee, or consultant of such person.

(d) RULE OF CONSTRUCTION.—The rule of construction set forth in section 20109(h) of title 49, United States Code, shall also apply to this section.

SEC. 154. CONSTRUCTION REGARDING COLLECTIVE BARGAINING.

Nothing in this division shall be construed to alter of supercede any statutory or other obligation to engage in collective bargaining over the terms and conditions of employment related to health care.

SEC. 155. SEVERABILITY.

If any provision of this Act, or any application of such provision to any person or circumstance, is held to be unconstitutional, the remainder of the provisions of this Act and the application of the provision to any other person or circumstance shall not be affected.

SEC. 156. APPLICATION OF STATE AND FEDERAL LAWS REGARDING ABORTION.

(a) NO PREEMPTION OF STATE LAWS REGARDING ABORTION.—Nothing in this Act shall be construed to preempt or otherwise have any effect on State laws regarding the prohibition of (or requirement of) coverage, funding, or procedural requirements on abortions, including parental notification or consent for the performance of an abortion on a minor.

(b) NO EFFECT ON FEDERAL LAWS REGARDING ABORTION.—

(1) IN GENERAL.—Nothing in this Act shall be construed to have any effect on Federal laws regarding—

(A) conscience protection;

(B) willingness or refusal to provide abortion; and

(C) discrimination on the basis of the willingness or refusal to provide, pay for, cover, or refer for abortion or to provide or participate in training to provide abortion.

(c) NO EFFECT ON FEDERAL CIVIL RIGHTS LAW.—Nothing in this section shall alter the rights and obligations of employees and employers under title VII of the Civil Rights Act of 1964.

SEC. 157. NON-DISCRIMINATION ON ABORTION AND RESPECT FOR RIGHTS OF CONSCIENCE.

(a) NON-DISCRIMINATION.—A Federal agency or program, and any State or local government that receives Federal financial assistance under this Act (or an amendment made by this Act), may not—

(1) subject any individual or institutional health care entity to discrimination, or

(2) require any health plan created or regulated under this Act (or an amendment made by this Act) to subject any individual or institutional health care entity to discrimination,

on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.

(b) DEFINITION.—In this section, the term "health care entity" includes an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan.

(c) ADMINISTRATION.—The Office for Civil Rights of the Department of Health and Human Services is designated to receive complaints of discrimination based on this section, and coordinate the investigation of such complaints.

Subtitle G—Early Investments

SEC. 161. ENSURING VALUE AND LOWER PREMIUMS.

(a) GROUP HEALTH INSURANCE COVERAGE.—Title XXVII of the Public Health Service Act is amended by inserting after section 2713 the following new section:

"SEC. 2714. ENSURING VALUE AND LOWER PREMIUMS.

"(a) IN GENERAL.—Each health insurance issuer that offers health insurance coverage in the small or large group market shall provide that for any plan year in which the coverage has a medical loss ratio below a level specified by the Secretary, the issuer shall provide in a manner specified by the Secretary for rebates to enrollees of payment sufficient to meet such loss ratio. Such methodology shall be set at the highest level medical loss ratio possible that is designed to ensure adequate participation by issuers, competition in the health insurance market, and value for consumers so that their premiums are used for services.

"(b) UNIFORM DEFINITIONS.—The Secretary shall establish a uniform definition of medical loss ratio and methodology for determining how to calculate the medical loss ratio. Such methodology shall be designed to take into account the special circumstances of smaller plans, different types of plans, and newer plans.".

(b) INDIVIDUAL HEALTH INSURANCE COVERAGE.—Such title is further amended by inserting after section 2753 the following new section:

"SEC. 2754. ENSURING VALUE AND LOWER PREMIUMS.

"The provisions of section 2714 shall apply to health insurance coverage offered in the individual market in the same manner as such provisions apply to health insurance coverage offered in the small or large group market.".

(c) IMMEDIATE IMPLEMENTATION.—The amendments made by this section shall apply in the group and individual market for plan years beginning on or after January 1, 2011.

SEC. 162. ENDING HEALTH INSURANCE RESCISSION ABUSE.

(a) CLARIFICATION REGARDING APPLICATION OF GUARANTEED RENEWABILITY OF INDIVIDUAL HEALTH INSURANCE COVERAGE.—Section 2742 of the Public Health Service Act (42 U.S.C. 300gg–42) is amended—

(1) in its heading, by inserting "**AND CONTINUATION IN FORCE, INCLUDING PROHIBITION OF RESCISSION,**" after "**GUARANTEED RENEWABILITY**"; and

(2) in subsection (a), by inserting ", including without rescission," after "continue in force".

(b) SECRETARIAL GUIDANCE REGARDING RESCISSIONS.—Section 2742 of such Act (42 U.S.C. 300gg–42) is amended by adding at the end the following:

"(f) RESCISSION.—A health insurance issuer may rescind health insurance coverage only upon clear and convincing evidence of fraud described in subsection (b)(2). The Secretary, no later than July 1, 2010, shall issue guidance implementing this requirement, including procedures for independent, external third party review.".

(c) OPPORTUNITY FOR INDEPENDENT, EXTERNAL THIRD PARTY REVIEW IN CERTAIN CASES.—Subpart 1 of part B of title XXVII of such Act (42 U.S.C. 300gg–41 et seq.) is amended by adding at the end the following:

"SEC. 2746. OPPORTUNITY FOR INDEPENDENT, EXTERNAL THIRD PARTY REVIEW IN CASES OF RESCISSION.

"(a) NOTICE AND REVIEW RIGHT.—If a health insurance issuer determines to rescind health insurance coverage for an individual in the individual market, before such rescission may take effect the issuer shall provide the individual with notice of such proposed rescission and an opportunity for a review of such determination

by an independent, external third party under procedures specified by the Secretary under section 2742(f).

"(b) INDEPENDENT DETERMINATION.—If the individual requests such review by an independent, external third party of a rescission of health insurance coverage, the coverage shall remain in effect until such third party determines that the coverage may be rescinded under the guidance issued by the Secretary under section 2742(f).".

(d) EFFECTIVE DATE.—The amendments made by this section shall apply on and after October 1, 2010, with respect to health insurance coverage issued before, on, or after such date.

SEC. 163. ENDING HEALTH INSURANCE DENIALS AND DELAYS OF NECESSARY TREATMENT FOR CHILDREN WITH DEFORMITIES.

(a) IN GENERAL.—Subpart 2 of part A of title XXVII of the Public Health Service Act is amended by adding at the end the following new section:

"SEC. 2708. STANDARDS RELATING TO BENEFITS FOR MINOR CHILD'S CONGENITAL OR DEVELOPMENTAL DEFORMITY OR DISORDER.

"(a) REQUIREMENTS FOR TREATMENT FOR CHILDREN WITH DEFORMITIES.—

"(1) IN GENERAL.—A group health plan, and a health insurance issuer offering group health insurance coverage, that provides coverage for surgical benefits shall provide coverage for outpatient and inpatient diagnosis and treatment of a minor child's congenital or developmental deformity, disease, or injury. A minor child shall include any individual who 21 years of age or younger.

"(2) REQUIREMENTS.—Any coverage provided under paragraph (1) shall be subject to pre-authorization or pre-certification as required by the plan or issuer, and such coverage shall include any surgical treatment which, in the opinion of the treating physician, is medically necessary to approximate a normal appearance.

"(3) TREATMENT DEFINED.—

"(A) IN GENERAL.—In this section, the term 'treatment' includes reconstructive surgical procedures (procedures that are generally performed to improve function, but may also be performed to approximate a normal appearance) that are performed on abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease, including—

"(i) procedures that do not materially affect the function of the body part being treated; and

"(ii) procedures for secondary conditions and follow-up treatment.

"(B) EXCEPTION.—Such term does not include cosmetic surgery performed to reshape normal structures of the body to improve appearance or self-esteem.

"(b) NOTICE.—A group health plan under this part shall comply with the notice requirement under section 714(b) of the Employee Retirement Income Security Act of 1974 with respect to the requirements of this section as if such section applied to such plan.".

(b) INDIVIDUAL HEALTH INSURANCE.—Subpart 2 of part B of title XXVII of the Public Health Service Act, as amended by section 161(b), is further amended by adding at the end the following new section:

"SEC. 2755. STANDARDS RELATING TO BENEFITS FOR MINOR CHILD'S CONGENITAL OR DEVELOPMENTAL DEFORMITY OR DISORDER.

"(a) REQUIREMENTS FOR RECONSTRUCTIVE SURGERY.—

"(1) IN GENERAL.—A health insurance issuer offering health insurance coverage in the individual market that provides coverage for surgical benefits shall provide coverage for outpatient and inpatient diagnosis and treatment of a minor child's congenital or developmental deformity, disease, or injury. A minor child shall include any individual through 21 years of age.

"(2) REQUIREMENTS.—Any coverage provided under paragraph (1) shall be subject to pre-authorization or pre-certification as required by the insurance issuer offering such coverage, and such coverage shall include any surgical treatment which, in the opinion of the treating physician, is medically necessary to approximate a normal appearance.

"(3) TREATMENT DEFINED.—

"(A) IN GENERAL.—In this section, the term 'treatment' includes reconstructive surgical procedures (procedures that are generally performed to improve function, but may also be performed to approximate a normal appearance) that are performed on abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease, including—

"(i) procedures that do not materially affect the function of the body part being treated; and

"(ii) procedures for secondary conditions and follow-up treatment.

"(B) EXCEPTION.—Such term does not include cosmetic surgery performed to reshape normal structures of the body to improve appearance or self-esteem.

"(b) NOTICE.—A health insurance issuer under this part shall comply with the notice requirement under section 714(b) of the Employee Retirement Income Security Act of 1974 with respect to the requirements referred to in subsection (a) as if such section applied to such issuer and such issuer were a group health plan.".

(c) CONFORMING AMENDMENTS.—

(1) Section 2723(c) of such Act (42 U.S.C. 300gg–23(c)) is amended by striking "section 2704" and inserting "sections 2704 and 2708".

(2) Section 2762(b)(2) of such Act (42 U.S.C. 300gg–62(b)(2)) is amended by striking "section 2751" and inserting "sections 2751 and 2754".

(d) EFFECTIVE DATES.—

(1) The amendments made by subsection (a) shall apply with respect to group health plans for plan years beginning on or after January 1, 2010.

(2) The amendment made by subsection (b) shall apply with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market on or after such date.

(e) COORDINATION RULES.—

(1) The amendments made by subsection (a) shall remain in effect until such time as benefit standards are adopted subject to section 124 of this title.

(2) Section 104(1) of the Health Insurance Portability and Accountability Act of 1996 is amended by striking "this subtitle (and the amendments made by this subtitle and section 401)" and inserting "the provisions of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, the provisions of parts A and C of title XXVII of the Public Health Service Act, and chapter 100 of the Internal Revenue Code of 1986".

SEC. 164. ADMINISTRATIVE SIMPLIFICATION.

(a) STANDARDIZING ELECTRONIC ADMINISTRATIVE TRANSACTIONS.—

(1) IN GENERAL.—Part C of title XI of the Social Security Act (42 U.S.C. 1320d et seq.) is amended by inserting after section 1173 the following new sections:

"SEC. 1173A. STANDARDIZE ELECTRONIC ADMINISTRATIVE TRANSACTIONS.

"(a) STANDARDS FOR FINANCIAL AND ADMINISTRATIVE TRANSACTIONS.—

"(1) IN GENERAL.—The Secretary shall adopt and regularly update standards consistent with the goals described in paragraph (2).

"(2) GOALS FOR FINANCIAL AND ADMINISTRATIVE TRANSACTIONS.—The goals for standards under paragraph (1) are that such standards shall—

"(A) be unique with no conflicting or redundant standards;

"(B) be authoritative, permitting no additions or constraints for electronic transactions, including companion guides;

"(C) be comprehensive, efficient and robust, requiring minimal augmentation by paper transactions or clarification by further communications;

"(D) enable the real-time (or near real-time) determination of an individual's financial responsibility at the point of service and, to the extent possible, prior to service, including whether the individual is eligible for a specific service with a specific physician at a specific facility, which may include utilization of a machine-readable health plan beneficiary identification card;

"(E) enable, where feasible, near real-time adjudication of claims;

"(F) provide for timely acknowledgment, response, and status reporting applicable to any electronic transaction deemed appropriate by the Secretary;

"(G) describe all data elements (such as reason and remark codes) in unambiguous terms, not permit optional fields, require that data elements be either required or conditioned upon set values in other fields, and prohibit additional conditions; and

"(H) harmonize all common data elements across administrative and clinical transaction standards.

"(3) TIME FOR ADOPTION.—Not later than 2 years after the date of implementation of the X12 Version 5010 transaction standards implemented under this part, the Secretary shall adopt standards under this section.

"(4) REQUIREMENTS FOR SPECIFIC STANDARDS.—The standards under this section shall be developed, adopted, and enforced so as to—

"(A) clarify, refine, complete, and expand, as needed, the standards required under section 1173;

"(B) require paper versions of standardized transactions to comply with the same standards as to data content such that a fully compliant, equivalent electronic transaction can be populated from the data from a paper version;

"(C) enable electronic funds transfers, in order to allow automated reconciliation with the related health care payment and remittance advice;

"(D) require timely and transparent claim and denial management processes, including tracking, adjudication, and appeal processing;

"(E) require the use of a standard electronic transaction with which health care providers may quickly and efficiently enroll with a health plan to conduct the other electronic transactions provided for in this part; and

"(F) provide for other requirements relating to administrative simplification as identified by the Secretary, in consultation with stakeholders.

"(5) BUILDING ON EXISTING STANDARDS.—In developing the standards under this section, the Secretary shall build upon existing and planned standards.

"(6) IMPLEMENTATION AND ENFORCEMENT.—Not later than 6 months after the date of the enactment of this section, the Secretary shall submit to the appropriate committees of Congress a plan for the implementation and enforcement, by not later than 5 years after such date of enactment, of the standards under this section. Such plan shall include—

"(A) a process and timeframe with milestones for developing the complete set of standards;

"(B) an expedited upgrade program for continually developing and approving additions and modifications to the standards as often as annually to improve their quality and extend their functionality to meet evolving requirements in health care;

"(C) programs to provide incentives for, and ease the burden of, implementation for certain health care providers, with special consideration given to such providers serving rural or underserved areas and ensure coordination with standards, implementation specifications, and certification criteria being adopted under the HITECH Act;

"(D) programs to provide incentives for, and ease the burden of, health care providers who volunteer to participate in the process of setting standards for electronic transactions;

"(E) an estimate of total funds needed to ensure timely completion of the implementation plan; and

"(F) an enforcement process that includes timely investigation of complaints, random audits to ensure compliance, civil monetary and programmatic penalties for non-compliance consistent with existing laws and regulations, and a fair and reasonable appeals process building off of enforcement provisions under this part.

"(b) LIMITATIONS ON USE OF DATA.—Nothing in this section shall be construed to permit the use of information collected under this section in a manner that would adversely affect any individual.

"(c) PROTECTION OF DATA.—The Secretary shall ensure (through the promulgation of regulations or otherwise) that all data collected pursuant to subsection (a) are—

"(1) used and disclosed in a manner that meets the HIPAA privacy and security law (as defined in section 3009(a)(2) of the Public Health Service Act), including any privacy or security standard adopted under section 3004 of such Act; and

"(2) protected from all inappropriate internal use by any entity that collects, stores, or receives the data, including use of such data in determinations of eligibility (or continued eligibility) in health plans, and from other inappropriate uses, as defined by the Secretary.

"SEC. 1173B. OPERATING RULES.

"(a) IN GENERAL.—The Secretary shall adopt operating rules for each transaction described in section 1173(a)(2) of the Social Security Act (42 U.S.C. 1320d-2(a))

"(b) OPERATING RULES DEVELOPMENT.—In adopting such rules, the Secretary shall take into account the development of operating rules that have been developed by a nonprofit entity that meets the following criteria:

"(1) The entity focuses its mission on administrative simplification.

"(2) The entity demonstrates a established multi-stakeholder process that creates consensus based operating rules using a voting policy with balanced representation by the critical stakeholders (including health plans and health care providers) so that no one group dominates the entity and shall include others such as standards development organizations, and relevant Federal agencies.

"(3) The entity has in place a public set of guiding principles that ensure the operating rules and process are open and transparent.

"(4) The entity shall coordinate its activities with the HIT Policy Committee and the HIT Standards Committee (established under title XXX of the Public Health Service Act) and complements the efforts of the Office of the National Healthcare Coordinator and its related health information exchange goals.

"(5) The entity incorporates national standards, including the transaction standards issued under Health Insurance Portability and Accountability Act of 1996.

"(6) The entity uses existing market research and proven best practices.

"(7) The entity has a set of measures that allow for the evaluation of their market impact and public reporting of aggregate stakeholder impact.

"(8) The entity supports nondiscrimination and conflict of interest policies that demonstrate a commitment to open, fair, and nondiscriminatory practices.

"(9) The entity allows for public reviews and updates of the operating rules.

"(c) IMPLEMENTATION.—The Secretary shall adopt operating rules under this section, by regulation or otherwise, only after taking into account the rules developed by the entity under subsection (b) and having ensured consultation with providers. The first set of operating rules for the transactions for eligibility for health plan and health claims status under this section shall be adopted not later than October 1, 2011, in a manner such that such set of rules is effective beginning not later than January 1, 2013. The second set of operating rules for the remainder of the transactions described in section 1173(a)(2) of the Social Security Act (42 U.S.C. 1320d-2(a)) shall be adopted not later than October 1, 2012, in a manner such that such set of rules is effective beginning not later than January 1, 2014.".

(2) DEFINITIONS.—Section 1171 of such Act (42 U.S.C. 1320d) is amended—

(A) in paragraph (7), by striking "with reference to" and all that follows and inserting "with reference to a transaction or data element of health information in section 1173 means implementation specifications, certification criteria, operating rules, messaging formats, codes, and code sets adopted or established by the Secretary for the electronic exchange and use of information."; and

(B) by adding at the end the following new paragraph:

"(9) OPERATING RULES.—The term 'operating rules' means business rules for using and processing transactions. Operating rules should address the following:

"(A) Requirements for data content using available and established national standards.

"(B) Infrastructure requirements that establish best practices for streamlining data flow to yield timely execution of transactions.

"(C) Policies defining the transaction related rights and responsibilities for entities that are transmitting or receiving data.".

(3) CONFORMING AMENDMENT.—Section 1179 of such Act (42 U.S.C. 1320d–8) is amended, in the matter before paragraph (1)—

(A) by inserting "on behalf of an individual" after "1978)"; and

(B) by inserting "on behalf of an individual" after "for a financial institution".

(b) STANDARDS FOR CLAIMS ATTACHMENTS AND COORDINATION OF BENEFITS .—

(1) STANDARD FOR HEALTH CLAIMS ATTACHMENTS.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate a final rule to establish a standard for health claims attachment transaction described in section 1173(a)(2)(B) of the Social Security Act (42 U.S.C. 1320d-2(a)(2)(B)) and coordination of benefits.

(2) REVISION IN PROCESSING PAYMENT TRANSACTIONS BY FINANCIAL INSTITUTIONS.—

(A) IN GENERAL.—Section 1179 of the Social Security Act (42 U.S.C. 1320d–8) is amended, in the matter before paragraph (1)—

(i) by striking "or is engaged" and inserting "and is engaged"; and

(ii) by inserting "(other than as a business associate for a covered entity)" after "for a financial institution".

(B) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to transactions occurring on or after such date (not later than 6 months after the date of the enactment of this Act) as the Secretary of Health and Human Services shall specify.

(c) UNIQUE HEALTH PLAN IDENTIFIER.—Not later than 2 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall promulgate a final rule to establish a unique health plan identifier described in section 1173(b) of the Social Security Act (42 U.S.C. 1320d-2(b)) based on the input of the National Committee of Vital and Health Statistics and consultation with health plans. The Secretary may do so on an interim final basis and effective not later than October 1, 2012.

SEC. 165. EXPANSION OF ELECTRONIC TRANSACTIONS IN MEDICARE.

(a) IN GENERAL.—Section 1862(a) of the Social Security Act (42 U.S.C. 1395y(a)) is amended—

(1) in paragraph (23), by striking the "or" at the end;

(2) in paragraph (24), by striking the period and inserting "; or"; and

(3) by inserting after paragraph (24) the following new paragraph:

"(25) subject to subsection (h), not later than January 1, 2015, for which the payment is other than by electronic funds transfer (EFT) or an electronic remittance in a form as specified in ASC X12 835 Health Care Payment and Remittance Advice or subsequent standard.".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall take effect upon the date of the enactment of this Act.

SEC. 166. REINSURANCE PROGRAM FOR RETIREES.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—Not later than 90 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall establish a temporary reinsurance program (in this section referred to as the "reinsurance program") to provide reimbursement to assist participating employment-based plans with the cost of providing health benefits to retirees and to eligible spouses, surviving spouses and dependents of such retirees.

(2) DEFINITIONS.—For purposes of this section:

(A) The term "eligible employment-based plan" means a group health benefits plan that—

(i) is maintained by one or more employers, former employers or employee associations, or a voluntary employees' beneficiary association, or a committee or board of individuals appointed to administer such plan, and

(ii) provides health benefits to retirees.

(B) The term "health benefits" means medical, surgical, hospital, prescription drug, and such other benefits as shall be determined by the Secretary, whether self-funded or delivered through the purchase of insurance or otherwise.

(C) The term "participating employment-based plan" means an eligible employment-based plan that is participating in the reinsurance program.

(D) The term "retiree" means, with respect to a participating employment-benefit plan, an individual who—

(i) is 55 years of age or older;

(ii) is not eligible for coverage under title XVIII of the Social Security Act; and

(iii) is not an active employee of an employer maintaining the plan or of any employer that makes or has made substantial contributions to fund such plan.

(E) The term "Secretary" means Secretary of Health and Human Services.

(b) PARTICIPATION.—To be eligible to participate in the reinsurance program, an eligible employment-based plan shall submit to the Secretary an application for participation in the program, at such time, in such manner, and containing such information as the Secretary shall require.

(c) PAYMENT.—

(1) SUBMISSION OF CLAIMS.—

(A) IN GENERAL.—Under the reinsurance program, a participating employment-based plan shall submit claims for reimbursement to the Secretary which shall contain documentation of the actual costs of the items and services for which each claim is being submitted.

(B) BASIS FOR CLAIMS.—Each claim submitted under subparagraph (A) shall be based on the actual amount expended by the participating employment-based plan involved within the plan year for the appropriate employment based health benefits provided to a retiree or to the spouse, surviving spouse, or dependent of a retiree. In determining the amount of any claim for purposes of this subsection, the participating employment-based plan shall take into account any negotiated price concessions (such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations) obtained by such plan with respect to such health benefits. For purposes of calculating the amount of any claim, the costs paid by the retiree or by the spouse, surviving spouse, or dependent of the retiree in the form of deductibles, co-payments, and co-insurance shall be included along with the amounts paid by the participating employment-based plan.

(2) PROGRAM PAYMENTS AND LIMIT.—If the Secretary determines that a participating employment-based plan has submitted a valid claim under paragraph (1), the Secretary shall reimburse such plan for 80 percent of that portion of the costs attributable to such claim that exceeds $15,000, but is less than $90,000. Such amounts shall be adjusted each year based on the percentage increase in the medical care component of the Consumer Price Index (rounded to the nearest multiple of $1,000) for the year involved.

(3) USE OF PAYMENTS.—Amounts paid to a participating employment-based plan under this subsection shall be used to lower the costs borne directly by the participants and beneficiaries for health benefits provided under such plan in the form of premiums, co-payments, deductibles, co-insurance, or other out-of-pocket costs. Such payments shall not be used to reduce the costs of an employer maintaining the participating employment-based plan. The Secretary shall develop a mechanism to monitor the appropriate use of such payments by such plans.

(4) APPEALS AND PROGRAM PROTECTIONS.—The Secretary shall establish—

(A) an appeals process to permit participating employment-based plans to appeal a determination of the Secretary with respect to claims submitted under this section; and

(B) procedures to protect against fraud, waste, and abuse under the program.

(5) AUDITS.—The Secretary shall conduct annual audits of claims data submitted by participating employment-based plans under this section to ensure that they are in compliance with the requirements of this section.

(d) RETIREE RESERVE TRUST FUND.—

(1) ESTABLISHMENT.—

(A) IN GENERAL.—There is established in the Treasury of the United States a trust fund to be known as the "Retiree Reserve Trust Fund" (referred to in this section as the "Trust Fund"), that shall consist of such amounts as may be appropriated or credited to the Trust Fund as provided for in this subsection to enable the Secretary to carry out the reinsurance program. Such amounts shall remain available until expended.

(B) FUNDING.—There are hereby appropriated to the Trust Fund, out of any moneys in the Treasury not otherwise appropriated, an amount requested by the Secretary as necessary to carry out this section, except that the total of all such amounts requested shall not exceed $10,000,000,000.

(C) APPROPRIATIONS FROM THE TRUST FUND.—

(i) IN GENERAL.—Amounts in the Trust Fund are appropriated to provide funding to carry out the reinsurance program and shall be used to carry out such program.

(ii) BUDGETARY IMPLICATIONS.—Amounts appropriated under clause (i), and outlays flowing from such appropriations, shall not be taken into account for purposes of any budget enforcement procedures including allocations under section 302(a) and (b) of the Balanced Budget and Emergency Deficit Control Act and budget resolutions for fiscal years during which appropriations are made from the Trust Fund.

(iii) LIMITATION TO AVAILABLE FUNDS.—The Secretary has the authority to stop taking applications for participation in the program or take such other steps in reducing expenditures under the reinsurance program in order to ensure that expenditures under the reinsurance program do not exceed the funds available under this subsection.

SEC. 167. LIMITATIONS ON PREEXISTING CONDITION EXCLUSIONS IN GROUP HEALTH PLANS AND HEALTH INSURANCE COVERAGE IN THE GROUP AND INDIVIDUAL MARKETS IN ADVANCE OF APPLICABILITY OF NEW PROHIBITION OF PREEXISTING CONDITION EXCLUSIONS.

(a) AMENDMENTS RELATING TO PREEXISTING CONDITION EXCLUSIONS UNDER GROUP HEALTH PLANS.—

(1) REDUCTION IN LOOK-BACK PERIOD.—Section 2701(a)(1) of the Public Health Service Act (42 U.S.C. 300gg(a)(1)) is amended by striking "6-month period" and inserting "30-day period".

(2) REDUCTION IN PERMITTED PREEXISTING CONDITION LIMITATION PERIOD.—Section 2701(a)(2) of such Act (42 U.S.C. 300gg(a)(2)) is amended by striking "12 months" and inserting "3 months", and by striking "18 months" and inserting "9 months".

(3) EFFECTIVE DATE.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the amendments made by this subsection shall apply with respect to group health plans for plan years beginning after the end of the 6th calendar month following the date of the enactment of this Act.

(B) SPECIAL RULE FOR COLLECTIVE BARGAINING AGREEMENTS.—In the case of a group health plan maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers ratified before the date of the enactment of this Act, the amendments made by this subsection shall not apply to plan years beginning before the earlier of—

(i) the date on which the last of the collective bargaining agreements relating to the plan terminates (determined without regard to any extension thereof agreed to after the date of the enactment of this Act), or

(ii) 3 years after the date of the enactment of this Act.

For purposes of clause (i), any plan amendment made pursuant to a collective bargaining agreement relating to the plan which amends the plan solely to conform to any requirement added by the amendments made by this section shall not be treated as a termination of such collective bargaining agreement.

(b) AMENDMENTS RELATING TO PREEXISTING CONDITION EXCLUSIONS IN HEALTH INSURANCE COVERAGE IN THE INDIVIDUAL MARKET UNDER GRANDFATHERED HEALTH INSURANCE COVERAGE.—

(1) APPLICABILITY OF GROUP HEALTH INSURANCE LIMITATIONS ON IMPOSITION OF PREEXISTING CONDITION EXCLUSIONS.—

(A) IN GENERAL.—Section 2741 of the Public Health Service Act (42 U.S.C. 300gg–41) is amended—

(i) by redesignating the second subsection (e) (relating to market requirements) and subsection (f) as subsections (f) and (g), respectively; and

(ii) by adding at the end the following new subsection:

"(h) APPLICATION OF GROUP HEALTH INSURANCE LIMITATIONS ON IMPOSITION OF PREEXISTING CONDITION EXCLUSIONS.—

"(1) IN GENERAL.—Subject to paragraph (2), a health insurance issuer that provides individual health insurance coverage may not impose a preexisting condition exclusion (as defined in subsection (b)(1)(A) of section 2701) with respect to such coverage except to the extent that such exclusion could be imposed consistent with such section if such coverage were group health insurance coverage.

"(2) LIMITATION.—In the case of an individual who—

"(A) is enrolled in individual health insurance coverage;

"(B) during the period of such enrollment has a condition for which no medical advice, diagnosis, care, or treatment had been recommended or received as of the enrollment date; and

"(C) seeks to enroll under other individual health insurance coverage which provides benefits different from those provided under the coverage referred to in subparagraph (A) with respect to such condition,

the issuer of the individual health insurance coverage described in subparagraph (C) may impose a preexisting condition exclusion with respect to such condition and any benefits in addition to those provided under the coverage referred to in subparagraph (A), but such exclusion may not extend for a period of more than 3 months.".

(B) ELIMINATION OF COBRA REQUIREMENT.—Subsection (b) of such section is amended—

(i) by adding "and" at the end of paragraph (2);

(ii) by striking the semicolon at the end of paragraph (3) and inserting a period; and

(iii) by striking paragraphs (4) and (5).

(C) CONFORMING AMENDMENT.—Section 2744(a)(1) of such Act (42 U.S.C. 300gg–44(a)(1)) is amended by inserting "(other than subsection (h))" after "section 2741".

(2) EFFECTIVE DATE.—The amendments made by this subsection shall apply with respect to health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market beginning after the end of the 6th calendar month following the date of the enactment of this Act.

(c) INAPPLICABILITY OF INTERIM LIMITATIONS UPON APPLICABILITY OF TOTAL PROHIBITION OF EXCLUSION.—Section 2701 of such Act and the amendments made by subsection (b) of this section to sections 2741 and 2744 of such Act shall cease to be effective in the case of any health benefits plan as of the date on which such plan becomes subject to the requirements of section 111 of this Act (relating to prohibiting preexisting condition exclusions).

TITLE II—HEALTH INSURANCE EXCHANGE AND RELATED PROVISIONS

Subtitle A—Health Insurance Exchange

SEC. 201. ESTABLISHMENT OF HEALTH INSURANCE EXCHANGE; OUTLINE OF DUTIES; DEFINITIONS.

(a) ESTABLISHMENT.—There is established within the Health Choices Administration and under the direction of the Commissioner a Health Insurance Exchange in order to facilitate access of individuals and employers, through a transparent process, to a variety of choices of affordable, quality health insurance coverage, including a public health insurance option.

(b) OUTLINE OF DUTIES OF COMMISSIONER.—In accordance with this subtitle and in coordination with appropriate Federal and State officials as provided under section 143(b), the Commissioner shall—

(1) under section 204 establish standards for, accept bids from, and negotiate and enter into contracts with, QHBP offering entities for the offering of health benefits plans through the Health Insurance Exchange, with different levels of benefits required under section 203, and including with respect to oversight and enforcement;

(2) under section 205 facilitate outreach and enrollment in such plans of Exchange-eligible individuals and employers described in section 202; and

(3) conduct such activities related to the Health Insurance Exchange as required, including establishment of a risk pooling mechanism under section 206 and consumer protections under subtitle D of title I.

(c) EXCHANGE-PARTICIPATING HEALTH BENEFITS PLAN DEFINED.—In this division, the term "Exchange-participating health benefits plan" means a qualified health benefits plan that is offered through the Health Insurance Exchange.

SEC. 202. EXCHANGE-ELIGIBLE INDIVIDUALS AND EMPLOYERS.

(a) ACCESS TO COVERAGE.—Except as provided in subsection (i) and in accordance with this section, all individuals are eligible to obtain coverage through enrollment in an Exchange-participating health benefits plan offered through the Health Insurance Exchange unless such individuals are enrolled in another qualified health benefits plan or other acceptable coverage.

(b) DEFINITIONS.—In this division:

(1) EXCHANGE-ELIGIBLE INDIVIDUAL.—The term "Exchange-eligible individual" means an individual who is eligible under this section to be enrolled through the Health Insurance Exchange in an Exchange-participating health benefits plan and, with respect to family coverage, includes dependents of such individual.

(2) EXCHANGE-ELIGIBLE EMPLOYER.—The term "Exchange-eligible employer" means an employer that is eligible under this section to enroll through the Health Insurance Exchange employees of the employer (and their dependents) in Exchange-eligible health benefits plans.

(3) EMPLOYMENT-RELATED DEFINITIONS.—The terms "employer", "employee", "full-time employee", and "part-time employee" have the meanings given such terms by the Commissioner for purposes of this division.

(c) TRANSITION.—Individuals and employers shall only be eligible to enroll or participate in the Health Insurance Exchange in accordance with the following transition schedule:

(1) FIRST YEAR.—In Y1 (as defined in section 100(c))—

(A) individuals described in subsection (d)(1), including individuals described in paragraphs (3) and (4) of subsection (d); and

(B) smallest employers described in subsection (e)(1).

(2) SECOND YEAR.—In Y2—

(A) individuals and employers described in paragraph (1); and

(B) smaller employers described in subsection (e)(2).

(3) THIRD AND SUBSEQUENT YEARS.—In Y3 and subsequent years—

(A) individuals and employers described in paragraph (2); and

(B) larger employers as permitted by the Commissioner under subsection (e)(3).

(d) INDIVIDUALS.—

(1) INDIVIDUAL DESCRIBED.—Subject to the succeeding provisions of this subsection, an individual described in this paragraph is an individual who—

(A) is not enrolled in coverage described in subparagraphs (C) through (F) of paragraph (2); and

(B) is not enrolled in coverage as a full-time employee (or as a dependent of such an employee) under a group health plan if the coverage and an employer contribution under the plan meet the requirements of section 312.

For purposes of subparagraph (B), in the case of an individual who is self-employed, who has at least 1 employee, and who meets the requirements of section 312, such individual shall be deemed a full-time employee described in such subparagraph.

(2) ACCEPTABLE COVERAGE.—For purposes of this division, the term "acceptable coverage" means any of the following:

(A) QUALIFIED HEALTH BENEFITS PLAN COVERAGE.—Coverage under a qualified health benefits plan.

(B) GRANDFATHERED HEALTH INSURANCE COVERAGE; COVERAGE UNDER CURRENT GROUP HEALTH PLAN.—Coverage under a grandfathered health insurance coverage (as defined in subsection (a) of section 102) or under a current group health plan (described in subsection (b) of such section).

(C) MEDICARE.—Coverage under part A of title XVIII of the Social Security Act.

(D) MEDICAID.—Coverage for medical assistance under title XIX of the Social Security Act, excluding such coverage that is only available because of the application of subsection (u), (z), or (aa) of section 1902 of such Act

(E) MEMBERS OF THE ARMED FORCES AND DEPENDENTS (INCLUDING TRICARE).—Coverage under chapter 55 of title 10, United States Code, including similar coverage furnished under section 1781 of title 38 of such Code.

(F) VA.—Coverage under the veteran's health care program under chapter 17 of title 38, United States Code, but only if the coverage for the individual involved is determined by the Commissioner in coordination with the Secretary of Treasury to be not less than a level specified by the Commissioner and Secretary of Veteran's Affairs, in coordination with the Secretary of Treasury, based on the individual's priority for services as provided under section 1705(a) of such title.

(G) OTHER COVERAGE.—Such other health benefits coverage, such as a State health benefits risk pool, as the Commissioner, in coordination with the Secretary of the Treasury, recognizes for purposes of this paragraph.

The Commissioner shall make determinations under this paragraph in coordination with the Secretary of the Treasury.

(3) TREATMENT OF CERTAIN NON-TRADITIONAL MEDICAID ELIGIBLE INDIVIDUALS.—An individual who is a non-traditional Medicaid eligible individual (as defined in section 205(e)(4)(C)) in a State may be an Exchange-eligible individual if the individual was enrolled in a qualified health benefits plan, grandfathered health insurance coverage, or current group health plan during the 6 months before the individual became a non-traditional Medicaid eligible individual. During the period in which such an individual has chosen to enroll in an Exchange-participating health benefits plan, the individual is not also eligible for medical assistance under Medicaid.

(4) CONTINUING ELIGIBILITY PERMITTED.—

(A) IN GENERAL.—Except as provided in subparagraph (B), once an individual qualifies as an Exchange-eligible individual under this subsection (including as an employee or dependent of an employee of an Exchange-eligible employer) and enrolls under an Exchange-participating health benefits plan through the Health Insurance Exchange, the individual shall continue to be treated as an Exchange-eligible individual until the individual is no longer enrolled with an Exchange-participating health benefits plan.

(B) EXCEPTIONS.—

(i) IN GENERAL.—Subparagraph (A) shall not apply to an individual once the individual becomes eligible for coverage—

(I) under part A of the Medicare program;

(II) under the Medicaid program as a Medicaid eligible individual, except as permitted under paragraph (3) or clause (ii); or

(III) in such other circumstances as the Commissioner may provide.

(ii) TRANSITION PERIOD.—In the case described in clause (i)(II), the Commissioner shall permit the individual to continue treatment under subparagraph (A) until such limited time as the Commissioner determines it is administratively feasible, consistent with minimizing disruption in the individual's access to health care.

(e) EMPLOYERS.—

(1) SMALLEST EMPLOYER.—Subject to paragraph (4), smallest employers described in this paragraph are employers with 10 or fewer employees.

(2) SMALLER EMPLOYERS.—Subject to paragraph (4), smaller employers described in this paragraph are employers that are not smallest employers described in paragraph (1) and have 20 or fewer employees.

(3) LARGER EMPLOYERS.—

(A) IN GENERAL.—Beginning with Y3, the Commissioner may permit employers not described in paragraph (1) or (2) to be Exchange-eligible employers.

(B) PHASE-IN.—In applying subparagraph (A), the Commissioner may phase-in the application of such subparagraph based on the number of full-time employees of an employer and such other considerations as the Commissioner deems appropriate.

(4) CONTINUING ELIGIBILITY.—Once an employer is permitted to be an Exchange-eligible employer under this subsection and enrolls employees through the Health Insurance Exchange, the employer shall continue to be treated as an Exchange-eligible employer for each subsequent plan year regardless of the number of employees involved unless and until the employer meets the requirement of section 311(a) through paragraph (1) of such section by offering a group health plan and not through offering an Exchange-participating health benefits plan.

(5) EMPLOYER PARTICIPATION AND CONTRIBUTIONS.—

(A) SATISFACTION OF EMPLOYER RESPONSIBILITY.—For any year in which an employer is an Exchange-eligible employer, such employer may meet the requirements of section 312 with respect to employees of such employer by offering such employees the option of enrolling with Exchange-participating health benefits plans through the Health Insurance Exchange consistent with the provisions of subtitle B of title III.

(B) EMPLOYEE CHOICE.—Any employee offered Exchange-participating health benefits plans by the employer of such employee under subparagraph (A) may choose coverage under any such plan. That choice includes, with respect to family coverage, coverage of the dependents of such employee.

(6) AFFILIATED GROUPS.—Any employer which is part of a group of employers who are treated as a single employer under subsection (b), (c), (m), or (o) of section 414 of the Internal Revenue Code of 1986 shall be treated, for purposes of this subtitle, as a single employer.

(7) OTHER COUNTING RULES.—The Commissioner shall establish rules relating to how employees are counted for purposes of carrying out this subsection.

(f) SPECIAL SITUATION AUTHORITY.—The Commissioner shall have the authority to establish such rules as may be necessary to deal with special situations with regard to uninsured individuals and employers participating as Exchange-eligible individuals and employers, such as transition periods for individuals and employers who gain, or lose, Exchange-eligible participation status, and to establish grace periods for premium payment.

(g) SURVEYS OF INDIVIDUALS AND EMPLOYERS.—The Commissioner shall provide for periodic surveys of Exchange-eligible individuals and employers concerning satisfaction of such individuals and employers with the Health Insurance Exchange and Exchange-participating health benefits plans.

(h) EXCHANGE ACCESS STUDY.—

(1) IN GENERAL.—The Commissioner shall conduct a study of access to the Health Insurance Exchange for individuals and for employers, including individuals and employers who are not eligible and enrolled in Exchange-participating health benefits plans. The goal of the study is to determine if there are significant groups and types of individuals and employers who are not Exchange-eligible individuals or employers, but who would have improved benefits and affordability if made eligible for coverage in the Exchange.

(2) ITEMS INCLUDED IN STUDY.—Such study also shall examine—

(A) the terms, conditions, and affordability of group health coverage offered by employers and QHBP offering entities outside of the Exchange compared to Exchange-participating health benefits plans; and

(B) the affordability-test standard for access of certain employed individuals to coverage in the Health Insurance Exchange.

(3) REPORT.—Not later than January 1 of Y3, in Y6, and thereafter, the Commissioner shall submit to Congress on the study conducted under this subsection and shall include in such report recommendations regarding changes in standards for Exchange eligibility for individuals and employers.

(i) EXCEPTION FOR VETERANS AND MEMBERS OF ARMED FORCES.—Notwithstanding any other provision of this Act, an individual with acceptable coverage described in subparagraph (E) or (F) of subsection (d)(2) is eligible to obtain coverage through

enrollment in an Exchange-participating health benefits plan offered through the Health Insurance Exchange.

(j) DEPARTMENT OF VETERANS AFFAIRS AND DEPARTMENT OF DEFENSE HEALTH PROGRAMS.—Nothing in this section shall be construed as affecting any authority under title 38, United States Code, or chapter 55 of title 10, United States Code.

(k) REPORT ON COMPARABLE COVERAGE FOR CHIP CHILDREN; SPECIAL RULE FOR CHIP CHILDREN.—

(1) REPORT.—No later than December 31, 2011, the Secretary of Health and Human Services shall submit to Congress a report that compares the benefits packages offered in 2011 to an average State child health plan under title XXI of the Social Security Act and to the benefit standards adopted under section 124 for the essential benefits package and the affordability credits under subtitle C.

(2) CERTIFICATION OF SECRETARY.—Notwithstanding the previous provisions of this section, no child who would be eligible for coverage under title XXI of the Social Security Act shall be enrolled in an Exchange participating health benefits plan until the Secretary of Health and Human Services has certified, based on the findings in the report under paragraph (1) and changes made pursuant to the recommendations in the report, if any, that the coverage (as described in section 121(a)) is at least comparable to the coverage provided to children under an average State child health plan under such title as in effect in 2011.

SEC. 203. BENEFITS PACKAGE LEVELS.

(a) IN GENERAL.—The Commissioner shall specify the benefits to be made available under Exchange-participating health benefits plans during each plan year, consistent with subtitle C of title I and this section.

(b) LIMITATION ON HEALTH BENEFITS PLANS OFFERED BY OFFERING ENTITIES.—The Commissioner may not enter into a contract with a QHBP offering entity under section 204(c) for the offering of an Exchange-participating health benefits plan in a service area unless the following requirements are met:

(1) REQUIRED OFFERING OF BASIC PLAN.—The entity offers only one basic plan for such service area.

(2) OPTIONAL OFFERING OF ENHANCED PLAN.—If and only if the entity offers a basic plan for such service area, the entity may offer one enhanced plan for such area.

(3) OPTIONAL OFFERING OF PREMIUM PLAN.—If and only if the entity offers an enhanced plan for such service area, the entity may offer one premium plan for such area.

(4) OPTIONAL OFFERING OF PREMIUM-PLUS PLANS.—If and only if the entity offers a premium plan for such service area, the entity may offer one or more premium-plus plans for such area.

All such plans may be offered under a single contract with the Commissioner.

(c) SPECIFICATION OF BENEFIT LEVELS FOR PLANS.—

(1) IN GENERAL.—The Commissioner shall establish the following standards consistent with this subsection and title I:

(A) BASIC, ENHANCED, AND PREMIUM PLANS.—Standards for 3 levels of Exchange-participating health benefits plans: basic, enhanced, and premium (in this division referred to as a "basic plan", "enhanced plan", and "premium plan", respectively).

(B) PREMIUM-PLUS PLAN BENEFITS.—Standards for additional benefits that may be offered, consistent with this subsection and subtitle C of title I, under a premium plan (such a plan with additional benefits referred to in this division as a "premium-plus plan") .

(2) BASIC PLAN.—

(A) IN GENERAL.—A basic plan shall offer the essential benefits package required under title I for a qualified health benefits plan.

(B) TIERED COST-SHARING FOR AFFORDABLE CREDIT ELIGIBLE INDIVIDUALS.—In the case of an affordable credit eligible individual (as defined in section 242(a)(1)) enrolled in an Exchange-participating health benefits plan, the benefits under a basic plan are modified to provide for the reduced cost-sharing for the income tier applicable to the individual under section 244(c).

(3) ENHANCED PLAN.—An enhanced plan shall offer, in addition to the level of benefits under the basic plan, a lower level of cost-sharing as provided under title I consistent with section 123(b)(5)(A).

(4) PREMIUM PLAN.—A premium plan shall offer, in addition to the level of benefits under the basic plan, a lower level of cost-sharing as provided under title I consistent with section 123(b)(5)(B).

(5) PREMIUM-PLUS PLAN.—A premium-plus plan is a premium plan that also provides additional benefits, such as adult oral health and vision care, approved by the Commissioner. The portion of the premium that is attributable to such additional benefits shall be separately specified.

(6) RANGE OF PERMISSIBLE VARIATION IN COST-SHARING.—The Commissioner shall establish a permissible range of variation of cost-sharing for each basic, enhanced, and premium plan, except with respect to any benefit for which there is no cost-sharing permitted under the essential benefits package. Such variation shall permit a variation of not more than plus (or minus) 10 percent in cost-sharing with respect to each benefit category specified under section 122.

(d) TREATMENT OF STATE BENEFIT MANDATES.—Insofar as a State requires a health insurance issuer offering health insurance coverage to include benefits beyond the essential benefits package, such requirement shall continue to apply to an Exchange-participating health benefits plan, if the State has entered into an arrangement satisfactory to the Commissioner to reimburse the Commissioner for the amount of any net increase in affordability premium credits under subtitle C as a result of an increase in premium in basic plans as a result of application of such requirement.

(e) RULES REGARDING COVERAGE OF AND AFFORDABILITY CREDITS FOR SPECIFIED SERVICES.—

(1) ASSURED AVAILABILITY OF VARIED COVERAGE THROUGH THE HEALTH INSURANCE EXCHANGE.—The Commissioner shall assure that, of the Exchange participating health benefits plan offered in each premium rating area of the Health Insurance Exchange—

(A) there is at least one such plan that provides coverage of services described in subparagraphs (A) and (B) of section 122(d)(4); and

(B) there is at least one such plan that does not provide coverage of services described in section 122(d)(4)(A) which plan may also be one that does not provide coverage of services described in section 122(d)(4)(B).

(2) SEGREGATION OF FUNDS.—If a qualified health benefits plan provides coverage of services described in section 122(d)(4)(A), the plan shall provide assurances satisfactory to the Commissioner that—

(A) any affordability credits provided under subtitle C of title II are not used for purposes of paying for such services; and

(B) only premium amounts attributable to the actuarial value described in section 113(b) are used for such purpose.

SEC. 204. CONTRACTS FOR THE OFFERING OF EXCHANGE-PARTICIPATING HEALTH BENEFITS PLANS.

(a) CONTRACTING DUTIES.—In carrying out section 201(b)(1) and consistent with this subtitle:

(1) OFFERING ENTITY AND PLAN STANDARDS.—The Commissioner shall—

(A) establish standards necessary to implement the requirements of this title and title I for—

(i) QHBP offering entities for the offering of an Exchange-participating health benefits plan; and

(ii) for Exchange-participating health benefits plans; and

(B) certify QHBP offering entities and qualified health benefits plans as meeting such standards and requirements of this title and title I for purposes of this subtitle.

(2) SOLICITING AND NEGOTIATING BIDS; CONTRACTS.—The Commissioner shall—

(A) solicit bids from QHBP offering entities for the offering of Exchange-participating health benefits plans;

(B) based upon a review of such bids, negotiate with such entities for the offering of such plans; and

(C) enter into contracts with such entities for the offering of such plans through the Health Insurance Exchange under terms (consistent with this title) negotiated between the Commissioner and such entities.

(3) FAR NOT APPLICABLE.—The provisions of the Federal Acquisition Regulation shall not apply to contracts between the Commissioner and QHBP offering entities for the offering of Exchange-participating health benefits plans under this title.

(b) STANDARDS FOR QHBP OFFERING ENTITIES TO OFFER EXCHANGE-PARTICIPATING HEALTH BENEFITS PLANS.—The standards established under subsection (a)(1)(A) shall require that, in order for a QHBP offering entity to offer an Exchange-participating health benefits plan, the entity must meet the following requirements:

(1) LICENSED.—The entity shall be licensed to offer health insurance coverage under State law for each State in which it is offering such coverage.

(2) DATA REPORTING.—The entity shall provide for the reporting of such information as the Commissioner may specify, including information necessary to administer the risk pooling mechanism described in section 206(b) and information to address disparities in health and health care.

(3) IMPLEMENTING AFFORDABILITY CREDITS.—The entity shall provide for implementation of the affordability credits provided for enrollees under subtitle C, including the reduction in cost-sharing under section 244(c).

(4) ENROLLMENT.—The entity shall accept all enrollments under this subtitle, subject to such exceptions (such as capacity limitations) in accordance with the requirements under title I for a qualified health benefits plan. The entity shall notify the Commissioner if the entity projects or anticipates reaching such a capacity limitation that would result in a limitation in enrollment.

(5) RISK POOLING PARTICIPATION.—The entity shall participate in such risk pooling mechanism as the Commissioner establishes under section 206(b).

(6) ESSENTIAL COMMUNITY PROVIDERS.—With respect to the basic plan offered by the entity, the entity shall contract for outpatient services with covered entities (as defined in section 340B(a)(4) of the Public Health Service Act, as in effect as of July 1, 2009). The Commissioner shall specify the extent to which and manner in which the previous sentence shall apply in the case of a basic plan with respect to which the Commissioner determines provides substantially all benefits through a health maintenance organization, as defined in section 2791(b)(3) of the Public Health Service Act.

(7) CULTURALLY AND LINGUISTICALLY APPROPRIATE SERVICES AND COMMUNICATIONS.—The entity shall provide for culturally and linguistically appropriate communication and health services.

(8) ADDITIONAL REQUIREMENTS.—The entity shall comply with other applicable requirements of this title, as specified by the Commissioner, which shall include standards regarding billing and collection practices for premiums and related grace periods and which may include standards to ensure that the entity does not use coercive practices to force providers not to contract with other entities offering coverage through the Health Insurance Exchange.

(c) CONTRACTS.—

(1) BID APPLICATION.—To be eligible to enter into a contract under this section, a QHBP offering entity shall submit to the Commissioner a bid at such time, in such manner, and containing such information as the Commissioner may require.

(2) TERM.—Each contract with a QHBP offering entity under this section shall be for a term of not less than one year, but may be made automatically renewable from term to term in the absence of notice of termination by either party.

(3) ENFORCEMENT OF NETWORK ADEQUACY.—In the case of a health benefits plan of a QHBP offering entity that uses a provider network, the contract under this section with the entity shall provide that if—

(A) the Commissioner determines that such provider network does not meet such standards as the Commissioner shall establish under section 115; and

(B) an individual enrolled in such plan receives an item or service from a provider that is not within such network;

then any cost-sharing for such item or service shall be equal to the amount of such cost-sharing that would be imposed if such item or service was furnished by a provider within such network.

(4) OVERSIGHT AND ENFORCEMENT RESPONSIBILITIES.—The Commissioner shall establish processes, in coordination with State insurance regulators, to oversee, monitor, and enforce applicable requirements of this title with respect to QHBP offering entities offering Exchange-participating health benefits plans and such plans, including the marketing of such plans. Such processes shall include the following:

(A) GRIEVANCE AND COMPLAINT MECHANISMS.—The Commissioner shall establish, in coordination with State insurance regulators, a process under which Exchange-eligible individuals and employers may file complaints concerning violations of such standards.

(B) ENFORCEMENT.—In carrying out authorities under this division relating to the Health Insurance Exchange, the Commissioner may impose one or more of the intermediate sanctions described in section 142(c).

(C) TERMINATION.—

(i) IN GENERAL.—The Commissioner may terminate a contract with a QHBP offering entity under this section for the offering of an Exchange-participating health benefits plan if such entity fails to comply with the applicable requirements of this title. Any determination by the

Commissioner to terminate a contract shall be made in accordance with formal investigation and compliance procedures established by the Commissioner under which—

(I) the Commissioner provides the entity with the reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that were the basis of the Commissioner's determination; and

(II) the Commissioner provides the entity with reasonable notice and opportunity for hearing (including the right to appeal an initial decision) before terminating the contract.

(ii) EXCEPTION FOR IMMINENT AND SERIOUS RISK TO HEALTH.—Clause (i) shall not apply if the Commissioner determines that a delay in termination, resulting from compliance with the procedures specified in such clause prior to termination, would pose an imminent and serious risk to the health of individuals enrolled under the qualified health benefits plan of the QHBP offering entity.

(D) CONSTRUCTION.—Nothing in this subsection shall be construed as preventing the application of other sanctions under subtitle E of title I with respect to an entity for a violation of such a requirement.

(d) NO DISCRIMINATION ON THE BASIS OF PROVISION OF ABORTION.—No Exchange participating health benefits plan may discriminate against any individual health care provider or health care facility because of its willingness or unwillingness to provide, pay for, provide coverage of, or refer for abortions.

SEC. 205. OUTREACH AND ENROLLMENT OF EXCHANGE-ELIGIBLE INDIVIDUALS AND EMPLOYERS IN EXCHANGE-PARTICIPATING HEALTH BENEFITS PLANS.

(a) IN GENERAL.—

(1) OUTREACH.—The Commissioner shall conduct outreach activities consistent with subsection (c), including through use of appropriate entities as described in paragraph (3) of such subsection, to inform and educate individuals and employers about the Health Insurance Exchange and Exchange-participating health benefits plan options. Such outreach shall include outreach specific to vulnerable populations, such as children, individuals with disabilities, individuals with mental illness, and individuals with other cognitive impairments.

(2) ELIGIBILITY.—The Commissioner shall make timely determinations of whether individuals and employers are Exchange-eligible individuals and employers (as defined in section 202).

(3) ENROLLMENT.—The Commissioner shall establish and carry out an enrollment process for Exchange-eligible individuals and employers, including at community locations, in accordance with subsection (b).

(b) ENROLLMENT PROCESS.—

(1) IN GENERAL.—The Commissioner shall establish a process consistent with this title for enrollments in Exchange-participating health benefits plans. Such process shall provide for enrollment through means such as the mail, by telephone, electronically, and in person.

(2) ENROLLMENT PERIODS.—

(A) OPEN ENROLLMENT PERIOD.—The Commissioner shall establish an annual open enrollment period during which an Exchange-eligible individual or employer may elect to enroll in an Exchange-participating health benefits plan for the following plan year and an enrollment period for affordability credits under subtitle C. Such periods shall be during September through November of each year, or such other time that would maximize timeliness of income verification for purposes of such subtitle. The open enrollment period shall not be less than 30 days.

(B) SPECIAL ENROLLMENT.—The Commissioner shall also provide for special enrollment periods to take into account special circumstances of individuals and employers, such as an individual who—

(i) loses acceptable coverage;

(ii) experiences a change in marital or other dependent status;

(iii) moves outside the service area of the Exchange-participating health benefits plan in which the individual is enrolled; or

(iv) experiences a significant change in income.

(C) ENROLLMENT INFORMATION.—The Commissioner shall provide for the broad dissemination of information to prospective enrollees on the enrollment process, including before each open enrollment period. In carrying out the previous sentence, the Commissioner may work with other appropriate entities to facilitate such provision of information.

(3) AUTOMATIC ENROLLMENT FOR NON-MEDICAID ELIGIBLE INDIVIDUALS.—

(A) IN GENERAL.—The Commissioner shall provide for a process under which individuals who are Exchange-eligible individuals described in subparagraph (B) are automatically enrolled under an appropriate Exchange-participating health benefits plan. Such process may involve a random assignment or some other form of assignment that takes into account the health care providers used by the individual involved or such other relevant factors as the Commissioner may specify.

(B) SUBSIDIZED INDIVIDUALS DESCRIBED.—An individual described in this subparagraph is an Exchange-eligible individual who is either of the following:

(i) AFFORDABILITY CREDIT ELIGIBLE INDIVIDUALS.—The individual—

(I) has applied for, and been determined eligible for, affordability credits under subtitle C;

(II) has not opted out from receiving such affordability credit; and

(III) does not otherwise enroll in another Exchange-participating health benefits plan.

(ii) INDIVIDUALS ENROLLED IN A TERMINATED PLAN.—The individual is enrolled in an Exchange-participating health benefits plan that is terminated (during or at the end of a plan year) and who does not otherwise enroll in another Exchange-participating health benefits plan.

(4) DIRECT PAYMENT OF PREMIUMS TO PLANS.—Under the enrollment process, individuals enrolled in an Exchange-participating health benefits plan shall pay such plans directly, and not through the Commissioner or the Health Insurance Exchange.

(c) COVERAGE INFORMATION AND ASSISTANCE.—

(1) COVERAGE INFORMATION.—The Commissioner shall provide for the broad dissemination of information on Exchange-participating health benefits plans offered under this title. Such information shall be provided in a comparative manner, and shall include information on benefits, premiums, cost-sharing, quality, provider networks, and consumer satisfaction.

(2) CONSUMER ASSISTANCE WITH CHOICE.—To provide assistance to Exchange-eligible individuals and employers, the Commissioner shall—

(A) provide for the operation of a toll-free telephone hotline to respond to requests for assistance and maintain an Internet website through which individuals may obtain information on coverage under Exchange-participating health benefits plans and file complaints;

(B) develop and disseminate information to Exchange-eligible enrollees on their rights and responsibilities;

(C) assist Exchange-eligible individuals in selecting Exchange-participating health benefits plans and obtaining benefits through such plans; and

(D) ensure that the Internet website described in subparagraph (A) and the information described in subparagraph (B) is developed using plain language (as defined in section 133(a)(2)).

(3) USE OF OTHER ENTITIES.—In carrying out this subsection, the Commissioner may work with other appropriate entities to facilitate the dissemination of information under this subsection and to provide assistance as described in paragraph (2).

(d) SPECIAL DUTIES RELATED TO MEDICAID AND CHIP.—

(1) COVERAGE FOR CERTAIN NEWBORNS.—

(A) IN GENERAL.—In the case of a child born in the United States who at the time of birth is not otherwise covered under acceptable coverage, for the period of time beginning on the date of birth and ending on the date the child otherwise is covered under acceptable coverage (or, if earlier, the end of the month in which the 60-day period, beginning on the date of birth, ends), the child shall be deemed—

(i) to be a non-traditional Medicaid eligible individual (as defined in subsection (e)(5)) for purposes of this division and Medicaid; and

(ii) to have elected to enroll in Medicaid through the application of paragraph (3).

(B) EXTENDED TREATMENT AS TRADITIONAL MEDICAID ELIGIBLE INDIVIDUAL.—In the case of a child described in subparagraph (A) who at the end of the period referred to in such subparagraph is not otherwise covered under acceptable coverage, the child shall be deemed (until such time as the child obtains such coverage or the State otherwise makes a determination of the child's eligibility for medical assistance under its Medicaid plan pursuant to section 1943(c)(1) of the Social Security Act) to be a traditional Medicaid eligible individual described in section 1902(l)(1)(B) of such Act.

(2) CHIP TRANSITION.—A child who, as of the day before the first day of Y1, is eligible for child health assistance under title XXI of the Social Security Act (including a child receiving coverage under an arrangement described in section 2101(a)(2) of such Act) is deemed as of such first day to be an Exchange-eligible individual unless the individual is a traditional Medicaid eligible individual as of such day.

(3) AUTOMATIC ENROLLMENT OF MEDICAID ELIGIBLE INDIVIDUALS INTO MEDICAID.—The Commissioner shall provide for a process under which an individual who is described in section 202(d)(3) and has not elected to enroll in an Exchange-participating health benefits plan is automatically enrolled under Medicaid.

(4) NOTIFICATIONS.—The Commissioner shall notify each State in Y1 and for purposes of section 1902(gg)(1) of the Social Security Act (as added by section 1703(a)) whether the Health Insurance Exchange can support enrollment of children described in paragraph (2) in such State in such year.

(e) MEDICAID COVERAGE FOR MEDICAID ELIGIBLE INDIVIDUALS.—

(1) IN GENERAL.—

(A) CHOICE FOR LIMITED EXCHANGE-ELIGIBLE INDIVIDUALS.—As part of the enrollment process under subsection (b), the Commissioner shall provide the option, in the case of an Exchange-eligible individual described in section 202(d)(3), for the individual to elect to enroll under Medicaid instead of under an Exchange-participating health benefits plan. Such an individual may change such election during an enrollment period under subsection (b)(2).

(B) MEDICAID ENROLLMENT OBLIGATION.—An Exchange eligible individual may apply, in the manner described in section 241(b)(1), for a determination of whether the individual is a Medicaid-eligible individual. If the individual is determined to be so eligible, the Commissioner, through the Medicaid memorandum of understanding, shall provide for the enrollment of the individual under the State Medicaid plan in accordance with the Medicaid memorandum of understanding under paragraph (4). In the case of such an enrollment, the State shall provide for the same periodic redetermination of eligibility under Medicaid as would otherwise apply if the individual had directly applied for medical assistance to the State Medicaid agency.

(2) NON-TRADITIONAL MEDICAID ELIGIBLE INDIVIDUALS.—In the case of a non-traditional Medicaid eligible individual described in section 202(d)(3) who elects to enroll under Medicaid under paragraph (1)(A), the Commissioner shall provide for the enrollment of the individual under the State Medicaid plan in accordance with the Medicaid memorandum of understanding under paragraph (3).

(3) COORDINATED ENROLLMENT WITH STATE THROUGH MEMORANDUM OF UNDERSTANDING.—The Commissioner, in consultation with the Secretary of Health and Human Services, shall enter into a memorandum of understanding with each State (each in this division referred to as a "Medicaid memorandum of understanding") with respect to coordinating enrollment of individuals in Exchange-participating health benefits plans and under the State's Medicaid program consistent with this section and to otherwise coordinate the implementation of the provisions of this division with respect to the Medicaid program. Such memorandum shall permit the exchange of information consistent with the limitations described in section 1902(a)(7) of the Social Security Act. Nothing in this section shall be construed as permitting such memorandum to modify or vitiate any requirement of a State Medicaid plan.

(4) MEDICAID ELIGIBLE INDIVIDUALS.—For purposes of this division:

(A) MEDICAID ELIGIBLE INDIVIDUAL.—The term "Medicaid eligible individual" means an individual who is eligible for medical assistance under Medicaid.

(B) TRADITIONAL MEDICAID ELIGIBLE INDIVIDUAL.—The term "traditional Medicaid eligible individual" means a Medicaid eligible individual other than an individual who is—

(i) a Medicaid eligible individual by reason of the application of subclause (VIII) of section 1902(a)(10)(A)(i) of the Social Security Act; or

(ii) a childless adult not described in section 1902(a)(10)(A) or (C) of such Act (as in effect as of the day before the date of the enactment of this Act).

(C) NON-TRADITIONAL MEDICAID ELIGIBLE INDIVIDUAL.—The term "non-traditional Medicaid eligible individual" means a Medicaid eligible individual who is not a traditional Medicaid eligible individual.

(f) EFFECTIVE CULTURALLY AND LINGUISTICALLY APPROPRIATE COMMUNICATION.—In carrying out this section, the Commissioner shall establish effective methods for communicating in plain language and a culturally and linguistically appropriate manner.

(g) ROLE FOR ENROLLMENT AGENTS AND BROKERS.—Nothing in this division shall be construed to affect the role of enrollment agents and brokers under State law, including with regard to the enrollment of individuals and employers in qualified health benefits plans including the public health insurance option.

SEC. 206. OTHER FUNCTIONS.

(a) COORDINATION OF AFFORDABILITY CREDITS.—The Commissioner shall coordinate the distribution of affordability premium and cost-sharing credits under subtitle C to QHBP offering entities offering Exchange-participating health benefits plans.

(b) COORDINATION OF RISK POOLING.—The Commissioner shall establish a mechanism whereby there is an adjustment made of the premium amounts payable among QHBP offering entities offering Exchange-participating health benefits plans of premiums collected for such plans that takes into account (in a manner specified by the Commissioner) the differences in the risk characteristics of individuals and employers enrolled under the different Exchange-participating health benefits plans offered by such entities so as to minimize the impact of adverse selection of enrollees among the plans offered by such entities.

(c) SPECIAL INSPECTOR GENERAL FOR THE HEALTH INSURANCE EXCHANGE.—

(1) ESTABLISHMENT; APPOINTMENT.—There is hereby established the Office of the Special Inspector General for the Health Insurance Exchange, to be headed by a Special Inspector General for the Health Insurance Exchange (in this subsection referred to as the "Special Inspector General") to be appointed by the President, by and with the advice and consent of the Senate. The nomination of an individual as Special Inspector General shall be made as soon as practicable after the establishment of the program under this subtitle.

(2) DUTIES.—The Special Inspector General shall—

(A) conduct, supervise, and coordinate audits, evaluations and investigations of the Health Insurance Exchange to protect the integrity of the Health Insurance Exchange, as well as the health and welfare of participants in the Exchange;

(B) report both to the Commissioner and to the Congress regarding program and management problems and recommendations to correct them;

(C) have other duties (described in paragraphs (2) and (3) of section 121 of division A of Public Law 110–343) in relation to the duties described in the previous subparagraphs; and

(D) have the authorities provided in section 6 of the Inspector General Act of 1978 in carrying out duties under this paragraph.

(3) APPLICATION OF OTHER SPECIAL INSPECTOR GENERAL PROVISIONS.—The provisions of subsections (b) (other than paragraphs (1) and (3)), (d) (other than paragraph (1)), and (e) of section 121 of division A of the Emergency Economic Stabilization Act of 2009 (Public Law 110–343) shall apply to the Special Inspector General under this subsection in the same manner as such provisions apply to the Special Inspector General under such section.

(4) REPORTS.—Not later than one year after the confirmation of the Special Inspector General, and annually thereafter, the Special Inspector General shall submit to the appropriate committees of Congress a report summarizing the activities of the Special Inspector General during the one year period ending on the date such report is submitted.

(5) TERMINATION.—The Office of the Special Inspector General shall terminate five years after the date of the enactment of this Act.

SEC. 207. HEALTH INSURANCE EXCHANGE TRUST FUND.

(a) ESTABLISHMENT OF HEALTH INSURANCE EXCHANGE TRUST FUND.—There is created within the Treasury of the United States a trust fund to be known as the "Health Insurance Exchange Trust Fund" (in this section referred to as the "Trust Fund"), consisting of such amounts as may be appropriated or credited to the Trust Fund under this section or any other provision of law.

(b) PAYMENTS FROM TRUST FUND.—The Commissioner shall pay from time to time from the Trust Fund such amounts as the Commissioner determines are necessary to make payments to operate the Health Insurance Exchange, including payments under subtitle C (relating to affordability credits).

(c) TRANSFERS TO TRUST FUND.—

(1) DEDICATED PAYMENTS.—There is hereby appropriated to the Trust Fund amounts equivalent to the following:

(A) TAXES ON INDIVIDUALS NOT OBTAINING ACCEPTABLE COVERAGE.—The amounts received in the Treasury under section 59B of the Internal Revenue Code of 1986 (relating to requirement of health insurance coverage for individuals).

(B) EMPLOYMENT TAXES ON EMPLOYERS NOT PROVIDING ACCEPTABLE COVERAGE.—The amounts received in the Treasury under section 3111(c) of the Internal Revenue Code of 1986 (relating to employers electing to not provide health benefits).

(C) EXCISE TAX ON FAILURES TO MEET CERTAIN HEALTH COVERAGE REQUIREMENTS.—The amounts received in the Treasury under section 4980H(b) (relating to excise tax with respect to failure to meet health coverage participation requirements).

(2) APPROPRIATIONS TO COVER GOVERNMENT CONTRIBUTIONS.—There are hereby appropriated, out of any moneys in the Treasury not otherwise appropriated, to the Trust Fund, an amount equivalent to the amount of payments made from the Trust Fund under subsection (b) plus such amounts as are necessary reduced by the amounts deposited under paragraph (1).

(d) APPLICATION OF CERTAIN RULES.—Rules similar to the rules of subchapter B of chapter 98 of the Internal Revenue Code of 1986 shall apply with respect to the Trust Fund.

SEC. 208. OPTIONAL OPERATION OF STATE-BASED HEALTH INSURANCE EXCHANGES.

(a) IN GENERAL.—If—

(1) a State (or group of States, subject to the approval of the Commissioner) applies to the Commissioner for approval of a State-based Health Insurance Exchange to operate in the State (or group of States); and

(2) the Commissioner approves such State-based Health Insurance Exchange, then, subject to subsections (c) and (d), the State-based Health Insurance Exchange shall operate, instead of the Health Insurance Exchange, with respect to such State (or group of States). The Commissioner shall approve a State-based Health Insurance Exchange if it meets the requirements for approval under subsection (b).

(b) REQUIREMENTS FOR APPROVAL.—

(1) IN GENERAL.—The Commissioner may not approve a State-based Health Insurance Exchange under this section unless the following requirements are met:

(A) The State-based Health Insurance Exchange must demonstrate the capacity to and provide assurances satisfactory to the Commissioner that the State-based Health Insurance Exchange will carry out the functions specified for the Health Insurance Exchange in the State (or States) involved, including—

(i) negotiating and contracting with QHBP offering entities for the offering of Exchange-participating health benefits plan, which satisfy the standards and requirements of this title and title I;

(ii) enrolling Exchange-eligible individuals and employers in such State in such plans;

(iii) the establishment of sufficient local offices to meet the needs of Exchange-eligible individuals and employers;

(iv) administering affordability credits under subtitle B using the same methodologies (and at least the same income verification methods) as would otherwise apply under such subtitle and at a cost to the Federal Government which does exceed the cost to the Federal Government if this section did not apply; and

(v) enforcement activities consistent with federal requirements.

(B) There is no more than one Health Insurance Exchange operating with respect to any one State.

(C) The State provides assurances satisfactory to the Commissioner that approval of such an Exchange will not result in any net increase in expenditures to the Federal Government.

(D) The State provides for reporting of such information as the Commissioner determines and assurances satisfactory to the Commissioner that it will vigorously enforce violations of applicable requirements.

(E) The State is eligible to receive an incentive payment for enacting and implementing medical liability reforms as specified in subsection (g).

(F) Such other requirements as the Commissioner may specify.

(2) PRESUMPTION FOR CERTAIN STATE-OPERATED EXCHANGES.—

(A) IN GENERAL.—In the case of a State operating an Exchange prior to January 1, 2010 that seeks to operate the State-based Health Insurance Exchange under this section, the Commissioner shall presume that such Exchange meets the standards under this section unless the Commissioner de-

termines, after completion of the process established under subparagraph (B), that the Exchange does not comply with such standards.

(B) PROCESS.—The Commissioner shall establish a process to work with a State described in subparagraph (A) to provide assistance necessary to assure that the State's Exchange comes into compliance with the standards for approval under this section.

(c) CEASING OPERATION.—

(1) IN GENERAL.—A State-based Health Insurance Exchange may, at the option of each State involved, and only after providing timely and reasonable notice to the Commissioner, cease operation as such an Exchange, in which case the Health Insurance Exchange shall operate, instead of such State-based Health Insurance Exchange, with respect to such State (or States).

(2) TERMINATION; HEALTH INSURANCE EXCHANGE RESUMPTION OF FUNCTIONS.—The Commissioner may terminate the approval (for some or all functions) of a State-based Health Insurance Exchange under this section if the Commissioner determines that such Exchange no longer meets the requirements of subsection (b) or is no longer capable of carrying out such functions in accordance with the requirements of this subtitle. In lieu of terminating such approval, the Commissioner may temporarily assume some or all functions of the State-based Health Insurance Exchange until such time as the Commissioner determines the State-based Health Insurance Exchange meets such requirements of subsection (b) and is capable of carrying out such functions in accordance with the requirements of this subtitle.

(3) EFFECTIVENESS.—The ceasing or termination of a State-based Health Insurance Exchange under this subsection shall be effective in such time and manner as the Commissioner shall specify.

(d) RETENTION OF AUTHORITY.—

(1) AUTHORITY RETAINED.—Enforcement authorities of the Commissioner shall be retained by the Commissioner.

(2) DISCRETION TO RETAIN ADDITIONAL AUTHORITY.—The Commissioner may specify functions of the Health Insurance Exchange that—

(A) may not be performed by a State-based Health Insurance Exchange under this section; or

(B) may be performed by the Commissioner and by such a State-based Health Insurance Exchange.

(e) REFERENCES.—In the case of a State-based Health Insurance Exchange, except as the Commissioner may otherwise specify under subsection (d), any references in this subtitle to the Health Insurance Exchange or to the Commissioner in the area in which the State-based Health Insurance Exchange operates shall be deemed a reference to the State-based Health Insurance Exchange and the head of such Exchange, respectively.

(f) FUNDING.—In the case of a State-based Health Insurance Exchange, there shall be assistance provided for the operation of such Exchange in the form of a matching grant with a State share of expenditures required.

(g) MEDICAL LIABILITY ALTERNATIVES.—

(1) PURPOSES.—The purposes of this subsection are—

(A) to ensure quality healthcare is readily available by providing an alternative framework to reduce the costs of defensive medicine and allow victims of malpractice to be fairly compensated; and

(B) to do the above without limiting attorneys fees or imposing caps on damages.

(2) INCENTIVE PAYMENTS FOR MEDICAL LIABILITY REFORM.—

(A) IN GENERAL.—Each State is eligible to receive an incentive payment, in an amount determined by the Secretary subject to the availability of appropriations, if the State enacts after the date of the enactment of this subsection, and is implementing, an alternative medical liability law that complies with this subsection.

(B) DETERMINATION BY SECRETARY.—The Secretary shall determine that a State's alternative medical liability law complies with this subsection if the Secretary is satisfied that the State—

(i) has enacted and is currently implementing that law; and

(ii) that law is effective.

(C) CONSIDERATIONS FOR DETERMINATION.—In making a determination of the effectiveness of a law, the Secretary shall consider whether the law—

(i) makes the medical liability system more reliable through prevention of or prompt and fair resolution of disputes;

(ii) encourages the disclosure of health care errors; and

(iii) maintains access to affordable liability insurance.

(D) OPTIONAL CONTENTS OF ALTERNATIVE MEDICAL LIABILITY LAW.—An alternative medical liability law shall contain any one or a combination of the following litigation alternatives:

(i) Certificate of Merit.

(ii) Early offer.

(E) USE OF INCENTIVE PAYMENTS.—The State shall use an incentive payment received under this subsection to improve health care in that State.

(3) APPLICATION.—Each State seeking an incentive payment under this subsection shall submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require.

(4) TECHNICAL ASSISTANCE.—The Secretary may provide technical assistance to the States applying for or awarded an incentive payment under this subsection.

(5) REPORTS.—Beginning not later than one year after the date of the enactment of this subsection, the Secretary shall submit to Congress an annual report on the progress States have made in adopting and implementing alternative medical liability laws that comply with this subsection. Such reports shall contain sufficient documentation regarding the effectiveness of such laws to enable an objective comparative analysis of them.

(6) RULEMAKING.—The Secretary may make rules to carry out this subsection.

(7) DEFINITION.—In this subsection—

(A) the term "Secretary" means the Secretary of Health and Human Services; and

(B) the term "State" includes the District of Columbia, Puerto Rico, and each other territory or possession of the United States.

(8) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection such sums as may be necessary, to remain available until expended.

SEC. 209. LIMITATION ON PREMIUM INCREASES UNDER EXCHANGE-PARTICIPATING HEALTH BENEFITS PLANS.

(a) IN GENERAL.—The annual increase in the premiums charged under any Exchange-participating health benefits plan may not exceed 150 percent of the annual percentage increase in medical inflation for the 12-month period ending in June of the prior year, unless the plan receives approval for a higher rate increase in accordance with subsection (b) or (c).

(b) EXCEPTION FOR ADDITIONAL REQUIRED BENEFITS.—If the Health Choices Commissioner requires Exchange-participating health benefits plans to provide additional benefits, the annual increase permitted under subsection (a) with respect to the first year to which such benefits are required shall be increased to take into account the costs of such additional benefits.

(c) EXCEPTION TO WHERE FINANCIAL VIABILITY THREATENED.—Subsection (a) shall not apply to any Exchange-participating health benefits plan for any year if such plan demonstrates to the Commissioner (or, if determined appropriate by the Commissioner, the insurance commissioner for the State in which the plan is offered) that complying with subsection (a) for such year would threaten its financial viability or its ability to provide timely benefits to plan participants.

(d) NON-PREEMPTION.—Nothing in this section shall be construed as preempting existing State prior approval laws.

Subtitle B—Public Health Insurance Option

SEC. 221. ESTABLISHMENT AND ADMINISTRATION OF A PUBLIC HEALTH INSURANCE OPTION AS AN EXCHANGE-QUALIFIED HEALTH BENEFITS PLAN.

(a) ESTABLISHMENT.—For years beginning with Y1, the Secretary of Health and Human Services (in this subtitle referred to as the "Secretary") shall provide for the offering of an Exchange-participating health benefits plan (in this division referred to as the "public health insurance option") that ensures choice, competition, and stability of affordable, high quality coverage throughout the United States in accordance with this subtitle. In designing the option, the Secretary's primary responsibility is to create a low-cost plan without compromising quality or access to care.

(b) OFFERING AS AN EXCHANGE-PARTICIPATING HEALTH BENEFITS PLAN.—

(1) EXCLUSIVE TO THE EXCHANGE.—The public health insurance option shall only be made available through the Health Insurance Exchange.

(2) ENSURING A LEVEL PLAYING FIELD.—Consistent with this subtitle, the public health insurance option shall comply with requirements that are applicable under this title to an Exchange-participating health benefits plan, including re-

quirements related to benefits, benefit levels, provider networks, notices, consumer protections, and cost sharing.

(3) PROVISION OF BENEFIT LEVELS.—The public health insurance option—

(A) shall offer basic, enhanced, and premium plans; and

(B) may offer premium-plus plans.

(c) ADMINISTRATIVE CONTRACTING.—The Secretary may enter into contracts for the purpose of performing administrative functions (including functions described in subsection (a)(4) of section 1874A of the Social Security Act) with respect to the public health insurance option in the same manner as the Secretary may enter into contracts under subsection (a)(1) of such section. The Secretary has the same authority with respect to the public health insurance option as the Secretary has under subsections (a)(1) and (b) of section 1874A of the Social Security Act with respect to title XVIII of such Act. Contracts under this subsection shall not involve the transfer of insurance risk to such entity.

(d) OMBUDSMAN.—The Secretary shall establish an office of the ombudsman for the public health insurance option which shall have duties with respect to the public health insurance option similar to the duties of the Medicare Beneficiary Ombudsman under section 1808(c)(2) of the Social Security Act.

(e) DATA COLLECTION.—The Secretary shall collect such data as may be required to establish premiums and payment rates for the public health insurance option and for other purposes under this subtitle, including to improve quality and to reduce racial, ethnic, and other disparities in health and health care.

(f) TREATMENT OF PUBLIC HEALTH INSURANCE OPTION.—With respect to the public health insurance option, the Secretary shall be treated as a QHBP offering entity offering an Exchange-participating health benefits plan.

(g) ACCESS TO FEDERAL COURTS.—The provisions of Medicare (and related provisions of title II of the Social Security Act) relating to access of Medicare beneficiaries to Federal courts for the enforcement of rights under Medicare, including with respect to amounts in controversy, shall apply to the public health insurance option and individuals enrolled under such option under this title in the same manner as such provisions apply to Medicare and Medicare beneficiaries.

SEC. 222. PREMIUMS AND FINANCING.

(a) ESTABLISHMENT OF PREMIUMS.—

(1) IN GENERAL.—The Secretary shall establish geographically-adjusted premium rates for the public health insurance option in a manner—

(A) that complies with the premium rules established by the Commissioner under section 113 for Exchange-participating health benefit plans; and

(B) at a level sufficient to fully finance the costs of—

(i) health benefits provided by the public health insurance option; and

(ii) administrative costs related to operating the public health insurance option.

(2) CONTINGENCY MARGIN.—In establishing premium rates under paragraph (1), the Secretary shall include an appropriate amount for a contingency margin (which shall be not less than 90 days of estimated claims). Before setting such appropriate amount for years starting with Y3, the Secretary shall solicit a recommendation on such amount from the American Academy of Actuaries.

(b) ACCOUNT.—

(1) ESTABLISHMENT.—There is established in the Treasury of the United States an Account for the receipts and disbursements attributable to the operation of the public health insurance option, including the start-up funding under paragraph (2). Section 1854(g) of the Social Security Act shall apply to receipts described in the previous sentence in the same manner as such section applies to payments or premiums described in such section.

(2) START-UP FUNDING.—

(A) IN GENERAL.—In order to provide for the establishment of the public health insurance option there is hereby appropriated to the Secretary, out of any funds in the Treasury not otherwise appropriated, $2,000,000,000. In order to provide for initial claims reserves before the collection of premiums, there is hereby appropriated to the Secretary, out of any funds in the Treasury not otherwise appropriated, such sums as necessary to cover 90 days worth of claims reserves based on projected enrollment.

(B) AMORTIZATION OF START-UP FUNDING.—The Secretary shall provide for the repayment of the startup funding provided under subparagraph (A) to the Treasury in an amortized manner over the 10-year period beginning with Y1.

(C) LIMITATION ON FUNDING.—Nothing in this section shall be construed as authorizing any additional appropriations to the Account, other than such amounts as are otherwise provided with respect to other Exchange-participating health benefits plans.

(3) NO BAILOUTS.—In no case shall the public health insurance option receive any Federal funds for purposes of insolvency in any manner similar to the manner in which entities receive Federal funding under the Troubled Assets Relief Program of the Secretary of the Treasury.

SEC. 223. NEGOTIATED PAYMENT RATES FOR ITEMS AND SERVICES.

(a) NEGOTIATION OF PAYMENT RATES.—

(1) IN GENERAL.—The Secretary shall negotiate payment rates for the public health insurance option for services and health care providers consistent with this section and section 224.

(2) MANNER OF NEGOTIATION.—The Secretary shall negotiate such rates in a manner that results in payment rates that are not lower, in the aggregate, than rates under title XVIII of the Social Security Act, and not higher, in the aggregate, than the average rates paid by other QHBP offering entities for services and health care providers.

(3) INNOVATIVE PAYMENT METHODS.—Nothing in this subsection shall be construed as preventing the use of innovative payment methods such as those described in section 224 in connection with the negotiation of payment rates under this subsection.

(4) PRESCRIPTION DRUGS.—Notwithstanding any other provision of law, the Secretary shall establish a particular formulary for prescription drugs under the public health insurance option.

(b) ESTABLISHMENT OF A PROVIDER NETWORK.—

(1) IN GENERAL.—Health care providers (including physicians and hospitals) participating in Medicare are participating providers in the public health insurance option unless they opt out in a process established by the Secretary consistent with this subsection.

(2) REQUIREMENTS FOR OPT-OUT PROCESS.—Under the process established under paragraph (1)—

(A) providers described in such subparagraph shall be provided at least a 1-year period prior to the first day of Y1 to opt out of participating in the public health insurance option;

(B) no provider shall be subject to a penalty for not participating in the public health insurance option;

(C) the Secretary shall include information on how providers participating in Medicare who chose to opt out of participating in the public health insurance option may opt back in; and

(D) there shall be an annual enrollment period in which providers may decide whether to participate in the public health insurance option.

(3) RULEMAKING.—Not later than 18 months before the first day of Y1, the Secretary shall promulgate rules (pursuant to notice and comment) for the process described in paragraph (1).

(c) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review of a payment rate or methodology established under this section or under section 224.

SEC. 224. MODERNIZED PAYMENT INITIATIVES AND DELIVERY SYSTEM REFORM.

(a) IN GENERAL.—For plan years beginning with Y1, the Secretary may utilize innovative payment mechanisms and policies to determine payments for items and services under the public health insurance option. The payment mechanisms and policies under this section may include patient-centered medical home and other care management payments, accountable care organizations, value-based purchasing, bundling of services, differential payment rates, performance or utilization based payments, partial capitation, and direct contracting with providers.

(b) REQUIREMENTS FOR INNOVATIVE PAYMENTS.—The Secretary shall design and implement the payment mechanisms and policies under this section in a manner that—

(1) seeks to—

(A) improve health outcomes;

(B) reduce health disparities (including racial, ethnic, and other disparities);

(C) provide efficient and affordable care;

(D) address geographic variation in the provision of health services; or

(E) prevent or manage chronic illness; and

(2) promotes care that is integrated, patient-centered, quality, and efficient.

(c) ENCOURAGING THE USE OF HIGH VALUE SERVICES.—To the extent allowed by the benefit standards applied to all Exchange-participating health benefits plans, the public health insurance option may modify cost sharing and payment rates to encourage the use of services that promote health and value.

(d) PROMOTION OF DELIVERY SYSTEM REFORM.—The Secretary shall monitor and evaluate the progress of payment and delivery system reforms under this section and shall seek to implement such reforms subject to the following:

(1) To the extent that the Secretary finds a payment and delivery system reform successful in improving quality and reducing costs, the Secretary shall implement such reform on as large a geographic scale as practical and economical.

(2) The Secretary may delay the implementation of such a reform in geographic areas in which such implementation would place the public health insurance option at a competitive disadvantage.

(3) The Secretary may prioritize implementation of such a reform in high cost geographic areas or otherwise in order to reduce total program costs or to promote high value care.

(e) NON-UNIFORMITY PERMITTED.—Nothing in this subtitle shall prevent the Secretary from varying payments based on different payment structure models (such as accountable care organizations and medical homes) under the public health insurance option for different geographic areas.

SEC. 225. PROVIDER PARTICIPATION.

(a) IN GENERAL.—The Secretary shall establish conditions of participation for health care providers under the public health insurance option.

(b) LICENSURE OR CERTIFICATION.—The Secretary shall not allow a health care provider to participate in the public health insurance option unless such provider is appropriately licensed or certified under State law.

(c) PAYMENT TERMS FOR PROVIDERS.—The Secretary shall establish terms and conditions for the participation (on an annual or other basis specified by the Secretary) of physicians and other health care providers under the public health insurance option, for which payment may be made for services furnished during the year.

(d) EXCLUSION OF CERTAIN PROVIDERS.—The Secretary shall exclude from participation under the public health insurance option a health care provider that is excluded from participation in a Federal health care program (as defined in section 1128B(f) of the Social Security Act).

SEC. 226. APPLICATION OF FRAUD AND ABUSE PROVISIONS.

Provisions of law (other than criminal law provisions) identified by the Secretary by regulation, in consultation with the Inspector General of the Department of Health and Human Services, that impose sanctions with respect to waste, fraud, and abuse under Medicare, such as the False Claims Act (31 U.S.C. 3729 et seq.), shall also apply to the public health insurance option.

SEC. 227. APPLICATION OF HIPAA INSURANCE REQUIREMENTS.

The requirements of sections 2701 through 2792 of the Public Health Service Act shall apply to the public health insurance option in the same manner as they apply to health insurance coverage offered by a health insurance issuer in the individual market.

SEC. 228. APPLICATION OF HEALTH INFORMATION PRIVACY, SECURITY, AND ELECTRONIC TRANSACTION REQUIREMENTS.

Part C of title XI of the Social Security Act, relating to standards for protections against the wrongful disclosure of individually identifiable health information, health information security, and the electronic exchange of health care information, shall apply to the public health insurance option in the same manner as such part applies to other health plans (as defined in section 1171(5) of such Act).

SEC. 229. ENROLLMENT IN PUBLIC HEALTH INSURANCE OPTION IS VOLUNTARY.

Nothing in this division shall be construed as requiring anyone to enroll in the public health insurance option. Enrollment in such option is voluntary.

Subtitle C—Individual Affordability Credits

SEC. 241. AVAILABILITY THROUGH HEALTH INSURANCE EXCHANGE.

(a) IN GENERAL.—Subject to the succeeding provisions of this subtitle, in the case of an affordable credit eligible individual enrolled in an Exchange-participating health benefits plan—

(1) the individual shall be eligible for, in accordance with this subtitle, affordability credits consisting of—

(A) an affordability premium credit under section 243 to be applied against the premium for the Exchange-participating health benefits plan in which the individual is enrolled; and

(B) an affordability cost-sharing credit under section 244 to be applied as a reduction of the cost-sharing otherwise applicable to such plan; and

(2) the Commissioner shall pay the QHBP offering entity that offers such plan from the Health Insurance Exchange Trust Fund the aggregate amount of affordability credits for all affordable credit eligible individuals enrolled in such plan.

(b) APPLICATION.—

(1) IN GENERAL.—An Exchange eligible individual may apply to the Commissioner through the Health Insurance Exchange or through another entity under an arrangement made with the Commissioner, in a form and manner specified by the Commissioner. The Commissioner through the Health Insurance Exchange or through another public entity under an arrangement made with the Commissioner shall make a determination as to eligibility of an individual for affordability credits under this subtitle. The Commissioner shall establish a process whereby, on the basis of information otherwise available, individuals may be deemed to be affordable credit eligible individuals. In carrying this subtitle, the Commissioner shall establish effective methods that ensure that individuals with limited English proficiency are able to apply for affordability credits.

(2) USE OF STATE MEDICAID AGENCIES.—If the Commissioner determines that a State Medicaid agency has the capacity to make a determination of eligibility for affordability credits under this subtitle and under the same standards as used by the Commissioner, under the Medicaid memorandum of understanding (as defined in section 205(c)(4))—

(A) the State Medicaid agency is authorized to conduct such determinations for any Exchange-eligible individual who requests such a determination; and

(B) the Commissioner shall reimburse the State Medicaid agency for the costs of conducting such determinations.

(3) MEDICAID SCREEN AND ENROLL OBLIGATION.—In the case of an application made under paragraph (1), there shall be a determination of whether the individual is a Medicaid-eligible individual. If the individual is determined to be so eligible, the Commissioner, through the Medicaid memorandum of understanding, shall provide for the enrollment of the individual under the State Medicaid plan in accordance with the Medicaid memorandum of understanding. In the case of such an enrollment, the State shall provide for the same periodic redetermination of eligibility under Medicaid as would otherwise apply if the individual had directly applied for medical assistance to the State Medicaid agency.

(c) USE OF AFFORDABILITY CREDITS.—

(1) IN GENERAL.—In Y1 and Y2 an affordable credit eligible individual may use an affordability credit only with respect to a basic plan.

(2) FLEXIBILITY IN PLAN ENROLLMENT AUTHORIZED.—Beginning with Y3, the Commissioner shall establish a process to allow an affordability credit to be used for enrollees in enhanced or premium plans. In the case of an affordable credit eligible individual who enrolls in an enhanced or premium plan, the individual shall be responsible for any difference between the premium for such plan and the affordable credit amount otherwise applicable if the individual had enrolled in a basic plan.

(3) PROHIBITION OF USE OF PUBLIC FUNDS FOR ABORTION COVERAGE.—An affordability credit may not be used for payment for services described in section 122(d)(4)(A).

(d) ACCESS TO DATA.—In carrying out this subtitle, the Commissioner shall request from the Secretary of the Treasury consistent with section 6103 of the Internal Revenue Code of 1986 such information as may be required to carry out this subtitle.

(e) NO CASH REBATES.—In no case shall an affordable credit eligible individual receive any cash payment as a result of the application of this subtitle.

SEC. 242. AFFORDABLE CREDIT ELIGIBLE INDIVIDUAL.

(a) DEFINITION.—

(1) IN GENERAL.—For purposes of this division, the term "affordable credit eligible individual" means, subject to subsection (b), an individual who is lawfully present in a State in the United States (other than as a nonimmigrant described in a subparagraph (excluding subparagraphs (K), (T), (U), and (V)) of section 101(a)(15) of the Immigration and Nationality Act)—

(A) who is enrolled under an Exchange-participating health benefits plan and is not enrolled under such plan as an employee (or dependent of an employee) through an employer qualified health benefits plan that meets the requirements of section 312;

(B) with family income below 400 percent of the Federal poverty level for a family of the size involved; and

(C) who is not a Medicaid eligible individual, other than an individual described in section 202(d)(3) or an individual during a transition period under section 202(d)(4)(B)(ii).

(2) TREATMENT OF FAMILY.—Except as the Commissioner may otherwise provide, members of the same family who are affordable credit eligible individuals shall be treated as a single affordable credit individual eligible for the applicable credit for such a family under this subtitle.

(3) EQUAL TREATMENT OF CERTAIN EMPLOYED INDIVIDUALS.—

(A) IN GENERAL.—For purposes of applying this section with respect to an individual who is an employee of an employer that has an annual payroll (for the preceding calendar year) which does not exceed $750,000 and that makes the contribution which would be required under section 313(a) if the table specified in subparagraph (B) were substituted for the table specified in section 313(b)(1) (and if, in applying section 313(b)(2), $750,000 were substituted for $400,000), such individual shall be treated in the same manner as an employee of an employer that makes the contribution described in section 313(a) (without regard to this paragraph).

(B) TABLE.—The table specified in this subparagraph is the following:

If the annual payroll of such employer for the preceding calendar year:	The applicable percentage is:
Does not exceed $500,000	0 percent
Exceeds $500,000, but does not exceed $585,000	2 percent
Exceeds $585,000, but does not exceed $670,000	4 percent
Exceeds $670,000, but does not exceed $750,000	6 percent

(b) LIMITATIONS ON EMPLOYEE AND DEPENDENT DISQUALIFICATION.—

(1) IN GENERAL.—Subject to paragraph (2), the term "affordable credit eligible individual" does not include a full-time employee of an employer if the employer offers the employee coverage (for the employee and dependents) as a full-time employee under a group health plan if the coverage and employer contribution under the plan meet the requirements of section 312.

(2) EXCEPTIONS.—

(A) FOR CERTAIN FAMILY CIRCUMSTANCES.—The Commissioner shall establish such exceptions and special rules in the case described in paragraph (1) as may be appropriate in the case of a divorced or separated individual or such a dependent of an employee who would otherwise be an affordable credit eligible individual.

(B) FOR UNAFFORDABLE EMPLOYER COVERAGE.—Beginning in Y2, in the case of full-time employees for which the cost of the employee premium for coverage under a group health plan would exceed 12 percent of current family income (determined by the Commissioner on the basis of verifiable documentation and without regard to section 245), paragraph (1) shall not apply.

(c) INCOME DEFINED.—

(1) IN GENERAL.—In this title, the term "income" means modified adjusted gross income (as defined in section 59B of the Internal Revenue Code of 1986).

(2) STUDY OF INCOME DISREGARDS.—The Commissioner shall conduct a study that examines the application of income disregards for purposes of this subtitle. Not later than the first day of Y2, the Commissioner shall submit to Congress a report on such study and shall include such recommendations as the Commissioner determines appropriate.

(d) CLARIFICATION OF TREATMENT OF AFFORDABILITY CREDITS.—Affordability credits under this subtitle shall not be treated, for purposes of title IV of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, to be a benefit provided under section 403 of such title.

SEC. 243. AFFORDABLE PREMIUM CREDIT.

(a) IN GENERAL.—The affordability premium credit under this section for an affordable credit eligible individual enrolled in an Exchange-participating health benefits plan is in an amount equal to the amount (if any) by which the premium for the plan (or, if less, the reference premium amount specified in subsection (c)), exceeds the affordable premium amount specified in subsection (b) for the individual.

(b) AFFORDABLE PREMIUM AMOUNT.—

(1) IN GENERAL.—The affordable premium amount specified in this subsection for an individual for monthly premium in a plan year shall be equal to 1/12 of the product of—

(A) the premium percentage limit specified in paragraph (2) for the individual based upon the individual's family income for the plan year; and

(B) the individual's family income for such plan year.

(2) PREMIUM PERCENTAGE LIMITS BASED ON TABLE.—The Commissioner shall establish premium percentage limits so that for individuals whose family income is within an income tier specified in the table in subsection (d) such percentage limits shall increase, on a sliding scale in a linear manner, from the initial premium percentage to the final premium percentage specified in such table for such income tier.

(c) REFERENCE PREMIUM AMOUNT.—The reference premium amount specified in this subsection for a plan year for an individual in a premium rating area is equal to the average premium for the 3 basic plans in the area for the plan year with the lowest premium levels. In computing such amount the Commissioner may exclude plans with extremely limited enrollments.

(d) TABLE OF PREMIUM PERCENTAGE LIMITS AND ACTUARIAL VALUE PERCENTAGES BASED ON INCOME TIER.—

(1) IN GENERAL.—For purposes of this subtitle, subject to paragraphs (3) and (4), the table specified in this subsection is as follows:

In the case of family income (expressed as a percent of FPL) within the following income tier:	The initial premium percentage is—	The final premium percentage is—	The actuarial value percentage is—
133% through 150%	1.5%	3.0%	97%
150% through 200%	3.0%	5.5%	93%
200% through 250%	5.5%	8%	85%
250% through 300%	8%	10%	78%
300% through 350%	10%	11%	72%
350% through 400%	11%	12%	70%

(2) SPECIAL RULES.—For purposes of applying the table under paragraph (1)—

(A) FOR LOWEST LEVEL OF INCOME.—In the case of an individual with income that does not exceed 133 percent of FPL, the individual shall be considered to have income that is 133% of FPL.

(B) APPLICATION OF HIGHER ACTUARIAL VALUE PERCENTAGE AT TIER TRANSITION POINTS.—If two actuarial value percentages may be determined with respect to an individual, the actuarial value percentage shall be the higher of such percentages.

(3) INDEXING.—For years after Y1, the Commissioner shall adjust the initial and final premium percentages to maintain the ratio of governmental to enrollee shares of premiums over time, for each income tier identified in the table in paragraph (1).

(4) CONTINGENT ADJUSTMENT FOR ADDITIONAL SAVINGS.—

(A) IN GENERAL.—Before the beginning of each year beginning with Y2—

(i) the Chief Actuary of the Centers of Medicare & Medicaid Services shall estimate the amount of savings in the previous year under this division resulting from the application of the provisions described in subparagraph (B) and shall report such estimate to the Commissioner; and

(ii) the Commissioner, based upon such estimate, shall provide for an appropriate increase in the initial and final premium percentages in the table specified in paragraph (1) in a manner that is designed to result in an increase in aggregate affordability credits equivalent to the amount so estimated.

(B) PROVISIONS DESCRIBED.—The provisions described in this subparagraph are as follows:

(i) FORMULARY UNDER PUBLIC OPTION.—Section 223(a)(4).

(ii) PBM TRANSPARENCY.—Section 133(d).

(iii) ACO IN MEDICAID.—Section 1730.

(iv) ADMINISTRATIVE SIMPLIFICATION.—

(I) Section 1173A of the Social Security Act, as added by section 163(a)(1).

(II) Section 163(c).

(III) Section 164.

(v) LIMITATION ON PREMIUM INCREASES IN EXCHANGE-PARTICIPATING PLANS.—Section 209.

(vi) NEGOTIATION OF LOWER PART D DRUG PRICES.—Section 1186.

SEC. 244. AFFORDABILITY COST-SHARING CREDIT.

(a) IN GENERAL.—The affordability cost-sharing credit under this section for an affordable credit eligible individual enrolled in an Exchange-participating health benefits plan is in the form of the cost-sharing reduction described in subsection (b) provided under this section for the income tier in which the individual is classified based on the individual's family income.

(b) COST-SHARING REDUCTIONS.—The Commissioner shall specify a reduction in cost-sharing amounts and the annual limitation on cost-sharing specified in section 122(c)(2)(B) under a basic plan for each income tier specified in the table under section 243(d), with respect to a year, in a manner so that, as estimated by the Commissioner, the actuarial value of the coverage with such reduced cost-sharing amounts (and the reduced annual cost-sharing limit) is equal to the actuarial value percentage (specified in the table under section 243(d) for the income tier involved) of the full actuarial value if there were no cost-sharing imposed under the plan.

(c) DETERMINATION AND PAYMENT OF COST-SHARING AFFORDABILITY CREDIT.—In the case of an affordable credit eligible individual in a tier enrolled in an Exchange-participating health benefits plan offered by a QHBP offering entity, the Commissioner shall provide for payment to the offering entity of an amount equivalent to the increased actuarial value of the benefits under the plan provided under section 203(c)(2)(B) resulting from the reduction in cost-sharing described in subsection (b).

SEC. 245. INCOME DETERMINATIONS.

(a) IN GENERAL.—In applying this subtitle for an affordability credit for an individual for a plan year, the individual's income shall be the income (as defined in section 242(c)) for the individual for the most recent taxable year (as determined in accordance with rules of the Commissioner). The Federal poverty level applied shall be such level in effect as of the date of the application.

(b) PROGRAM INTEGRITY; INCOME VERIFICATION PROCEDURES.—

(1) PROGRAM INTEGRITY.—The Commissioner shall take such steps as may be appropriate to ensure the accuracy of determinations and redeterminations under this subtitle.

(2) INCOME VERIFICATION.—

(A) IN GENERAL.—Upon an initial application of an individual for an affordability credit under this subtitle (or in applying section 242(b)) or upon an application for a change in the affordability credit based upon a significant change in family income described in subparagraph (A)—

(i) the Commissioner shall request from the Secretary of the Treasury the disclosure to the Commissioner of such information as may be permitted to verify the information contained in such application; and

(ii) the Commissioner shall use the information so disclosed to verify such information.

(B) ALTERNATIVE PROCEDURES.—The Commissioner shall establish procedures for the verification of income for purposes of this subtitle if no income tax return is available for the most recent completed tax year.

(c) SPECIAL RULES.—

(1) CHANGES IN INCOME AS A PERCENT OF FPL.—In the case that an individual's income (expressed as a percentage of the Federal poverty level for a family of the size involved) for a plan year is expected (in a manner specified by the Commissioner) to be significantly different from the income (as so expressed) used under subsection (a), the Commissioner shall establish rules requiring an individual to report, consistent with the mechanism established under paragraph (2), significant changes in such income (including a significant change in family composition) to the Commissioner and requiring the substitution of such income for the income otherwise applicable.

(2) REPORTING OF SIGNIFICANT CHANGES IN INCOME.—The Commissioner shall establish rules under which an individual determined to be an affordable credit eligible individual would be required to inform the Commissioner when there is a significant change in the family income of the individual (expressed as a percentage of the FPL for a family of the size involved) and of the information regarding such change. Such mechanism shall provide for guidelines that specify the circumstances that qualify as a significant change, the verifiable information required to document such a change, and the process for submission of such information. If the Commissioner receives new information from an individual regarding the family income of the individual, the Commissioner shall provide for a redetermination of the individual's eligibility to be an affordable credit eligible individual.

(3) TRANSITION FOR CHIP.—In the case of a child described in section 205(d)(2), the Commissioner shall establish rules under which the family income of the child is deemed to be no greater than the family income of the child

as most recently determined before Y1 by the State under title XXI of the Social Security Act.

(4) STUDY OF GEOGRAPHIC VARIATION IN APPLICATION OF FPL.—

(A) IN GENERAL.—The Commissioner shall examine the feasibility and implication of adjusting the application of the Federal poverty level under this subtitle for different geographic areas so as to reflect the variations in cost-of-living among different areas within the United States. If the Commissioner determines that an adjustment is feasible, the study should include a methodology to make such an adjustment. Not later than the first day of Y2, the Commissioner shall submit to Congress a report on such study and shall include such recommendations as the Commissioner determines appropriate.

(B) INCLUSION OF TERRITORIES.—

(i) IN GENERAL.—The Commissioner shall ensure that the study under subparagraph (A) covers the territories of the United States and that special attention is paid to the disparity that exists among poverty levels and the cost of living in such territories and to the impact of such disparity on efforts to expand health coverage and ensure health care.

(ii) TERRITORIES DEFINED.— In this subparagraph, the term "territories of the United States" includes the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, the Northern Mariana Islands, and any other territory or possession of the United States.

(d) PENALTIES FOR MISREPRESENTATION.—In the case of an individual intentionally misrepresents family income or the individual fails (without regard to intent) to disclose to the Commissioner a significant change in family income under subsection (c) in a manner that results in the individual becoming an affordable credit eligible individual when the individual is not or in the amount of the affordability credit exceeding the correct amount—

(1) the individual is liable for repayment of the amount of the improper affordability credit; ;and

(2) in the case of such an intentional misrepresentation or other egregious circumstances specified by the Commissioner, the Commissioner may impose an additional penalty.

SEC. 246. NO FEDERAL PAYMENT FOR UNDOCUMENTED ALIENS.

Nothing in this subtitle shall allow Federal payments for affordability credits on behalf of individuals who are not lawfully present in the United States.

Subtitle D—Health Insurance Cooperatives

SEC. 251. ESTABLISHMENT.

Not later than 6 months after the date of the enactment of this Act, the Commissioner, in consultation with the Secretary of the Treasury, shall establish a Consumer Operated and Oriented Plan program (in this subtitle referred to as the "CO–OP program") under which the Commissioner may make grants and loans for the establishment and initial operation of not-for-profit, member–run health insurance cooperatives (in this subtitle individually referred to as a "cooperative") that provide insurance through the Health Insurance Exchange or a State-based Health Insurance Exchange under section 208. Nothing in this subtitle shall be construed as requiring a State to establish such a cooperative.

SEC. 252. START-UP AND SOLVENCY GRANTS AND LOANS.

(a) IN GENERAL.—Not later than 36 months after the date of the enactment of this Act, the Commissioner, acting through the CO–OP program, may make—

(1) loans (of such period and with such terms as the Secretary may specify) to cooperatives to assist such cooperatives with start-up costs; and

(2) grants to cooperatives to assist such cooperatives in meeting State solvency requirements in the States in which such cooperative offers or issues insurance coverage.

(b) CONDITIONS.—A grant or loan may not be awarded under this section with respect to a cooperative unless the following conditions are met:

(1) The cooperative is structured as a not-for-profit, member organization under the law of each State in which such cooperative offers, intends to offer, or issues insurance coverage, with the membership of the cooperative being made up entirely of beneficiaries of the insurance coverage offered by such cooperative.

(2) The cooperative did not offer insurance on or before July 16, 2009, and the cooperatives is not an affiliate or successor to an insurance company offering insurance on or before such date.

(3) The governing documents of the cooperatives incorporate ethical and conflict of interest standards designed to protect against insurance industry involvement and interference in the governance of the cooperative.

(4) The cooperative is not sponsored by a State government.

(5) Substantially all of the activities of the cooperative consist of the issuance of qualified health benefit plans through the Health Insurance Exchange or a State-based health insurance exchange.

(6) The cooperative is licenced to offer insurance in each State in which it offers insurance.

(7) The governance of the cooperative must be subject to a majority vote of its members.

(8) As provided in guidance issued by the Secretary of Health and Human Services, the cooperative operates with a strong consumer focus, including timeliness, responsiveness, and accountability to members.

(9) Any profits made by the cooperative are used to lower premiums, improve benefits, or to otherwise improve the quality of health care delivered to members.

(c) PRIORITY.—The Commissioner, in making grants and loans under this section, shall give priority to cooperatives that—

(1) operate on a Statewide basis;

(2) use an integrated delivery system; or

(3) have a significant level of financial support from non-governmental sources.

(d) RULES OF CONSTRUCTION.—Nothing in this subtitle shall be construed to prevent a cooperative established in one State from integrating with a cooperative established in another State the administration, issuance of coverage, or other activities related to acting as a QHBP offering entity. Nothing in this subtitle shall be construed as preventing State governments from taking actions to permit such integration.

(e) REPAYMENT FOR VIOLATIONS OF TERMS OF PROGRAM.—If a cooperative violates the terms of the CO–OP program and fails to correct the violation within a reasonable period of time, as determined by the Commissioner, the cooperative shall repay the total amount of any loan or grant received by such cooperative under this section, plus interest (at a rate determined by the Secretary).

(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated $5,000,000,000 for the period of fiscal years 2010 through 2014 to provide for grants and loans under this section.

SEC. 253. DEFINITIONS.

For purposes of this subtitle:

(1) STATE.—The term "State" means each of the 50 States and the District of Columbia.

(2) MEMBER.—The term "member", with respect to a cooperative, means an individual who, after the cooperative offers health insurance coverage, is enrolled in such coverage.

TITLE III—SHARED RESPONSIBILITY

Subtitle A—Individual Responsibility

SEC. 301. INDIVIDUAL RESPONSIBILITY.

For an individual's responsibility to obtain acceptable coverage, see section 59B of the Internal Revenue Code of 1986 (as added by section 401 of this Act).

Subtitle B—Employer Responsibility

PART 1—HEALTH COVERAGE PARTICIPATION REQUIREMENTS

SEC. 311. HEALTH COVERAGE PARTICIPATION REQUIREMENTS.

An employer meets the requirements of this section if such employer does all of the following:

(1) OFFER OF COVERAGE.—The employer offers each employee individual and family coverage under a qualified health benefits plan (or under a current employment-based health plan (within the meaning of section 102(b))) in accordance with section 312.

(2) CONTRIBUTION TOWARDS COVERAGE.—If an employee accepts such offer of coverage, the employer makes timely contributions towards such coverage in accordance with section 312.

(3) CONTRIBUTION IN LIEU OF COVERAGE.—Beginning with Y2, if an employee declines such offer but otherwise obtains coverage in an Exchange-participating health benefits plan (other than by reason of being covered by family coverage as a spouse or dependent of the primary insured), the employer shall make a timely contribution to the Health Insurance Exchange with respect to each such employee in accordance with section 313.

SEC. 312. EMPLOYER RESPONSIBILITY TO CONTRIBUTE TOWARDS EMPLOYEE AND DEPENDENT COVERAGE.

(a) IN GENERAL.—An employer meets the requirements of this section with respect to an employee if the following requirements are met:

(1) OFFERING OF COVERAGE.—The employer offers the coverage described in section 311(1) either through an Exchange-participating health benefits plan or other than through such a plan.

(2) EMPLOYER REQUIRED CONTRIBUTION.—The employer timely pays to the issuer of such coverage an amount not less than the employer required contribution specified in subsection (b) for such coverage.

(3) PROVISION OF INFORMATION.—The employer provides the Health Choices Commissioner, the Secretary of Labor, the Secretary of Health and Human Services, and the Secretary of the Treasury, as applicable, with such information as the Commissioner may require to ascertain compliance with the requirements of this section.

(4) AUTOENROLLMENT OF EMPLOYEES.—The employer provides for autoenrollment of the employee in accordance with subsection (c).

(b) REDUCTION OF EMPLOYEE PREMIUMS THROUGH MINIMUM EMPLOYER CONTRIBUTION.—

(1) FULL-TIME EMPLOYEES.—The minimum employer contribution described in this subsection for coverage of a full-time employee (and, if any, the employee's spouse and qualifying children (as defined in section 152(c) of the Internal Revenue Code of 1986) under a qualified health benefits plan (or current employment-based health plan) is equal to—

(A) in case of individual coverage, not less than 72.5 percent of the applicable premium (as defined in section 4980B(f)(4) of such Code, subject to paragraph (2)) of the lowest cost plan offered by the employer that is a qualified health benefits plan (or is such current employment-based health plan); and

(B) in the case of family coverage which includes coverage of such spouse and children, not less 65 percent of such applicable premium of such lowest cost plan.

(2) APPLICABLE PREMIUM FOR EXCHANGE COVERAGE.—In this subtitle, the amount of the applicable premium of the lowest cost plan with respect to coverage of an employee under an Exchange-participating health benefits plan is the reference premium amount under section 243(c) for individual coverage (or, if elected, family coverage) for the premium rating area in which the individual or family resides.

(3) MINIMUM EMPLOYER CONTRIBUTION FOR EMPLOYEES OTHER THAN FULL-TIME EMPLOYEES.—In the case of coverage for an employee who is not a full-time employee, the amount of the minimum employer contribution under this subsection shall be a proportion (as determined in accordance with rules of the Health Choices Commissioner, the Secretary of Labor, the Secretary of Health and Human Services, and the Secretary of the Treasury, as applicable) of the minimum employer contribution under this subsection with respect to a full-time employee that reflects the proportion of—

(A) the average weekly hours of employment of the employee by the employer, to

(B) the minimum weekly hours specified by the Commissioner for an employee to be a full-time employee.

(4) SALARY REDUCTIONS NOT TREATED AS EMPLOYER CONTRIBUTIONS.—For purposes of this section, any contribution on behalf of an employee with respect to which there is a corresponding reduction in the compensation of the employee shall not be treated as an amount paid by the employer.

(c) AUTOMATIC ENROLLMENT FOR EMPLOYER SPONSORED HEALTH BENEFITS.—

(1) IN GENERAL.—The requirement of this subsection with respect to an employer and an employee is that the employer automatically enroll such employee into the employment-based health benefits plan for individual coverage under the plan option with the lowest applicable employee premium.

(2) OPT-OUT.—In no case may an employer automatically enroll an employee in a plan under paragraph (1) if such employee makes an affirmative election to opt out of such plan or to elect coverage under an employment-based health benefits plan offered by such employer. An employer shall provide an employee with a 30-day period to make such an affirmative election before the employer may automatically enroll the employee in such a plan.

(3) NOTICE REQUIREMENTS.—

(A) IN GENERAL.—Each employer described in paragraph (1) who automatically enrolls an employee into a plan as described in such paragraph shall provide the employees, within a reasonable period before the beginning of each plan year (or, in the case of new employees, within a reasonable period before the end of the enrollment period for such a new employee), written notice of the employees' rights and obligations relating to the automatic enrollment requirement under such paragraph. Such notice must be comprehensive and understood by the average employee to whom the automatic enrollment requirement applies.

(B) INCLUSION OF SPECIFIC INFORMATION.—The written notice under subparagraph (A) must explain an employee's right to opt out of being automatically enrolled in a plan and in the case that more than one level of benefits or employee premium level is offered by the employer involved, the notice must explain which level of benefits and employee premium level the employee will be automatically enrolled in the absence of an affirmative election by the employee.

SEC. 313. EMPLOYER CONTRIBUTIONS IN LIEU OF COVERAGE.

(a) IN GENERAL.—A contribution is made in accordance with this section with respect to an employee if such contribution is equal to an amount equal to 8 percent of the average wages paid by the employer during the period of enrollment (determined by taking into account all employees of the employer and in such manner as the Commissioner provides, including rules providing for the appropriate aggregation of related employers). Any such contribution—

(1) shall be paid to the Health Choices Commissioner for deposit into the Health Insurance Exchange Trust Fund, and

(2) shall not be applied against the premium of the employee under the Exchange-participating health benefits plan in which the employee is enrolled.

(b) SPECIAL RULES FOR SMALL EMPLOYERS.—

(1) IN GENERAL.—In the case of any employer who is a small employer for any calendar year, subsection (a) shall be applied by substituting the applicable percentage determined in accordance with the following table for "8 percent":

If the annual payroll of such employer for the preceding calendar year:	The applicable percentage is:
Does not exceed $250,000	0 percent
Exceeds $250,000, but does not exceed $300,000	2 percent
Exceeds $300,000, but does not exceed $350,000	4 percent
Exceeds $350,000, but does not exceed $400,000	6 percent

(2) SMALL EMPLOYER.—For purposes of this subsection, the term "small employer" means any employer for any calendar year if the annual payroll of such employer for the preceding calendar year does not exceed $400,000.

(3) ANNUAL PAYROLL.—For purposes of this paragraph, the term "annual payroll" means, with respect to any employer for any calendar year, the aggregate wages paid by the employer during such calendar year.

(4) AGGREGATION RULES.—Related employers and predecessors shall be treated as a single employer for purposes of this subsection.

SEC. 314. AUTHORITY RELATED TO IMPROPER STEERING.

The Health Choices Commissioner (in coordination with the Secretary of Labor, the Secretary of Health and Human Services, and the Secretary of the Treasury) shall have authority to set standards for determining whether employers or insurers are undertaking any actions to affect the risk pool within the Health Insurance Exchange by inducing individuals to decline coverage under a qualified health benefits plan (or current employment-based health plan (within the meaning of section 102(b)) offered by the employer and instead to enroll in an Exchange-participating health benefits plan. An employer violating such standards shall be treated as not meeting the requirements of this section.

PART 2—SATISFACTION OF HEALTH COVERAGE PARTICIPATION REQUIREMENTS

[For sections 321 and 322, see text of bill as introduced on June 14, 2009.]

SEC. 323. SATISFACTION OF HEALTH COVERAGE PARTICIPATION REQUIREMENTS UNDER THE PUBLIC HEALTH SERVICE ACT.

(a) IN GENERAL.—Part C of title XXVII of the Public Health Service Act is amended by adding at the end the following new section:

"SEC. 2793. NATIONAL HEALTH COVERAGE PARTICIPATION REQUIREMENTS.

"(a) ELECTION OF EMPLOYER TO BE SUBJECT TO NATIONAL HEALTH COVERAGE PARTICIPATION REQUIREMENTS.—

"(1) IN GENERAL.—An employer may make an election with the Secretary to be subject to the health coverage participation requirements.

"(2) TIME AND MANNER.—An election under paragraph (1) may be made at such time and in such form and manner as the Secretary may prescribe.

"(b) TREATMENT OF COVERAGE RESULTING FROM ELECTION.—

"(1) IN GENERAL.—If an employer makes an election to the Secretary under subsection (a)—

"(A) such election shall be treated as the establishment and maintenance of a group health plan for purposes of this title, subject to section 151 of the America's Affordable Health Choices Act of 2009, and

"(B) the health coverage participation requirements shall be deemed to be included as terms and conditions of such plan.

"(2) PERIODIC INVESTIGATIONS TO DETERMINE COMPLIANCE WITH HEALTH COVERAGE PARTICIPATION REQUIREMENTS.—The Secretary shall regularly audit a representative sampling of employers and conduct investigations and other activities with respect to such sampling of employers so as to discover noncompliance with the health coverage participation requirements in connection with such employers (during any period with respect to which an election under subsection (a) is in effect). The Secretary shall communicate findings of noncompliance made by the Secretary under this subsection to the Secretary of the Treasury and the Health Choices Commissioner. The Secretary shall take such timely enforcement action as appropriate to achieve compliance.

"(c) HEALTH COVERAGE PARTICIPATION REQUIREMENTS.—For purposes of this section, the term 'health coverage participation requirements' means the requirements of part 1 of subtitle B of title III of division A of the America's Affordable Health Choices Act of 2009 (as in effect on the date of the enactment of this section).

"(d) SEPARATE ELECTIONS.—Under regulations prescribed by the Secretary, separate elections may be made under subsection (a) with respect to full-time employees and employees who are not full-time employees.

"(e) TERMINATION OF ELECTION IN CASES OF SUBSTANTIAL NONCOMPLIANCE.—The Secretary may terminate the election of any employer under subsection (a) if the Secretary (in coordination with the Health Choices Commissioner) determines that such employer is in substantial noncompliance with the health coverage participation requirements and shall refer any such determination to the Secretary of the Treasury as appropriate.

"(f) ENFORCEMENT OF HEALTH COVERAGE PARTICIPATION REQUIREMENTS.—

"(1) CIVIL PENALTIES.—In the case of any employer who fails (during any period with respect to which the election under subsection (a) is in effect) to satisfy the health coverage participation requirements with respect to any employee, the Secretary may assess a civil penalty against the employer of $100 for each day in the period beginning on the date such failure first occurs and ending on the date such failure is corrected.

"(2) LIMITATIONS ON AMOUNT OF PENALTY.—

"(A) PENALTY NOT TO APPLY WHERE FAILURE NOT DISCOVERED EXERCISING REASONABLE DILIGENCE.—No penalty shall be assessed under paragraph (1) with respect to any failure during any period for which it is established to the satisfaction of the Secretary that the employer did not know, or exercising reasonable diligence would not have known, that such failure existed.

"(B) PENALTY NOT TO APPLY TO FAILURES CORRECTED WITHIN 30 DAYS.—No penalty shall be assessed under paragraph (1) with respect to any failure if—

"(i) such failure was due to reasonable cause and not to willful neglect, and

"(ii) such failure is corrected during the 30-day period beginning on the 1st date that the employer knew, or exercising reasonable diligence would have known, that such failure existed.

"(C) OVERALL LIMITATION FOR UNINTENTIONAL FAILURES.—In the case of failures which are due to reasonable cause and not to willful neglect, the penalty assessed under paragraph (1) for failures during any 1-year period shall not exceed the amount equal to the lesser of—

"(i) 10 percent of the aggregate amount paid or incurred by the employer (or predecessor employer) during the preceding taxable year for group health plans, or

"(ii) $500,000.

"(3) ADVANCE NOTIFICATION OF FAILURE PRIOR TO ASSESSMENT.—Before a reasonable time prior to the assessment of any penalty under paragraph (1) with respect to any failure by an employer, the Secretary shall inform the employer in writing of such failure and shall provide the employer information regarding efforts and procedures which may be undertaken by the employer to correct such failure.

"(4) ACTIONS TO ENFORCE ASSESSMENTS.—The Secretary may bring a civil action in any District Court of the United States to collect any civil penalty under this subsection.

"(5) COORDINATION WITH EXCISE TAX.—Under regulations prescribed in accordance with section 324 of the America's Affordable Health Choices Act of 2009, the Secretary and the Secretary of the Treasury shall coordinate the assessment of penalties under paragraph (1) in connection with failures to satisfy health coverage participation requirements with the imposition of excise taxes on such failures under section 4980H(b) of the Internal Revenue Code of 1986 so as to avoid duplication of penalties with respect to such failures.

"(6) DEPOSIT OF PENALTY COLLECTED.—Any amount of penalty collected under this subsection shall be deposited as miscellaneous receipts in the Treasury of the United States.

"(g) REGULATIONS.—The Secretary may promulgate such regulations as may be necessary or appropriate to carry out the provisions of this section, in accordance with section 324(a) of the America's Affordable Health Choices Act of 2009. The Secretary may promulgate any interim final rules as the Secretary determines are appropriate to carry out this section.".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to periods beginning after December 31, 2012.

SEC. 324. ADDITIONAL RULES RELATING TO HEALTH COVERAGE PARTICIPATION REQUIREMENTS.

(a) ASSURING COORDINATION.—The officers consisting of the Secretary of Labor, the Secretary of the Treasury, the Secretary of Health and Human Services, and the Health Choices Commissioner shall ensure, through the execution of an interagency memorandum of understanding among such officers, that—

(1) regulations, rulings, and interpretations issued by such officers relating to the same matter over which two or more of such officers have responsibility under subpart B of part 6 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, section 4980H of the Internal Revenue Code of 1986, and section 2793 of the Public Health Service Act are administered so as to have the same effect at all times; and

(2) coordination of policies relating to enforcing the same requirements through such officers in order to have a coordinated enforcement strategy that avoids duplication of enforcement efforts and assigns priorities in enforcement.

(b) MULTIEMPLOYER PLANS.—In the case of a group health plan that is a multiemployer plan (as defined in section 3(37) of the Employee Retirement Income Security Act of 1974), the regulations prescribed in accordance with subsection (a) by the officers referred to in subsection (a) shall provide for the application of the health coverage participation requirements to the plan sponsor and contributing sponsors of such plan.

[TITLE IV—AMENDMENTS TO INTERNAL REVENUE CODE OF 1986]

[For title IV, see text of bill as introduced on June 14, 2009.]

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DIVISION B—MEDICARE AND MEDICAID IMPROVEMENTS

Sec. 1001. Table of contents of division.

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TITLE I—IMPROVING HEALTH CARE VALUE

[Subtitle A—Provisions Related to Medicare Part A]

[For subtitle A of title I of division B, see text of bill as introduced on June 14, 2009.]

Subtitle B—Provisions Related to Medicare Part B

PART 1—PHYSICIANS' SERVICES

SEC. 1121. SUSTAINABLE GROWTH RATE REFORM.

(a) TRANSITIONAL UPDATE FOR 2010.—Section 1848(d) of the Social Security Act (42 U.S.C. 1395w–4(d)) is amended by adding at the end the following new paragraph:

"(10) UPDATE FOR 2010.—The update to the single conversion factor established in paragraph (1)(C) for 2010 shall be the percentage increase in the MEI (as defined in section 1842(i)(3)) for that year.".

(b) REBASING SGR USING 2009; LIMITATION ON CUMULATIVE ADJUSTMENT PERIOD.—Section 1848(d)(4) of such Act (42 U.S.C. 1395w–4(d)(4)) is amended—

(1) in subparagraph (B), by striking "subparagraph (D)" and inserting "subparagraphs (D) and (G)"; and

(2) by adding at the end the following new subparagraph:

"(G) REBASING USING 2009 FOR FUTURE UPDATE ADJUSTMENTS.—In determining the update adjustment factor under subparagraph (B) for 2011 and subsequent years—

"(i) the allowed expenditures for 2009 shall be equal to the amount of the actual expenditures for physicians' services during 2009; and

"(ii) the reference in subparagraph (B)(ii)(I) to 'April 1, 1996' shall be treated as a reference to 'January 1, 2009 (or, if later, the first day of the fifth year before the year involved)'.".

(c) LIMITATION ON PHYSICIANS' SERVICES INCLUDED IN TARGET GROWTH RATE COMPUTATION TO SERVICES COVERED UNDER PHYSICIAN FEE SCHEDULE.—Effective for services furnished on or after January 1, 2009, section 1848(f)(4)(A) of such Act is amended by striking "(such as clinical" and all that follows through "in a physician's office" and inserting "for which payment under this part is made under the fee schedule under this section, for services for practitioners described in section 1842(b)(18)(C) on a basis related to such fee schedule, or for services described in section 1861(p) (other than such services when furnished in the facility of a provider of services)".

(d) ESTABLISHMENT OF SEPARATE TARGET GROWTH RATES FOR CATEGORIES OF SERVICES.—

(1) ESTABLISHMENT OF SERVICE CATEGORIES.—Subsection (j) of section 1848 of the Social Security Act (42 U.S.C. 1395w–4) is amended by adding at the end the following new paragraph:

"(5) SERVICE CATEGORIES.—For services furnished on or after January 1, 2009, each of the following categories of physicians' services (as defined in paragraph (3)) shall be treated as a separate 'service category':

"(A) Evaluation and management services that are procedure codes (for services covered under this title) for—

"(i) services in the category designated Evaluation and Management in the Health Care Common Procedure Coding System (established by the Secretary under subsection (c)(5) as of December 31, 2009, and as subsequently modified by the Secretary); and

"(ii) preventive services (as defined in section 1861(iii)) for which payment is made under this section.

"(B) All other services not described in subparagraph (A).

Service categories established under this paragraph shall apply without regard to the specialty of the physician furnishing the service.".

(2) ESTABLISHMENT OF SEPARATE CONVERSION FACTORS FOR EACH SERVICE CATEGORY.—Subsection (d)(1) of section 1848 of the Social Security Act (42 U.S.C. 1395w–4) is amended—

(A) in subparagraph (A)—

(i) by designating the sentence beginning "The conversion factor" as clause (i) with the heading "APPLICATION OF SINGLE CONVERSION FACTOR.—" and with appropriate indentation;

(ii) by striking "The conversion factor" and inserting "Subject to clause (ii), the conversion factor"; and

(iii) by adding at the end the following new clause:

"(ii) APPLICATION OF MULTIPLE CONVERSION FACTORS BEGINNING WITH 2011.—

"(I) IN GENERAL.—In applying clause (i) for years beginning with 2011, separate conversion factors shall be established for each service category of physicians' services (as defined in subsection (j)(5)) and any reference in this section to a conversion factor for such years shall be deemed to be a reference to the conversion factor for each of such categories.

"(II) INITIAL CONVERSION FACTORS.—Such factors for 2011 shall be based upon the single conversion factor for the previous year multiplied by the update established under paragraph (11) for such category for 2011.

"(III) UPDATING OF CONVERSION FACTORS.—Such factor for a service category for a subsequent year shall be based upon the conversion factor for such category for the previous year and adjusted by the update established for such category under paragraph (11) for the year involved."; and

(B) in subparagraph (D), by striking "other physicians' services" and inserting "physicians' services described in the service category described in subsection (j)(5)(B)".

(3) ESTABLISHING UPDATES FOR CONVERSION FACTORS FOR SERVICE CATEGORIES.—Section 1848(d) of the Social Security Act (42 U.S.C. 1395w–4(d)), as amended by subsection (a), is amended—

(A) in paragraph (4)(C)(iii), by striking "The allowed" and inserting "Subject to paragraph (11)(B), the allowed"; and

(B) by adding at the end the following new paragraph:

"(11) UPDATES FOR SERVICE CATEGORIES BEGINNING WITH 2011.—

"(A) IN GENERAL.—In applying paragraph (4) for a year beginning with 2011, the following rules apply:

"(i) APPLICATION OF SEPARATE UPDATE ADJUSTMENTS FOR EACH SERVICE CATEGORY.—Pursuant to paragraph (1)(A)(ii)(I), the update shall be made to the conversion factor for each service category (as defined in subsection (j)(5)) based upon an update adjustment factor for the respective category and year and the update adjustment factor shall be computed, for a year, separately for each service category.

"(ii) COMPUTATION OF ALLOWED AND ACTUAL EXPENDITURES BASED ON SERVICE CATEGORIES.—In computing the prior year adjustment component and the cumulative adjustment component under clauses (i) and (ii) of paragraph (4)(B), the following rules apply:

"(I) APPLICATION BASED ON SERVICE CATEGORIES.—The allowed expenditures and actual expenditures shall be the allowed and actual expenditures for the service category, as determined under subparagraph (B).

"(II) APPLICATION OF CATEGORY SPECIFIC TARGET GROWTH RATE.—The growth rate applied under clause (ii)(II) of such paragraph shall be the target growth rate for the service category involved under subsection (f)(5).

"(B) DETERMINATION OF ALLOWED EXPENDITURES.—In applying paragraph (4) for a year beginning with 2010, notwithstanding subparagraph (C)(iii) of such paragraph, the allowed expenditures for a service category for a year is an amount computed by the Secretary as follows:

"(i) FOR 2010.—For 2010:

"(I) TOTAL 2009 ACTUAL EXPENDITURES FOR ALL SERVICES INCLUDED IN SGR COMPUTATION FOR EACH SERVICE CATEGORY.—Com-

pute total actual expenditures for physicians' services (as defined in subsection (f)(4)(A)) for 2009 for each service category.

"(II) INCREASE BY GROWTH RATE TO OBTAIN 2010 ALLOWED EXPENDITURES FOR SERVICE CATEGORY.—Compute allowed expenditures for the service category for 2010 by increasing the allowed expenditures for the service category for 2009 computed under subclause (I) by the target growth rate for such service category under subsection (f) for 2010.

"(ii) FOR SUBSEQUENT YEARS.—For a subsequent year, take the amount of allowed expenditures for such category for the preceding year (under clause (i) or this clause) and increase it by the target growth rate determined under subsection (f) for such category and year.".

(4) APPLICATION OF SEPARATE TARGET GROWTH RATES FOR EACH CATEGORY.—

(A) IN GENERAL.—Section 1848(f) of the Social Security Act (42 U.S.C. 1395w–4(f)) is amended by adding at the end the following new paragraph:

"(5) APPLICATION OF SEPARATE TARGET GROWTH RATES FOR EACH SERVICE CATEGORY BEGINNING WITH 2010.—The target growth rate for a year beginning with 2010 shall be computed and applied separately under this subsection for each service category (as defined in subsection (j)(5)) and shall be computed using the same method for computing the target growth rate except that the factor described in paragraph (2)(C) for—

"(A) the service category described in subsection (j)(5)(A) shall be increased by 0.02; and

"(B) the service category described in subsection (j)(5)(B) shall be increased by 0.01.".

(B) USE OF TARGET GROWTH RATES.—Section 1848 of such Act is further amended—

(i) in subsection (d)—

(I) in paragraph (1)(E)(ii), by inserting "or target" after "sustainable"; and

(II) in paragraph (4)(B)(ii)(II), by inserting "or target" after "sustainable"; and

(ii) in the heading of subsection (f), by inserting "AND TARGET GROWTH RATE" after "SUSTAINABLE GROWTH RATE";

(iii) in subsection (f)(1)—

(I) by striking "and" at the end of subparagraph (A);

(II) in subparagraph (B), by inserting "before 2010" after "each succeeding year" and by striking the period at the end and inserting "; and"; and

(III) by adding at the end the following new subparagraph:

"(C) November 1 of each succeeding year the target growth rate for such succeeding year and each of the 2 preceding years."; and

(iv) in subsection (f)(2), in the matter before subparagraph (A), by inserting after "beginning with 2000" the following: "and ending with 2009".

(e) APPLICATION TO ACCOUNTABLE CARE ORGANIZATION PILOT PROGRAM.—In applying the target growth rate under subsections (d) and (f) of section 1848 of the Social Security Act to services furnished by a practitioner to beneficiaries who are attributable to an accountable care organization under the pilot program provided under section 1866D of such Act, the Secretary of Health and Human Services shall develop, not later than January 1, 2012, for application beginning with 2012, a method that—

(1) allows each such organization to have its own expenditure targets and updates for such practitioners, with respect to beneficiaries who are attributable to that organization, that are consistent with the methodologies described in such subsection (f); and

(2) provides that the target growth rate applicable to other physicians shall not apply to such physicians to the extent that the physicians' services are furnished through the accountable care organization.

In applying paragraph (1), the Secretary of Health and Human Services may apply the difference in the update under such paragraph on a claim-by-claim or lump sum basis and such a payment shall be taken into account under the pilot program.

SEC. 1122. MISVALUED CODES UNDER THE PHYSICIAN FEE SCHEDULE.

(a) IN GENERAL.—Section 1848(c)(2) of the Social Security Act (42 U.S.C. 1395w-4(c)(2)) is amended by adding at the end the following new subparagraphs:

"(K) POTENTIALLY MISVALUED CODES.—

"(i) IN GENERAL.—The Secretary shall—

"(I) periodically identify services as being potentially misvalued using criteria specified in clause (ii); and

"(II) review and make appropriate adjustments to the relative values established under this paragraph for services identified as being potentially misvalued under subclause (I).

"(ii) IDENTIFICATION OF POTENTIALLY MISVALUED CODES.—For purposes of identifying potentially misvalued services pursuant to clause (i)(I), the Secretary shall examine (as the Secretary determines to be appropriate) codes (and families of codes as appropriate) for which there has been the fastest growth; codes (and families of codes as appropriate) that have experienced substantial changes in practice expenses; codes for new technologies or services within an appropriate period (such as three years) after the relative values are initially established for such codes; multiple codes that are frequently billed in conjunction with furnishing a single service; codes with low relative values, particularly those that are often billed multiple times for a single treatment; codes which have not been subject to review since the implementation of the RBRVS (the so-called 'Harvard-valued codes'); and such other codes determined to be appropriate by the Secretary.

"(iii) REVIEW AND ADJUSTMENTS.—

"(I) The Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services described clause (i)(II).

"(II) The Secretary may conduct surveys, other data collection activities, studies, or other analyses as the Secretary determines to be appropriate to facilitate the review and appropriate adjustment described in clause (i)(II).

"(III) The Secretary may use analytic contractors to identify and analyze services identified under clause (i)(I), conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of services described in clause (i)(II).

"(IV) The Secretary may coordinate the review and appropriate adjustment described in clause (i)(II) with the periodic review described in subparagraph (B).

"(V) As part of the review and adjustment described in clause (i)(II), including with respect to codes with low relative values described in clause (ii), the Secretary may make appropriate coding revisions (including using existing processes for consideration of coding changes) which may include consolidation of individual services into bundled codes for payment under the fee schedule under subsection (b).

"(VI) The provisions of subparagraph (B)(ii)(II) shall apply to adjustments to relative value units made pursuant to this subparagraph in the same manner as such provisions apply to adjustments under subparagraph (B)(ii)(II).

"(L) VALIDATING RELATIVE VALUE UNITS.—

"(i) IN GENERAL.—The Secretary shall establish a process to validate relative value units under the fee schedule under subsection (b).

"(ii) COMPONENTS AND ELEMENTS OF WORK.—The process described in clause (i) may include validation of work elements (such as time, mental effort and professional judgment, technical skill and physical effort, and stress due to risk) involved with furnishing a service and may include validation of the pre, post, and intra-service components of work.

"(iii) SCOPE OF CODES.—The validation of work relative value units shall include a sampling of codes for services that is the same as the codes listed under subparagraph (K)(ii)

"(iv) METHODS.—The Secretary may conduct the validation under this subparagraph using methods described in subclauses (I) through (V) of subparagraph (K)(iii) as the Secretary determines to be appropriate.

"(v) ADJUSTMENTS.—The Secretary shall make appropriate adjustments to the work relative value units under the fee schedule under subsection (b). The provisions of subparagraph (B)(ii)(II) shall apply to adjustments to relative value units made pursuant to this subparagraph in the same manner as such provisions apply to adjustments under subparagraph (B)(ii)(II).".

(b) IMPLEMENTATION.—

(1) FUNDING.—For purposes of carrying out the provisions of subparagraphs (K) and (L) of 1848(c)(2) of the Social Security Act, as added by subsection (a),

in addition to funds otherwise available, out of any funds in the Treasury not otherwise appropriated, there are appropriated to the Secretary of Health and Human Services for the Center for Medicare & Medicaid Services Program Management Account $20,000,000 for fiscal year 2010 and each subsequent fiscal year. Amounts appropriated under this paragraph for a fiscal year shall be available until expended.

(2) ADMINISTRATION.—

(A) Chapter 35 of title 44, United States Code and the provisions of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to this section or the amendment made by this section.

(B) Notwithstanding any other provision of law, the Secretary may implement subparagraphs (K) and (L) of 1848(c)(2) of the Social Security Act, as added by subsection (a), by program instruction or otherwise.

(C) Section 4505(d) of the Balanced Budget Act of 1997 is repealed.

(D) Except for provisions related to confidentiality of information, the provisions of the Federal Acquisition Regulation shall not apply to this section or the amendment made by this section.

(3) FOCUSING CMS RESOURCES ON POTENTIALLY OVERVALUED CODES.—Section 1868(a) of the Social Security Act (42 1395ee(a)) is repealed.

SEC. 1123. PAYMENTS FOR EFFICIENT AREAS.

Section 1833 of the Social Security Act (42 U.S.C. 1395l) is amended by adding at the end the following new subsection:

"(x) INCENTIVE PAYMENTS FOR EFFICIENT AREAS.—

"(1) IN GENERAL.—In the case of services furnished under the physician fee schedule under section 1848 on or after January 1, 2011, and before January 1, 2013, by a supplier that is paid under such fee schedule in an efficient area (as identified under paragraph (2)), in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid (on a monthly or quarterly basis) an amount equal to 5 percent of the payment amount for the services under this part.

"(2) IDENTIFICATION OF EFFICIENT AREAS.—

"(A) IN GENERAL.—Based upon available data, the Secretary shall identify those counties or equivalent areas in the United States in the lowest fifth percentile of utilization based on per capita spending under this part and part A for services provided in the most recent year for which data are available as of the date of the enactment of this subsection, as standardized to eliminate the effect of geographic adjustments in payment rates.

"(B) IDENTIFICATION OF COUNTIES WHERE SERVICE IS FURNISHED..—For purposes of paying the additional amount specified in paragraph (1), if the Secretary uses the 5-digit postal ZIP Code where the service is furnished, the dominant county of the postal ZIP Code (as determined by the United States Postal Service, or otherwise) shall be used to determine whether the postal ZIP Code is in a county described in subparagraph (A).

"(C) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, respecting—

"(i) the identification of a county or other area under subparagraph (A); or

"(ii) the assignment of a postal ZIP Code to a county or other area under subparagraph (B).

"(D) PUBLICATION OF LIST OF COUNTIES; POSTING ON WEBSITE.—With respect to a year for which a county or area is identified under this paragraph, the Secretary shall identify such counties or areas as part of the proposed and final rule to implement the physician fee schedule under section 1848 for the applicable year. The Secretary shall post the list of counties identified under this paragraph on the Internet website of the Centers for Medicare & Medicaid Services.".

SEC. 1124. MODIFICATIONS TO THE PHYSICIAN QUALITY REPORTING INITIATIVE (PQRI).

(a) FEEDBACK.—Section 1848(m)(5) of the Social Security Act (42 U.S.C. 1395w–4(m)(5)) is amended by adding at the end the following new subparagraph:

"(H) FEEDBACK.—The Secretary shall provide timely feedback to eligible professionals on the performance of the eligible professional with respect to satisfactorily submitting data on quality measures under this subsection.".

(b) APPEALS.—Such section is further amended—

(1) in subparagraph (E), by striking "There shall be" and inserting "Subject to subparagraph (I), there shall be"; and

(2) by adding at the end the following new subparagraph:

"(I) INFORMAL APPEALS PROCESS.—Notwithstanding subparagraph (E), by not later than January 1, 2011, the Secretary shall establish and have in

place an informal process for eligible professionals to appeal the determination that an eligible professional did not satisfactorily submit data on quality measures under this subsection.".

(c) INTEGRATION OF PHYSICIAN QUALITY REPORTING AND EHR REPORTING.—Section 1848(m) of such Act is amended by adding at the end the following new paragraph:

"(7) INTEGRATION OF PHYSICIAN QUALITY REPORTING AND EHR REPORTING.—Not later than January 1, 2012, the Secretary shall develop a plan to integrate clinical reporting on quality measures under this subsection with reporting requirements under subsection (o) relating to the meaningful use of electronic health records. Such integration shall consist of the following:

"(A) The development of measures, the reporting of which would both demonstrate—

"(i) meaningful use of an electronic health record for purposes of subsection (o); and

"(ii) clinical quality of care furnished to an individual.

"(B) The collection of health data to identify deficiencies in the quality and coordination of care for individuals eligible for benefits under this part.

"(C) Such other activities as specified by the Secretary.".

(d) EXTENSION OF INCENTIVE PAYMENTS.—Section 1848(m)(1) of such Act (42 U.S.C. 1395w–4(m)(1)) is amended—

(1) in subparagraph (A), by striking "2010" and inserting "2012"; and

(2) in subparagraph (B)(ii), by striking "2009 and 2010" and inserting "each of the years 2009 through 2012".

SEC. 1125. ADJUSTMENT TO MEDICARE PAYMENT LOCALITIES.

(a) IN GENERAL.—Section 1848(e) of the Social Security Act (42 U.S.C.1395w–4(e)) is amended by adding at the end the following new paragraph:

"(6) TRANSITION TO USE OF MSAS AS FEE SCHEDULE AREAS IN CALIFORNIA.—

"(A) IN GENERAL.—

"(i) REVISION.—Subject to clause (ii) and notwithstanding the previous provisions of this subsection, for services furnished on or after January 1, 2011, the Secretary shall revise the fee schedule areas used for payment under this section applicable to the State of California using the Metropolitan Statistical Area (MSA) iterative Geographic Adjustment Factor methodology as follows:

"(I) The Secretary shall configure the physician fee schedule areas using the Core-Based Statistical Areas-Metropolitan Statistical Areas (each in this paragraph referred to as an 'MSA'), as defined by the Director of the Office of Management and Budget, as the basis for the fee schedule areas. The Secretary shall employ an iterative process to transition fee schedule areas. First, the Secretary shall list all MSAs within the State by Geographic Adjustment Factor described in paragraph (2) (in this paragraph referred to as a 'GAF') in descending order. In the first iteration, the Secretary shall compare the GAF of the highest cost MSA in the State to the weighted-average GAF of the group of remaining MSAs in the State. If the ratio of the GAF of the highest cost MSA to the weighted-average GAF of the rest of State is 1.05 or greater then the highest cost MSA becomes a separate fee schedule area.

"(II) In the next iteration, the Secretary shall compare the MSA of the second-highest GAF to the weighted-average GAF of the group of remaining MSAs. If the ratio of the second-highest MSA's GAF to the weighted-average of the remaining lower cost MSAs is 1.05 or greater, the second-highest MSA becomes a separate fee schedule area. The iterative process continues until the ratio of the GAF of the highest-cost remaining MSA to the weighted-average of the remaining lower-cost MSAs is less than 1.05, and the remaining group of lower cost MSAs form a single fee schedule area. If two MSAs have identical GAFs, they shall be combined in the iterative comparison.

"(ii) TRANSITION.—For services furnished on or after January 1, 2011, and before January 1, 2016, in the State of California, after calculating the work, practice expense, and malpractice geographic indices described in clauses (i), (ii), and (iii) of paragraph (1)(A) that would otherwise apply through application of this paragraph, the Secretary shall increase any such index to the county-based fee schedule area value on December 31, 2009, if such index would otherwise be less than the value on January 1, 2010.

"(B) SUBSEQUENT REVISIONS.—

"(i) PERIODIC REVIEW AND ADJUSTMENTS IN FEE SCHEDULE AREAS.—Subsequent to the process outlined in paragraph (1)(C), not less often than every three years, the Secretary shall review and update the California Rest-of-State fee schedule area using MSAs as defined by the Director of the Office of Management and Budget and the iterative methodology described in subparagraph (A)(i).

"(ii) LINK WITH GEOGRAPHIC INDEX DATA REVISION.—The revision described in clause (i) shall be made effective concurrently with the application of the periodic review of the adjustment factors required under paragraph (1)(C) for California for 2012 and subsequent periods. Upon request, the Secretary shall make available to the public any county-level or MSA derived data used to calculate the geographic practice cost index.

"(C) REFERENCES TO FEE SCHEDULE AREAS.—Effective for services furnished on or after January 1, 2010, for the State of California, any reference in this section to a fee schedule area shall be deemed a reference to an MSA in the State.".

(b) CONFORMING AMENDMENT TO DEFINITION OF FEE SCHEDULE AREA.—Section 1848(j)(2) of the Social Security Act (42 U.S.C. 1395w(j)(2)) is amended by striking "The term" and inserting "Except as provided in subsection (e)(6)(C), the term".

SEC. 1126. RESOURCE-BASED FEEDBACK PROGRAM FOR PHYSICIANS IN MEDICARE.

(a) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the "Secretary") shall provide for the measurement and confidential communication of reports (each in this section referred to as a "feedback report") to physicians and other practitioners regarding the utilization of services under the Medicare program under title XVIII of the Social Security Act. Such reports shall be based upon claims data and shall include quality data reported under section 1848(m)(5) of such Act (42 U.S.C. 1395w-4(m)(5)) and such other information as the Secretary determines appropriate.

(b) TIMELINE FOR FEEDBACK PROGRAM.—

(1) ANALYSIS TOOL.—Not later than December 31, 2010, the Secretary shall initially develop an episode grouper or other initial resource analysis tool described in subsection (c)(4).

(2) EVALUATION.—During 2011 the Secretary shall conduct the evaluation specified in subsection (e)(1).

(3) EXPANSION.—The Secretary shall expand the program as specified in subsection (e)(2).

(c) FEEDBACK REPORTS.—

(1) COMPARISON OF RESOURCE USE PATTERNS.—Feedback reports shall include information allowing the comparison of a physician's resource use pattern to such pattern for peers. Such reports may include resource use data on—

(A) a per capita basis;

(B) a per episode basis; or

(C) both.

(2) PEER COMPARISON.—Reports under this section shall include information regarding nationwide groups of similarly situated physicians (taking into consideration specialty, practice setting, and such other criteria as the Secretary finds appropriate) and comparing the pattern of services of each physician in the group to the group average pattern of services.

(3) DETAILED INFORMATION.—The Secretary shall include in feedback reports details about the services, procedures, and relevant clinical information to identify factors that may account for significant variation of a physician from national norms, such as high rates of elective surgeries, diagnostic services, or other utilization attributable to the judgment of the physician.

(4) DEVELOPMENT OF EPISODE GROUPER.—The Secretary shall, in consultation with physicians and others as the Secretary determines to be appropriate, develop an episode grouper or other resource analysis tool that could be used to measure physician resource use. The Secretary may update such grouper from time to time as appropriate.

(d) FEEDBACK PROGRAM.—The Secretary shall engage in efforts to disseminate feedback reports. In disseminating such reports, the Secretary shall seek to estalish their validity and credibility to physicians and shall experiment with communications methods such as the following:

(1) Direct meetings between contracted physicians, facilitated by the Secretary, to discuss the contents of feedback reports, including any reasons for divergence from national averages.

(2) Contracts with local, non-profit entities engaged in quality improvement efforts at the community level. Such entities shall use the feedback reports, or such equivalent tool as specified by the Secretary. Any exchange of data under this paragraph shall be protected by appropriate privacy safeguards.

(3) Mailings or other methods of communication that facilitate large-scale dissemination.

(4) Other methods specified by the Secretary.

(e) EVALUATION AND EXPANSION.—

(1) EVALUATION.—The Secretary shall evaluate the methods specified in subsection (d) with regard to their efficacy in changing practice patterns to improve quality and decrease costs.

(2) EXPANSION.—Taking into account the cost of each method, the Secretary shall develop a plan to disseminate such reports in a significant manner in the regions and cities of the country with the highest utilization of services under Medicare. The Secretary shall disseminate, to the extent practicable, feedback reports in a manner consistent with the following:

(A) During 2011, at least 1,000 reports.

(B) During 2012, at least 10,000 reports.

(C) During 2013, at least 25,000 reports.

(D) During 2014 and subsequent years, reports to the physicians with utilization within the highest 5 percent of physicians, subject to the authority to focus under subsection (f).

(3) OPT OUT.—The Secretary shall establish a process by which a physician may opt not to receive feedback reports under this section.

(f) AUTHORITY TO FOCUS PROGRAM APPLICATION.—The secretary may focus the application of the program under this section and dissemination of feedback reports on physicians, as appropriate, such as on physicians who—

(1) practice in geographic areas that account for unusually high rates of spending per capita;

(2) treat conditions that have a high cost or volume under Medicare;

(3) use a high amount of resources compared to other physicians; or

(4) treat at least a minimum number of Medicare beneficiaries.

(g) INCLUSION OF CERTAIN PRACTITIONERS.—For purposes of this section, the term "physician" includes a practitioner who furnishes services for which payment is made under Medicare and for which such payment would be made if furnished by a physician.

(h) ADMINISTRATION.—

(1) Chapter 35 of title 44, United States Code shall not apply to this section.

(2) Notwithstanding any other provision of law, the Secretary may implement the provisions of this section by program instruction or otherwise.

PART 2—MARKET BASKET UPDATES

SEC. 1131. INCORPORATING PRODUCTIVITY IMPROVEMENTS INTO MARKET BASKET UPDATES THAT DO NOT ALREADY INCORPORATE SUCH IMPROVEMENTS.

(a) OUTPATIENT HOSPITALS.—

(1) IN GENERAL.—The first sentence of section 1833(t)(3)(C)(iv) of the Social Security Act (42 U.S.C. 1395l(t)(3)(C)(iv)) is amended—

(A) by inserting "(which is subject to the productivity adjustment described in subclause (II) of such section)" after "1886(b)(3)(B)(iii)"; and

(B) by inserting "(but not below 0)" after "reduced".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to increase factors for services furnished in years beginning with 2010.

(b) AMBULANCE SERVICES.—Section 1834(l)(3)(B) of such Act (42 U.S.C. 1395m(l)(3)(B))) is amended by inserting before the period at the end the following: "and, in the case of years beginning with 2010, subject to the productivity adjustment described in section 1886(b)(3)(B)(iii)(II)".

(c) AMBULATORY SURGICAL CENTER SERVICES.—Section 1833(i)(2)(D) of such Act (42 U.S.C. 1395l(i)(2)(D)) is amended—

(1) by redesignating clause (v) as clause (vi); and

(2) by inserting after clause (iv) the following new clause:

"(v) In implementing the system described in clause (i), for services furnished during 2010 or any subsequent year, to the extent that an annual percentage change factor applies, such factor shall be subject to the productivity adjustment described in section 1886(b)(3)(B)(iii)(II).".

(d) LABORATORY SERVICES.—Section 1833(h)(2)(A) of such Act (42 U.S.C. 1395l(h)(2)(A)) is amended—

(1) in clause (i), by striking "for each of the years 2009 through 2013" and inserting "for 2009"; and

(2) clause (ii)—

(A) by striking "and" at the end of subclause (III);

(B) by striking the period at the end of subclause (IV) and inserting "; and"; and

(C) by adding at the end the following new subclause:

"(V) the annual adjustment in the fee schedules determined under clause (i) for years beginning with 2010 shall be subject to the productivity adjustment described in section 1886(b)(3)(B)(iii)(II).".

(e) CERTAIN DURABLE MEDICAL EQUIPMENT.—Section 1834(a)(14) of such Act (42 U.S.C. 1395m(a)(14)) is amended—

(1) in subparagraph (K), by inserting before the semicolon at the end the following: ", subject to the productivity adjustment described in section 1886(b)(3)(B)(iii)(II)";

(2) in subparagraph (L)(i), by inserting after "June 2013," the following: "subject to the productivity adjustment described in section 1886(b)(3)(B)(iii)(II),";

(3) in subparagraph (L)(ii), by inserting after "June 2013" the following: ", subject to the productivity adjustment described in section 1886(b)(3)(B)(iii)(II)"; and

(4) in subparagraph (M), by inserting before the period at the end the following: ", subject to the productivity adjustment described in section 1886(b)(3)(B)(iii)(II)".

PART 3—OTHER PROVISIONS

SEC. 1141. RENTAL AND PURCHASE OF POWER-DRIVEN WHEELCHAIRS.

(a) IN GENERAL.—Section 1834(a)(7)(A)(iii) of the Social Security Act (42 U.S.C. 1395m(a)(7)(A)(iii)) is amended—

(1) in the heading, by inserting "CERTAIN COMPLEX REHABILITATIVE" after "OPTION FOR"; and

(2) by striking "power-driven wheelchair" and inserting "complex rehabilitative power-driven wheelchair recognized by the Secretary as classified within group 3 or higher".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall take effect on January 1, 2011, and shall apply to power-driven wheelchairs furnished on or after such date. Such amendments shall not apply to contracts entered into under section 1847 of the Social Security Act (42 U.S.C. 1395w–3) pursuant to a bid submitted under such section before October 1, 2010, under subsection (a)(1)(B)(i)(I) of such section.

SEC. 1141A. ELECTION TO TAKE OWNERSHIP, OR TO DECLINE OWNERSHIP, OF A CERTAIN ITEM OF COMPLEX DURABLE MEDICAL EQUIPMENT AFTER THE 13-MONTH CAPPED RENTAL PERIOD ENDS.

(a) IN GENERAL.—Section 1834(a)(7)(A) of the Social Security Act (42 U.S.C. 1395m(a)(7)(A)) is amended—

(1) in clause (ii)—

(A) by striking "RENTAL.—On" and inserting "RENTAL.—

"(I) IN GENERAL.—Except as provided in subclause (II), on"; and

(B) by adding at the end the following new subclause:

"(II) OPTION TO ACCEPT OR REJECT TRANSFER OF TITLE TO GROUP 3 SUPPORT SURFACE.—

"(aa) IN GENERAL.—During the 10th continuous month during which payment is made for the rental of a Group 3 Support Surface under clause (i), the supplier of such item shall offer the individual the option to accept or reject transfer of title to a Group 3 Support Surface after the 13th continuous month during which payment is made for the rental of the Group 3 Support Surface under clause (i). Such title shall be transferred to the individual only if the individual notifies the supplier not later than 1 month after the supplier makes such offer that the individual agrees to accept transfer of the title to the Group 3 Support Surface. Unless the individual accepts transfer of title to the Group 3 Support Surface in the manner set forth in this subclause, the individual shall be deemed to have rejected transfer of title. If the individual agrees to accept the transfer of the title to the Group 3 Support Surface, the supplier shall transfer such title to the individual on the first day that begins after the 13th continuous month during which

payment is made for the rental of the Group 3 Support Surface under clause (i). If the supplier transfers title to the Group 3 Support Surface under this subclause, payments for maintenance and servicing after the transfer of title shall be made in accordance with clause (iv). If the individual rejects transfer of title under this subclause, payments for maintenance and servicing after the end of the period of medical need during which payment is made under clause (i) shall be made in accordance with clause (v).

"(bb) SPECIAL RULE.—If, on the effective date of this subclause, an individual's rental period for a Group 3 Support Surface has exceeded 10 continuous months, but the first day that begins after the 13th continuous month during which payment is made for the rental under clause (i) has not been reached, the supplier shall, within 1 month following such effective date, offer the individual the option to accept or reject transfer of title to a Group 3 Support Surface. Such title shall be transferred to the individual only if the individual notifies the supplier not later than 1 month after the supplier makes such offer that the individual agrees to accept transfer of title to the Group 3 Support Surface. Unless the individual accepts transfer of title to the Group 3 Support Surface in the manner set forth in this subclause, the individual shall be deemed to have rejected transfer of title. If the individual agrees to accept the transfer of the title to the Group 3 Support Surface, the supplier shall transfer such title to the individual on the first day that begins after the 13th continuous month during which payment is made for the rental of the Group 3 Support Surface under clause (i) unless that day has passed, in which case the supplier shall transfer such title to the individual not later than 1 month after notification that the individual accepts transfer of title. If the supplier transfers title to the Group 3 Support Surface under this subclause, payments for maintenance and servicing after the transfer of title shall be made in accordance with clause (iv). If the individual rejects transfer of title under this subclause, payments for maintenance and servicing after the end of the period of medical need during which payment is made under clause (i) shall be made in accordance with clause (v).";

(2) in clause (iv), in the heading, by inserting "AFTER TRANSFER OF TITLE" after "SERVICING"; and

(3) by adding at the end the following new clause:

"(v) MAINTENANCE AND SERVICING OF GROUP 3 SUPPORT SURFACE IF INDIVIDUAL REJECTS TRANSFER OF TITLE.—In the case of a Group 3 Support Surface for which the individual has rejected transfer of title under subclause (ii)(II)—

"(I) during the first 6-month period of medical need that follows the period of medical need during which payment is made under clause (i), no payment shall be made for rental or maintenance and servicing of the Group 3 Support Surface; and

"(II) during the first month of each succeeding 6-month period of medical need, a maintenance and servicing payment may be made (for parts and labor not covered by the supplier's or manufacturer's warranty, as determined by the Secretary to be appropriate for the Group 3 Support Surface) and the amount recognized for each such 6-month period is the lower of—

"(aa) a reasonable and necessary maintenance and servicing fee or fees established by the Secretary; or

"(bb) 10 percent of the total of the purchase price recognized under paragraph (8) with respect to the Group 3 Support Surface.".

(b) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date of enactment of this Act.

SEC. 1142. EXTENSION OF PAYMENT RULE FOR BRACHYTHERAPY.

Section 1833(t)(16)(C) of the Social Security Act (42 U.S.C. 1395l(t)(16)(C)), as amended by section 142 of the Medicare Improvements for Patients and Providers Act of 2008 (Public Law 110–275), is amended by striking, the first place it appears, "January 1, 2010" and inserting "January 1, 2012".

SEC. 1143. HOME INFUSION THERAPY REPORT TO CONGRESS.

Not later than 12 months after the date of enactment of this Act, the Medicare Payment Advisory Commission shall submit to Congress a report on the following:

(1) The scope of coverage for home infusion therapy in the fee-for-service Medicare program under title XVIII of the Social Security Act, Medicare Advantage under part C of such title, the veteran's health care program under chapter 17 of title 38, United States Code, and among private payers, including an analysis of the scope of services provided by home infusion therapy providers to their patients in such programs.

(2) The benefits and costs of providing such coverage under the Medicare program, including a calculation of the potential savings achieved through avoided or shortened hospital and nursing home stays as a result of Medicare coverage of home infusion therapy.

(3) An assessment of sources of data on the costs of home infusion therapy that might be used to construct payment mechanisms in the Medicare program.

(4) Recommendations, if any, on the structure of a payment system under the Medicare program for home infusion therapy, including an analysis of the payment methodologies used under Medicare Advantage plans and private health plans for the provision of home infusion therapy and their applicability to the Medicare program.

SEC. 1144. REQUIRE AMBULATORY SURGICAL CENTERS (ASCS) TO SUBMIT COST DATA AND OTHER DATA.

(a) COST REPORTING.—

(1) IN GENERAL.—Section 1833(i) of the Social Security Act (42 U.S.C. 1395l(i)) is amended by adding at the end the following new paragraph:

"(8) The Secretary shall require, as a condition of the agreement described in section 1832(a)(2)(F)(i), the submission of such cost report as the Secretary may specify, taking into account the requirements for such reports under section 1815 in the case of a hospital.".

(2) DEVELOPMENT OF COST REPORT.—Not later than 3 years after the date of the enactment of this Act, the Secretary of Health and Human Services shall develop a cost report form for use under section 1833(i)(8) of the Social Security Act, as added by paragraph (1).

(3) AUDIT REQUIREMENT.—The Secretary shall provide for periodic auditing of cost reports submitted under section 1833(i)(8) of the Social Security Act, as added by paragraph (1).

(4) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to agreements applicable to cost reporting periods beginning 18 months after the date the Secretary develops the cost report form under paragraph (2).

(b) ADDITIONAL DATA ON QUALITY.—

(1) IN GENERAL.—Section 1833(i)(7) of such Act (42 U.S.C. 1395l(i)(7)) is amended—

(A) in subparagraph (B), by inserting "subject to subparagraph (C)," after "may otherwise provide,"; and

(B) by adding at the end the following new subparagraph:

"(C) Under subparagraph (B) the Secretary shall require the reporting of such additional data relating to quality of services furnished in an ambulatory surgical facility, including data on health care associated infections, as the Secretary may specify.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall to reporting for years beginning with 2012.

SEC. 1145. TREATMENT OF CERTAIN CANCER HOSPITALS.

Section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)) is amended by adding at the end the following new paragraph:

"(18) AUTHORIZATION OF ADJUSTMENT FOR CANCER HOSPITALS.—

"(A) STUDY.—The Secretary shall conduct a study to determine if, under the system under this subsection, costs incurred by hospitals described in section 1886(d)(1)(B)(v) with respect to ambulatory payment classification groups exceed those costs incurred by other hospitals furnishing services under this subsection (as determined appropriate by the Secretary).

"(B) AUTHORIZATION OF ADJUSTMENT.—Insofar as the Secretary determines under subparagraph (A) that costs incurred by hospitals described in section 1886(d)(1)(B)(v) exceed those costs incurred by other hospitals furnishing services under this subsection, the Secretary shall provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs effective for services furnished on or after January 1, 2011.".

SEC. 1146. MEDICARE IMPROVEMENT FUND.

Section 1898(b)(1)(A) of the Social Security Act (42 U.S.C. 1395iii(b)(1)(A)) is amended to read as follows:

"(A) the period beginning with fiscal year 2011 and ending with fiscal year 2019, $8,000,000,000; and".

SEC. 1147. PAYMENT FOR IMAGING SERVICES.

(a) ADJUSTMENT IN PRACTICE EXPENSE TO REFLECT HIGHER PRESUMED UTILIZATION.—Section 1848 of the Social Security Act (42 U.S.C. 1395w) is amended—

(1) in subsection (b)(4)—

(A) in subparagraph (B), by striking "subparagraph (A)" and inserting "this paragraph"; and

(B) by adding at the end the following new subparagraph:

"(C) ADJUSTMENT IN PRACTICE EXPENSE TO REFLECT HIGHER PRESUMED UTILIZATION.—In computing the number of practice expense relative value units under subsection (c)(2)(C)(ii) with respect to advanced diagnostic imaging services (as defined in section 1834(e)(1)(B)) , the Secretary shall adjust such number of units so it reflects a 75 percent (rather than 50 percent) presumed rate of utilization of imaging equipment."; and

(2) in subsection (c)(2)(B)(v)(II), by inserting "AND OTHER PROVISIONS" after "OPD PAYMENT CAP".

(b) ADJUSTMENT IN TECHNICAL COMPONENT "DISCOUNT" ON SINGLE-SESSION IMAGING TO CONSECUTIVE BODY PARTS.—Section 1848(b)(4) of such Act is further amended by adding at the end the following new subparagraph:

"(D) ADJUSTMENT IN TECHNICAL COMPONENT DISCOUNT ON SINGLE-SESSION IMAGING INVOLVING CONSECUTIVE BODY PARTS.—The Secretary shall increase the reduction in expenditures attributable to the multiple procedure payment reduction applicable to the technical component for imaging under the final rule published by the Secretary in the Federal Register on November 21, 2005 (part 405 of title 42, Code of Federal Regulations) from 25 percent to 50 percent.".

(c) EFFECTIVE DATE.—Except as otherwise provided, this section, and the amendments made by this section, shall apply to services furnished on or after January 1, 2011.

SEC. 1148. DURABLE MEDICAL EQUIPMENT PROGRAM IMPROVEMENTS.

(a) WAIVER OF SURETY BOND REQUIREMENT.—Section 1834(a)(16) of the Social Security Act (42 U.S.C. 1395m(a)(16)) is amended by adding at the end the following: "The requirement for a surety bond described in subparagraph (B) shall not apply in the case of a pharmacy (i) that has been enrolled under section 1866(j) as a supplier of durable medical equipment, prosthetics, orthotics, and supplies and has been issued (which may include renewal of) a provider number (as described in the first sentence of this paragraph) for at least 5 years, and (ii) for which a final adverse action (as defined in section 424.57(a) of title 42, Code of Federal Regulations) has never been imposed.".

(b) ENSURING SUPPLY OF OXYGEN EQUIPMENT .—

(1) IN GENERAL.—Section 1834(a)(5)(F) of the Social Security Act (42 U.S.C. 1395m(a)(5)(F)) is amended—

(A) in clause (ii), by striking "After the" and inserting "Except as provided in clause (iii), after the"; and

(B) by adding at the end the following new clause:

"(iii) CONTINUATION OF SUPPLY.—In the case of a supplier furnishing such equipment to an individual under this subsection as of the 27th month of the 36 months described in clause (i), the supplier furnishing such equipment as of such month shall continue to furnish such equipment to such individual (either directly or though arrangements with other suppliers of such equipment) during any subsequent period of medical need for the remainder of the reasonable useful lifetime of the equipment, as determined by the Secretary, regardless of the location of the individual, unless another supplier has accepted responsibility for continuing to furnish such equipment during the remainder of such period.".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall take effect as of the date of the enactment of this Act and shall apply to the furnishing of equipment to individuals for whom the 27th month of a continuous period of use of oxygen equipment described in section 1834(a)(5)(F) of the Social Security Act occurs on or after July 1, 2010.

(c) TREATMENT OF CURRENT ACCREDITATION APPLICATIONS.—Section 1834(a)(20)(F) of such Act (42 U.S.C. 1395m(a)(20)(F)) is amended—

(1) in clause (i)—

(A) by striking "clause (ii)" and inserting "clauses (ii) and (iii)"; and

(B) by striking "and" at the end;

(2) by striking the period at the end of clause (ii)(II) and by inserting "; and"; and

(3) by adding at the end the following:

"(iii) the requirement for accreditation described in clause (i) shall not apply for purposes of supplying diabetic testing supplies, canes, and crutches in the case of a pharmacy that is enrolled under section 1866(j) as a supplier of durable medical equipment, prosthetics, orthotics, and supplies.

Any supplier that has submitted an application for accreditation before August 1, 2009, shall be deemed as meeting applicable standards and accreditation requirement under this subparagraph until such time as the independent accreditation organization takes action on the supplier's application.".

(d) RESTORING 36-MONTH OXYGEN RENTAL PERIOD IN CASE OF SUPPLIER BANKRUPTCY FOR CERTAIN INDIVIDUALS.—Section 1834(a)(5)(F) of such Act (42 U.S.C. 1395m(a)(5)(F)) is amended by adding at the end the following new clause:

"(iv) EXCEPTION FOR BANKRUPTCY.—If a supplier of oxygen to an individual is declared bankrupt and its assets are liquidated and at the time of such declaration and liquidation more than 24 months of rental payments have been made, the individual may begin under this subparagraph a new 36-month rental period with another supplier of oxygen.".

(e) PAYMENT ADJUSTMENT.—Section 1834(a)(14)(K) of such Act (42 U.S.C. 1395m(a)(14)(K)), as amended by section 1131(e), is amended by inserting before the semicolon at the end the following: ", -0.5 percent".

SEC. 1149. MEDPAC STUDY AND REPORT ON BONE MASS MEASUREMENT.

(a) IN GENERAL.—The Medicare Payment Advisory Commission shall conduct a study regarding bone mass measurement, including computed tomography, duel-energy x-ray absorptriometry, and vertebral fracture assessment. The study shall focus on the following:

(1) An assessment of the adequacy of Medicare payment rates for such services, taking into account costs of acquiring the necessary equipment, professional work time, and practice expense costs.

(2) The impact of Medicare payment changes since 2006 on beneficiary access to bone mass measurement benefits in general and in rural and minority communities specifically.

(3) A review of the clinically appropriate and recommended use among Medicare beneficiaries and how usage rates among such beneficiaries compares to such recommendations.

(4) In conjunction with the findings under (3), recommendations, if necessary, regarding methods for reaching appropriate use of bone mass measurement studies among Medicare beneficiaries.

(b) REPORT.—The Commission shall submit a report to the Congress, not later than 9 months after the date of the enactment of this Act, containing a description of the results of the study conducted under subsection (a) and the conclusions and recommendations, if any, regarding each of the issues described in paragraphs (1), (2) (3) and (4) of such subsection.

SEC. 1149A. EXCLUSION OF CUSTOMARY PROMPT PAY DISCOUNTS EXTENDED TO WHOLESALERS FROM MANUFACTURER'S AVERAGE SALES PRICE FOR PAYMENTS FOR DRUGS AND BIOLOGICALS UNDER MEDICARE PART B.

Section 1847A(c)(3) of the Social Security Act (42 U.S.C. 1395w–3a(c)(3)) is amended—

(1) in the first sentence, by inserting after "prompt pay discounts" the following: "(other than, for drugs and biologicals that are sold on or after January 1, 2011, and before January 1, 2016, customary prompt pay discounts extended to wholesalers, but only to the extent such discounts do not exceed 2 percent of the wholesale acquisition cost)"; and

(2) in the second sentence, by inserting after "other price concessions" the following: "(other than, for drugs and biologicals that are sold on or after January 1, 2011, and before January 1, 2016, customary prompt pay discounts extended to wholesalers, but only to the extent such discounts do not exceed 2 percent of the wholesale acquisition cost)".

SEC. 1149B. TIMELY ACCESS TO POSTMASTECTOMY ITEMS.

(a) IN GENERAL.—Section 1834(h)(1) of the Social Security Act (42 U.S.C. 1395m(h)(1)) is amended—

(1) by redesignating subparagraph (H) as subparagraph (I); and

(2) by inserting after subparagraph (G) the following new subparagraph:

"(H) SPECIAL PAYMENT RULE FOR POSTMASTECTOMY EXTERNAL BREAST PROSTHESIS GARMENTS.—Payment for postmastectomy external breast prosthesis garments shall be made regardless of whether such items are supplied to the beneficiary prior to or after the mastectomy procedure or other breast cancer surgical procedure. The Secretary shall develop policies to ensure appropriate beneficiary access and utilization safeguards for such items supplied to a beneficiary prior to the mastectomy or other breast cancer surgical procedure."

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect the date of the enactment of this Act.

SEC. 1149C. MORATORIUM ON MEDICARE REDUCTIONS IN PAYMENT RATES FOR CERTAIN INTERVENTIONAL PAIN MANAGEMENT PROCEDURES COVERED UNDER THE ASC FEE SCHEDULE.

(a) IN GENERAL.—Notwithstanding any other provision of law, the payment rate applied under section 1833(i)(2) of the Social Security Act (42 U.S.C. 13951(i)(2)) for interventional pain management procedures specified in subsection (b) which are furnished on or after January 1, 2010, and before January 1, 2012, shall not be less than the payment rate applied under such section for such procedures in effect as of January 1, 2007.

(b) PROCEDURES SPECIFIED.—For purposes of this section, the interventional pain management procedures specified in this subsection are the following:

(1) Epidural injections (CPT 62310, 62311, 64483, 64484).

(2) Facet joint injections (CPT 64470, 64472, 64475, 64476).

(3) Sacroiliac joint injection (CPT 27096).

SEC. 1149D. MEDICARE COVERAGE OF SERVICES OF QUALIFIED RESPIRATORY THERAPISTS PERFORMED UNDER THE GENERAL SUPERVISION OF A PHYSICIAN.

(a) IN GENERAL.—Section 1861 of the Social Security Act (42 U.S.C. 1395x), as amended by sections 1233(a) and 1309, is amended—

(1) in subsection (s)(2)—

(A) by striking "and" at the end of subparagraph (GG);

(B) by adding "and" at the end of subparagraph (HH); and

(C) by adding at the end the following new subparagraph:

"(II) respiratory therapy services which would be physicians' services if furnished by a physician (as defined in subsection (r)(1)) for the diagnosis and treatment of respiratory illnesses and which are performed by a respiratory therapist (as defined in subsection (mmm)) under the general supervision of a physician and which the respiratory therapist is legally authorized to perform by the State in which the services are performed, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services;"; and

(2) by adding after subsection (lll) the following new subsection:

"Respiratory Therapist

"(mmm) For purposes of subsection (s)(2)(II) and section 1833(a)(1)(X) only, the term 'respiratory therapist' means an individual who—

"(1) is credentialed by a national credentialing board recognized by the Secretary;

"(2)(A) is licensed to practice respiratory therapy in the State in which the respiratory therapy services are performed, or

"(B) in the case of an individual in a State which does not provide for such licensure, is legally authorized to perform respiratory therapy services (in the State in which the individual performed such services) under State law (or the State regulatory mechanism provided by State law);

"(3) is a registered respiratory therapist; and

"(4) holds a bachelor's degree.".

(b) PAYMENT.—Section 1833(a)(1) of such Act (42 U.S.C. 1395l(a)(1)), as amended by sections 1309(a)(4) and 1309(b)(4), is amended—

(1) by striking "and" before "(Y)"; and

(2) by inserting before the semicolon at the end the following: ", and (Z) with respect to services described in section 1861(s)(2)(II) (relating to services furnished by a respiratory therapist) that are furnished by a respiratory therapist (as defined in section 1861(mmm)), the amount paid shall be equal to 80 percent of the lesser of the actual charge for the services or 85 percent of the fee schedule amount provided under section 1848 for the same services if furnished by a physician".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after January 1, 2010.

Subtitle C—Provisions Related to Medicare Parts A and B

SEC. 1151. REDUCING POTENTIALLY PREVENTABLE HOSPITAL READMISSIONS.

(a) HOSPITALS.—

(1) IN GENERAL.—Section 1886 of the Social Security Act (42 U.S.C. 1395ww), as amended by section 1103(a), is amended by adding at the end the following new subsection:

"(p) ADJUSTMENT TO HOSPITAL PAYMENTS FOR EXCESS READMISSIONS.—

"(1) IN GENERAL.—With respect to payment for discharges from an applicable hospital (as defined in paragraph (5)(C)) occurring during a fiscal year beginning on or after October 1, 2011, in order to account for excess readmissions in the hospital, the Secretary shall reduce the payments that would otherwise be made to such hospital under subsection (d) (or section 1814(b)(3), as the case may be) for such a discharge by an amount equal to the product of—

"(A) the base operating DRG payment amount (as defined in paragraph (2)) for the discharge; and

"(B) the adjustment factor (described in paragraph (3)(A)) for the hospital for the fiscal year.

"(2) BASE OPERATING DRG PAYMENT AMOUNT.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), for purposes of this subsection, the term 'base operating DRG payment amount' means, with respect to a hospital for a fiscal year, the payment amount that would otherwise be made under subsection (d) for a discharge if this subsection did not apply, reduced by any portion of such amount that is attributable to payments under subparagraphs (B) and (F) of paragraph (5).

"(B) ADJUSTMENTS.—For purposes of subparagraph (A), in the case of a hospital that is paid under section 1814(b)(3), the term 'base operating DRG payment amount' means the payment amount under such section.

"(3) ADJUSTMENT FACTOR.—

"(A) IN GENERAL.—For purposes of paragraph (1), the adjustment factor under this paragraph for an applicable hospital for a fiscal year is equal to the greater of—

"(i) the ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or

"(ii) the floor adjustment factor specified in subparagraph (C).

"(B) RATIO.—The ratio described in this subparagraph for a hospital for an applicable period is equal to 1 minus the ratio of—

"(i) the aggregate payments for excess readmissions (as defined in paragraph (4)(A)) with respect to an applicable hospital for the applicable period; and

"(ii) the aggregate payments for all discharges (as defined in paragraph (4)(B)) with respect to such applicable hospital for such applicable period.

"(C) FLOOR ADJUSTMENT FACTOR.—For purposes of subparagraph (A), the floor adjustment factor specified in this subparagraph for—

"(i) fiscal year 2012 is 0.99;

"(ii) fiscal year 2013 is 0.98;

"(iii) fiscal year 2014 is 0.97; or

"(iv) a subsequent fiscal year is 0.95.

"(4) AGGREGATE PAYMENTS, EXCESS READMISSION RATIO DEFINED.—For purposes of this subsection:

"(A) AGGREGATE PAYMENTS FOR EXCESS READMISSIONS.—The term 'aggregate payments for excess readmissions' means, for a hospital for a fiscal year, the sum, for applicable conditions (as defined in paragraph (5)(A)), of the product, for each applicable condition, of—

"(i) the base operating DRG payment amount for such hospital for such fiscal year for such condition;

"(ii) the number of admissions for such condition for such hospital for such fiscal year; and

"(iii) the excess readmissions ratio (as defined in subparagraph (C)) for such hospital for the applicable period for such fiscal year minus 1.

"(B) AGGREGATE PAYMENTS FOR ALL DISCHARGES.—The term 'aggregate payments for all discharges' means, for a hospital for a fiscal year, the sum of the base operating DRG payment amounts for all discharges for all conditions from such hospital for such fiscal year.

"(C) EXCESS READMISSION RATIO.—

"(i) IN GENERAL.—Subject to clauses (ii) and (iii), the term 'excess readmissions ratio' means, with respect to an applicable condition for a hospital for an applicable period, the ratio (but not less than 1.0) of—

"(I) the risk adjusted readmissions based on actual readmissions, as determined consistent with a readmission measure methodology that has been endorsed under paragraph (5)(A)(ii)(I), for an applicable hospital for such condition with respect to the applicable period; to

"(II) the risk adjusted expected readmissions (as determined consistent with such a methodology) for such hospital for such condition with respect to such applicable period.

"(ii) EXCLUSION OF CERTAIN READMISSIONS.—For purposes of clause (i), with respect to a hospital, excess readmissions shall not include readmissions for an applicable condition for which there are fewer than a minimum number (as determined by the Secretary) of discharges for such applicable condition for the applicable period and such hospital.

"(iii) ADJUSTMENT.—In order to promote a reduction over time in the overall rate of readmissions for applicable conditions, the Secretary may provide, beginning with discharges for fiscal year 2014, for the determination of the excess readmissions ratio under subparagraph (C) to be based on a ranking of hospitals by readmission ratios (from lower to higher readmission ratios) normalized to a benchmark that is lower than the 50th percentile.

"(5) DEFINITIONS.—For purposes of this subsection:

"(A) APPLICABLE CONDITION.—The term 'applicable condition' means, subject to subparagraph (B), a condition or procedure selected by the Secretary among conditions and procedures for which—

"(i) readmissions (as defined in subparagraph (E)) that represent conditions or procedures that are high volume or high expenditures under this title (or other criteria specified by the Secretary); and

"(ii) measures of such readmissions—

"(I) have been endorsed by the entity with a contract under section 1890(a); and

"(II) such endorsed measures have appropriate exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital).

"(B) EXPANSION OF APPLICABLE CONDITIONS.—Beginning with fiscal year 2013, the Secretary shall expand the applicable conditions beyond the 3 conditions for which measures have been endorsed as described in subparagraph (A)(ii)(I) as of the date of the enactment of this subsection to the additional 4 conditions that have been so identified by the Medicare Payment Advisory Commission in its report to Congress in June 2007 and to other conditions and procedures which may include an all-condition measure of readmissions, as determined appropriate by the Secretary. In expanding such applicable conditions, the Secretary shall seek the endorsement described in subparagraph (A)(ii)(I) but may apply such measures without such an endorsement.

"(C) APPLICABLE HOSPITAL.—The term 'applicable hospital' means a subsection (d) hospital or a hospital that is paid under section 1814(b)(3).

"(D) APPLICABLE PERIOD.—The term 'applicable period' means, with respect to a fiscal year, such period as the Secretary shall specify for purposes of determining excess readmissions.

"(E) READMISSION.—The term 'readmission' means, in the case of an individual who is discharged from an applicable hospital, the admission of the individual to the same or another applicable hospital within a time period specified by the Secretary from the date of such discharge. Insofar as the discharge relates to an applicable condition for which there is an endorsed measure described in subparagraph (A)(ii)(I), such time period (such as 30 days) shall be consistent with the time period specified for such measure.

"(6) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of—

"(A) the determination of base operating DRG payment amounts;

"(B) the methodology for determining the adjustment factor under paragraph (3), including excess readmissions ratio under paragraph (4)(C), ag-

gregate payments for excess readmissions under paragraph (4)(A), and aggregate payments for all discharges under paragraph (4)(B), and applicable periods and applicable conditions under paragraph (5);

"(C) the measures of readmissions as described in paragraph (5)(A)(ii); and

"(D) the determination of a targeted hospital under paragraph (8)(B)(i), the increase in payment under paragraph (8)(B)(ii), the aggregate cap under paragraph (8)(C)(i), the hospital-specific limit under paragraph (8)(C)(ii), and the form of payment made by the Secretary under paragraph (8)(D).

"(7) MONITORING INAPPROPRIATE CHANGES IN ADMISSIONS PRACTICES.—The Secretary shall monitor the activities of applicable hospitals to determine if such hospitals have taken steps to avoid patients at risk in order to reduce the likelihood of increasing readmissions for applicable conditions. If the Secretary determines that such a hospital has taken such a step, after notice to the hospital and opportunity for the hospital to undertake action to alleviate such steps, the Secretary may impose an appropriate sanction.

"(8) ASSISTANCE TO CERTAIN HOSPITALS.—

"(A) IN GENERAL.—For purposes of providing funds to applicable hospitals to take steps described in subparagraph (E) to address factors that may impact readmissions of individuals who are discharged from such a hospital, for fiscal years beginning on or after October 1, 2011, the Secretary shall make a payment adjustment for a hospital described in subparagraph (B), with respect to each such fiscal year, by a percent estimated by the Secretary to be consistent with subparagraph (C).

"(B) TARGETED HOSPITALS.—Subparagraph (A) shall apply to an applicable hospital that—

"(i) received (or, in the case of an 1814(b)(3) hospital, otherwise would have been eligible to receive) $10,000,000 or more in disproportionate share payments using the latest available data as estimated by the Secretary; and

"(ii) provides assurances satisfactory to the Secretary that the increase in payment under this paragraph shall be used for purposes described in subparagraph (E).

"(C) CAPS.—

"(i) AGGREGATE CAP.—The aggregate amount of the payment adjustment under this paragraph for a fiscal year shall not exceed 5 percent of the estimated difference in the spending that would occur for such fiscal year with and without application of the adjustment factor described in paragraph (3) and applied pursuant to paragraph (1).

"(ii) HOSPITAL-SPECIFIC LIMIT.—The aggregate amount of the payment adjustment for a hospital under this paragraph shall not exceed the estimated difference in spending that would occur for such fiscal year for such hospital with and without application of the adjustment factor described in paragraph (3) and applied pursuant to paragraph (1).

"(D) FORM OF PAYMENT.—The Secretary may make the additional payments under this paragraph on a lump sum basis, a periodic basis, a claim by claim basis, or otherwise.

"(E) USE OF ADDITIONAL PAYMENT.—Funding under this paragraph shall be used by targeted hospitals for transitional care activities designed to address the patient noncompliance issues that result in higher than normal readmission rates, such as one or more of the following:

"(i) Providing care coordination services to assist in transitions from the targeted hospital to other settings.

"(ii) Hiring translators and interpreters.

"(iii) Increasing services offered by discharge planners.

"(iv) Ensuring that individuals receive a summary of care and medication orders upon discharge.

"(v) Developing a quality improvement plan to assess and remedy preventable readmission rates.

"(vi) Assigning discharged individuals to a medical home.

"(vii) Doing other activities as determined appropriate by the Secretary.

"(F) GAO REPORT ON USE OF FUNDS.—Not later than 3 years after the date on which funds are first made available under this paragraph, the Comptroller General of the United States shall submit to Congress a report on the use of such funds.

"(G) DISPROPORTIONATE SHARE HOSPITAL PAYMENT.—In this paragraph, the term 'disproportionate share hospital payment' means an additional payment amount under subsection (d)(5)(F).".

(b) APPLICATION TO CRITICAL ACCESS HOSPITALS.—Section 1814(l) of the Social Security Act (42 U.S.C. 1395f(l)) is amended—

(1) in paragraph (5)—

(A) by striking "and" at the end of subparagraph (C);

(B) by striking the period at the end of subparagraph (D) and inserting "; and";

(C) by inserting at the end the following new subparagraph:

"(E) the methodology for determining the adjustment factor under paragraph (5), including the determination of aggregate payments for actual and expected readmissions, applicable periods, applicable conditions and measures of readmissions."; and

(D) by redesignating such paragraph as paragraph (6); and

(2) by inserting after paragraph (4) the following new paragraph:

"(5) The adjustment factor described in section 1886(p)(3) shall apply to payments with respect to a critical access hospital with respect to a cost reporting period beginning in fiscal year 2012 and each subsequent fiscal year (after application of paragraph (4) of this subsection) in a manner similar to the manner in which such section applies with respect to a fiscal year to an applicable hospital as described in section 1886(p)(2).".

(c) POST ACUTE CARE PROVIDERS.—

(1) INTERIM POLICY.—

(A) IN GENERAL.—With respect to a readmission to an applicable hospital or a critical access hospital (as described in section 1814(l) of the Social Security Act) from a post acute care provider (as defined in paragraph (3)) and such a readmission is not governed by section 412.531 of title 42, Code of Federal Regulations, if the claim submitted by such a post-acute care provider under title XVIII of the Social Security Act indicates that the individual was readmitted to a hospital from such a post-acute care provider or admitted from home and under the care of a home health agency within 30 days of an initial discharge from an applicable hospital or critical access hospital, the payment under such title on such claim shall be the applicable percent specified in subparagraph (B) of the payment that would otherwise be made under the respective payment system under such title for such post-acute care provider if this subsection did not apply.

(B) APPLICABLE PERCENT DEFINED.—For purposes of subparagraph (A), the applicable percent is—

(i) for fiscal or rate year 2012 is 0.996;

(ii) for fiscal or rate year 2013 is 0.993; and

(iii) for fiscal or rate year 2014 is 0.99.

(C) EFFECTIVE DATE.—Subparagraph (1) shall apply to discharges or services furnished (as the case may be with respect to the applicable post acute care provider) on or after the first day of the fiscal year or rate year, beginning on or after October 1, 2011, with respect to the applicable post acute care provider.

(2) DEVELOPMENT AND APPLICATION OF PERFORMANCE MEASURES.—

(A) IN GENERAL.—The Secretary of Health and Human Services shall develop appropriate measures of readmission rates for post acute care providers. The Secretary shall seek endorsement of such measures by the entity with a contract under section 1890(a) of the Social Security Act but may adopt and apply such measures under this paragraph without such an endorsement. The Secretary shall expand such measures in a manner similar to the manner in which applicable conditions are expanded under paragraph (5)(B) of section 1886(p) of the Social Security Act, as added by subsection (a).

(B) IMPLEMENTATION.—The Secretary shall apply, on or after October 1, 2014, with respect to post acute care providers, policies similar to the policies applied with respect to applicable hospitals and critical access hospitals under the amendments made by subsection (a). The provisions of paragraph (1) shall apply with respect to any period on or after October 1, 2014, and before such application date described in the previous sentence in the same manner as such provisions apply with respect to fiscal or rate year 2014.

(C) MONITORING AND PENALTIES.—The provisions of paragraph (7) of such section 1886(p) shall apply to providers under this paragraph in the same manner as they apply to hospitals under such section.

(3) DEFINITIONS.—For purposes of this subsection:

(A) POST ACUTE CARE PROVIDER.—The term "post acute care provider" means—

(i) a skilled nursing facility (as defined in section 1819(a) of the Social Security Act);

(ii) an inpatient rehabilitation facility (described in section 1886(h)(1)(A) of such Act);

(iii) a home health agency (as defined in section 1861(o) of such Act); and

(iv) a long term care hospital (as defined in section 1861(ccc) of such Act).

(B) OTHER TERMS .—The terms "applicable condition", "applicable hospital", and "readmission" have the meanings given such terms in section 1886(p)(5) of the Social Security Act, as added by subsection (a)(1).

(d) PHYSICIANS.—

(1) STUDY.—The Secretary of Health and Human Services shall conduct a study to determine how the readmissions policy described in the previous subsections could be applied to physicians.

(2) CONSIDERATIONS.—In conducting the study, the Secretary shall consider approaches such as—

(A) creating a new code (or codes) and payment amount (or amounts) under the fee schedule in section 1848 of the Social Security Act (in a budget neutral manner) for services furnished by an appropriate physician who sees an individual within the first week after discharge from a hospital or critical access hospital;

(B) developing measures of rates of readmission for individuals treated by physicians;

(C) applying a payment reduction for physicians who treat the patient during the initial admission that results in a readmission; and

(D) methods for attributing payments or payment reductions to the appropriate physician or physicians.

(3) REPORT.—The Secretary shall issue a public report on such study not later than the date that is one year after the date of the enactment of this Act.

(e) FUNDING.—For purposes of carrying out the provisions of this section, in addition to funds otherwise available, out of any funds in the Treasury not otherwise appropriated, there are appropriated to the Secretary of Health and Human Services for the Center for Medicare & Medicaid Services Program Management Account $25,000,000 for each fiscal year beginning with 2010. Amounts appropriated under this subsection for a fiscal year shall be available until expended.

SEC. 1152. POST ACUTE CARE SERVICES PAYMENT REFORM PLAN AND BUNDLING PILOT PROGRAM.

(a) PLAN.—

(1) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the "Secretary") shall develop a detailed plan to reform payment for post acute care (PAC) services under the Medicare program under title XVIII of the Social Security Act (in this section referred to as the "Medicare program)". The goals of such payment reform are to—

(A) improve the coordination, quality, and efficiency of such services; and

(B) improve outcomes for individuals such as reducing the need for readmission to hospitals from providers of such services.

(2) BUNDLING POST ACUTE SERVICES.—The plan described in paragraph (1) shall include detailed specifications for a bundled payment for post acute services (in this section referred to as the "post acute care bundle"), and may include other approaches determined appropriate by the Secretary.

(3) POST ACUTE SERVICES.—For purposes of this section, the term "post acute services" means services for which payment may be made under the Medicare program that are furnished by skilled nursing facilities, inpatient rehabilitation facilities, long term care hospitals, hospital based outpatient rehabilitation facilities and home health agencies to an individual after discharge of such individual from a hospital, and such other services determined appropriate by the Secretary.

(b) DETAILS.—The plan described in subsection (a)(1) shall include consideration of the following issues:

(1) The nature of payments under a post acute care bundle, including the type of provider or entity to whom payment should be made, the scope of activities and services included in the bundle, whether payment for physicians' services should be included in the bundle, and the period covered by the bundle.

(2) Whether the payment should be consolidated with the payment under the inpatient prospective system under section 1886 of the Social Security Act (in this section referred to as MS-DRGs) or a separate payment should be estab-

lished for such bundle, and if a separate payment is established, whether it should be made only upon use of post acute care services or for every discharge.

(3) Whether the bundle should be applied across all categories of providers of inpatient services (including critical access hospitals) and post acute care services or whether it should be limited to certain categories of providers, services, or discharges, such as high volume or high cost MS-DRGs.

(4) The extent to which payment rates could be established to achieve offsets for efficiencies that could be expected to be achieved with a bundle payment, whether such rates should be established on a national basis or for different geographic areas, should vary according to discharge, case mix, outliers, and geographic differences in wages or other appropriate adjustments, and how to update such rates.

(5) The nature of protections needed for individuals under a system of bundled payments to ensure that individuals receive quality care, are furnished the level and amount of services needed as determined by an appropriate assessment instrument, are offered choice of provider, and the extent to which transitional care services would improve quality of care for individuals and the functioning of a bundled post-acute system.

(6) The nature of relationships that may be required between hospitals and providers of post acute care services to facilitate bundled payments, including the application of gainsharing, anti-referral, anti-kickback, and anti-trust laws.

(7) Quality measures that would be appropriate for reporting by hospitals and post acute providers (such as measures that assess changes in functional status and quality measures appropriate for each type of post acute services provider including how the reporting of such quality measures could be coordinated with other reporting of such quality measures by such providers otherwise required).

(8) How cost-sharing for a post acute care bundle should be treated relative to current rules for cost-sharing for inpatient hospital, home health, skilled nursing facility, and other services.

(9) How other programmatic issues should be treated in a post acute care bundle, including rules specific to various types of post-acute providers such as the post-acute transfer policy, three-day hospital stay to qualify for services furnished by skilled nursing facilities, and the coordination of payments and care under the Medicare program and the Medicaid program.

(10) Such other issues as the Secretary deems appropriate.

(c) CONSULTATIONS AND ANALYSIS.—

(1) CONSULTATION WITH STAKEHOLDERS.—In developing the plan under subsection (a)(1), the Secretary shall consult with relevant stakeholders and shall consider experience with such research studies and demonstrations that the Secretary determines appropriate.

(2) ANALYSIS AND DATA COLLECTION.—In developing such plan, the Secretary shall—

(A) analyze the issues described in subsection (b) and other issues that the Secretary determines appropriate;

(B) analyze the impacts (including geographic impacts) of post acute service reform approaches, including bundling of such services on individuals, hospitals, post acute care providers, and physicians;

(C) use existing data (such as data submitted on claims) and collect such data as the Secretary determines are appropriate to develop such plan required in this section; and

(D) if patient functional status measures are appropriate for the analysis, to the extent practical, build upon the CARE tool being developed pursuant to section 5008 of the Deficit Reduction Act of 2005.

(d) ADMINISTRATION.—

(1) FUNDING.—For purposes of carrying out the provisions of this section, in addition to funds otherwise available, out of any funds in the Treasury not otherwise appropriated, there are appropriated to the Secretary for the Center for Medicare & Medicaid Services Program Management Account $15,000,000 for each of the fiscal years 2010 through 2012. Amounts appropriated under this paragraph for a fiscal year shall be available until expended.

(2) EXPEDITED DATA COLLECTION.—Chapter 35 of title 44, United States Code shall not apply to this section.

(e) PUBLIC REPORTS.—

(1) INTERIM REPORTS.—The Secretary shall issue interim public reports on a periodic basis on the plan described in subsection (a)(1), the issues described in subsection (b), and impact analyses as the Secretary determines appropriate.

(2) FINAL REPORT.—Not later than the date that is 3 years after the date of the enactment of this Act, the Secretary shall issue a final public report on such

plan, including analysis of issues described in subsection (b) and impact analyses.

(f) CONVERSION OF ACUTE CARE EPISODE DEMONSTRATION TO PILOT PROGRAM AND EXPANSION TO INCLUDE POST ACUTE SERVICES.—

(1) IN GENERAL.—Part E of title XVIII of the Social Security Act is amended by inserting after section 1866C the following new section:

"CONVERSION OF ACUTE CARE EPISODE DEMONSTRATION TO PILOT PROGRAM AND EXPANSION TO INCLUDE POST ACUTE SERVICES

"SEC. 1866D. (a) IN GENERAL.—By not later than January 1, 2011, the Secretary shall, for the purpose of promoting the use of bundled payments to promote efficient and high quality delivery of care—

"(1) convert the acute care episode demonstration program conducted under section 1866C to a pilot program; and

"(2) subject to subsection (c), expand such program as so converted to include post acute services and such other services the Secretary determines to be appropriate, which may include transitional services.

"(b) SCOPE.—The Secretary shall set specific goals for the number of acute and post-acute bundling test sites under the pilot program to ensure that the pilot program is of sufficient size and scope to—

"(1) test the approaches under the pilot program in a variety of settings, including urban, rural, and underserved areas;

"(2) include geographic areas and additional conditions that account for significant program spending, as defined by the Secretary; and

"(3) subject to subsection (d), disseminate the pilot program rapidly on a national basis.

To the extent that the Secretary finds inpatient and post-acute care bundling to be successful in improving quality and reducing costs, the Secretary shall implement such mechanisms and reforms under the pilot program on as large a geographic scale as practical and economical, consistent with subsection (e).

"(c) LIMITATION.—The Secretary shall only expand the pilot program under subsection (a)(2) if the Secretary finds that—

"(1) the demonstration program under section 1866C and pilot program under this section maintain or increase the quality of care received by individuals enrolled under this title; and

"(2) such demonstration program and pilot program reduce program expenditures and, based on the certification under subsection (d), that the expansion of such pilot program would result in estimated spending that would be less than what spending would otherwise be in the absence of this section.

"(d) CERTIFICATION.—For purposes of subsection (c), the Chief Actuary of the Centers for Medicare & Medicaid Services shall certify whether expansion of the pilot program under this section would result in estimated spending that would be less than what spending would otherwise be in the absence of this section.

"(e) VOLUNTARY PARTICIPATION.—Nothing in this paragraph shall be construed as requiring the participation of an entity in the pilot program under this section.".

(2) CONFORMING AMENDMENT.—Section 1866C(b) of the Social Security Act (42 U.S.C. 1395cc–3(b)) is amended by striking "The Secretary" and inserting "Subject to section 1866D, the Secretary".

SEC. 1153. HOME HEALTH PAYMENT UPDATE FOR 2010.

Section 1895(b)(3)(B)(ii) of the Social Security Act (42 U.S.C. 1395fff(b)(3)(B)(ii)) is amended—

(1) in subclause (IV), by striking "and";

(2) by redesignating subclause (V) as subclause (VII); and

(3) by inserting after subclause (IV) the following new subclauses:

"(V) 2007, 2008, and 2009, subject to clause (v), the home health market basket percentage increase;

"(VI) 2010, subject to clause (v), 0 percent; and".

SEC. 1154. PAYMENT ADJUSTMENTS FOR HOME HEALTH CARE.

(a) ACCELERATION OF ADJUSTMENT FOR CASE MIX CHANGES.—Section 1895(b)(3)(B) of the Social Security Act (42 U.S.C. 1395fff(b)(3)(B)) is amended—

(1) in clause (iv), by striking "Insofar as" and inserting "Subject to clause (vi), insofar as"; and

(2) by adding at the end the following new clause:

"(vi) SPECIAL RULE FOR CASE MIX CHANGES FOR 2011.—

"(I) IN GENERAL.—With respect to the case mix adjustments established in section 484.220(a) of title 42, Code of Federal Regulations, the Secretary shall apply, in 2010, the adjustment estab-

lished in paragraph (3) of such section for 2011, in addition to applying the adjustment established in paragraph (2) for 2010.

"(II) CONSTRUCTION.—Nothing in this clause shall be construed as limiting the amount of adjustment for case mix for 2010 or 2011 if more recent data indicate an appropriate adjustment that is greater than the amount established in the section described in subclause (I).".

(b) REBASING HOME HEALTH PROSPECTIVE PAYMENT AMOUNT.—Section 1895(b)(3)(A) of the Social Security Act (42 U.S.C. 1395fff(b)(3)(A)) is amended—

(1) in clause (i)—

(A) in subclause (III), by inserting "and before 2011" after "after the period described in subclause (II)"; and

(B) by inserting after subclause (III) the following new subclauses:

"(IV) Subject to clause (iii)(I), for 2011, such amount (or amounts) shall be adjusted by a uniform percentage determined to be appropriate by the Secretary based on analysis of factors such as changes in the average number and types of visits in an episode, the change in intensity of visits in an episode, growth in cost per episode, and other factors that the Secretary considers to be relevant.

"(V) Subject to clause (iii)(II), for a year after 2011, such a amount (or amounts) shall be equal to the amount (or amounts) determined under this clause for the previous year, updated under subparagraph (B).."; and

(2) by adding at the end the following new clause:

"(iii) SPECIAL RULE IN CASE OF INABILITY TO EFFECT TIMELY REBASING.—

"(I) APPLICATION OF PROXY AMOUNT FOR 2011.—If the Secretary is not able to compute the amount (or amounts) under clause (i)(IV) so as to permit, on a timely basis, the application of such clause for 2011, the Secretary shall substitute for such amount (or amounts) 95 percent of the amount (or amounts) that would otherwise be specified under clause (i)(III) if it applied for 2011.

"(II) ADJUSTMENT FOR SUBSEQUENT YEARS BASED ON DATA.—If the Secretary applies subclause (I), the Secretary before July 1, 2011, shall compare the amount (or amounts) applied under such subclause with the amount (or amounts) that should have been applied under clause (i)(IV). The Secretary shall decrease or increase the prospective payment amount (or amounts) under clause (i)(V) for 2012 (or, at the Secretary's discretion, over a period of several years beginning with 2012) by the amount (if any) by which the amount (or amounts) applied under subclause (I) is greater or less, respectively, than the amount (or amounts) that should have been applied under clause (i)(IV).".

SEC. 1155. INCORPORATING PRODUCTIVITY IMPROVEMENTS INTO MARKET BASKET UPDATE FOR HOME HEALTH SERVICES.

(a) IN GENERAL.—Section 1895(b)(3)(B) of the Social Security Act (42 U.S.C. 1395fff(b)(3)(B)) is amended—

(1) in clause (iii), by inserting "(including being subject to the productivity adjustment described in section 1886(b)(3)(B)(iii)(II))" after "in the same manner"; and

(2) in clause (v)(I), by inserting "(but not below 0)" after "reduced".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to home health market basket percentage increases for years beginning with 2010.

SEC. 1156. LIMITATION ON MEDICARE EXCEPTIONS TO THE PROHIBITION ON CERTAIN PHYSICIAN REFERRALS MADE TO HOSPITALS.

(a) IN GENERAL.—Section 1877 of the Social Security Act (42 U.S.C. 1395nn) is amended—

(1) in subsection (d)(2)—

(A) in subparagraph (A), by striking "and" at the end;

(B) in subparagraph (B), by striking the period at the end and inserting "; and"; and

(C) by adding at the end the following new subparagraph:

"(C) in the case where the entity is a hospital, the hospital meets the requirements of paragraph (3)(D).";

(2) in subsection (d)(3)—

(A) in subparagraph (B), by striking "and" at the end;

(B) in subparagraph (C), by striking the period at the end and inserting "; and"; and

(C) by adding at the end the following new subparagraph:

"(D) the hospital meets the requirements described in subsection (i)(1).";

(3) by amending subsection (f) to read as follows:

"(f) REPORTING AND DISCLOSURE REQUIREMENTS.—

"(1) IN GENERAL.—Each entity providing covered items or services for which payment may be made under this title shall provide the Secretary with the information concerning the entity's ownership, investment, and compensation arrangements, including—

"(A) the covered items and services provided by the entity, and

"(B) the names and unique physician identification numbers of all physicians with an ownership or investment interest (as described in subsection (a)(2)(A)), or with a compensation arrangement (as described in subsection (a)(2)(B)), in the entity, or whose immediate relatives have such an ownership or investment interest or who have such a compensation relationship with the entity.

Such information shall be provided in such form, manner, and at such times as the Secretary shall specify. The requirement of this subsection shall not apply to designated health services provided outside the United States or to entities which the Secretary determines provide services for which payment may be made under this title very infrequently.

"(2) REQUIREMENTS FOR HOSPITALS WITH PHYSICIAN OWNERSHIP OR INVESTMENT.—In the case of a hospital that meets the requirements described in subsection (i)(1), the hospital shall—

"(A) submit to the Secretary an initial report, and periodic updates at a frequency determined by the Secretary, containing a detailed description of the identity of each physician owner and physician investor and any other owners or investors of the hospital;

"(B) require that any referring physician owner or investor discloses to the individual being referred, by a time that permits the individual to make a meaningful decision regarding the receipt of services, as determined by the Secretary, the ownership or investment interest, as applicable, of such referring physician in the hospital; and

"(C) disclose the fact that the hospital is partially or wholly owned by one or more physicians or has one or more physician investors—

"(i) on any public website for the hospital; and

"(ii) in any public advertising for the hospital.

The information to be reported or disclosed under this paragraph shall be provided in such form, manner, and at such times as the Secretary shall specify. The requirements of this paragraph shall not apply to designated health services furnished outside the United States or to entities which the Secretary determines provide services for which payment may be made under this title very infrequently.

"(3) PUBLICATION OF INFORMATION.—The Secretary shall publish, and periodically update, the information submitted by hospitals under paragraph (2)(A) on the public Internet website of the Centers for Medicare & Medicaid Services.";

(4) by amending subsection (g)(5) to read as follows:

"(5) FAILURE TO REPORT OR DISCLOSE INFORMATION.—

"(A) REPORTING.—Any person who is required, but fails, to meet a reporting requirement of paragraphs (1) and (2)(A) of subsection (f) is subject to a civil money penalty of not more than $10,000 for each day for which reporting is required to have been made.

"(B) DISCLOSURE.—Any physician who is required, but fails, to meet a disclosure requirement of subsection (f)(2)(B) or a hospital that is required, but fails, to meet a disclosure requirement of subsection (f)(2)(C) is subject to a civil money penalty of not more than $10,000 for each case in which disclosure is required to have been made.

"(C) APPLICATION.—The provisions of section 1128A (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under subparagraphs (A) and (B) in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).''; and

(5) by adding at the end the following new subsection:

"(i) REQUIREMENTS TO QUALIFY FOR RURAL PROVIDER AND HOSPITAL OWNERSHIP EXCEPTIONS TO SELF-REFERRAL PROHIBITION.—

"(1) REQUIREMENTS DESCRIBED.—For purposes of subsection (d)(3)(D), the requirements described in this paragraph are as follows:

"(A) PROVIDER AGREEMENT.—The hospital had—

"(i) physician ownership or investment on January 1, 2009; and

"(ii) a provider agreement under section 1866 in effect on such date.

"(B) PROHIBITION ON PHYSICIAN OWNERSHIP OR INVESTMENT.—The percentage of the total value of the ownership or investment interests held in the hospital, or in an entity whose assets include the hospital, by physician owners or investors in the aggregate does not exceed such percentage as of the date of enactment of this subsection.

"(C) PROHIBITION ON EXPANSION OF FACILITY CAPACITY.—Except as provided in paragraph (2), the number of operating rooms, procedure rooms, or beds of the hospital at any time on or after the date of the enactment of this subsection are no greater than the number of operating rooms, procedure rooms, or beds, respectively, as of such date.

"(D) ENSURING BONA FIDE OWNERSHIP AND INVESTMENT.—

"(i) Any ownership or investment interests that the hospital offers to a physician are not offered on more favorable terms than the terms offered to a person who is not in a position to refer patients or otherwise generate business for the hospital.

"(ii) The hospital (or any investors in the hospital) does not directly or indirectly provide loans or financing for any physician owner or investor in the hospital.

"(iii) The hospital (or any investors in the hospital) does not directly or indirectly guarantee a loan, make a payment toward a loan, or otherwise subsidize a loan, for any physician owner or investor or group of physician owners or investors that is related to acquiring any ownership or investment interest in the hospital.

"(iv) Ownership or investment returns are distributed to each owner or investor in the hospital in an amount that is directly proportional to the ownership or investment interest of such owner or investor in the hospital.

"(v) The investment interest of the owner or investor is directly proportional to the owner's or investor's capital contributions made at the time the ownership or investment interest is obtained.

"(vi) Physician owners and investors do not receive, directly or indirectly, any guaranteed receipt of or right to purchase other business interests related to the hospital, including the purchase or lease of any property under the control of other owners or investors in the hospital or located near the premises of the hospital.

"(vii) The hospital does not offer a physician owner or investor the opportunity to purchase or lease any property under the control of the hospital or any other owner or investor in the hospital on more favorable terms than the terms offered to a person that is not a physician owner or investor.

"(viii) The hospital does not condition any physician ownership or investment interests either directly or indirectly on the physician owner or investor making or influencing referrals to the hospital or otherwise generating business for the hospital.

"(E) PATIENT SAFETY.—In the case of a hospital that does not offer emergency services, the hospital has the capacity to—

"(i) provide assessment and initial treatment for medical emergencies; and

"(ii) if the hospital lacks additional capabilities required to treat the emergency involved, refer and transfer the patient with the medical emergency to a hospital with the required capability.

"(F) LIMITATION ON APPLICATION TO CERTAIN CONVERTED FACILITIES.—The hospital was not converted from an ambulatory surgical center to a hospital on or after the date of enactment of this subsection.

"(2) EXCEPTION TO PROHIBITION ON EXPANSION OF FACILITY CAPACITY.—

"(A) PROCESS.—

"(i) ESTABLISHMENT.—The Secretary shall establish and implement a process under which a hospital may apply for an exception from the requirement under paragraph (1)(C).

"(ii) OPPORTUNITY FOR COMMUNITY INPUT.—The process under clause (i) shall provide persons and entities in the community in which the hospital applying for an exception is located with the opportunity to provide input with respect to the application.

"(iii) TIMING FOR IMPLEMENTATION.—The Secretary shall implement the process under clause (i) on the date that is one month after the promulgation of regulations described in clause (iv).

"(iv) REGULATIONS.—Not later than the first day of the month beginning 18 months after the date of the enactment of this subsection, the Secretary shall promulgate regulations to carry out the process under clause (i). The Secretary may issue such regulations as interim final regulations.

"(B) FREQUENCY.—The process described in subparagraph (A) shall permit a hospital to apply for an exception up to once every 2 years.

"(C) PERMITTED INCREASE.—

"(i) IN GENERAL.—Subject to clause (ii) and subparagraph (D), a hospital granted an exception under the process described in subparagraph (A) may increase the number of operating rooms, procedure rooms, or beds of the hospital above the baseline number of operating rooms, procedure rooms, or beds, respectively, of the hospital (or, if the hospital has been granted a previous exception under this paragraph, above the number of operating rooms, procedure rooms, or beds, respectively, of the hospital after the application of the most recent increase under such an exception).

"(ii) 100 PERCENT INCREASE LIMITATION.—The Secretary shall not permit an increase in the number of operating rooms, procedure rooms, or beds of a hospital under clause (i) to the extent such increase would result in the number of operating rooms, procedure rooms, or beds of the hospital exceeding 200 percent of the baseline number of operating rooms, procedure rooms, or beds of the hospital.

"(iii) BASELINE NUMBER OF OPERATING ROOMS, PROCEDURE ROOMS, OR BEDS.—In this paragraph, the term 'baseline number of operating rooms, procedure rooms, or beds' means the number of operating rooms, procedure rooms, or beds of a hospital as of the date of enactment of this subsection.

"(D) INCREASE LIMITED TO FACILITIES ON THE MAIN CAMPUS OF THE HOSPITAL.—Any increase in the number of operating rooms, procedure rooms, or beds of a hospital pursuant to this paragraph may only occur in facilities on the main campus of the hospital.

"(E) CONDITIONS FOR APPROVAL OF AN INCREASE IN FACILITY CAPACITY.—The Secretary may grant an exception under the process described in subparagraph (A) only to a hospital—

"(i) that is located in a county in which the percentage increase in the population during the most recent 5-year period for which data are available is estimated to be at least 150 percent of the percentage increase in the population growth of the State in which the hospital is located during that period, as estimated by Bureau of the Census and available to the Secretary;

"(ii) whose annual percent of total inpatient admissions that represent inpatient admissions under the program under title XIX is estimated to be equal to or greater than the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located;

"(iii) that does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries;

"(iv) that is located in a State in which the average bed capacity in the State is estimated to be less than the national average bed capacity;

"(v) that has an average bed occupancy rate that is estimated to be greater than the average bed occupancy rate in the State in which the hospital is located; and

"(vi) that meets other conditions as determined by the Secretary.

"(F) PROCEDURE ROOMS.—In this subsection, the term 'procedure rooms' includes rooms in which catheterizations, angiographies, angiograms, and endoscopies are furnished, but such term shall not include emergency rooms or departments (except for rooms in which catheterizations, angiographies, angiograms, and endoscopies are furnished).

"(G) PUBLICATION OF FINAL DECISIONS.—Not later than 120 days after receiving a complete application under this paragraph, the Secretary shall publish on the public Internet website of the Centers for Medicare & Medicaid Services the final decision with respect to such application.

"(H) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the exception process under this paragraph, including the establishment of such process, and any determination made under such process.

"(3) PHYSICIAN OWNER OR INVESTOR DEFINED.—For purposes of this subsection and subsection (f)(2), the term 'physician owner or investor' means a physician (or an immediate family member of such physician) with a direct or an indirect ownership or investment interest in the hospital.

"(4) PATIENT SAFETY REQUIREMENT.—In the case of a hospital to which the requirements of paragraph (1) apply, insofar as the hospital admits a patient and does not have any physician available on the premises 24 hours per day, 7 days per week, before admitting the patient—

"(A) the hospital shall disclose such fact to the patient; and

"(B) following such disclosure, the hospital shall receive from the patient a signed acknowledgment that the patient understands such fact.

"(5) CLARIFICATION.—Nothing in this subsection shall be construed as preventing the Secretary from terminating a hospital's provider agreement if the hospital is not in compliance with regulations pursuant to section 1866.".

(b) VERIFYING COMPLIANCE.—The Secretary of Health and Human Services shall establish policies and procedures to verify compliance with the requirements described in subsections (i)(1) and (i)(4) of section 1877 of the Social Security Act, as added by subsection (a)(5). The Secretary may use unannounced site reviews of hospitals and audits to verify compliance with such requirements.

(c) IMPLEMENTATION.—

(1) FUNDING.—For purposes of carrying out the amendments made by subsection (a) and the provisions of subsection (b), in addition to funds otherwise available, out of any funds in the Treasury not otherwise appropriated there are appropriated to the Secretary of Health and Human Services for the Centers for Medicare & Medicaid Services Program Management Account $5,000,000 for each fiscal year beginning with fiscal year 2010. Amounts appropriated under this paragraph for a fiscal year shall be available until expended.

(2) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to the amendments made by subsection (a) and the provisions of subsection (b).

SEC. 1157. INSTITUTE OF MEDICINE STUDY OF GEOGRAPHIC ADJUSTMENT FACTORS UNDER MEDICARE.

(a) IN GENERAL.—The Secretary of Health and Human Services shall enter into a contract with the Institute of Medicine of the National Academy of Science to conduct a comprehensive empirical study, and provide recommendations as appropriate, on the accuracy of the geographic adjustment factors established under sections 1848(e) and 1886(d)(3)(E) of the Social Security Act (42 U.S.C. 1395w–4(e), 11395ww(d)(3)).

(b) MATTERS INCLUDED.—Such study shall include an evaluation and assessment of the following with respect to such adjustment factors:

(1) Empirical validity of the adjustment factors.

(2) Methodology used to determine the adjustment factors.

(3) Measures used for the adjustment factors, taking into account—

(A) timeliness of data and frequency of revisions to such data;

(B) sources of data and the degree to which such data are representative of costs; and

(C) operational costs of providers who participate in Medicare.

(c) EVALUATION.—Such study shall, within the context of the United States health care marketplace, evaluate and consider the following:

(1) The effect of the adjustment factors on the level and distribution of the health care workforce and resources, including—

(A) recruitment and retention that takes into account workforce mobility between urban and rural areas;

(B) ability of hospitals and other facilities to maintain an adequate and skilled workforce; and

(C) patient access to providers and needed medical technologies.

(2) The effect of the adjustment factors on population health and quality of care.

(3) The effect of the adjustment factors on the ability of providers to furnish efficient, high value care.

(d) REPORT.—The contract under subsection (a) shall provide for the Institute of Medicine to submit, not later than one year after the date of the enactment of this Act, to the Secretary and the Congress a report containing results and recommendations of the study conducted under this section.

(e) FUNDING.—There are authorized to be appropriated to carry out this section such sums as may be necessary.

SEC. 1158. REVISION OF MEDICARE PAYMENT SYSTEMS TO ADDRESS GEOGRAPHIC INEQUITIES. .

(a) IN GENERAL.—Taking into account the recommendations described in the report under section 1157(d), and notwithstanding the geographic adjustments that would otherwise apply under sections 1848(e) and 1886(d)(3)(E) of the Social Security Act (42 U.S.C. 1395w–4(e), 1395ww(d)(3)(E)), the Secretary of Health and Human Services shall include in proposed rules applicable to the rulemaking cycle for payment systems for physicians' services and inpatient hospital services under sections 1848 and 1886(d) of such Act, respectively, proposals (as the Secretary determines to be appropriate) to revise the geographic adjustment factors used in such systems. Such proposals shall be contained in the next rulemaking cycle following the submission to the Secretary of the report under section 1157(d).

(b) PAYMENT ADJUSTMENTS.—

(1) FUNDING FOR IMPROVEMENTS.—The Secretary shall use funds as provided under subsection (c) in making changes to the geographic adjustment factors pursuant to subsection (a). In making such changes to such geographic adjustment factors, the Secretary shall ensure that the estimated increased expenditures resulting from such changes does not exceed the amounts provided under subsection (c).

(2) ENSURING FAIRNESS.—In carrying out this subsection, the Secretary shall not reduce the geographic adjustment below the factor that applied for such payment system in the payment year before such changes.

(c) FUNDING.—Amounts in the Medicare Improvement Fund under section 1898, as amended by section 1146, shall be available to the Secretary to make changes to the geographic adjustments factors as described in subsections (a) and (b) with respect to services furnished before January 1, 2014. No more than one-half of such amounts shall be available with respect to services furnished in any one payment year.

Subtitle D—Medicare Advantage Reforms

PART 1—PAYMENT AND ADMINISTRATION

SEC. 1161. PHASE-IN OF PAYMENT BASED ON FEE-FOR-SERVICE COSTS.

Section 1853 of the Social Security Act (42 U.S.C. 1395w–23) is amended—

(1) in subsection (j)(1)(A)—

(A) by striking "beginning with 2007" and inserting "for 2007, 2008, 2009, and 2010"; and

(B) by inserting after "(k)(1)" the following: ", or, beginning with 2011, 1/12 of the blended benchmark amount determined under subsection (n)(1)"; and

(2) by adding at the end the following new subsection:

"(n) DETERMINATION OF BLENDED BENCHMARK AMOUNT.—

"(1) IN GENERAL.—For purposes of subsection (j), subject to paragraphs (3) and (4), the term 'blended benchmark amount' means for an area—

"(A) for 2011 the sum of—

"(i) 2/3 of the applicable amount (as defined in subsection (k)) for the area and year; and

"(ii) 1/3 of the amount specified in paragraph (2) for the area and year;

"(B) for 2012 the sum of—

"(i) 1/3 of the applicable amount for the area and year; and

"(ii) 2/3 of the amount specified in paragraph (2) for the area and year; and

"(C) for a subsequent year the amount specified in paragraph (2) for the area and year.

"(2) SPECIFIED AMOUNT.—The amount specified in this paragraph for an area and year is the amount specified in subsection (c)(1)(D)(i) for the area and year adjusted (in a manner specified by the Secretary) to take into account the phase-out in the indirect costs of medical education from capitation rates described in subsection (k)(4).

"(3) FEE-FOR-SERVICE PAYMENT FLOOR.—In no case shall the blended benchmark amount for an area and year be less than the amount specified in paragraph (2).

"(4) EXCEPTION FOR PACE PLANS.—This subsection shall not apply to payments to a PACE program under section 1894.".

SEC. 1162. QUALITY BONUS PAYMENTS.

(a) IN GENERAL.—Section 1853 of the Social Security Act (42 U.S.C. 1395w-23), as amended by section 1161, is amended—

(1) in subsection (j), by inserting "subject to subsection (o)," after "For purposes of this part,"; and

(2) by adding at the end the following new subsection:

"(o) QUALITY BASED PAYMENT ADJUSTMENT.—

"(1) HIGH QUALITY PLAN ADJUSTMENT.—For years beginning with 2011, in the case of a Medicare Advantage plan that is identified (under paragraph (3)(E)(ii)) as a high quality MA plan with respect to the year, the blended benchmark amount under subsection (n)(1) shall be increased—

"(A) for 2011, by 1.0 percent;

"(B) for 2012, by 2.0 percent; and

"(C) for a subsequent year, by 3.0 percent.

"(2) IMPROVED QUALITY PLAN ADJUSTMENT.—For years beginning with 2011, in the case of a Medicare Advantage plan that is identified (under paragraph (3)(E)(iii)) as an improved quality MA plan with respect to the year, blended benchmark amount under subsection (n)(1) shall be increased—

"(A) for 2011, by 0.33 percent;

"(B) for 2012, by 0.66 percent; and

"(C) for a subsequent year, by 1.0 percent.

"(3) DETERMINATIONS OF QUALITY.—

"(A) QUALITY PERFORMANCE.—The Secretary shall provide for the computation of a quality performance score for each Medicare Advantage plan to be applied for each year beginning with 2010.

"(B) COMPUTATION OF SCORE.—

"(i) FOR YEARS BEFORE 2014.—For years before 2014, the quality performance score for a Medicare Advantage plan shall be computed based on a blend (as designated by the Secretary) of the plan's performance on—

"(I) HEDIS effectiveness of care quality measures;

"(II) CAHPS quality measures; and

"(III) such other measures of clinical quality as the Secretary may specify.

Such measures shall be risk-adjusted as the Secretary deems appropriate.

"(ii) ESTABLISHMENT OF OUTCOME-BASED MEASURES.—By not later than for 2013 the Secretary shall implement reporting requirements for quality under this section on measures selected under clause (iii) that reflect the outcomes of care experienced by individuals enrolled in Medicare Advantage plans (in addition to measures described in clause (i)). Such measures may include—

"(I) measures of rates of admission and readmission to a hospital;

"(II) measures of prevention quality, such as those established by the Agency for Healthcare Research and Quality (that include hospital admission rates for specified conditions);

"(III) measures of patient mortality and morbidity following surgery;

"(IV) measures of health functioning (such as limitations on activities of daily living) and survival for patients with chronic diseases;

"(V) measures of patient safety; and

"(VI) other measure of outcomes and patient quality of life as determined by the Secretary.

Such measures shall be risk-adjusted as the Secretary deems appropriate. In determining the quality measures to be used under this clause, the Secretary shall take into consideration the recommendations of the Medicare Payment Advisory Commission in its report to Congress under section 168 of the Medicare Improvements for Patients and Providers Act of 2008 (Public Law 110–275) and shall provide preference to measures collected on and comparable to measures used in measuring quality under parts A and B.

"(iii) RULES FOR SELECTION OF MEASURES.—The Secretary shall select measures for purposes of clause (ii) consistent with the following:

"(I) The Secretary shall provide preference to clinical quality measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a).

"(II) Prior to any measure being selected under this clause, the Secretary shall publish in the Federal Register such measure and provide for a period of public comment on such measure.

"(iv) TRANSITIONAL USE OF BLEND.—For payments for 2014 and 2015, the Secretary may compute the quality performance score for a Medicare Advantage plan based on a blend of the measures specified in clause (i) and the measures described in clause (ii) and selected under clause (iii).

"(v) USE OF QUALITY OUTCOMES MEASURES.—For payments beginning with 2016, the preponderance of measures used under this paragraph shall be quality outcomes measures described in clause (ii) and selected under clause (iii).

"(C) DATA USED IN COMPUTING SCORE.—Such score for application for—

"(i) payments in 2011 shall be based on quality performance data for plans for 2009; and

"(ii) payments in 2012 and a subsequent year shall be based on quality performance data for plans for the second preceding year.

"(D) REPORTING OF DATA.—Each Medicare Advantage organization shall provide for the reporting to the Secretary of quality performance data described in subparagraph (B) (in order to determine a quality performance score under this paragraph) in such time and manner as the Secretary shall specify.

"(E) RANKING OF PLANS.—

"(i) INITIAL RANKING.—Based on the quality performance score described in subparagraph (B) achieved with respect to a year, the Secretary shall rank plan performance—

"(I) from highest to lowest based on absolute scores; and

"(II) from highest to lowest based on percentage improvement in the score for the plan from the previous year.

A plan which does not report quality performance data under subparagraph (D) shall be counted, for purposes of such ranking, as having the lowest plan performance and lowest percentage improvement.

"(ii) IDENTIFICATION OF HIGH QUALITY PLANS IN TOP QUINTILE BASED ON PROJECTED ENROLLMENT.—The Secretary shall, based on the scores for each plan under clause (i)(I) and the Secretary's projected enrollment for each plan and subject to clause (iv), identify those Medicare Advantage plans with the highest score that, based upon projected enrollment, are projected to include in the aggregate 20 percent of the total projected enrollment for the year. For purposes of this subsection, a plan so identified shall be referred to in this subsection as a 'high quality MA plan'.

"(iii) IDENTIFICATION OF IMPROVED QUALITY PLANS IN TOP QUINTILE BASED ON PROJECTED ENROLLMENT.—The Secretary shall, based on the percentage improvement score for each plan under clause (i)(II) and the Secretary's projected enrollment for each plan and subject to clause (iv), identify those Medicare Advantage plans with the greatest percentage improvement score that, based upon projected enrollment, are projected to include in the aggregate 20 percent of the total projected enrollment for the year. For purposes of this subsection, a plan so identified that is not a high quality plan for the year shall be referred to in this subsection as an 'improved quality MA plan'.

"(iv) AUTHORITY TO DISQUALIFY CERTAIN PLANS.—In applying clauses (ii) and (iii), the Secretary may determine not to identify a Medicare Advantage plan if the Secretary has identified deficiencies in the plan's compliance with rules for such plans under this part.

"(F) NOTIFICATION.—The Secretary, in the annual announcement required under subsection (b)(1)(B) in 2011 and each succeeding year, shall notify the Medicare Advantage organization that is offering a high quality plan or an improved quality plan of such identification for the year and the quality performance payment adjustment for such plan for the year. The Secretary shall provide for publication on the website for the Medicare program of the information described in the previous sentence.".

SEC. 1163. EXTENSION OF SECRETARIAL CODING INTENSITY ADJUSTMENT AUTHORITY.

Section 1853(a)(1)(C)(ii) of the Social Security Act (42 U.S.C. 1395w–23(a)(1)(C)(ii) is amended—

(1) in the matter before subclause (I), by striking "through 2010" and inserting "and each subsequent year"; and

(2) in subclause (II)—

(A) by inserting "periodically" before "conduct an analysis";

(B) by inserting "on a timely basis" after "are incorporated"; and

(C) by striking "only for 2008, 2009, and 2010" and inserting "for 2008 and subsequent years".

SEC. 1164. SIMPLIFICATION OF ANNUAL BENEFICIARY ELECTION PERIODS.

(a) 2 WEEK PROCESSING PERIOD FOR ANNUAL ENROLLMENT PERIOD (AEP).—Paragraph (3)(B) of section 1851(e) of the Social Security Act (42 U.S.C. 1395w–21(e)) is amended—

(1) by striking "and" at the end of clause (iii);

(2) in clause (iv)—

(A) by striking "and succeeding years" and inserting ", 2008, 2009, and 2010"; and

(B) by striking the period at the end and inserting "; and"; and

(3) by adding at the end the following new clause:

"(v) with respect to 2011 and succeeding years, the period beginning on November 1 and ending on December 15 of the year before such year.".

(b) ELIMINATION OF 3-MONTH ADDITIONAL OPEN ENROLLMENT PERIOD (OEP).—Effective for plan years beginning with 2011, paragraph (2) of such section is amended by striking subparagraph (C).

SEC. 1165. EXTENSION OF REASONABLE COST CONTRACTS.

Section 1876(h)(5)(C) of the Social Security Act (42 U.S.C. 1395mm(h)(5)(C)) is amended—

(1) in clause (ii), by striking "January 1, 2010" and inserting "January 1, 2012"; and

(2) in clause (iii), by striking "the service area for the year" and inserting "the portion of the plan's service area for the year that is within the service area of a reasonable cost reimbursement contract".

SEC. 1166. LIMITATION OF WAIVER AUTHORITY FOR EMPLOYER GROUP PLANS.

(a) IN GENERAL.—The first sentence of paragraph (2) of section 1857(i) of the Social Security Act (42 U.S.C. 1395w–27(i)) is amended by inserting before the period at the end the following: ", but only if 90 percent of the Medicare Advantage eligible individuals enrolled under such plan reside in a county in which the MA organization offers an MA local plan".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply for plan years beginning on or after January 1, 2011, and shall not apply to plans which were in effect as of December 31, 2010.

SEC. 1167. IMPROVING RISK ADJUSTMENT FOR PAYMENTS.

(a) REPORT TO CONGRESS.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report that evaluates the adequacy of the risk adjustment system under section 1853(a)(1)(C) of the Social Security Act (42 U.S.C. 1395-23(a)(1)(C)) in predicting costs for beneficiaries with chronic or co-morbid conditions, beneficiaries dually-eligible for Medicare and Medicaid, and non-Medicaid eligible low-income beneficiaries; and the need and feasibility of including further gradations of diseases or conditions and multiple years of beneficiary data.

(b) IMPROVEMENTS TO RISK ADJUSTMENT.—Not later than January 1, 2012, the Secretary shall implement necessary improvements to the risk adjustment system under section 1853(a)(1)(C) of the Social Security Act (42 U.S.C. 1395–23(a)(1)(C)), taking into account the evaluation under subsection (a).

SEC. 1168. ELIMINATION OF MA REGIONAL PLAN STABILIZATION FUND.

(a) IN GENERAL.—Section 1858 of the Social Security Act (42 U.S.C. 1395w–27a) is amended by striking subsection (e).

(b) TRANSITION.—Any amount contained in the MA Regional Plan Stabilization Fund as of the date of the enactment of this Act shall be transferred to the Federal Supplementary Medical Insurance Trust Fund.

SEC. 1169. STUDY REGARDING THE EFFECTS OF CALCULATING MEDICARE ADVANTAGE PAYMENT RATES ON A REGIONAL AVERAGE OF MEDICARE FEE FOR SERVICE RATES.

(a) IN GENERAL.—The Administrator of the Centers for Medicare and Medicaid Services shall conduct a study to determine the potential effects of calculating Medicare Advantage payment rates on a more aggregated geographic basis (such as metropolitan statistical areas or other regional delineations) rather than using county boundaries. In conducting such study, the Administrator shall consider whether such alternative geographic basis would result in the following:

(1) Improvements in the quality of care.

(2) Greater equity among providers.

(3) More predictable benchmark amounts for Medicare advantage plans.

(b) CONSULTATIONS.—In conducting the study, the Administrator shall consult with the following:

(1) Experts in health care financing.

(2) Representatives of foundations and other nonprofit entities that have conducted or supported research on Medicare financing issues.

(3) Representatives from Medicare Advantage plans.

(4) Such other entities or people as determined by the Secretary.

(c) REPORT.—Not later than one year after the date of the enactment of this Act, the Administrator shall transmit a report to the Congress on the study conducted under this section. The report shall contain a detailed statement of findings and conclusions of the study, together with its recommendations for such legislation and administrative actions as the Administrator considers appropriate.

PART 2—BENEFICIARY PROTECTIONS AND ANTI-FRAUD

SEC. 1171. LIMITATION ON COST-SHARING FOR INDIVIDUAL HEALTH SERVICES.

(a) IN GENERAL.—Section 1852(a)(1) of the Social Security Act (42 U.S.C. 1395w–22(a)(1)) is amended—

(1) in subparagraph (A), by inserting before the period at the end the following: "with cost-sharing that is no greater (and may be less) than the cost-sharing that would otherwise be imposed under such program option";

(2) in subparagraph (B)(i), by striking "or an actuarially equivalent level of cost-sharing as determined in this part"; and

(3) by amending clause (ii) of subparagraph (B) to read as follows:

"(ii) PERMITTING USE OF FLAT COPAYMENT OR PER DIEM RATE.—Nothing in clause (i) shall be construed as prohibiting a Medicare Advantage plan from using a flat copayment or per diem rate, in lieu of the cost-sharing that would be imposed under part A or B, so long as the amount of the cost-sharing imposed does not exceed the amount of the cost-sharing that would be imposed under the respective part if the individual were not enrolled in a plan under this part.".

(b) LIMITATION FOR DUAL ELIGIBLES AND QUALIFIED MEDICARE BENEFICIARIES.—Section 1852(a) of such Act is amended to read as follows:

"(7) LIMITATION ON COST-SHARING FOR DUAL ELIGIBLES AND QUALIFIED MEDICARE BENEFICIARIES.—In the case of a individual who is a full-benefit dual eligible individual (as defined in section 1935(c)(6)) or a qualified medicare beneficiary (as defined in section 1905(p)(1)) who is enrolled in a Medicare Advantage plan, the plan may not impose cost-sharing that exceeds the amount of cost-sharing that would be permitted with respect to the individual under this title and title XIX if the individual were not enrolled with such plan.".

(c) EFFECTIVE DATES.—

(1) The amendments made by subsection (a) shall apply to plan years beginning on or after January 1, 2011.

(2) The amendments made by subsection (b) shall apply to plan years beginning on or after January 1, 2011.

SEC. 1172. CONTINUOUS OPEN ENROLLMENT FOR ENROLLEES IN PLANS WITH ENROLLMENT SUSPENSION.

Section 1851(e)(4) of the Social Security Act (42 U.S.C. 1395w(e)(4)) is amended—

(1) in subparagraph (C), by striking at the end "or";

(2) in subparagraph (D)—

(A) by inserting ", taking into account the health or well-being of the individual" before the period; and

(B) by redesignating such subparagraph as subparagraph (E); and

(3) by inserting after subparagraph (C) the following new subparagraph:

"(D) the individual is enrolled in an MA plan and enrollment in the plan is suspended under paragraph (2)(B) or (3)(C) of section 1857(g) because of a failure of the plan to meet applicable requirements; or".

SEC. 1173. INFORMATION FOR BENEFICIARIES ON MA PLAN ADMINISTRATIVE COSTS.

(a) DISCLOSURE OF MEDICAL LOSS RATIOS AND OTHER EXPENSE DATA.—Section 1851 of the Social Security Act (42 U.S.C. 1395w–21), as previously amended by this subtitle, is amended by adding at the end the following new subsection:

"(p) PUBLICATION OF MEDICAL LOSS RATIOS AND OTHER COST-RELATED INFORMATION.—

"(1) IN GENERAL.—The Secretary shall publish, not later than November 1 of each year (beginning with 2011), for each MA plan contract, the medical loss ratio of the plan in the previous year.

"(2) SUBMISSION OF DATA.—

"(A) IN GENERAL.—Each MA organization shall submit to the Secretary, in a form and manner specified by the Secretary, data necessary for the Secretary to publish the medical loss ratio on a timely basis.

"(B) DATA FOR 2010 AND 2011.—The data submitted under subparagraph (A) for 2010 and for 2011 shall be consistent in content with the data reported as part of the MA plan bid in June 2009 for 2010.

"(C) USE OF STANDARDIZED ELEMENTS AND DEFINITIONS.—The data to be submitted under subparagraph (A) relating to medical loss ratio for a year, beginning with 2012, shall be submitted based on the standardized elements and definitions developed under paragraph (3).

"(3) DEVELOPMENT OF DATA REPORTING STANDARDS.—

"(A) IN GENERAL.—The Secretary shall develop and implement standardized data elements and definitions for reporting under this subsection, for contract years beginning with 2012, of data necessary for the calculation of the medical loss ratio for MA plans. Not later than December 31, 2010, the Secretary shall publish a report describing the elements and definitions so developed.

"(B) CONSULTATION.—The Secretary shall consult with the Health Choices Commissioner, representatives of MA organizations, experts on health plan accounting systems, and representatives of the National Association of Insurance Commissioners, in the development of such data elements and definitions.

"(4) MEDICAL LOSS RATIO TO BE DEFINED.—For purposes of this part, the term 'medical loss ratio' has the meaning given such term by the Secretary, taking into account the meaning given such term by the Health Choices Commissioner under section 116 of the America's Affordable Health Choices Act of 2009.".

(b) MINIMUM MEDICAL LOSS RATIO.—Section 1857(e) of the Social Security Act (42 U.S.C. 1395w–27(e)) is amended by adding at the end the following new paragraph:

"(4) REQUIREMENT FOR MINIMUM MEDICAL LOSS RATIO.—If the Secretary determines for a contract year (beginning with 2014) that an MA plan has failed to have a medical loss ratio (as defined in section 1851(p)(4)) of at least .85—

"(A) the Secretary shall require the Medicare Advantage organization offering the plan to give enrollees a rebate (in the second succeeding contract year) of premiums under this part (or part B or part D, if applicable) by such amount as would provide for a benefits ratio of at least .85;

"(B) for 3 consecutive contract years, the Secretary shall not permit the enrollment of new enrollees under the plan for coverage during the second succeeding contract year; and

"(C) the Secretary shall terminate the plan contract if the plan fails to have such a medical loss ratio for 5 consecutive contract years.".

SEC. 1174. STRENGTHENING AUDIT AUTHORITY.

(a) FOR PART C PAYMENTS RISK ADJUSTMENT.—Section 1857(d)(1) of the Social Security Act (42 U.S.C. 1395w–27(d)(1)) is amended by inserting after "section 1858(c))" the following: ", and data submitted with respect to risk adjustment under section 1853(a)(3)".

(b) ENFORCEMENT OF AUDITS AND DEFICIENCIES.—

(1) IN GENERAL.—Section 1857(e) of such Act, as amended by section 1173, is amended by adding at the end the following new paragraph:

"(5) ENFORCEMENT OF AUDITS AND DEFICIENCIES.—

"(A) INFORMATION IN CONTRACT.—The Secretary shall require that each contract with an MA organization under this section shall include terms that inform the organization of the provisions in subsection (d).

"(B) ENFORCEMENT AUTHORITY.—The Secretary is authorized, in connection with conducting audits and other activities under subsection (d), to take such actions, including pursuit of financial recoveries, necessary to address deficiencies identified in such audits or other activities.".

(2) APPLICATION UNDER PART D.—For provision applying the amendment made by paragraph (1) to prescription drug plans under part D, see section 1860D–12(b)(3)(D) of the Social Security Act.

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date of the enactment of this Act and shall apply to audits and activities conducted for contract years beginning on or after January 1, 2011.

SEC. 1175. AUTHORITY TO DENY PLAN BIDS.

(a) IN GENERAL.—Section 1854(a)(5) of the Social Security Act (42 U.S.C. 1395w–24(a)(5)) is amended by adding at the end the following new subparagraph:

"(C) REJECTION OF BIDS.—Nothing in this section shall be construed as requiring the Secretary to accept any or every bid by an MA organization under this subsection.".

(b) APPLICATION UNDER PART D.—Section 1860D–11(d) of such Act (42 U.S.C. 1395w–111(d)) is amended by adding at the end the following new paragraph:

"(3) REJECTION OF BIDS.—Paragraph (5)(C) of section 1854(a) shall apply with respect to bids under this section in the same manner as it applies to bids by an MA organization under such section.".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to bids for contract years beginning on or after January 1, 2011.

PART 3—TREATMENT OF SPECIAL NEEDS PLANS

SEC. 1176. LIMITATION ON ENROLLMENT OUTSIDE OPEN ENROLLMENT PERIOD OF INDIVIDUALS INTO CHRONIC CARE SPECIALIZED MA PLANS FOR SPECIAL NEEDS INDIVIDUALS.

Section 1859(f)(4) of the Social Security Act (42 U.S.C. 1395w–28(f)(4)) is amended by adding at the end the following new subparagraph:

"(C) The plan does not enroll an individual on or after January 1, 2011, other than during an annual, coordinated open enrollment period or when at the time of the diagnosis of the disease or condition that qualifies the individual as an individual described in subsection (b)(6)(B)(iii).".

SEC. 1177. EXTENSION OF AUTHORITY OF SPECIAL NEEDS PLANS TO RESTRICT ENROLLMENT.

(a) IN GENERAL.—Section 1859(f)(1) of the Social Security Act (42 U.S.C. 1395w–28(f)(1)) is amended by striking "January 1, 2011" and inserting "January 1, 2013 (or January 1, 2016, in the case of a plan described in section 1177(b)(1) of the America's Affordable Health Choices Act of 2009)".

(b) GRANDFATHERING OF CERTAIN PLANS.—

(1) PLANS DESCRIBED.—For purposes of section 1859(f)(1) of the Social Security Act (42 U.S.C. 1395w–28(f)(1)), a plan described in this paragraph is a plan that had a contract with a State that had a State program to operate an integrated Medicaid-Medicare program that had been approved by the Centers for Medicare & Medicaid Services as of January 1, 2004.

(2) ANALYSIS; REPORT.—The Secretary of Health and Human Services shall provide, through a contract with an independent health services evaluation organization, for an analysis of the plans described in paragraph (1) with regard to the impact of such plans on cost, quality of care, patient satisfaction, and other subjects as specified by the Secretary. Not later than December 31, 2011, the Secretary shall submit to Congress a report on such analysis and shall include in such report such recommendations with regard to the treatment of such plans as the Secretary deems appropriate.

Subtitle E—Improvements to Medicare Part D

SEC. 1181. ELIMINATION OF COVERAGE GAP.

(a) IN GENERAL.—Section 1860D–2(b) of such Act (42 U.S.C. 1395w–102(b)) is amended—

(1) in paragraph (3)(A), by striking "paragraph (4)" and inserting "paragraphs (4) and (7)";

(2) in paragraph (4)(B)(i), by inserting "subject to paragraph (7)," after "purposes of this part,"; and

(3) by adding at the end the following new paragraph:

"(7) PHASED-IN ELIMINATION OF COVERAGE GAP.—

"(A) IN GENERAL.—For each year beginning with 2011, the Secretary shall consistent with this paragraph progressively increase the initial coverage limit (described in subsection (b)(3)) and decrease the annual out-of-pocket threshold from the amounts otherwise computed until there is a continuation of coverage from the initial coverage limit for expenditures incurred through the total amount of expenditures at which benefits are available under paragraph (4).

"(B) INCREASE IN INITIAL COVERAGE LIMIT.—For a year beginning with 2011, the initial coverage limit otherwise computed without regard to this

paragraph shall be increased by ½ of the cumulative phase-in percentage (as defined in subparagraph (D)(ii) for the year) times the out-of-pocket gap amount (as defined in subparagraph (E)) for the year.

"(C) DECREASE IN ANNUAL OUT-OF-POCKET THRESHOLD.—For a year beginning with 2011, the annual out-of-pocket threshold otherwise computed without regard to this paragraph shall be decreased by ½ of the cumulative phase-in percentage of the out-of-pocket gap amount for the year multiplied by 1.75.

"(D) PHASE–IN.—For purposes of this paragraph:

"(i) ANNUAL PHASE-IN PERCENTAGE.—The term 'annual phase-in percentage' means—

"(I) for 2011, 13 percent;

"(II) for 2012, 2013, 2014, and 2015, 5 percent;

"(III) for 2016 through 2018, 7.5 percent; and

"(IV) for 2019 and each subsequent year, 10 percent.

"(ii) CUMULATIVE PHASE-IN PERCENTAGE.—The term 'cumulative phase-in percentage' means for a year the sum of the annual phase-in percentage for the year and the annual phase-in percentages for each previous year beginning with 2011, but in no case more than 100 percent.

"(E) OUT-OF-POCKET GAP AMOUNT.—For purposes of this paragraph, the term 'out-of-pocket gap amount' means for a year the amount by which—

"(i) the annual out-of-pocket threshold specified in paragraph (4)(B) for the year (as determined as if this paragraph did not apply), exceeds

"(ii) the sum of—

"(I) the annual deductible under paragraph (1) for the year; and

"(II) ¼ of the amount by which the initial coverage limit under paragraph (3) for the year (as determined as if this paragraph did not apply) exceeds such annual deductible.".

(b) REQUIRING DRUG MANUFACTURERS TO PROVIDE DRUG REBATES FOR FULL-BENEFIT DUAL ELIGIBLES.—

(1) IN GENERAL.—Section 1860D–2 of the Social Security Act (42 U.S.C. 1396r–8) is amended—

(A) in subsection (e)(1), in the matter before subparagraph (A), by inserting "and subsection (f)" after "this subsection"; and

(B) by adding at the end the following new subsection:

"(f) PRESCRIPTION DRUG REBATE AGREEMENT FOR FULL-BENEFIT DUAL ELIGIBLE INDIVIDUALS.—

"(1) IN GENERAL.—In this part, the term 'covered part D drug' does not include any drug or biologic that is manufactured by a manufacturer that has not entered into and have in effect a rebate agreement described in paragraph (2).

"(2) REBATE AGREEMENT.—A rebate agreement under this subsection shall require the manufacturer to provide to the Secretary a rebate for each rebate period (as defined in paragraph (6)(B)) ending after December 31, 2010, in the amount specified in paragraph (3) for any covered part D drug of the manufacturer dispensed after December 31, 2010, to any full-benefit dual eligible individual (as defined in paragraph (6)(A)) for which payment was made by a PDP sponsor under part D or a MA organization under part C for such period. Such rebate shall be paid by the manufacturer to the Secretary not later than 30 days after the date of receipt of the information described in section 1860D–12(b)(7), including as such section is applied under section 1857(f)(3).

"(3) REBATE FOR FULL-BENEFIT DUAL ELIGIBLE MEDICARE DRUG PLAN ENROLLEES.—

"(A) IN GENERAL.—The amount of the rebate specified under this paragraph for a manufacturer for a rebate period, with respect to each dosage form and strength of any covered part D drug provided by such manufacturer and dispensed to a full-benefit dual eligible individual, shall be equal to the product of—

"(i) the total number of units of such dosage form and strength of the drug so provided and dispensed for which payment was made by a PDP sponsor under part D or a MA organization under part C for the rebate period (as reported under section 1860D–12(b)(7), including as such section is applied under section 1857(f)(3)); and

"(ii) the amount (if any) by which—

"(I) the Medicaid rebate amount (as defined in subparagraph (B)) for such form, strength, and period, exceeds

"(II) the average Medicare drug program full-benefit dual eligible rebate amount (as defined in subparagraph (C)) for such form, strength, and period.

"(B) MEDICAID REBATE AMOUNT.—For purposes of this paragraph, the term 'Medicaid rebate amount' means, with respect to each dosage form and strength of a covered part D drug provided by the manufacturer for a rebate period—

"(i) in the case of a single source drug or an innovator multiple source drug, the amount specified in paragraph (1)(A)(ii) of section 1927(c) plus the amount, if any, specified in paragraph (2)(A)(ii) of such section, for such form, strength, and period; or

"(ii) in the case of any other covered outpatient drug, the amount specified in paragraph (3)(A)(i) of such section for such form, strength, and period.

"(C) AVERAGE MEDICARE DRUG PROGRAM FULL-BENEFIT DUAL ELIGIBLE REBATE AMOUNT.—For purposes of this subsection, the term 'average Medicare drug program full-benefit dual eligible rebate amount' means, with respect to each dosage form and strength of a covered part D drug provided by a manufacturer for a rebate period, the sum, for all PDP sponsors under part D and MA organizations administering a MA–PD plan under part C, of—

"(i) the product, for each such sponsor or organization, of—

"(I) the sum of all rebates, discounts, or other price concessions (not taking into account any rebate provided under paragraph (2) for such dosage form and strength of the drug dispensed, calculated on a per-unit basis, but only to the extent that any such rebate, discount, or other price concession applies equally to drugs dispensed to full-benefit dual eligible Medicare drug plan enrollees and drugs dispensed to PDP and MA–PD enrollees who are not full-benefit dual eligible individuals; and

"(II) the number of the units of such dosage and strength of the drug dispensed during the rebate period to full-benefit dual eligible individuals enrolled in the prescription drug plans administered by the PDP sponsor or the MA–PD plans administered by the MA–PD organization; divided by

"(ii) the total number of units of such dosage and strength of the drug dispensed during the rebate period to full-benefit dual eligible individuals enrolled in all prescription drug plans administered by PDP sponsors and all MA–PD plans administered by MA–PD organizations.

"(4) LENGTH OF AGREEMENT.—The provisions of paragraph (4) of section 1927(b) (other than clauses (iv) and (v) of subparagraph (B)) shall apply to rebate agreements under this subsection in the same manner as such paragraph applies to a rebate agreement under such section.

"(5) OTHER TERMS AND CONDITIONS.—The Secretary shall establish other terms and conditions of the rebate agreement under this subsection, including terms and conditions related to compliance, that are consistent with this subsection.

"(6) DEFINITIONS.—In this subsection and section 1860D–12(b)(7):

"(A) FULL-BENEFIT DUAL ELIGIBLE INDIVIDUAL.—The term 'full-benefit dual eligible individual' has the meaning given such term in section 1935(c)(6).

"(B) REBATE PERIOD.—The term 'rebate period' has the meaning given such term in section 1927(k)(8).".

(2) REPORTING REQUIREMENT FOR THE DETERMINATION AND PAYMENT OF REBATES BY MANUFACTURES RELATED TO REBATE FOR FULL-BENEFIT DUAL ELIGIBLE MEDICARE DRUG PLAN ENROLLEES.—

(A) REQUIREMENTS FOR PDP SPONSORS.—Section 1860D–12(b) of the Social Security Act (42 U.S.C. 1395w–112(b)) is amended by adding at the end the following new paragraph:

"(7) REPORTING REQUIREMENT FOR THE DETERMINATION AND PAYMENT OF REBATES BY MANUFACTURERS RELATED TO REBATE FOR FULL-BENEFIT DUAL ELIGIBLE MEDICARE DRUG PLAN ENROLLEES.—

"(A) IN GENERAL.—For purposes of the rebate under section 1860D–2(f) for contract years beginning on or after January 1, 2011, each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan shall require that the sponsor comply with subparagraphs (B) and (C).

"(B) REPORT FORM AND CONTENTS.—Not later than 60 days after the end of each rebate period (as defined in section 1860D–2(f)(6)(B)) within such a contract year to which such section applies, a PDP sponsor of a prescription drug plan under this part shall report to each manufacturer—

"(i) information (by National Drug Code number) on the total number of units of each dosage, form, and strength of each drug of such manu-

facturer dispensed to full-benefit dual eligible Medicare drug plan enrollees under any prescription drug plan operated by the PDP sponsor during the rebate period;

"(ii) information on the price discounts, price concessions, and rebates for such drugs for such form, strength, and period;

"(iii) information on the extent to which such price discounts, price concessions, and rebates apply equally to full-benefit dual eligible Medicare drug plan enrollees and PDP enrollees who are not full-benefit dual eligible Medicare drug plan enrollees; and

"(iv) any additional information that the Secretary determines is necessary to enable the Secretary to calculate the average Medicare drug program full-benefit dual eligible rebate amount (as defined in paragraph (3)(C) of such section), and to determine the amount of the rebate required under this section, for such form, strength, and period.

Such report shall be in a form consistent with a standard reporting format established by the Secretary.

"(C) SUBMISSION TO SECRETARY.—Each PDP sponsor shall promptly transmit a copy of the information reported under subparagraph (B) to the Secretary for the purpose of audit oversight and evaluation.

"(D) CONFIDENTIALITY OF INFORMATION.—The provisions of subparagraph (D) of section 1927(b)(3), relating to confidentiality of information, shall apply to information reported by PDP sponsors under this paragraph in the same manner that such provisions apply to information disclosed by manufacturers or wholesalers under such section, except—

"(i) that any reference to 'this section' in clause (i) of such subparagraph shall be treated as being a reference to this section;

"(ii) the reference to the Director of the Congressional Budget Office in clause (iii) of such subparagraph shall be treated as including a reference to the Medicare Payment Advisory Commission; and

"(iii) clause (iv) of such subparagraph shall not apply.

"(E) OVERSIGHT.—Information reported under this paragraph may be used by the Inspector General of the Department of Health and Human Services for the statutorily authorized purposes of audit, investigation, and evaluations.

"(F) PENALTIES FOR FAILURE TO PROVIDE TIMELY INFORMATION AND PROVISION OF FALSE INFORMATION.—In the case of a PDP sponsor—

"(i) that fails to provide information required under subparagraph (B) on a timely basis, the sponsor is subject to a civil money penalty in the amount of $10,000 for each day in which such information has not been provided; or

"(ii) that knowingly (as defined in section 1128A(i)) provides false information under such subparagraph, the sponsor is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information.

Such civil money penalties are in addition to other penalties as may be prescribed by law. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).".

(B) APPLICATION TO MA ORGANIZATIONS.—Section 1857(f)(3) of the Social Security Act (42 U.S.C. 1395w–27(f)(3)) is amended by adding at the end the following:

"(D) REPORTING REQUIREMENT RELATED TO REBATE FOR FULL-BENEFIT DUAL ELIGIBLE MEDICARE DRUG PLAN ENROLLEES.—Section 1860D–12(b)(7).".

(3) DEPOSIT OF REBATES INTO MEDICARE PRESCRIPTION DRUG ACCOUNT.—Section 1860D–16(c) of such Act (42 U.S.C. 1395w–116(c)) is amended by adding at the end the following new paragraph:

"(6) REBATE FOR FULL-BENEFIT DUAL ELIGIBLE MEDICARE DRUG PLAN ENROLLEES.—Amounts paid under a rebate agreement under section 1860D–2(f) shall be deposited into the Account and shall be used to pay for all or part of the gradual elimination of the coverage gap under section 1860D–2(b)(7).".

SEC. 1182. DISCOUNTS FOR CERTAIN PART D DRUGS IN ORIGINAL COVERAGE GAP.

Section 1860D–2 of the Social Security Act (42 U.S.C. 1395w–102), as amended by section 1181, is amended—

(1) in subsection (b)(4)(C)(ii), by inserting "subject to subsection (g)(2)(C)," after "(ii)";

(2) in subsection (e)(1), in the matter before subparagraph (A), by striking "subsection (f)" and inserting "subsections (f) and (g)"; and

(3) by adding at the end the following new subsection:

"(g) REQUIREMENT FOR MANUFACTURER DISCOUNT AGREEMENT FOR CERTAIN QUALIFYING DRUGS.—

"(1) IN GENERAL.—In this part, the term 'covered part D drug' does not include any drug or biologic that is manufactured by a manufacturer that has not entered into and have in effect for all qualifying drugs (as defined in paragraph (5)(A)) a discount agreement described in paragraph (2).

"(2) DISCOUNT AGREEMENT.—

"(A) PERIODIC DISCOUNTS.—A discount agreement under this paragraph shall require the manufacturer involved to provide, to each PDP sponsor with respect to a prescription drug plan or each MA organization with respect to each MA-PD plan, a discount in an amount specified in paragraph (3) for qualifying drugs (as defined in paragraph (5)(A)) of the manufacturer dispensed to a qualifying enrollee after December 31, 2010, insofar as the individual is in the original gap in coverage (as defined in paragraph (5)(E)).

"(B) DISCOUNT AGREEMENT.—Insofar as not inconsistent with this subsection, the Secretary shall establish terms and conditions of such agreement, including terms and conditions relating to compliance, similar to the terms and conditions for rebate agreements under paragraphs (2), (3), and (4) of section 1927(b), except that—

"(i) discounts shall be applied under this subsection to prescription drug plans and MA-PD plans instead of State plans under title XIX;

"(ii) PDP sponsors and MA organizations shall be responsible, instead of States, for provision of necessary utilization information to drug manufacturers; and

"(iii) sponsors and MA organizations shall be responsible for reporting information on drug-component negotiated price, instead of other manufacturer prices.

"(C) COUNTING DISCOUNT TOWARD TRUE OUT-OF-POCKET COSTS.—Under the discount agreement, in applying subsection (b)(4), with regard to subparagraph (C)(i) of such subsection, if a qualified enrollee purchases the qualified drug insofar as the enrollee is in an actual gap of coverage (as defined in paragraph (5)(D)), the amount of the discount under the agreement shall be treated and counted as costs incurred by the plan enrollee.

"(3) DISCOUNT AMOUNT.—The amount of the discount specified in this paragraph for a discount period for a plan is equal to 50 percent of the amount of the drug-component negotiated price (as defined in paragraph (5)(C)) for qualifying drugs for the period involved.

"(4) ADDITIONAL TERMS.—In the case of a discount provided under this subsection with respect to a prescription drug plan offered by a PDP sponsor or an MA-PD plan offered by an MA organization, if a qualified enrollee purchases the qualified drug—

"(A) insofar as the enrollee is in an actual gap of coverage (as defined in paragraph (5)(D)), the sponsor or plan shall provide the discount to the enrollee at the time the enrollee pays for the drug; and

"(B) insofar as the enrollee is in the portion of the original gap in coverage (as defined in paragraph (5)(E)) that is not in the actual gap in coverage, the discount shall not be applied against the negotiated price (as defined in subsection (d)(1)(B)) for the purpose of calculating the beneficiary payment.

"(5) DEFINITIONS.—In this subsection:

"(A) QUALIFYING DRUG.—The term 'qualifying drug' means, with respect to a prescription drug plan or MA-PD plan, a drug or biological product that—

"(i)(I) is a drug produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application;

"(II) is a drug that was originally marketed under an original new drug application approved by the Food and Drug Administration; or

"(III) is a biological product as approved under section 351(a) of the Public Health Services Act;

"(ii) is covered under the formulary of the plan; and

"(iii) is dispensed to an individual who is in the original gap in coverage.

"(B) QUALIFYING ENROLLEE.—The term 'qualifying enrollee' means an individual enrolled in a prescription drug plan or MA-PD plan other than

such an individual who is a subsidy-eligible individual (as defined in section 1860D–14(a)(3)).

"(C) DRUG-COMPONENT NEGOTIATED PRICE.—The term 'drug-component negotiated price' means, with respect to a qualifying drug, the negotiated price (as defined in subsection (d)(1)(B)), as determined without regard to any dispensing fee, of the drug under the prescription drug plan or MA-PD plan involved.

"(D) ACTUAL GAP IN COVERAGE.—The term 'actual gap in coverage' means the gap in prescription drug coverage that occurs between the initial coverage limit (as modified under subparagraph (B) of subsection (b)(7)) and the annual out-of-pocket threshold (as modified under subparagraph (C) of such subsection).

"(E) ORIGINAL GAP IN COVERAGE.—The term 'original in gap coverage' means the gap in prescription drug coverage that would occur between the initial coverage limit (described in subsection (b)(3)) and the annual out-of-pocket threshold (as defined in subsection (b)(4)(B)) if subsection (b)(7) did not apply.".

SEC. 1183. REPEAL OF PROVISION RELATING TO SUBMISSION OF CLAIMS BY PHARMACIES LOCATED IN OR CONTRACTING WITH LONG-TERM CARE FACILITIES.

(a) PART D SUBMISSION.—Section 1860D–12(b) of the Social Security Act (42 U.S.C. 1395w–112(b)), as amended by section 172(a)(1) of Public Law 110-275, is amended by striking paragraph (5) and redesignating paragraph (6) and paragraph (7), as added by section 1181(b)(2), as paragraph (5) and paragraph (6), respectively.

(b) SUBMISSION TO MA-PD PLANS.—Section 1857(f)(3) of the Social Security Act (42 U.S.C. 1395w-27(f)(3)), as added by section 171(b) of Public Law 110-275 and amended by section 172(a)(2) of such Public Law and section 1181 of this Act, is amended by striking subparagraph (B) and redesignating subparagraphs (C) and (D) as subparagraphs (B) and (C), respectively.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply for contract years beginning with 2010.

SEC. 1184. INCLUDING COSTS INCURRED BY AIDS DRUG ASSISTANCE PROGRAMS AND INDIAN HEALTH SERVICE IN PROVIDING PRESCRIPTION DRUGS TOWARD THE ANNUAL OUT-OF-POCKET THRESHOLD UNDER PART D.

(a) IN GENERAL.—Section 1860D–2(b)(4)(C) of the Social Security Act (42 U.S.C. 1395w–102(b)(4)(C)) is amended—

(1) in clause (i), by striking "and" at the end;

(2) in clause (ii)—

(A) by striking "such costs shall be treated as incurred only if" and inserting "subject to clause (iii), such costs shall be treated as incurred only if";

(B) by striking ", under section 1860D–14, or under a State Pharmaceutical Assistance Program"; and

(C) by striking the period at the end and inserting "; and"; and

(3) by inserting after clause (ii) the following new clause:

"(iii) such costs shall be treated as incurred and shall not be considered to be reimbursed under clause (ii) if such costs are borne or paid—

"(I) under section 1860D–14;

"(II) under a State Pharmaceutical Assistance Program;

"(III) by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act); or

"(IV) under an AIDS Drug Assistance Program under part B of title XXVI of the Public Health Service Act.".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to costs incurred on or after January 1, 2011.

SEC. 1185. PERMITTING MID-YEAR CHANGES IN ENROLLMENT FOR FORMULARY CHANGES THAT ADVERSELY IMPACT AN ENROLLEE.

(a) IN GENERAL.—Section 1860D–1(b)(3) of the Social Security Act (42 U.S.C. 1395w–101(b)(3)) is amended by adding at the end the following new subparagraph:

"(F) CHANGE IN FORMULARY RESULTING IN INCREASE IN COST-SHARING.—

"(i) IN GENERAL.—Except as provided in clause (ii), in the case of an individual enrolled in a prescription drug plan (or MA–PD plan) who has been prescribed and is using a covered part D drug while so enrolled, if the formulary of the plan is materially changed (other than at the end of a contract year) so to reduce the coverage (or increase the cost-sharing) of the drug under the plan.

"(ii) EXCEPTION.—Clause (i) shall not apply in the case that a drug is removed from the formulary of a plan because of a recall or withdrawal of the drug issued by the Food and Drug Administration, be-

cause the drug is replaced with a generic drug that is a therapeutic equivalent, or because of utilization management applied to—

"(I) a drug whose labeling includes a boxed warning required by the Food and Drug Administration under section 210.57(c)(1) of title 21, Code of Federal Regulations (or a successor regulation); or

"(II) a drug required under subsection (c)(2) of section 505–1 of the Federal Food, Drug, and Cosmetic Act to have a Risk Evaluation and Management Strategy that includes elements under subsection (f) of such section.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to contract years beginning on or after January 1, 2011.

SEC. 1186. NEGOTIATION OF LOWER COVERED PART D DRUG PRICES ON BEHALF OF MEDICARE BENEFICIARIES.

(a) NEGOTIATION BY SECRETARY.—Section 1860D–11 of the Social Security Act (42 U.S.C. 1395w–111) is amended by striking subsection (i) (relating to noninterference) and inserting the following:

"(i) NEGOTIATION OF LOWER DRUG PRICES.—

"(1) IN GENERAL.—Notwithstanding any other provision of law, the Secretary shall negotiate with pharmaceutical manufacturers the prices (including discounts, rebates, and other price concessions) that may be charged to PDP sponsors and MA organizations for covered part D drugs for part D eligible individuals who are enrolled under a prescription drug plan or under an MA-PD plan.

"(2) NO CHANGE IN RULES FOR FORMULARIES.—

"(A) IN GENERAL.—Nothing in paragraph (1) shall be construed to authorize the Secretary to establish or require a particular formulary.

"(B) CONSTRUCTION.—Subparagraph (A) shall not be construed as affecting the Secretary's authority to ensure appropriate and adequate access to covered part D drugs under prescription drug plans and under MA-PD plans, including compliance of such plans with formulary requirements under section 1860D–4(b)(3).

"(3) CONSTRUCTION.—Nothing in this subsection shall be construed as preventing the sponsor of a prescription drug plan, or an organization offering an MA-PD plan, from obtaining a discount or reduction of the price for a covered part D drug below the price negotiated under paragraph (1).

"(4) SEMI-ANNUAL REPORTS TO CONGRESS.—Not later than June 1, 2011, and every six months thereafter, the Secretary shall submit to the Committees on Ways and Means, Energy and Commerce, and Oversight and Government Reform of the House of Representatives and the Committee on Finance of the Senate a report on negotiations conducted by the Secretary to achieve lower prices for Medicare beneficiaries, and the prices and price discounts achieved by the Secretary as a result of such negotiations.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date of the enactment of this Act and shall first apply to negotiations and prices for plan years beginning on January 1, 2011.

SEC. 1187. STATE CERTIFICATION PRIOR TO WAIVER OF LICENSURE REQUIREMENTS UNDER MEDICARE PRESCRIPTION DRUG PROGRAM.

(a) IN GENERAL.—Section 1860D–12(c) of the Social Security Act (42 U.S.C. 1395w–112(c)) is amended—

(1) in paragraph (1)(A), by striking "In the case" and inserting "Subject to paragraph (5), in the case"; and

(2) by adding at the end the following new paragraph:

"(5) STATE CERTIFICATION REQUIRED.—

"(A) IN GENERAL.—The Secretary may only grant a waiver under paragraph (1)(A) if the Secretary has received a certification from the State insurance commissioner that the prescription drug plan has a substantially complete application pending in the State.

"(B) REVOCATION OF WAIVER UPON FINDING OF FRAUD AND ABUSE.—The Secretary shall revoke a waiver granted under paragraph (1)(A) if the State insurance commissioner submits a certification to the Secretary that the recipient of such a waiver—

"(i) has committed fraud or abuse with respect to such waiver;

"(ii) has failed to make a good faith effort to satisfy State licensing requirements; or

"(iii) was determined ineligible for licensure by the State.".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply with respect to plan years beginning on or after January 1, 2010.

Subtitle F—Medicare Rural Access Protections

SEC. 1191. TELEHEALTH EXPANSION AND ENHANCEMENTS. .

(a) ADDITIONAL TELEHEALTH SITE.—

(1) IN GENERAL.—Paragraph (4)(C)(ii) of section 1834(m) of the Social Security Act (42 U.S.C. 1395m(m)) is amended by adding at the end the following new subclause:

"(IX) A renal dialysis facility."

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to services furnished on or after January 1, 2011.

(b) TELEHEALTH ADVISORY COMMITTEE.—

(1) ESTABLISHMENT.—Section 1868 of the Social Security Act (42 U.S.C. 1395ee) is amended—

(A) in the heading, by adding at the end the following: "TELEHEALTH ADVISORY COMMITTEE"; and

(B) by adding at the end the following new subsection:

"(c) TELEHEALTH ADVISORY COMMITTEE.—

"(1) IN GENERAL.—The Secretary shall appoint a Telehealth Advisory Committee (in this subsection referred to as the 'Advisory Committee') to make recommendations to the Secretary on policies of the Centers for Medicare & Medicaid Services regarding telehealth services as established under section 1834(m), including the appropriate addition or deletion of services (and HCPCS codes) to those specified in paragraphs (4)(F)(i) and (4)(F)(ii) of such section and for authorized payment under paragraph (1) of such section.

"(2) MEMBERSHIP; TERMS.—

"(A) MEMBERSHIP.—

"(i) IN GENERAL.—The Advisory Committee shall be composed of 9 members, to be appointed by the Secretary, of whom—

"(I) 5 shall be practicing physicians;

"(II) 2 shall be practicing non-physician health care practitioners; and

"(III) 2 shall be administrators of telehealth programs.

"(ii) REQUIREMENTS FOR APPOINTING MEMBERS.—In appointing members of the Advisory Committee, the Secretary shall—

"(I) ensure that each member has prior experience with the practice of telemedicine or telehealth;

"(II) give preference to individuals who are currently providing telemedicine or telehealth services or who are involved in telemedicine or telehealth programs;

"(III) ensure that the membership of the Advisory Committee represents a balance of specialties and geographic regions; and

"(IV) take into account the recommendations of stakeholders.

"(B) TERMS.—The members of the Advisory Committee shall serve for such term as the Secretary may specify.

"(C) CONFLICTS OF INTEREST.—An advisory committee member may not participate with respect to a particular matter considered in an advisory committee meeting if such member (or an immediate family member of such member) has a financial interest that could be affected by the advice given to the Secretary with respect to such matter.

"(3) MEETINGS.—The Advisory Committee shall meet twice each calendar year and at such other times as the Secretary may provide.

"(4) PERMANENT COMMITTEE.—Section 14 of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the Advisory Committee."

(2) FOLLOWING RECOMMENDATIONS.—Section 1834(m)(4)(F) of such Act (42 U.S.C. 1395m(m)(4)(F)) is amended by adding at the end the following new clause:

"(iii) RECOMMENDATIONS OF THE TELEHEALTH ADVISORY COMMITTEE.—In making determinations under clauses (i) and (ii), the Secretary shall take into account the recommendations of the Telehealth Advisory Committee (established under section 1868(c)) when adding or deleting services (and HCPCS codes) and in establishing policies of the Centers for Medicare & Medicaid Services regarding the delivery of telehealth services. If the Secretary does not implement such a recommendation, the Secretary shall publish in the Federal Register a statement regarding the reason such recommendation was not implemented."

(3) WAIVER OF ADMINISTRATIVE LIMITATION.—The Secretary of Health and Human Services shall establish the Telehealth Advisory Committee under the amendment made by paragraph (1) notwithstanding any limitation that may

apply to the number of advisory committees that may be established (within the Department of Health and Human Services or otherwise).

SEC. 1192. EXTENSION OF OUTPATIENT HOLD HARMLESS PROVISION.

Section 1833(t)(7)(D)(i) of the Social Security Act (42 U.S.C. 1395l(t)(7)(D)(i)) is amended—

(1) in subclause (II)—

(A) in the first sentence, by striking '"2010" and inserting "2012"; and

(B) in the second sentence, by striking "or 2009" and inserting ", 2009, 2010, or 2011"; and

(2) in subclause (III), by striking "January 1, 2010" and inserting "January 1, 2012".

SEC. 1193. EXTENSION OF SECTION 508 HOSPITAL RECLASSIFICATIONS.

Subsection (a) of section 106 of division B of the Tax Relief and Health Care Act of 2006 (42 U.S.C. 1395 note), as amended by section 117 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Public Law 110–173) and section 124 of the Medicare Improvements for Patients and Providers Act of 2008 (Public Law 110–275), is amended by striking "September 30, 2009" and inserting "September 30, 2011".

SEC. 1194. EXTENSION OF GEOGRAPHIC FLOOR FOR WORK.

Section 1848(e)(1)(E) of the Social Security Act (42 U.S.C. 1395w–4(e)(1)(E)) is amended by striking "before January 1, 2010" and inserting "before January 1, 2012".

SEC. 1195. EXTENSION OF PAYMENT FOR TECHNICAL COMPONENT OF CERTAIN PHYSICIAN PATHOLOGY SERVICES.

Section 542(c) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (as enacted into law by section 1(a)(6) of Public Law 106–554), as amended by section 732 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (42 U.S.C. 1395w–4 note), section 104 of division B of the Tax Relief and Health Care Act of 2006 (42 U.S.C. 1395w–4 note), section 104 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (Public Law 110–173), and section 136 of the Medicare Improvements for Patients and Providers Act of 1008 (Public Law 110–275), is amended by striking "and 2009" and inserting "2009, 2010, and 2011".

SEC. 1196. EXTENSION OF AMBULANCE ADD-ONS.

(a) IN GENERAL.—Section 1834(l)(13) of the Social Security Act (42 U.S.C. 1395m(l)(13)) is amended—

(1) in subparagraph (A)—

(A) in the matter preceding clause (i), by striking "before January 1, 2010" and inserting "before January 1, 2012"; and

(B) in each of clauses (i) and (ii), by striking "before January 1, 2010" and inserting "before January 1, 2012".

(b) AIR AMBULANCE IMPROVEMENTS.—Section 146(b)(1) of the Medicare Improvements for Patients and Providers Act of 2008 (Public Law 110–275) is amended by striking "ending on December 31, 2009" and inserting "ending on December 31, 2011".

SEC. 1197. ENSURING PROPORTIONAL REPRESENTATION OF INTERESTS OF RURAL AREAS ON MEDPAC.

(a) IN GENERAL.—Section 1805(c)(2) of the Social Security Act (42 U.S.C. 1395b-6(c)(2)) is amended—

(1) in subparagraph (A), by inserting "consistent with subparagraph (E)" after "rural representatives"; and

(2) by adding at the end the following new subparagraph:

"(E) PROPORTIONAL REPRESENTATION OF INTERESTS OF RURAL AREAS.—In order to provide a balance between urban and rural representatives under subparagraph (A), the proportion of members of the Commission who represent the interests of health care providers and Medicare beneficiaries located in rural areas shall be no less than the proportion of the total number of Medicare beneficiaries who reside in rural areas.".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to appointments to the Medicare Payment Advisory Commission made after the date of the enactment of this Act.

TITLE II—MEDICARE BENEFICIARY IMPROVEMENTS

Subtitle A—Improving and Simplifying Financial Assistance for Low Income Medicare Beneficiaries

SEC. 1201. IMPROVING ASSETS TESTS FOR MEDICARE SAVINGS PROGRAM AND LOW-INCOME SUBSIDY PROGRAM.

(a) APPLICATION OF HIGHEST LEVEL PERMITTED UNDER LIS TO ALL SUBSIDY ELIGIBLE INDIVIDUALS.—

(1) IN GENERAL.—Section 1860D–14(a)(1) of the Social Security Act (42 U.S.C. 1395w–114(a)(1)) is amended in the matter before subparagraph (A), by inserting "(or, beginning with 2012, paragraph (3)(E))" after "paragraph (3)(D)".

(2) ANNUAL INCREASE IN LIS RESOURCE TEST.—Section 1860D–14(a)(3)(E)(i) of such Act (42 U.S.C. 1395w–114(a)(3)(E)(i)) is amended—

(A) by striking "and" at the end of subclause (I);

(B) in subclause (II), by inserting "(before 2012)" after "subsequent year";

(C) by striking the period at the end of subclause (II) and inserting a semicolon;

(D) by inserting after subclause (II) the following new subclauses:

"(III) for 2012, $17,000 (or $34,000 in the case of the combined value of the individual's assets or resources and the assets or resources of the individual's spouse); and

"(IV) for a subsequent year, the dollar amounts specified in this subclause (or subclause (III)) for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year."; and

(E) in the last sentence, by inserting "or (IV)" after "subclause (II)".

(3) APPLICATION OF LIS TEST UNDER MEDICARE SAVINGS PROGRAM.—Section 1905(p)(1)(C) of such Act (42 U.S.C. 1396d(p)(1)(C)) is amended—

(A) by striking "effective beginning with January 1, 2010" and inserting "effective for the period beginning with January 1, 2010, and ending with December 31, 2011"; and

(B) by inserting before the period at the end the following: "or, effective beginning with January 1, 2012, whose resources (as so determined) do not exceed the maximum resource level applied for the year under subparagraph (E) of section 1860D–14(a)(3) (determined without regard to the life insurance policy exclusion provided under subparagraph (G) of such section) applicable to an individual or to the individual and the individual's spouse (as the case may be)".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to eligibility determinations for income-related subsidies and medicare cost-sharing furnished for periods beginning on or after January 1, 2012.

SEC. 1202. ELIMINATION OF PART D COST-SHARING FOR CERTAIN NONINSTITUTIONALIZED FULL-BENEFIT DUAL ELIGIBLE INDIVIDUALS.

(a) IN GENERAL.—Section 1860D–14(a)(1)(D)(i) of the Social Security Act (42 U.S.C. 1395w–114(a)(1)(D)(i)) is amended—

(1) by striking "INSTITUTIONALIZED INDIVIDUALS.—In" and inserting "ELIMINATION OF COST-SHARING FOR CERTAIN FULL-BENEFIT DUAL ELIGIBLE INDIVIDUALS.—

"(I) INSTITUTIONALIZED INDIVIDUALS.—In"; and

(2) by adding at the end the following new subclause:

"(II) CERTAIN OTHER INDIVIDUALS.—In the case of an individual who is a full-benefit dual eligible individual and with respect to whom there has been a determination that but for the provision of home and community based care (whether under section 1915, 1932, or under a waiver under section 1115) the individual would require the level of care provided in a hospital or a nursing facility or intermediate care facility for the mentally retarded the cost of which could be reimbursed under the State plan under title XIX, the elimination of any beneficiary coinsurance described in section 1860D–2(b)(2) (for all amounts through the total amount of expenditures at which benefits are available under section 1860D–2(b)(4)).".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to drugs dispensed on or after January 1, 2011.

SEC. 1203. ELIMINATING BARRIERS TO ENROLLMENT.

(a) ADMINISTRATIVE VERIFICATION OF INCOME AND RESOURCES UNDER THE LOW-INCOME SUBSIDY PROGRAM.—

(1) IN GENERAL.—Clause (iii) of section 1860D–14(a)(3)(E) of the Social Security Act (42 U.S.C. 1395w–114(a)(3)(E)) is amended to read as follows:

"(iii) CERTIFICATION OF INCOME AND RESOURCES.—For purposes of applying this section—

"(I) an individual shall be permitted to apply on the basis of self-certification of income and resources; and

"(II) matters attested to in the application shall be subject to appropriate methods of verification without the need of the individual to provide additional documentation, except in extraordinary situations as determined by the Commissioner.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply beginning January 1, 2010.

(b) DISCLOSURES TO FACILITATE IDENTIFICATION OF INDIVIDUALS LIKELY TO BE INELIGIBLE FOR THE LOW-INCOME ASSISTANCE UNDER THE MEDICARE PRESCRIPTION DRUG PROGRAM TO ASSIST SOCIAL SECURITY ADMINISTRATION'S OUTREACH TO ELIGIBLE INDIVIDUALS.—For provision authorizing disclosure of return information to facilitate identification of individuals likely to be ineligible for low-income subsidies under Medicare prescription drug program, see section 1801.

SEC. 1204. ENHANCED OVERSIGHT RELATING TO REIMBURSEMENTS FOR RETROACTIVE LOW INCOME SUBSIDY ENROLLMENT.

(a) IN GENERAL.—In the case of a retroactive LIS enrollment beneficiary who is enrolled under a prescription drug plan under part D of title XVIII of the Social Security Act (or an MA-PD plan under part C of such title), the beneficiary (or any eligible third party) is entitled to reimbursement by the plan for covered drug costs incurred by the beneficiary during the retroactive coverage period of the beneficiary in accordance with subsection (b) and in the case of such a beneficiary described in subsection (c)(4)(A)(i), such reimbursement shall be made automatically by the plan upon receipt of appropriate notice the beneficiary is eligible for assistance described in such subsection (c)(4)(A)(i) without further information required to be filed with the plan by the beneficiary.

(b) ADMINISTRATIVE REQUIREMENTS RELATING TO REIMBURSEMENTS.—

(1) LINE-ITEM DESCRIPTION.—Each reimbursement made by a prescription drug plan or MA-PD plan under subsection (a) shall include a line-item description of the items for which the reimbursement is made.

(2) TIMING OF REIMBURSEMENTS.—A prescription drug plan or MA-PD plan must make a reimbursement under subsection (a) to a retroactive LIS enrollment beneficiary, with respect to a claim, not later than 45 days after—

(A) in the case of a beneficiary described in subsection (c)(4)(A)(i), the date on which the plan receives notice from the Secretary that the beneficiary is eligible for assistance described in such subsection; or

(B) in the case of a beneficiary described in subsection (c)(4)(A)(ii), the date on which the beneficiary files the claim with the plan.

(3) REPORTING REQUIREMENT.—For each month beginning with January 2011, each prescription drug plan and each MA-PD plan shall report to the Secretary the following:

(A) The number of claims the plan has readjudicated during the month due to a beneficiary becoming retroactively eligible for subsidies available under section 1860D-14 of the Social Security Act.

(B) The total value of the readjudicated claim amount for the month.

(C) The Medicare Health Insurance Claims Number of beneficiaries for whom claims were readjudicated.

(D) For the claims described in subparagraphs (A) and (B), an attestation to the Administrator of the Centers for Medicare & Medicaid Services of the total amount of reimbursement the plan has provided to beneficiaries for premiums and cost-sharing that the beneficiary overpaid for which the plan received payment from the Centers for Medicare & Medicaid Services.

(c) DEFINITIONS.—For purposes of this section:

(1) COVERED DRUG COSTS.—The term "covered drug costs" means, with respect to a retroactive LIS enrollment beneficiary enrolled under a prescription drug plan under part D of title XVIII of the Social Security Act (or an MA-PD plan under part C of such title), the amount by which—

(A) the costs incurred by such beneficiary during the retroactive coverage period of the beneficiary for covered part D drugs, premiums, and cost-sharing under such title; exceeds

(B) such costs that would have been incurred by such beneficiary during such period if the beneficiary had been both enrolled in the plan and recog-

nized by such plan as qualified during such period for the low income subsidy under section 1860D-14 of the Social Security Act to which the individual is entitled.

(2) ELIGIBLE THIRD PARTY.—The term "eligible third party" means, with respect to a retroactive LIS enrollment beneficiary, an organization or other third party that is owed payment on behalf of such beneficiary for covered drug costs incurred by such beneficiary during the retroactive coverage period of such beneficiary.

(3) RETROACTIVE COVERAGE PERIOD.—The term "retroactive coverage period" means—

(A) with respect to a retroactive LIS enrollment beneficiary described in paragraph (4)(A)(i), the period—

(i) beginning on the effective date of the assistance described in such paragraph for which the individual is eligible; and

(ii) ending on the date the plan effectuates the status of such individual as so eligible; and

(B) with respect to a retroactive LIS enrollment beneficiary described in paragraph (4)(A)(ii), the period—

(i) beginning on the date the individual is both entitled to benefits under part A, or enrolled under part B, of title XVIII of the Social Security Act and eligible for medical assistance under a State plan under title XIX of such Act; and

(ii) ending on the date the plan effectuates the status of such individual as a full-benefit dual eligible individual (as defined in section 1935(c)(6) of such Act).

(4) RETROACTIVE LIS ENROLLMENT BENEFICIARY.—

(A) IN GENERAL.—The term "retroactive LIS enrollment beneficiary" means an individual who—

(i) is enrolled in a prescription drug plan under part D of title XVIII of the Social Security Act (or an MA-PD plan under part C of such title) and subsequently becomes eligible as a full-benefit dual eligible individual (as defined in section 1935(c)(6) of such Act), an individual receiving a low-income subsidy under section 1860D-14 of such Act, an individual receiving assistance under the Medicare Savings Program implemented under clauses (i), (iii), and (iv) of section 1902(a)(10)(E) of such Act, or an individual receiving assistance under the supplemental security income program under section 1611 of such Act; or

(ii) subject to subparagraph (B)(i), is a full-benefit dual eligible individual (as defined in section 1935(c)(6) of such Act) who is automatically enrolled in such a plan under section 1860D-1(b)(1)(C) of such Act.

(B) EXCEPTION FOR BENEFICIARIES ENROLLED IN RFP PLAN.—

(i) IN GENERAL.—In no case shall an individual described in subparagraph (A)(ii) include an individual who is enrolled, pursuant to a RFP contract described in clause (ii), in a prescription drug plan offered by the sponsor of such plan awarded such contract.

(ii) RFP CONTRACT DESCRIBED.—The RFP contract described in this section is a contract entered into between the Secretary and a sponsor of a prescription drug plan pursuant to the Centers for Medicare & Medicaid Services' request for proposals issued on February 17, 2009, relating to Medicare part D retroactive coverage for certain low income beneficiaries, or a similar subsequent request for proposals.

SEC. 1205. INTELLIGENT ASSIGNMENT IN ENROLLMENT.

(a) IN GENERAL.—Section 1860D–1(b)(1)(C) of the Social Security Act (42 U.S.C. 1395w–101(b)(1)(C)) is amended by adding after "PDP region" the following: "or through use of an intelligent assignment process that is designed to maximize the access of such individual to necessary prescription drugs while minimizing costs to such individual and to the program under this part to the greatest extent possible. In the case the Secretary enrolls such individuals through use of an intelligent assignment process, such process shall take into account the extent to which prescription drugs necessary for the individual are covered in the case of a PDP sponsor of a prescription drug plan that uses a formulary, the use of prior authorization or other restrictions on access to coverage of such prescription drugs by such a sponsor, and the overall quality of a prescription drug plan as measured by quality ratings established by the Secretary"

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect for contract years beginning with 2012.

SEC. 1206. SPECIAL ENROLLMENT PERIOD AND AUTOMATIC ENROLLMENT PROCESS FOR CERTAIN SUBSIDY ELIGIBLE INDIVIDUALS.

(a) SPECIAL ENROLLMENT PERIOD.—Section 1860D–1(b)(3)(D) of the Social Security Act (42 U.S.C. 1395w–101(b)(3)(D)) is amended to read as follows:

"(D) SUBSIDY ELIGIBLE INDIVIDUALS.—In the case of an individual (as determined by the Secretary) who is determined under subparagraph (B) of section 1860D–14(a)(3) to be a subsidy eligible individual.".

(b) AUTOMATIC ENROLLMENT.—Section 1860D–1(b)(1) of the Social Security Act (42 U.S.C. 1395w–101(b)(1)) is amended by adding at the end the following new subparagraph:

"(D) SPECIAL RULE FOR SUBSIDY ELIGIBLE INDIVIDUALS.—The process established under subparagraph (A) shall include, in the case of an individual described in paragraph (3)(D) who fails to enroll in a prescription drug plan or an MA–PD plan during the special enrollment established under such section applicable to such individual, the application of the assignment process described in subparagraph (C) to such individual in the same manner as such assignment process applies to a part D eligible individual described in such subparagraph (C). Nothing in the previous sentence shall prevent an individual described in such sentence from declining enrollment in a plan determined appropriate by the Secretary (or in the program under this part) or from changing such enrollment.".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to subsidy determinations made for months beginning with January 2011.

SEC. 1207. APPLICATION OF MA PREMIUMS PRIOR TO REBATE IN CALCULATION OF LOW INCOME SUBSIDY BENCHMARK.

(a) IN GENERAL.—Section 1860D–14(b)(2)(B)(iii) of the Social Security Act (42 U.S.C. 1395w–114(b)(2)(B)(iii)) is amended by inserting before the period the following: "before the application of the monthly rebate computed under section 1854(b)(1)(C)(i) for that plan and year involved".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to subsidy determinations made for months beginning with January 2011.

Subtitle B—Reducing Health Disparities

SEC. 1221. ENSURING EFFECTIVE COMMUNICATION IN MEDICARE.

(a) ENSURING EFFECTIVE COMMUNICATION BY THE CENTERS FOR MEDICARE & MEDICAID SERVICES.—

(1) STUDY ON MEDICARE PAYMENTS FOR LANGUAGE SERVICES.—The Secretary of Health and Human Services shall conduct a study that examines the extent to which Medicare service providers utilize, offer, or make available language services for beneficiaries who are limited English proficient and ways that Medicare should develop payment systems for language services.

(2) ANALYSES.—The study shall include an analysis of each of the following:

(A) How to develop and structure appropriate payment systems for language services for all Medicare service providers.

(B) The feasibility of adopting a payment methodology for on-site interpreters, including interpreters who work as independent contractors and interpreters who work for agencies that provide on-site interpretation, pursuant to which such interpreters could directly bill Medicare for services provided in support of physician office services for an LEP Medicare patient.

(C) The feasibility of Medicare contracting directly with agencies that provide off-site interpretation including telephonic and video interpretation pursuant to which such contractors could directly bill Medicare for the services provided in support of physician office services for an LEP Medicare patient.

(D) The feasibility of modifying the existing Medicare resource-based relative value scale (RBRVS) by using adjustments (such as multipliers or add-ons) when a patient is LEP.

(E) How each of options described in a previous paragraph would be funded and how such funding would affect physician payments, a physician's practice, and beneficiary cost-sharing.

(F) The extent to which providers under parts A and B of title XVIII of the Social Security Act, MA organizations offering Medicare Advantage plans under part C of such title and PDP sponsors of a prescription drug plan under part D of such title utilize, offer, or make available language services for beneficiaries with limited English proficiency.

(G) The nature and type of language services provided by States under title XIX of the Social Security Act and the extent to which such services could be utilized by beneficiaries and providers under title XVIII of such Act.

(3) VARIATION IN PAYMENT SYSTEM DESCRIBED.—The payment systems described in paragraph (2)(A) may allow variations based upon types of service providers, available delivery methods, and costs for providing language services including such factors as—

(A) the type of language services provided (such as provision of health care or health care related services directly in a non-English language by a bilingual provider or use of an interpreter);

(B) type of interpretation services provided (such as in-person, telephonic, video interpretation);

(C) the methods and costs of providing language services (including the costs of providing language services with internal staff or through contract with external independent contractors or agencies, or both);

(D) providing services for languages not frequently encountered in the United States; and

(E) providing services in rural areas.

(4) REPORT.—The Secretary shall submit a report on the study conducted under subsection (a) to appropriate committees of Congress not later than 12 months after the date of the enactment of this Act.

(5) EXEMPTION FROM PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code (commonly known as the "Paperwork Reduction Act"), shall not apply for purposes of carrying out this subsection.

(6) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection such sums as are necessary.

(b) HEALTH PLANS.—Section 1857(g)(1) of the Social Security Act (42 U.S.C. 1395w–27(g)(1)) is amended—

(1) by striking "or" at the end of subparagraph (F);

(2) by adding "or" at the end of subparagraph (G); and

(3) by inserting after subparagraph (G) the following new subparagraph:

"(H) fails substantially to provide language services to limited English proficient beneficiaries enrolled in the plan that are required under law;".

SEC. 1222. DEMONSTRATION TO PROMOTE ACCESS FOR MEDICARE BENEFICIARIES WITH LIMITED-ENGLISH PROFICIENCY BY PROVIDING REIMBURSEMENT FOR CULTURALLY AND LINGUISTICALLY APPROPRIATE SERVICES.

(a) IN GENERAL.—Not later than 6 months after the date of the completion of the study described in section 1221(a), the Secretary, acting through the Centers for Medicare & Medicaid Services and the Center for Medicare and Medicaid Payment Innovation established under section 1115A of the Social Security Act (as added by section 1910) and consistent with the applicable provisions of such section, shall carry out a demonstration program under which the Secretary shall award not fewer than 24 3-year grants to eligible Medicare service providers (as described in subsection (b)(1)) to improve effective communication between such providers and Medicare beneficiaries who are living in communities where racial and ethnic minorities, including populations that face language barriers, are underserved with respect to such services. In designing and carrying out the demonstration the Secretary shall take into consideration the results of the study conducted under section 1221(a) and adjust, as appropriate, the distribution of grants so as to better target Medicare beneficiaries who are in the greatest need of language services. The Secretary shall not authorize a grant larger than $500,000 over three years for any grantee.

(b) ELIGIBILITY; PRIORITY.—

(1) ELIGIBILITY.—To be eligible to receive a grant under subsection (a) an entity shall—

(A) be—

(i) a provider of services under part A of title XVIII of the Social Security Act;

(ii) a service provider under part B of such title;

(iii) a part C organization offering a Medicare part C plan under part C of such title; or

(iv) a PDP sponsor of a prescription drug plan under part D of such title; and

(B) prepare and submit to the Secretary an application, at such time, in such manner, and accompanied by such additional information as the Secretary may require.

(2) PRIORITY.—

(A) DISTRIBUTION.—To the extent feasible, in awarding grants under this section, the Secretary shall award—

(i) at least 6 grants to providers of services described in paragraph (1)(A)(i);

(ii) at least 6 grants to service providers described in paragraph (1)(A)(ii);

(iii) at least 6 grants to organizations described in paragraph (1)(A)(iii); and

(iv) at least 6 grants to sponsors described in paragraph (1)(A)(iv).

(B) FOR COMMUNITY ORGANIZATIONS.—The Secretary shall give priority to applicants that have developed partnerships with community organizations or with agencies with experience in language access.

(C) VARIATION IN GRANTEES.—The Secretary shall also ensure that the grantees under this section represent, among other factors, variations in—

(i) different types of language services provided and of service providers and organizations under parts A through D of title XVIII of the Social Security Act;

(ii) languages needed and their frequency of use;

(iii) urban and rural settings;

(iv) at least two geographic regions, as defined by the Secretary; and

(v) at least two large metropolitan statistical areas with diverse populations.

(c) USE OF FUNDS.—

(1) IN GENERAL.—A grantee shall use grant funds received under this section to pay for the provision of competent language services to Medicare beneficiaries who are limited-English proficient. Competent interpreter services may be provided through on-site interpretation, telephonic interpretation, or video interpretation or direct provision of health care or health care related services by a bilingual health care provider. A grantee may use bilingual providers, staff, or contract interpreters. A grantee may use grant funds to pay for competent translation services. A grantee may use up to 10 percent of the grant funds to pay for administrative costs associated with the provision of competent language services and for reporting required under subsection (e).

(2) ORGANIZATIONS.—Grantees that are part C organizations or PDP sponsors must ensure that their network providers receive at least 50 percent of the grant funds to pay for the provision of competent language services to Medicare beneficiaries who are limited-English proficient, including physicians and pharmacies.

(3) DETERMINATION OF PAYMENTS FOR LANGUAGE SERVICES.—Payments to grantees shall be calculated based on the estimated numbers of limited-English proficient Medicare beneficiaries in a grantee's service area utilizing—

(A) data on the numbers of limited-English proficient individuals who speak English less than "very well" from the most recently available data from the Bureau of the Census or other State-based study the Secretary determines likely to yield accurate data regarding the number of such individuals served by the grantee; or

(B) the grantee's own data if the grantee routinely collects data on Medicare beneficiaries' primary language in a manner determined by the Secretary to yield accurate data and such data shows greater numbers of limited-English proficient individuals than the data listed in subparagraph (A).

(4) LIMITATIONS.—

(A) REPORTING.—Payments shall only be provided under this section to grantees that report their costs of providing language services as required under subsection (e) and may be modified annually at the discretion of the Secretary. If a grantee fails to provide the reports under such section for the first year of a grant, the Secretary may terminate the grant and solicit applications from new grantees to participate in the subsequent two years of the demonstration program.

(B) TYPE OF SERVICES.—

(i) IN GENERAL.—Subject to clause (ii), payments shall be provided under this section only to grantees that utilize competent bilingual staff or competent interpreter or translation services which—

(I) if the grantee operates in a State that has statewide health care interpreter standards, meet the State standards currently in effect; or

(II) if the grantee operates in a State that does not have statewide health care interpreter standards, utilizes competent interpreters who follow the National Council on Interpreting in Health Care's Code of Ethics and Standards of Practice.

(ii) EXEMPTIONS.—The requirements of clause (i) shall not apply—

(I) in the case of a Medicare beneficiary who is limited-English proficient (who has been informed in the beneficiary's primary language of the availability of free interpreter and translation services) and who requests the use of family, friends, or other persons untrained in interpretation or translation and the grantee documents the request in the beneficiary's record; and

(II) in the case of a medical emergency where the delay directly associated with obtaining a competent interpreter or translation services would jeopardize the health of the patient.

Nothing in clause (ii)(II) shall be construed to exempt emergency rooms or similar entities that regularly provide health care services in medical emergencies from having in place systems to provide competent interpreter and translation services without undue delay.

(d) ASSURANCES.—Grantees under this section shall—

(1) ensure that appropriate clinical and support staff receive ongoing education and training in linguistically appropriate service delivery;

(2) ensure the linguistic competence of bilingual providers;

(3) offer and provide appropriate language services at no additional charge to each patient with limited-English proficiency at all points of contact, in a timely manner during all hours of operation;

(4) notify Medicare beneficiaries of their right to receive language services in their primary language;

(5) post signage in the languages of the commonly encountered group or groups present in the service area of the organization; and

(6) ensure that—

(A) primary language data are collected for recipients of language services; and

(B) consistent with the privacy protections provided under the regulations promulgated pursuant to section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note), if the recipient of language services is a minor or is incapacitated, the primary language of the parent or legal guardian is collected and utilized.

(e) REPORTING REQUIREMENTS.—Grantees under this section shall provide the Secretary with reports at the conclusion of the each year of a grant under this section. Each report shall include at least the following information:

(1) The number of Medicare beneficiaries to whom language services are provided.

(2) The languages of those Medicare beneficiaries.

(3) The types of language services provided (such as provision of services directly in non-English language by a bilingual health care provider or use of an interpreter).

(4) Type of interpretation (such as in-person, telephonic, or video interpretation).

(5) The methods of providing language services (such as staff or contract with external independent contractors or agencies).

(6) The length of time for each interpretation encounter.

(7) The costs of providing language services (which may be actual or estimated, as determined by the Secretary).

(f) NO COST SHARING.—Limited-English proficient Medicare beneficiaries shall not have to pay cost-sharing or co-pays for language services provided through this demonstration program.

(g) EVALUATION AND REPORT.—The Secretary shall conduct an evaluation of the demonstration program under this section and shall submit to the appropriate committees of Congress a report not later than 1 year after the completion of the program. The report shall include the following:

(1) An analysis of the patient outcomes and costs of furnishing care to the limited-English proficient Medicare beneficiaries participating in the project as compared to such outcomes and costs for limited-English proficient Medicare beneficiaries not participating.

(2) The effect of delivering culturally and linguistically appropriate services on beneficiary access to care, utilization of services, efficiency and cost-effectiveness of health care delivery, patient satisfaction, and select health outcomes.

(3) Recommendations, if any, regarding the extension of such project to the entire Medicare program.

(h) GENERAL PROVISIONS.—Nothing in this section shall be construed to limit otherwise existing obligations of recipients of Federal financial assistance under title VI of the Civil Rights Act of 1964 (42 U.S.C. 2000(d) et seq.) or any other statute.

(i) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $16,000,000 for each fiscal year of the demonstration program.

SEC. 1223. IOM REPORT ON IMPACT OF LANGUAGE ACCESS SERVICES.

(a) IN GENERAL.—The Secretary of Health and Human Services shall enter into an arrangement with the Institute of Medicine under which the Institute will prepare and publish, not later than 3 years after the date of the enactment of this Act, a report on the impact of language access services on the health and health care of limited-English proficient populations.

(b) CONTENTS.—Such report shall include—

(1) recommendations on the development and implementation of policies and practices by health care organizations and providers for limited-English proficient patient populations;

(2) a description of the effect of providing language access services on quality of health care and access to care and reduced medical error; and

(3) a description of the costs associated with or savings related to provision of language access services.

SEC. 1224. DEFINITIONS.

In this subtitle:

(1) BILINGUAL.—The term "bilingual" with respect to an individual means a person who has sufficient degree of proficiency in two languages and can ensure effective communication can occur in both languages.

(2) COMPETENT INTERPRETER SERVICES.—The term "competent interpreter services" means a trans-language rendition of a spoken message in which the interpreter comprehends the source language and can speak comprehensively in the target language to convey the meaning intended in the source language. The interpreter knows health and health-related terminology and provides accurate interpretations by choosing equivalent expressions that convey the best matching and meaning to the source language and captures, to the greatest possible extent, all nuances intended in the source message.

(3) COMPETENT TRANSLATION SERVICES.—The term "competent translation services" means a trans-language rendition of a written document in which the translator comprehends the source language and can write comprehensively in the target language to convey the meaning intended in the source language. The translator knows health and health-related terminology and provides accurate translations by choosing equivalent expressions that convey the best matching and meaning to the source language and captures, to the greatest possible extent, all nuances intended in the source document.

(4) EFFECTIVE COMMUNICATION.—The term "effective communication" means an exchange of information between the provider of health care or health care-related services and the limited-English proficient recipient of such services that enables limited-English proficient individuals to access, understand, and benefit from health care or health care-related services.

(5) INTERPRETING/INTERPRETATION.—The terms "interpreting" and "interpretation" mean the transmission of a spoken message from one language into another, faithfully, accurately, and objectively.

(6) HEALTH CARE SERVICES.—The term "health care services" means services that address physical as well as mental health conditions in all care settings.

(7) HEALTH CARE-RELATED SERVICES.—The term "health care-related services" means human or social services programs or activities that provide access, referrals or links to health care.

(8) LANGUAGE ACCESS.—The term "language access" means the provision of language services to an LEP individual designed to enhance that individual's access to, understanding of or benefit from health care or health care-related services.

(9) LANGUAGE SERVICES.—The term "language services" means provision of health care services directly in a non-English language, interpretation, translation, and non-English signage.

(10) LIMITED-ENGLISH PROFICIENT.—The term "limited-English proficient" or "LEP" with respect to an individual means an individual who speaks a primary language other than English and who cannot speak, read, write or understand the English language at a level that permits the individual to effectively communicate with clinical or nonclinical staff at an entity providing health care or health care related services.

(11) MEDICARE BENEFICIARY.—The term "Medicare beneficiary" means an individual entitled to benefits under part A of title XVIII of the Social Security Act or enrolled under part B of such title.

(12) MEDICARE PROGRAM.—The term "Medicare program" means the programs under parts A through D of title XVIII of the Social Security Act.

(13) SERVICE PROVIDER.—The term "service provider" includes all suppliers, providers of services, or entities under contract to provide coverage, items or services under any part of title XVIII of the Social Security Act.

Subtitle C—Miscellaneous Improvements

SEC. 1231. EXTENSION OF THERAPY CAPS EXCEPTIONS PROCESS.

Section 1833(g)(5) of the Social Security Act (42 U.S.C. 1395l(g)(5)), as amended by section 141 of the Medicare Improvements for Patients and Providers Act of 2008 (Public Law 110–275), is amended by striking "December 31, 2009" and inserting "December 31, 2011".

SEC. 1232. EXTENDED MONTHS OF COVERAGE OF IMMUNOSUPPRESSIVE DRUGS FOR KIDNEY TRANSPLANT PATIENTS AND OTHER RENAL DIALYSIS PROVISIONS.

(a) PROVISION OF APPROPRIATE COVERAGE OF IMMUNOSUPPRESSIVE DRUGS UNDER THE MEDICARE PROGRAM FOR KIDNEY TRANSPLANT RECIPIENTS.—

(1) CONTINUED ENTITLEMENT TO IMMUNOSUPPRESSIVE DRUGS.—

(A) KIDNEY TRANSPLANT RECIPIENTS.—Section 226A(b)(2) of the Social Security Act (42 U.S.C. 426–1(b)(2)) is amended by inserting "(except for coverage of immunosuppressive drugs under section 1861(s)(2)(J))" before ", with the thirty-sixth month".

(B) APPLICATION.—Section 1836 of such Act (42 U.S.C. 1395o) is amended—

(i) by striking "Every individual who" and inserting "(a) IN GENERAL.—Every individual who"; and

(ii) by adding at the end the following new subsection:

"(b) SPECIAL RULES APPLICABLE TO INDIVIDUALS ONLY ELIGIBLE FOR COVERAGE OF IMMUNOSUPPRESSIVE DRUGS.—

"(1) IN GENERAL.—In the case of an individual whose eligibility for benefits under this title has ended on or after January 1, 2012, except for the coverage of immunosuppressive drugs by reason of section 226A(b)(2), the following rules shall apply:

"(A) The individual shall be deemed to be enrolled under this part for purposes of receiving coverage of such drugs.

"(B) The individual shall be responsible for providing for payment of the portion of the premium under section 1839 which is not covered under the Medicare savings program (as defined in section 1144(c)(7)) in order to receive such coverage.

"(C) The provision of such drugs shall be subject to the application of—

"(i) the deductible under section 1833(b); and

"(ii) the coinsurance amount applicable for such drugs (as determined under this part).

"(D) If the individual is an inpatient of a hospital or other entity, the individual is entitled to receive coverage of such drugs under this part.

"(2) ESTABLISHMENT OF PROCEDURES IN ORDER TO IMPLEMENT COVERAGE.—The Secretary shall establish procedures for—

"(A) identifying individuals that are entitled to coverage of immunosuppressive drugs by reason of section 226A(b)(2); and

"(B) distinguishing such individuals from individuals that are enrolled under this part for the complete package of benefits under this part.".

(C) TECHNICAL AMENDMENT TO CORRECT DUPLICATE SUBSECTION DESIGNATION.—Subsection (c) of section 226A of such Act (42 U.S.C. 426–1), as added by section 201(a)(3)(D)(ii) of the Social Security Independence and Program Improvements Act of 1994 (Public Law 103–296; 108 Stat. 1497), is redesignated as subsection (d).

(2) EXTENSION OF SECONDARY PAYER REQUIREMENTS FOR ESRD BENEFICIARIES.—Section 1862(b)(1)(C) of such Act (42 U.S.C. 1395y(b)(1)(C)) is amended by adding at the end the following new sentence: "With regard to immunosuppressive drugs furnished on or after the date of the enactment of the America's Affordable Health Choices Act of 2009, this subparagraph shall be applied without regard to any time limitation.".

(b) MEDICARE COVERAGE FOR ESRD PATIENTS.—Section 1881 of such Act is further amended—

(1) in subsection (b)(14)(B)(iii), by inserting ", including oral drugs that are not the oral equivalent of an intravenous drug (such as oral phosphate binders and calcimimetics)," after "other drugs and biologicals";

(2) in subsection (b)(14)(E)(ii)—

(A) in the first sentence—

(i) by striking "a one-time election to be excluded from the phase-in" and inserting "an election, with respect to 2011, 2012, or 2013, to be excluded from the phase-in (or the remainder of the phase-in)"; and

(ii) by adding before the period at the end the following: "for such year and for each subsequent year during the phase-in described in clause (i)"; and

(B) in the second sentence—

(i) by striking "January 1, 2011" and inserting "the first date of such year"; and

(ii) by inserting "and at a time" after "form and manner"; and

(3) in subsection (h)(4)(E), by striking "lesser" and inserting "greater".

SEC. 1233. ADVANCE CARE PLANNING CONSULTATION.

(a) MEDICARE.—

(1) IN GENERAL.—Section 1861 of the Social Security Act (42 U.S.C. 1395x) is amended—

(A) in subsection (s)(2)—

(i) by striking "and" at the end of subparagraph (DD);

(ii) by adding "and" at the end of subparagraph (EE); and

(iii) by adding at the end the following new subparagraph:

"(FF) advance care planning consultation (as defined in subsection (hhh)(1));"; and

(B) by adding at the end the following new subsection:

"Advance Care Planning Consultation

"(hhh)(1) Subject to paragraphs (3) and (4), the term 'advance care planning consultation' means a consultation between the individual and a practitioner described in paragraph (2) regarding advance care planning, if, subject to paragraph (3), the individual involved has not had such a consultation within the last 5 years. Such consultation shall include the following:

"(A) An explanation by the practitioner of advance care planning, including key questions and considerations, important steps, and suggested people to talk to.

"(B) An explanation by the practitioner of advance directives, including living wills and durable powers of attorney, and their uses.

"(C) An explanation by the practitioner of the role and responsibilities of a health care proxy.

"(D) The provision by the practitioner of a list of national and State-specific resources to assist consumers and their families with advance care planning, including the national toll-free hotline, the advance care planning clearinghouses, and State legal service organizations (including those funded through the Older Americans Act of 1965).

"(E) An explanation by the practitioner of the continuum of end-of-life services and supports available, including palliative care and hospice, and benefits for such services and supports that are available under this title.

"(F)(i) Subject to clause (ii), an explanation of orders regarding life sustaining treatment or similar orders, which shall include—

"(I) the reasons why the development of such an order is beneficial to the individual and the individual's family and the reasons why such an order should be updated periodically as the health of the individual changes;

"(II) the information needed for an individual or legal surrogate to make informed decisions regarding the completion of such an order; and

"(III) the identification of resources that an individual may use to determine the requirements of the State in which such individual resides so that the treatment wishes of that individual will be carried out if the individual is unable to communicate those wishes, including requirements regarding the designation of a surrogate decisionmaker (also known as a health care proxy).

"(ii) The Secretary shall limit the requirement for explanations under clause (i) to consultations furnished in a State—

"(I) in which all legal barriers have been addressed for enabling orders for life sustaining treatment to constitute a set of medical orders respected across all care settings; and

"(II) that has in effect a program for orders for life sustaining treatment described in clause (iii).

"(iii) A program for orders for life sustaining treatment for a States described in this clause is a program that—

"(I) ensures such orders are standardized and uniquely identifiable throughout the State;

"(II) distributes or makes accessible such orders to physicians and other health professionals that (acting within the scope of the professional's authority under State law) may sign orders for life sustaining treatment;

"(III) provides training for health care professionals across the continuum of care about the goals and use of orders for life sustaining treatment; and

"(IV) is guided by a coalition of stakeholders includes representatives from emergency medical services, emergency department physicians or nurses, state long-term care association, state medical association, state surveyors, agency responsible for senior services, state department of health, state hospital association, home health association, state bar association, and state hospice association.

"(2) A practitioner described in this paragraph is—

"(A) a physician (as defined in subsection (r)(1)); and

"(B) a nurse practitioner or physician assistant who has the authority under State law to sign orders for life sustaining treatments.

"(3)(A) An initial preventive physical examination under subsection (WW), including any related discussion during such examination, shall not be considered an advance care planning consultation for purposes of applying the 5-year limitation under paragraph (1).

"(B) An advance care planning consultation with respect to an individual may be conducted more frequently than provided under paragraph (1) if there is a significant change in the health condition of the individual, including diagnosis of a chronic, progressive, life-limiting disease, a life-threatening or terminal diagnosis or life-threatening injury, or upon admission to a skilled nursing facility, a long-term care facility (as defined by the Secretary), or a hospice program.

"(4) A consultation under this subsection may include the formulation of an order regarding life sustaining treatment or a similar order.

"(5)(A) For purposes of this section, the term 'order regarding life sustaining treatment' means, with respect to an individual, an actionable medical order relating to the treatment of that individual that—

"(i) is signed and dated by a physician (as defined in subsection (r)(1)) or another health care professional (as specified by the Secretary and who is acting within the scope of the professional's authority under State law in signing such an order, including a nurse practitioner or physician assistant) and is in a form that permits it to stay with the individual and be followed by health care professionals and providers across the continuum of care;

"(ii) effectively communicates the individual's preferences regarding life sustaining treatment, including an indication of the treatment and care desired by the individual;

"(iii) is uniquely identifiable and standardized within a given locality, region, or State (as identified by the Secretary); and

"(iv) may incorporate any advance directive (as defined in section 1866(f)(3)) if executed by the individual.

"(B) The level of treatment indicated under subparagraph (A)(ii) may range from an indication for full treatment to an indication to limit some or all or specified interventions. Such indicated levels of treatment may include indications respecting, among other items—

"(i) the intensity of medical intervention if the patient is pulse less, apneic, or has serious cardiac or pulmonary problems;

"(ii) the individual's desire regarding transfer to a hospital or remaining at the current care setting;

"(iii) the use of antibiotics; and

"(iv) the use of artificially administered nutrition and hydration.".

(2) PAYMENT.—Section 1848(j)(3) of such Act (42 U.S.C. 1395w-4(j)(3)) is amended by inserting "(2)(FF)," after "(2)(EE),".

(3) FREQUENCY LIMITATION.—Section 1862(a) of such Act (42 U.S.C. 1395y(a)) is amended—

(A) in paragraph (1)—

(i) in subparagraph (N), by striking "and" at the end;

(ii) in subparagraph (O) by striking the semicolon at the end and inserting ", and"; and

(iii) by adding at the end the following new subparagraph:

"(P) in the case of advance care planning consultations (as defined in section 1861(hhh)(1)), which are performed more frequently than is covered under such section;"; and

(B) in paragraph (7), by striking "or (K)" and inserting "(K), or (P)".

(4) EFFECTIVE DATE.—The amendments made by this subsection shall apply to consultations furnished on or after January 1, 2011.

(b) EXPANSION OF PHYSICIAN QUALITY REPORTING INITIATIVE FOR END OF LIFE CARE.—

(1) PHYSICIAN'S QUALITY REPORTING INITIATIVE.—Section 1848(k)(2) of the Social Security Act (42 U.S.C. 1395w–4(k)(2)) is amended by adding at the end the following new subparagraph:

"(E) PHYSICIAN'S QUALITY REPORTING INITIATIVE.—

"(i) IN GENERAL.—For purposes of reporting data on quality measures for covered professional services furnished during 2011 and any subsequent year, to the extent that measures are available, the Secretary shall include quality measures on end of life care and advanced care planning that have been adopted or endorsed by a consensus-based organization, if appropriate. Such measures shall measure both the creation of and adherence to orders for life-sustaining treatment.

"(ii) PROPOSED SET OF MEASURES.—The Secretary shall publish in the Federal Register proposed quality measures on end of life care and advanced care planning that the Secretary determines are described in subparagraph (A) and would be appropriate for eligible professionals to use to submit data to the Secretary. The Secretary shall provide for a period of public comment on such set of measures before finalizing such proposed measures.".

(c) INCLUSION OF INFORMATION IN MEDICARE & YOU HANDBOOK.—

(1) MEDICARE & YOU HANDBOOK.—

(A) IN GENERAL.—Not later than 1 year after the date of the enactment of this Act, the Secretary of Health and Human Services shall update the online version of the Medicare & You Handbook to include the following:

(i) An explanation of advance care planning and advance directives, including—

(I) living wills;

(II) durable power of attorney;

(III) orders of life-sustaining treatment; and

(IV) health care proxies.

(ii) A description of Federal and State resources available to assist individuals and their families with advance care planning and advance directives, including—

(I) available State legal service organizations to assist individuals with advance care planning, including those organizations that receive funding pursuant to the Older Americans Act of 1965 (42 U.S.C. 93001 et seq.);

(II) website links or addresses for State-specific advance directive forms; and

(III) any additional information, as determined by the Secretary.

(B) UPDATE OF PAPER AND SUBSEQUENT VERSIONS.—The Secretary shall include the information described in subparagraph (A) in all paper and electronic versions of the Medicare & You Handbook that are published on or after the date that is 1 year after the date of the enactment of this Act.

SEC. 1234. PART B SPECIAL ENROLLMENT PERIOD AND WAIVER OF LIMITED ENROLLMENT PENALTY FOR TRICARE BENEFICIARIES.

(a) PART B SPECIAL ENROLLMENT PERIOD.—

(1) IN GENERAL.—Section 1837 of the Social Security Act (42 U.S.C. 1395p) is amended by adding at the end the following new subsection:

"(l)(1) In the case of any individual who is a covered beneficiary (as defined in section 1072(5) of title 10, United States Code) at the time the individual is entitled to hospital insurance benefits under part A under section 226(b) or section 226A and who is eligible to enroll but who has elected not to enroll (or to be deemed enrolled) during the individual's initial enrollment period, there shall be a special enrollment period described in paragraph (2).

"(2) The special enrollment period described in this paragraph, with respect to an individual, is the 12-month period beginning on the day after the last day of the initial enrollment period of the individual or, if later, the 12-month period beginning with the month the individual is notified of enrollment under this section.

"(3) In the case of an individual who enrolls during the special enrollment period provided under paragraph (1), the coverage period under this part shall begin on the first day of the month in which the individual enrolls or, at the option of the individual, on the first day of the second month following the last month of the individual's initial enrollment period.

"(4) The Secretary of Defense shall establish a method for identifying individuals described in paragraph (1) and providing notice to them of their eligibility for enrollment during the special enrollment period described in paragraph (2).".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to elections made on or after the date of the enactment of this Act.

(b) WAIVER OF INCREASE OF PREMIUM.—

(1) IN GENERAL.—Section 1839(b) of the Social Security Act (42 U.S.C. 1395r(b)) is amended by striking "section 1837(i)(4)" and inserting "subsection (i)(4) or (l) of section 1837".

(2) EFFECTIVE DATE.—

(A) IN GENERAL.—The amendment made by paragraph (1) shall apply with respect to elections made on or after the date of the enactment of this Act.

(B) REBATES FOR CERTAIN DISABLED AND ESRD BENEFICIARIES.—

(i) IN GENERAL.—With respect to premiums for months on or after January 2005 and before the month of the enactment of this Act, no increase in the premium shall be effected for a month in the case of any individual who is a covered beneficiary (as defined in section 1072(5) of title 10, United States Code) at the time the individual is entitled to hospital insurance benefits under part A of title XVIII of the Social Security Act under section 226(b) or 226A of such Act, and who is eligible to enroll, but who has elected not to enroll (or to be deemed enrolled), during the individual's initial enrollment period, and who enrolls under this part within the 12-month period that begins on the first day of the month after the month of notification of entitlement under this part.

(ii) CONSULTATION WITH DEPARTMENT OF DEFENSE.—The Secretary of Health and Human Services shall consult with the Secretary of Defense in identifying individuals described in this paragraph.

(iii) REBATES.—The Secretary of Health and Human Services shall establish a method for providing rebates of premium increases paid for months on or after January 1, 2005, and before the month of the enactment of this Act for which a penalty was applied and collected.

SEC. 1235. EXCEPTION FOR USE OF MORE RECENT TAX YEAR IN CASE OF GAINS FROM SALE OF PRIMARY RESIDENCE IN COMPUTING PART B INCOME-RELATED PREMIUM.

(a) IN GENERAL.—Section 1839(i)(4)(C)(ii)(II) of the Social Security Act (42 U.S.C. 1395r(i)(4)(C)(ii)(II)) is amended by inserting "sale of primary residence," after "divorce of such individual,".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to premiums and payments for years beginning with 2011.

SEC. 1236. DEMONSTRATION PROGRAM ON USE OF PATIENT DECISIONS AIDS.

(a) IN GENERAL.—The Secretary of Health and Human Services, acting through the Center for Medicare and Medicaid Payment Innovation established under section 1115A of the Social Security Act (as added by section 1910) and consistent with the applicable provisions of such section, shall establish a shared decision making demonstration program (in this subsection referred to as the "program") under the Medicare program using patient decision aids to meet the objective of improving the understanding by Medicare beneficiaries of their medical treatment options, as compared to comparable Medicare beneficiaries who do not participate in a shared decision making process using patient decision aids.

(b) SITES.—

(1) ENROLLMENT.—The Secretary shall enroll in the program not more than 30 eligible providers who have experience in implementing, and have invested in the necessary infrastructure to implement, shared decision making using patient decision aids.

(2) APPLICATION.—An eligible provider seeking to participate in the program shall submit to the Secretary an application at such time and containing such information as the Secretary may require.

(3) PREFERENCE.—In enrolling eligible providers in the program, the Secretary shall give preference to eligible providers that—

(A) have documented experience in using patient decision aids for the conditions identified by the Secretary and in using shared decision making;

(B) have the necessary information technology infrastructure to collect the information required by the Secretary for reporting purposes; and

(C) are trained in how to use patient decision aids and shared decision making.

(c) FOLLOW-UP COUNSELING VISIT.—

(1) IN GENERAL.—An eligible provider participating in the program shall routinely schedule Medicare beneficiaries for a counseling visit after the viewing of such a patient decision aid to answer any questions the beneficiary may have with respect to the medical care of the condition involved and to assist the beneficiary in thinking through how their preferences and concerns relate to their medical care.

(2) PAYMENT FOR FOLLOW-UP COUNSELING VISIT.—The Secretary shall establish procedures for making payments for such counseling visits provided to Medicare beneficiaries under the program. Such procedures shall provide for the establishment—

(A) of a code (or codes) to represent such services; and

(B) of a single payment amount for such service that includes the professional time of the health care provider and a portion of the reasonable costs of the infrastructure of the eligible provider such as would be made under the applicable payment systems to that provider for similar covered services.

(d) COSTS OF AIDS.—An eligible provider participating in the program shall be responsible for the costs of selecting, purchasing, and incorporating such patient decision aids into the provider's practice, and reporting data on quality and outcome measures under the program.

(e) FUNDING.—The Secretary shall provide for the transfer from the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of the Social Security Act (42 U.S.C. 1395t) of such funds as are necessary for the costs of carrying out the program.

(f) WAIVER AUTHORITY.—The Secretary may waive such requirements of titles XI and XVIII of the Social Security Act (42 U.S.C. 1301 et seq. and 1395 et seq.) as may be necessary for the purpose of carrying out the program.

(g) REPORT.—Not later than 12 months after the date of completion of the program, the Secretary shall submit to Congress a report on such program, together with recommendations for such legislation and administrative action as the Secretary determines to be appropriate. The final report shall include an evaluation of the impact of the use of the program on health quality, utilization of health care services, and on improving the quality of life of such beneficiaries.

(h) DEFINITIONS.—In this section:

(1) ELIGIBLE PROVIDER.—The term "eligible provider" means the following:

(A) A primary care practice.

(B) A specialty practice.

(C) A multispecialty group practice.

(D) A hospital.

(E) A rural health clinic.

(F) A Federally qualified health center (as defined in section 1861(aa)(4) of the Social Security Act (42 U.S.C. 1395x(aa)(4)).

(G) An integrated delivery system.

(H) A State cooperative entity that includes the State government and at least one other health care provider which is set up for the purpose of testing shared decision making and patient decision aids.

(2) PATIENT DECISION AID.—The term "patient decision aid" means an educational tool (such as the Internet, a video, or a pamphlet) that helps patients (or, if appropriate, the family caregiver of the patient) understand and communicate their beliefs and preferences related to their treatment options, and to decide with their health care provider what treatments are best for them based on their treatment options, scientific evidence, circumstances, beliefs, and preferences.

(3) SHARED DECISION MAKING.—The term "shared decision making" means a collaborative process between patient and clinician that engages the patient in decision making, provides patients with information about trade-offs among treatment options, and facilitates the incorporation of patient preferences and values into the medical plan.

TITLE III—PROMOTING PRIMARY CARE, MENTAL HEALTH SERVICES, AND COORDINATED CARE

SEC. 1301. ACCOUNTABLE CARE ORGANIZATION PILOT PROGRAM.

Title XVIII of the Social Security Act is amended by inserting after section 1866D, as added by section 1152(f) of this Act, the following new section:

"ACCOUNTABLE CARE ORGANIZATION PILOT PROGRAM

"SEC. 1866E. (a) ESTABLISHMENT.—

"(1) IN GENERAL.—The Secretary shall conduct a pilot program (in this section referred to as the 'pilot program') to test different payment incentive models, including (to the extent practicable) the specific payment incentive models described in subsection (c), designed to reduce the growth of expenditures and improve health outcomes in the provision of items and services under this title to applicable beneficiaries (as defined in subsection (d)) by qualifying accountable care organizations (as defined in subsection (b)(1)) in order to—

"(A) promote accountability for a patient population and coordinate items and services under parts A and B;

"(B) encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery; and

"(C) reward physician practices and other physician organizational models for the provision of high quality and efficient health care services.

"(2) SCOPE.—The Secretary shall set specific goals for the number of accountable care organizations, participating practitioners, and patients served in the initial tests under the pilot program to ensure that the pilot program is of sufficient size and scope to—

"(A) test the approach involved in a variety of settings, including urban, rural, and underserved areas; and

"(B) subject to subsection (f)(1), disseminate such approach rapidly on a national basis.

To the extent that the Secretary finds a qualifying accountable care organization model to be successful in improving quality and reducing costs, the Secretary shall attempt to attract at least 10 percent of all eligible providers to act as accountable care organizations and implement such mechanisms and reforms within 5 years after the date of the enactment of this section. If the Secretary further finds such accountable care organization models to be successful, the Secretary shall seek to implement such mechanisms and reforms on as large a geographic scale as practical and economical.

"(b) QUALIFYING ACCOUNTABLE CARE ORGANIZATIONS (ACOS).—

"(1) QUALIFYING ACO DEFINED.—In this section:

"(A) IN GENERAL.—The terms 'qualifying accountable care organization' and 'qualifying ACO' mean a group of physicians or other physician organizational model (as defined in subparagraph (D)) that—

"(i) is organized at least in part for the purpose of providing physicians' services; and

"(ii) meets such criteria as the Secretary determines to be appropriate to participate in the pilot program, including the criteria specified in paragraph (2).

"(B) INCLUSION OF OTHER PROVIDERS.—Nothing in this subsection shall be construed as preventing a qualifying ACO from including a hospital or any other provider of services or supplier furnishing items or services for which payment may be made under this title that is affiliated with the ACO under an arrangement structured so that such provider or supplier participates in the pilot program and shares in any incentive payments under the pilot program.

"(C) PHYSICIAN.—The term 'physician' includes, except as the Secretary may otherwise provide, any individual who furnishes services for which payment may be made as physicians' services.

"(D) OTHER PHYSICIAN ORGANIZATIONAL MODEL.—The term 'other physician organization model' means, with respect to a qualifying ACO any model of organization under which physicians enter into agreements with other providers for the purposes of participation in the pilot program in order to provide high quality and efficient health care services and share in any incentive payments under such program

"(E) OTHER SERVICES.—Nothing in this paragraph shall be construed as preventing a qualifying ACO from furnishing items or services, for which payment may not be made under this title, for purposes of achieving performance goals under the pilot program.

"(2) QUALIFYING CRITERIA.—The following are criteria described in this paragraph for an organized group of physicians to be a qualifying ACO:

"(A) The group has a legal structure that would allow the group to receive and distribute incentive payments under this section.

"(B) The group includes a sufficient number of primary care physicians (regardless of specialty) for the applicable beneficiaries for whose care the group is accountable (as determined by the Secretary).

"(C) The group reports on quality measures in such form, manner, and frequency as specified by the Secretary (which may be for the group, for providers of services and suppliers, or both).

"(D) The group reports to the Secretary (in a form, manner and frequency as specified by the Secretary) such data as the Secretary determines appropriate to monitor and evaluate the pilot program.

"(E) The group provides notice to applicable beneficiaries regarding the pilot program (as determined appropriate by the Secretary).

"(F) The group contributes to a best practices network or website, that shall be maintained by the Secretary for the purpose of sharing strategies on quality improvement, care coordination, and efficiency that the groups believe are effective.

"(G) The group utilizes patient-centered processes of care, including those that emphasize patient and caregiver involvement in planning and monitoring of ongoing care management plan.

"(H) The group meets other criteria determined to be appropriate by the Secretary.

"(c) SPECIFIC PAYMENT INCENTIVE MODELS.—The specific payment incentive models described in this subsection are the following:

"(1) PERFORMANCE TARGET MODEL.—Under the performance target model under this paragraph (in this paragraph referred to as the 'performance target model'):

"(A) IN GENERAL.—A qualifying ACO qualifies to receive an incentive payment if expenditures for applicable beneficiaries are less than a target spending level or a target rate of growth. The incentive payment shall be made only if savings are greater than would result from normal variation in expenditures for items and services covered under parts A and B.

"(B) COMPUTATION OF PERFORMANCE TARGET.—

"(i) IN GENERAL.—The Secretary shall establish a performance target for each qualifying ACO comprised of a base amount (described in clause (ii)) increased to the current year by an adjustment factor (described in clause (iii)). Such a target may be established on a per capita basis, as the Secretary determines to be appropriate.

"(ii) BASE AMOUNT.—For purposes of clause (i), the base amount in this subparagraph is equal to the average total payments (or allowed charges) under parts A and B (and may include part D, if the Secretary determines appropriate) for applicable beneficiaries for whom the qualifying ACO furnishes items and services in a base period determined by the Secretary. Such base amount may be determined on a per capita basis.

"(iii) ADJUSTMENT FACTOR.—For purposes of clause (i), the adjustment factor in this clause may equal an annual per capita amount that reflects changes in expenditures from the period of the base amount to the current year that would represent an appropriate performance target for applicable beneficiaries (as determined by the Secretary). Such adjustment factor may be determined as an amount or rate, may be determined on a national, regional, local, or organization-specific basis, and may be determined on a per capita basis. Such adjustment factor also may be adjusted for risk as determined appropriate by the Secretary.

"(iv) REBASING.—Under this model the Secretary shall periodically rebase the base expenditure amount described in clause (ii).

"(C) MEETING TARGET.—

"(i) IN GENERAL.—Subject to clause (ii), a qualifying ACO that meet or exceeds annual quality and performance targets for a year shall receive an incentive payment for such year equal to a portion (as determined appropriate by the Secretary) of the amount by which payments under this title for such year relative are estimated to be below the performance target for such year, as determined by the Secretary. The Secretary may establish a cap on incentive payments for a year for a qualifying ACO.

"(ii) LIMITATION.—The Secretary shall limit incentive payments to each qualifying ACO under this paragraph as necessary to ensure that the aggregate expenditures with respect to applicable beneficiaries for such ACOs under this title (inclusive of incentive payments described in this subparagraph) do not exceed the amount that the Secretary estimates would be expended for such ACO for such beneficiaries if the pilot program under this section were not implemented.

"(D) REPORTING AND OTHER REQUIREMENTS.—In carrying out such model, the Secretary may (as the Secretary determines to be appropriate) incorporate reporting requirements, incentive payments, and penalties related to the physician quality reporting initiative (PQRI), electronic prescribing, electronic health records, and other similar initiatives under section 1848, and may use alternative criteria than would otherwise apply under such section for determining whether to make such payments. The incentive payments described in this subparagraph shall not be included in the limit described in subparagraph (C)(ii) or in the performance target model described in this paragraph.

"(2) PARTIAL CAPITATION MODEL.—

"(A) IN GENERAL.—Subject to subparagraph (B), a partial capitation model described in this paragraph (in this paragraph referred to as a 'partial capitation model') is a model in which a qualifying ACO would be at financial risk for some, but not all, of the items and services covered under parts A and B, such as at risk for some or all physicians' services or all items and services under part B. The Secretary may limit a partial capitation model to ACOs that are highly integrated systems of care and to ACOs capable of bearing risk, as determined to be appropriate by the Secretary.

"(B) NO ADDITIONAL PROGRAM EXPENDITURES.—Payments to a qualifying ACO for applicable beneficiaries for a year under the partial capitation model shall be established in a manner that does not result in spending more for such ACO for such beneficiaries than would otherwise be expended for such ACO for such beneficiaries for such year if the pilot program were not implemented, as estimated by the Secretary.

"(3) OTHER PAYMENT MODELS.—

"(A) IN GENERAL.—Subject to subparagraph (B), the Secretary may develop other payment models that meet the goals of this pilot program to improve quality and efficiency.

"(B) NO ADDITIONAL PROGRAM EXPENDITURES.—Subparagraph (B) of paragraph (2) shall apply to a payment model under subparagraph (A) in a similar manner as such subparagraph (B) applies to the payment model under paragraph (2).

"(d) APPLICABLE BENEFICIARIES.—

"(1) IN GENERAL.—In this section, the term 'applicable beneficiary' means, with respect to a qualifying ACO, an individual who—

"(A) is enrolled under part B and entitled to benefits under part A;

"(B) is not enrolled in a Medicare Advantage plan under part C or a PACE program under section 1894; and

"(C) meets such other criteria as the Secretary determines appropriate, which may include criteria relating to frequency of contact with physicians in the ACO

"(2) FOLLOWING APPLICABLE BENEFICIARIES.—The Secretary may monitor data on expenditures and quality of services under this title after an applicable beneficiary discontinues receiving services under this title through a qualifying ACO.

"(e) IMPLEMENTATION.—

"(1) STARTING DATE.—The pilot program shall begin no later than January 1, 2012. An agreement with a qualifying ACO under the pilot program may cover a multi-year period of between 3 and 5 years.

"(2) WAIVER.—The Secretary may waive such provisions of this title (including section 1877) and title XI in the manner the Secretary determines necessary in order implement the pilot program.

"(3) PERFORMANCE RESULTS REPORTS.—The Secretary shall report performance results to qualifying ACOs under the pilot program at least annually.

"(4) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of—

"(A) the elements, parameters, scope, and duration of the pilot program;

"(B) the selection of qualifying ACOs for the pilot program;

"(C) the establishment of targets, measurement of performance, determinations with respect to whether savings have been achieved and the amount of savings;

"(D) determinations regarding whether, to whom, and in what amounts incentive payments are paid; and

"(E) decisions about the extension of the program under subsection (g), expansion of the program under subsection (h) or extensions under subsection (i).

"(5) ADMINISTRATION.—Chapter 35 of title 44, United States Code shall not apply to this section.

"(f) EVALUATION; MONITORING.—

"(1) IN GENERAL.—The Secretary shall evaluate the payment incentive model for each qualifying ACO under the pilot program to assess impacts on beneficiaries, providers of services, suppliers and the program under this title. The Secretary shall make such evaluation publicly available within 60 days of the date of completion of such report.

"(2) MONITORING.—The Inspector General of the Department of Health and Human Services shall provide for monitoring of the operation of ACOs under the pilot program with regard to violations of section 1877 (popularly known as the 'Stark law').

"(g) EXTENSION OF PILOT AGREEMENT WITH SUCCESSFUL ORGANIZATIONS.—

"(1) REPORTS TO CONGRESS.—Not later than 2 years after the date the first agreement is entered into under this section, and biennially thereafter for six years, the Secretary shall submit to Congress and make publicly available a report on the use of authorities under the pilot program. Each report shall address the impact of the use of those authorities on expenditures, access, and quality under this title.

"(2) EXTENSION.—Subject to the report provided under paragraph (1), with respect to a qualifying ACO, the Secretary may extend the duration of the agreement for such ACO under the pilot program as the Secretary determines appropriate if—

"(A) the ACO receives incentive payments with respect to any of the first 4 years of the pilot agreement and is consistently meeting quality standards or

"(B) the ACO is consistently exceeding quality standards and is not increasing spending under the program.

"(3) TERMINATION.—The Secretary may terminate an agreement with a qualifying ACO under the pilot program if such ACO did not receive incentive payments or consistently failed to meet quality standards in any of the first 3 years under the program.

"(h) EXPANSION TO ADDITIONAL ACOS.—

"(1) TESTING AND REFINEMENT OF PAYMENT INCENTIVE MODELS.—Subject to the evaluation described in subsection (f), the Secretary may enter into agreements under the pilot program with additional qualifying ACOs to further test and refine payment incentive models with respect to qualifying ACOs.

"(2) EXPANDING USE OF SUCCESSFUL MODELS TO PROGRAM IMPLEMENTATION.—

"(A) IN GENERAL.—Subject to subparagraph (B), the Secretary may issue regulations to implement, on a permanent basis, 1 or more models if, and to the extent that, such models are beneficial to the program under this title, as determined by the Secretary.

"(B) CERTIFICATION.—The Chief Actuary of the Centers for Medicare & Medicaid Services shall certify that 1 or more of such models described in subparagraph (A) would result in estimated spending that would be less than what spending would otherwise be estimated to be in the absence of such expansion.

"(i) TREATMENT OF PHYSICIAN GROUP PRACTICE DEMONSTRATION.—

"(1) EXTENSION.—The Secretary may enter in to an agreement with a qualifying ACO under the demonstration under section 1866A, subject to rebasing and other modifications deemed appropriate by the Secretary, until the pilot program under this section is operational.

"(2) TRANSITION.—For purposes of extension of an agreement with a qualifying ACO under subsection (g)(2), the Secretary shall treat receipt of an incentive payment for a year by an organization under the physician group practice demonstration pursuant to section 1866A as a year for which an incentive payment is made under such subsection, as long as such practice group practice organization meets the criteria under subsection (b)(2).

"(j) ADDITIONAL PROVISIONS.—

"(1) AUTHORITY FOR SEPARATE INCENTIVE ARRANGEMENTS.—The Secretary may create separate incentive arrangements (including using multiple years of data, varying thresholds, varying shared savings amounts, and varying shared savings limits) for different categories of qualifying ACOs to reflect natural variations in data availability, variation in average annual attributable expenditures, program integrity, and other matters the Secretary deems appropriate.

"(2) ENCOURAGEMENT OF PARTICIPATION OF SMALLER ORGANIZATIONS.—In order to encourage the participation of smaller accountable care organizations under the pilot program, the Secretary may limit a qualifying ACO's exposure to high cost patients under the program.

"(3) TREATMENT OF HIGH-COST BENEFICIARIES WITH CHRONIC DISEASES.—Nothing in this section shall be construed as preventing a qualifying ACO from en-

tering into an arrangement with an Independence at Home Medical Practice or from providing home based services for the treatment of beneficiaries who are eligible for that program.

"(4) INVOLVEMENT IN PRIVATE PAYER ARRANGEMENTS.—Nothing in this section shall be construed as preventing qualifying ACOs participating in the pilot program from negotiating similar contracts with private payers.

"(5) ANTIDISCRIMINATION LIMITATION.—The Secretary shall not enter into an agreement with an entity to provide health care items or services under the pilot program, or with an entity to administer the program, unless such entity guarantees that it will not deny, limit, or condition the coverage or provision of benefits under the program, for individuals eligible to be enrolled under such program, based on any health status-related factor described in section 2702(a)(1) of the Public Health Service Act.

"(6) CONSTRUCTION.—Nothing in this section shall be construed to compel or require an organization to use an organization-specific target growth rate for an accountable care organization under this section for purposes of section 1848.

"(7) FUNDING.—For purposes of administering and carrying out the pilot program, other than for payments for items and services furnished under this title and incentive payments under subsection (c)(1), in addition to funds otherwise appropriated, there are appropriated to the Secretary for the Center for Medicare & Medicaid Services Program Management Account $25,000,000 for each of fiscal years 2010 through 2014 and $20,000,000 for fiscal year 2015. Amounts appropriated under this paragraph for a fiscal year shall be available until expended.".

SEC. 1302. MEDICAL HOME PILOT PROGRAM.

(a) IN GENERAL.—Title XVIII of the Social Security Act is amended by inserting after section 1866E, as inserted by section 1301, the following new section:

"MEDICAL HOME PILOT PROGRAM

"SEC. 1866F. (a) ESTABLISHMENT AND MEDICAL HOME MODELS.—

"(1) ESTABLISHMENT OF PILOT PROGRAM.—The Secretary shall establish a medical home pilot program (in this section referred to as the 'pilot program') for the purpose of evaluating the feasibility and advisability of reimbursing qualified patient-centered medical homes for furnishing medical home services (as defined under subsection (b)(1)) to high need beneficiaries (as defined in subsection (d)(1)(C)) and to targeted high need beneficiaries (as defined in subsection (c)(1)(C)).

"(2) SCOPE.—Subject to subsection (g), the Secretary shall set specific goals for the number of practices and communities, and the number of patients served, under the pilot program in the initial tests to ensure that the pilot program is of sufficient size and scope to—

"(A) test the approach involved in a variety of settings, including urban, rural, and underserved areas; and

"(B) subject to subsection (e)(1), disseminate such approach rapidly on a national basis.

To the extent that the Secretary finds a medical home model to be successful in improving quality and reducing costs, the Secretary shall implement such mechanisms and reforms on as large a geographic scale as practical and economical.

"(3) MODELS OF MEDICAL HOMES IN THE PILOT PROGRAM.—The pilot program shall evaluate each of the following medical home models:

"(A) INDEPENDENT PATIENT-CENTERED MEDICAL HOME MODEL.—Independent patient-centered medical home model under subsection (c).

"(B) COMMUNITY-BASED MEDICAL HOME MODEL.—Community-based medical home model under subsection (d).

"(4) PARTICIPATION OF NURSE PRACTITIONERS AND PHYSICIAN ASSISTANTS.—

"(A) Nothing in this section shall be construed as preventing a nurse practitioner from leading a patient centered medical home so long as—

"(i) all the requirements of this section are met; and

"(ii) the nurse practitioner is acting consistently with State law.

"(B) Nothing in this section shall be construed as preventing a physician assistant from participating in a patient centered medical home so long as—

"(i) all the requirements of this section are met; and

"(ii) the physician assistant is acting consistently with State law.

"(b) DEFINITIONS.—For purposes of this section:

"(1) PATIENT-CENTERED MEDICAL HOME SERVICES.—The term 'patient-centered medical home services' means services that—

"(A) provide beneficiaries with direct and ongoing access to a primary care or principal care by a physician or nurse practitioner who accepts responsibility for providing first contact, continuous and comprehensive care to such beneficiary;

"(B) coordinate the care provided to a beneficiary by a team of individuals at the practice level across office, institutional and home settings led by a primary care or principal care physician or nurse practitioner, as needed and appropriate;

"(C) provide for all the patient's health care needs or take responsibility for appropriately arranging care with other qualified providers for all stages of life;

"(D) provide continuous access to care and communication with participating beneficiaries;

"(E) provide support for patient self-management, proactive and regular patient monitoring, support for family caregivers, use patient-centered processes, and coordination with community resources;

"(F) integrate readily accessible, clinically useful information on participating patients that enables the practice to treat such patients comprehensively and systematically; and

"(G) implement evidence-based guidelines and apply such guidelines to the identified needs of beneficiaries over time and with the intensity needed by such beneficiaries.

"(2) PRIMARY CARE.—The term 'primary care' means health care that is provided by a physician, nurse practitioner, or physician assistant who practices in the field of family medicine, general internal medicine, geriatric medicine, or pediatric medicine.

"(3) PRINCIPAL CARE.—The term 'principal care' means integrated, accessible health care that is provided by a physician who is a medical subspecialist that addresses the majority of the personal health care needs of patients with chronic conditions requiring the subspecialist's expertise, and for whom the subspecialist assumes care management.

"(c) INDEPENDENT PATIENT-CENTERED MEDICAL HOME MODEL.—

"(1) IN GENERAL.—

"(A) PAYMENT AUTHORITY.—Under the independent patient-centered medical home model under this subsection, the Secretary shall make payments for medical home services furnished by an independent patient-centered medical home (as defined in subparagraph (B)) pursuant to paragraph (3)(B) for a targeted high need beneficiaries (as defined in subparagraph (C)).

"(B) INDEPENDENT PATIENT-CENTERED MEDICAL HOME DEFINED.—In this section, the term 'independent patient-centered medical home' means a physician-directed or nurse-practitioner-directed practice that is qualified under paragraph (2) as—

"(i) providing beneficiaries with patient-centered medical home services; and

"(ii) meets such other requirements as the Secretary may specify.

"(C) TARGETED HIGH NEED BENEFICIARY DEFINED.—For purposes of this subsection, the term 'targeted high need beneficiary' means a high need beneficiary who, based on a risk score as specified by the Secretary, is generally within the upper 50th percentile of Medicare beneficiaries.

"(D) BENEFICIARY ELECTION TO PARTICIPATE.—The Secretary shall determine an appropriate method of ensuring that beneficiaries have agreed to participate in the pilot program.

"(E) IMPLEMENTATION.—The pilot program under this subsection shall begin no later than 6 months after the date of the enactment of this section.

"(2) STANDARD SETTING AND QUALIFICATION PROCESS FOR PATIENT-CENTERED MEDICAL HOMES.—The Secretary shall review alternative models for standard setting and qualification, and shall establish a process—

"(A) to establish standards to enable medical practices to qualify as patient-centered medical homes; and

"(B) to initially provide for the review and certification of medical practices as meeting such standards.

"(3) PAYMENT.—

"(A) ESTABLISHMENT OF METHODOLOGY.—The Secretary shall establish a methodology for the payment for medical home services furnished by independent patient-centered medical homes. Under such methodology, the Secretary shall adjust payments to medical homes based on beneficiary risk scores to ensure that higher payments are made for higher risk beneficiaries.

"(B) PER BENEFICIARY PER MONTH PAYMENTS.—Under such payment methodology, the Secretary shall pay independent patient-centered medical homes a monthly fee for each targeted high need beneficiary who consents to receive medical home services through such medical home.

"(C) PROSPECTIVE PAYMENT.—The fee under subparagraph (B) shall be paid on a prospective basis.

"(D) AMOUNT OF PAYMENT.—In determining the amount of such fee, the Secretary shall consider the following:

"(i) The clinical work and practice expenses involved in providing the medical home services provided by the independent patient-centered medical home (such as providing increased access, care coordination, population disease management, and teaching self-care skills for managing chronic illnesses) for which payment is not made under this title as of the date of the enactment of this section.

"(ii) Allow for differential payments based on capabilities of the independent patient-centered medical home.

"(iii) Use appropriate risk-adjustment in determining the amount of the per beneficiary per month payment under this paragraph in a manner that ensures that higher payments are made for higher risk beneficiaries.

"(4) ENCOURAGING PARTICIPATION OF VARIETY OF PRACTICES.—The pilot program under this subsection shall be designed to include the participation of physicians in practices with fewer than 10 full-time equivalent physicians, as well as physicians in larger practices, particularly in underserved and rural areas, as well as federally qualified community health centers, and rural health centers.

"(5) NO DUPLICATION IN PILOT PARTICIPATION.—A physician in a group practice that participates in the accountable care organization pilot program under section 1866D shall not be eligible to participate in the pilot program under this subsection, unless the pilot program under this section has been implemented on a permanent basis under subsection (e)(3).

"(d) COMMUNITY-BASED MEDICAL HOME MODEL.—

"(1) IN GENERAL.—

"(A) AUTHORITY FOR PAYMENTS.—Under the community-based medical home model under this subsection (in this section referred to as the 'CBMH model'), the Secretary shall make payments for the furnishing of medical home services by a community-based medical home (as defined in subparagraph (B)) pursuant to paragraph (5)(B) for high need beneficiaries.

"(B) COMMUNITY-BASED MEDICAL HOME DEFINED.—In this section, the term 'community-based medical home' means a nonprofit community-based or State-based organization that is certified under paragraph (2) as meeting the following requirements:

"(i) The organization provides beneficiaries with medical home services.

"(ii) The organization provides medical home services under the supervision of and in close collaboration with the primary care or principal care physician, nurse practitioner, or physician assistant designated by the beneficiary as his or her community-based medical home provider.

"(iii) The organization employs community health workers, including nurses or other non-physician practitioners, lay health workers, or other persons as determined appropriate by the Secretary, that assist the primary or principal care physician, nurse practitioner, or physician assistant in chronic care management activities such as teaching self-care skills for managing chronic illnesses, transitional care services, care plan setting, medication therapy management services for patients with multiple chronic diseases, or help beneficiaries access the health care and community-based resources in their local geographic area.

"(iv) The organization meets such other requirements as the Secretary may specify.

"(C) HIGH NEED BENEFICIARY.—In this section, the term 'high need beneficiary' means an individual who requires regular medical monitoring, advising, or treatment, including such an individual with cognitive impairment that leads to functional impairment.

"(2) QUALIFICATION PROCESS FOR COMMUNITY-BASED MEDICAL HOMES.—The Secretary shall establish a process—

"(A) for the initial qualification of community-based or State-based organizations as community-based medical homes; and

"(B) to provide for the review and qualification of such community-based and State-based organizations pursuant to criteria established by the Secretary.

"(3) DURATION.—The pilot program for community-based medical homes under this subsection shall start no later than 2 years after the date of the enactment of this section. Each demonstration site under the pilot program shall operate for a period of up to 5 years after the initial implementation phase, without regard to the receipt of a initial implementation funding under subsection (i).

"(4) PREFERENCE.—In selecting sites for the CBMH model, the Secretary shall seek to eliminate racial, ethnic, gender, and geographic health disparities and may give preference to—

"(A) applications from geographic areas that propose to coordinate health care services for chronically ill beneficiaries across a variety of health care settings, such as primary care physician practices with fewer than 10 physicians, specialty physicians, nurse practitioner practices, Federally qualified health centers, rural health clinics, and other settings;

"(B) applications that include other payors that furnish medical home services for chronically ill patients covered by such payors; and

"(C) applications from States that propose to use the medical home model to coordinate health care services for individuals enrolled under this title, individuals enrolled under title XIX, and full-benefit dual eligible individuals (as defined in section 1935(c)(6)) with chronic diseases across a variety of health care settings.

"(5) PAYMENTS.—

"(A) ESTABLISHMENT OF METHODOLOGY.—The Secretary shall establish a methodology for the payment for medical home services furnished under the CBMH model.

"(B) PER BENEFICIARY PER MONTH PAYMENTS.—Under such payment methodology, the Secretary shall make two separate monthly payments for each high need beneficiary who consents to receive medical home services through such medical home, as follows:

"(i) PAYMENT TO COMMUNITY-BASED ORGANIZATION.—One monthly payment to a community-based or State-based organization.

"(ii) PAYMENT TO PRIMARY OR PRINCIPAL CARE PRACTICE.—One monthly payment to the primary or principal care practice for such beneficiary.

"(C) PROSPECTIVE PAYMENT.—The payments under subparagraph (B) shall be paid on a prospective basis.

"(D) AMOUNT OF PAYMENT.—In determining the amount of such payment, the Secretary shall consider the following:

"(i) The clinical work and practice expenses involved in providing the medical home services provided by the community-based medical home (such as providing increased access, care coordination, care plan setting, population disease management, and teaching self-care skills for managing chronic illnesses) for which payment is not made under this title as of the date of the enactment of this section.

"(ii) Use appropriate risk-adjustment in determining the amount of the per beneficiary per month payment under this paragraph.

"(6) INITIAL IMPLEMENTATION FUNDING.—The Secretary may make available initial implementation funding to a community based or State-based organization or a State that is participating in the pilot program under this subsection. Such organization shall provide the Secretary with a detailed implementation plan that includes how such funds will be used. The Secretary shall select a territory of the United States as one of the locations in which to implement the pilot program under this subsection.

"(e) EXPANSION OF PROGRAM.—

"(1) EVALUATION OF COST AND QUALITY.—The Secretary shall evaluate the pilot program to determine—

"(A) the extent to which medical homes result in—

"(i) improvement in the quality and coordination of health care services, particularly with regard to the care of complex patients;

"(ii) improvement in reducing health disparities;

"(iii) reductions in preventable hospitalizations;

"(iv) prevention of readmissions;

"(v) reductions in emergency room visits;

"(vi) improvement in health outcomes, including patient functional status where applicable;

"(vii) improvement in patient satisfaction;

"(viii) improved efficiency of care such as reducing duplicative diagnostic tests and laboratory tests; and

"(ix) reductions in health care expenditures; and

"(B) the feasability and advisability of reimbursing medical homes for medical home services under this title on a permanent basis.

"(2) REPORT.—Not later than 60 days after the date of completion of the evaluation under paragraph (1), the Secretary shall submit to Congress and make available to the public a report on the findings of the evaluation under paragraph (1).

"(3) EXPANSION OF PROGRAM.—

"(A) IN GENERAL.—Subject to the results of the evaluation under paragraph (1) and subparagraph (B), the Secretary may issue regulations to implement, on a permanent basis, one or more models, if, and to the extent that such model or models, are beneficial to the program under this title, including that such implementation will improve quality of care, as determined by the Secretary.

"(B) CERTIFICATION REQUIREMENT.—The Secretary may not issue such regulations unless the Chief Actuary of the Centers for Medicare & Medicaid Services certifies that the expansion of the components of the pilot program described in subparagraph (A) would result in estimated spending under this title that would be no more than the level of spending that the Secretary estimates would otherwise be spent under this title in the absence of such expansion.

"(f) ADMINISTRATIVE PROVISIONS.—

"(1) NO DUPLICATION IN PAYMENTS.—During any month, the Secretary may not make payments under this section under more than one model or through more than one medical home under any model for the furnishing of medical home services to an individual.

"(2) NO EFFECT ON PAYMENT FOR EVALUATION AND MANAGEMENT SERVICES.—Payments made under this section are in addition to, and have no effect on the amount of, payment for evaluation and management services made under this title

"(3) ADMINISTRATION.—Chapter 35 of title 44, United States Code shall not apply to this section.

"(g) FUNDING.—

"(1) OPERATIONAL COSTS.—For purposes of administering and carrying out the pilot program (including the design, implementation, technical assistance for and evaluation of such program), in addition to funds otherwise available, there shall be transferred from the Federal Supplementary Medical Insurance Trust Fund under section 1841 to the Secretary for the Centers for Medicare & Medicaid Services Program Management Account $6,000,000 for each of fiscal years 2010 through 2014. Amounts appropriated under this paragraph for a fiscal year shall be available until expended.

"(2) PATIENT-CENTERED MEDICAL HOME SERVICES.—In addition to funds otherwise available, there shall be available to the Secretary for the Centers for Medicare & Medicaid Services, from the Federal Supplementary Medical Insurance Trust Fund under section 1841—

"(A) $200,000,000 for each of fiscal years 2010 through 2014 for payments for medical home services under subsection (c)(3); and

"(B) $125,000,000 for each of fiscal years 2012 through 2016, for payments under subsection (d)(5).

Amounts available under this paragraph for a fiscal year shall be available until expended.

"(3) INITIAL IMPLEMENTATION.—In addition to funds otherwise available, there shall be available to the Secretary for the Centers for Medicare & Medicaid Services, from the Federal Supplementary Medical Insurance Trust Fund under section 1841, $2,500,000 for each of fiscal years 2010 through 2012, under subsection (d)(6). Amounts available under this paragraph for a fiscal year shall be available until expended.

"(h) TREATMENT OF TRHCA MEDICARE MEDICAL HOME DEMONSTRATION FUNDING.—

"(1) In addition to funds otherwise available for payment of medical home services under subsection (c)(3), there shall also be available the amount provided in subsection (g) of section 204 of division B of the Tax Relief and Health Care Act of 2006 (42 U.S.C. 1395b–1 note).

"(2) Notwithstanding section 1302(c) of the America's Affordable Health Choices Act of 2009, in addition to funds provided in paragraph (1) and subsection (g)(2)(A), the funding for medical home services that would otherwise have been available if such section 204 medical home demonstration had been

implemented (without regard to subsection (g) of such section) shall be available to the independent patient-centered medical home model described in subsection (c).".

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to services furnished on or after the date of the enactment of this Act.

(c) CONFORMING REPEAL.—Section 204 of division B of the Tax Relief and Health Care Act of 2006 (42 U.S.C. 1395b–1 note), as amended by section 133(a)(2) of the Medicare Improvements for Patients and Providers Act of 2008 (Public Law 110–275), is repealed.

SEC. 1303. INDEPENDENCE AT HOME PILOT PROGRAM.

Title XVIII of the Social Security Act is amended by inserting after section 1866F, as inserted by section 1302, the following new section:

"INDEPENDENCE AT HOME MEDICAL PRACTICE PILOT PROGRAM

"SEC. 1866G. (a) IN GENERAL.—The Secretary shall conduct a pilot program (in this section referred to as the 'pilot program') to test a payment incentive and service delivery model that utilizes physician and nurse practitioner directed home-based primary care teams designed to reduce expenditures and improve health outcomes in the provision of items and services under this title to applicable beneficiaries (as defined in subsection (d)). The pilot program tests whether such a model, which is accountable for providing comprehensive, coordinated, continuous, and accessible care to high-need populations at home and coordinating health care across all treatment settings, results in—

"(1) reducing preventable hospitalizations;

"(2) preventing hospital readmissions;

"(3) reducing emergency room visits;

"(4) improving health outcomes;

"(5) improving the efficiency of care, such as by reducing duplicative diagnostic and laboratory tests;

"(6) reducing the cost of health care services covered under this title; and

"(7) achieving beneficiary and family caregiver satisfaction.

"(b) QUALIFYING INDEPENDENCE AT HOME MEDICAL PRACTICE.—

"(1) DEFINITION.—In this section, the term 'qualifying independence at home medical practice' means a legal entity comprised of an individual physician or nurse practitioner or group of physicians and nurse practitioners who are certified or have experience and training in providing home-based primary care services to high cost chronically ill beneficiaries as determined appropriate by the Secretary and which has entered into an agreement with the Secretary. Care is provided by a team, including physicians, nurses, physician assistants, pharmacists, and other health and social services staff as appropriate who are certified or have experience providing home-based primary care to applicable beneficiaries, make in-home visits and carry out plans of care that are tailored to the individual beneficiary's chronic conditions and designed to achieve the results in subsection (a) and report the clinical and quality of care outcomes as determined by the Secretary. The pilot program shall be designed to include the participation of physician and nurse practitioner practices with fewer than 10 full-time equivalent physicians, as well as physicians in larger practices, particularly in underserved rural areas.

"(2) PARTICIPATION OF NURSE PRACTITIONERS AND PHYSICIAN ASSISTANTS.—Nothing in this section shall be construed to prevent a nurse practitioner or physician assistant from leading a home-based primary care team as part of an Independence at Home Medical Practice if—

"(A) all the requirements of this section are met; and

"(B) the nurse practitioner or physician assistant, as the case may be, is acting consistently with State law.

"(3) INCLUSION OF PROVIDERS AND PRACTITIONERS.—Nothing in this subsection shall be construed as preventing a qualifying Independence at Home Medical Practice from including a provider or participating practitioner that is affiliated with the medical practice under an arrangement structured so that such provider or practitioner participates in the pilot program and shares in any savings under the pilot program.

"(c) PAYMENT.—

"(1) SHARED SAVINGS.—A qualifying Independence at Home Medical Practice may receive 80 percent of savings in excess of 5 percent if expenditures under this title for applicable beneficiaries participating in the pilot program are at least 5 percent less than a target spending level or a target rate of growth. The shared savings payment shall be made only if savings are at a minimum 5 percent greater than would result from normal variation in expenditures for items

and services covered under parts A and B (and part D to the extent the Secretary decides to include such costs).

"(2) ESTABLISHMENT OF LEVELS, THRESHOLDS, AND LIMITS.—The Secretary may establish target spending levels, savings thresholds, and limits on shared savings amounts for each participating Independence at Home Medical Practice based upon the size of the practice, characteristics of the enrolled individuals, and such other factors as the Secretary determines appropriate.

"(3) INTERIM PAYMENTS.—A qualifying Independence at Home Medical Practice may receive payments for geriatric assessments and monthly care coordination services as determined by the Secretary but in the event that an Independence at Home Medical Practice does not achieve the required savings in this subsection, those payments or a fraction of them, as appropriate, are at risk of being recouped by the Secretary to ensure that no Independence at Home Medical Practice receives Medicare payments in excess of what Medicare otherwise would have paid for the services provided to the beneficiaries receiving medical care from the Independence at Home Medical Practice in the absence of the pilot program.

"(4) ASSURANCE OF FINANCIAL SOLVENCY.—In order to receive payments under paragraph (3), a qualifying Independence at Home Medical Practice shall demonstrate to the satisfaction of the Secretary that the organization is able to assume financial risk for the 5 percent savings requirements through available reserves, reinsurance, or withholding of funding provided under this title, or such other means as the Secretary determines appropriate.

"(5) NO ADDITIONAL PROGRAM EXPENDITURES.—The Secretary shall limit shared savings payments to each qualifying Independence at Home Medical Practice under this subsection as necessary to ensure that the aggregate expenditures with respect to applicable beneficiaries for such Independence at Home Medical Practice under this title (inclusive of shared savings payments described in this paragraph) do not exceed the amount that the Secretary estimates would be expended for such Independence at Home Medical Practice for such beneficiaries if the pilot program under this section were not implemented.

"(d) APPLICABLE BENEFICIARIES.—

"(1) DEFINITION.—In this section, the term 'applicable beneficiary' means, with respect to a qualifying Independence at Home Medical Practice, an individual who—

"(A) is enrolled under part B and entitled to benefits under part A;

"(B) is not enrolled in a Medicare Advantage plan under part C or a PACE program under section 1894;

"(C) is in the top 20 percent of Medicare patient risk scores;

"(D) has two or more chronic illnesses, including congestive heart failure, diabetes, chronic obstructive pulmonary disease, ischemic heart disease, stroke, Alzheimer's Disease and other dementias designated by the Secretary, pressure ulcers, hypertension, neurodegenerative diseases designated by the Secretary which result in high costs under this title including amyotropic lateral sclerosis (ALS), multiple sclerosis, and Parkinson's disease, and other chronic conditions identified by the Secretary that result in high costs when in combination with one or more of the diseases listed in this subparagraph;

"(E) had a nonelective hospital admission within the past 12 months;

"(F) has received acute or subacute rehabilitation services;

"(G) continues to have two or more functional dependencies requiring the assistance of another person (for example, bathing, dressing, toileting, walking, or feeding); and

"(H) fulfills such other criteria as the Secretary determines appropriate.

"(2) PUBLICATION OF REQUIREMENTS.—The Secretary shall publish eligibility requirements for beneficiaries that are sufficiently clear to be understood by beneficiaries and the individuals providing services to them as part of the pilot program.

"(3) PATIENT ELECTION TO PARTICIPATE.—The Secretary shall determine an appropriate method of ensuring that applicable beneficiaries have agreed to participate in an Independence at Home Medical Practice. Participation shall be entirely voluntary.

"(4) BENEFICIARY ACCESS TO SERVICES.—Except as provided in subsection (e)(2), nothing in this section shall be construed as encouraging physicians or nurse practitioners to limit beneficiary access to services covered under title XVIII and beneficiaries shall not be required to relinquish access to any benefit under this title as a condition of receiving services from an Independence at Home Medical Practice.

"(e) IMPLEMENTATION.—

"(1) STARTING DATE.—The pilot program shall begin not later than January 1, 2012. An agreement with a qualifying Independence at Home Medical Practice under the pilot program may cover a 3 year period.

"(2) NO DUPLICATION IN PILOT PARTICIPATION.—A physician or nurse practitioner who participates in the accountable care organization pilot program under section 1866D or the medical home pilot program under section 1866E shall not be eligible to participate in the pilot program under this subsection.

"(3) PREFERENCE.—In approving an Independence at Home Medical Practice, the Secretary shall give preference to medical practices that are—

"(A) located in high cost areas of the country;

"(B) have experience in furnishing health care services to applicable beneficiaries in the home; and

"(C) use electronic medical records, health information technology, and individualized plans of care.

"(4) WAIVER.—The Secretary may waive such provisions of this title (including section 1877) and title XI in the manner the Secretary determines necessary in order implement the pilot program.

"(5) ADMINISTRATION.—Chapter 35 of title 44, United States Code shall not apply to this section.

"(f) MINIMUM NUMBER OF SITES.—To the extent practicable, at least two unaffiliated Independence at Home Medical Practices will be established in the 13 highest cost States and the District of Columbia and in 13 additional States that are representative of other regions of the United States and include medically underserved rural and urban areas as determined by the Secretary.

"(g) EVALUATION AND MONITORING.—The Secretary shall annually evaluate each qualifying Independence at Home Medical Practice under the pilot program to assess whether it achieved the minimum savings of 5 percent and the results described in subsection (a). The Secretary shall have the discretion to terminate an agreement with an Independence at Home Medical Practice that fails to achieve a preponderance of those results. The Secretary shall make evaluations publicly available within 60 days of the date of completion of such report.

"(h) REPORTS TO CONGRESS.—Not later than 2 years after the date the first agreement is entered into under this section, and biennially thereafter until the pilot is completed, the Secretary shall submit to Congress and make publicly available a report on best practices under the pilot program. Each report shall address the impact of such best practices on expenditures, access, and quality under this title.

"(i) EXPANSION TO PROGRAM IMPLEMENTATIONS.—

"(1) TESTING AND REFINEMENT OF PAYMENT INCENTIVE AND SERVICE DELIVERY MODELS.—Subject to the evaluation described in subsection (f), the Secretary may enter into agreements under the pilot program with additional qualifying Independence at Home Medical Practices to further test and refine models with respect to qualifying Independence at Home Medical Practices.

"(2) EXPANDING USE OF SUCCESSFUL MODELS TO PROGRAM IMPLEMENTATION.—

"(A) IN GENERAL.—Subject to subparagraph (B), the Secretary may issue regulations to implement, on a permanent basis, the Independence at Home Medical Practice Model if, and to the extent that, such models are beneficial to the program under this title, as determined by the Secretary.

"(B) CERTIFICATION.—The Chief Actuary of the Centers for Medicare and Medicaid Services shall certify that the Independence at Home Medical Model described in subparagraph (A) would result in estimated spending that would be less than what spending would otherwise be estimated to be in the absence of such expansion.

"(j) FUNDING.—For purposes of administering and carrying out the pilot program, other than for payments for items and services furnished under this title, shared savings and monthly fees, or other payments under subsection (c), in addition to funds otherwise appropriated, there are appropriated to the Secretary for the Center for Medicare and Medicaid Services Program Management Account $5,000,000 for each of fiscal years 2010 through 2014. Amounts appropriated under this paragraph for a fiscal year shall be available until expended.".

SEC. 1304. PAYMENT INCENTIVE FOR SELECTED PRIMARY CARE SERVICES.

(a) IN GENERAL.—Section 1833 of the Social Security Act is amended by inserting after subsection (o) the following new subsection:

"(p) PRIMARY CARE PAYMENT INCENTIVES.—

"(1) IN GENERAL.—In the case of primary care services (as defined in paragraph (2)) furnished on or after January 1, 2011, by a primary care practitioner (as defined in paragraph (3)) for which amounts are payable under section 1848, in addition to the amount otherwise paid under this part there shall also be paid to the practitioner (or to an employer or facility in the cases described in

clause (A) of section 1842(b)(6)) (on a monthly or quarterly basis) from the Federal Supplementary Medical Insurance Trust Fund an amount equal 5 percent (or 10 percent if the practitioner predominately furnishes such services in an area that is designated (under section 332(a)(1)(A) of the Public Health Service Act) as a primary care health professional shortage area.

"(2) PRIMARY CARE SERVICES DEFINED.—In this subsection, the term 'primary care services'—

"(A) means services which are evaluation and management services as defined in section 1848(j)(5)(A); and

"(B) includes services furnished by another health care professional that would be described in subparagraph (A) if furnished by a physician.

"(3) PRIMARY CARE PRACTITIONER DEFINED.—In this subsection, the term 'primary care practitioner'—

"(A) means a physician or other health care practitioner (including a nurse practitioner) who—

"(i) specializes in family medicine, general internal medicine, general pediatrics, geriatrics, or obstetrics and gynecology; and

"(ii) has allowed charges for primary care services that account for at least 50 percent of the physician's or practitioner's total allowed charges under section 1848, as determined by the Secretary for the most recent period for which data are available; and

"(B) includes a physician assistant who is under the supervision of a physician described in subparagraph (A).

"(4) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, respecting—

"(A) any determination or designation under this subsection;

"(B) the identification of services as primary care services under this subsection; and

"(C) the identification of a practitioner as a primary care practitioner under this subsection.

"(5) COORDINATION WITH OTHER PAYMENTS.—

"(A) WITH OTHER PRIMARY CARE INCENTIVES.—The provisions of this subsection shall not be taken into account in applying subsections (m) and (u) and any payment under such subsections shall not be taken into account in computing payments under this subsection.

"(B) WITH QUALITY INCENTIVES.—Payments under this subsection shall not be taken into account in determining the amounts that would otherwise be paid under this part for purposes of section 1834(g)(2)(B).".

(b) CONFORMING AMENDMENTS.—

(1) Section 1833(m) of such Act (42 U.S.C. 1395l(m)) is amended by redesignating paragraph (4) as paragraph (5) and by inserting after paragraph (3) the following new paragraph:

"(4) The provisions of this subsection shall not be taken into account in applying subsections (m) or (u) and any payment under such subsections shall not be taken into account in computing payments under this subsection.".

(2) Section 1848(m)(5)(B) of such Act (42 U.S.C. 1395w–4(m)(5)(B)) is amended by inserting ", (p)," after "(m)".

(3) Section 1848(o)(1)(B)(iv) of such Act (42 U.S.C. 1395w–4(o)(1)(B)(iv)) is amended by inserting "primary care" before "health professional shortage area".

SEC. 1305. INCREASED REIMBURSEMENT RATE FOR CERTIFIED NURSE-MIDWIVES.

(a) IN GENERAL.—Section 1833(a)(1)(K) of the Social Security Act (42 U.S.C.1395l(a)(1)(K)) is amended by striking "(but in no event" and all that follows through "performed by a physician)".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to services furnished on or after January 1, 2011.

SEC. 1306. COVERAGE AND WAIVER OF COST-SHARING FOR PREVENTIVE SERVICES.

(a) MEDICARE COVERED PREVENTIVE SERVICES DEFINED.—Section 1861 of the Social Security Act (42 U.S.C. 1395x), as amended by section 1233(a), is amended by adding at the end the following new subsection:

"Medicare Covered Preventive Services

"(iii)(1) Subject to the succeeding provisions of this subsection, the term 'Medicare covered preventive services' means the following:

"(A) Prostate cancer screening tests (as defined in subsection (oo)).

"(B) Colorectal cancer screening tests (as defined in subsection (pp) and when applicable as described in section 1305).

"(C) Diabetes outpatient self-management training services (as defined in subsection (qq)).

"(D) Screening for glaucoma for certain individuals (as described in subsection (s)(2)(U)).

"(E) Medical nutrition therapy services for certain individuals (as described in subsection (s)(2)(V)).

"(F) An initial preventive physical examination (as defined in subsection (ww)).

"(G) Cardiovascular screening blood tests (as defined in subsection (xx)(1)).

"(H) Diabetes screening tests (as defined in subsection (yy)).

"(I) Ultrasound screening for abdominal aortic aneurysm for certain individuals (as described in described in subsection (s)(2)(AA)).

"(J) Pneumococcal and influenza vaccines and their administration (as described in subsection (s)(10)(A)) and hepatitis B vaccine and its administration for certain individuals (as described in subsection (s)(10)(B)).

"(K) Screening mammography (as defined in subsection (jj)).

"(L) Screening pap smear and screening pelvic exam (as defined in subsection (nn)).

"(M) Bone mass measurement (as defined in subsection (rr)).

"(N) Kidney disease education services (as defined in subsection (ggg)).

"(O) Additional preventive services (as defined in subsection (ddd)).

"(2) With respect to specific Medicare covered preventive services, the limitations and conditions described in the provisions referenced in paragraph (1) with respect to such services shall apply.".

(b) PAYMENT AND ELIMINATION OF COST-SHARING.—

(1) IN GENERAL.—

(A) IN GENERAL.—Section 1833(a) of the Social Security Act (42 U.S.C. 1395l(a)) is amended by adding after and below paragraph (9) the following: "With respect to Medicare covered preventive services, in any case in which the payment rate otherwise provided under this part is computed as a percent of less than 100 percent of an actual charge, fee schedule rate, or other rate, such percentage shall be increased to 100 percent.".

(B) APPLICATION TO SIGMOIDOSCOPIES AND COLONOSCOPIES.—Section 1834(d) of such Act (42 U.S.C. 1395m(d)) is amended—

(i) in paragraph (2)(C), by amending clause (ii) to read as follows:

"(ii) NO COINSURANCE.—In the case of a beneficiary who receives services described in clause (i), there shall be no coinsurance applied."; and

(ii) in paragraph (3)(C), by amending clause (ii) to read as follows:

"(ii) NO COINSURANCE.—In the case of a beneficiary who receives services described in clause (i), there shall be no coinsurance applied.".

(2) ELIMINATION OF COINSURANCE IN OUTPATIENT HOSPITAL SETTINGS.—

(A) EXCLUSION FROM OPD FEE SCHEDULE.—Section 1833(t)(1)(B)(iv) of the Social Security Act (42 U.S.C. 1395l(t)(1)(B)(iv)) is amended by striking "screening mammography (as defined in section 1861(jj)) and diagnostic mammography" and inserting "diagnostic mammograms and Medicare covered preventive services (as defined in section 1861(iii)(1))".

(B) CONFORMING AMENDMENTS.—Section 1833(a)(2) of the Social Security Act (42 U.S.C. 1395l(a)(2)) is amended—

(i) in subparagraph (F), by striking "and" after the semicolon at the end;

(ii) in subparagraph (G), by adding "and" at the end; and

(iii) by adding at the end the following new subparagraph:

"(H) with respect to additional preventive services (as defined in section 1861(ddd)) furnished by an outpatient department of a hospital, the amount determined under paragraph (1)(W);".

(3) WAIVER OF APPLICATION OF DEDUCTIBLE FOR ALL PREVENTIVE SERVICES.—The first sentence of section 1833(b) of the Social Security Act (42 U.S.C. 1395l(b)) is amended—

(A) in clause (1), by striking "items and services described in section 1861(s)(10)(A)" and inserting "Medicare covered preventive services (as defined in section 1861(iii))"; and

(B) by striking clause (5) and all that follows through "(9)" and inserting "and (5)".

(4) APPLICATION TO PROVIDERS OF SERVICES.—Section 1866(a)(2)(A)(ii) of such Act (42 U.S.C. 1395cc(a)(2)(A)(ii)) is amended by inserting "other than for Medicare covered preventive services and" after "for such items and services (".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after January 1, 2011.

(d) REPORT TO CONGRESS ON BARRIERS TO PREVENTIVE SERVICES.—Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall report to Congress on Medicare beneficiary barriers, such as physician referral requirements or being a part of the Welcome to Medicare Physical Exam, to abdominal aortic aneurysm screening and other preventative services as approved by the U.S. Preventive Services Task Force. Furthermore, using existing educational resources, the Secretary shall make educating patients and physicians regarding the risk factors for an abdominal aortic aneurysm and when beneficiaries should be screened, a priority.

SEC. 1307. WAIVER OF DEDUCTIBLE FOR COLORECTAL CANCER SCREENING TESTS REGARDLESS OF CODING, SUBSEQUENT DIAGNOSIS, OR ANCILLARY TISSUE REMOVAL.

(a) IN GENERAL.—Section 1833(b) of the Social Security Act (42 U.S.C. 1395l(b)), as amended by section 1306(b)(3), is amended by adding at the end the following new sentence: "Clause (1) of the first sentence of this subsection shall apply with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as, the screening test.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to items and services furnished on or after January 1, 2011.

SEC. 1308. EXCLUDING CLINICAL SOCIAL WORKER SERVICES FROM COVERAGE UNDER THE MEDICARE SKILLED NURSING FACILITY PROSPECTIVE PAYMENT SYSTEM AND CONSOLIDATED PAYMENT.

(a) IN GENERAL.—Section 1888(e)(2)(A)(ii) of the Social Security Act (42 U.S.C. 1395yy(e)(2)(A)(ii)) is amended by inserting "clinical social worker services," after "qualified psychologist services,".

(b) CONFORMING AMENDMENT.—Section 1861(hh)(2) of the Social Security Act (42 U.S.C. 1395x(hh)(2)) is amended by striking "and other than services furnished to an inpatient of a skilled nursing facility which the facility is required to provide as a requirement for participation".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to items and services furnished on or after July 1, 2010.

SEC. 1309. COVERAGE OF MARRIAGE AND FAMILY THERAPIST SERVICES AND MENTAL HEALTH COUNSELOR SERVICES.

(a) COVERAGE OF MARRIAGE AND FAMILY THERAPIST SERVICES.—

(1) COVERAGE OF SERVICES.—Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)), as amended by section 1233, is amended—

(A) in subparagraph (EE), by striking "and" at the end;

(B) in subparagraph (FF), by adding "and" at the end; and

(C) by adding at the end the following new subparagraph:

"(GG) marriage and family therapist services (as defined in subsection (jjj));".

(2) DEFINITION.—Section 1861 of the Social Security Act (42 U.S.C. 1395x), as amended by sections 1233 and 1306, is amended by adding at the end the following new subsection:

"Marriage and Family Therapist Services

"(jjj)(1) The term 'marriage and family therapist services' means services performed by a marriage and family therapist (as defined in paragraph (2)) for the diagnosis and treatment of mental illnesses, which the marriage and family therapist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are performed, as would otherwise be covered if furnished by a physician or as incident to a physician's professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services.

"(2) The term 'marriage and family therapist' means an individual who—

"(A) possesses a master's or doctoral degree which qualifies for licensure or certification as a marriage and family therapist pursuant to State law;

"(B) after obtaining such degree has performed at least 2 years of clinical supervised experience in marriage and family therapy; and

"(C) is licensed or certified as a marriage and family therapist in the State in which marriage and family therapist services are performed.".

(3) PROVISION FOR PAYMENT UNDER PART B.—Section 1832(a)(2)(B) of the Social Security Act (42 U.S.C. 1395k(a)(2)(B)) is amended by adding at the end the following new clause:

"(v) marriage and family therapist services;".

(4) AMOUNT OF PAYMENT.—

(A) IN GENERAL.—Section 1833(a)(1) of the Social Security Act (42 U.S.C. 1395l(a)(1)) is amended—

(i) by striking "and" before "(W)"; and

(ii) by inserting before the semicolon at the end the following: ", and (X) with respect to marriage and family therapist services under section 1861(s)(2)(GG), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or 75 percent of the amount determined for payment of a psychologist under clause (L)".

(B) DEVELOPMENT OF CRITERIA WITH RESPECT TO CONSULTATION WITH A HEALTH CARE PROFESSIONAL.—The Secretary of Health and Human Services shall, taking into consideration concerns for patient confidentiality, develop criteria with respect to payment for marriage and family therapist services for which payment may be made directly to the marriage and family therapist under part B of title XVIII of the Social Security Act (42 U.S.C. 1395j et seq.) under which such a therapist must agree to consult with a patient's attending or primary care physician or nurse practitioner in accordance with such criteria.

(5) EXCLUSION OF MARRIAGE AND FAMILY THERAPIST SERVICES FROM SKILLED NURSING FACILITY PROSPECTIVE PAYMENT SYSTEM.—Section 1888(e)(2)(A)(ii) of the Social Security Act (42 U.S.C. 1395yy(e)(2)(A)(ii)), as amended by section 1308(a), is amended by inserting "marriage and family therapist services (as defined in subsection (jjj)(1))," after "clinical social worker services,".

(6) COVERAGE OF MARRIAGE AND FAMILY THERAPIST SERVICES PROVIDED IN RURAL HEALTH CLINICS AND FEDERALLY QUALIFIED HEALTH CENTERS.—Section 1861(aa)(1)(B) of the Social Security Act (42 U.S.C. 1395x(aa)(1)(B)) is amended by striking "or by a clinical social worker (as defined in subsection (hh)(1))," and inserting ", by a clinical social worker (as defined in subsection (hh)(1)), or by a marriage and family therapist (as defined in subsection (jjj)(2))," .

(7) INCLUSION OF MARRIAGE AND FAMILY THERAPISTS AS PRACTITIONERS FOR ASSIGNMENT OF CLAIMS.—Section 1842(b)(18)(C) of the Social Security Act (42 U.S.C. 1395u(b)(18)(C)) is amended by adding at the end the following new clause:

"(vii) A marriage and family therapist (as defined in section 1861(jjj)(2)).".

(b) COVERAGE OF MENTAL HEALTH COUNSELOR SERVICES.—

(1) COVERAGE OF SERVICES.—Section 1861(s)(2) of the Social Security Act (42 U.S.C. 1395x(s)(2)), as previously amended, is further amended—

(A) in subparagraph (FF), by striking "and" at the end;

(B) in subparagraph (GG), by inserting "and" at the end; and

(C) by adding at the end the following new subparagraph:

"(HH) mental health counselor services (as defined in subsection (kkk)(1));".

(2) DEFINITION.—Section 1861 of the Social Security Act (42 U.S.C. 1395x), as previously amended, is amended by adding at the end the following new subsection:

"Mental Health Counselor Services

"(kkk)(1) The term 'mental health counselor services' means services performed by a mental health counselor (as defined in paragraph (2)) for the diagnosis and treatment of mental illnesses which the mental health counselor is legally authorized to perform under State law (or the State regulatory mechanism provided by the State law) of the State in which such services are performed, as would otherwise be covered if furnished by a physician or as incident to a physician's professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services.

"(2) The term 'mental health counselor' means an individual who—

"(A) possesses a master's or doctor's degree which qualifies the individual for licensure or certification for the practice of mental health counseling in the State in which the services are performed;

"(B) after obtaining such a degree has performed at least 2 years of supervised mental health counselor practice; and

"(C) is licensed or certified as a mental health counselor or professional counselor by the State in which the services are performed.".

(3) PROVISION FOR PAYMENT UNDER PART B.—Section 1832(a)(2)(B) of the Social Security Act (42 U.S.C. 1395k(a)(2)(B)), as amended by subsection (a)(3), is further amended—

(A) by striking "and" at the end of clause (iv);

(B) by adding "and" at the end of clause (v); and

(C) by adding at the end the following new clause:

"(vi) mental health counselor services; and".

(4) AMOUNT OF PAYMENT.—

(A) IN GENERAL.—Section 1833(a)(1) of the Social Security Act (42 U.S.C. 1395l(a)(1)), as amended by subsection (a), is further amended—

(i) by striking "and" before "(X)"; and

(ii) by inserting before the semicolon at the end the following: ", and (Y) with respect to mental health counselor services under section 1861(s)(2)(HH), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or 75 percent of the amount determined for payment of a psychologist under clause (L)".

(B) DEVELOPMENT OF CRITERIA WITH RESPECT TO CONSULTATION WITH A PHYSICIAN.—The Secretary of Health and Human Services shall, taking into consideration concerns for patient confidentiality, develop criteria with respect to payment for mental health counselor services for which payment may be made directly to the mental health counselor under part B of title XVIII of the Social Security Act (42 U.S.C. 1395j et seq.) under which such a counselor must agree to consult with a patient's attending or primary care physician in accordance with such criteria.

(5) EXCLUSION OF MENTAL HEALTH COUNSELOR SERVICES FROM SKILLED NURSING FACILITY PROSPECTIVE PAYMENT SYSTEM.—Section 1888(e)(2)(A)(ii) of the Social Security Act (42 U.S.C. 1395yy(e)(2)(A)(ii)), as amended by section 1308(a) and subsection (a), is amended by inserting "mental health counselor services (as defined in section 1861(kkk)(1))," after "marriage and family therapist services (as defined in subsection (jjj)(1)),".

(6) COVERAGE OF MENTAL HEALTH COUNSELOR SERVICES PROVIDED IN RURAL HEALTH CLINICS AND FEDERALLY QUALIFIED HEALTH CENTERS.—Section 1861(aa)(1)(B) of the Social Security Act (42 U.S.C. 1395x(aa)(1)(B)), as amended by subsection (a), is amended by striking "or by a marriage and family therapist (as defined in subsection (jjj)(2))," and inserting "by a marriage and family therapist (as defined in subsection (jjj)(2)), or a mental health counselor (as defined in subsection (kkk)(2))),".

(7) INCLUSION OF MENTAL HEALTH COUNSELORS AS PRACTITIONERS FOR ASSIGNMENT OF CLAIMS.—Section 1842(b)(18)(C) of the Social Security Act (42 U.S.C. 1395u(b)(18)(C)), as amended by subsection (a)(7), is amended by adding at the end the following new clause:

"(viii) A mental health counselor (as defined in section 1861(kkk)(2)).".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to items and services furnished on or after January 1, 2011.

SEC. 1310. EXTENSION OF PHYSICIAN FEE SCHEDULE MENTAL HEALTH ADD-ON.

Section 138(a)(1) of the Medicare Improvements for Patients and Providers Act of 2008 (Public Law 110–275) is amended by striking "December 31, 2009" and inserting "December 31, 2011".

SEC. 1311. EXPANDING ACCESS TO VACCINES.

(a) IN GENERAL.—Paragraph (10) of section 1861(s) of the Social Security Act (42 U.S.C. 1395w(s)) is amended to read as follows:

"(10) federally recommended vaccines (as defined in subsection (lll)) and their respective administration;".

(b) FEDERALLY RECOMMENDED VACCINES DEFINED.—Section 1861 of such Act, as previously amended, is further amended by adding at the end the following new subsection:

"Federally Recommended Vaccines

"(lll) The term 'federally recommended vaccine' means an approved vaccine recommended by the Advisory Committee on Immunization Practices (an advisory committee established by the Secretary, acting through the Director of the Centers for Disease Control and Prevention).".

(c) CONFORMING AMENDMENTS.—

(1) Section 1833 of such Act (42 U.S.C. 1395l) is amended, in each of subsections (a)(1)(B), (a)(2)(G), (a)(3)(A), by striking "1861(s)(10)(A)" and inserting "1861(s)(10)" each place it appears.

(2) Section 1842(o)(1)(A)(iv) of such Act (42 U.S.C. 1395u(o)(1)(A)(iv)) is amended—

(A) by striking "subparagraph (A) or (B) of"; and

(B) by inserting before the period the following: "and before January 1, 2011, and influenza vaccines furnished on or after January 1, 2011".

(3) Section 1847A(c)(6) of such Act (42 U.S.C. 1395w–3a(c)(6)) is amended by striking subparagraph (G) and inserting the following:

"(G) IMPLEMENTATION.—Chapter 35 of title 44, United States Code shall not apply to manufacturer provision of information pursuant to section 1927(b)(3)(A)(iii) for purposes of implementation of this section.".

(4) Section 1860D–2(e)(1) of such Act (42 U.S.C. 1395w–102(e)(1)) is amended by striking "such term includes a vaccine" and all that follows through "its administration) and".

(5) Section 1861(ww)(2)(A) of such Act (42 U.S.C. 1395x(ww)(2)(A))) is amended by striking "Pneumococcal, influenza, and hepatitis B vaccine and administration" and inserting "Federally recommended vaccines (as defined in subsection (lll)) and their respective administration".

(6) Section 1861(iii)(1) of such Act, as added by section 1306(a), is amended by amending subparagraph (J) to read as follows:

"(J) Federally recommended vaccines (as defined in subsection (lll)) and their respective administration.".

(7) Section 1927(b)(3)(A)(iii) of such Act (42 U.S.C. 1396r–8(b)(3)(A)(iii)) is amended, in the matter following subclause (III), by inserting "(A)(iv) (including influenza vaccines furnished on or after January 1, 2011)," after "described in subparagraph"

(d) EFFECTIVE DATES.—The amendments made by—

(1) this section (other than by subsection (c)(7)) shall apply to vaccines administered on or after January 1, 2011; and

(2) by subsection (c)(7) shall apply to calendar quarters beginning on or after January 1, 2010.

SEC. 1312. RECOGNITION OF CERTIFIED DIABETES EDUCATORS AS CERTIFIED PROVIDERS FOR PURPOSES OF MEDICARE DIABETES OUTPATIENT SELF-MANAGEMENT TRAINING SERVICES.

(a) IN GENERAL.—Section 1861(qq) of the Social Security Act (42 U.S.C. 1395x(qq)) is amended—

(1) in paragraph (1), by inserting "or by a certified diabetes educator (as defined in paragraph (3))" after "paragraph (2)(B)"; and

(2) by adding at the end the following new paragraphs:

"(3) For purposes of paragraph (1), the term 'certified diabetes educator' means an individual who—

"(A) is licensed or registered by the State in which the services are performed as a health care professional;

"(B) specializes in teaching individuals with diabetes to develop the necessary skills and knowledge to manage the individual's diabetic condition; and

"(C) is certified as a diabetes educator by a recognized certifying body (as defined in paragraph (4)).

"(4)(A) For purposes of paragraph (3)(C), the term 'recognized certifying body' means—

"(i) the National Certification Board for Diabetes Educators, or

"(ii) a certifying body for diabetes educators, which is recognized by the Secretary as authorized to grant certification of diabetes educators for purposes of this subsection pursuant to standards established by the Secretary, if the Secretary determines such Board or body, respectively, meets the requirement of subparagraph (B).

"(B) The National Certification Board for Diabetes Educators or a certifying body for diabetes educators meets the requirement of this subparagraph, with respect to the certification of an individual, if the Board or body, respectively, is incorporated and registered to do business in the United States and requires as a condition of such certification each of the following:

"(i) The individual has a qualifying credential in a specified health care profession.

"(ii) The individual has professional practice experience in diabetes self-management training that includes a minimum number of hours and years of experience in such training.

"(iii) The individual has successfully completed a national certification examination offered by such entity.

"(iv) The individual periodically renews certification status following initial certification.".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to diabetes outpatient self-management training services furnished on or after the first day of the first calendar year that is at least 6 months after the date of the enactment of this Act.

TITLE IV—QUALITY

Subtitle A—Comparative Effectiveness Research

SEC. 1401. COMPARATIVE EFFECTIVENESS RESEARCH.

(a) IN GENERAL.—Title XI of the Social Security Act is amended by adding at the end the following new part:

"PART D—COMPARATIVE EFFECTIVENESS RESEARCH

"COMPARATIVE EFFECTIVENESS RESEARCH

"SEC. 1181. (a) CENTER FOR COMPARATIVE EFFECTIVENESS RESEARCH ESTABLISHED.—

"(1) IN GENERAL.—The Secretary shall establish within the Agency for Healthcare Research and Quality a Center for Comparative Effectiveness Research (in this section referred to as the 'Center') to conduct, support, and synthesize research (including research conducted or supported under section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003) with respect to the outcomes, effectiveness, and appropriateness of health care services and procedures in order to identify the manner in which diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically.

"(2) DUTIES.—The Center shall—

"(A) conduct, support, and synthesize research relevant to the comparative effectiveness of the full spectrum of health care items, services and systems, including pharmaceuticals, medical devices, medical and surgical procedures, and other medical interventions;

"(B) conduct and support systematic reviews of clinical research, including original research conducted subsequent to the date of the enactment of this section;

"(C) continuously develop rigorous scientific methodologies for conducting comparative effectiveness studies, and use such methodologies appropriately;

"(D) submit to the Comparative Effectiveness Research Commission, the Secretary, and Congress appropriate relevant reports described in subsection (d)(2); and

"(E) encourage, as appropriate, the development and use of clinical registries and the development of clinical effectiveness research data networks from electronic health records, post marketing drug and medical device surveillance efforts, and other forms of electronic health data.

"(3) POWERS.—

"(A) OBTAINING OFFICIAL DATA.—The Center may secure directly from any department or agency of the United States information necessary to enable it to carry out this section. Upon request of the Center, the head of that department or agency shall furnish that information to the Center on an agreed upon schedule.

"(B) DATA COLLECTION.—In order to carry out its functions, the Center shall—

"(i) utilize existing information, both published and unpublished, where possible, collected and assessed either by its own staff or under other arrangements made in accordance with this section,

"(ii) carry out, or award grants or contracts for, original research and experimentation, where existing information is inadequate, and

"(iii) adopt procedures allowing any interested party to submit information for the use by the Center and Commission under subsection (b) in making reports and recommendations.

"(C) ACCESS OF GAO TO INFORMATION.—The Comptroller General shall have unrestricted access to all deliberations, records, and nonproprietary data of the Center and Commission under subsection (b), immediately upon request.

"(D) PERIODIC AUDIT.—The Center and Commission under subsection (b) shall be subject to periodic audit by the Comptroller General.

"(b) OVERSIGHT BY COMPARATIVE EFFECTIVENESS RESEARCH COMMISSION.—

"(1) IN GENERAL.—The Secretary shall establish an independent Comparative Effectiveness Research Commission (in this section referred to as the 'Commission') to oversee and evaluate the activities carried out by the Center under sub-

section (a), subject to the authority of the Secretary, to ensure such activities result in highly credible research and information resulting from such research.

"(2) DUTIES.—The Commission shall—

"(A) determine national priorities for research described in subsection (a) and in making such determinations consult with a broad array of public and private stakeholders, including patients and health care providers and payers;

"(B) monitor the appropriateness of use of the CERTF described in subsection (g) with respect to the timely production of comparative effectiveness research determined to be a national priority under subparagraph (A);

"(C) identify highly credible research methods and standards of evidence for such research to be considered by the Center;

"(D) review the methodologies developed by the center under subsection (a)(2)(C);

"(E) not later than one year after the date of the enactment of this section, enter into an arrangement under which the Institute of Medicine of the National Academy of Sciences shall conduct an evaluation and report on standards of evidence for such research;

"(F) support forums to increase stakeholder awareness and permit stakeholder feedback on the efforts of the Center to advance methods and standards that promote highly credible research;

"(G) make recommendations for policies that would allow for public access of data produced under this section, in accordance with appropriate privacy and proprietary practices, while ensuring that the information produced through such data is timely and credible;

"(H) appoint a clinical perspective advisory panel for each research priority determined under subparagraph (A), which shall consult with patients and advise the Center on research questions, methods, and evidence gaps in terms of clinical outcomes for the specific research inquiry to be examined with respect to such priority to ensure that the information produced from such research is clinically relevant to decisions made by clinicians and patients at the point of care;

"(I) make recommendations for the priority for periodic reviews of previous comparative effectiveness research and studies conducted by the Center under subsection (a);

"(J) routinely review processes of the Center with respect to such research to confirm that the information produced by such research is objective, credible, consistent with standards of evidence established under this section, and developed through a transparent process that includes consultations with appropriate stakeholders; and

"(K) make recommendations to the center for the broad dissemination of the findings of research conducted and supported under this section that enables clinicians, patients, consumers, and payers to make more informed health care decisions that improve quality and value.

"(3) COMPOSITION OF COMMISSION.—

"(A) IN GENERAL.—The members of the Commission shall consist of—

"(i) the Director of the Agency for Healthcare Research and Quality;

"(ii) the Chief Medical Officer of the Centers for Medicare & Medicaid Services; and

"(iii) 15 additional members who shall represent broad constituencies of stakeholders including clinicians, patients, researchers, third-party payers, consumers of Federal and State beneficiary programs.

Of such members, at least 9 shall be practicing physicians, health care practitioners, consumers, or patients.

"(B) QUALIFICATIONS.—

"(i) DIVERSE REPRESENTATION OF PERSPECTIVES.—The members of the Commission shall represent a broad range of perspectives and shall collectively have experience in the following areas:

"(I) Epidemiology.

"(II) Health services research.

"(III) Bioethics.

"(IV) Decision sciences.

"(V) Health disparities.

"(VI) Economics.

"(ii) DIVERSE REPRESENTATION OF HEALTH CARE COMMUNITY.—At least one member shall represent each of the following health care communities:

"(I) Patients.

"(II) Health care consumers.

"(III) Practicing Physicians, including surgeons.
"(IV) Other health care practitioners engaged in clinical care.
"(V) Employers.
"(VI) Public payers.
"(VII) Insurance plans.
"(VIII) Clinical researchers who conduct research on behalf of pharmaceutical or device manufacturers.

"(C) LIMITATION.—No more than 3 of the Members of the Commission may be representatives of pharmaceutical or device manufacturers and such representatives shall be clinical researchers described under subparagraph (B)(ii)(VIII).

"(4) APPOINTMENT.—

"(A) IN GENERAL.—The Secretary shall appoint the members of the Commission.

"(B) CONSULTATION.—In considering candidates for appointment to the Commission, the Secretary may consult with the Government Accountability Office and the Institute of Medicine of the National Academy of Sciences.

"(5) CHAIRMAN; VICE CHAIRMAN.—The Secretary shall designate a member of the Commission, at the time of appointment of the member, as Chairman and a member as Vice Chairman for that term of appointment, except that in the case of vacancy of the Chairmanship or Vice Chairmanship, the Secretary may designate another member for the remainder of that member's term. The Chairman shall serve as an ex officio member of the National Advisory Council of the Agency for Health Care Research and Quality under section 931(c)(3)(B) of the Public Health Service Act.

"(6) TERMS.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), each member of the Commission shall be appointed for a term of 4 years.

"(B) TERMS OF INITIAL APPOINTEES.—Of the members first appointed—

"(i) 8 shall be appointed for a term of 4 years; and

"(ii) 7 shall be appointed for a term of 3 years.

"(7) COORDINATION.—To enhance effectiveness and coordination, the Secretary is encouraged, to the greatest extent possible, to seek coordination between the Commission and the National Advisory Council of the Agency for Healthcare Research and Quality.

"(8) CONFLICTS OF INTEREST.—

"(A) IN GENERAL.—In appointing the members of the Commission or a clinical perspective advisory panel described in paragraph (2)(H), the Secretary or the Commission, respectively, shall take into consideration any financial interest (as defined in subparagraph (D)), consistent with this paragraph, and develop a plan for managing any identified conflicts.

"(B) EVALUATION AND CRITERIA.—When considering an appointment to the Commission or a clinical perspective advisory panel described paragraph (2)(H) the Secretary or the Commission shall review the expertise of the individual and the financial disclosure report filed by the individual pursuant to the Ethics in Government Act of 1978 for each individual under consideration for the appointment, so as to reduce the likelihood that an appointed individual will later require a written determination as referred to in section 208(b)(1) of title 18, United States Code, a written certification as referred to in section 208(b)(3) of title 18, United States Code, or a waiver as referred to in subparagraph (D)(iii) for service on the Commission at a meeting of the Commission.

"(C) DISCLOSURES; PROHIBITIONS ON PARTICIPATION; WAIVERS.—

"(i) DISCLOSURE OF FINANCIAL INTEREST.—Prior to a meeting of the Commission or a clinical perspective advisory panel described in paragraph (2)(H) regarding a 'particular matter' (as that term is used in section 208 of title 18, United States Code), each member of the Commission or the clinical perspective advisory panel who is a full-time Government employee or special Government employee shall disclose to the Secretary financial interests in accordance with subsection (b) of such section 208.

"(ii) PROHIBITIONS ON PARTICIPATION.—Except as provided under clause (iii), a member of the Commission or a clinical perspective advisory panel described in paragraph (2)(H) may not participate with respect to a particular matter considered in meeting of the Commission or the clinical perspective advisory panel if such member (or an immediate family member of such member) has a financial interest that could be affected by the advice given to the Secretary with respect to

such matter, excluding interests exempted in regulations issued by the Director of the Office of Government Ethics as too remote or inconsequential to affect the integrity of the services of the Government officers or employees to which such regulations apply.

"(iii) WAIVER.—If the Secretary determines it necessary to afford the Commission or a clinical perspective advisory panel described in paragraph 2(H) essential expertise, the Secretary may grant a waiver of the prohibition in clause (ii) to permit a member described in such subparagraph to—

"(I) participate as a non-voting member with respect to a particular matter considered in a Commission or a clinical perspective advisory panel meeting; or

"(II) participate as a voting member with respect to a particular matter considered in a Commission or a clinical perspective advisory panel meeting.

"(iv) LIMITATION ON WAIVERS AND OTHER EXCEPTIONS.—

"(I) DETERMINATION OF ALLOWABLE EXCEPTIONS FOR THE COMMISSION.—The number of waivers granted to members of the Commission cannot exceed one-half of the total number of members for the Commission.

"(II) PROHIBITION ON VOTING STATUS ON CLINICAL PERSPECTIVE ADVISORY PANELS.—No voting member of any clinical perspective advisory panel shall be in receipt of a waiver. No more than two nonvoting members of any clinical perspective advisory panel shall receive a waiver.

"(D) FINANCIAL INTEREST DEFINED.—For purposes of this paragraph, the term 'financial interest' means a financial interest under section 208(a) of title 18, United States Code.

"(9) COMPENSATION.—While serving on the business of the Commission (including travel time), a member of the Commission shall be entitled to compensation at the per diem equivalent of the rate provided for level IV of the Executive Schedule under section 5315 of title 5, United States Code; and while so serving away from home and the member's regular place of business, a member may be allowed travel expenses, as authorized by the Director of the Commission.

"(10) AVAILABILITY OF REPORTS.—The Commission shall transmit to the Secretary a copy of each report submitted under this subsection and shall make such reports available to the public.

"(11) DIRECTOR AND STAFF; EXPERTS AND CONSULTANTS.—Subject to such review as the Secretary deems necessary to assure the efficient administration of the Commission, the Commission may—

"(A) appoint an Executive Director (subject to the approval of the Secretary) and such other personnel as Federal employees under section 2105 of title 5, United States Code, as may be necessary to carry out its duties (without regard to the provisions of title 5, United States Code, governing appointments in the competitive service);

"(B) seek such assistance and support as may be required in the performance of its duties from appropriate Federal departments and agencies;

"(C) enter into contracts or make other arrangements, as may be necessary for the conduct of the work of the Commission (without regard to section 3709 of the Revised Statutes (41 U.S.C. 5));

"(D) make advance, progress, and other payments which relate to the work of the Commission;

"(E) provide transportation and subsistence for persons serving without compensation; and

"(F) prescribe such rules and regulations as it deems necessary with respect to the internal organization and operation of the Commission.

"(c) RESEARCH REQUIREMENTS.—Any research conducted, supported, or synthesized under this section shall meet the following requirements:

"(1) ENSURING TRANSPARENCY, CREDIBILITY, AND ACCESS.—

"(A) The establishment of the agenda and conduct of the research shall be insulated from inappropriate political or stakeholder influence.

"(B) Methods of conducting such research shall be scientifically based.

"(C) All aspects of the prioritization of research, conduct of the research, and development of conclusions based on the research shall be transparent to all stakeholders.

"(D) The process and methods for conducting such research shall be publicly documented and available to all stakeholders.

"(E) Throughout the process of such research, the Center shall provide opportunities for all stakeholders involved to review and provide public comment on the methods and findings of such research.

"(2) USE OF CLINICAL PERSPECTIVE ADVISORY PANELS.—The research shall meet a national research priority determined under subsection (b)(2)(A) and shall consider advice given to the Center by the clinical perspective advisory panel for the national research priority.

"(3) STAKEHOLDER INPUT.—

"(A) IN GENERAL.—The Commission shall consult with patients, health care providers, health care consumer representatives, and other appropriate stakeholders with an interest in the research through a transparent process recommended by the Commission.

"(B) SPECIFIC AREAS OF CONSULTATION.—Consultation shall include where deemed appropriate by the Commission—

"(i) recommending research priorities and questions;

"(ii) recommending research methodologies; and

"(iii) advising on and assisting with efforts to disseminate research findings.

"(C) OMBUDSMAN.—The Secretary shall designate a patient ombudsman. The ombudsman shall—

"(i) serve as an available point of contact for any patients with an interest in proposed comparative effectiveness studies by the Center; and

"(ii) ensure that any comments from patients regarding proposed comparative effectiveness studies are reviewed by the Commission.

"(4) TAKING INTO ACCOUNT POTENTIAL DIFFERENCES.—Research shall—

"(A) be designed, as appropriate, to take into account the potential for differences in the effectiveness of health care items and services used with various subpopulations such as racial and ethnic minorities, women, different age groups (including children, adolescents, adults, and seniors), and individuals with different comorbidities; and—

"(B) seek, as feasible and appropriate, to include members of such subpopulations as subjects in the research.

"(d) PUBLIC ACCESS TO COMPARATIVE EFFECTIVENESS INFORMATION.—

"(1) IN GENERAL.—Not later than 90 days after receipt by the Center or Commission, as applicable, of a relevant report described in paragraph (2) made by the Center, Commission, or clinical perspective advisory panel under this section, appropriate information contained in such report shall be posted on the official public Internet site of the Center and of the Commission, as applicable.

"(2) RELEVANT REPORTS DESCRIBED.—For purposes of this section, a relevant report is each of the following submitted by the Center or a grantee or contractor of the Center:

"(A) Any interim or progress reports as deemed appropriate by the Secretary.

"(B) Stakeholder comments.

"(C) A final report.

"(e) DISSEMINATION AND INCORPORATION OF COMPARATIVE EFFECTIVENESS INFORMATION.—

"(1) DISSEMINATION.—The Center shall provide for the dissemination of appropriate findings produced by research supported, conducted, or synthesized under this section to health care providers, patients, vendors of health information technology focused on clinical decision support, appropriate professional associations, and Federal and private health plans, and other relevant stakeholders. In disseminating such findings the Center shall—

"(A) convey findings of research so that they are comprehensible and useful to patients and providers in making health care decisions;

"(B) discuss findings and other considerations specific to certain sub-populations, risk factors, and comorbidities as appropriate;

"(C) include considerations such as limitations of research and what further research may be needed, as appropriate;

"(D) not include any data that the dissemination of which would violate the privacy of research participants or violate any confidentiality agreements made with respect to the use of data under this section; and

"(E) assist the users of health information technology focused on clinical decision support to promote the timely incorporation of such findings into clinical practices and promote the ease of use of such incorporation.

"(2) DISSEMINATION PROTOCOLS AND STRATEGIES.—The Center shall develop protocols and strategies for the appropriate dissemination of research findings in order to ensure effective communication of findings and the use and incorporation of such findings into relevant activities for the purpose of informing high-

er quality and more effective and efficient decisions regarding medical items and services. In developing and adopting such protocols and strategies, the Center shall consult with stakeholders concerning the types of dissemination that will be most useful to the end users of information and may provide for the utilization of multiple formats for conveying findings to different audiences, including dissemination to individuals with limited English proficiency.

"(f) REPORTS TO CONGRESS.—

"(1) ANNUAL REPORTS.—Beginning not later than one year after the date of the enactment of this section, the Director of the Agency of Healthcare Research and Quality and the Commission shall submit to Congress an annual report on the activities of the Center and the Commission, as well as the research, conducted under this section. Each such report shall include a discussion of the Center's compliance with subsection (c)(4)(B), including any reasons for lack of complicance with such subsection.

"(2) RECOMMENDATION FOR FAIR SHARE PER CAPITA AMOUNT FOR ALL-PAYER FINANCING.—Beginning not later than December 31, 2011, the Secretary shall submit to Congress an annual recommendation for a fair share per capita amount described in subsection (c)(1) of section 9511 of the Internal Revenue Code of 1986 for purposes of funding the CERTF under such section.

"(3) ANALYSIS AND REVIEW.—Not later than December 31, 2013, the Secretary, in consultation with the Commission, shall submit to Congress a report on all activities conducted or supported under this section as of such date. Such report shall include an evaluation of the overall costs of such activities and an analysis of the backlog of any research proposals approved by the Commission but not funded.

"(g) FUNDING OF COMPARATIVE EFFECTIVENESS RESEARCH.—For fiscal year 2010 and each subsequent fiscal year, amounts in the Comparative Effectiveness Research Trust Fund (referred to in this section as the 'CERTF') under section 9511 of the Internal Revenue Code of 1986 shall be available, without the need for further appropriations and without fiscal year limitation, to the Secretary to carry out this section.

"(h) CONSTRUCTION.—Nothing in this section shall be construed to permit the Commission or the Center to mandate coverage, reimbursement, or other policies for any public or private payer.

"(i) RESEARCH NOT TO BE USED TO DENY OR RATION CARE.—In no case may any research conducted, supported, or developed by the Center, the Commission, or the Federal Coordinating Council for Comparative Effectiveness Research be used by the federal government to deny or ration care.

"(j) APPLICATION OF FEDERALLY FUNDED CLINICAL COMPARATIVE EFFECTIVENESS RESEARCH.—The Centers for Medicare & Medicaid Services may not use Federally funded clinical comparative effectiveness research data under this section to make coverage determinations for medical treatments, services, or items under title XVIII on the basis of cost.

"(k) CONDITIONS ON RECOMMENDATIONS OF STANDARDS OR PROTOCOLS.—

"(1) IN GENERAL.—The work performed by the Commission or the Center shall be based upon consultation with, and review by, the specialty colleges and academies of medicine to determine best practices within their field of specialty. Any recommendations made or best practices developed by the Commission or the Center —

"(A) shall be based upon evidence-based medicine; and

"(B) shall not violate standards and protocols of clinical excellence of the specialty colleges and academies.

"(2) DEFINITIONS.—For purposes of this subsection:

"(A) SPECIALTY COLLEGES AND ACADEMIES OF MEDICINE.—The term 'specialty colleges and academies of medicine' means the trade associations and professional membership societies that represent physicians based on the field of medicine in which each such physician practices or is board certified.

"(B) STANDARDS AND PROTOCOLS OF CLINICAL EXCELLENCE.—The term 'standards and protocols of clinical excellence' means clinical or practice guidelines that consist of a set of directions or principles that is based on evidence and is designed to assist a health care practitioner with decisions about appropriate diagnostic, therapeutic, or other clinical procedures for specific clinical circumstances.".

(b) COMPARATIVE EFFECTIVENESS RESEARCH TRUST FUND; FINANCING FOR THE TRUST FUND.—For provision establishing a Comparative Effectiveness Research Trust Fund and financing such Trust Fund, see section 1802.

Subtitle B—Nursing Home Transparency

PART 1—IMPROVING TRANSPARENCY OF INFORMATION ON SKILLED NURSING FACILITIES AND NURSING FACILITIES

SEC. 1411. REQUIRED DISCLOSURE OF OWNERSHIP AND ADDITIONAL DISCLOSABLE PARTIES INFORMATION.

(a) IN GENERAL.—Section 1124 of the Social Security Act (42 U.S.C. 1320a–3) is amended by adding at the end the following new subsection:

"(c) REQUIRED DISCLOSURE OF OWNERSHIP AND ADDITIONAL DISCLOSABLE PARTIES INFORMATION.—

"(1) DISCLOSURE.—A facility (as defined in paragraph (7)(B)) shall have the information described in paragraph (3) available—

"(A) during the period beginning on the date of the enactment of this subsection and ending on the date such information is made available to the public under section 1411(b) of the America's Affordable Health Choices Act of 2009, for submission to the Secretary, the Inspector General of the Department of Health and Human Services, the State in which the facility is located, and the State long-term care ombudsman in the case where the Secretary, the Inspector General, the State, or the State long-term care ombudsman requests such information; and

"(B) beginning on the effective date of the final regulations promulgated under paragraph (4)(A), for reporting such information in accordance with such final regulations.

Nothing in subparagraph (A) shall be construed as authorizing a facility to dispose of or delete information described in such subparagraph after the effective date of the final regulations promulgated under paragraph (4)(A).

"(2) PUBLIC AVAILABILITY OF INFORMATION.—During the period described in paragraph (1)(A), a facility shall—

"(A) make the information described in paragraph (3) available to the public upon request and update such information as may be necessary to reflect changes in such information; and

"(B) post a notice of the availability of such information in the lobby of the facility in a prominent manner.

"(3) INFORMATION DESCRIBED.—

"(A) IN GENERAL.—The following information is described in this paragraph:

"(i) The information described in subsections (a) and (b), subject to subparagraph (C).

"(ii) The identity of and information on—

"(I) each member of the governing body of the facility, including the name, title, and period of service of each such member;

"(II) each person or entity who is an officer, director, member, partner, trustee, or managing employee of the facility, including the name, title, and date of start of service of each such person or entity; and

"(III) each person or entity who is an additional disclosable party of the facility.

"(iii) The organizational structure of each person and entity described in subclauses (II) and (III) of clause (ii) and a description of the relationship of each such person or entity to the facility and to one another.

"(B) SPECIAL RULE WHERE INFORMATION IS ALREADY REPORTED OR SUBMITTED.—To the extent that information reported by a facility to the Internal Revenue Service on Form 990, information submitted by a facility to the Securities and Exchange Commission, or information otherwise submitted to the Secretary or any other Federal agency contains the information described in clauses (i), (ii), or (iii) of subparagraph (A), the Secretary may allow, to the extent practicable, such Form or such information to meet the requirements of paragraph (1) and to be submitted in a manner specified by the Secretary.

"(C) SPECIAL RULE.—In applying subparagraph (A)(i)—

"(i) with respect to subsections (a) and (b), 'ownership or control interest' shall include direct or indirect interests, including such interests in intermediate entities; and

"(ii) subsection (a)(3)(A)(ii) shall include the owner of a whole or part interest in any mortgage, deed of trust, note, or other obligation se-

cured, in whole or in part, by the entity or any of the property or assets thereof, if the interest is equal to or exceeds 5 percent of the total property or assets of the entirety.

"(4) REPORTING.—

"(A) IN GENERAL.—Not later than the date that is 2 years after the date of the enactment of this subsection, the Secretary shall promulgate regulations requiring, effective on the date that is 90 days after the date on which such final regulations are published in the Federal Register, a facility to report the information described in paragraph (3) to the Secretary in a standardized format, and such other regulations as are necessary to carry out this subsection. Such final regulations shall ensure that the facility certifies, as a condition of participation and payment under the program under title XVIII or XIX, that the information reported by the facility in accordance with such final regulations is accurate and current.

"(B) GUIDANCE.—The Secretary shall provide guidance and technical assistance to States on how to adopt the standardized format under subparagraph (A).

"(5) NO EFFECT ON EXISTING REPORTING REQUIREMENTS.—Nothing in this subsection shall reduce, diminish, or alter any reporting requirement for a facility that is in effect as of the date of the enactment of this subsection.

"(6) DEFINITIONS.—In this subsection:

"(A) ADDITIONAL DISCLOSABLE PARTY.—The term 'additional disclosable party' means, with respect to a facility, any person or entity who—

"(i) exercises operational, financial, or managerial control over the facility or a part thereof, or provides policies or procedures for any of the operations of the facility, or provides financial or cash management services to the facility;

"(ii) leases or subleases real property to the facility, or owns a whole or part interest equal to or exceeding 5 percent of the total value of such real property;

"(iii) lends funds or provides a financial guarantee to the facility in an amount which is equal to or exceeds $50,000; or

"(iv) provides management or administrative services, clinical consulting services, or accounting or financial services to the facility.

"(B) FACILITY.—The term 'facility' means a disclosing entity which is—

"(i) a skilled nursing facility (as defined in section 1819(a)); or

"(ii) a nursing facility (as defined in section 1919(a)).

"(C) MANAGING EMPLOYEE.—The term 'managing employee' means, with respect to a facility, an individual (including a general manager, business manager, administrator, director, or consultant) who directly or indirectly manages, advises, or supervises any element of the practices, finances, or operations of the facility.

"(D) ORGANIZATIONAL STRUCTURE.—The term 'organizational structure' means, in the case of—

"(i) a corporation, the officers, directors, and shareholders of the corporation who have an ownership interest in the corporation which is equal to or exceeds 5 percent;

"(ii) a limited liability company, the members and managers of the limited liability company (including, as applicable, what percentage each member and manager has of the ownership interest in the limited liability company);

"(iii) a general partnership, the partners of the general partnership;

"(iv) a limited partnership, the general partners and any limited partners of the limited partnership who have an ownership interest in the limited partnership which is equal to or exceeds 10 percent;

"(v) a trust, the trustees of the trust;

"(vi) an individual, contact information for the individual; and

"(vii) any other person or entity, such information as the Secretary determines appropriate.".

(b) PUBLIC AVAILABILITY OF INFORMATION.—

(1) IN GENERAL.—Not later than the date that is 1 year after the date on which the final regulations promulgated under section 1124(c)(4)(A) of the Social Security Act, as added by subsection (a), are published in the Federal Register, the information reported in accordance with such final regulations shall be made available to the public in accordance with procedures established by the Secretary.

(2) DEFINITIONS.—In this subsection:

(A) NURSING FACILITY.—The term "nursing facility" has the meaning given such term in section 1919(a) of the Social Security Act (42 U.S.C. 1396r(a)).

(B) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

(C) SKILLED NURSING FACILITY.—The term "skilled nursing facility" has the meaning given such term in section 1819(a) of the Social Security Act (42 U.S.C. 1395i–3(a)).

(c) CONFORMING AMENDMENTS.—

(1) SKILLED NURSING FACILITIES.—Section 1819(d)(1) of the Social Security Act (42 U.S.C. 1395i–3(d)(1)) is amended by striking subparagraph (B) and redesignating subparagraph (C) as subparagraph (B).

(2) NURSING FACILITIES.—Section 1919(d)(1) of the Social Security Act (42 U.S.C. 1396r(d)(1)) is amended by striking subparagraph (B) and redesignating subparagraph (C) as subparagraph (B).

SEC. 1412. ACCOUNTABILITY REQUIREMENTS.

(a) EFFECTIVE COMPLIANCE AND ETHICS PROGRAMS.—

(1) SKILLED NURSING FACILITIES.—Section 1819(d)(1) of the Social Security Act (42 U.S.C. 1395i–3(d)(1)), as amended by section 1411(c)(1), is amended by adding at the end the following new subparagraph:

"(C) COMPLIANCE AND ETHICS PROGRAMS.—

"(i) REQUIREMENT.—On or after the date that is 36 months after the date of the enactment of this subparagraph, a skilled nursing facility shall, with respect to the entity that operates the facility (in this subparagraph referred to as the 'operating organization' or 'organization'), have in operation a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations under this Act and in promoting quality of care consistent with regulations developed under clause (ii).

"(ii) DEVELOPMENT OF REGULATIONS.—

"(I) IN GENERAL.—Not later than the date that is 2 years after such date of the enactment, the Secretary, in consultation with the Inspector General of the Department of Health and Human Services, shall promulgate regulations for an effective compliance and ethics program for operating organizations, which may include a model compliance program.

"(II) DESIGN OF REGULATIONS.—Such regulations with respect to specific elements or formality of a program may vary with the size of the organization, such that larger organizations should have a more formal and rigorous program and include established written policies defining the standards and procedures to be followed by its employees. Such requirements shall specifically apply to the corporate level management of multi-unit nursing home chains.

"(III) EVALUATION.—Not later than 3 years after the date of promulgation of regulations under this clause, the Secretary shall complete an evaluation of the compliance and ethics programs required to be established under this subparagraph. Such evaluation shall determine if such programs led to changes in deficiency citations, changes in quality performance, or changes in other metrics of resident quality of care. The Secretary shall submit to Congress a report on such evaluation and shall include in such report such recommendations regarding changes in the requirements for such programs as the Secretary determines appropriate.

"(iii) REQUIREMENTS FOR COMPLIANCE AND ETHICS PROGRAMS.—In this subparagraph, the term 'compliance and ethics program' means, with respect to a skilled nursing facility, a program of the operating organization that—

"(I) has been reasonably designed, implemented, and enforced so that it generally will be effective in preventing and detecting criminal, civil, and administrative violations under this Act and in promoting quality of care; and

"(II) includes at least the required components specified in clause (iv).

"(iv) REQUIRED COMPONENTS OF PROGRAM.—The required components of a compliance and ethics program of an organization are the following:

"(I) The organization must have established compliance standards and procedures to be followed by its employees, contractors,

and other agents that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations under this Act.

"(II) Specific individuals within high-level personnel of the organization must have been assigned overall responsibility to oversee compliance with such standards and procedures and have sufficient resources and authority to assure such compliance.

"(III) The organization must have used due care not to delegate substantial discretionary authority to individuals whom the organization knew, or should have known through the exercise of due diligence, had a propensity to engage in criminal, civil, and administrative violations under this Act.

"(IV) The organization must have taken steps to communicate effectively its standards and procedures to all employees and other agents, such as by requiring participation in training programs or by disseminating publications that explain in a practical manner what is required.

"(V) The organization must have taken reasonable steps to achieve compliance with its standards, such as by utilizing monitoring and auditing systems reasonably designed to detect criminal, civil, and administrative violations under this Act by its employees and other agents and by having in place and publicizing a reporting system whereby employees and other agents could report violations by others within the organization without fear of retribution.

"(VI) The standards must have been consistently enforced through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect an offense.

"(VII) After an offense has been detected, the organization must have taken all reasonable steps to respond appropriately to the offense and to prevent further similar offenses, including repayment of any funds to which it was not entitled and any necessary modification to its program to prevent and detect criminal, civil, and administrative violations under this Act.

"(VIII) The organization must periodically undertake reassessment of its compliance program to identify changes necessary to reflect changes within the organization and its facilities.

"(v) COORDINATION.—The provisions of this subparagraph shall apply with respect to a skilled nursing facility in lieu of section 1874(d).".

(2) NURSING FACILITIES.—Section 1919(d)(1) of the Social Security Act (42 U.S.C. 1396r(d)(1)), as amended by section 1411(c)(2), is amended by adding at the end the following new subparagraph:

"(C) COMPLIANCE AND ETHICS PROGRAM.—

"(i) REQUIREMENT.—On or after the date that is 36 months after the date of the enactment of this subparagraph, a nursing facility shall, with respect to the entity that operates the facility (in this subparagraph referred to as the 'operating organization' or 'organization'), have in operation a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations under this Act and in promoting quality of care consistent with regulations developed under clause (ii).

"(ii) DEVELOPMENT OF REGULATIONS.—

"(I) IN GENERAL.—Not later than the date that is 2 years after such date of the enactment, the Secretary, in consultation with the Inspector General of the Department of Health and Human Services, shall develop regulations for an effective compliance and ethics program for operating organizations, which may include a model compliance program.

"(II) DESIGN OF REGULATIONS.—Such regulations with respect to specific elements or formality of a program may vary with the size of the organization, such that larger organizations should have a more formal and rigorous program and include established written policies defining the standards and procedures to be followed by its employees. Such requirements may specifically apply to the corporate level management of multi-unit nursing home chains.

"(III) EVALUATION.—Not later than 3 years after the date of promulgation of regulations under this clause the Secretary shall complete an evaluation of the compliance and ethics programs required to be established under this subparagraph. Such evaluation shall determine if such programs led to changes in deficiency citations,

changes in quality performance, or changes in other metrics of resident quality of care. The Secretary shall submit to Congress a report on such evaluation and shall include in such report such recommendations regarding changes in the requirements for such programs as the Secretary determines appropriate.

"(iii) REQUIREMENTS FOR COMPLIANCE AND ETHICS PROGRAMS.—In this subparagraph, the term 'compliance and ethics program' means, with respect to a nursing facility, a program of the operating organization that—

"(I) has been reasonably designed, implemented, and enforced so that it generally will be effective in preventing and detecting criminal, civil, and administrative violations under this Act and in promoting quality of care; and

"(II) includes at least the required components specified in clause (iv).

"(iv) REQUIRED COMPONENTS OF PROGRAM.—The required components of a compliance and ethics program of an organization are the following:

"(I) The organization must have established compliance standards and procedures to be followed by its employees and other agents that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations under this Act.

"(II) Specific individuals within high-level personnel of the organization must have been assigned overall responsibility to oversee compliance with such standards and procedures and has sufficient resources and authority to assure such compliance.

"(III) The organization must have used due care not to delegate substantial discretionary authority to individuals whom the organization knew, or should have known through the exercise of due diligence, had a propensity to engage in criminal, civil, and administrative violations under this Act.

"(IV) The organization must have taken steps to communicate effectively its standards and procedures to all employees and other agents, such as by requiring participation in training programs or by disseminating publications that explain in a practical manner what is required.

"(V) The organization must have taken reasonable steps to achieve compliance with its standards, such as by utilizing monitoring and auditing systems reasonably designed to detect criminal, civil, and administrative violations under this Act by its employees and other agents and by having in place and publicizing a reporting system whereby employees and other agents could report violations by others within the organization without fear of retribution.

"(VI) The standards must have been consistently enforced through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect an offense.

"(VII) After an offense has been detected, the organization must have taken all reasonable steps to respond appropriately to the offense and to prevent further similar offenses, including repayment of any funds to which it was not entitled and any necessary modification to its program to prevent and detect criminal, civil, and administrative violations under this Act.

"(VIII) The organization must periodically undertake reassessment of its compliance program to identify changes necessary to reflect changes within the organization and its facilities.

"(v) COORDINATION.—The provisions of this subparagraph shall apply with respect to a nursing facility in lieu of section 1902(a)(77).".

(b) QUALITY ASSURANCE AND PERFORMANCE IMPROVEMENT PROGRAM.—

(1) SKILLED NURSING FACILITIES.—Section 1819(b)(1)(B) of the Social Security Act (42 U.S.C. 1396r(b)(1)(B)) is amended—

(A) by striking "ASSURANCE" and inserting "ASSURANCE AND QUALITY ASSURANCE AND PERFORMANCE IMPROVEMENT PROGRAM";

(B) by designating the matter beginning with "A skilled nursing facility" as a clause (i) with the heading "IN GENERAL.—" and the appropriate indentation;

(C) in clause (i) (as so designated by subparagraph (B)), by redesignating clauses (i) and (ii) as subclauses (I) and (II), respectively; and

(D) by adding at the end the following new clause:

"(ii) QUALITY ASSURANCE AND PERFORMANCE IMPROVEMENT PROGRAM.—

"(I) IN GENERAL.—Not later than December 31, 2011, the Secretary shall establish and implement a quality assurance and performance improvement program (in this clause referred to as the 'QAPI program') for skilled nursing facilities, including multi-unit chains of such facilities. Under the QAPI program, the Secretary shall establish standards relating to such facilities and provide technical assistance to such facilities on the development of best practices in order to meet such standards. Not later than 1 year after the date on which the regulations are promulgated under subclause (II), a skilled nursing facility must submit to the Secretary a plan for the facility to meet such standards and implement such best practices, including how to coordinate the implementation of such plan with quality assessment and assurance activities conducted under clause (i).

"(II) REGULATIONS.—The Secretary shall promulgate regulations to carry out this clause.".

(2) NURSING FACILITIES.—Section 1919(b)(1)(B) of the Social Security Act (42 U.S.C. 1396r(b)(1)(B)) is amended—

(A) by striking "ASSURANCE" and inserting "ASSURANCE AND QUALITY ASSURANCE AND PERFORMANCE IMPROVEMENT PROGRAM";

(B) by designating the matter beginning with "A nursing facility" as a clause (i) with the heading "IN GENERAL.—" and the appropriate indentation; and

(C) by adding at the end the following new clause:

"(ii) QUALITY ASSURANCE AND PERFORMANCE IMPROVEMENT PROGRAM.—

"(I) IN GENERAL.—Not later than December 31, 2011, the Secretary shall establish and implement a quality assurance and performance improvement program (in this clause referred to as the 'QAPI program') for nursing facilities, including multi-unit chains of such facilities. Under the QAPI program, the Secretary shall establish standards relating to such facilities and provide technical assistance to such facilities on the development of best practices in order to meet such standards. Not later than 1 year after the date on which the regulations are promulgated under subclause (II), a nursing facility must submit to the Secretary a plan for the facility to meet such standards and implement such best practices, including how to coordinate the implementation of such plan with quality assessment and assurance activities conducted under clause (i).

"(II) REGULATIONS.—The Secretary shall promulgate regulations to carry out this clause.".

(3) PROPOSAL TO REVISE QUALITY ASSURANCE AND PERFORMANCE IMPROVEMENT PROGRAMS.—The Secretary shall include in the proposed rule published under section 1888(e) of the Social Security Act (42 U.S.C. 1395yy(e)(5)(A)) for the subsequent fiscal year to the extent otherwise authorized under section 1819(b)(1)(B) or 1819(d)(1)(C) of the Social Security Act or other statutory or regulatory authority, one or more proposals for skilled nursing facilities to modify and strengthen quality assurance and performance improvement programs in such facilities. At the time of publication of such proposed rule and to the extent otherwise authorized under section 1919(b)(1)(B) or 1919(d)(1)(C) of such Act or other regulatory authority.

(4) FACILITY PLAN.—Not later than 1 year after the date on which the regulations are promulgated under subclause (II) of clause (ii) of sections 1819(b)(1)(B) and 1919(b)(1)(B) of the Social Security Act, as added by paragraphs (1) and (2), a skilled nursing facility and a nursing facility must submit to the Secretary a plan for the facility to meet the standards under such regulations and implement such best practices, including how to coordinate the implementation of such plan with quality assessment and assurance activities conducted under clause (i) of such sections.

(c) GAO STUDY ON NURSING FACILITY UNDERCAPITALIZATION.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study that examines the following:

(A) The extent to which corporations that own or operate large numbers of nursing facilities, taking into account ownership type (including private equity and control interests), are undercapitalizing such facilities.

(B) The effects of such undercapitalization on quality of care, including staffing and food costs, at such facilities.

(C) Options to address such undercapitalization, such as requirements relating to surety bonds, liability insurance, or minimum capitalization.

(2) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1).

(3) NURSING FACILITY.—In this subsection, the term "nursing facility" includes a skilled nursing facility.

SEC. 1413. NURSING HOME COMPARE MEDICARE WEBSITE.

(a) SKILLED NURSING FACILITIES.—

(1) IN GENERAL.—Section 1819 of the Social Security Act (42 U.S.C. 1395i–3) is amended—

(A) by redesignating subsection (i) as subsection (j); and

(B) by inserting after subsection (h) the following new subsection:

"(i) NURSING HOME COMPARE WEBSITE.—

"(1) INCLUSION OF ADDITIONAL INFORMATION.—

"(A) IN GENERAL.—The Secretary shall ensure that the Department of Health and Human Services includes, as part of the information provided for comparison of nursing homes on the official Internet website of the Federal Government for Medicare beneficiaries (commonly referred to as the 'Nursing Home Compare' Medicare website) (or a successor website), the following information in a manner that is prominent, easily accessible, readily understandable to consumers of long-term care services, and searchable:

"(i) Information that is reported to the Secretary under section 1124(c)(4).

"(ii) Information on the 'Special Focus Facility program' (or a successor program) established by the Centers for Medicare and Medicaid Services, according to procedures established by the Secretary. Such procedures shall provide for the inclusion of information with respect to, and the names and locations of, those facilities that, since the previous quarter—

"(I) were newly enrolled in the program;

"(II) are enrolled in the program and have failed to significantly improve;

"(III) are enrolled in the program and have significantly improved;

"(IV) have graduated from the program; and

"(V) have closed voluntarily or no longer participate under this title.

"(iii) Staffing data for each facility (including resident census data and data on the hours of care provided per resident per day) based on data submitted under subsection (b)(8)(C), including information on staffing turnover and tenure, in a format that is clearly understandable to consumers of long-term care services and allows such consumers to compare differences in staffing between facilities and State and national averages for the facilities. Such format shall include—

"(I) concise explanations of how to interpret the data (such as a plain English explanation of data reflecting 'nursing home staff hours per resident day');

"(II) differences in types of staff (such as training associated with different categories of staff);

"(III) the relationship between nurse staffing levels and quality of care; and

"(IV) an explanation that appropriate staffing levels vary based on patient case mix.

"(iv) Links to State Internet websites with information regarding State survey and certification programs, links to Form 2567 State inspection reports (or a successor form) on such websites, information to guide consumers in how to interpret and understand such reports, and the facility plan of correction or other response to such report.

"(v) The standardized complaint form developed under subsection (f)(8), including explanatory material on what complaint forms are, how they are used, and how to file a complaint with the State survey and certification program and the State long-term care ombudsman program.

"(vi) Summary information on the number, type, severity, and outcome of substantiated complaints.

"(vii) The number of adjudicated instances of criminal violations by employees of a a nursing facility—

"(I) that were committed inside the facility;

"(II) with respect to such instances of violations or crimes committed inside of the facility that were the violations or crimes of abuse, neglect, and exploitation, criminal sexual abuse, or other violations or crimes that resulted in serious bodily injury; and

"(III) the number of civil monetary penalties levied against the facility, employees, contractors, and other agents.

"(B) DEADLINE FOR PROVISION OF INFORMATION.—

"(i) IN GENERAL.—Except as provided in clause (ii), the Secretary shall ensure that the information described in subparagraph (A) is included on such website (or a successor website) not later than 1 year after the date of the enactment of this subsection.

"(ii) EXCEPTION.—The Secretary shall ensure that the information described in subparagraph (A)(i) and (A)(iii) is included on such website (or a successor website) not later than the date on which the requirements under section 1124(c)(4) and subsection (b)(8)(C)(ii) are implemented.

"(2) REVIEW AND MODIFICATION OF WEBSITE.—

"(A) IN GENERAL.—The Secretary shall establish a process—

"(i) to review the accuracy, clarity of presentation, timeliness, and comprehensiveness of information reported on such website as of the day before the date of the enactment of this subsection; and

"(ii) not later than 1 year after the date of the enactment of this subsection, to modify or revamp such website in accordance with the review conducted under clause (i).

"(B) CONSULTATION.—In conducting the review under subparagraph (A)(i), the Secretary shall consult with—

"(i) State long-term care ombudsman programs;

"(ii) consumer advocacy groups;

"(iii) provider stakeholder groups; and

"(iv) any other representatives of programs or groups the Secretary determines appropriate.".

(2) TIMELINESS OF SUBMISSION OF SURVEY AND CERTIFICATION INFORMATION.—

(A) IN GENERAL.—Section 1819(g)(5) of the Social Security Act (42 U.S.C. 1395i–3(g)(5)) is amended by adding at the end the following new subparagraph:

"(E) SUBMISSION OF SURVEY AND CERTIFICATION INFORMATION TO THE SECRETARY.—In order to improve the timeliness of information made available to the public under subparagraph (A) and provided on the Nursing Home Compare Medicare website under subsection (i), each State shall submit information respecting any survey or certification made respecting a skilled nursing facility (including any enforcement actions taken by the State) to the Secretary not later than the date on which the State sends such information to the facility. The Secretary shall use the information submitted under the preceding sentence to update the information provided on the Nursing Home Compare Medicare website as expeditiously as practicable but not less frequently than quarterly.".

(B) EFFECTIVE DATE.—The amendment made by this paragraph shall take effect 1 year after the date of the enactment of this Act.

(3) SPECIAL FOCUS FACILITY PROGRAM.—Section 1819(f) of such Act is amended by adding at the end the following new paragraph:

"(8) SPECIAL FOCUS FACILITY PROGRAM.—

"(A) IN GENERAL.—The Secretary shall conduct a special focus facility program for enforcement of requirements for skilled nursing facilities that the Secretary has identified as having substantially failed to meet applicable requirement of this Act.

"(B) PERIODIC SURVEYS.—Under such program the Secretary shall conduct surveys of each facility in the program not less than once every 6 months.".

(b) NURSING FACILITIES.—

(1) IN GENERAL.—Section 1919 of the Social Security Act (42 U.S.C. 1396r) is amended—

(A) by redesignating subsection (i) as subsection (j); and

(B) by inserting after subsection (h) the following new subsection:

"(i) NURSING HOME COMPARE WEBSITE.—

"(1) INCLUSION OF ADDITIONAL INFORMATION.—

"(A) IN GENERAL.—The Secretary shall ensure that the Department of Health and Human Services includes, as part of the information provided for comparison of nursing homes on the official Internet website of the Federal Government for Medicare beneficiaries (commonly referred to as the 'Nursing Home Compare' Medicare website) (or a successor website), the following information in a manner that is prominent, easily accessible, readily understandable to consumers of long-term care services, and searchable:

"(i) Staffing data for each facility (including resident census data and data on the hours of care provided per resident per day) based on data submitted under subsection (b)(8)(C)(ii), including information on staffing turnover and tenure, in a format that is clearly understandable to consumers of long-term care services and allows such consumers to compare differences in staffing between facilities and State and national averages for the facilities. Such format shall include—

"(I) concise explanations of how to interpret the data (such as plain English explanation of data reflecting 'nursing home staff hours per resident day');

"(II) differences in types of staff (such as training associated with different categories of staff);

"(III) the relationship between nurse staffing levels and quality of care; and

"(IV) an explanation that appropriate staffing levels vary based on patient case mix.

"(ii) Links to State Internet websites with information regarding State survey and certification programs, links to Form 2567 State inspection reports (or a successor form) on such websites, information to guide consumers in how to interpret and understand such reports, and the facility plan of correction or other response to such report.

"(iii) The standardized complaint form developed under subsection (f)(10), including explanatory material on what complaint forms are, how they are used, and how to file a complaint with the State survey and certification program and the State long-term care ombudsman program.

"(iv) Summary information on the number, type, severity, and outcome of substantiated complaints.

"(v) The number of adjudicated instances of criminal violations by employees of a nursing facility—

"(I) that were committed inside of the facility; and

"(II) with respect to such instances of violations or crimes committed outside of the facility, that were the violations or crimes that resulted in the serious bodily injury of an elder.

"(B) DEADLINE FOR PROVISION OF INFORMATION.—

"(i) IN GENERAL.—Except as provided in clause (ii), the Secretary shall ensure that the information described in subparagraph (A) is included on such website (or a successor website) not later than 1 year after the date of the enactment of this subsection.

"(ii) EXCEPTION.—The Secretary shall ensure that the information described in subparagraph (A)(i) and (A)(iii) is included on such website (or a successor website) not later than the date on which the requirements under section 1124(c)(4) and subsection (b)(8)(C)(ii) are implemented.

"(2) REVIEW AND MODIFICATION OF WEBSITE.—

"(A) IN GENERAL.—The Secretary shall establish a process—

"(i) to review the accuracy, clarity of presentation, timeliness, and comprehensiveness of information reported on such website as of the day before the date of the enactment of this subsection; and

"(ii) not later than 1 year after the date of the enactment of this subsection, to modify or revamp such website in accordance with the review conducted under clause (i).

"(B) CONSULTATION.—In conducting the review under subparagraph (A)(i), the Secretary shall consult with—

"(i) State long-term care ombudsman programs;

"(ii) consumer advocacy groups;

"(iii) provider stakeholder groups;

"(iv) skilled nursing facility employees and their representatives; and

"(v) any other representatives of programs or groups the Secretary determines appropriate.".

(2) TIMELINESS OF SUBMISSION OF SURVEY AND CERTIFICATION INFORMATION.—

(A) IN GENERAL.—Section 1919(g)(5) of the Social Security Act (42 U.S.C. 1396r(g)(5)) is amended by adding at the end the following new subparagraph:

"(E) SUBMISSION OF SURVEY AND CERTIFICATION INFORMATION TO THE SECRETARY.—In order to improve the timeliness of information made available to the public under subparagraph (A) and provided on the Nursing Home Compare Medicare website under subsection (i), each State shall submit information respecting any survey or certification made respecting a nursing facility (including any enforcement actions taken by the State) to the Secretary not later than the date on which the State sends such information to the facility. The Secretary shall use the information submitted under the preceding sentence to update the information provided on the Nursing Home Compare Medicare website as expeditiously as practicable but not less frequently than quarterly.".

(B) EFFECTIVE DATE.—The amendment made by this paragraph shall take effect 1 year after the date of the enactment of this Act.

(3) SPECIAL FOCUS FACILITY PROGRAM.—Section 1919(f) of such Act is amended by adding at the end of the following new paragraph:

"(10) SPECIAL FOCUS FACILITY PROGRAM.—

"(A) IN GENERAL.—The Secretary shall conduct a special focus facility program for enforcement of requirements for nursing facilities that the Secretary has identified as having substantially failed to meet applicable requirements of this Act.

"(B) PERIODIC SURVEYS.—Under such program the Secretary shall conduct surveys of each facility in the program not less often than once every 6 months.".

(c) AVAILABILITY OF REPORTS ON SURVEYS, CERTIFICATIONS, AND COMPLAINT INVESTIGATIONS.—

(1) SKILLED NURSING FACILITIES.—Section 1819(d)(1) of the Social Security Act (42 U.S.C. 1395i–3(d)(1)), as amended by sections 1411 and 1412, is amended by adding at the end the following new subparagraph:

"(D) AVAILABILITY OF SURVEY, CERTIFICATION, AND COMPLAINT INVESTIGATION REPORTS.—A skilled nursing facility must—

"(i) have reports with respect to any surveys, certifications, and complaint investigations made respecting the facility during the 3 preceding years available for any individual to review upon request; and

"(ii) post notice of the availability of such reports in areas of the facility that are prominent and accessible to the public.

The facility shall not make available under clause (i) identifying information about complainants or residents.".

(2) NURSING FACILITIES.—Section 1919(d)(1) of the Social Security Act (42 U.S.C. 1396r(d)(1)), as amended by sections 1411 and 1412, is amended by adding at the end the following new subparagraph:

"(D) AVAILABILITY OF SURVEY, CERTIFICATION, AND COMPLAINT INVESTIGATION REPORTS.—A nursing facility must—

"(i) have reports with respect to any surveys, certifications, and complaint investigations made respecting the facility during the 3 preceding years available for any individual to review upon request; and

"(ii) post notice of the availability of such reports in areas of the facility that are prominent and accessible to the public.

The facility shall not make available under clause (i) identifying information about complainants or residents.".

(3) EFFECTIVE DATE.—The amendments made by this subsection shall take effect 1 year after the date of the enactment of this Act.

(d) GUIDANCE TO STATES ON FORM 2567 STATE INSPECTION REPORTS AND COMPLAINT INVESTIGATION REPORTS.—

(1) GUIDANCE.—The Secretary of Health and Human Services (in this subtitle referred to as the "Secretary") shall provide guidance to States on how States can establish electronic links to Form 2567 State inspection reports (or a successor form), complaint investigation reports, and a facility's plan of correction or other response to such Form 2567 State inspection reports (or a successor form) on the Internet website of the State that provides information on skilled nursing facilities and nursing facilities and the Secretary shall, if possible, include such information on Nursing Home Compare.

(2) REQUIREMENT.—Section 1902(a)(9) of the Social Security Act (42 U.S.C. 1396a(a)(9)) is amended—

(A) by striking "and" at the end of subparagraph (B);

(B) by striking the semicolon at the end of subparagraph (C) and inserting ", and"; and

(C) by adding at the end the following new subparagraph:

"(D) that the State maintain a consumer-oriented website providing useful information to consumers regarding all skilled nursing facilities and all nursing facilities in the State, including for each facility, Form 2567 State inspection reports (or a successor form), complaint investigation reports, the facility's plan of correction, and such other information that the State or the Secretary considers useful in assisting the public to assess the quality of long term care options and the quality of care provided by individual facilities;".

(3) DEFINITIONS.—In this subsection:

(A) NURSING FACILITY.—The term "nursing facility" has the meaning given such term in section 1919(a) of the Social Security Act (42 U.S.C. 1396r(a)).

(B) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

(C) SKILLED NURSING FACILITY.—The term "skilled nursing facility" has the meaning given such term in section 1819(a) of the Social Security Act (42 U.S.C. 1395i–3(a)).

SEC. 1414. REPORTING OF EXPENDITURES.

Section 1888 of the Social Security Act (42 U.S.C. 1395yy) is amended by adding at the end the following new subsection:

"(f) REPORTING OF DIRECT CARE EXPENDITURES.—

"(1) IN GENERAL.—For cost reports submitted under this title for cost reporting periods beginning on or after the date that is 3 years after the date of the enactment of this subsection, skilled nursing facilities shall separately report expenditures for wages and benefits for direct care staff (breaking out (at a minimum) registered nurses, licensed professional nurses, certified nurse assistants, and other medical and therapy staff).

"(2) MODIFICATION OF FORM.—The Secretary, in consultation with private sector accountants experienced with skilled nursing facility cost reports, shall redesign such reports to meet the requirement of paragraph (1) not later than 1 year after the date of the enactment of this subsection.

"(3) CATEGORIZATION BY FUNCTIONAL ACCOUNTS.—Not later than 30 months after the date of the enactment of this subsection, the Secretary, working in consultation with the Medicare Payment Advisory Commission, the Inspector General of the Department of Health and Human Services, and other expert parties the Secretary determines appropriate, shall take the expenditures listed on cost reports, as modified under paragraph (1), submitted by skilled nursing facilities and categorize such expenditures, regardless of any source of payment for such expenditures, for each skilled nursing facility into the following functional accounts on an annual basis:

"(A) Spending on direct care services (including nursing, therapy, and medical services).

"(B) Spending on indirect care (including housekeeping and dietary services).

"(C) Capital assets (including building and land costs).

"(D) Administrative services costs.

"(4) AVAILABILITY OF INFORMATION SUBMITTED.—The Secretary shall establish procedures to make information on expenditures submitted under this subsection readily available to interested parties upon request, subject to such requirements as the Secretary may specify under the procedures established under this paragraph.".

SEC. 1415. STANDARDIZED COMPLAINT FORM.

(a) SKILLED NURSING FACILITIES.—

(1) DEVELOPMENT BY THE SECRETARY.—Section 1819(f) of the Social Security Act (42 U.S.C. 1395i–3(f)), as amended by section 1413(a)(3), is amended by adding at the end the following new paragraph:

"(9) STANDARDIZED COMPLAINT FORM.—The Secretary shall develop a standardized complaint form for use by a resident (or a person acting on the resident's behalf) in filing a complaint with a State survey and certification agency and a State long-term care ombudsman program with respect to a skilled nursing facility.".

(2) STATE REQUIREMENTS.—Section 1819(e) of the Social Security Act (42 U.S.C. 1395i–3(e)) is amended by adding at the end the following new paragraph:

"(6) COMPLAINT PROCESSES AND WHISTLE-BLOWER PROTECTION.—

"(A) COMPLAINT FORMS.—The State must make the standardized complaint form developed under subsection (f)(9) available upon request to—

"(i) a resident of a skilled nursing facility;

"(ii) any person acting on the resident's behalf; and

"(iii) any person who works at a skilled nursing facility or is a representative of such a worker.

"(B) COMPLAINT RESOLUTION PROCESS.—The State must establish a complaint resolution process in order to ensure that a resident, the legal representative of a resident of a skilled nursing facility, or other responsible party is not retaliated against if the resident, legal representative, or responsible party has complained, in good faith, about the quality of care or other issues relating to the skilled nursing facility, that the legal representative of a resident of a skilled nursing facility or other responsible party is not denied access to such resident or otherwise retaliated against if such representative party has complained, in good faith, about the quality of care provided by the facility or other issues relating to the facility, and that a person who works at a skilled nursing facility is not retaliated against if the worker has complained, in good faith, about quality of care or services or an issue relating to the quality of care or services provided at the facility, whether the resident, legal representative, other responsible party, or worker used the form developed under subsection (f)(9) or some other method for submitting the complaint. Such complaint resolution process shall include—

"(i) procedures to assure accurate tracking of complaints received, including notification to the complainant that a complaint has been received;

"(ii) procedures to determine the likely severity of a complaint and for the investigation of the complaint;

"(iii) deadlines for responding to a complaint and for notifying the complainant of the outcome of the investigation; and

"(iv) procedures to ensure that the identity of the complainant will be kept confidential.

"(C) WHISTLEBLOWER PROTECTION.—

"(i) PROHIBITION AGAINST RETALIATION.—No person who works at a skilled nursing facility may be penalized, discriminated, or retaliated against with respect to any aspect of employment, including discharge, promotion, compensation, terms, conditions, or privileges of employment, or have a contract for services terminated, because the person (or anyone acting at the person's request) complained, in good faith, about the quality of care or services provided by a nursing facility or about other issues relating to quality of care or services, whether using the form developed under subsection (f)(9) or some other method for submitting the complaint.

"(ii) RETALIATORY REPORTING.—A skilled nursing facility may not file a complaint or a report against a person who works (or has worked at the facility with the appropriate State professional disciplinary agency because the person (or anyone acting at the person's request) complained in good faith, as described in clause (i).

"(iii) COMMENCEMENT OF ACTION.—Any person who believes the person has been penalized, discriminated , or retaliated against or had a contract for services terminated in violation of clause (i) or against whom a complaint has been filed in violation of clause (ii) may bring an action at law or equity in the appropriate district court of the United States, which shall have jurisdiction over such action without regard to the amount in controversy or the citizenship of the parties, and which shall have jurisdiction to grant complete relief, including, but not limited to, injunctive relief (such as reinstatement, compensatory damages (which may include reimbursement of lost wages, compensation, and benefits), costs of litigation (including reasonable attorney and expert witness fees), exemplary damages where appropriate, and such other relief as the court deems just and proper.

"(iv) RIGHTS NOT WAIVABLE.—The rights protected by this paragraph may not be diminished by contract or other agreement, and nothing in this paragraph shall be construed to diminish any greater or additional protection provided by Federal or State law or by contract or other agreement.

"(v) REQUIREMENT TO POST NOTICE OF EMPLOYEE RIGHTS.—Each skilled nursing facility shall post conspicuously in an appropriate location a sign (in a form specified by the Secretary) specifying the rights of persons under this paragraph and including a statement that an employee may file a complaint with the Secretary against a skilled nurs-

ing facility that violates the provisions of this paragraph and information with respect to the manner of filing such a complaint.

"(D) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed as preventing a resident of a skilled nursing facility (or a person acting on the resident's behalf) from submitting a complaint in a manner or format other than by using the standardized complaint form developed under subsection (f)(9) (including submitting a complaint orally).

"(E) GOOD FAITH DEFINED.—For purposes of this paragraph, an individual shall be deemed to be acting in good faith with respect to the filing of a complaint if the individual reasonably believes—

"(i) the information reported or disclosed in the complaint is true; and

"(ii) the violation of this title has occurred or may occur in relation to such information.".

(b) NURSING FACILITIES.—

(1) DEVELOPMENT BY THE SECRETARY.—Section 1919(f) of the Social Security Act (42 U.S.C. 1395i–3(f)), as amended by section 1413(b), is amended by adding at the end the following new paragraph:

"(11) STANDARDIZED COMPLAINT FORM.—The Secretary shall develop a standardized complaint form for use by a resident (or a person acting on the resident's behalf) in filing a complaint with a State survey and certification agency and a State long-term care ombudsman program with respect to a nursing facility.".

(2) STATE REQUIREMENTS.—Section 1919(e) of the Social Security Act (42 U.S.C. 1395i–3(e)) is amended by adding at the end the following new paragraph:

"(8) COMPLAINT PROCESSES AND WHISTLEBLOWER PROTECTION.—

"(A) COMPLAINT FORMS.—The State must make the standardized complaint form developed under subsection (f)(11) available upon request to—

"(i) a resident of a nursing facility;

"(ii) any person acting on the resident's behalf; and

"(iii) any person who works at a nursing facility or a representative of such a worker.

"(B) COMPLAINT RESOLUTION PROCESS.—The State must establish a complaint resolution process in order to ensure that a resident, the legal representative of a resident of a nursing facility, or other responsible party is not retaliated against if the resident, legal representative, or responsible party has complained, in good faith, about the quality of care or other issues relating to the nursing facility, that the legal representative of a resident of a nursing facility or other responsible party is not denied access to such resident or otherwise retaliated against if such representative party has complained, in good faith, about the quality of care provided by the facility or other issues relating to the facility, and that a person who works at a nursing facility is not retaliated against if the worker has complained, in good faith, about quality of care or services or an issue relating to the quality of care or services provided at the facility, whether the resident, legal representative, other responsible party, or worker used the form developed under subsection (f)(11) or some other method for submitting the complaint. Such complaint resolution process shall include—

"(i) procedures to assure accurate tracking of complaints received, including notification to the complainant that a complaint has been received;

"(ii) procedures to determine the likely severity of a complaint and for the investigation of the complaint;

"(iii) deadlines for responding to a complaint and for notifying the complainant of the outcome of the investigation; and

"(iv) procedures to ensure that the identity of the complainant will be kept confidential.

"(C) WHISTLEBLOWER PROTECTION.—

"(i) PROHIBITION AGAINST RETALIATION.—No person who works at a nursing facility may be penalized, discriminated, or retaliated against with respect to any aspect of employment, including discharge, promotion, compensation, terms, conditions, or privileges of employment, or have a contract for services terminated, because the person (or anyone acting at the person's request) complained, in good faith, about the quality of care or services provided by a nursing facility or about other issues relating to quality of care or services, whether using the form developed under subsection (f)(11) or some other method for submitting the complaint.

"(ii) RETALIATORY REPORTING.—A nursing facility may not file a complaint or a report against a person who works (or has worked at the facility with the appropriate State professional disciplinary agency because the person (or anyone acting at the person's request) complained in good faith, as described in clause (i).

"(iii) COMMENCEMENT OF ACTION.—Any person who believes the person has been penalized, discriminated, or retaliated against or had a contract for services terminated in violation of clause (i) or against whom a complaint has been filed in violation of clause (ii) may bring an action at law or equity in the appropriate district court of the United States, which shall have jurisdiction over such action without regard to the amount in controversy or the citizenship of the parties, and which shall have jurisdiction to grant complete relief, including, but not limited to, injunctive relief (such as reinstatement, compensatory damages (which may include reimbursement of lost wages, compensation, and benefits), costs of litigation (including reasonable attorney and expert witness fees), exemplary damages where appropriate, and such other relief as the court deems just and proper.

"(iv) RIGHTS NOT WAIVABLE.—The rights protected by this paragraph may not be diminished by contract or other agreement, and nothing in this paragraph shall be construed to diminish any greater or additional protection provided by Federal or State law or by contract or other agreement.

"(v) REQUIREMENT TO POST NOTICE OF EMPLOYEE RIGHTS.—Each nursing facility shall post conspicuously in an appropriate location a sign (in a form specified by the Secretary) specifying the rights of persons under this paragraph and including a statement that an employee may file a complaint with the Secretary against a nursing facility that violates the provisions of this paragraph and information with respect to the manner of filing such a complaint.

"(D) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed as preventing a resident of a nursing facility (or a person acting on the resident's behalf) from submitting a complaint in a manner or format other than by using the standardized complaint form developed under subsection (f)(11) (including submitting a complaint orally).

"(E) GOOD FAITH DEFINED.—For purposes of this paragraph, an individual shall be deemed to be acting in good faith with respect to the filing of a complaint if the individual reasonably believes—

"(i) the information reported or disclosed in the complaint is true; and

"(ii) the violation of this title has occurred or may occur in relation to such information.".

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect 1 year after the date of the enactment of this Act.

SEC. 1416. ENSURING STAFFING ACCOUNTABILITY.

(a) SKILLED NURSING FACILITIES.—Section 1819(b)(8) of the Social Security Act (42 U.S.C. 1395i–3(b)(8)) is amended by adding at the end the following new subparagraph:

"(C) SUBMISSION OF STAFFING INFORMATION BASED ON PAYROLL DATA IN A UNIFORM FORMAT.—Beginning not later than 2 years after the date of the enactment of this subparagraph, and after consulting with State long-term care ombudsman programs, consumer advocacy groups, provider stakeholder groups, employees and their representatives, and other parties the Secretary deems appropriate, the Secretary shall require a skilled nursing facility to electronically submit to the Secretary direct care staffing information (including information with respect to agency and contract staff) based on payroll and other verifiable and auditable data in a uniform format (according to specifications established by the Secretary in consultation with such programs, groups, and parties). Such specifications shall require that the information submitted under the preceding sentence—

"(i) specify the category of work a certified employee performs (such as whether the employee is a registered nurse, licensed practical nurse, licensed vocational nurse, certified nursing assistant, therapist, or other medical personnel);

"(ii) include resident census data and information on resident case mix;

"(iii) include a regular reporting schedule; and

"(iv) include information on employee turnover and tenure and on the hours of care provided by each category of certified employees referenced in clause (i) per resident per day.

Nothing in this subparagraph shall be construed as preventing the Secretary from requiring submission of such information with respect to specific categories, such as nursing staff, before other categories of certified employees. Information under this subparagraph with respect to agency and contract staff shall be kept separate from information on employee staffing.".

(b) NURSING FACILITIES.—Section 1919(b)(8) of the Social Security Act (42 U.S.C. 1396r(b)(8)) is amended by adding at the end the following new subparagraph:

"(C) SUBMISSION OF STAFFING INFORMATION BASED ON PAYROLL DATA IN A UNIFORM FORMAT.—Beginning not later than 2 years after the date of the enactment of this subparagraph, and after consulting with State long-term care ombudsman programs, consumer advocacy groups, provider stakeholder groups, employees and their representatives, and other parties the Secretary deems appropriate, the Secretary shall require a nursing facility to electronically submit to the Secretary direct care staffing information (including information with respect to agency and contract staff) based on payroll and other verifiable and auditable data in a uniform format (according to specifications established by the Secretary in consultation with such programs, groups, and parties). Such specifications shall require that the information submitted under the preceding sentence—

"(i) specify the category of work a certified employee performs (such as whether the employee is a registered nurse, licensed practical nurse, licensed vocational nurse, certified nursing assistant, therapist, or other medical personnel);

"(ii) include resident census data and information on resident case mix;

"(iii) include a regular reporting schedule; and

"(iv) include information on employee turnover and tenure and on the hours of care provided by each category of certified employees referenced in clause (i) per resident per day.

Nothing in this subparagraph shall be construed as preventing the Secretary from requiring submission of such information with respect to specific categories, such as nursing staff, before other categories of certified employees. Information under this subparagraph with respect to agency and contract staff shall be kept separate from information on employee staffing.".

PART 2—TARGETING ENFORCEMENT

SEC. 1421. CIVIL MONEY PENALTIES.

(a) SKILLED NURSING FACILITIES.—

(1) IN GENERAL.—Section 1819(h)(2)(B)(ii) of the Social Security Act (42 U.S.C. 1395i–3(h)(2)(B)(ii)) is amended to read as follows:

"(ii) AUTHORITY WITH RESPECT TO CIVIL MONEY PENALTIES.—

"(I) AMOUNT.—The Secretary may impose a civil money penalty in the applicable per instance or per day amount (as defined in subclause (II) and (III)) for each day or instance, respectively, of noncompliance (as determined appropriate by the Secretary).

"(II) APPLICABLE PER INSTANCE AMOUNT.—In this clause, the term 'applicable per instance amount' means—

"(aa) in the case where the deficiency is found to be a direct proximate cause of death of a resident of the facility, an amount not to exceed $100,000;

"(bb) in each case of a deficiency where the facility is cited for actual harm or immediate jeopardy, an amount not less than $3,050 and not more than $25,000; and

"(cc) in each case of any other deficiency, an amount not less than $250 and not to exceed $3050.

"(III) APPLICABLE PER DAY AMOUNT.—In this clause, the term 'applicable per day amount' means—

"(aa) in each case of a deficiency where the facility is cited for actual harm or immediate jeopardy, an amount not less than $3,050 and not more than $25,000, and

"(bb) in each case of any other deficiency, an amount not less than $250 and not to exceed $3,050.

"(IV) REDUCTION OF CIVIL MONEY PENALTIES IN CERTAIN CIRCUMSTANCES.—Subject to subclauses (V) and (VI), in the case where a facility self-reports and promptly corrects a deficiency for which a penalty was imposed under this clause not later than 10 calendar days after the date of such imposition, the Secretary may reduce the amount of the penalty imposed by not more than 50 percent.

"(V) PROHIBITION ON REDUCTION FOR CERTAIN DEFICIENCIES.—

"(aa) REPEAT DEFICIENCIES.—The Secretary may not reduce under subclause (IV) the amount of a penalty if the deficiency is a repeat deficiency.

"(bb) CERTAIN OTHER DEFICIENCIES.—The Secretary may not reduce under subclause (IV) the amount of a penalty if the penalty is imposed for a deficiency described in subclause (II)(aa) or (III)(aa) and the actual harm or widespread harm immediately jeopardizes the health or safety of a resident or residents of the facility, or if the penalty is imposed for a deficiency described in subclause (II)(bb).

"(VI) LIMITATION ON AGGREGATE REDUCTIONS.—The aggregate reduction in a penalty under subclause (IV) may not exceed 35 percent on the basis of self-reporting, on the basis of a waiver or an appeal (as provided for under regulations under section 488.436 of title 42, Code of Federal Regulations), or on the basis of both.

"(VII) COLLECTION OF CIVIL MONEY PENALTIES.—In the case of a civil money penalty imposed under this clause, the Secretary—

"(aa) subject to item (cc), shall, not later than 30 days after the date of imposition of the penalty, provide the opportunity for the facility to participate in an independent informal dispute resolution process which generates a written record prior to the collection of such penalty, but such opportunity shall not affect the responsibility of the State survey agency for making final recommendations for such penalties;

"(bb) in the case where the penalty is imposed for each day of noncompliance, shall not impose a penalty for any day during the period beginning on the initial day of the imposition of the penalty and ending on the day on which the informal dispute resolution process under item (aa) is completed;

"(cc) may provide for the collection of such civil money penalty and the placement of such amounts collected in an escrow account under the direction of the Secretary on the earlier of the date on which the informal dispute resolution process under item (aa) is completed or the date that is 90 days after the date of the imposition of the penalty;

"(dd) may provide that such amounts collected are kept in such account pending the resolution of any subsequent appeals;

"(ee) in the case where the facility successfully appeals the penalty, may provide for the return of such amounts collected (plus interest) to the facility; and

"(ff) in the case where all such appeals are unsuccessful, may provide that some portion of such amounts collected may be used to support activities that benefit residents, including assistance to support and protect residents of a facility that closes (voluntarily or involuntarily) or is decertified (including offsetting costs of relocating residents to home and community-based settings or another facility), projects that support resident and family councils and other consumer involvement in assuring quality care in facilities, and facility improvement initiatives approved by the Secretary (including joint training of facility staff and surveyors, technical assistance for facilities under quality assurance programs, the appointment of temporary management, and other activities approved by the Secretary).

"(VIII) PROCEDURE.—The provisions of section 1128A (other than subsections (a) and (b) and except to the extent that such provisions require a hearing prior to the imposition of a civil money penalty) shall apply to a civil money penalty under this clause in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).".

(2) CONFORMING AMENDMENT.—The second sentence of section 1819(h)(5) of the Social Security Act (42 U.S.C. 1395i–3(h)(5)) is amended by inserting "(ii),"after "(i),".

(b) NURSING FACILITIES.—

(1) PENALTIES IMPOSED BY THE STATE.—

(A) IN GENERAL.—Section 1919(h)(2) of the Social Security Act (42 U.S.C. 1396r(h)(2)) is amended—

(i) in subparagraph (A)(ii), by striking the first sentence and inserting the following: "A civil money penalty in accordance with subparagraph (G).."; and

(ii) by adding at the end the following new subparagraph:

"(G) CIVIL MONEY PENALTIES.—

"(i) IN GENERAL.—The State may impose a civil money penalty under subparagraph (A)(ii) in the applicable per instance or per day amount (as defined in subclause (II) and (III)) for each day or instance, respectively, of noncompliance (as determined appropriate by the Secretary).

"(ii) APPLICABLE PER INSTANCE AMOUNT.—In this subparagraph, the term 'applicable per instance amount' means—

"(I) in the case where the deficiency is found to be a direct proximate cause of death of a resident of the facility, an amount not to exceed $100,000.

"(II) in each case of a deficiency where the facility is cited for actual harm or immediate jeopardy, an amount not less than $3,050 and not more than $25,000; and

"(III) in each case of any other deficiency, an amount not less than $250 and not to exceed $3050.

"(iii) APPLICABLE PER DAY AMOUNT.—In this subparagraph, the term 'applicable per day amount' means—

"(I) in each case of a deficiency where the facility is cited for actual harm or immediate jeopardy, an amount not less than $3,050 and not more than $25,000 and

"(II) in each case of any other deficiency, an amount not less than $250 and not to exceed $3,050.

"(iv) REDUCTION OF CIVIL MONEY PENALTIES IN CERTAIN CIRCUMSTANCES.—Subject to clauses (v) and (vi), in the case where a facility self-reports and promptly corrects a deficiency for which a penalty was imposed under subparagraph (A)(ii) not later than 10 calendar days after the date of such imposition, the State may reduce the amount of the penalty imposed by not more than 50 percent.

"(v) PROHIBITION ON REDUCTION FOR CERTAIN DEFICIENCIES.—

"(I) REPEAT DEFICIENCIES.—The State may not reduce under clause (iv) the amount of a penalty if the State had reduced a penalty imposed on the facility in the preceding year under such clause with respect to a repeat deficiency.

"(II) CERTAIN OTHER DEFICIENCIES.—The State may not reduce under clause (iv) the amount of a penalty if the penalty is imposed for a deficiency described in clause (ii)(II) or (iii)(I) and the actual harm or widespread harm that immediately jeopardizes the health or safety of a resident or residents of the facility, or if the penalty is imposed for a deficiency described in clause (ii)(I).

"(III) LIMITATION ON AGGREGATE REDUCTIONS.—The aggregate reduction in a penalty under clause (iv) may not exceed 35 percent on the basis of self-reporting, on the basis of a waiver or an appeal (as provided for under regulations under section 488.436 of title 42, Code of Federal Regulations), or on the basis of both.

"(vi) COLLECTION OF CIVIL MONEY PENALTIES.—In the case of a civil money penalty imposed under subparagraph (A)(ii), the State—

"(I) subject to subclause (III), shall, not later than 30 days after the date of imposition of the penalty, provide the opportunity for the facility to participate in an independent informal dispute resolution process which generates a written record prior to the collection of such penalty, but such opportunity shall not affect the responsibility of the State survey agency for making final recommendations for such penalties;

"(II) in the case where the penalty is imposed for each day of noncompliance, shall not impose a penalty for any day during the period beginning on the initial day of the imposition of the penalty and ending on the day on which the informal dispute resolution process under subclause (I) is completed;

"(III) may provide for the collection of such civil money penalty and the placement of such amounts collected in an escrow account under the direction of the State on the earlier of the date on which the informal dispute resolution process under subclause (I) is completed or the date that is 90 days after the date of the imposition of the penalty;

"(IV) may provide that such amounts collected are kept in such account pending the resolution of any subsequent appeals;

"(V) in the case where the facility successfully appeals the penalty, may provide for the return of such amounts collected (plus interest) to the facility; and

"(VI) in the case where all such appeals are unsuccessful, may provide that such funds collected shall be used for the purposes described in the second sentence of subparagraph (A)(ii).".

(B) CONFORMING AMENDMENT.—The second sentence of section 1919(h)(2)(A)(ii) of the Social Security Act (42 U.S.C. 1396r(h)(2)(A)(ii)) is amended by inserting before the period at the end the following: ", and some portion of such funds may be used to support activities that benefit residents, including assistance to support and protect residents of a facility that closes (voluntarily or involuntarily) or is decertified (including offsetting costs of relocating residents to home and community-based settings or another facility), projects that support resident and family councils and other consumer involvement in assuring quality care in facilities, and facility improvement initiatives approved by the Secretary (including joint training of facility staff and surveyors, providing technical assistance to facilities under quality assurance programs, the appointment of temporary management, and other activities approved by the Secretary)".

(2) PENALTIES IMPOSED BY THE SECRETARY.—

(A) IN GENERAL.—Section 1919(h)(3)(C)(ii) of the Social Security Act (42 U.S.C. 1396r(h)(3)(C)) is amended to read as follows:

"(ii) AUTHORITY WITH RESPECT TO CIVIL MONEY PENALTIES.—

"(I) AMOUNT.—Subject to subclause (II), the Secretary may impose a civil money penalty in an amount not to exceed $10,000 for each day or each instance of noncompliance (as determined appropriate by the Secretary).

"(II) REDUCTION OF CIVIL MONEY PENALTIES IN CERTAIN CIRCUMSTANCES.—Subject to subclause (III), in the case where a facility self-reports and promptly corrects a deficiency for which a penalty was imposed under this clause not later than 10 calendar days after the date of such imposition, the Secretary may reduce the amount of the penalty imposed by not more than 50 percent.

"(III) PROHIBITION ON REDUCTION FOR REPEAT DEFICIENCIES.—The Secretary may not reduce the amount of a penalty under subclause (II) if the Secretary had reduced a penalty imposed on the facility in the preceding year under such subclause with respect to a repeat deficiency.

"(IV) COLLECTION OF CIVIL MONEY PENALTIES.—In the case of a civil money penalty imposed under this clause, the Secretary—

"(aa) subject to item (bb), shall, not later than 30 days after the date of imposition of the penalty, provide the opportunity for the facility to participate in an independent informal dispute resolution process which generates a written record prior to the collection of such penalty;

"(bb) in the case where the penalty is imposed for each day of noncompliance, shall not impose a penalty for any day during the period beginning on the initial day of the imposition of the penalty and ending on the day on which the informal dispute resolution process under item (aa) is completed;

"(cc) may provide for the collection of such civil money penalty and the placement of such amounts collected in an escrow account under the direction of the Secretary on the earlier of the date on which the informal dispute resolution process under item (aa) is completed or the date that is 90 days after the date of the imposition of the penalty;

"(dd) may provide that such amounts collected are kept in such account pending the resolution of any subsequent appeals;

"(ee) in the case where the facility successfully appeals the penalty, may provide for the return of such amounts collected (plus interest) to the facility; and

"(ff) in the case where all such appeals are unsuccessful, may provide that some portion of such amounts collected may be used to support activities that benefit residents, including assistance to support and protect residents of a facility that closes (voluntarily or involuntarily) or is decertified (including offsetting costs of relocating residents to home and community-based settings or another facility), projects that support resident and family councils and other consumer involvement in assuring quality care in facilities, and facility improvement initiatives approved by the Secretary (including joint training of facility staff and surveyors, technical assistance for facilities under quality assurance programs, the appointment of temporary management, and other activities approved by the Secretary).

"(V) PROCEDURE.—The provisions of section 1128A (other than subsections (a) and (b) and except to the extent that such provisions require a hearing prior to the imposition of a civil money penalty) shall apply to a civil money penalty under this clause in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).".

(B) CONFORMING AMENDMENT.—Section 1919(h)(8) of the Social Security Act (42 U.S.C. 1396r(h)(5)(8)) is amended by inserting "and in paragraph (3)(C)(ii)" after "paragraph (2)(A)".

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect 1 year after the date of the enactment of this Act.

SEC. 1422. NATIONAL INDEPENDENT MONITOR PILOT PROGRAM.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—The Secretary, in consultation with the Inspector General of the Department of Health and Human Services, shall establish a pilot program (in this section referred to as the "pilot program") to develop, test, and implement use of an independent monitor to oversee interstate and large intrastate chains of skilled nursing facilities and nursing facilities.

(2) SELECTION.—The Secretary shall select chains of skilled nursing facilities and nursing facilities described in paragraph (1) to participate in the pilot program from among those chains that submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(3) DURATION.—The Secretary shall conduct the pilot program for a two-year period.

(4) IMPLEMENTATION.—The Secretary shall implement the pilot program not later than one year after the date of the enactment of this Act.

(b) REQUIREMENTS.—The Secretary shall evaluate chains selected to participate in the pilot program based on criteria selected by the Secretary, including where evidence suggests that one or more facilities of the chain are experiencing serious safety and quality of care problems. Such criteria may include the evaluation of a chain that includes one or more facilities participating in the "Special Focus Facility" program (or a successor program) or one or more facilities with a record of repeated serious safety and quality of care deficiencies.

(c) RESPONSIBILITIES OF THE INDEPENDENT MONITOR.—An independent monitor that enters into a contract with the Secretary to participate in the conduct of such program shall—

(1) conduct periodic reviews and prepare root-cause quality and deficiency analyses of a chain to assess if facilities of the chain are in compliance with State and Federal laws and regulations applicable to the facilities;

(2) undertake sustained oversight of the chain, whether publicly or privately held, to involve the owners of the chain and the principal business partners of such owners in facilitating compliance by facilities of the chain with State and Federal laws and regulations applicable to the facilities;

(3) analyze the management structure, distribution of expenditures, and nurse staffing levels of facilities of the chain in relation to resident census, staff turnover rates, and tenure;

(4) report findings and recommendations with respect to such reviews, analyses, and oversight to the chain and facilities of the chain, to the Secretary and to relevant States; and

(5) publish the results of such reviews, analyses, and oversight.

(d) IMPLEMENTATION OF RECOMMENDATIONS.—

(1) RECEIPT OF FINDING BY CHAIN.—Not later than 10 days after receipt of a finding of an independent monitor under subsection (c)(4), a chain participating in the pilot program shall submit to the independent monitor a report—

(A) outlining corrective actions the chain will take to implement the recommendations in such report; or

(B) indicating that the chain will not implement such recommendations and why it will not do so.

(2) RECEIPT OF REPORT BY INDEPENDENT MONITOR.—Not later than 10 days after the date of receipt of a report submitted by a chain under paragraph (1), an independent monitor shall finalize its recommendations and submit a report to the chain and facilities of the chain, the Secretary, and the State (or States) involved, as appropriate, containing such final recommendations.

(e) COST OF APPOINTMENT.—A chain shall be responsible for a portion of the costs associated with the appointment of independent monitors under the pilot program. The chain shall pay such portion to the Secretary (in an amount and in accordance with procedures established by the Secretary).

(f) WAIVER AUTHORITY.—The Secretary may waive such requirements of titles XVIII and XIX of the Social Security Act (42 U.S.C. 1395 et seq.; 1396 et seq.) as may be necessary for the purpose of carrying out the pilot program.

(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.

(h) DEFINITIONS.—In this section:

(1) FACILITY.—The term "facility" means a skilled nursing facility or a nursing facility.

(2) NURSING FACILITY.—The term "nursing facility" has the meaning given such term in section 1919(a) of the Social Security Act (42 U.S.C. 1396r(a)).

(3) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services, acting through the Assistant Secretary for Planning and Evaluation.

(4) SKILLED NURSING FACILITY.—The term "skilled nursing facility" has the meaning given such term in section 1819(a) of the Social Security Act (42 U.S.C. 1395(a)).

(i) EVALUATION AND REPORT.—

(1) EVALUATION.—The Inspector General of the Department of Health and Human Services shall evaluate the pilot program. Such evaluation shall—

(A) determine whether the independent monitor program should be established on a permanent basis; and

(B) if the Inspector General determines that the independent monitor program should be established on a permanent basis, recommend appropriate procedures and mechanisms for such establishment.

(2) REPORT.—Not later than 180 days after the completion of the pilot program, the Inspector General shall submit to Congress and the Secretary a report containing the results of the evaluation conducted under paragraph (1), together with recommendations for such legislation and administrative action as the Inspector General determines appropriate.

SEC. 1423. NOTIFICATION OF FACILITY CLOSURE.

(a) SKILLED NURSING FACILITIES.—

(1) IN GENERAL.—Section 1819(c) of the Social Security Act (42 U.S.C. 1395i–3(c)) is amended by adding at the end the following new paragraph:

"(7) NOTIFICATION OF FACILITY CLOSURE.—

"(A) IN GENERAL.—Any individual who is the administrator of a skilled nursing facility must—

"(i) submit to the Secretary, the State long-term care ombudsman, residents of the facility, and the legal representatives of such residents or other responsible parties, written notification of an impending closure—

"(I) subject to subclause (II), not later than the date that is 60 days prior to the date of such closure; and

"(II) in the case of a facility where the Secretary terminates the facility's participation under this title, not later than the date that the Secretary determines appropriate;

"(ii) ensure that the facility does not admit any new residents on or after the date on which such written notification is submitted; and

"(iii) include in the notice a plan for the transfer and adequate relocation of the residents of the facility by a specified date prior to closure that has been approved by the State, including assurances that the residents will be transferred to the most appropriate facility or other

setting in terms of quality, services, and location, taking into consideration the needs and best interests of each resident.

"(B) RELOCATION.—

"(i) IN GENERAL.—The State shall ensure that, before a facility closes, all residents of the facility have been successfully relocated to another facility or an alternative home and community-based setting.

"(ii) CONTINUATION OF PAYMENTS UNTIL RESIDENTS RELOCATED.—The Secretary may, as the Secretary determines appropriate, continue to make payments under this title with respect to residents of a facility that has submitted a notification under subparagraph (A) during the period beginning on the date such notification is submitted and ending on the date on which the resident is successfully relocated.".

(2) CONFORMING AMENDMENTS.—Section 1819(h)(4) of the Social Security Act (42 U.S.C. 1395i–3(h)(4)) is amended—

(A) in the first sentence, by striking "the Secretary shall terminate" and inserting "the Secretary, subject to subsection (c)(7), shall terminate"; and

(B) in the second sentence, by striking "subsection (c)(2)" and inserting "paragraphs (2) and (7) of subsection (c)".

(b) NURSING FACILITIES.—

(1) IN GENERAL.—Section 1919(c) of the Social Security Act (42 U.S.C. 1396r(c)) is amended by adding at the end the following new paragraph:

"(9) NOTIFICATION OF FACILITY CLOSURE.—

"(A) IN GENERAL.—Any individual who is an administrator of a nursing facility must—

"(i) submit to the Secretary, the State long-term care ombudsman, residents of the facility, and the legal representatives of such residents or other responsible parties, written notification of an impending closure—

"(I) subject to subclause (II), not later than the date that is 60 days prior to the date of such closure; and

"(II) in the case of a facility where the Secretary terminates the facility's participation under this title, not later than the date that the Secretary determines appropriate;

"(ii) ensure that the facility does not admit any new residents on or after the date on which such written notification is submitted; and

"(iii) include in the notice a plan for the transfer and adequate relocation of the residents of the facility by a specified date prior to closure that has been approved by the State, including assurances that the residents will be transferred to the most appropriate facility or other setting in terms of quality, services, and location, taking into consideration the needs and best interests of each resident.

"(B) RELOCATION.—

"(i) IN GENERAL.—The State shall ensure that, before a facility closes, all residents of the facility have been successfully relocated to another facility or an alternative home and community-based setting.

"(ii) CONTINUATION OF PAYMENTS UNTIL RESIDENTS RELOCATED.—The Secretary may, as the Secretary determines appropriate, continue to make payments under this title with respect to residents of a facility that has submitted a notification under subparagraph (A) during the period beginning on the date such notification is submitted and ending on the date on which the resident is successfully relocated.".

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect 1 year after the date of the enactment of this Act.

PART 3—IMPROVING STAFF TRAINING

SEC. 1431. DEMENTIA AND ABUSE PREVENTION TRAINING.

(a) SKILLED NURSING FACILITIES.—Section 1819(f)(2)(A)(i)(I) of the Social Security Act (42 U.S.C. 1395i–3(f)(2)(A)(i)(I)) is amended by inserting "(including, in the case of initial training and, if the Secretary determines appropriate, in the case of ongoing training, dementia management training and resident abuse prevention training)" after "curriculum".

(b) NURSING FACILITIES.—Section 1919(f)(2)(A)(i)(I) of the Social Security Act (42 U.S.C. 1396r(f)(2)(A)(i)(I)) is amended by inserting "(including, in the case of initial training and, if the Secretary determines appropriate, in the case of ongoing training, dementia management training and resident abuse prevention training)" after "curriculum".

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect 1 year after the date of the enactment of this Act.

SEC. 1432. STUDY AND REPORT ON TRAINING REQUIRED FOR CERTIFIED NURSE AIDES AND SUPERVISORY STAFF.

(a) STUDY.—

(1) IN GENERAL.—The Secretary shall conduct a study on the content of training for certified nurse aides and supervisory staff of skilled nursing facilities and nursing facilities. The study shall include an analysis of the following:

(A) Whether the number of initial training hours for certified nurse aides required under sections 1819(f)(2)(A)(i)(II) and 1919(f)(2)(A)(i)(II) of the Social Security Act (42 U.S.C. 1395i–3(f)(2)(A)(i)(II); 1396r(f)(2)(A)(i)(II)) should be increased from 75 and, if so, what the required number of initial training hours should be, including any recommendations for the content of such training (including training related to dementia).

(B) Whether requirements for ongoing training under such sections 1819(f)(2)(A)(i)(II) and 1919(f)(2)(A)(i)(II) should be increased from 12 hours per year, including any recommendations for the content of such training.

(2) CONSULTATION.—In conducting the analysis under paragraph (1)(A), the Secretary shall consult with States that, as of the date of the enactment of this Act, require more than 75 hours of training for certified nurse aides.

(3) DEFINITIONS.—In this section:

(A) NURSING FACILITY.—The term "nursing facility" has the meaning given such term in section 1919(a) of the Social Security Act (42 U.S.C. 1396r(a)).

(B) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services, acting through the Assistant Secretary for Planning and Evaluation.

(C) SKILLED NURSING FACILITY.—The term "skilled nursing facility" has the meaning given such term in section 1819(a) of the Social Security Act (42 U.S.C. 1395(a)).

(b) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Secretary shall submit to Congress a report containing the results of the study conducted under subsection (a), together with recommendations for such legislation and administrative action as the Secretary determines appropriate.

SEC. 1433. QUALIFICATION OF DIRECTOR OF FOOD SERVICES OF A MEDICAID NURSING FACILITY.

(a) IN GENERAL.—Section 1919(b)(4)(A) of the Social Security Act (42 U.S.C. 1396r(b)(4)(A)) is amended by adding at the end the following: "With respect to meeting the staffing requirement imposed by the Secretary to carry out clause (iv), the full-time director of food services of the facility, if not a qualified dietitian (as defined in section 483.35(a)(2) of title 42, Code of Federal Regulations, as in effect as of the date of the enactment of this section), shall be a Certified Dietary Manager meeting the requirements of the Certifying Board for Dietary Managers, or a Dietetic Technician, Registered meeting the requirements of the Commission on Dietetic Registration or have equivalent military or academic qualifications (as specified by the Secretary).".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date that is 180 days after the date of enactment of this Act.

Subtitle C—Quality Measurements

SEC. 1441. ESTABLISHMENT OF NATIONAL PRIORITIES FOR QUALITY IMPROVEMENT.

Title XI of the Social Security Act, as amended by section 1401(a), is further amended by adding at the end the following new part:

"PART E—QUALITY IMPROVEMENT

"ESTABLISHMENT OF NATIONAL PRIORITIES FOR PERFORMANCE IMPROVEMENT

"SEC. 1191. (a) ESTABLISHMENT OF NATIONAL PRIORITIES BY THE SECRETARY.—The Secretary shall establish and periodically update, not less frequently than triennially, national priorities for performance improvement.

"(b) RECOMMENDATIONS FOR NATIONAL PRIORITIES.—In establishing and updating national priorities under subsection (a), the Secretary shall solicit and consider recommendations from multiple outside stakeholders.

"(c) CONSIDERATIONS IN SETTING NATIONAL PRIORITIES.—With respect to such priorities, the Secretary shall ensure that priority is given to areas in the delivery of health care services in the United States that—

"(1) contribute to a large burden of disease, including those that address the health care provided to patients with prevalent, high-cost chronic diseases;

"(2) have the greatest potential to decrease morbidity and mortality in this country, including those that are designed to eliminate harm to patients;

"(3) have the greatest potential for improving the performance, affordability, and patient-centeredness of health care, including those due to variations in care;

"(4) address health disparities across groups and areas; and

"(5) have the potential for rapid improvement due to existing evidence, standards of care or other reasons.

"(d) DEFINITIONS.—In this part:

"(1) CONSENSUS-BASED ENTITY.—The term 'consensus-based entity' means an entity with a contract with the Secretary under section 1890.

"(2) QUALITY MEASURE.—The term 'quality measure' means a national consensus standard for measuring the performance and improvement of population health, or of institutional providers of services, physicians, and other health care practitioners in the delivery of health care services.

"(e) FUNDING.—

"(1) IN GENERAL.—The Secretary shall provide for the transfer, from the Federal Hospital Insurance Trust Fund under section 1817 and the Federal Supplementary Medical Insurance Trust Fund under section 1841 (in such proportion as the Secretary determines appropriate), of $2,000,000, for the activities under this section for each of the fiscal years 2010 through 2014.

"(2) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out the provisions of this section, in addition to funds otherwise available, out of any funds in the Treasury not otherwise appropriated, there are appropriated to the Secretary of Health and Human Services $2,000,000 for each of the fiscal years 2010 through 2014.".

SEC. 1442. DEVELOPMENT OF NEW QUALITY MEASURES; GAO EVALUATION OF DATA COLLECTION PROCESS FOR QUALITY MEASUREMENT.

Part E of title XI of the Social Security Act, as added by section 1441, is amended by adding at the end the following new sections:

"SEC. 1192. DEVELOPMENT OF NEW QUALITY MEASURES.

"(a) AGREEMENTS WITH QUALIFIED ENTITIES.—

"(1) IN GENERAL.—The Secretary shall enter into agreements with qualified entities to develop quality measures for the delivery of health care services in the United States.

"(2) FORM OF AGREEMENTS.—The Secretary may carry out paragraph (1) by contract, grant, or otherwise.

"(3) RECOMMENDATIONS OF CONSENSUS-BASED ENTITY.—In carrying out this section, the Secretary shall—

"(A) seek public input; and

"(B) take into consideration recommendations of the consensus-based entity with a contract with the Secretary under section 1890(a).

"(b) DETERMINATION OF AREAS WHERE QUALITY MEASURES ARE REQUIRED.—Consistent with the national priorities established under this part and with the programs administered by the Centers for Medicare & Medicaid Services and in consultation with other relevant Federal agencies, the Secretary shall determine areas in which quality measures for assessing health care services in the United States are needed.

"(c) DEVELOPMENT OF QUALITY MEASURES.—

"(1) PATIENT-CENTERED AND POPULATION-BASED MEASURES.—Quality measures developed under agreements under subsection (a) shall be designed—

"(A) to assess outcomes, presence of impairment, and functional status of patients;

"(B) to assess the continuity and coordination of care and care transitions for patients across providers and health care settings, including end of life care;

"(C) to assess patient experience and patient engagement;

"(D) to assess the safety, effectiveness, and timeliness of care;

"(E) to assess health disparities including those associated with individual race, ethnicity, age, gender, place of residence or language;

"(F) to assess the efficiency and resource use in the provision of care;

"(G) to the extent feasible, to be collected as part of health information technologies supporting better delivery of health care services;

"(H) to be available free of charge to users for the use of such measures; and

"(I) to assess delivery of health care services to individuals regardless of age.

"(2) AVAILABILITY OF MEASURES.—The Secretary shall make quality measures developed under this section available to the public.

"(3) TESTING OF PROPOSED MEASURES.—The Secretary may use amounts made available under subsection (f) to fund the testing of proposed quality measures by qualified entities. Testing funded under this paragraph shall include testing of the feasibility and usability of proposed measures.

"(4) UPDATING OF ENDORSED MEASURES.—The Secretary may use amounts made available under subsection (f) to fund the updating (and testing, if applicable) by consensus-based entities of quality measures that have been previously endorsed by such an entity as new evidence is developed, in a manner consistent with section 1890(b)(3).

"(d) QUALIFIED ENTITIES.—Before entering into agreements with a qualified entity, the Secretary shall ensure that the entity is a public, nonprofit or academic institution with technical expertise in the area of health quality measurement.

"(e) APPLICATION FOR GRANT.—A grant may be made under this section only if an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

"(f) FUNDING.—

"(1) IN GENERAL.—The Secretary shall provide for the transfer, from the Federal Hospital Insurance Trust Fund under section 1817 and the Federal Supplementary Medical Insurance Trust Fund under section 1841 (in such proportion as the Secretary determines appropriate), of $25,000,000, to the Secretary for purposes of carrying out this section for each of the fiscal years 2010 through 2014.

"(2) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out the provisions of this section, in addition to funds otherwise available, out of any funds in the Treasury not otherwise appropriated, there are appropriated to the Secretary of Health and Human Services $25,000,000 for each of the fiscal years 2010 through 2014.

"SEC. 1193. GAO EVALUATION OF DATA COLLECTION PROCESS FOR QUALITY MEASUREMENT.

"(a) GAO EVALUATIONS.—The Comptroller General of the United States shall conduct periodic evaluations of the implementation of the data collection processes for quality measures used by the Secretary.

"(b) CONSIDERATIONS.—In carrying out the evaluation under subsection (a), the Comptroller General shall determine—

"(1) whether the system for the collection of data for quality measures provides for validation of data as relevant and scientifically credible;

"(2) whether data collection efforts under the system use the most efficient and cost-effective means in a manner that minimizes administrative burden on persons required to collect data and that adequately protects the privacy of patients' personal health information and provides data security;

"(3) whether standards under the system provide for an appropriate opportunity for physicians and other clinicians and institutional providers of services to review and correct findings; and

"(4) the extent to which quality measures are consistent with section 1192(c)(1) or result in direct or indirect costs to users of such measures.

"(c) REPORT.—The Comptroller General shall submit reports to Congress and to the Secretary containing a description of the findings and conclusions of the results of each such evaluation.".

SEC. 1443. MULTISTAKEHOLDER PRERULEMAKING INPUT INTO SELECTION OF QUALITY MEASURES.

Section 1808 of the Social Security Act (42 U.S.C. 1395b–9) is amended by adding at the end the following new subsection:

"(d) MULTI-STAKEHOLDER PRE-RULEMAKING INPUT INTO SELECTION OF QUALITY MEASURES.—

"(1) LIST OF MEASURES.—Not later than December 1 before each year (beginning with 2011), the Secretary shall make public a list of measures being considered for selection for quality measurement by the Secretary in rulemaking with respect to payment systems under this title beginning in the payment year beginning in such year and for payment systems beginning in the calendar year following such year, as the case may be.

"(2) CONSULTATION ON SELECTION OF ENDORSED QUALITY MEASURES.—A consensus-based entity that has entered into a contract under section 1890 shall,

as part of such contract, convene multi-stakeholder groups to provide recommendations on the selection of individual or composite quality measures, for use in reporting performance information to the public or for use in public health care programs.

"(3) MULTI-STAKEHOLDER INPUT.—Not later than February 1 of each year (beginning with 2011), the consensus-based entity described in paragraph (2) shall transmit to the Secretary the recommendations of multi-stakeholder groups provided under paragraph (2). Such recommendations shall be included in the transmissions the consensus-based entity makes to the Secretary under the contract provided for under section 1890.

"(4) REQUIREMENT FOR TRANSPARENCY IN PROCESS.—

"(A) IN GENERAL.—In convening multi-stakeholder groups under paragraph (2) with respect to the selection of quality measures, the consensus-based entity described in such paragraph shall provide for an open and transparent process for the activities conducted pursuant to such convening.

"(B) SELECTION OF ORGANIZATIONS PARTICIPATING IN MULTI-STAKEHOLDER GROUPS.—The process under paragraph (2) shall ensure that the selection of representatives of multi-stakeholder groups includes provision for public nominations for, and the opportunity for public comment on, such selection.

"(5) USE OF INPUT.—The respective proposed rule shall contain a summary of the recommendations made by the multi-stakeholder groups under paragraph (2), as well as other comments received regarding the proposed measures, and the extent to which such proposed rule follows such recommendations and the rationale for not following such recommendations.

"(6) MULTI-STAKEHOLDER GROUPS.—For purposes of this subsection, the term 'multi-stakeholder groups' means, with respect to a quality measure, a voluntary collaborative of organizations representing persons interested in or affected by the use of such quality measure, such as the following:

"(A) Hospitals and other institutional providers.

"(B) Physicians.

"(C) Health care quality alliances.

"(D) Nurses and other health care practitioners.

"(E) Health plans.

"(F) Patient advocates and consumer groups.

"(G) Employers.

"(H) Public and private purchasers of health care items and services.

"(I) Labor organizations.

"(J) Relevant departments or agencies of the United States.

"(K) Biopharmaceutical companies and manufacturers of medical devices.

"(L) Licensing, credentialing, and accrediting bodies.

"(7) FUNDING.—

"(A) IN GENERAL.—The Secretary shall provide for the transfer, from the Federal Hospital Insurance Trust Fund under section 1817 and the Federal Supplementary Medical Insurance Trust Fund under section 1841 (in such proportion as the Secretary determines appropriate), of $1,000,000, to the Secretary for purposes of carrying out this subsection for each of the fiscal years 2010 through 2014.

"(B) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out the provisions of this subsection, in addition to funds otherwise available, out of any funds in the Treasury not otherwise appropriated, there are appropriated to the Secretary of Health and Human Services $1,000,000 for each of the fiscal years 2010 through 2014.".

SEC. 1444. APPLICATION OF QUALITY MEASURES.

(a) INPATIENT HOSPITAL SERVICES.—Section 1886(b)(3)(B) of such Act (42 U.S.C. 1395ww(b)(3)(B)) is amended by adding at the end the following new clause:

"(x)(I) Subject to subclause (II), for purposes of reporting data on quality measures for inpatient hospital services furnished during fiscal year 2012 and each subsequent fiscal year, the quality measures specified under clause (viii) shall be measures selected by the Secretary from measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a).

"(II) In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical quality measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. The Secretary shall submit such a non-endorsed measure to the entity for consideration for endorsement. If the entity considers but does not endorse such a measure and if the Secretary does not phase-out use of such measure, the

Secretary shall include the rationale for continued use of such a measure in rulemaking.".

(b) OUTPATIENT HOSPITAL SERVICES.—Section 1833(t)(17) of such Act (42 U.S.C. 1395l(t)(17)) is amended by adding at the end the following new subparagraph:

"(F) USE OF ENDORSED QUALITY MEASURES.—The provisions of clause (x) of section 1886(b)(3)(C) shall apply to quality measures for covered OPD services under this paragraph in the same manner as such provisions apply to quality measures for inpatient hospital services.".

(c) PHYSICIANS' SERVICES.—Section 1848(k)(2)(C)(ii) of such Act (42 U.S.C. 1395w-4(k)(2)(C)(ii)) is amended by adding at the end the following: "The Secretary shall submit such a non-endorsed measure to the entity for consideration for endorsement. If the entity considers but does not endorse such a measure and if the Secretary does not phase-out use of such measure, the Secretary shall include the rationale for continued use of such a measure in rulemaking.".

(d) RENAL DIALYSIS SERVICES.—Section 1881(h)(2)(B)(ii) of such Act (42 U.S.C. 1395rr(h)(2)(B)(ii)) is amended by adding at the end the following: "The Secretary shall submit such a non-endorsed measure to the entity for consideration for endorsement. If the entity considers but does not endorse such a measure and if the Secretary does not phase-out use of such measure, the Secretary shall include the rationale for continued use of such a measure in rulemaking.".

(e) ENDORSEMENT OF STANDARDS.—Section 1890(b)(2) of the Social Security Act (42 U.S.C. 1395aaa(b)(2)) is amended by adding after and below subparagraph (B) the following:

"If the entity does not endorse a measure, such entity shall explain the reasons and provide suggestions about changes to such measure that might make it a potentially endorsable measure.".

(f) EFFECTIVE DATE.—Except as otherwise provided, the amendments made by this section shall apply to quality measures applied for payment years beginning with 2012 or fiscal year 2012, as the case may be.

SEC. 1445. CONSENSUS-BASED ENTITY FUNDING.

Section 1890(d) of the Social Security Act (42 U.S.C. 1395aaa(d)) is amended by striking "for each of fiscal years 2009 through 2012" and inserting "for fiscal year 2009, and $12,000,000 for each of the fiscal years 2010 through 2012".

SEC. 1446. QUALITY INDICATORS FOR CARE OF PEOPLE WITH ALZHEIMER'S DISEASE.

(a) QUALITY INDICATORS.—The Secretary of Health and Human Services, acting through the Agency for Healthcare Research and Quality (AHRQ), shall develop, either directly or with commissioned projects, a core set of quality indicators for the provision of medical services to people with Alzheimer's disease and other dementias and a plan for implementing the indicators to measure the quality of care provided for people with these conditions by physicians, hospitals, and other medical, residential and home care agencies and providers.

(b) REPORT.—The Secretary shall submit a report to the Committees on Energy and Commerce and Ways and Means of the United States House of Representatives and to the Committees on Finance and Health, Education, and Pensions of the United States Senate not later than 12 months after the date of the enactment of this Act setting forth the status of their efforts to implement the requirements of subsection (a).

SEC. 1447. STUDY ON FIVE STAR QUALITY RATING SYSTEM.

(a) STUDY.—The Comptroller General of the United States shall conduct a study on the Five-Star Quality Rating System (or a successor program) established by the Centers for Medicare & Medicaid Services. The study shall—

(1) determine whether the composite star rating should be eliminated in favor of a multi-dimensional system under which a star rating is assigned to each individual domain;

(2) determine whether an appeals process should be implemented for the Five Star Rating System to address situations in which questionable, inaccurate, or incomplete data has been identified;

(3) evaluate the appropriateness of any weighting methodology used to adjust quality measures, including an assessment of whether such methodology is validated, whether it takes into account resident characteristics, the appropriateness of the weighting of individual quality measures, and whether the accuracy of information to consumers would be enhanced if the standard survey were weighted more heavily than the complaint survey;

(4) assess the appropriateness of the case-mix adjustment methodology used to evaluate staffing levels, along with the appropriateness of the staffing levels established by the Centers for Medicare & Medicaid Services to achieve a 5-star

rating given the absence of any existing Federal nursing home staffing guidelines or Medicare funding to support these staffing levels;

(5) if the Comptroller General determines that such target staffing levels are appropriate, evaluate, in consultation with the Secretary of Health and Human Services, the cost of modifying the Medicare Skilled Nursing Facility Resource Utilization Groups to reflect the costs to facilities of providing staffing at these target levels;

(6) evaluate how best to represent resident/consumer satisfaction under the rating system, and review approaches to report other facility-specific characteristics to enable consumers to better identify facilities that will meet their individual needs;

(7) evaluate the impact of the rating system on Medicare skilled nursing facilities and Medicaid nursing facilities, including a review of potential problems associated with inaccurate or incomplete data and other unanticipated consequences reported by facilities; and

(8) assess whether the national program should be suspended and replaced with a pilot program testing potential nursing home quality rating systems in a limited number of States.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress and the Secretary of Health and Human Services a report containing the results of the study conducted under subsection (a), together with recommendations for such modifications to the Five-Star Quality Rating System as the Comptroller General determines appropriate.

Subtitle D—Physician Payments Sunshine Provision

SEC. 1451. REPORTS ON FINANCIAL RELATIONSHIPS BETWEEN MANUFACTURERS AND DISTRIBUTORS OF COVERED DRUGS, DEVICES, BIOLOGICALS, OR MEDICAL SUPPLIES UNDER MEDICARE, MEDICAID, OR CHIP AND PHYSICIANS AND OTHER HEALTH CARE ENTITIES AND BETWEEN PHYSICIANS AND OTHER HEALTH CARE ENTITIES.

(a) IN GENERAL.—Part A of title XI of the Social Security Act (42 U.S.C. 1301 et seq.), as amended by section 1631(a), is further amended by inserting after section 1128G the following new section:

"SEC. 1128H. FINANCIAL REPORTS ON PHYSICIANS' FINANCIAL RELATIONSHIPS WITH MANUFACTURERS AND DISTRIBUTORS OF COVERED DRUGS, DEVICES, BIOLOGICALS, OR MEDICAL SUPPLIES UNDER MEDICARE, MEDICAID, OR CHIP AND WITH ENTITIES THAT BILL FOR SERVICES UNDER MEDICARE.

"(a) REPORTING OF PAYMENTS OR OTHER TRANSFERS OF VALUE.—

"(1) IN GENERAL.—Except as provided in this subsection, not later than March 31, 2011 and annually thereafter, each applicable manufacturer or distributor that provides a payment or other transfer of value to a covered recipient, or to an entity or individual at the request of or designated on behalf of a covered recipient, shall submit to the Secretary, in such electronic form as the Secretary shall require, the following information with respect to the preceding calendar year:

"(A) With respect to the covered recipient, the recipient's name, business address, physician specialty, and national provider identifier.

"(B) With respect to the payment or other transfer of value, other than a drug sample—

"(i) its value and date;

"(ii) the name of the related drug, device, or supply, if available; and

"(iii) a description of its form, indicated (as appropriate for all that apply) as—

"(I) cash or a cash equivalent;

"(II) in-kind items or services;

"(III) stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment; or

"(IV) any other form (as defined by the Secretary).

"(C) With respect to a drug sample, the name, number, date, and dosage units of the sample.

"(2) AGGREGATE REPORTING.—Information submitted by an applicable manufacturer or distributor under paragraph (1) shall include the aggregate amount of all payments or other transfers of value provided by the manufacturer or distributor to covered recipients (and to entities or individuals at the request of or designated on behalf of a covered recipient) during the year involved, includ-

ing all payments and transfers of value regardless of whether such payments or transfer of value were individually disclosed.

"(3) SPECIAL RULE FOR CERTAIN PAYMENTS OR OTHER TRANSFERS OF VALUE.—In the case where an applicable manufacturer or distributor provides a payment or other transfer of value to an entity or individual at the request of or designated on behalf of a covered recipient, the manufacturer or distributor shall disclose that payment or other transfer of value under the name of the covered recipient.

"(4) DELAYED REPORTING FOR PAYMENTS MADE PURSUANT TO PRODUCT DEVELOPMENT AGREEMENTS.—In the case of a payment or other transfer of value made to a covered recipient by an applicable manufacturer or distributor pursuant to a product development agreement for services furnished in connection with the development of a new drug, device, biological, or medical supply, the applicable manufacturer or distributor may report the value and recipient of such payment or other transfer of value in the first reporting period under this subsection in the next reporting deadline after the earlier of the following:

"(A) The date of the approval or clearance of the covered drug, device, biological, or medical supply by the Food and Drug Administration.

"(B) Two calendar years after the date such payment or other transfer of value was made.

"(5) DELAYED REPORTING FOR PAYMENTS MADE PURSUANT TO CLINICAL INVESTIGATIONS.—In the case of a payment or other transfer of value made to a covered recipient by an applicable manufacturer or distributor in connection with a clinical investigation regarding a new drug, device, biological, or medical supply, the applicable manufacturer or distributor may report as required under this section in the next reporting period under this subsection after the earlier of the following:

"(A) The date that the clinical investigation is registered on the website maintained by the National Institutes of Health pursuant to section 671 of the Food and Drug Administration Amendments Act of 2007.

"(B) Two calendar years after the date such payment or other transfer of value was made.

"(6) CONFIDENTIALITY.—Information described in paragraph (4) or (5) shall be considered confidential and shall not be subject to disclosure under section 552 of title 5, United States Code, or any other similar Federal, State, or local law, until or after the date on which the information is made available to the public under such paragraph.

"(b) REPORTING OF OWNERSHIP INTEREST BY PHYSICIANS IN HOSPITALS AND OTHER ENTITIES THAT BILL MEDICARE.—Not later than March 31 of each year (beginning with 2011), each hospital or other health care entity (not including a Medicare Advantage organization) that bills the Secretary under part A or part B of title XVIII for services shall report on the ownership shares (other than ownership shares described in section 1877(c)) of each physician who, directly or indirectly, owns an interest in the entity. In this subsection, the term 'physician' includes a physician's immediate family members (as defined for purposes of section 1877(a)).

"(c) PUBLIC AVAILABILITY.—

"(1) IN GENERAL.—The Secretary shall establish procedures to ensure that, not later than September 30, 2011, and on June 30 of each year beginning thereafter, the information submitted under subsections (a) and (b), other than information regard drug samples, with respect to the preceding calendar year is made available through an Internet website that—

"(A) is searchable and is in a format that is clear and understandable;

"(B) contains information that is presented by the name of the applicable manufacturer or distributor, the name of the covered recipient, the business address of the covered recipient, the specialty (if applicable) of the covered recipient, the value of the payment or other transfer of value, the date on which the payment or other transfer of value was provided to the covered recipient, the form of the payment or other transfer of value, indicated (as appropriate) under subsection (a)(1)(B)(ii), the nature of the payment or other transfer of value, indicated (as appropriate) under subsection (a)(1)(B)(iii), and the name of the covered drug, device, biological, or medical supply, as applicable;

"(C) contains information that is able to be easily aggregated and downloaded;

"(D) contains a description of any enforcement actions taken to carry out this section, including any penalties imposed under subsection (d), during the preceding year;

"(E) contains background information on industry-physician relationships;

"(F) in the case of information submitted with respect to a payment or other transfer of value described in subsection (a)(5), lists such information separately from the other information submitted under subsection (a) and designates such separately listed information as funding for clinical research;

"(G) contains any other information the Secretary determines would be helpful to the average consumer; and

"(H) provides the covered recipient an opportunity to submit corrections to the information made available to the public with respect to the covered recipient.

"(2) ACCURACY OF REPORTING.—The accuracy of the information that is submitted under subsections (a) and (b) and made available under paragraph (1) shall be the responsibility of the applicable manufacturer or distributor of a covered drug, device, biological, or medical supply reporting under subsection (a) or hospital or other health care entity reporting physician ownership under subsection (b). The Secretary shall establish procedures to ensure that the covered recipient is provided with an opportunity to submit corrections to the manufacturer, distributor, hospital, or other entity reporting under subsection (a) or (b) with regard to information made public with respect to the covered recipient and, under such procedures, the corrections shall be transmitted to the Secretary.

"(3) SPECIAL RULE FOR DRUG SAMPLES.—Information relating to drug samples provided under subsection (a) shall not be made available to the public by the Secretary but may be made available outside the Department of Health and Human Services by the Secretary for research or legitimate business purposes pursuant to data use agreements.

"(4) SPECIAL RULE FOR NATIONAL PROVIDER IDENTIFIERS.—Information relating to national provider identifiers provided under subsection (a) shall not be made available to the public by the Secretary but may be made available outside the Department of Health and Human Services by the Secretary for research or legitimate business purposes pursuant to data use agreements.

"(d) PENALTIES FOR NONCOMPLIANCE.—

"(1) FAILURE TO REPORT.—

"(A) IN GENERAL.—Subject to subparagraph (B), except as provided in paragraph (2), any applicable manufacturer or distributor that fails to submit information required under subsection (a) in a timely manner in accordance with regulations promulgated to carry out such subsection, and any hospital or other entity that fails to submit information required under subsection (b) in a timely manner in accordance with regulations promulgated to carry out such subsection shall be subject to a civil money penalty of not less than $1,000, but not more than $10,000, for each payment or other transfer of value or ownership or investment interest not reported as required under such subsection. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.

"(B) LIMITATION.—The total amount of civil money penalties imposed under subparagraph (A) with respect to each annual submission of information under subsection (a) by an applicable manufacturer or distributor or other entity shall not exceed $150,000.

"(2) KNOWING FAILURE TO REPORT.—

"(A) IN GENERAL.—Subject to subparagraph (B), any applicable manufacturer or distributor that knowingly fails to submit information required under subsection (a) in a timely manner in accordance with regulations promulgated to carry out such subsection and any hospital or other entity that fails to submit information required under subsection (b) in a timely manner in accordance with regulations promulgated to carry out such subsection, shall be subject to a civil money penalty of not less than $10,000, but not more than $100,000, for each payment or other transfer of value or ownership or investment interest not reported as required under such subsection. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.

"(B) LIMITATION.—The total amount of civil money penalties imposed under subparagraph (A) with respect to each annual submission of information under subsection (a) or (b) by an applicable manufacturer, distributor, or entity shall not exceed $1,000,000, or, if greater, 0.1 percentage of the total annual revenues of the manufacturer, distributor, or entity.

"(3) USE OF FUNDS.—Funds collected by the Secretary as a result of the imposition of a civil money penalty under this subsection shall be used to carry out this section.

"(4) ENFORCEMENT THROUGH STATE ATTORNEYS GENERAL.—The attorney general of a State, after providing notice to the Secretary of an intent to proceed under this paragraph in a specific case and providing the Secretary with an opportunity to bring an action under this subsection and the Secretary declining such opportunity, may proceed under this subsection against a manufacturer or distributor in the State.

"(e) ANNUAL REPORT TO CONGRESS.—Not later than April 1 of each year beginning with 2011, the Secretary shall submit to Congress a report that includes the following:

"(1) The information submitted under this section during the preceding year, aggregated for each applicable manufacturer or distributor of a covered drug, device, biological, or medical supply that submitted such information during such year.

"(2) A description of any enforcement actions taken to carry out this section, including any penalties imposed under subsection (d), during the preceding year.

"(f) DEFINITIONS.—In this section:

"(1) APPLICABLE MANUFACTURER; APPLICABLE DISTRIBUTOR.—The term 'applicable manufacturer' means a manufacturer of a covered drug, device, biological, or medical supply, and the term 'applicable distributor' means a distributor of a covered drug, device, or medical supply.

"(2) CLINICAL INVESTIGATION.—The term 'clinical investigation' means any experiment involving one or more human subjects, or materials derived from human subjects, in which a drug or device is administered, dispensed, or used.

"(3) COVERED DRUG, DEVICE, BIOLOGICAL, OR MEDICAL SUPPLY.—The term 'covered' means, with respect to a drug, device, biological, or medical supply, such a drug, device, biological, or medical supply for which payment is available under title XVIII or a State plan under title XIX or XXI (or a waiver of such a plan).

"(4) COVERED RECIPIENT.—The term 'covered recipient' means the following:

"(A) A physician.

"(B) A physician group practice.

"(C) Any other prescriber of a covered drug, device, biological, or medical supply.

"(D) A pharmacy or pharmacist.

"(E) A health insurance issuer, group health plan, or other entity offering a health benefits plan, including any employee of such an issuer, plan, or entity.

"(F) A pharmacy benefit manager, including any employee of such a manager.

"(G) A hospital.

"(H) A medical school.

"(I) A sponsor of a continuing medical education program.

"(J) A patient advocacy or disease specific group.

"(K) A organization of health care professionals.

"(L) A biomedical researcher.

"(M) A group purchasing organization.

"(5) DISTRIBUTOR OF A COVERED DRUG, DEVICE, OR MEDICAL SUPPLY.—The term 'distributor of a covered drug, device, or medical supply' means any entity which is engaged in the marketing or distribution of a covered drug, device, or medical supply (or any subsidiary of or entity affiliated with such entity), but does not include a wholesale pharmaceutical distributor.

"(6) EMPLOYEE.—The term 'employee' has the meaning given such term in section 1877(h)(2).

"(7) KNOWINGLY.—The term 'knowingly' has the meaning given such term in section 3729(b) of title 31, United States Code.

"(8) MANUFACTURER OF A COVERED DRUG, DEVICE, BIOLOGICAL, OR MEDICAL SUPPLY.—The term 'manufacturer of a covered drug, device, biological, or medical supply' means any entity which is engaged in the production, preparation, propagation, compounding, conversion, processing, marketing, or distribution of a covered drug, device, biological, or medical supply (or any subsidiary of or entity affiliated with such entity).

"(9) PAYMENT OR OTHER TRANSFER OF VALUE.—

"(A) IN GENERAL.—The term 'payment or other transfer of value' means a transfer of anything of value for or of any of the following:

"(i) Gift, food, or entertainment.

"(ii) Travel or trip.
"(iii) Honoraria.
"(iv) Research funding or grant.
"(v) Education or conference funding.
"(vi) Consulting fees.
"(vii) Ownership or investment interest and royalties or license fee.

"(B) INCLUSIONS.—Subject to subparagraph (C), the term 'payment or other transfer of value' includes any compensation, gift, honorarium, speaking fee, consulting fee, travel, services, dividend, profit distribution, stock or stock option grant, or any ownership or investment interest held by a physician in a manufacturer (excluding a dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund (as described in section 1877(c))).

"(C) EXCLUSIONS.—The term 'payment or other transfer of value' does not include the following:

"(i) Any payment or other transfer of value provided by an applicable manufacturer or distributor to a covered recipient where the amount transferred to, requested by, or designated on behalf of the covered recipient does not exceed $5.

"(ii) The loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient.

"(iii) Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.

"(iv) A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient.

"(v) In-kind items used for the provision of charity care.

"(vi) A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund (as described in section 1877(c)).

"(vii) Compensation paid by a manufacturer or distributor of a covered drug, device, biological, or medical supply to a covered recipient who is directly employed by and works solely for such manufacturer or distributor.

"(viii) Any discount or cash rebate.

"(10) PHYSICIAN.—The term 'physician' has the meaning given that term in section 1861(r). For purposes of this section, such term does not include a physician who is an employee of the applicable manufacturer that is required to submit information under subsection (a).

"(g) ANNUAL REPORTS TO STATES.—Not later than April 1 of each year beginning with 2011, the Secretary shall submit to States a report that includes a summary of the information submitted under subsections (a) and (d) during the preceding year with respect to covered recipients or other hospitals and entities in the State.

"(h) RELATION TO STATE LAWS.—

"(1) IN GENERAL.—Effective on January 1, 2011, subject to paragraph (2), the provisions of this section shall preempt any law or regulation of a State or of a political subdivision of a State that requires an applicable manufacturer and applicable distributor (as such terms are defined in subsection (f)) to disclose or report, in any format, the type of information (described in subsection (a)) regarding a payment or other transfer of value provided by the manufacturer to a covered recipient (as so defined).

"(2) NO PREEMPTION OF ADDITIONAL REQUIREMENTS.—Paragraph (1) shall not preempt any law or regulation of a State or of a political subdivision of a State that requires any of the following:

"(A) The disclosure or reporting of information not of the type required to be disclosed or reported under this section.

"(B) The disclosure or reporting, in any format, of the type of information required to be disclosed or reported under this section to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes.

"(C) The discovery or admissibility of information described in this section in a criminal, civil, or administrative proceeding.".

(b) AVAILABILITY OF INFORMATION FROM THE DISCLOSURE OF FINANCIAL RELATIONSHIP REPORT (DFRR).—The Secretary of Health and Human Services shall submit to Congress a report on the full results of the Disclosure of Physician Financial Relationships surveys required pursuant to section 5006 of the Deficit Reduction Act

of 2005. Such report shall be submitted to Congress not later than the date that is 6 months after the date such surveys are collected and shall be made publicly available on an Internet website of the Department of Health and Human Services.

Subtitle E—Public Reporting on Health Care-Associated Infections

SEC. 1461. REQUIREMENT FOR PUBLIC REPORTING BY HOSPITALS AND AMBULATORY SURGICAL CENTERS ON HEALTH CARE-ASSOCIATED INFECTIONS.

(a) IN GENERAL.—Title XI of the Social Security Act is amended by inserting after section 1138 the following section:

"SEC. 1138A. REQUIREMENT FOR PUBLIC REPORTING BY HOSPITALS AND AMBULATORY SURGICAL CENTERS ON HEALTH CARE-ASSOCIATED INFECTIONS.

"(a) REPORTING REQUIREMENT.—

"(1) IN GENERAL.—The Secretary shall provide that a hospital (as defined in subsection (g)) or ambulatory surgical center meeting the requirements of titles XVIII or XIX may participate in the programs established under such titles (pursuant to the applicable provisions of law, including sections 1866(a)(1) and 1832(a)(1)(F)(i)) only if, in accordance with this section, the hospital or center reports such information on health care-associated infections that develop in the hospital or center (and such demographic information associated with such infections) as the Secretary specifies.

"(2) REPORTING PROTOCOLS.— Such information shall be reported in accordance with reporting protocols established by the Secretary through the Director of the Centers for Disease Control and Prevention (in this section referred to as the 'CDC') and to the National Healthcare Safety Network of the CDC or under such another reporting system of such Centers as determined appropriate by the Secretary in consultation with such Director.

"(3) COORDINATION WITH HIT.—The Secretary, through the Director of the CDC and the Office of the National Coordinator for Health Information Technology, shall ensure that the transmission of information under this subsection is coordinated with systems established under the HITECH Act, where appropriate.

"(4) PROCEDURES TO ENSURE THE VALIDITY OF INFORMATION.—The Secretary shall establish procedures regarding the validity of the information submitted under this subsection in order to ensure that such information is appropriately compared across hospitals and centers. Such procedures shall address failures to report as well as errors in reporting.

"(5) IMPLEMENTATION.—Not later than 1 year after the date of enactment of this section, the Secretary, through the Director of CDC, shall promulgate regulations to carry out this section.

"(b) PUBLIC POSTING OF INFORMATION.—The Secretary shall promptly post, on the official public Internet site of the Department of Health and Human Services, the information reported under subsection (a). Such information shall be set forth in a manner that allows for the comparison of information on health care-associated infections—

"(1) among hospitals and ambulatory surgical centers; and

"(2) by demographic information.

"(c) ANNUAL REPORT TO CONGRESS.—On an annual basis the Secretary shall submit to the Congress a report that summarizes each of the following:

"(1) The number and types of health care-associated infections reported under subsection (a) in hospitals and ambulatory surgical centers during such year.

"(2) Factors that contribute to the occurrence of such infections, including health care worker immunization rates.

"(3) Based on the most recent information available to the Secretary on the composition of the professional staff of hospitals and ambulatory surgical centers, the number of certified infection control professionals on the staff of hospitals and ambulatory surgical centers.

"(4) The total increases or decreases in health care costs that resulted from increases or decreases in the rates of occurrence of each such type of infection during such year.

"(5) Recommendations, in coordination with the Center for Quality Improvement established under section 931 of the Public Health Service Act, for best practices to eliminate the rates of occurrence of each such type of infection in hospitals and ambulatory surgical centers.

"(d) NON-PREEMPTION OF STATE LAWS.—Nothing in this section shall be construed as preempting or otherwise affecting any provision of State law relating to the dis-

closure of information on health care-associated infections or patient safety procedures for a hospital or ambulatory surgical center.

"(e) HEALTH CARE-ASSOCIATED INFECTION.—For purposes of this section:

"(1) IN GENERAL.—The term 'health care-associated infection' means an infection that develops in a patient who has received care in any institutional setting where health care is delivered and is related to receiving health care.

"(2) RELATED TO RECEIVING HEALTH CARE.—The term 'related to receiving health care', with respect to an infection, means that the infection was not incubating or present at the time health care was provided.

"(f) APPLICATION TO CRITICAL ACCESS HOSPITALS.—For purposes of this section, the term 'hospital' includes a critical access hospital, as defined in section 1861(mm)(1).".

(b) EFFECTIVE DATE.—With respect to section 1138A of the Social Security Act (as inserted by subsection (a) of this section), the requirement under such section that hospitals and ambulatory surgical centers submit reports takes effect on such date (not later than 2 years after the date of the enactment of this Act) as the Secretary of Health and Human Services shall specify. In order to meet such deadline, the Secretary may implement such section through guidance or other instructions.

(c) GAO REPORT.—Not later than 18 months after the date of the enactment of this Act, the Comptroller General of the United States shall submit to Congress a report on the program established under section 1138A of the Social Security Act, as inserted by subsection (a). Such report shall include an analysis of the appropriateness of the types of information required for submission, compliance with reporting requirements, the success of the validity procedures established, and any conflict or overlap between the reporting required under such section and any other reporting systems mandated by either the States or the Federal Government.

(d) REPORT ON ADDITIONAL DATA.—Not later than 18 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to the Congress a report on the appropriateness of expanding the requirements under such section to include additional information (such as health care worker immunization rates), in order to improve health care quality and patient safety.

TITLE V—MEDICARE GRADUATE MEDICAL EDUCATION

SEC. 1501. DISTRIBUTION OF UNUSED RESIDENCY POSITIONS.

(a) IN GENERAL.—Section 1886(h) of the Social Security Act (42 U.S.C. 1395ww(h)) is amended—

(1) in paragraph (4)(F)(i), by striking "paragraph (7)" and inserting "paragraphs (7) and (8)";

(2) in paragraph (4)(H)(i), by striking "paragraph (7)" and inserting "paragraphs (7) and (8)";

(3) in paragraph (7)(E), by inserting "and paragraph (8)" after "this paragraph"; and

(4) by adding at the end the following new paragraph:

"(8) ADDITIONAL REDISTRIBUTION OF UNUSED RESIDENCY POSITIONS.—

"(A) REDUCTIONS IN LIMIT BASED ON UNUSED POSITIONS.—

"(i) PROGRAMS SUBJECT TO REDUCTION.—If a hospital's reference resident level (specified in clause (ii)) is less than the otherwise applicable resident limit (as defined in subparagraph (C)(ii)), effective for portions of cost reporting periods occurring on or after July 1, 2011, the otherwise applicable resident limit shall be reduced by 90 percent of the difference between such otherwise applicable resident limit and such reference resident level.

"(ii) REFERENCE RESIDENT LEVEL.—

"(I) IN GENERAL.—Except as otherwise provided in a subsequent subclause, the reference resident level specified in this clause for a hospital is the highest resident level for any of the 3 most recent cost reporting periods (ending before the date of the enactment of this paragraph) of the hospital for which a cost report has been settled (or, if not, submitted (subject to audit)), as determined by the Secretary.

"(II) USE OF MOST RECENT ACCOUNTING PERIOD TO RECOGNIZE EXPANSION OF EXISTING PROGRAMS.—If a hospital submits a timely request to increase its resident level due to an expansion, or planned expansion, of an existing residency training program that is not reflected on the most recent settled or submitted cost report, after

audit and subject to the discretion of the Secretary, subject to subclause (IV), the reference resident level for such hospital is the resident level that includes the additional residents attributable to such expansion or establishment, as determined by the Secretary. The Secretary is authorized to determine an alternative reference resident level for a hospital that submitted to the Secretary a timely request, before the start of the 2009–2010 academic year, for an increase in its reference resident level due to a planned expansion.

"(III) SPECIAL PROVIDER AGREEMENT.—In the case of a hospital described in paragraph (4)(H)(v), the reference resident level specified in this clause is the limitation applicable under subclause (I) of such paragraph.

"(IV) PREVIOUS REDISTRIBUTION.—The reference resident level specified in this clause for a hospital shall be increased to the extent required to take into account an increase in resident positions made available to the hospital under paragraph (7)(B) that are not otherwise taken into account under a previous subclause.

"(iii) AFFILIATION.—The provisions of clause (i) shall be applied to hospitals which are members of the same affiliated group (as defined by the Secretary under paragraph (4)(H)(ii)) and to the extent the hospitals can demonstrate that they are filling any additional resident slots allocated to other hospitals through an affiliation agreement, the Secretary shall adjust the determination of available slots accordingly, or which the Secretary otherwise has permitted the resident positions (under section 402 of the Social Security Amendments of 1967) to be aggregated for purposes of applying the resident position limitations under this subsection.

"(B) REDISTRIBUTION.—

"(i) IN GENERAL.—The Secretary shall increase the otherwise applicable resident limit for each qualifying hospital that submits an application under this subparagraph by such number as the Secretary may approve for portions of cost reporting periods occurring on or after July 1, 2011. The estimated aggregate number of increases in the otherwise applicable resident limit under this subparagraph may not exceed the Secretary's estimate of the aggregate reduction in such limits attributable to subparagraph (A).

"(ii) REQUIREMENTS FOR QUALIFYING HOSPITALS.—A hospital is not a qualifying hospital for purposes of this paragraph unless the following requirements are met:

"(I) MAINTENANCE OF PRIMARY CARE RESIDENT LEVEL.—The hospital maintains the number of primary care residents at a level that is not less than the base level of primary care residents increased by the number of additional primary care resident positions provided to the hospital under this subparagraph. For purposes of this subparagraph, the 'base level of primary care residents' for a hospital is the level of such residents as of a base period (specified by the Secretary), determined without regard to whether such positions were in excess of the otherwise applicable resident limit for such period but taking into account the application of subclauses (II) and (III) of subparagraph (A)(ii).

"(II) DEDICATED ASSIGNMENT OF ADDITIONAL RESIDENT POSITIONS TO PRIMARY CARE.—The hospital assigns all such additional resident positions for primary care residents.

"(III) ACCREDITATION.—The hospital's residency programs in primary care are fully accredited or, in the case of a residency training program not in operation as of the base year, the hospital is actively applying for such accreditation for the program for such additional resident positions (as determined by the Secretary).

"(iii) CONSIDERATIONS IN REDISTRIBUTION.—In determining for which qualifying hospitals the increase in the otherwise applicable resident limit is provided under this subparagraph, the Secretary shall take into account the demonstrated likelihood of the hospital filling the positions within the first 3 cost reporting periods beginning on or after July 1, 2011, made available under this subparagraph, as determined by the Secretary.

"(iv) PRIORITY FOR CERTAIN HOSPITALS.—In determining for which qualifying hospitals the increase in the otherwise applicable resident limit is provided under this subparagraph, the Secretary shall dis-

tribute the increase to qualifying hospitals based on the following criteria:

"(I) The Secretary shall give preference to hospitals that had a reduction in resident training positions under subparagraph (A).

"(II) The Secretary shall give preference to hospitals with 3-year primary care residency training programs, such as family practice and general internal medicine.

"(III) The Secretary shall give preference to hospitals insofar as they have in effect formal arrangements (as determined by the Secretary) that place greater emphasis upon training in Federally qualified health centers, rural health clinics, and other nonprovider settings, and to hospitals that receive additional payments under subsection (d)(5)(F) and emphasize training in an outpatient department.

"(IV) The Secretary shall give preference to hospitals with a number of positions (as of July 1, 2009) in excess of the otherwise applicable resident limit for such period.

"(V) The Secretary shall give preference to hospitals that place greater emphasis upon training in a health professional shortage area (designated under section 332 of the Public Health Service Act) or a health professional needs area (designated under section 2211 of such Act).

"(VI) The Secretary shall give preference to hospitals in States that have low resident-to-population ratios (including a greater preference for those States with lower resident-to-population ratios).

"(v) LIMITATION.—In no case shall more than 20 full-time equivalent additional residency positions be made available under this subparagraph with respect to any hospital.

"(vi) APPLICATION OF PER RESIDENT AMOUNTS FOR PRIMARY CARE.—With respect to additional residency positions in a hospital attributable to the increase provided under this subparagraph, the approved FTE resident amounts are deemed to be equal to the hospital per resident amounts for primary care and nonprimary care computed under paragraph (2)(D) for that hospital.

"(vi) DISTRIBUTION.—The Secretary shall distribute the increase in resident training positions to qualifying hospitals under this subparagraph not later than July 1, 2011.

"(C) RESIDENT LEVEL AND LIMIT DEFINED.—In this paragraph:

"(i) The term 'resident level' has the meaning given such term in paragraph (7)(C)(i).

"(ii) The term 'otherwise applicable resident limit' means, with respect to a hospital, the limit otherwise applicable under subparagraphs (F)(i) and (H) of paragraph (4) on the resident level for the hospital determined without regard to this paragraph but taking into account paragraph (7)(A).

"(D) MAINTENANCE OF PRIMARY CARE RESIDENT LEVEL.—In carrying out this paragraph, the Secretary shall require hospitals that receive additional resident positions under subparagraph (B)—

"(i) to maintain records, and periodically report to the Secretary, on the number of primary care residents in its residency training programs; and

"(ii) as a condition of payment for a cost reporting period under this subsection for such positions, to maintain the level of such positions at not less than the sum of—

"(I) the base level of primary care resident positions (as determined under subparagraph (B)(ii)(I)) before receiving such additional positions; and

"(II) the number of such additional positions.".

(b) IME.—

(1) IN GENERAL.—Section 1886(d)(5)(B)(v) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(B)(v)), in the third sentence, is amended—

(A) by striking "subsection (h)(7)" and inserting "subsections (h)(7) and (h)(8)"; and

(B) by striking "it applies" and inserting "they apply".

(2) CONFORMING PROVISION.—Section 1886(d)(5)(B) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(B)) is amended by adding at the end the following clause:

"(x) For discharges occurring on or after July 1, 2011, insofar as an additional payment amount under this subparagraph is attributable to resident positions distributed to a hospital under subsection (h)(8)(B), the indirect teaching adjustment factor shall be computed in the same manner as provided under clause (ii) with respect to such resident positions.".

(c) CONFORMING AMENDMENT.—Section 422(b)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173) is amended by striking "section 1886(h)(7)" and all that follows and inserting "paragraphs (7) and (8) of subsection (h) of section 1886 of the Social Security Act.".

SEC. 1502. INCREASING TRAINING IN NONPROVIDER SETTINGS.

(a) DIRECT GME.—Section 1886(h)(4)(E) of the Social Security Act (42 U.S.C. 1395ww(h)) is amended—

(1) by designating the first sentence as a clause (i) with the heading "IN GENERAL.—" and appropriate indentation;

(2) by striking "shall be counted and that all the time" and inserting "shall be counted and that—

"(I) effective for cost reporting periods beginning before July 1, 2009, all the time";

(3) in subclause (I), as inserted by paragraph (1), by striking the period at the end and inserting "; and"; and

(A) by inserting after subclause (I), as so inserted, the following:

"(II) effective for cost reporting periods beginning on or after July 1, 2009, all the time so spent by a resident shall be counted towards the determination of full-time equivalency, without regard to the setting in which the activities are performed, if the hospital incurs the costs of the stipends and fringe benefits of the resident during the time the resident spends in that setting.

Any hospital claiming under this subparagraph for time spent in a nonprovider setting shall maintain and make available to the Secretary records regarding the amount of such time and such amount in comparison with amounts of such time in such base year as the Secretary shall specify.".

(b) IME.—Section 1886(d)(5)(B)(iv) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(B)(iv)) is amended—

(1) by striking "(iv) Effective for discharges occurring on or after October 1, 1997" and inserting "(iv)(I) Effective for discharges occurring on or after October 1, 1997, and before July 1, 2009"; and

(2) by inserting after subclause (I), as inserted by paragraph (1), the following new subclause:

"(II) Effective for discharges occurring on or after July 1, 2009, all the time spent by an intern or resident in patient care activities at an entity in a nonprovider setting shall be counted towards the determination of full-time equivalency if the hospital incurs the costs of the stipends and fringe benefits of the intern or resident during the time the intern or resident spends in that setting.".

(c) OIG STUDY ON IMPACT ON TRAINING.—The Inspector General of the Department of Health and Human Services shall analyze the data collected by the Secretary of Health and Human Services from the records made available to the Secretary under section 1886(h)(4)(E) of the Social Security Act, as amended by subsection (a), in order to assess the extent to which there is an increase in time spent by medical residents in training in nonprovider settings as a result of the amendments made by this section. Not later than 4 years after the date of the enactment of this Act, the Inspector General shall submit a report to Congress on such analysis and assessment.

(d) DEMONSTRATION PROJECT FOR APPROVED TEACHING HEALTH CENTERS.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall conduct a demonstration project under which an approved teaching health center (as defined in paragraph (3)) would be eligible for payment under subsections (h) and (k) of section 1886 of the Social Security Act (42 U.S.C. 1395ww) of amounts for its own direct costs of graduate medical education activities for primary care residents, as well as for the direct costs of graduate medical education activities of its contracting hospital for such residents, in a manner similar to the manner in which such payments would be made to a hospital if the hospital were to operate such a program.

(2) CONDITIONS.—Under the demonstration project—

(A) an approved teaching health center shall contract with an accredited teaching hospital to carry out the inpatient responsibilities of the primary care residency program of the hospital involved and is responsible for pay-

ment to the hospital for the hospital's costs of the salary and fringe benefits for residents in the program;

(B) the number of primary care residents of the center shall not count against the contracting hospital's resident limit; and

(C) the contracting hospital shall agree not to diminish the number of residents in its primary care residency training program.

(3) APPROVED TEACHING HEALTH CENTER DEFINED.—In this subsection, the term "approved teaching health center" means a nonprovider setting, such as a Federally qualified health center or rural health clinic (as defined in section 1861(aa) of the Social Security Act), that develops and operates an accredited primary care residency program for which funding would be available if it were operated by a hospital.

SEC. 1503. RULES FOR COUNTING RESIDENT TIME FOR DIDACTIC AND SCHOLARLY ACTIVITIES AND OTHER ACTIVITIES.

(a) DIRECT GME.—Section 1886(h) of the Social Security Act (42 U.S.C. 1395ww(h)) is amended—

(1) in paragraph (4)(E), as amended by section 1502(a)—

(A) in clause (i), by striking "Such rules" and inserting "Subject to clause (ii), such rules"; and

(B) by adding at the end the following new clause:

"(ii) TREATMENT OF CERTAIN NONPROVIDER AND DIDACTIC ACTIVITIES.—Such rules shall provide that all time spent by an intern or resident in an approved medical residency training program in a nonprovider setting that is primarily engaged in furnishing patient care (as defined in paragraph (5)(K)) in nonpatient care activities, such as didactic conferences and seminars, but not including research not associated with the treatment or diagnosis of a particular patient, as such time and activities are defined by the Secretary, shall be counted toward the determination of full-time equivalency.";

(2) in paragraph (4), by adding at the end the following new subparagraph:

"(I) TREATMENT OF CERTAIN TIME IN APROVED MEDICAL RESIDENCY TRAINING PROGRAM.—In determining the hospital's number of full-time equivalent residents for purposes of this subsection, all the time that is spent by an intern or resident in an approved medical residency training program on vacation, sick leave, or other approved leave, as such time is defined by the Secretary, and that does not prolong the total time the resident is participating in the approved program beyond the normal duration of the program shall be counted toward the determination of full-time equivalency."; and

(3) in paragraph (5), by adding at the end the following new subparagraph:

"(K) NONPROVIDER SETTING THAT IS PRIMARILY ENGAGED IN FURNISHING PATIENT CARE.—The term 'nonprovider setting that is primarily engaged in furnishing patient care' means a nonprovider setting in which the primary activity is the care and treatment of patients, as defined by the Secretary.".

(b) IME DETERMINATIONS.—Section 1886(d)(5)(B) of such Act (42 U.S.C. 1395ww(d)(5)(B)), as amended by section 1501(b), is amended by adding at the end the following new clause:

"(xi)(I) The provisions of subparagraph (I) of subsection (h)(4) shall apply under this subparagraph in the same manner as they apply under such subsection.

"(II) In determining the hospital's number of full-time equivalent residents for purposes of this subparagraph, all the time spent by an intern or resident in an approved medical residency training program in nonpatient care activities, such as didactic conferences and seminars, as such time and activities are defined by the Secretary, that occurs in the hospital shall be counted toward the determination of full-time equivalency if the hospital—

"(aa) is recognized as a subsection (d) hospital;

"(bb) is recognized as a subsection (d) Puerto Rico hospital;

"(cc) is reimbursed under a reimbursement system authorized under section 1814(b)(3); or

"(dd) is a provider-based hospital outpatient department.

"(III) In determining the hospital's number of full-time equivalent residents for purposes of this subparagraph, all the time spent by an intern or resident in an approved medical residency training program in research activities that are not associated with the treatment or diagnosis of a particular patient, as such time and activities are defined by the Secretary, shall not be counted toward the determination of full-time equivalency.".

(c) EFFECTIVE DATES; APPLICATION.—

(1) IN GENERAL.—Except as otherwise provided, the Secretary of Health and Human Services shall implement the amendments made by this section in a

manner so as to apply to cost reporting periods beginning on or after January 1, 1983.

(2) DIRECT GME.—Section 1886(h)(4)(E)(ii) of the Social Security Act, as added by subsection (a)(1)(B), shall apply to cost reporting periods beginning on or after July 1, 2008.

(3) IME.—Section 1886(d)(5)(B)(x)(III) of the Social Security Act, as added by subsection (b), shall apply to cost reporting periods beginning on or after October 1, 2001. Such section, as so added, shall not give rise to any inference on how the law in effect prior to such date should be interpreted.

(4) APPLICATION.—The amendments made by this section shall not be applied in a manner that requires reopening of any settled hospital cost reports as to which there is not a jurisdictionally proper appeal pending as of the date of the enactment of this Act on the issue of payment for indirect costs of medical education under section 1886(d)(5)(B) of the Social Security Act or for direct graduate medical education costs under section 1886(h) of such Act.

SEC. 1504. PRESERVATION OF RESIDENT CAP POSITIONS FROM CLOSED HOSPITALS.

(a) DIRECT GME.—Section 1886(h)(4)(H) of the Social Security Act (42 U.S.C. Section 1395ww(h)(4)(H)) is amended by adding at the end the following new clause:

"(vi) REDISTRIBUTION OF RESIDENCY SLOTS AFTER A HOSPITAL CLOSES.—

"(I) IN GENERAL.—The Secretary shall, by regulation, establish a process consistent with subclauses (II) and (III) under which, in the case where a hospital (other than a hospital described in clause (v)) with an approved medical residency program in a State closes on or after the date that is 2 years before the date of the enactment of this clause, the Secretary shall increase the otherwise applicable resident limit under this paragraph for other hospitals in the State in accordance with this clause.

"(II) PROCESS FOR HOSPITALS IN CERTAIN AREAS.—In determining for which hospitals the increase in the otherwise applicable resident limit described in subclause (I) is provided, the Secretary shall establish a process to provide for such increase to one or more hospitals located in the State. Such process shall take into consideration the recommendations submitted to the Secretary by the senior health official (as designated by the chief executive officer of such State) if such recommendations are submitted not later than 180 days after the date of the hospital closure involved (or, in the case of a hospital that closed after the date that is 2 years before the date of the enactment of this clause, 180 days after such date of enactment).

"(III) LIMITATION.—The estimated aggregate number of increases in the otherwise applicable resident limits for hospitals under this clause shall be equal to the estimated number of resident positions in the approved medical residency programs that closed on or after the date described in subclause (I).".

(b) NO EFFECT ON TEMPORARY FTE CAP ADJUSTMENTS.—The amendments made by this section shall not effect any temporary adjustment to a hospital's FTE cap under section 413.79(h) of title 42, Code of Federal Regulations (as in effect on the date of enactment of this Act) and shall not affect the application of section 1886(h)(4)(H)(v) of the Social Security Act.

(c) CONFORMING AMENDMENTS.—

(1) Section 422(b)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173), as amended by section 1501(c), is amended by striking "(7) and" and inserting "(4)(H)(vi), (7), and".

(2) Section 1886(h)(7)(E) of the Social Security Act (42 U.S.C. 1395ww(h)(7)(E)) is amended by inserting "or under paragraph (4)(H)(vi)" after "under this paragraph".

SEC. 1505. IMPROVING ACCOUNTABILITY FOR APPROVED MEDICAL RESIDENCY TRAINING.

(a) SPECIFICATION OF GOALS FOR APPROVED MEDICAL RESIDENCY TRAINING PROGRAMS.—Section 1886(h)(1) of the Social Security Act (42 U.S.C. 1395ww(h)(1)) is amended—

(1) by designating the matter beginning with "Notwithstanding" as a subparagraph (A) with the heading "IN GENERAL.—" and with appropriate indentation; and

(2) by adding at the end the following new subparagraph:

"(B) GOALS AND ACCOUNTABILITY FOR APPROVED MEDICAL RESIDENCY TRAINING PROGRAMS.—The goals of medical residency training programs are

to foster a physician workforce so that physicians are trained to be able to do the following:

"(i) Work effectively in various health care delivery settings, such as nonprovider settings.

"(ii) Coordinate patient care within and across settings relevant to their specialties.

"(iii) Understand the relevant cost and value of various diagnostic and treatment options.

"(iv) Work in inter-professional teams and multi-disciplinary team-based models in provider and nonprovider settings to enhance safety and improve quality of patient care.

"(v) Be knowledgeable in methods of identifying systematic errors in health care delivery and in implementing systematic solutions in case of such errors, including experience and participation in continuous quality improvement projects to improve health outcomes of the population the physicians serve.

"(vi) Be meaningful EHR users (as determined under section 1848(o)(2)) in the delivery of care and in improving the quality of the health of the community and the individuals that the hospital serves."

(b) GAO STUDY ON EVALUATION OF TRAINING PROGRAMS.—

(1) IN GENERAL.—The Comptroller General of the United States shall conduct a study to evaluate the extent to which medical residency training programs—

(A) are meeting the goals described in section 1886(h)(1)(B) of the Social Security Act, as added by subsection (a), in a range of residency programs, including primary care and other specialties; and

(B) have the appropriate faculty expertise to teach the topics required to achieve such goals.

(2) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on such study and shall include in such report recommendations as to how medical residency training programs could be further encouraged to meet such goals through means such as—

(A) development of curriculum requirements; and

(B) assessment of the accreditation processes of the Accreditation Council for Graduate Medical Education and the American Osteopathic Association and effectiveness of those processes in accrediting medical residency programs that meet the goals referred to in paragraph (1)(A).

TITLE VI—PROGRAM INTEGRITY

Subtitle A—Increased Funding To Fight Waste, Fraud, and Abuse

SEC. 1601. INCREASED FUNDING AND FLEXIBILITY TO FIGHT FRAUD AND ABUSE.

(a) IN GENERAL.—Section 1817(k) of the Social Security Act (42 U.S.C. 1395i(k)) is amended—

(1) by adding at the end the following new paragraph:

"(7) ADDITIONAL FUNDING.—In addition to the funds otherwise appropriated to the Account from the Trust Fund under paragraphs (3) and (4) and for purposes described in paragraphs (3)(C) and (4)(A), there are hereby appropriated an additional $100,000,000 to such Account from such Trust Fund for each fiscal year beginning with 2011. The funds appropriated under this paragraph shall be allocated in the same proportion as the total funding appropriated with respect to paragraphs (3)(A) and (4)(A) was allocated with respect to fiscal year 2010, and shall be available without further appropriation until expended.".

(2) in paragraph (4)(A)—

(A) by inserting "for activities described in paragraph (3)(C) and" after "necessary"; and

(B) by inserting "until expended" after "appropriation".

(b) FLEXIBILITY IN PURSUING FRAUD AND ABUSE.—Section 1893(a) of the Social Security Act (42 U.S.C. 1395ddd(a)) is amended by inserting ", or otherwise," after "entities".

Subtitle B—Enhanced Penalties for Fraud and Abuse

SEC. 1611. ENHANCED PENALTIES FOR FALSE STATEMENTS ON PROVIDER OR SUPPLIER ENROLLMENT APPLICATIONS.

(a) IN GENERAL.—Section 1128A(a) of the Social Security Act (42 U.S.C. 1320a–7a(a)) is amended—

(1) in paragraph (1)(D), by striking all that follows "in which the person was excluded" and inserting "under Federal law from the Federal health care program under which the claim was made, or";

(2) by striking "or" at the end of paragraph (6);

(3) in paragraph (7), by inserting at the end "or";

(4) by inserting after paragraph (7) the following new paragraph:

"(8) knowingly makes or causes to be made any false statement, omission, or misrepresentation of a material fact in any application, agreement, bid, or contract to participate or enroll as a provider of services or supplier under a Federal health care program, including managed care organizations under title XIX, Medicare Advantage organizations under part C of title XVIII, prescription drug plan sponsors under part D of title XVIII, and entities that apply to participate as providers of services or suppliers in such managed care organizations and such plans;";

(5) in the matter following paragraph (8), as inserted by paragraph (4), by striking "or in cases under paragraph (7), $50,000 for each such act)" and inserting "in cases under paragraph (7), $50,000 for each such act, or in cases under paragraph (8), $50,000 for each false statement, omission, or misrepresentation of a material fact)"; and

(6) in the second sentence, by striking "for a lawful purpose)" and inserting "for a lawful purpose, or in cases under paragraph (8), an assessment of not more than 3 times the amount claimed as the result of the false statement, omission, or misrepresentation of material fact claimed by a provider of services or supplier whose application to participate contained such false statement, omission, or misrepresentation)".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to acts committed on or after January 1, 2010.

SEC. 1612. ENHANCED PENALTIES FOR SUBMISSION OF FALSE STATEMENTS MATERIAL TO A FALSE CLAIM.

(a) IN GENERAL.—Section 1128A(a) of the Social Security Act (42 U.S.C. 1320a–7a(a)), as amended by section 1611, is further amended—

(1) in paragraph (7), by striking "or" at the end;

(2) in paragraph (8), by inserting "or" at the end; and

(3) by inserting after paragraph (8), the following new paragraph:

"(9) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a Federal health care program;"; and

(4) in the matter following paragraph (9), as inserted by paragraph (3)—

(A) by striking "or in cases under paragraph (8)" and inserting "in cases under paragraph (8)"; and

(B) by striking "a material fact)" and inserting "a material fact, in cases under paragraph (9), $50,000 for each false record or statement)".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to acts committed on or after January 1, 2010.

SEC. 1613. ENHANCED PENALTIES FOR DELAYING INSPECTIONS.

(a) IN GENERAL.—Section 1128A(a) of the Social Security Act (42 U.S.C. 1320a–7a(a)), as amended by sections 1611 and 1612, is further amended—

(1) in paragraph (8), by striking "or" at the end;

(2) in paragraph (9), by inserting "or" at the end;

(3) by inserting after paragraph (9) the following new paragraph:

"(10) fails to grant timely access, upon reasonable request (as defined by the Secretary in regulations), to the Inspector General of the Department of Health and Human Services, for the purpose of audits, investigations, evaluations, or other statutory functions of the Inspector General of the Department of Health and Human Services;"; and

(4) in the matter following paragraph (10), as inserted by paragraph (3), by inserting ", or in cases under paragraph (10), $15,000 for each day of the failure described in such paragraph" after "false record or statement".

(b) ENSURING TIMELY INSPECTIONS RELATING TO CONTRACTS WITH MA ORGANIZATIONS.—Section 1857(d)(2) of such Act (42 U.S.C. 1395w–27(d)(2)) is amended—

(1) in subparagraph (A), by inserting "timely" before "inspect"; and

(2) in subparagraph (B), by inserting "timely" before "audit and inspect".

(c) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to violations committed on or after January 1, 2010.

SEC. 1614. ENHANCED HOSPICE PROGRAM SAFEGUARDS.

(a) MEDICARE.—Part A of title XVIII of the Social Security Act is amended by inserting after section 1819 the following new section:

"SEC. 1819A. ASSURING QUALITY OF CARE IN HOSPICE CARE.

"(a) IN GENERAL.—If the Secretary determines on the basis of a survey or otherwise, that a hospice program that is certified for participation under this title has demonstrated a substandard quality of care and failed to meet such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are provided care and services by the agency or organization involved and determines—

"(1) that the deficiencies involved immediately jeopardize the health and safety of the individuals to whom the program furnishes items and services, the Secretary shall take immediate action to remove the jeopardy and correct the deficiencies through the remedy specified in subsection (b)(2)(A)(iii) or terminate the certification of the program, and may provide, in addition, for 1 or more of the other remedies described in subsection (b)(2)(A); or

"(2) that the deficiencies involved do not immediately jeopardize the health and safety of the individuals to whom the program furnishes items and services, the Secretary may—

"(A) impose intermediate sanctions developed pursuant to subsection (b), in lieu of terminating the certification of the program; and

"(B) if, after such a period of intermediate sanctions, the program is still not in compliance with such requirements, the Secretary shall terminate the certification of the program.

If the Secretary determines that a hospice program that is certified for participation under this title is in compliance with such requirements but, as of a previous period, was not in compliance with such requirements, the Secretary may provide for a civil money penalty under subsection (b)(2)(A)(i) for the days in which it finds that the program was not in compliance with such requirements.

"(b) INTERMEDIATE SANCTIONS.—

"(1) DEVELOPMENT AND IMPLEMENTATION.—The Secretary shall develop and implement, by not later than July 1, 2012—

"(A) a range of intermediate sanctions to apply to hospice programs under the conditions described in subsection (a), and

"(B) appropriate procedures for appealing determinations relating to the imposition of such sanctions.

"(2) SPECIFIED SANCTIONS.—

"(A) IN GENERAL.—The intermediate sanctions developed under paragraph (1) may include—

"(i) civil money penalties in an amount not to exceed $10,000 for each day of noncompliance or, in the case of a per instance penalty applied by the Secretary, not to exceed $25,000,

"(ii) denial of all or part of the payments to which a hospice program would otherwise be entitled under this title with respect to items and services furnished by a hospice program on or after the date on which the Secretary determines that intermediate sanctions should be imposed pursuant to subsection (a)(2),

"(iii) the appointment of temporary management to oversee the operation of the hospice program and to protect and assure the health and safety of the individuals under the care of the program while improvements are made,

"(iv) corrective action plans, and

"(v) in-service training for staff.

The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under clause (i) in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). The temporary management under clause (iii) shall not be terminated until the Secretary has determined that the program has the management capability to ensure continued compliance with all requirements referred to in that clause.

"(B) CLARIFICATION.—The sanctions specified in subparagraph (A) are in addition to sanctions otherwise available under State or Federal law and

shall not be construed as limiting other remedies, including any remedy available to an individual at common law.

"(C) COMMENCEMENT OF PAYMENT.—A denial of payment under subparagraph (A)(ii) shall terminate when the Secretary determines that the hospice program no longer demonstrates a substandard quality of care and meets such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are provided care and services by the agency or organization involved.

"(3) SECRETARIAL AUTHORITY.—The Secretary shall develop and implement, by not later than July 1, 2011, specific procedures with respect to the conditions under which each of the intermediate sanctions developed under paragraph (1) is to be applied, including the amount of any fines and the severity of each of these sanctions. Such procedures shall be designed so as to minimize the time between identification of deficiencies and imposition of these sanctions and shall provide for the imposition of incrementally more severe fines for repeated or uncorrected deficiencies.".

(b) APPLICATION TO MEDICAID.—Section 1905(o) of the Social Security Act (42 U.S.C. 1396d(o)) is amended by adding at the end the following new paragraph:

"(4) The provisions of section 1819A shall apply to a hospice program providing hospice care under this title in the same manner as such provisions apply to a hospice program providing hospice care under title XVIII.".

(c) APPLICATION TO CHIP.—Title XXI of the Social Security Act is amended by adding at the end the following new section:

"SEC. 2114. ASSURING QUALITY OF CARE IN HOSPICE CARE.

"The provisions of section 1819A shall apply to a hospice program providing hospice care under this title in the same manner such provisions apply to a hospice program providing hospice care under title XVIII.".

SEC. 1615. ENHANCED PENALTIES FOR INDIVIDUALS EXCLUDED FROM PROGRAM PARTICIPATION.

(a) IN GENERAL.—Section 1128A(a) of the Social Security Act (42 U.S.C. 1320a–7a(a)), as amended by the previous sections, is further amended—

(1) by striking "or" at the end of paragraph (9);

(2) by inserting "or" at the end of paragraph (10);

(3) by inserting after paragraph (10) the following new paragraph:

"(11) orders or prescribes an item or service, including without limitation home health care, diagnostic and clinical lab tests, prescription drugs, durable medical equipment, ambulance services, physical or occupational therapy, or any other item or service, during a period when the person has been excluded from participation in a Federal health care program, and the person knows or should know that a claim for such item or service will be presented to such a program;"; and

(4) in the matter following paragraph (11), as inserted by paragraph (3), by striking "or in cases under paragraph (10), $15,000 for each day of the failure described in such paragraph" and inserting "in cases under paragraph (10), $15,000 for each day of the failure described in such paragraph, or in cases under paragraph (11), $50,000 for each order or prescription for an item or service by an excluded individual".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to violations committed on or after January 1, 2010.

SEC. 1616. ENHANCED PENALTIES FOR PROVISION OF FALSE INFORMATION BY MEDICARE ADVANTAGE AND PART D PLANS.

(a) IN GENERAL.—Section 1857(g)(2)(A) of the Social Security Act (42 U.S.C. 1395w—27(g)(2)(A)) is amended by inserting "except with respect to a determination under subparagraph (E), an assessment of not more than 3 times the amount claimed by such plan or plan sponsor based upon the misrepresentation or falsified information involved," after "for each such determination,".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to violations committed on or after January 1, 2010.

SEC. 1617. ENHANCED PENALTIES FOR MEDICARE ADVANTAGE AND PART D MARKETING VIOLATIONS.

(a) IN GENERAL.—Section 1857(g)(1) of the Social Security Act (42 U.S.C. 1395w—27(g)(1)), as amended by section 1221(b), is amended—

(1) in subparagraph (G), by striking "or" at the end;

(2) by inserting after subparagraph (H) the following new subparagraphs:

"(I) except as provided under subparagraph (C) or (D) of section 1860D–1(b)(1), enrolls an individual in any plan under this part without the prior consent of the individual or the designee of the individual;

"(J) transfers an individual enrolled under this part from one plan to another without the prior consent of the individual or the designee of the individual or solely for the purpose of earning a commission;

"(K) fails to comply with marketing restrictions described in subsections (h) and (j) of section 1851 or applicable implementing regulations or guidance; or

"(L) employs or contracts with any individual or entity who engages in the conduct described in subparagraphs (A) through (K) of this paragraph;"; and

(3) by adding at the end the following new sentence: "The Secretary may provide, in addition to any other remedies authorized by law, for any of the remedies described in paragraph (2), if the Secretary determines that any employee or agent of such organization, or any provider or supplier who contracts with such organization, has engaged in any conduct described in subparagraphs (A) through (L) of this paragraph."

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to violations committed on or after January 1, 2010.

SEC. 1618. ENHANCED PENALTIES FOR OBSTRUCTION OF PROGRAM AUDITS.

(a) IN GENERAL.—Section 1128(b)(2) of the Social Security Act (42 U.S.C. 1320a–7(b)(2)) is amended—

(1) in the heading, by inserting "OR AUDIT" after "INVESTIGATION"; and

(2) by striking "investigation into" and all that follows through the period and inserting "investigation or audit related to—"

"(A) any offense described in paragraph (1) or in subsection (a); or

"(B) the use of funds received, directly or indirectly, from any Federal health care program (as defined in section 1128B(f)).".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to violations committed on or after January 1, 2010.

SEC. 1619. EXCLUSION OF CERTAIN INDIVIDUALS AND ENTITIES FROM PARTICIPATION IN MEDICARE AND STATE HEALTH CARE PROGRAMS.

(a) IN GENERAL.—Section 1128(c) of the Social Security Act, as previously amended by this division, is further amended—

(1) in the heading, by striking "AND PERIOD" and inserting "PERIOD, AND EFFECT"; and

(2) by adding at the end the following new paragraph:

"(4)(A) For purposes of this Act, subject to subparagraph (C), the effect of exclusion is that no payment may be made by any Federal health care program (as defined in section 1128B(f)) with respect to any item or service furnished—

"(i) by an excluded individual or entity; or

"(ii) at the medical direction or on the prescription of a physician or other authorized individual when the person submitting a claim for such item or service knew or had reason to know of the exclusion of such individual.

"(B) For purposes of this section and sections 1128A and 1128B, subject to subparagraph (C), an item or service has been furnished by an individual or entity if the individual or entity directly or indirectly provided, ordered, manufactured, distributed, prescribed, or otherwise supplied the item or service regardless of how the item or service was paid for by a Federal health care program or to whom such payment was made.

"(C)(i) Payment may be made under a Federal health care program for emergency items or services (not including items or services furnished in an emergency room of a hospital) furnished by an excluded individual or entity, or at the medical direction or on the prescription of an excluded physician or other authorized individual during the period of such individual's exclusion.

"(ii) In the case that an individual eligible for benefits under title XVIII or XIX submits a claim for payment for items or services furnished by an excluded individual or entity, and such individual eligible for such benefits did not know or have reason to know that such excluded individual or entity was so excluded, then, notwithstanding such exclusion, payment shall be made for such items or services. In such case the Secretary shall notify such individual eligible for such benefits of the exclusion of the individual or entity furnishing the items or services. Payment shall not be made for items or services furnished by an excluded individual or entity to an individual eligible for such benefits after a reasonable time (as determined by the Secretary in regulations) after the Secretary has notified the individual eligible for such benefits of the exclusion of the individual or entity furnishing the items or services.

"(iii) In the case that a claim for payment for items or services furnished by an excluded individual or entity is submitted by an individual or entity other than an individual eligible for benefits under title XVIII or XIX or the excluded individual

or entity, and the Secretary determines that the individual or entity that submitted the claim took reasonable steps to learn of the exclusion and reasonably relied upon inaccurate or misleading information from the relevant Federal health care program or its contractor, the Secretary may waive repayment of the amount paid in violation of the exclusion to the individual or entity that submitted the claim for the items or services furnished by the excluded individual or entity. If a Federal health care program contractor provided inaccurate or misleading information that resulted in the waiver of an overpayment under this clause, the Secretary shall take appropriate action to recover the improperly paid amount from the contractor.".

Subtitle C—Enhanced Program and Provider Protections

SEC. 1631. ENHANCED CMS PROGRAM PROTECTION AUTHORITY.

(a) IN GENERAL.—Title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by inserting after section 1128F the following new section:

"SEC. 1128G. ENHANCED PROGRAM AND PROVIDER PROTECTIONS IN THE MEDICARE, MEDICAID, AND CHIP PROGRAMS.

"(a) CERTAIN AUTHORIZED SCREENING, ENHANCED OVERSIGHT PERIODS, AND ENROLLMENT MORATORIA.—

"(1) IN GENERAL.—For periods beginning after January 1, 2011, in the case that the Secretary determines there is a significant risk of fraudulent activity (as determined by the Secretary based on relevant complaints, reports, referrals by law enforcement or other sources, data analysis, trending information, or claims submissions by providers of services and suppliers) with respect to a category of provider of services or supplier of items or services, including a category within a geographic area, under title XVIII, XIX, or XXI, the Secretary may impose any of the following requirements with respect to a provider of services or a supplier (whether such provider or supplier is initially enrolling in the program or is renewing such enrollment):

"(A) Screening under paragraph (2).

"(B) Enhanced oversight periods under paragraph (3).

"(C) Enrollment moratoria under paragraph (4).

In applying this subsection for purposes of title XIX and XXI the Secretary may require a State to carry out the provisions of this subsection as a requirement of the State plan under title XIX or the child health plan under title XXI. Actions taken and determinations made under this subsection shall not be subject to review by a judicial tribunal.

"(2) SCREENING.—For purposes of paragraph (1), the Secretary shall establish procedures under which screening is conducted with respect to providers of services and suppliers described in such paragraph. Such screening may include—

"(A) licensing board checks;

"(B) screening against the list of individuals and entities excluded from the program under title XVIII, XIX, or XXI;

"(C) the excluded provider list system;

"(D) background checks; and

"(E) unannounced pre-enrollment or other site visits.

"(3) ENHANCED OVERSIGHT PERIOD.—For purposes of paragraph (1), the Secretary shall establish procedures to provide for a period of not less than 30 days and not more than 365 days during which providers of services and suppliers described in such paragraph, as the Secretary determines appropriate, would be subject to enhanced oversight, such as required or unannounced (or required and unannounced) site visits or inspections, prepayment review, enhanced review of claims, and such other actions as specified by the Secretary, under the programs under titles XVIII, XIX, and XXI. Under such procedures, the Secretary may extend such period for more than 365 days if the Secretary determines that after the initial period such additional period of oversight is necessary.

"(4) MORATORIUM ON ENROLLMENT OF PROVIDERS AND SUPPLIERS.—For purposes of paragraph (1), the Secretary, based upon a finding of a risk of serious ongoing fraud within a program under title XVIII, XIX, or XXI, may impose a moratorium on the enrollment of providers of services and suppliers within a category of providers of services and suppliers (including a category within a specific geographic area) under such title. Such a moratorium may only be imposed if the Secretary makes a determination that the moratorium would not adversely impact access of individuals to care under such program.

"(5) CLARIFICATION.—Nothing in this subsection shall be interpreted to preclude or limit the ability of a State to engage in provider screening or enhanced provider oversight activities beyond those required by the Secretary.".

(b) CONFORMING AMENDMENTS.—

(1) MEDICAID.—Section 1902(a) of the Social Security Act (42 U.S.C. 42 U.S.C. 1396a(a)) is amended—

(A) in paragraph (23), by inserting before the semicolon at the end the following: "or by a person to whom or entity to which a moratorium under section 1128G(a)(4) is applied during the period of such moratorium";

(B) in paragraph (72); by striking at the end "and";

(C) in paragraph (73), by striking the period at the end and inserting "; and"; and

(D) by inserting after paragraph (73) the following new paragraph:

"(74) provide that the State will enforce any determination made by the Secretary under subsection (a) of section 1128G (relating to a significant risk of fraudulent activity with respect to a category of provider or supplier described in such subsection (a) through use of the appropriate procedures described in such subsection (a)), and that the State will carry out any activities as required by the Secretary for purposes of such subsection (a).".

(2) CHIP.—Section 2102 of such Act (42 U.S.C. 1397bb) is amended by adding at the end the following new subsection:

"(d) PROGRAM INTEGRITY.—A State child health plan shall include a description of the procedures to be used by the State—

"(1) to enforce any determination made by the Secretary under subsection (a) of section 1128G (relating to a significant risk of fraudulent activity with respect to a category of provider or supplier described in such subsection through use of the appropriate procedures described in such subsection); and

"(2) to carry out any activities as required by the Secretary for purposes of such subsection.".

(3) MEDICARE.—Section 1866(j) of such Act (42 U.S.C. 1395cc(j)) is amended by adding at the end the following new paragraph:

"(3) PROGRAM INTEGRITY.—The provisions of section 1128G(a) apply to enrollments and renewals of enrollments of providers of services and suppliers under this title.".

SEC. 1632. ENHANCED MEDICARE, MEDICAID, AND CHIP PROGRAM DISCLOSURE REQUIREMENTS RELATING TO PREVIOUS AFFILIATIONS.

(a) IN GENERAL.—Section 1128G of the Social Security Act, as inserted by section 1631, is amended by adding at the end the following new subsection:

"(b) ENHANCED PROGRAM DISCLOSURE REQUIREMENTS.—

"(1) DISCLOSURE.—A provider of services or supplier who submits on or after July 1, 2011, an application for enrollment and renewing enrollment in a program under title XVIII, XIX, or XXI shall disclose (in a form and manner determined by the Secretary) any current affiliation or affiliation within the previous 10-year period with a provider of services or supplier that has uncollected debt or with a person or entity that has been suspended or excluded under such program, subject to a payment suspension, or has had its billing privileges revoked.

"(2) ENHANCED SAFEGUARDS.—If the Secretary determines that such previous affiliation of such provider or supplier poses a risk of fraud, waste, or abuse, the Secretary may apply such enhanced safeguards as the Secretary determines necessary to reduce such risk associated with such provider or supplier enrolling or participating in the program under title XVIII, XIX, or XXI. Such safeguards may include enhanced oversight, such as enhanced screening of claims, required or unannounced (or required and unannounced) site visits or inspections, additional information reporting requirements, and conditioning such enrollment on the provision of a surety bond.

"(3) AUTHORITY TO DENY PARTICIPATION.—If the Secretary determines that there has been at least one such affiliation and that such affiliation or affiliations, as applicable, of such provider or supplier poses a serious risk of fraud, waste, or abuse, the Secretary may deny the application of such provider or supplier.".

(b) CONFORMING AMENDMENTS.—

(1) MEDICAID.—Paragraph (74) of section 1902(a) of such Act (42 U.S.C. 1396a(a)), as added by section 1631(b)(1), is amended—

(A) by inserting "or subsection (b) of such section (relating to disclosure requirements)" before ", and that the State"; and

(B) by inserting before the period the following: "and apply any enhanced safeguards, with respect to a provider or supplier described in such subsection (b), as the Secretary determines necessary under such subsection (b)".

(2) CHIP.—Subsection (d) of section 2102 of such Act (42 U.S.C. 1397bb), as added by section 1631(b)(2), is amended—

(A) in paragraph (1), by striking at the end "and";

(B) in paragraph (2) by striking the period at the end and inserting "; and'" and

(C) by adding at the end the following new paragraph:

"(3) to enforce any determination made by the Secretary under subsection (b) of section 1128G (relating to disclosure requirements) and to apply any enhanced safeguards, with respect to a provider or supplier described in such subsection, as the Secretary determines necessary under such subsection.".

SEC. 1633. REQUIRED INCLUSION OF PAYMENT MODIFIER FOR CERTAIN EVALUATION AND MANAGEMENT SERVICES.

Section 1848 of the Social Security Act (42 U.S.C. 1395w–4), as amended by section 4101 of the HITECH Act (Public Law 111–5), is amended by adding at the end the following new subsection:

"(p) PAYMENT MODIFIER FOR CERTAIN EVALUATION AND MANAGEMENT SERVICES.—The Secretary shall establish a payment modifier under the fee schedule under this section for evaluation and management services (as specified in section 1842(b)(16)(B)(ii)) that result in the ordering of additional services (such as lab tests), the prescription of drugs, the furnishing or ordering of durable medical equipment in order to enable better monitoring of claims for payment for such additional services under this title, or the ordering, furnishing, or prescribing of other items and services determined by the Secretary to pose a high risk of waste, fraud, and abuse. The Secretary may require providers of services or suppliers to report such modifier in claims submitted for payment.".

SEC. 1634. EVALUATIONS AND REPORTS REQUIRED UNDER MEDICARE INTEGRITY PROGRAM.

(a) IN GENERAL.—Section 1893(c) of the Social Security Act (42 U.S.C. 1395ddd(c)) is amended—

(1) in paragraph (3), by striking at the end "and";

(2) by redesignating paragraph (4) as paragraph (5); and

(3) by inserting after paragraph (3) the following new paragraph:

"(4) for the contract year beginning in 2011 and each subsequent contract year, the entity provides assurances to the satisfaction of the Secretary that the entity will conduct periodic evaluations of the effectiveness of the activities carried out by such entity under the Program and will submit to the Secretary an annual report on such activities; and".

(b) REFERENCE TO MEDICAID INTEGRITY PROGRAM.—For a similar provision with respect to the Medicaid Integrity Program, see section 1752.

SEC. 1635. REQUIRE PROVIDERS AND SUPPLIERS TO ADOPT PROGRAMS TO REDUCE WASTE, FRAUD, AND ABUSE.

(a) IN GENERAL.—Section 1874 of the Social Security Act (42 U.S.C. 42 U.S.C. 1395kk) is amended by adding at the end the following new subsection:

"(e) COMPLIANCE PROGRAMS FOR PROVIDERS OF SERVICES AND SUPPLIERS.—

"(1) IN GENERAL.—The Secretary may disenroll a provider of services or a supplier (other than a physician or a skilled nursing facility) under this title (or may impose any civil monetary penalty or other intermediate sanction under paragraph (4)) if such provider of services or supplier fails to, subject to paragraph (5), establish a compliance program that contains the core elements established under paragraph (2).

"(2) ESTABLISHMENT OF CORE ELEMENTS.—The Secretary, in consultation with the Inspector General of the Department of Health and Human Services, shall establish core elements for a compliance program under paragraph (1). Such elements may include written policies, procedures, and standards of conduct, a designated compliance officer and a compliance committee; effective training and education pertaining to fraud, waste, and abuse for the organization's employees and contractors; a confidential or anonymous mechanism, such as a hotline, to receive compliance questions and reports of fraud, waste, or abuse; disciplinary guidelines for enforcement of standards; internal monitoring and auditing procedures, including monitoring and auditing of contractors; procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives, including responses to potential offenses; and procedures to return all identified overpayments to the programs under this title, title XIX, and title XXI.

"(3) TIMELINE FOR IMPLEMENTATION.—The Secretary shall determine a timeline for the establishment of the core elements under paragraph (2) and the date on which a provider of services and suppliers (other than physicians) shall be required to have established such a program for purposes of this subsection.

"(4) CMS ENFORCEMENT AUTHORITY.—The Administrator for the Centers of Medicare & Medicaid Services shall have the authority to determine whether a provider of services or supplier described in subparagraph (3) has met the requirement of this subsection and to impose a civil monetary penalty not to exceed $50,000 for each violation. The Secretary may also impose other intermediate sanctions, including corrective action plans and additional monitoring in the case of a violation of this subsection.

"(5) PILOT PROGRAM.—The Secretary may conduct a pilot program on the application of this subsection with respect to a category of providers of services or suppliers (other than physicians) that the Secretary determines to be a category which is at high risk for waste, fraud, and abuse before implementing the requirements of this subsection to all providers of services and suppliers described in paragraph (3).".

(b) REFERENCE TO SIMILAR MEDICAID PROVISION.—For a similar provision with respect to the Medicaid program under title XIX of the Social Security Act, see section 1753.

SEC. 1636. MAXIMUM PERIOD FOR SUBMISSION OF MEDICARE CLAIMS REDUCED TO NOT MORE THAN 12 MONTHS.

(a) PURPOSE.—In general, the 36-month period currently allowed for claims filing under parts A, B, C, and, D of title XVIII of the Social Security Act presents opportunities for fraud schemes in which processing patterns of the Centers for Medicare & Medicaid Services can be observed and exploited. Narrowing the window for claims processing will not overburden providers and will reduce fraud and abuse.

(b) REDUCING MAXIMUM PERIOD FOR SUBMISSION.—

(1) PART A.—Section 1814(a) of the Social Security Act (42 U.S.C. 1395f(a)) is amended—

(A) in paragraph (1), by striking "period of 3 calendar years" and all that follows and inserting "period of 1 calendar year from which such services are furnished; and"; and

(B) by adding at the end the following new sentence: "In applying paragraph (1), the Secretary may specify exceptions to the 1 calendar year period specified in such paragraph.".

(2) PART B.—Section 1835(a) of such Act (42 U.S.C. 1395n(a)) is amended—

(A) in paragraph (1), by striking "period of 3 calendar years" and all that follows and inserting "period of 1 calendar year from which such services are furnished; and"; and

(B) by adding at the end the following new sentence: "In applying paragraph (1), the Secretary may specify exceptions to the 1 calendar year period specified in such paragraph.".

(3) PARTS C AND D.—Section 1857(d) of such Act is amended by adding at the end the following new paragraph:

"(7) PERIOD FOR SUBMISSION OF CLAIMS.—The contract shall require an MA organization or PDP sponsor to require any provider of services under contract with, in partnership with, or affiliated with such organization or sponsor to ensure that, with respect to items and services furnished by such provider to an enrollee of such organization, written request, signed by such enrollee, except in cases in which the Secretary finds it impracticable for the enrollee to do so, is filed for payment for such items and services in such form, in such manner, and by such person or persons as the Secretary may by regulation prescribe, no later than the close of the 1 calendar year period after such items and services are furnished. In applying the previous sentence, the Secretary may specify exceptions to the 1 calendar year period specified.".

(c) EFFECTIVE DATE.—The amendments made by subsection (b) shall be effective for items and services furnished on or after January 1, 2011.

SEC. 1637. PHYSICIANS WHO ORDER DURABLE MEDICAL EQUIPMENT OR HOME HEALTH SERVICES REQUIRED TO BE MEDICARE-ENROLLED PHYSICIANS OR ELIGIBLE PROFESSIONALS.

(a) DME.—Section 1834(a)(11)(B) of the Social Security Act (42 U.S.C. 1395m(a)(11)(B)) is amended by striking "physician" and inserting "physician enrolled under section 1866(j) or an eligible professional under section 1848(k)(3)(B)".

(b) HOME HEALTH SERVICES.—

(1) PART A.—Section 1814(a)(2) of such Act (42 U.S.C. 1395(a)(2)) is amended in the matter preceding subparagraph (A) by inserting "in the case of services described in subparagraph (C), a physician enrolled under section 1866(j) or an eligible professional under section 1848(k)(3)(B)," before "or, in the case of services".

(2) PART B.—Section 1835(a)(2) of such Act (42 U.S.C. 1395n(a)(2)) is amended in the matter preceding subparagraph (A) by inserting ", or in the case of serv-

ices described in subparagraph (A), a physician enrolled under section 1866(j) or an eligible professional under section 1848(k)(3)(B)," after "a physician".

(c) DISCRETION TO EXPAND APPLICATION.—The Secretary may extend the requirement applied by the amendments made by subsections (a) and (b) to durable medical equipment and home health services (relating to requiring certifications and written orders to be made by enrolled physicians and health professions) to other categories of items or services under this title, including covered part D drugs as defined in section 1860D-2(e), if the Secretary determines that such application would help to reduce the risk of waste, fraud, and abuse with respect to such other categories under title XVIII of the Social Security Act.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to written orders and certifications made on or after July 1, 2010.

SEC. 1638. REQUIREMENT FOR PHYSICIANS TO PROVIDE DOCUMENTATION ON REFERRALS TO PROGRAMS AT HIGH RISK OF WASTE AND ABUSE.

(a) PHYSICIANS AND OTHER SUPPLIERS.—Section 1842(h) of the Social Security Act is amended by adding at the end the following new paragraph

"(10) The Secretary may disenroll, for a period of not more than one year for each act, a physician or supplier under section 1866(j) if such physician or supplier fails to maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by such physician or supplier under this title, as specified by the Secretary.".

(b) PROVIDERS OF SERVICES.—Section 1866(a)(1) of such Act (42 U.S.C. 1395cc) is amended—

(1) in subparagraph (U), by striking at the end "and";

(2) in subparagraph (V), by striking the period at the end and adding ", and"; and

(3) by adding at the end the following new subparagraph:

"(W) maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by the provider under this title, as specified by the Secretary.".

(c) OIG PERMISSIVE EXCLUSION AUTHORITY.—Section 1128(b)(11) of the Social Security Act (42 U.S.C. 1320a–7(b)(11)) is amended by inserting ", ordering, referring for furnishing, or certifying the need for" after "furnishing".

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to orders, certifications, and referrals made on or after January 1, 2010.

SEC. 1639. FACE-TO-FACE ENCOUNTER WITH PATIENT REQUIRED BEFORE PHYSICIANS MAY CERTIFY ELIGIBILITY FOR HOME HEALTH SERVICES OR DURABLE MEDICAL EQUIPMENT UNDER MEDICARE.

(a) CONDITION OF PAYMENT FOR HOME HEALTH SERVICES.—

(1) PART A.—Section 1814(a)(2)(C) of such Act is amended—

(A) by striking "and such services" and inserting "such services"; and

(B) by inserting after "care of a physician" the following: ", and, in the case of a certification or recertification made by a physician after January 1, 2010, prior to making such certification the physician must document that the physician has had a face-to-face encounter (including through use of telehealth and other than with respect to encounters that are incident to services involved) with the individual during the 6-month period preceding such certification, or other reasonable timeframe as determined by the Secretary".

(2) PART B.—Section 1835(a)(2)(A) of the Social Security Act is amended—

(A) by striking "and" before "(iii)"; and

(B) by inserting after "care of a physician" the following: ", and (iv) in the case of a certification or recertification after January 1, 2010, prior to making such certification the physician must document that the physician has had a face-to-face encounter (including through use of telehealth and other than with respect to encounters that are incident to services involved) with the individual during the 6-month period preceding such certification or recertification, or other reasonable timeframe as determined by the Secretary".

(b) CONDITION OF PAYMENT FOR DURABLE MEDICAL EQUIPMENT.—Section 1834(a)(11)(B) of the Social Security Act (42 U.S.C. 1395m(a)(11)(B)) is amended by adding before the period at the end the following: "and shall require that such an order be written pursuant to the physician documenting that the physician has had a face-to-face encounter (including through use of telehealth and other than with re-

spect to encounters that are incident to services involved) with the individual involved during the 6-month period preceding such written order, or other reasonable timeframe as determined by the Secretary".

(c) APPLICATION TO OTHER AREAS UNDER MEDICARE.—The Secretary may apply the face-to-face encounter requirement described in the amendments made by subsections (a) and (b) to other items and services for which payment is provided under title XVIII of the Social Security Act based upon a finding that such an decision would reduce the risk of waste, fraud, or abuse.

(d) APPLICATION TO MEDICAID AND CHIP.—The requirements pursuant to the amendments made by subsections (a) and (b) shall apply in the case of physicians making certifications for home health services under title XIX or XXI of the Social Security Act, in the same manner and to the same extent as such requirements apply in the case of physicians making such certifications under title XVIII of such Act.

SEC. 1640. EXTENSION OF TESTIMONIAL SUBPOENA AUTHORITY TO PROGRAM EXCLUSION INVESTIGATIONS.

(a) IN GENERAL.—Section 1128(f) of the Social Security Act (42 U.S.C. 1320a-7(f)) is amended by adding at the end the following new paragraph:

"(4) The provisions of subsections (d) and (e) of section 205 shall apply with respect to this section to the same extent as they are applicable with respect to title II. The Secretary may delegate the authority granted by section 205(d) (as made applicable to this section) to the Inspector General of the Department of Health and Human Services or the Administrator of the Centers for Medicare & Medicaid Services for purposes of any investigation under this section.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to investigations beginning on or after January 1, 2010.

SEC. 1641. REQUIRED REPAYMENTS OF MEDICARE AND MEDICAID OVERPAYMENTS.

Section 1128G of the Social Security Act, as inserted by section 1631 and amended by section 1632, is further amended by adding at the end the following new subsection:

"(c) REPORTS ON AND REPAYMENT OF OVERPAYMENTS IDENTIFIED THROUGH INTERNAL AUDITS AND REVIEWS.—

"(1) REPORTING AND RETURNING OVERPAYMENTS.—If a person knows of an overpayment, the person must—

"(A) report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address, and

"(B) notify the Secretary, the State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.

"(2) TIMING.—An overpayment must be reported and returned under paragraph (1)(A) by not later than the date that is 60 days after the date the person knows of the overpayment. Any known overpayment retained later than the applicable date specified in this paragraph creates an obligation as defined in section 3729(b)(3) of title 31 of the United States Code.

"(3) CLARIFICATION.—Repayment of any overpayments (or refunding by withholding of future payments) by a provider of services or supplier does not otherwise limit the provider or supplier's potential liability for administrative obligations such as applicable interests, fines, and specialties or civil or criminal sanctions involving the same claim if it is determined later that the reason for the overpayment was related to fraud by the provider or supplier or the employees or agents of such provider or supplier.

"(4) DEFINITIONS.—In this subsection:

"(A) KNOWS.—The term 'knows' has the meaning given the terms 'knowing' and 'knowingly' in section 3729(b) of title 31 of the United States Code.

"(B) OVERPAYMENT.—The term "overpayment" means any finally determined funds that a person receives or retains under title XVIII, XIX, or XXI to which the person, after applicable reconciliation, is not entitled under such title.

"(C) PERSON.—The term 'person' means a provider of services, supplier, Medicaid managed care organization (as defined in section 1903(m)(1)(A)), Medicare Advantage organization (as defined in section 1859(a)(1)), or PDP sponsor (as defined in section 1860D–41(a)(13)), but excluding a beneficiary.".

SEC. 1642. EXPANDED APPLICATION OF HARDSHIP WAIVERS FOR OIG EXCLUSIONS TO BENEFICIARIES OF ANY FEDERAL HEALTH CARE PROGRAM.

Section 1128(c)(3)(B) of the Social Security Act (42 U.S.C. 1320a–7(c)(3)(B)) is amended by striking "individuals entitled to benefits under part A of title XVIII or enrolled under part B of such title, or both" and inserting "beneficiaries (as defined in section 1128A(i)(5)) of that program".

SEC. 1643. ACCESS TO CERTAIN INFORMATION ON RENAL DIALYSIS FACILITIES.

Section 1881(b) of the Social Security Act (42 U.S.C. 1395rr(b)) is amended by adding at the end the following new paragraph:

"(15) For purposes of evaluating or auditing payments made to renal dialysis facilities for items and services under this section under paragraph (1), each such renal dialysis facility, upon the request of the Secretary, shall provide to the Secretary access to information relating to any ownership or compensation arrangement between such facility and the medical director of such facility or between such facility and any physician.".

SEC. 1644. BILLING AGENTS, CLEARINGHOUSES, OR OTHER ALTERNATE PAYEES REQUIRED TO REGISTER UNDER MEDICARE.

(a) MEDICARE.—Section 1866(j)(1) of the Social Security Act (42 U.S.C. 1395cc(j)(1)) is amended by adding at the end the following new subparagraph:

"(D) BILLING AGENTS AND CLEARINGHOUSES REQUIRED TO BE REGISTERED UNDER MEDICARE.—Any agent, clearinghouse, or other alternate payee that submits claims on behalf of a health care provider must be registered with the Secretary in a form and manner specified by the Secretary.".

(b) MEDICAID.—For a similar provision with respect to the Medicaid program under title XIX of the Social Security Act, see section 1759.

(c) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to claims submitted on or after January 1, 2012.

SEC. 1645. CONFORMING CIVIL MONETARY PENALTIES TO FALSE CLAIMS ACT AMENDMENTS.

Section 1128A of the Social Security Act, as amended by sections 1611, 1612, 1613, and 1615, is further amended—

(1) in subsection (a)—

(A) in paragraph (1), by striking "to an officer, employee, or agent of the United States, or of any department or agency thereof, or of any State agency (as defined in subsection (i)(1))";

(B) in paragraph (4)—

(i) in the matter preceding subparagraph (A), by striking "participating in a program under title XVIII or a State health care program" and inserting "participating in a Federal health care program (as defined in section 1128B(f))"; and

(ii) in subparagraph (A), by striking "title XVIII or a State health care program" and inserting "a Federal health care program (as defined in section 1128B(f))";

(C) by striking "or" at the end of paragraph (10);

(D) by inserting after paragraph (11) the following new paragraphs:

"(12) conspires to commit a violation of this section; or

"(13) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to a Federal health care program, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to a Federal health care program;"; and

(E) in the matter following paragraph (13), as inserted by subparagraph (D),—

(i) by striking "or" before "in cases under paragraph (11)"; and

(ii) by inserting ", in cases under paragraph (12), $50,000 for any violation described in this section committed in furtherance of the conspiracy involved; or in cases under paragraph (13), $50,000 for each false record or statement, or concealment, avoidance, or decrease" after "by an excluded individual"; and

(F) in the second sentence, by striking "such false statement, omission, or misrepresentation)" and inserting "such false statement or misrepresentation, in cases under paragraph (12), an assessment of not more than 3 times the total amount that would otherwise apply for any violation described in this section committed in furtherance of the conspiracy involved, or in cases under paragraph (13), an assessment of not more than 3 times the total amount of the obligation to which the false record or statment was material or that was avoided or decreased)".

(2) in subsection (c)(1), by striking "six years" and inserting "10 years"; and

(3) in subsection (i)—

(A) by amending paragraph (2) to read as follows:

"(2) The term 'claim' means any application, request, or demand, whether under contract, or otherwise, for money or property for items and services under a Federal health care program (as defined in section 1128B(f)), whether or not the United States or a State agency has title to the money or property, that—

"(A) is presented or caused to be presented to an officer, employee, or agent of the United States, or of any department or agency thereof, or of any State agency (as defined in subsection (i)(1)); or

"(B) is made to a contractor, grantee, or other recipient if the money or property is to be spent or used on the Federal health care program's behalf or to advance a Federal health care program interest, and if the Federal health care program—

"(i) provides or has provided any portion of the money or property requested or demanded; or

"(ii) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.";

(B) by amending paragraph (3) to read as follows:

"(3) The term 'item or service' means, without limitation, any medical, social, management, administrative, or other item or service used in connection with or directly or indirectly related to a Federal health care program.";

(C) in paragraph (6)—

(i) in subparagraph (C), by striking at the end "or";

(ii) in the first subparagraph (D), by striking at the end the period and inserting "; or"; and

(iii) by redesignating the second subparagraph (D) as a subparagraph (E);

(D) by amending paragraph (7) to read as follows:

"(7) The terms 'knowing', 'knowingly', and 'should know' mean that a person, with respect to information—

"(A) has actual knowledge of the information;

"(B) acts in deliberate ignorance of the truth or falsity of the information; or

"(C) acts in reckless disregard of the truth or falsity of the information; and require no proof of specific intent to defraud."; and

(E) by adding at the end the following new paragraphs:

"(8) The term 'obligation' means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment.

"(9) The term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.".

Subtitle D—Access to Information Needed To Prevent Fraud, Waste, and Abuse

SEC. 1651. ACCESS TO INFORMATION NECESSARY TO IDENTIFY FRAUD, WASTE, AND ABUSE.

Section 1128G of the Social Security Act, as added by section 1631 and amended by sections 1632 and 1641, is further amended by adding at the end the following new subsection;

"(d) ACCESS TO INFORMATION NECESSARY TO IDENTIFY FRAUD, WASTE, AND ABUSE.—For purposes of law enforcement activity, and to the extent consistent with applicable disclosure, privacy, and security laws, including the Health Insurance Portability and Accountability Act of 1996 and the Privacy Act of 1974, and subject to any information systems security requirements enacted by law or otherwise required by the Secretary, the Attorney General shall have access, facilitation by the Inspector General of the Department of Health and Human Services, to claims and payment data relating to titles XVIII and XIX, in consultation with the Centers for Medicare & Medicaid Services or the owner of such data.".

SEC. 1652. ELIMINATION OF DUPLICATION BETWEEN THE HEALTHCARE INTEGRITY AND PROTECTION DATA BANK AND THE NATIONAL PRACTITIONER DATA BANK.

(a) IN GENERAL.—To eliminate duplication between the Healthcare Integrity and Protection Data Bank (HIPDB) established under section 1128E of the Social Security Act and the National Practitioner Data Bank (NPBD) established under the Health Care Quality Improvement Act of 1986, section 1128E of the Social Security Act (42 U.S.C. 1320a-7e) is amended—

(1) in subsection (a), by striking "Not later than" and inserting "Subject to subsection (h), not later than";

(2) in the first sentence of subsection (d)(2), by striking "(other than with respect to requests by Federal agencies)"; and

(3) by adding at the end the following new subsection:

"(h) SUNSET OF THE HEALTHCARE INTEGRITY AND PROTECTION DATA BANK; TRANSITION PROCESS.—Effective upon the enactment of this subsection, the Secretary shall implement a process to eliminate duplication between the Healthcare Integrity and Protection Data Bank (in this subsection referred to as the 'HIPDB' established pursuant to subsection (a) and the National Practitioner Data Bank (in this subsection referred to as the 'NPDB') as implemented under the Health Care Quality Improvement Act of 1986 and section 1921 of this Act, including systems testing necessary to ensure that information formerly collected in the HIPDB will be accessible through the NPDB, and other activities necessary to eliminate duplication between the two data banks. Upon the completion of such process, notwithstanding any other provision of law, the Secretary shall cease the operation of the HIPDB and shall collect information required to be reported under the preceding provisions of this section in the NPDB. Except as otherwise provided in this subsection, the provisions of subsections (a) through (g) shall continue to apply with respect to the reporting of (or failure to report), access to, and other treatment of the information specified in this section.".

(b) ELIMINATION OF THE RESPONSIBILITY OF THE HHS OFFICE OF THE INSPECTOR GENERAL.—Section 1128C(a)(1) of the Social Security Act (42 U.S.C. 1320a-7c(a)(1)) is amended—

(1) in subparagraph (C), by adding at the end "and";

(2) in subparagraph (D), by striking at the end ", and" and inserting a period; and

(3) by striking subparagraph (E).

(c) SPECIAL PROVISION FOR ACCESS TO THE NATIONAL PRACTITIONER DATA BANK BY THE DEPARTMENT OF VETERANS AFFAIRS.—

(1) IN GENERAL.—Notwithstanding any other provision of law, during the one year period that begins on the effective date specified in subsection (e)(1), the information described in paragraph (2) shall be available from the National Practitioner Data Bank (described in section 1921 of the Social Security Act) to the Secretary of Veterans Affairs without charge.

(2) INFORMATION DESCRIBED.—For purposes of paragraph (1), the information described in this paragraph is the information that would, but for the amendments made by this section, have been available to the Secretary of Veterans Affairs from the Healthcare Integrity and Protection Data Bank.

(d) FUNDING.—Notwithstanding any provisions of this Act, sections 1128E(d)(2) and 1817(k)(3) of the Social Security Act, or any other provision of law, there shall be available for carrying out the transition process under section 1128E(h) of the Social Security Act over the period required to complete such process, and for operation of the National Practitioner Data Bank until such process is completed, without fiscal year limitation—

(1) any fees collected pursuant to section 1128E(d)(2) of such Act; and

(2) such additional amounts as necessary, from appropriations available to the Secretary and to the Office of the Inspector General of the Department of Health and Human Services under clauses (i) and (ii), respectively, of section 1817(k)(3)(A) of such Act, for costs of such activities during the first 12 months following the date of the enactment of this Act.

(e) EFFECTIVE DATE.—The amendments made—

(1) by subsection (a)(2) shall take effect on the first day after the Secretary of Health and Human Services certifies that the process implemented pursuant to section 1128E(h) of the Social Security Act (as added by subsection (a)(3)) is complete; and

(2) by subsection (b) shall take effect on the earlier of the date specified in paragraph (1) or the first day of the second succeeding fiscal year after the fiscal year during which this Act is enacted.

SEC. 1653. COMPLIANCE WITH HIPAA PRIVACY AND SECURITY STANDARDS.

The provisions of sections 262(a) and 264 of the Health Insurance Portability and Accountability Act of 1996 (and standards promulgated pursuant to such sections) and the Privacy Act of 1974 shall apply with respect to the provisions of this subtitle and amendments made by this subtitle.

TITLE VII—MEDICAID AND CHIP

Subtitle A—Medicaid and Health Reform

SEC. 1701. ELIGIBILITY FOR INDIVIDUALS WITH INCOME BELOW 133⅓ PERCENT OF THE FEDERAL POVERTY LEVEL.

(a) ELIGIBILITY FOR NON-TRADITIONAL INDIVIDUALS WITH INCOME BELOW 133⅓ PERCENT OF THE FEDERAL POVERTY LEVEL.—

(1) IN GENERAL.—Section 1902(a)(10)(A)(i) of the Social Security Act (42 U.S.C. 1396b(a)(10)(A)(i) is amended—

(A) by striking "or" at the end of subclause (VI);

(B) by adding "or" at the end of subclause (VII); and

(C) by adding at the end the following new subclause:

"(VIII) who are under 65 years of age, who are not described in a previous subclause of this clause, and who are in families whose income (determined using methodologies and procedures specified by the Secretary in consultation with the Health Choices Commissioner) does not exceed 133⅓ percent of the income official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved;".

(2) INCREASED FMAP FOR NON-TRADITIONAL MEDICAID ELIGIBLE INDIVIDUALS.—Section 1905 of such Act (42 U.S.C. 1396d) is amended—

(A) in the first sentence of subsection (b), by striking "and" before "(4)" and by inserting before the period at the end the following: ", and (5) 100 percent (or 90 percent for periods beginning with 2015) with respect to amounts described in subsection (y)"; and

(B) by adding at the end the following new subsection:

"(y) ADDITIONAL EXPENDITURES SUBJECT TO INCREASED FMAP.—For purposes of section 1905(b)(5), the amounts described in this subsection are the following:

"(1) Amounts expended for medical assistance for individuals described in subclause (VIII) of section 1902(a)(10)(A)(i).".

(3) CONSTRUCTION.—Nothing in this subsection shall be construed as not providing for coverage under subclause (VIII) of section 1902(a)(10)(A)(i) of the Social Security Act, as added by paragraph (1) of, and an increased FMAP under the amendment made by paragraph (2) for, an individual who has been provided medical assistance under title XIX of the Act under a demonstration waiver approved under section 1115 of such Act or with State funds.

(4) CONFORMING AMENDMENTS.—

(A) Section 1903(f)(4) of the Social Security Act (42 U.S.C. 1396b(f)(4)) is amended by inserting "1902(a)(10)(A)(i)(VIII)," after "1902(a)(10)(A)(i)(VII),".

(B) Section 1905(a) of such Act (42 U.S.C. 1396d(a)), as amended by sections 1714(a)(4) and 1731(c), is further amended, in the matter preceding paragraph (1)—

(i) by striking "or" at the end of clause (xiv);

(ii) by adding "or" at the end of clause (xv); and

(iii) by inserting after clause (xv) the following:

"(xvi) individuals described in section 1902(a)(10)(A)(i)(VIII),".

(b) ELIGIBILITY FOR TRADITIONAL MEDICAID ELIGIBLE INDIVIDUALS WITH INCOME NOT EXCEEDING 133⅓ PERCENT OF THE FEDERAL POVERTY LEVEL .—

(1) IN GENERAL.—Section 1902(a)(10)(A)(i) of the Social Security Act (42 U.S.C. 1396b(a)(10)(A)(i)), as amended by subsection (a), is amended—

(A) by striking "or" at the end of subclause (VII);

(B) by adding "or" at the end of subclause (VIII); and

(C) by adding at the end the following new subclause:

"(IX) who are under 65 years of age, who would be eligible for medical assistance under the State plan under one of subclauses (I) through (VII) (based on the income standards, methodologies, and procedures in effect as of June 16, 2009) but for income and who are in families whose income does not exceed 133⅓ percent of the income official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved;".

(2) INCREASED FMAP FOR CERTAIN TRADITIONAL MEDICAID ELIGIBLE INDIVIDUALS.—Section 1905(y) of such Act (42 U.S.C. 1396d(b)), as added by subsection (a)(2)(B), is amended by inserting "or (IX)" after "(VIII)".

(3) CONSTRUCTION.—Nothing in this subsection shall be construed as not providing for coverage under subclause (IX) of section 1902(a)(10)(A)(i) of the Social Security Act, as added by paragraph (1) of, and an increased FMAP under the amendment made by paragraph (2) for, an individual who has been provided medical assistance under title XIX of the Act under a demonstration waiver approved under section 1115 of such Act or with State funds.

(4) CONFORMING AMENDMENT.—Section 1903(f)(4) of the Social Security Act (42 U.S.C. 1396b(f)(4)), as amended by subsection (a)(4), is amended by inserting "1902(a)(10)(A)(i)(IX)," after "1902(a)(10)(A)(i)(VIII),".

(c) INCREASED MATCHING RATE FOR TEMPORARY COVERAGE OF CERTAIN NEWBORNS.—Section 1905(y) of such Act, as added by subsection (a)(2)(B), is amended—

(1) in paragraph (1), by inserting before the period at the end the following: ", and who is not provided medical assistance under section 1943(b)(2) of this title or section 205(d)(1)(B) of the America's Affordable Health Choices Act of 2009"; and

(2) by adding at the end the following:

"(2) Amounts expended for medical assistance for children described in section 203(d)(1)(A) of the America's Affordable Health Choices Act of 2009 during the time period specified in such section.".

(d) NETWORK ADEQUACY.—Section 1932(a)(2) of the Social Security Act (42 U.S.C. 1396u–2(a)(2)) is amended by adding at the end the following new subparagraph:

"(D) ENROLLMENT OF NON-TRADITIONAL MEDICAID ELIGIBLES.—A State may not require under paragraph (1) the enrollment in a managed care entity of an individual described in section 1902(a)(10)(A)(i)(VIII) unless the State demonstrates, to the satisfaction of the Secretary, that the entity, through its provider network and other arrangements, has the capacity to meet the health, mental health, and substance abuse needs of such individuals.".

(e) EFFECTIVE DATE.—The amendments made by this section shall take effect on the first day of Y1, and shall apply with respect to items and services furnished on or after such date.

SEC. 1702. REQUIREMENTS AND SPECIAL RULES FOR CERTAIN MEDICAID ELIGIBLE INDIVIDUALS.

(a) IN GENERAL.—Title XIX of the Social Security Act is amended by adding at the end the following new section:

" REQUIREMENTS AND SPECIAL RULES FOR CERTAIN MEDICAID ELIGIBLE INDIVIDUALS

"SEC. 1943. (a) COORDINATION WITH NHI EXCHANGE THROUGH MEMORANDUM OF UNDERSTANDING.—

"(1) IN GENERAL.—The State shall enter into a Medicaid memorandum of understanding described in section 205(e)(3) of the America's Affordable Health Choices Act of 2009 with the Health Choices Commissioner, acting in consultation with the Secretary, with respect to coordinating the implementation of the provisions of division A of such Act with the State plan under this title in order to ensure the enrollment of Medicaid eligible individuals in acceptable coverage. Nothing in this section shall be construed as permitting such memorandum to modify or vitiate any requirement of a State plan under this title.

"(2) ENROLLMENT OF EXCHANGE-REFERRED INDIVIDUALS.—

"(A) NON-TRADITIONAL INDIVIDUALS.—Pursuant to such memorandum the State shall accept without further determination the enrollment under this title of an individual determined by the Commissioner to be a non-traditional Medicaid eligible individual. The State shall not do any redeterminations of eligibility for such individuals unless the periodicity of such redeterminations is consistent with the periodicity for redeterminations by the Commissioner of eligibility for affordability credits under subtitle C of title II of division A of the America's Affordable Health Choices Act of 2009, as specified under such memorandum.

"(B) TRADITIONAL INDIVIDUALS.—Pursuant to such memorandum, the State shall accept without further determination the enrollment under this title of an individual determined by the Commissioner to be a traditional Medicaid eligible individual. The State may do redeterminations of eligibility of such individual consistent with such section and the memorandum.

"(3) DETERMINATIONS OF ELIGIBILITY FOR AFFORDABILITY CREDITS.—If the Commissioner determines that a State Medicaid agency has the capacity to

make determinations of eligibility for affordability credits under subtitle C of title II of division A of the America's Affordable Health Choices Act of 2009, under such memorandum—

"(A) the State Medicaid agency shall conduct such determinations for any Exchange-eligible individual who requests such a determination;

"(B) in the case that a State Medicaid agency determines that an Exchange-eligible individual is not eligible for affordability credits, the agency shall forward the information on the basis of which such determination was made to the Commissioner; and

"(C) the Commissioner shall reimburse the State Medicaid agency for the costs of conducting such determinations.

"(b) TREATMENT OF CERTAIN NEWBORNS.—

"(1) IN GENERAL.—In the case of a child who is deemed under section 205(d)(1) of the America's Affordable Health Choices Act of 2009 to be a non-traditional Medicaid eligible individual and enrolled under this title pursuant to such section, the State shall provide for a determination, by not later than the end of the period referred to in subparagraph (A) of such section, of the child's eligibility for medical assistance under this title.

"(2) EXTENDED TREATMENT AS TRADITIONAL MEDICAID ELIGIBLE INDIVIDUAL.—In accordance with subparagraph (B) of section 205(d)(1) of the America's Affordable Health Choices Act of 2009, in the case of a child described in subparagraph (A) of such section who at the end of the period referred to in such subparagraph is not otherwise covered under acceptable coverage, the child shall be deemed (until such time as the child obtains such coverage or the State otherwise makes a determination of the child's eligibility for medical assistance under its plan under this title pursuant to paragraph (1)) to be a traditional Medicaid eligible individual described in section 1902(l)(1)(B).

"(c) DEFINITIONS.—In this section:

"(1) MEDICAID ELIGIBLE INDIVIDUALS.—In this section, the terms 'Medicaid eligible individual', 'traditional Medicaid eligible individual', and 'non-traditional Medicaid eligible individual' have the meanings given such terms in section 205(e)(4) of the America's Affordable Health Choices Act of 2009.

"(2) MEMORANDUM.—The term 'memorandum' means a Medicaid memorandum of understanding under section 205(e)(3) of the America's Affordable Health Choices Act of 2009.

"(3) Y1.—The term 'Y1' has the meaning given such term in section 100(c) of the America's Affordable Health Choices Act of 2009.".

(b) CONFORMING AMENDMENTS TO ERROR RATE.—

(1) Section 1903(u)(1)(D) of the Social Security Act (42 U.S.C. 1396b(u)(1)(D)) is amended by adding at the end the following new clause:

"(vi) In determining the amount of erroneous excess payments, there shall not be included any erroneous payments made that are attributable to an error in an eligibility determination under subtitle C of title II of division A of the America's Affordable Health Choices Act of 2009.".

(2) Section 2105(c)(11) of such Act (42 U.S.C. 1397ee(c)(11)) is amended by adding at the end the following new sentence: "Clause (vi) of section 1903(u)(1)(D) shall apply with respect to the application of such requirements under this title and title XIX.".

SEC. 1703. CHIP AND MEDICAID MAINTENANCE OF ELIGIBILITY.

(a) CHIP MAINTENANCE OF ELIGIBILITY.—Section 1902 of the Social Security Act (42 U.S.C. 1396a) is amended—

(1) in subsection (a), as amended by section 1631(b)(1)(D)—

(A) by striking "and" at the end of paragraph (73);

(B) by striking the period at the end of paragraph (74) and inserting "; and"; and

(C) by inserting after paragraph (74) the following new paragraph:

"(75) provide for maintenance of effort under the State child health plan under title XXI in accordance with subsection (gg).";; and

(2) by adding at the end the following new subsection:

"(gg) CHIP MAINTENANCE OF ELIGIBILITY REQUIREMENT.—

"(1) IN GENERAL.—Subject to paragraph (2), as a condition of its State plan under this title under subsection (a)(75) and receipt of any Federal financial assistance under section 1903(a) for calendar quarters beginning after the date of the enactment of this subsection and before CHIP MOE termination date specified in paragraph (3), a State shall not have in effect eligibility standards, methodologies, or procedures under its State child health plan under title XXI (including any waiver under such title or under section 1115 that is permitted to continue effect) that are more restrictive than the eligibility standards, meth-

odologies, or procedures, respectively, under such plan (or waiver) as in effect on June 16, 2009.

"(2) LIMITATION.—Paragraph (1) shall not be construed as preventing a State from imposing a limitation described in section 2110(b)(5)(C)(i)(II) for a fiscal year in order to limit expenditures under its State child health plan under title XXI to those for which Federal financial participation is available under section 2105 for the fiscal year.

"(3) CHIP MOE TERMINATION DATE.—In paragraph (1), the 'CHIP MOE termination date' for a State is the date that is the first day of Y1 (as defined in section 100(c) of the America's Affordable Health Choices Act of 2009) or, if later, the first day after such date that both of the following determinations have been made:

"(A) The Health Choices Commissioner has determined that the Health Insurance Exchange has the capacity to support the participation of CHIP enrollees who are Exchange-eligible individuals (as defined in section 202(b) of the America's Affordable Health Choices Act of 2009),

"(B) The Secretary has determined that—

"(i) comparable coverage, as specified in section 202(g) of the America's Affordable Health Choices Act of 2009, is available through such Exchange; and

"(ii) procedures have been established for transferring CHIP enrollees into acceptable coverage (as defined for purposes of such Act) without interruption of coverage or a written plan of treatment.

The Secretary shall recommend to Congress any legislative changes needed to effectuate this paragraph. In this paragraph, the term 'CHIP enrollee' means a targeted low-income child or (if the State has elected the option under section 2112, a targeted low-income pregnant woman) who is or otherwise would be (but for acceptable coverage) eligible for child health assistance or pregnancy-related assistance, respectively, under the State child health plan referred to in paragraph (1).".

(b) MEDICAID MAINTENANCE OF EFFORT; SIMPLIFYING AND COORDINATING ELIGIBILITY RULES BETWEEN EXCHANGE AND MEDICAID.—

(1) IN GENERAL.—Section 1903 of such Act (42 U.S.C. 1396b) is amended by adding at the end the following new subsection:

"(aa) MAINTENANCE OF MEDICAID EFFORT; SIMPLIFYING AND COORDINATING ELIGIBILITY RULES BETWEEN HEALTH INSURANCE EXCHANGE AND MEDICAID.—

"(1) MAINTENANCE OF EFFORT.—

"(A) IN GENERAL.—Subject to subparagraph (B), a State is not eligible for payment under subsection (a) for a calendar quarter beginning after the date of the enactment of this subsection if eligibility standards, methodologies, or procedures under its plan under this title (including any waiver under this title or under section 1115 that is permitted to continue effect) that are more restrictive than the eligibility standards, methodologies, or procedures, respectively, under such plan (or waiver) as in effect on June 16, 2009. The Secretary shall extend such a waiver (including the availability of Federal financial participation under such waiver) for such period as may be required for a State to meet the requirement of the previous sentence.

"(B) EXCEPTION FOR CERTAIN WAIVERS.—In the case of a State waiver under section 1115 in effect on June 16, 2009, that permits individuals to be eligible solely to receive a premium or cost-sharing subsidy for individual or group health insurance coverage, effective for coverage provided in Y1—

"(i) the Secretary shall permit the State to amend such waiver to apply more restrictive eligibility standards, methodologies, or procedures with respect to such individuals under such waiver; and

"(ii) the application of such more restrictive, standards, methodologies, or procedures under such an amendment shall not be considered in violation of the requirement of subparagraph (A).

"(2) REMOVAL OF ASSET TEST FOR CERTAIN ELIGIBILITY CATEGORIES.—

"(A) IN GENERAL.—A State is not eligible for payment under subsection (a) for a calendar quarter beginning on or after the first day of Y1 (as defined in section 100(c) of the America's Affordable Health Choices Act of 2009), if the State applies any asset or resource test in determining (or redetermining) eligibility of any individual on or after such first day under any of the following:

"(i) Subclause (I), (III), (IV), or (VI) of section 1902(a)(10)(A)(i).

"(ii) Subclause (II), (IX), (XIV) or (XVII) of section 1902(a)(10)(A)(ii).

"(iii) Section 1931(b).

"(B) OVERRIDING CONTRARY PROVISIONS; REFERENCES.—The provisions of this title that prevent the waiver of an asset or resource test described in subparagraph (A) are hereby waived.

"(C) REFERENCES.—Any reference to a provision described in a provision in subparagraph (A) shall be deemed to be a reference to such provision as modified through the application of subparagraphs (A) and (B).".

(2) CONFORMING AMENDMENTS.—(A) Section 1902(a)(10)(A) of such Act (42 U.S.C. 1396a(a)(10)(A)) is amended, in the matter before clause (i), by inserting "subject to section 1903(aa)(2)," after "(A)".

(B) Section 1931(b)(1) of such Act (42 U.S.C. 1396u–1(b)(1)) is amended by inserting "and section 1903(aa)(2)" after "and (3)".

(c) STANDARDS FOR BENCHMARK PACKAGES.—Section 1937(b) of such Act (42 U.S.C. 1396u–7(b)) is amended—

(1) in each of paragraphs (1) and (2), by inserting "subject to paragraph (5)," after "subsection (a)(1),"; and

(2) by adding at the end the following new paragraph:

"(5) MINIMUM STANDARDS.—Effective January 1, 2013, any benchmark benefit package (or benchmark equivalent coverage under paragraph (2)) must meet the minimum benefits and cost-sharing standards of a basic plan offered through the Health Insurance Exchange.".

SEC. 1704. REDUCTION IN MEDICAID DSH.

(a) REPORT.—

(1) IN GENERAL.—Not later than January 1, 2016, the Secretary of Health and Human Services (in this title referred to as the "Secretary") shall submit to Congress a report concerning the extent to which, based upon the impact of the health care reforms carried out under division A in reducing the number of uninsured individuals, there is a continued role for Medicaid DSH. In preparing the report, the Secretary shall consult with community-based health care networks serving low-income beneficiaries.

(2) MATTERS TO BE INCLUDED.—The report shall include the following:

(A) RECOMMENDATIONS.—Recommendations regarding—

(i) the appropriate targeting of Medicaid DSH within States; and

(ii) the distribution of Medicaid DSH among the States, taking into account the ratio of the amount of DSH funds allocated to a State to the number of uninsured individuals in such State.

(B) SPECIFICATION OF DSH HEALTH REFORM METHODOLOGY.—The DSH Health Reform methodology described in paragraph (2) of subsection (b) for purposes of implementing the requirements of such subsection.

(3) COORDINATION WITH MEDICARE DSH REPORT.—The Secretary shall coordinate the report under this subsection with the report on Medicare DSH under section 1112.

(4) MEDICAID DSH.—In this section, the term "Medicaid DSH" means adjustments in payments under section 1923 of the Social Security Act for inpatient hospital services furnished by disproportionate share hospitals.

(b) MEDICAID DSH REDUCTIONS.—

(1) IN GENERAL.—The Secretary shall reduce Medicaid DSH so as to reduce total Federal payments to all States for such purpose by $1,500,000,000 in fiscal year 2017, $2,500,000,000 in fiscal year 2018, and $6,000,000,000 in fiscal year 2019.

(2) DSH HEALTH REFORM METHODOLOGY.—The Secretary shall carry out paragraph (1) through use of a DSH Health Reform methodology issued by the Secretary that imposes the largest percentage reductions on the States that—

(A) have the lowest percentages of uninsured individuals (determined on the basis of audited hospital cost reports) during the most recent year for which such data are available; or

(B) do not target their DSH payments on—

(i) hospitals with high volumes of Medicaid inpatients (as defined in section 1923(b)(1)(A) of the Social Security Act (42 U.S.C. 1396r–4(b)(1)(A)); and

(ii) hospitals that have high levels of uncompensated care (excluding bad debt).

(3) DSH ALLOTMENT PUBLICATIONS.—

(A) IN GENERAL.—Not later than the publication deadline specified in subparagraph (B), the Secretary shall publish in the Federal Register a notice specifying the DSH allotment to each State under 1923(f) of the Social Security Act for the respective fiscal year specified in such subparagraph, consistent with the application of the DSH Health Reform methodology described in paragraph (2).

(B) PUBLICATION DEADLINE.—The publication deadline specified in this subparagraph is—

(i) January 1, 2016, with respect to DSH allotments described in subparagraph (A) for fiscal year 2017;

(ii) January 1, 2017, with respect to DSH allotments described in subparagraph (A) for fiscal year 2018; and

(iii) January 1, 2018, with respect to DSH allotments described in subparagraph (A) for fiscal year 2019.

(c) CONFORMING AMENDMENTS.—

(1) Section 1923(f) of the Social Security Act (42 U.S.C. 1396r–4(f)) is amended—

(A) by redesignating paragraph (7) as paragraph (8); and

(B) by inserting after paragraph (6) the following new paragraph:

"(7) SPECIAL RULE FOR FISCAL YEARS 2017, 2018, AND 2019.—

"(A) FISCAL YEAR 2017.—Notwithstanding paragraph (2), the total DSH allotments for all States for—

"(i) fiscal year 2017, shall be the total DSH allotments that would otherwise be determined under this subsection for such fiscal year decreased by $1,500,000,000;

"(ii) fiscal year 2018, shall be the total DSH allotments that would otherwise be determined under this subsection for such fiscal year decreased by $2,500,000,000; and

"(iii) fiscal year 2019, shall be the total DSH allotments that would otherwise be determined under this subsection for such fiscal year decreased by $6,000,000,000.".

(2) The second sentence of section 1923(b)(4) of such Act (42 U.S.C. 1396r–4(b)(4)) is amended by inserting before the period the following: "or to affect the authority of the Secretary to issue and implement the DSH Health Reform methodology under section 1704(b)(2) of the America's Health Choices Act of 2009".

(d) DISPROPORTIONATE SHARE HOSPITALS (DSH) AND ESSENTIAL ACCESS HOSPITAL (EAH) NON-DISCRIMINATION.—

(1) IN GENERAL.—Section 1923(d) of the Social Security Act (42 U.S.C. 1396r-4) is amended by adding at the end the following new paragraph:

"(4) No hospital may be defined or deemed as a disproportionate share hospital, or as an essential access hospital (for purposes of subsection (f)(6)(A)(iv)), under a State plan under this title or subsection (b) of this section (including any waiver under section 1115) unless the hospital—

"(A) provides services to beneficiaries under this title without discrimination on the ground of race, color, national origin, creed, source of payment, status as a beneficiary under this title, or any other ground unrelated to such beneficiary's need for the services or the availability of the needed services in the hospital; and

"(B) makes arrangements for, and accepts, reimbursement under this title for services provided to eligible beneficiaries under this title.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to expenditures made on or after July 1, 2010.

SEC. 1705. EXPANDED OUTSTATIONING.

(a) IN GENERAL.—Section 1902(a)(55) of the Social Security Act (42 U.S.C. 1396a(a)(55)) is amended by striking "under subsection (a)(10)(A)(i)(IV), (a)(10)(A)(i)(VI), (a)(10)(A)(i)(VII), or (a)(10)(A)(ii)(IX)" and inserting "(including receipt and processing of applications of individuals for affordability credits under subtitle C of title II of division A of the America's Affordable Health Choices Act of 2009 pursuant to a Medicaid memorandum of understanding under section 1943(a)(1))".

(b) EFFECTIVE DATE.—

(1) Except as provided in paragraph (2), the amendment made by subsection (a) shall apply to services furnished on or after July 1, 2010, without regard to whether or not final regulations to carry out such amendment have been promulgated by such date.

(2) In the case of a State plan for medical assistance under title XIX of the Social Security Act which the Secretary of Health and Human Services determines requires State legislation (other than legislation appropriating funds) in order for the plan to meet the additional requirement imposed by the amendment made by this section, the State plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet this additional requirement before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of the enactment of this Act. For purposes of the pre-

vious sentence, in the case of a State that has a 2-year legislative session, each year of such session shall be deemed to be a separate regular session of the State legislature.

Subtitle B—Prevention

SEC. 1711. REQUIRED COVERAGE OF PREVENTIVE SERVICES.

(a) COVERAGE.—Section 1905 of the Social Security Act (42 U.S.C. 1396d), as amended by section 1701(a)(2)(B), is amended—

(1) in subsection (a)(4)—

(A) by striking "and" before "(C)"; and

(B) by inserting before the semicolon at the end the following: "; and (D) preventive services described in subsection (z)"; and

(2) by adding at the end the following new subsection:

"(z) PREVENTIVE SERVICES.—The preventive services described in this subsection are services not otherwise described in subsection (a) or (r) that the Secretary determines are—

"(1)(A) recommended with a grade of A or B by the Task Force for Clinical Preventive Services; or

"(B) vaccines recommended for use as appropriate by the Director of the Centers for Disease Control and Prevention; and

"(2) appropriate for individuals entitled to medical assistance under this title.".

(b) ELIMINATION OF COST-SHARING.—

(1) Subsections (a)(2)(D) and (b)(2)(D) of section 1916 of such Act (42 U.S.C. 1396o) are each amended by inserting "preventive services described in section 1905(z)," after "emergency services (as defined by the Secretary),".

(2) Section 1916A(a)(1) of such Act (42 U.S.C. 1396o–1 (a)(1)) is amended by inserting ", preventive services described in section 1905(z)," after "subsection (c)".

(c) CONFORMING AMENDMENT.—Section 1928 of such Act (42 U.S.C. 1396s) is amended—

(1) in subsection (c)(2)(B)(i), by striking "the advisory committee referred to in subsection (e)" and inserting "the Director of the Centers for Disease Control and Prevention";

(2) in subsection (e), by striking "Advisory Committee" and all that follows and inserting "Director of the Centers for Disease Control and Prevention."; and

(3) by striking subsection (g).

(d) EFFECTIVE DATE.—

(1) Except as provided in paragraph (2), the amendments made by this section shall apply to services furnished on or after July 1, 2010, without regard to whether or not final regulations to carry out such amendments have been promulgated by such date.

(2) In the case of a State plan for medical assistance under title XIX of the Social Security Act which the Secretary of Health and Human Services determines requires State legislation (other than legislation appropriating funds) in order for the plan to meet the additional requirements imposed by the amendments made by this section, the State plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet these additional requirements before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of the enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of such session shall be deemed to be a separate regular session of the State legislature.

SEC. 1712. TOBACCO CESSATION.

(a) DROPPING TOBACCO CESSATION EXCLUSION FROM COVERED OUTPATIENT DRUGS.—Section 1927(d)(2) of the Social Security Act (42 U.S.C. 1396r–8(d)(2)) is amended—

(1) by striking subparagraph (E);

(2) in subparagraph (G), by inserting before the period at the end the following: ", except agents approved by the Food and Drug Administration for purposes of promoting, and when used to promote, tobacco cessation"; and

(3) by redesignating subparagraphs (F) through (K) as subparagraphs (E) through (J), respectively.

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to drugs and services furnished on or after January 1, 2010.

SEC. 1713. OPTIONAL COVERAGE OF NURSE HOME VISITATION SERVICES.

(a) IN GENERAL.—Section 1905 of the Social Security Act (42 U.S.C. 1396d), as amended by sections 1701(a)(2) and 1711(a), is amended—

(1) in subsection (a)—

(A) in paragraph (27), by striking "and" at the end;

(B) by redesignating paragraph (28) as paragraph (29); and

(C) by inserting after paragraph (27) the following new paragraph:

"(28) nurse home visitation services (as defined in subsection (aa)); and"; and

(2) by adding at the end the following new subsection:

"(aa) The term 'nurse home visitation services' means home visits by trained nurses to families with a first-time pregnant woman, or a child (under 2 years of age), who is eligible for medical assistance under this title, but only, to the extent determined by the Secretary based upon evidence, that such services are effective in one or more of the following:

"(1) Improving maternal or child health and pregnancy outcomes or increasing birth intervals between pregnancies.

"(2) Reducing the incidence of child abuse, neglect, and injury, improving family stability (including reduction in the incidence of intimate partner violence), or reducing maternal and child involvement in the criminal justice system.

"(3) Increasing economic self-sufficiency, employment advancement, school-readiness, and educational achievement, or reducing dependence on public assistance.".

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after January 1, 2010.

(c) CONSTRUCTION.—Nothing in the amendments made by this section shall be construed as affecting the ability of a State under title XIX or XXI of the Social Security Act to provide nurse home visitation services as part of another class of items and services falling within the definition of medical assistance or child health assistance under the respective title, or as an administrative expenditure for which payment is made under section 1903(a) or 2105(a) of such Act, respectively, on or after the date of the enactment of this Act.

SEC. 1714. STATE ELIGIBILITY OPTION FOR FAMILY PLANNING SERVICES.

(a) COVERAGE AS OPTIONAL CATEGORICALLY NEEDY GROUP.—

(1) IN GENERAL.—Section 1902(a)(10)(A)(ii) of the Social Security Act (42 U.S.C. 1396a(a)(10)(A)(ii)) is amended—

(A) in subclause (XVIII), by striking "or" at the end;

(B) in subclause (XIX), by adding "or" at the end; and

(C) by adding at the end the following new subclause:

"(XX) who are described in subsection (hh) (relating to individuals who meet certain income standards);".

(2) GROUP DESCRIBED.—Section 1902 of such Act (42 U.S.C. 1396a), as amended by section 1703, is amended by adding at the end the following new subsection:

"(hh)(1) Individuals described in this subsection are individuals—

"(A) whose income does not exceed an income eligibility level established by the State that does not exceed the highest income eligibility level established under the State plan under this title (or under its State child health plan under title XXI) for pregnant women; and

"(B) who are not pregnant.

"(2) At the option of a State, individuals described in this subsection may include individuals who, had individuals applied on or before January 1, 2007, would have been made eligible pursuant to the standards and processes imposed by that State for benefits described in clause (XV) of the matter following subparagraph (G) of section subsection (a)(10) pursuant to a waiver granted under section 1115.

"(3) At the option of a State, for purposes of subsection (a)(17)(B), in determining eligibility for services under this subsection, the State may consider only the income of the applicant or recipient.".

(3) LIMITATION ON BENEFITS.—Section 1902(a)(10) of such Act (42 U.S.C. 1396a(a)(10)) is amended in the matter following subparagraph (G)—

(A) by striking "and (XIV)" and inserting "(XIV)"; and

(B) by inserting ", and (XV) the medical assistance made available to an individual described in subsection (hh) shall be limited to family planning services and supplies described in section 1905(a)(4)(C) including medical diagnosis and treatment services that are provided pursuant to a family planning service in a family planning setting" after "cervical cancer".

(4) CONFORMING AMENDMENTS.—Section 1905(a) of such Act (42 U.S.C. 1396d(a)), as amended by section 1731(c), is amended in the matter preceding paragraph (1)—

(A) in clause (xiii), by striking "or" at the end;
(B) in clause (xiv), by adding "or" at the end; and
(C) by inserting after clause (xiv) the following:
"(xv) individuals described in section 1902(hh),".

(b) PRESUMPTIVE ELIGIBILITY.—

(1) IN GENERAL.—Title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) is amended by inserting after section 1920B the following:

"PRESUMPTIVE ELIGIBILITY FOR FAMILY PLANNING SERVICES

"SEC. 1920C. (a) STATE OPTION.—State plan approved under section 1902 may provide for making medical assistance available to an individual described in section 1902(hh) (relating to individuals who meet certain income eligibility standard) during a presumptive eligibility period. In the case of an individual described in section 1902(hh), such medical assistance shall be limited to family planning services and supplies described in 1905(a)(4)(C) and, at the State's option, medical diagnosis and treatment services that are provided in conjunction with a family planning service in a family planning setting.

"(b) DEFINITIONS.—For purposes of this section:

"(1) PRESUMPTIVE ELIGIBILITY PERIOD.—The term 'presumptive eligibility period' means, with respect to an individual described in subsection (a), the period that—

"(A) begins with the date on which a qualified entity determines, on the basis of preliminary information, that the individual is described in section 1902(hh); and

"(B) ends with (and includes) the earlier of—

"(i) the day on which a determination is made with respect to the eligibility of such individual for services under the State plan; or

"(ii) in the case of such an individual who does not file an application by the last day of the month following the month during which the entity makes the determination referred to in subparagraph (A), such last day.

"(2) QUALIFIED ENTITY.—

"(A) IN GENERAL.—Subject to subparagraph (B), the term 'qualified entity' means any entity that—

"(i) is eligible for payments under a State plan approved under this title; and

"(ii) is determined by the State agency to be capable of making determinations of the type described in paragraph (1)(A).

"(B) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed as preventing a State from limiting the classes of entities that may become qualified entities in order to prevent fraud and abuse.

"(c) ADMINISTRATION.—

"(1) IN GENERAL.—The State agency shall provide qualified entities with—

"(A) such forms as are necessary for an application to be made by an individual described in subsection (a) for medical assistance under the State plan; and

"(B) information on how to assist such individuals in completing and filing such forms.

"(2) NOTIFICATION REQUIREMENTS.—A qualified entity that determines under subsection (b)(1)(A) that an individual described in subsection (a) is presumptively eligible for medical assistance under a State plan shall—

"(A) notify the State agency of the determination within 5 working days after the date on which determination is made; and

"(B) inform such individual at the time the determination is made that an application for medical assistance is required to be made by not later than the last day of the month following the month during which the determination is made.

"(3) APPLICATION FOR MEDICAL ASSISTANCE.—In the case of an individual described in subsection (a) who is determined by a qualified entity to be presumptively eligible for medical assistance under a State plan, the individual shall apply for medical assistance by not later than the last day of the month following the month during which the determination is made.

"(d) PAYMENT.—Notwithstanding any other provision of law, medical assistance that—

"(1) is furnished to an individual described in subsection (a)—

"(A) during a presumptive eligibility period;

"(B) by a entity that is eligible for payments under the State plan; and

"(2) is included in the care and services covered by the State plan,

shall be treated as medical assistance provided by such plan for purposes of clause (4) of the first sentence of section 1905(b).".

(2) CONFORMING AMENDMENTS.—

(A) Section 1902(a)(47) of the Social Security Act (42 U.S.C. 1396a(a)(47)) is amended by inserting before the semicolon at the end the following: "and provide for making medical assistance available to individuals described in subsection (a) of section 1920C during a presumptive eligibility period in accordance with such section".

(B) Section 1903(u)(1)(D)(v) of such Act (42 U.S.C. 1396b(u)(1)(D)(v)) is amended—

(i) by striking "or for" and inserting "for"; and

(ii) by inserting before the period the following: ", or for medical assistance provided to an individual described in subsection (a) of section 1920C during a presumptive eligibility period under such section".

(c) CLARIFICATION OF COVERAGE OF FAMILY PLANNING SERVICES AND SUPPLIES.—Section 1937(b) of the Social Security Act (42 U.S.C. 1396u–7(b)), as amended by section 1703(c)(2), is amended by adding at the end the following:

"(6) COVERAGE OF FAMILY PLANNING SERVICES AND SUPPLIES.—Notwithstanding the previous provisions of this section, a State may not provide for medical assistance through enrollment of an individual with benchmark coverage or benchmark-equivalent coverage under this section unless such coverage includes for any individual described in section 1905(a)(4)(C), medical assistance for family planning services and supplies in accordance with such section.".

(d) EFFECTIVE DATE.—The amendments made by this section take effect on the date of the enactment of this Act and shall apply to items and services furnished on or after such date.

Subtitle C—Access

SEC. 1721. PAYMENTS TO PRIMARY CARE PRACTITIONERS.

(a) IN GENERAL.—

(1) FEE-FOR-SERVICE PAYMENTS.—Section 1902(a)(13) of the Social Security Act (42 U.S.C. 1396b(a)(13)) is amended—

(A) by striking "and" at the end of subparagraph (A);

(B) by adding "and" at the end of subparagraph (B); and

(C) by adding at the end the following new subparagraph:

"(C) payment for primary care services (as defined in section 1848(j)(5)(A), but applied without regard to clause (ii) thereof) furnished by physicians (or for services furnished by other health care professionals that would be primary care services under such section if furnished by a physician) at a rate not less than 80 percent of the payment rate applicable to such services and physicians or professionals (as the case may be) under part B of title XVIII for services furnished in 2010, 90 percent of such rate for services and physicians (or professionals) furnished in 2011, and 100 percent of such payment rate for services and physicians (or professionals) furnished in 2012 or a subsequent year;".

(2) UNDER MEDICAID MANAGED CARE PLANS.—Section 1932(f) of such Act (42 U.S.C. 1396u–2(f)) is amended—

(A) in the heading, by adding at the end the following: "; ADEQUACY OF PAYMENT FOR PRIMARY CARE SERVICES"; and

(B) by inserting before the period at the end the following: "and, in the case of primary care services described in section 1902(a)(13)(C), consistent with the minimum payment rates specified in such section (regardless of the manner in which such payments are made, including in the form of capitation or partial capitation)".

(b) INCREASE IN PAYMENT USING INCREASED FMAP.—Section 1905(y) of the Social Security Act, as added by section 1701(a)(2)(B) and as amended by section 1701(c)(2), is amended by adding at the end the following:

"(3)(A) The portion of the amounts expended for medical assistance for services described in section 1902(a)(13)(C) furnished on or after January 1, 2010, that is attributable to the amount by which the minimum payment rate required under such section (or, by application, section 1932(f)) exceeds the payment rate applicable to such services under the State plan as of June 16, 2009.

"(B) Subparagraphs (A) shall not be construed as preventing the payment of Federal financial participation based on the Federal medical assistance percentage for amounts in excess of those specified under such subparagraphs.".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to services furnished on or after January 1, 2010.

SEC. 1722. MEDICAL HOME PILOT PROGRAM.

(a) IN GENERAL.—The Secretary of Health and Human Services shall establish under this section a medical home pilot program under which a State may apply to the Secretary for approval of a medical home pilot project described in subsection (b) (in this section referred to as a "pilot project") for the application of the medical home concept under title XIX of the Social Security Act. The pilot program shall operate for a period of up to 5 years.

(b) PILOT PROJECT DESCRIBED.—

(1) IN GENERAL.—A pilot project is a project that applies one or more of the medical home models described in section 1866E(a)(3) of the Social Security Act (as inserted by section 1302(a)) or such other model as the Secretary may approve, to high need beneficiaries (including medically fragile children and high-risk pregnant women) who are eligible for medical assistance under title XIX of the Social Security Act. The Secretary shall provide for appropriate coordination of the pilot program under this section with the medical home pilot program under section 1866E of such Act.

(2) LIMITATION.—A pilot project shall be for a duration of not more than 5 years.

(c) ADDITIONAL INCENTIVES.—In the case of a pilot project, the Secretary may—

(1) waive the requirements of section 1902(a)(1) of the Social Security Act (relating to statewideness) and section 1902(a)(10)(B) of such Act (relating to comparability); and

(2) increase to up to 90 percent (for the first 2 years of the pilot program) or 75 percent (for the next 3 years) the matching percentage for administrative expenditures (such as those for community care workers).

(d) MEDICALLY FRAGILE CHILDREN.—In the case of a model involving medically fragile children, the model shall ensure that the patient-centered medical home services received by each child, in addition to fulfilling the requirements under 1866E(b)(1) of the Social Security Act, provide for continuous involvement and education of the parent or caregiver and for assistance to the child in obtaining necessary transitional care if a child's enrollment ceases for any reason.

(e) EVALUATION; REPORT.—

(1) EVALUATION.—The Secretary, using the criteria described in section 1866E(g)(1) of the Social Security Act (as inserted by section 1123), shall conduct an evaluation of the pilot program under this section.

(2) REPORT.—Not later than 60 days after the date of completion of the evaluation under paragraph (1), the Secretary shall submit to Congress and make available to the public a report on the findings of the evaluation under such paragraph.

(f) FUNDING.—The additional Federal financial participation resulting from the implementation of the pilot program under this section may not exceed in the aggregate $1,235,000,000 over the 5-year period of the program.

SEC. 1723. TRANSLATION OR INTERPRETATION SERVICES.

(a) IN GENERAL.—Section 1903(a)(2)(E) of the Social Security Act (42 U.S.C. 1396b(a)(2)), as added by section 201(b)(2)(A) of the Children's Health Insurance Program Reauthorization Act of 2009 (Public Law 111–3), is amended by inserting "and other individuals" after "children of families".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to payment for translation or interpretation services furnished on or after January 1, 2010.

SEC. 1724. OPTIONAL COVERAGE FOR FREESTANDING BIRTH CENTER SERVICES.

(a) IN GENERAL.—Section 1905 of the Social Security Act (42 U.S.C. 1396d), as amended by section 1713(a), is amended—

(1) in subsection (a)—

(A) by redesignating paragraph (29) as paragraph (30);

(B) in paragraph (28), by striking at the end "and"; and

(C) by inserting after paragraph (28) the following new paragraph:

"(29) freestanding birth center services (as defined in subsection (l)(3)(A)) and other ambulatory services that are offered by a freestanding birth center (as defined in subsection (l)(3)(B)) and that are otherwise included in the plan; and"; and

(2) in subsection (l), by adding at the end the following new paragraph:

"(3)(A) The term 'freestanding birth center services' means services furnished to an individual at a freestanding birth center (as defined in subparagraph (B)), including by a licensed birth attendant (as defined in subparagraph (C)) at such center.

"(B) The term 'freestanding birth center' means a health facility—

"(i) that is not a hospital; and

"(ii) where childbirth is planned to occur away from the pregnant woman's residence.

"(C) The term 'licensed birth attendant' means an individual who is licensed or registered by the State involved to provide health care at childbirth and who provides such care within the scope of practice under which the individual is legally authorized to perform such care under State law (or the State regulatory mechanism provided by State law), regardless of whether the individual is under the supervision of, or associated with, a physician or other health care provider. Nothing in this subparagraph shall be construed as changing State law requirements applicable to a licensed birth attendant.".

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to items and services furnished on or after the date of the enactment of this Act.

SEC. 1725. INCLUSION OF PUBLIC HEALTH CLINICS UNDER THE VACCINES FOR CHILDREN PROGRAM.

Section 1928(b)(2)(A)(iii)(I) of the Social Security Act (42 U.S.C. 1396s(b)(2)(A)(iii)(I)) is amended—

(1) by striking "or a rural health clinic" and inserting ", a rural health clinic"; and

(2) by inserting "or a public health clinic," after '"1905(l)(1)),".

SEC. 1726. REQUIRING COVERAGE OF SERVICES OF PODIATRISTS.

(a) IN GENERAL.—Section 1905(a)(5)(A) of the Social Security Act (42 U.S.C. 1396d(a)(5)(A)) is amended by striking "section 1861(r)(1)" and inserting "paragraphs (1) and (3) of section 1861(r)".

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendment made by subsection (a) shall apply to services furnished on or after January 1, 2010.

(2) EXTENSION OF EFFECTIVE DATE FOR STATE LAW AMENDMENT.—In the case of a State plan under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) which the Secretary of Health and Human Services determines requires State legislation in order for the plan to meet the additional requirement imposed by the amendment made by subsection (a), the State plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet these additional requirements before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of the session is considered to be a separate regular session of the State legislature.

SEC. 1726A. REQUIRING COVERAGE OF SERVICES OF OPTOMETRISTS.

(a) IN GENERAL.—Section 1905(a)(5) of the Social Security Act (42 U.S.C. 1396d(a)(5)) is amended—

(1) by striking "and" before "(B)"; and

(2) by inserting before the semicolon at the end the following: ", and (C) medical and other health services (as defined in section 1861(s)) as authorized by State law, furnished by an optometrist (described in section 1861(r)(4)) to the extent such services may be performed under State law".

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by subsection (a) shall take effect 90 days after the date of the enactment of this Act and shall apply to services furnished or other actions required on or after such date.

(2) EXCEPTION IF STATE LEGISLATION REQUIRED.—In the case of a State plan for medical assistance under title XIX of the Social Security Act which the Secretary of Health and Human Services determines requires State legislation (other than legislation appropriating funds) in order for the plan to meet the additional requirements made by the amendments made by subsection (a), the State plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet these additional requirements before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of such session shall be deemed to be a separate regular session of the State legislature.

SEC. 1727. THERAPEUTIC FOSTER CARE.

(a) RULE OF CONSTRUCTION.—Nothing in this title shall prevent or limit a State from covering therapeutic foster care for eligible children in out-of-home placements under section 1905(a) of the Social Security Act (42 U.S.C. 1396d(a)).

(b) THERAPEUTIC FOSTER CARE DEFINED.—For purposes of this section, the term "therapeutic foster care" means a foster care program that provides—

(1) to the child—

(A) structured daily activities that develop, improve, monitor, and reinforce age-appropriate social, communications, and behavioral skills;

(B) crisis intervention and crisis support services;

(C) medication monitoring;

(D) counseling; and

(E) case management services; and

(2) specialized training for the foster parent and consultation with the foster parent on the management of children with mental illnesses and related health and developmental conditions.

SEC. 1728. ASSURING ADEQUATE PAYMENT LEVELS FOR SERVICES.

(a) IN GENERAL.—Title XIX of the Social Security Act is amended by inserting after section 1925 the following new section:

"ASSURING ADEQUATE PAYMENT LEVELS FOR SERVICES

"SEC. 1926. (a) IN GENERAL.—A State plan under this title shall not be considered to meet the requirement of section 1902(a)(30)(A) for a year (beginning with 2011) unless, by not later than April 1 before the beginning of such year, the State submits to the Secretary an amendment to the plan that specifies the payment rates to be used for such services under the plan in such year and includes in such submission such additional data as will assist the Secretary in evaluating the State's compliance with such requirement, including data relating to how rates established for payments to medicaid managed care organizations under sections 1903(m) and 1932 take into account such payment rates.

"(b) SECRETARIAL REVIEW.—The Secretary, by not later than 90 days after the date of submission of a plan amendment under subsection (a), shall—

"(1) review each such amendment for compliance with the requirement of section 1902(a)(30)(A); and

"(2) approve or disapprove each such amendment.

If the Secretary disapproves such an amendment, the State shall immediately submit a revised amendment that meets such requirement.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date of the enactment of this Act.

SEC. 1729. PRESERVING MEDICAID COVERAGE FOR YOUTHS UPON RELEASE FROM PUBLIC INSTITUTIONS.

Section 1902(a) of the Social Security Act (42 U.S.C. 1396a), as amended by section 1631(b) and 1703(a), is amended—

(1) by striking "and" at the end of paragraph (74);

(2) by striking the period at the end of paragraph (75) and inserting "; and"; and

(3) by inserting after paragraph (75) the following new paragraph:

"(76) provide that in the case of any youth who is 18 years of age or younger, was enrolled for medical assistance under the State plan immediately before becoming an inmate of a public institution, is 18 years of age or younger upon release from such institution, and is eligible for such medical assistance under the State plan at the time of release from such institution—

"(A) during the period such youth is incarcerated in a public institution, the State shall not terminate eligibility for medical assistance under the State plan for such youth;

"(B) during the period such youth is incarcerated in a public institution, the State shall establish a process that ensures—

"(i) that the State does not claim federal financial participation for services that are provided to such youth and that are excluded under subsection 1905(a)(28)(A); and

"(ii) that the youth receives medical assistance for which federal participation is available under this title;

"(C) on or before the date such youth is released from such institution, the State shall ensure that such youth is enrolled for medical assistance under this title, unless and until there is a determination that the individual is no longer eligible to be so enrolled; and

"(D) the State shall ensure that enrollment under subparagraph (C) will be completed before such date so that the youth can access medical assistance under this title immediately upon leaving the institution."

SEC. 1730. QUALITY MEASURES FOR MATERNITY AND ADULT HEALTH SERVICES UNDER MEDICAID AND CHIP.

Title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by inserting after section 1139A the following new section:

"SEC. 1139B. QUALITY MEASURES FOR MATERNITY AND ADULT HEALTH SERVICES UNDER MEDICAID AND CHIP.

"(a) MATERNITY CARE QUALITY MEASURES UNDER MEDICAID AND CHIP.—

"(1) DEVELOPMENT OF MEASURES.—No later than January 1, 2011, the Secretary shall develop and publish for comment a proposed set of measures that accurately describe the quality of maternity care provided under State plans under titles XIX and XXI. The Secretary shall publish a final recommended set of such measures no later than July 1, 2011.

"(2) STANDARDIZED REPORTING FORMAT.—No later than January 1, 2012, the Secretary shall develop and publish a standardized reporting format for maternity care quality measures for use by State programs under titles XIX and XXI to collect data from managed care entities and providers and practitioners that participate in such programs and to report maternity care quality measures to the Secretary.

"(b) OTHER ADULT HEALTH QUALITY MEASURES UNDER MEDICAID.—

"(1) DEVELOPMENT OF MEASURES.—The Secretary shall develop quality measures that are not otherwise developed under section 1192 for services received under State plans under title XIX by individuals who are 21 years of age or older but have not attained age 65. The Secretary shall publish such quality measures through notice and comment rulemaking.

"(2) STANDARDIZED REPORTING FORMAT.—The Secretary shall develop and publish a standardized reporting format for quality measures developed under paragraph (1) and section 1192 for services furnished under State plans under title XIX to individuals who are 21 years of age or older but have not attained age 65 for use under such plans and State plans under title XXI. The format shall enable State agencies administering such plans to collect data from managed care entities and providers and practitioners that participate in such plans and to report quality measures to the Secretary.

"(c) DEVELOPMENT PROCESS.—With respect to the development of quality measures under subsections (a) and (b)—

"(1) USE OF QUALIFIED ENTITIES.—The Secretary may enter into agreements with public, nonprofit, or academic institutions with technical expertise in the area of health quality measurement to assist in such development. The Secretary may carry out these agreements by contract, grant, or otherwise.

"(2) MULTI-STAKEHOLDER PRE-RULEMAKING INPUT.—The Secretary shall obtain the input of stakeholders with respect to such quality measures using a process similar to that described in section 1808(d).

"(3) COORDINATION.—The Secretary shall coordinate the development of such measures under such subsections and with the development of child health quality measures under section 1139A.

"(d) ANNUAL REPORT TO CONGRESS.—No later than January 1, 2013, and annually thereafter, the Secretary shall report to the Committee on Energy and Commerce of the House of Representatives the Committee on Finance of the Senate regarding—

"(1) the availability of reliable data relating to the quality of maternity care furnished under State plans under titles XIX and XXI;

"(2) the availability of reliable data relating to the quality of services furnished under State plans under title XIX to adults who are 21 years of age or older but have not attained age 65; and

"(3) recommendations for improving the quality of such care and services furnished under such State plans.

"(e) RULE OF CONSTRUCTION.—Notwithstanding any other provision in this section, no quality measure developed, published, or used as a basis of measurement or reporting under this section may be used to establish an irrefutable presumption regarding either the medical necessity of care or the maximum permissible coverage for any individual who receives medical assistance under title XIX or child health assistance under title XXI.

"(f) APPROPRIATION.—For purposes of carrying out this section, in addition to funds otherwise available, out of any funds in the Treasury not otherwise appropriated, there are appropriated $40,000,000 for the 5-fiscal-year period beginning with fiscal year 2010. Funds appropriated under this subsection shall remain available until expended.".

SEC. 1730A. ACCOUNTABLE CARE ORGANIZATION PILOT PROGRAM.

(a) IN GENERAL.—The Secretary of Health and Human Services shall establish under this section an accountable care program under which a State may apply to the Secretary for approval of an accountable care organization pilot program described in subsection (b) (in this section referred to as a "pilot program") for the application of the accountable care organization concept under title XIX of the Social Security Act.

(b) PILOT PROGRAM DESCRIBED.—

(1) IN GENERAL.—The pilot program described in this subsection is a program that applies one or more of the accountable care organization models described in section 1866E of the Social Security Act, as added by section 1301 of this Act.

(2) LIMITATION.—The pilot program shall operate for a period of not more than 5 years.

(c) ADDITIONAL INCENTIVES.—In the case of the pilot program under this section, the Secretary may—

(1) waive the requirements of—

(A) section 1902(a)(1) of the Social Security Act (relating to statewideness);

(B) section 1902(a)(10)(B) of such Act (relating to comparability); and

(2) increase the matching percentage for administrative expenditures up to—

(A) 90 percent (for the first 2 years of the pilot program); and

(B) 75 percent (for the next 3 years).

(d) EVALUATION; REPORT.—

(1) EVALUATION.—The Secretary, using the criteria described in section 1866D(f)(1) of the Social Security Act (as inserted by section 1301 of this Act), shall conduct an evaluation of the pilot program under this section.

(2) REPORT.—Not later than 60 days after the date of completion of the evaluation under paragraph (1), the Secretary shall submit to Congress and make available to the public a report on the findings of the evaluation under such paragraph.

Subtitle D—Coverage

SEC. 1731. OPTIONAL MEDICAID COVERAGE OF LOW-INCOME HIV-INFECTED INDIVIDUALS.

(a) IN GENERAL.— Section 1902 of the Social Security Act (42 U.S.C. 1396a), as amended by section 1714(a)(1), is amended—

(1) in subsection (a)(10)(A)(ii)—

(A) by striking "or" at the end of subclause (XIX);

(B) by adding "or" at the end of subclause (XX); and

(C) by adding at the end the following:

"(XXI) who are described in subsection (ii) (relating to HIV-infected individuals);"; and

(2) by adding at the end, as amended by sections 1703 and 1714(a), the following:

"(ii) Individuals described in this subsection are individuals not described in subsection (a)(10)(A)(i)—

"(1) who have HIV infection;

"(2) whose income (as determined under the State plan under this title with respect to disabled individuals) does not exceed the maximum amount of income a disabled individual described in subsection (a)(10)(A)(i) may have and obtain medical assistance under the plan; and

"(3) whose resources (as determined under the State plan under this title with respect to disabled individuals) do not exceed the maximum amount of resources a disabled individual described in subsection (a)(10)(A)(i) may have and obtain medical assistance under the plan.".

(b) ENHANCED MATCH.—The first sentence of section 1905(b) of such Act (42 U.S.C. 1396d(b)) is amended by striking "section 1902(a)(10)(A)(ii)(XVIII)" and inserting "subclause (XVIII) or (XXI) of section 1902(a)(10)(A)(ii)".

(c) CONFORMING AMENDMENTS.—Section 1905(a) of such Act (42 U.S.C. 1396d(a)) is amended, in the matter preceding paragraph (1)—

(1) by striking "or" at the end of clause (xii);

(2) by adding "or" at the end of clause (xiii); and

(3) by inserting after clause (xiii) the following:

"(xiv) individuals described in section 1902(ii),".

(d) EXEMPTION FROM FUNDING LIMITATION FOR TERRITORIES.—Section 1108(g) of the Social Security Act (42 U.S.C. 1308(g)) is amended by adding at the end the following:

"(5) DISREGARDING MEDICAL ASSISTANCE FOR OPTIONAL LOW-INCOME HIV-INFECTED INDIVIDUALS.—The limitations under subsection (f) and the previous provisions of this subsection shall not apply to amounts expended for medical assistance for individuals described in section 1902(ii) who are only eligible for such assistance on the basis of section 1902(a)(10)(A)(ii)(XXI).".

(e) EFFECTIVE DATE; SUNSET.—The amendments made by this section shall apply to expenditures for calendar quarters beginning on or after the date of the enactment of this Act, and before January 1, 2013, without regard to whether or not final regulations to carry out such amendments have been promulgated by such date.

SEC. 1732. EXTENDING TRANSITIONAL MEDICAID ASSISTANCE (TMA).

Sections 1902(e)(1)(B) and 1925(f) of the Social Security Act (42 U.S.C. 1396a(e)(1)(B), 1396r–6(f)), as amended by section 5004(a)(1) of the American Recovery and Reinvestment Act of 2009 (Public Law 111–5), are each amended by striking "December 31, 2010" and inserting "December 31, 2012".

SEC. 1733. REQUIREMENT OF 12-MONTH CONTINUOUS COVERAGE UNDER CERTAIN CHIP PROGRAMS.

(a) IN GENERAL.—Section 2102(b) of the Social Security Act (42 U.S.C. 1397bb(b)) is amended by adding at the end the following new paragraph:

"(6) REQUIREMENT FOR 12-MONTH CONTINUOUS ELIGIBILITY.—In the case of a State child health plan that provides child health assistance under this title through a means other than described in section 2101(a)(2), the plan shall provide for implementation under this title of the 12-month continuous eligibility option described in section 1902(e)(12) for targeted low-income children whose family income is below 200 percent of the poverty line.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to determinations (and redeterminations) of eligibility made on or after January 1, 2010.

SEC. 1734. PREVENTING THE APPLICATION UNDER CHIP OF COVERAGE WAITING PERIODS FOR CERTAIN CHILDREN.

(a) IN GENERAL.—Section 2102(b)(1) of the Social Security Act (42 U.S.C. 1397bb(b)(1)) is amended—

(1) in subparagraph (B)—

(A) in clause (iii), by striking "and" at the end;

(B) in clause (iv), by striking the period at the end and inserting "; and"; and

(C) by adding at the end the following new clause:

"(v) may not apply a waiting period (including a waiting period to carry out paragraph (3)(C)) in the case of a child described in subparagraph (C).";

(2) by adding at the end the following new subparagraph:

"(C) DESCRIPTION OF CHILDREN NOT SUBJECT TO WAITING PERIOD.—For purposes of this paragraph, a child described in this subparagraph is a child who, on the date an application is submitted for such child for child health assistance under this title, meets any of the following requirements:

"(i) INFANTS AND TODDLERS.—The child is under two years of age.

"(ii) LOSS OF GROUP HEALTH PLAN COVERAGE.—The child previously had private health insurance coverage through a group health plan or health insurance coverage offered through an employer and lost such coverage due to—

"(I) termination of an individual's employment;

"(II) a reduction in hours that an individual works for an employer;

"(III) elimination of an individual's retiree health benefits; or

"(IV) termination of an individual's group health plan or health insurance coverage offered through an employer.

"(iii) UNAFFORDABLE PRIVATE COVERAGE.—

"(I) IN GENERAL.—The family of the child demonstrates that the cost of health insurance coverage (including the cost of premiums, co-payments, deductibles, and other cost sharing) for such family exceeds 10 percent of the income of such family.

"(II) DETERMINATION OF FAMILY INCOME.—For purposes of subclause (I), family income shall be determined in the same manner specified by the State for purposes of determining a child's eligibility for child health assistance under this title.".

(b) EFFECTIVE DATE.—The amendments made by this section shall take effect as of the date that is 90 days after the date of the enactment of this Act.

SEC. 1735. ADULT DAY HEALTH CARE SERVICES.

(a) IN GENERAL.—The Secretary of Health and Human Services shall not—

(1) withhold, suspend, disallow, or otherwise deny Federal financial participation under section 1903(a) of the Social Security Act (42 U.S.C. 1396b(a)) for the provision of adult day health care services, day activity and health services, or adult medical day care services, as defined under a State Medicaid plan approved during or before 1994, during such period if such services are provided consistent with such definition and the requirements of such plan; or

(2) withdraw Federal approval of any such State plan or part thereof regarding the provision of such services (by regulation or otherwise).

(b) EFFECTIVE DATE.—Subsection (a) shall apply with respect to services provided on or after October 1, 2008.

SEC. 1736. MEDICAID COVERAGE FOR CITIZENS OF FREELY ASSOCIATED STATES.

(a) IN GENERAL.—Section 402(b)(2) of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (8 U.S.C. 1612(b)(2)) is amended by adding at the end the following:

"(G) MEDICAID EXCEPTION FOR CITIZENS OF FREELY ASSOCIATED STATES.—With respect to eligibility for benefits for the designated Federal program defined in paragraph (3)(C) (relating to the Medicaid program), section 401(a) and paragraph (1) shall not apply to any individual who lawfully resides in the United States (including territories and possessions of the United States) in accordance with the Compacts of Free Association between the Government of the United States and the Governments of the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau.".

(b) EXCEPTION TO 5-YEAR LIMITED ELIGIBILITY.—Section 403(d) of such Act (8 U.S.C. 1613(d)) is amended—

(1) in paragraph (1), by striking "or" at the end;

(2) in paragraph (2), by striking the period at the end and inserting "; or"; and

(3) by adding at the end the following:

"(3) an individual described in section 402(b)(2)(G), but only with respect to the designated Federal program defined in section 402(b)(3)(C).".

(c) DEFINITION OF QUALIFIED ALIEN.—Section 431(b) of such Act (8 U.S.C. 1641(b)) is amended—

(1) in paragraph (6), by striking "; or" at the end and inserting a comma;

(2) in paragraph (7), by striking the period at the end and inserting ", or"; and

(3) by adding at the end the following:

"(8) an individual who lawfully resides in the United States (including territories and possessions of the United States) in accordance with a Compact of Free Association referred to in section 402(b)(2)(G), but only with respect to the designated Federal program defined in section 402(b)(3)(C) (relating to the Medicaid program).".

SEC. 1737. CONTINUING REQUIREMENT OF MEDICAID COVERAGE OF NONEMERGENCY TRANSPORTATION TO MEDICALLY NECESSARY SERVICES.

(a) REQUIREMENT.—Section 1902(a)(10) of the Social Security Act (42 U.S.C. 1396a(a)(10)) is amended—

(1) in subparagraph (A), in the matter preceding clause (i), by striking "and (21)" and inserting ", (21), and (28)"; and

(2) in subparagraph (C)(iv), by striking "and (17)" and inserting ", (17), and (28)".

(b) DESCRIPTION OF SERVICES.—Section 1905(a) of such Act (42 U.S.C. 1395d(a)), as amended by sections 1713(a)(1) and 1724(a)(1), is amended—

(1) in paragraph (29), by striking "and" at the end;

(2) by redesignating paragraph (30) as pararaph (31) and by striking the comma at the end and inserting a semicolon; and

(3) by inserting after paragraph (29) the following new paragraph:

"(30) nonemergency transportation to medically necessary services, consistent with the requirement of section 431.53 of title 42, Code of Federal Regulations, as in effect as of June 1, 2008; and".

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date of the enactment of this Act and shall apply to transportation on or after such date.

SEC. 1738. STATE OPTION TO DISREGARD CERTAIN INCOME IN PROVIDING CONTINUED MEDICAID COVERAGE FOR CERTAIN INDIVIDUALS WITH EXTREMELY HIGH PRESCRIPTION COSTS.

Section 1902(e) of the Social Security Act (42 U.S.C. 1396b(e)), as amended by section 203(a) of the Children's Health Insurance Program Reauthorization Act of 2009 (Public Law 111–3), is amended by adding at the end the following new paragraph:

"(14)(A) At the option of the State, in the case of an individual with extremely high prescription drug costs described in subparagraph (B) who has been determined (without the application of this paragraph) to be eligible for medical assistance under this title, the State may, in redetermining the individual's eligibility for medical assistance under this title, disregard any family income of the individual to the extent such income is less than an amount that is specified by the State and does not exceed the amount specified in subparagraph (C), or, if greater, income equal to the cost of the orphan drugs described in subparagraph (B)(iii).

"(B) An individual with extremely high prescription drug costs described in this subparagraph for a 12-month period is an individual—

"(i) who is covered under health insurance or a health benefits plan that has a maximum lifetime limit of not less than $1,000,000 which includes all prescription drug coverage;

"(ii) who has exhausted all available prescription drug coverage under the plan as of the beginning of such period;

"(iii) who incurs (or is reasonably expected to incur) on an annual basis during the period costs for orphan drugs in excess of the amount specified in subparagraph (C) for the period; and

"(iv) whose annual family income (determined without regard to this paragraph) as of the beginning of the period does not exceed 75 percent of the amount incurred for such drugs (as described in clause (iii)).

"(C) The amount specified in this subparagraph for a 12-month period beginning in—

"(i) 2009 or 2010, is $200,000; or

"(ii) a subsequent year, is the amount specified in clause (i) (or this subparagraph) for the previous year increased by the annual rate of increase in the medical care component of the consumer price index (U.S. city average) for the 12-month period ending in August of the previous year.

Any amount computed under clause (ii) that is not a multiple of $1,000 shall be rounded to the nearest multiple of $1,000.

"(D) In applying this paragraph, amounts incurred for prescription drugs for cosmetic purposes shall not be taken into account.

"(E) With respect to an individual described in subparagraph (A), notwithstanding section 1916, the State plan—

"(i) shall provide for the application of cost-sharing that is at least nominal as determined under section 1916; and

"(ii) may provide, consistent with section 1916A, for such additional cost-sharing as does not exceed a maximum level of cost-sharing that is specified by the Secretary and is adjusted by the Secretary on an annual basis.

"(F) A State electing the option under this paragraph shall provide for a determination on an individual's application for continued medical assistance under this title within 30 days of the date the application if filed with the State.

"(G) In this paragraph:

"(i) The term 'orphan drugs' means prescription drugs designated under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) as a drug for a rare disease or condition.

"(ii) The term 'health benefits plan' includes coverage under a plan offered under a State high risk pool.".

Subtitle E—Financing

SEC. 1741. PAYMENTS TO PHARMACISTS.

(a) PHARMACY REIMBURSEMENT LIMITS.—

(1) IN GENERAL.—Section 1927(e) of the Social Security Act (42 U.S.C. 1396r–8(e)) is amended—

(A) by striking paragraph (5) and inserting the following:

"(5) USE OF AMP IN UPPER PAYMENT LIMITS.—The Secretary shall calculate the Federal upper reimbursement limit established under paragraph (4) as 130 percent of the weighted average (determined on the basis of manufacturer utilization) of monthly average manufacturer prices."

(2) DEFINITION OF AMP.—Section 1927(k)(1)(B) of such Act (42 U.S.C. 1396r–8(k)(1)(B)) is amended—

(B) in the heading, by striking "EXTENDED TO WHOLESALERS" and inserting "AND OTHER PAYMENTS"; and

(C) by striking "regard to" and all that follows through the period and inserting the following: "regard to—

"(i) customary prompt pay discounts extended to wholesalers;

"(ii) bona fide service fees paid by manufacturers;

"(iii) reimbursement by manufacturers for recalled, damaged, expired, or otherwise unsalable returned goods, including reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction;

"(iv) sales directly to, or rebates, discounts, or other price concessions provided to, pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers, mail order pharmacies that are not open to all members of the public, or long term care providers, provided that these rebates, discounts, or price concessions are not passed through to retail pharmacies;

"(v) sales directly to, or rebates, discounts, or other price concessions provided to, hospitals, clinics, and physicians, unless the drug is an inhalation, infusion, or injectable drug, or unless the Secretary determines, as allowed for in Agency administrative procedures, that it is necessary to include such sales, rebates, discounts, and price concessions in order to obtain an accurate AMP for the drug. Such a determination shall not be subject to judicial review; or

"(vi) rebates, discounts, and other price concessions required to be provided under agreements under subsections (f) and (g) of section 1860D–2(f).".

(3) MANUFACTURER REPORTING REQUIREMENTS.—Section 1927(b)(3)(A) of such Act (42 U.S.C. 1396r–8(b)(3)(A)) is amended—

(A) in clause (ii), by striking "and" at the end;

(B) by striking the period at the end of clause (iii) and inserting "; and"; and

(C) by inserting after clause (iii) the following new clause:

"(iv) not later than 30 days after the last day of each month of a rebate period under the agreement, on the manufacturer's total number of units that are used to calculate the monthly average manufacturer price for each covered outpatient drug.".

(4) AUTHORITY TO PROMULGATE REGULATION.—The Secretary of Health and Human Services may promulgate regulations to clarify the requirements for upper payment limits and for the determination of the average manufacturer price in an expedited manner. Such regulations may become effective on an interim final basis, pending opportunity for public comment.

(5) PHARMACY REIMBURSEMENTS THROUGH DECEMBER 31, 2010.—The specific upper limit under section 447.332 of title 42, Code of Federal Regulations (as in effect on December 31, 2006) applicable to payments made by a State for multiple source drugs under a State Medicaid plan shall continue to apply through December 31, 2010, for purposes of the availability of Federal financial participation for such payments.

(b) DISCLOSURE OF PRICE INFORMATION TO THE PUBLIC.—Section 1927(b)(3) of such Act (42 U.S.C. 1396r–8(b)(3)) is amended—

(1) in subparagraph (A)—

(A) in clause (i), in the matter preceding subclause (I), by inserting "month of a" after "each"; and

(B) in the last sentence, by striking "and shall," and all that follows up to the period; and

(2) in subparagraph (D)(v), by inserting "weighted" before "average manufacturer prices".

SEC. 1742. PRESCRIPTION DRUG REBATES.

(a) ADDITIONAL REBATE FOR NEW FORMULATIONS OF EXISTING DRUGS.—

(1) IN GENERAL.—Section 1927(c)(2) of the Social Security Act (42 U.S.C. 1396r–8(c)(2)) is amended by adding at the end the following new subparagraph:

"(C) TREATMENT OF NEW FORMULATIONS.—In the case of a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form, the rebate obligation with respect to such drug under this section shall be the amount computed under this section for such new drug or, if greater, the product of—

"(i) the average manufacturer price of the line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form;

"(ii) the highest additional rebate (calculated as a percentage of average manufacturer price) under this section for any strength of the original single source drug or innovator multiple source drug; and

"(iii) the total number of units of each dosage form and strength of the line extension product paid for under the State plan in the rebate period (as reported by the State).

In this subparagraph, the term 'line extension' means, with respect to a drug, an extended release formulation of the drug.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to drugs dispensed after December 31, 2009.

(b) INCREASE MINIMUM REBATE PERCENTAGE FOR SINGLE SOURCE DRUGS.—Section 1927(c)(1)(B)(i) of the Social Security Act (42 U.S.C. 1396r–8(c)(1)(B)(i)) is amended—

(1) in subclause (IV), by striking "and" at the end;

(2) in subclause (V)—

(A) by inserting "and before January 1, 2010" after "December 31, 1995,"; and

(B) by striking the period at the end and inserting "; and"; and

(3) by adding at the end the following new subclause:

"(VI) after December 31, 2009, is 22.1 percent.".

SEC. 1743. EXTENSION OF PRESCRIPTION DRUG DISCOUNTS TO ENROLLEES OF MEDICAID MANAGED CARE ORGANIZATIONS.

(a) IN GENERAL.—Section 1903(m)(2)(A) of the Social Security Act (42 U.S.C. 1396b(m)(2)(A)) is amended—

(1) in clause (xi), by striking "and" at the end;

(2) in clause (xii), by striking the period at the end and inserting "; and"; and

(3) by adding at the end the following:

"(xiii) such contract provides that the entity shall report to the State such information, on such timely and periodic basis as specified by the Secretary, as the State may require in order to include, in the information submitted by the State to a manufacturer under section 1927(b)(2)(A), information on covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled with the entity and for which the entity is responsible for coverage of such drugs under this subsection.".

(b) CONFORMING AMENDMENTS.—Section 1927 of such Act (42 U.S.C. 1396r-8) is amended——

(1) in the first sentence of subsection (b)(1)(A), by inserting before the period at the end the following: ", including such drugs dispensed to individuals enrolled with a medicaid managed care organization if the organization is responsible for coverage of such drugs";

(2) in subsection (b)(2), by adding at the end the following new subparagraph:

"(C) REPORTING ON MMCO DRUGS.—On a quarterly basis, each State shall report to the Secretary the total amount of rebates in dollars received from pharmacy manufacturers for drugs provided to individuals enrolled with Medicaid managed care organizations that contract under section 1903(m).";

and

(3) in subsection (j)—

(A) in the heading by striking "EXEMPTION" and inserting "SPECIAL RULES"; and

(B) in paragraph (1), by striking "not".

(c) EFFECTIVE DATE.—The amendments made by this section take effect on July 1, 2010, and shall apply to drugs dispensed on or after such date, without regard to whether or not final regulations to carry out such amendments have been promulgated by such date.

SEC. 1744. PAYMENTS FOR GRADUATE MEDICAL EDUCATION.

(a) IN GENERAL.—Section 1905 of the Social Security Act (42 U.S.C. 1396d), as amended by sections 1701(a)(2), 1711(a), and 1713(a), is amended by adding at the end the following new subsection:

"(bb) PAYMENT FOR GRADUATE MEDICAL EDUCATION.—

"(1) IN GENERAL.—The term 'medical assistance' includes payment for costs of graduate medical education consistent with this subsection, whether provided in or outside of a hospital.

"(2) SUBMISSION OF INFORMATION.—For purposes of paragraph (1) and section 1902(a)(13)(A)(v), payment for such costs is not consistent with this subsection unless—

"(A) the State submits to the Secretary, in a timely manner and on an annual basis specified by the Secretary, information on total payments for graduate medical education and how such payments are being used for graduate medical education, including—

"(i) the institutions and programs eligible for receiving the funding;

"(ii) the manner in which such payments are calculated;

"(iii) the types and fields of education being supported;

"(iv) the workforce or other goals to which the funding is being applied;

"(v) State progress in meeting such goals; and

"(vi) such other information as the Secretary determines will assist in carrying out paragraphs (3) and (4); and

"(B) such expenditures are made consistent with such goals and requirements as are established under paragraph (4).

"(3) REVIEW OF INFORMATION.—The Secretary shall make the information submitted under paragraph (2) available to the Advisory Committee on Health Workforce Evaluation and Assessment (established under section 2261 of the Public Health Service Act). The Secretary and the Advisory Committee shall independently review the information submitted under paragraph (2), taking into account State and local workforce needs.

"(4) SPECIFICATION OF GOALS AND REQUIREMENTS.—The Secretary shall specify by rule, initially published by not later than December 31, 2011—

"(A) program goals for the use of funds described in paragraph (1), taking into account recommendations of the such Advisory Committee and the goals for approved medical residency training programs described in section 1886(h)(1)(B); and

"(B) requirements for use of such funds consistent with such goals.

Such rule may be effective on an interim basis pending revision after an opportunity for public comment.".

(b) CONFORMING AMENDMENT.—Section 1902(a)(13)(A) of such Act (42 U.S.C. 1396a(a)(13)(A)), as amended by section 1721(a)(1)(A), is amended—

(1) by striking "and" at the end of clause (iii);

(2) by striking the semicolon in clause (iv) and inserting ", and"; and

(3) by adding at the end the following new clause:

"(v) in the case of hospitals and at the option of a State, such rates may include, to the extent consistent with section 1905(bb), payment for graduate medical education; and".

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect on the date of the enactment of this Act. Nothing in this section shall be construed as affecting payments made before such date under a State plan under title XIX of the Social Security Act for graduate medical education.

SEC. 1745. REPORT ON MEDICAID PAYMENTS.

Section 1902 of the Social Security Act (42 U.S.C. 1396), as amended by sections 1703(a), 1714(a), and 1731(a), is amended by adding at the end the following new subsection:

"(jj) REPORT ON MEDICAID PAYMENTS.—Each year, on or before a date determined by the Secretary, a State participating in the Medicaid program under this title shall submit to the Administrator of the Centers for Medicare & Medicaid Services—

"(1) information on the determination of rates of payment to providers for covered services under the State plan, including—

"(A) the final rates;

"(B) the methodologies used to determine such rates; and

"(C) justifications for the rates; and

"(2) an explanation of the process used by the State to allow providers, beneficiaries and their representatives, and other concerned State residents a reasonable opportunity to review and comment on such rates, methodologies, and justifications before the State made such rates final.".

SEC. 1746. REVIEWS OF MEDICAID.

(a) GAO STUDY ON FMAP.—.

(1) STUDY.—The Comptroller General of the United States shall conduct a study regarding federal payments made to the State Medicaid programs under title XIX of the Social Security Act for the purposes of making recommendations to Congress.

(2) REPORT.—Not later than February 15, 2011, the Comptroller General shall submit to the appropriate committees of Congress a report on the study conducted under paragraph (1) and the effect on the federal government, States, providers, and beneficiaries of—

(A) removing the 50 percent floor, or 83 percent ceiling, or both, in the Federal medical assistance percentage under section 1905(b)(1) of the Social Security Act; and

(B) revising the current formula for such Federal medical assistance percentage to better reflect State fiscal capacity and State effort to pay for

health and long-term care services and to better adjust for national or regional economic downturns.

(b) GAO STUDY ON MEDICAID ADMINISTRATIVE COSTS..—

(1) STUDY.—The Comptroller General of the United States shall conduct a study of the administration of the Medicaid program by the Department of Health and Human Services, State Medicaid agencies, and local government agencies. The report shall address the following issues:

(A) The extent to which federal funds for each administrative function, such as survey and certification and claims processing, are being used effectively and efficiently.

(B) The administrative functions on which federal Medicaid funds are expended and the amounts of such expenditures (whether spent directly or by contract).

(2) REPORT.—Not later than February 15, 2011, the Comptroller General shall submit to the appropriate committees of Congress a report on the study conducted under paragraph (1).

SEC. 1747. EXTENSION OF DELAY IN MANAGED CARE ORGANIZATION PROVIDER TAX ELIMINATION.

Effective as if included in the enactment of section 6051 of the Deficit Reduction Act of 2005 (Public Law 109–171), subsection (b)(2)(A) of such section is amended by striking "October 1, 2009" and inserting "October 1, 2010".

Subtitle F—Waste, Fraud, and Abuse

SEC. 1751. HEALTH CARE ACQUIRED CONDITIONS.

(a) MEDICAID NON-PAYMENT FOR CERTAIN HEALTH CARE-ACQUIRED CONDITIONS.—Section 1903(i) of the Social Security Act (42 U.S.C. 1396b(i)) is amended—

(1) by striking "or" at the end of paragraph (23);

(2) by striking the period at the end of paragraph (24) and inserting "; or"; and

(3) by inserting after paragraph (24) the following new paragraph:

"(25) with respect to amounts expended for services related to the presence of a condition that could be identified by a secondary diagnostic code described in section 1886(d)(4)(D)(iv) and for any health care acquired condition determined as a non-covered service under title XVIII.".

(b) APPLICATION TO CHIP.—Section 2107(e)(1)(G) of such Act (42 U.S.C. 1397gg(e)(1)(G)) is amended by striking "and (17)" and inserting "(17), and (25)".

(c) PERMISSION TO INCLUDE ADDITIONAL HEALTH CARE-ACQUIRED CONDITIONS.—Nothing in this section shall prevent a State from including additional health care-acquired conditions for non-payment in its Medicaid program under title XIX of the Social Security Act.

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to discharges occurring on or after January 1, 2010.

SEC. 1752. EVALUATIONS AND REPORTS REQUIRED UNDER MEDICAID INTEGRITY PROGRAM.

Section 1936(c)(2)) of the Social Security Act (42 U.S.C. 1396u–7(c)(2)) is amended—

(1) by redesignating subparagraph (D) as subparagraph (E); and

(2) by inserting after subparagraph (C) the following new subparagraph:

"(D) For the contract year beginning in 2011 and each subsequent contract year, the entity provides assurances to the satisfaction of the Secretary that the entity will conduct periodic evaluations of the effectiveness of the activities carried out by such entity under the Program and will submit to the Secretary an annual report on such activities.".

SEC. 1753. REQUIRE PROVIDERS AND SUPPLIERS TO ADOPT PROGRAMS TO REDUCE WASTE, FRAUD, AND ABUSE.

Section 1902(a) of such Act (42 U.S.C. 42 U.S.C. 1396a(a)), as amended by sections 1631(b)(1), 1703, and 1729, is further amended—

(1) in paragraph (75), by striking at the end "and";

(2) in paragraph (76), by striking at the end the period and inserting "; and"; and

(3) by inserting after paragraph (76) the following new paragraph:

"(77) provide that any provider or supplier (other than a physician or nursing facility) providing services under such plan shall, subject to paragraph (5) of section 1874(d), establish a compliance program described in paragraph (1) of such section in accordance with such section.".

SEC. 1754. OVERPAYMENTS.

(a) IN GENERAL.—Section 1903(d)(2)(C) of the Social Security Act (42 U.S.C. 1396b(d)(2)(C)) is amended—

(1) in the first sentence, by inserting "(or of 1 year in the case of overpayments due to fraud)" after "60 days"; and

(2) in the second sentence, by striking "the 60 days" and inserting "such period".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply in the case of overpayments discovered on or after the date of the enactment of this Act.

SEC. 1755. MANAGED CARE ORGANIZATIONS.

(a) MINIMUM MEDICAL LOSS RATIO.—

(1) MEDICAID.—Section 1903(m)(2)(A) of the Social Security Act (42 U.S.C. 1396b(m)(2)(A)), as amended by section 1743(a)(3), is amended—

(A) by striking "and" at the end of clause (xii);

(B) by striking the period at the end of clause (xiii) and inserting "; and"; and

(C) by adding at the end the following new clause:

"(xiv) such contract has a medical loss ratio, as determined in accordance with a methodology specified by the Secretary that is a percentage (not less than 85 percent) as specified by the Secretary.".

(2) CHIP.—Section 2107(e)(1) of such Act (42 U.S.C. 1397gg(e)(1)) is amended—

(A) by redesignating subparagraphs (H) through (L) as subparagraphs (I) through (M); and

(B) by inserting after subparagraph (G) the following new subparagraph:

"(H) Section 1903(m)(2)(A)(xiv) (relating to application of minimum loss ratios), with respect to comparable contracts under this title.".

(3) EFFECTIVE DATE.—The amendments made by this subsection shall apply to contracts entered into or renewed on or after July 1, 2010.

(b) PATIENT ENCOUNTER DATA.—

(1) IN GENERAL.—Section 1903(m)(2)(A)(xi) of the Social Security Act (42 U.S.C. 1396b(m)(2)(A)(xi)) is amended by inserting "and for the provision of such data to the State at a frequency and level of detail to be specified by the Secretary" after "patients".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply with respect to contract years beginning on or after January 1, 2010.

SEC. 1756. TERMINATION OF PROVIDER PARTICIPATION UNDER MEDICAID AND CHIP IF TERMINATED UNDER MEDICARE OR OTHER STATE PLAN OR CHILD HEALTH PLAN.

(a) STATE PLAN REQUIREMENT.—Section 1902(a)(39) of the Social Security Act (42 U.S.C. 42 U.S.C. 1396a(a)) is amended by inserting after "1128A," the following: "terminate the participation of any individual or entity in such program if (subject to such exceptions are are permitted with respect to exclusion under sections 1128(b)(3)(C) and 1128(d)(3)(B)) participation of such individual or entity is terminated under title XVIII, any other State plan under this title, or any child health plan under title XXI,".

(b) APPLICATION TO CHIP.—Section 2107(e)(1)(A) of such Act (42 U.S.C. 1397gg(e)(1)(A)) is amended by inserting before the period at the end the following: "and section 1902(a)(39) (relating to exclusion and termination of participation)".

(c) EFFECTIVE DATE.—

(1) Except as provided in paragraph (2), the amendments made by this section shall apply to services furnished on or after January 1, 2011, without regard to whether or not final regulations to carry out such amendments have been promulgated by such date.

(2) In the case of a State plan for medical assistance under title XIX of the Social Security Act or a child health plan under title XXI of such Act which the Secretary of Health and Human Services determines requires State legislation (other than legislation appropriating funds) in order for the plan to meet the additional requirement imposed by the amendments made by this section, the State plan or child health plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet this additional requirement before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of the enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of such session shall be deemed to be a separate regular session of the State legislature.

SEC. 1757. MEDICAID AND CHIP EXCLUSION FROM PARTICIPATION RELATING TO CERTAIN OWNERSHIP, CONTROL, AND MANAGEMENT AFFILIATIONS.

(a) STATE PLAN REQUIREMENT.—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)), as amended by sections 1631(b)(1), 1703(a), 1729, and 1753, is further amended—

(1) in paragraph (76), by striking at the end "and";

(2) in paragraph (77), by striking at the end the period and inserting "; and"; and

(3) by inserting after paragraph (77) the following new paragraph:

"(78) provide that the State agency described in paragraph (9) exclude, with respect to a period, any individual or entity from participation in the program under the State plan if such individual or entity owns, controls, or manages an entity that (or if such entity is owned, controlled, or managed by an individual or entity that)—

"(A) has unpaid overpayments under this title during such period determined by the Secretary or the State agency to be delinquent;

"(B) is suspended or excluded from participation under or whose participation is terminated under this title during such period; or

"(C) is affiliated with an individual or entity that has been suspended or excluded from participation under this title or whose participation is terminated under this title during such period.".

(b) CHILD HEALTH PLAN REQUIREMENT.—Section 2107(e)(1)(A) of such Act (42 U.S.C. 1397gg(e)(1)(A)), as amended by section 1756(b), is amended by striking "section 1902(a)(39)" and inserting "sections 1902(a)(39) and 1902(a)(78)".

(c) EFFECTIVE DATE.—

(1) Except as provided in paragraph (2), the amendments made by this section shall apply to services furnished on or after January 1, 2011, without regard to whether or not final regulations to carry out such amendments have been promulgated by such date.

(2) In the case of a State plan for medical assistance under title XIX of the Social Security Act or a child health plan under title XXI of such Act which the Secretary of Health and Human Services determines requires State legislation (other than legislation appropriating funds) in order for the plan to meet the additional requirement imposed by the amendments made by this section, the State plan or child health plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet this additional requirement before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of the enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of such session shall be deemed to be a separate regular session of the State legislature.

SEC. 1758. REQUIREMENT TO REPORT EXPANDED SET OF DATA ELEMENTS UNDER MMIS TO DETECT FRAUD AND ABUSE.

Section 1903(r)(1)(F) of the Social Security Act (42 U.S.C. 1396b(r)(1)(F)) is amended by inserting after "necessary" the following: "and including, for data submitted to the Secretary on or after July 1, 2010, data elements from the automated data system that the Secretary determines to be necessary for detection of waste, fraud, and abuse".

SEC. 1759. BILLING AGENTS, CLEARINGHOUSES, OR OTHER ALTERNATE PAYEES REQUIRED TO REGISTER UNDER MEDICAID.

(a) IN GENERAL.—Section 1902(a) of the Social Security Act (42 U.S.C. 42 U.S.C. 1396a(a)), as amended by sections 1631(b), 1703(a), 1729, 1753, and 1757(a), is further amended—

(1) in paragraph (77); by striking at the end "and";

(2) in paragraph (78), by striking the period at the end and inserting "and"; and

(3) by inserting after paragraph (78) the following new paragraph:

"(79) provide that any agent, clearinghouse, or other alternate payee that submits claims on behalf of a health care provider must register with the State and the Secretary in a form and manner specified by the Secretary under section 1866(j)(1)(D).".

(b) DENIAL OF PAYMENT.—Section 1903(i) of such Act (42 U.S.C. 1396b(i)), as amended by section 1751, is amended—

(1) by striking "or" at the end of paragraph (24);

(2) by striking the period at the end of paragraph (25) and inserting "; or"; and

(3) by inserting after paragraph (25) the following new paragraph:

"(26) with respect to any amount paid to a billing agent, clearinghouse, or other alternate payee that is not registered with the State and the Secretary as required under section 1902(a)(79).".

(c) EFFECTIVE DATE.—

(1) Except as provided in paragraph (2), the amendments made by this section shall apply to claims submitted on or after January 1, 2012, without regard to whether or not final regulations to carry out such amendments have been promulgated by such date.

(2) In the case of a State plan for medical assistance under title XIX of the Social Security Act which the Secretary of Health and Human Services determines requires State legislation (other than legislation appropriating funds) in order for the plan to meet the additional requirement imposed by the amendments made by this section, the State plan or child health plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet this additional requirement before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of the enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of such session shall be deemed to be a separate regular session of the State legislature.

SEC. 1760. DENIAL OF PAYMENTS FOR LITIGATION-RELATED MISCONDUCT.

(a) IN GENERAL.—Section 1903(i) of the Social Security Act (42 U.S.C. 1396b(i)), as amended by sections 1751(a) and 1759(b), is amended—

(1) by striking "or" at the end of paragraph (25);

(2) by striking the period at the end of paragraph (26) and inserting "; or"; and

(3) by inserting after paragraph (26) the following new paragraph:

"(27) with respect to any amount expended—

"(A) on litigation in which a court imposes sanctions on the State, its employees, or its counsel for litigation-related misconduct; or

"(B) to reimburse (or otherwise compensate) a managed care entity for payment of legal expenses associated with any action in which a court imposes sanctions on the managed care entity for litigation-related misconduct.".

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall apply to amounts expended on or after January 1, 2010.

SEC. 1761. MANDATORY STATE USE OF NATIONAL CORRECT CODING INITIATIVE.

(a) IN GENERAL.—Section 1903(r) of the Social Security Act (42 U.S.C. 1396b(r)) is amended—

(1) in paragraph (1)(B)—

(A) in clause (ii), by striking "and" at the end;

(B) in clause (iii), by adding "and" after the semicolon; and

(C) by adding at the end the following new clause:

"(iv) effective for claims filed on or after October 1, 2010, incorporate compatible methodologies of the National Correct Coding Initiative administered by the Secretary (or any successor initiative to promote correct coding and to control improper coding leading to inappropriate payment) and such other methodologies of that Initiative (or such other national correct coding methodologies) as the Secretary identifies in accordance with paragraph (3);"; and

(2) by adding at the end the following new paragraph:

"(3) Not later than September 1, 2010, the Secretary shall do the following:

"(A) Identify those methodologies of the National Correct Coding Initiative administered by the Secretary (or any successor initiative to promote correct coding and to control improper coding leading to inappropriate payment) which are compatible to claims filed under this title.

"(B) Identify those methodologies of such Initiative (or such other national correct coding methodologies) that should be incorporated into claims filed under this title with respect to items or services for which States provide medical assistance under this title and no national correct coding methodologies have been established under such Initiative with respect to title XVIII.

"(C) Notify States of—

"(i) the methodologies identified under subparagraphs (A) and (B) (and of any other national correct coding methodologies identified under subparagraph (B)); and

"(ii) how States are to incorporate such methodologies into claims filed under this title.

"(D) Submit a report to Congress that includes the notice to States under subparagraph (C) and an analysis supporting the identification of the methodologies made under subparagraphs (A) and (B).".

(b) EXTENSION FOR STATE LAW AMENDMENT.—In the case of a State plan under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.) which the Secretary of Health and Human Services determines requires State legislation in order for the plan to meet the additional requirements imposed by the amendment made by subsection (a)(1)(C), the State plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet these additional requirements before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of the session is considered to be a separate regular session of the State legislature.

Subtitle G—Payments to the Territories

SEC. 1771. PAYMENT TO TERRITORIES.

(a) INCREASE IN CAP.—Section 1108 of the Social Security Act (42 U.S.C. 1308) is amended—

(1) in subsection (f), by striking "subsection (g)" and inserting "subsections (g) and (h)";

(2) in subsection (g)(1), by striking "With respect to" and inserting "Subject to subsection (h), with respect to"; and

(3) by adding at the end the following new subsection:

"(h) ADDITIONAL INCREASE FOR FISCAL YEARS 2011 THROUGH 2019.—With respect to fiscal years 2011 through 2019, the amounts otherwise determined under subsections (f) and (g) for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa shall be increased by the following amounts:

"(1) For Puerto Rico, for fiscal year 2011, $727,600,000; for fiscal year 2012, $775,000,000; for fiscal year 2013, $850,000,000; for fiscal year 2014, $925,000,000; for fiscal year 2015, $1,000,000,000; for fiscal year 2016, $1,075,000,000; for fiscal year 2017, $1,150,000,000; for fiscal year 2018, $1,225,000,000; and for fiscal year 2019, $1,396,400,000.

"(2) For the Virgin Islands, for fiscal year 2011, $34,000,000; for fiscal year 2012, $37,000,000; for fiscal year 2013, $40,000,000; for fiscal year 2014, $43,000,000; for fiscal year 2015, $46,000,000; for fiscal year 2016, $49,000,000; for fiscal year 2017, $52,000,000; for fiscal year 2018, $55,000,000; and for fiscal year 2019, $58,000,000.

"(3) For Guam, for fiscal year 2011, $34,000,000; for fiscal year 2012, $37,000,000; for fiscal year 2013, $40,000,000; for fiscal year 2014, $43,000,000; for fiscal year 2015, $46,000,000; for fiscal year 2016, $49,000,000; for fiscal year 2017, $52,000,000; for fiscal year 2018, $55,000,000; and for fiscal year 2019, $58,000,000.

"(4) For the Northern Mariana Islands, for fiscal year 2011, $13,500,000; fiscal year 2012, $14,500,000; for fiscal year 2013, $15,500,000; for fiscal year 2014, $16,500,000; for fiscal year 2015, $17,500,000; for fiscal year 2016, $18,500,000; for fiscal year 2017, $19,500,000; for fiscal year 2018, $21,000,000; and for fiscal year 2019, $22,000,000.

"(5) For American Samoa, fiscal year 2011, $22,000,000; fiscal year 2012, $23,687,500; for fiscal year 2013, $24,687,500; for fiscal year 2014, $25,687,500; for fiscal year 2015, $26,687,500; for fiscal year 2016, $27,687,500; for fiscal year 2017, $28,687,500; for fiscal year 2018, $29,687,500; and for fiscal year 2019, $30,687,500.".

(b) REPORT ON ACHIEVING MEDICAID PARITY PAYMENTS BEGINNING WITH FISCAL YEAR 2020.—

(1) IN GENERAL.—Not later than October 1, 2013, the Secretary of Health and Human Services shall submit to Congress a report that details a plan for the transition of each territory to full parity in Medicaid with the 50 States and the District of Columbia in fiscal year 2020 by modifying their existing Medicaid programs and outlining actions the Secretary and the governments of each territory must take by fiscal year 2020 to ensure parity in financing. Such report shall include what the Federal medical assistance percentages would be for each territory if the formula applicable to the 50 States were applied. Such report shall also include any recommendations that the Secretary may have as to whether the mandatory ceiling amounts for each territory provided for in section 1108 of the Social Security Act (42 U.S.C. 1308) should be increased any

time before fiscal year 2020 due to any factors that the Secretary deems relevant.

(2) PER CAPITA DATA.—As part of such report the Secretary shall include information about per capita income data that could be used to calculate Federal medical assistance percentages under section 1905(b) of the Social Security Act, under section 1108(a)(8)(B) of such Act, for each territory on how such data differ from the per capita income data used to promulgate Federal medical assistance percentages for the 50 States. The report under this subsection shall include recommendations on how the Federal medical assistance percentages can be calculated for the territories beginning in fiscal year 2020 to ensure parity with the 50 States.

(3) SUBSEQUENT REPORTS.—The Secretary shall submit subsequent reports to Congress in 2015, 2017, and 2019 detailing the progress that the Secretary and the governments of each territory have made in fulfilling the actions outlined in the plan submitted under paragraph (1).

(c) APPLICATION OF FMAP FOR ADDITIONAL FUNDS.—Section 1905(b) of such Act (42 U.S.C. 1396d(b)) is amended by adding at the end the following sentence: "Notwithstanding the first sentence of this subsection and any other provision of law, for fiscal years 2011 through 2019, the Federal medical assistance percentage for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa shall be the highest Federal medical assistance percentage applicable to any of the 50 States or the District of Columbia for the fiscal year involved, taking into account the application of subsections (a) and (b)(1) of section 5001 of division B of the American Recovery and Reinvestment Act of 2009 (Public Law 111–5) to such States and the District for calendar quarters during such fiscal years for which such subsections apply.".

(d) WAIVERS.—

(1) IN GENERAL.—Section 1902(j) of the Social Security Act (42 U.S.C. 1396a(j)) is amended—

(A) by striking "American Samoa and the Northern Mariana Islands" and inserting "Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa"; and

(B) by striking "American Samoa or the Northern Mariana Islands" and inserting "Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, or American Samoa".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply beginning with fiscal year 2011.

(e) TECHNICAL ASSISTANCE.—The Secretary shall provide technical assistance to the governments of Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa in upgrading their existing computer systems in order to anticipate meeting reporting requirements necessary to implement the plan contained in the report under subsection (b)(1). The provision of such technical assistance shall not be counted against any limitation on payment to the territories under section 1108 of the Social Security Act.

Subtitle H—Miscellaneous

SEC. 1781. TECHNICAL CORRECTIONS.

(a) TECHNICAL CORRECTION TO SECTION 1144 OF THE SOCIAL SECURITY ACT.—The first sentence of section 1144(c)(3) of the Social Security Act (42 U.S.C. 1320b—14(c)(3)) is amended—

(1) by striking "transmittal"; and

(2) by inserting before the period the following: "as specified in section 1935(a)(4)".

(b) CLARIFYING AMENDMENT TO SECTION 1935 OF THE SOCIAL SECURITY ACT.—Section 1935(a)(4) of the Social Security Act (42 U.S.C. 1396u—5(a)(4)), as amended by section 113(b) of Public Law 110–275, is amended—

(1) by striking the second sentence;

(2) by redesignating the first sentence as a subparagraph (A) with appropriate indentation and with the following heading: "IN GENERAL.—";

(3) by adding at the end the following subparagraphs:

"(B) FURNISHING MEDICAL ASSISTANCE WITH REASONABLE PROMPTNESS.—For the purpose of a State's obligation under section 1902(a)(8) to furnish medical assistance with reasonable promptness, the date of the electronic transmission of low-income subsidy program data, as described in section 1144(c), from the Commissioner of Social Security to the State Medicaid Agency, shall constitute the date of filing of such application for benefits under the Medicare Savings Program.

"(C) DETERMINING AVAILABILITY OF MEDICAL ASSISTANCE.—For the purpose of determining when medical assistance will be made available, the State shall consider the date of the individual's application for the low income subsidy program to constitute the date of filing for benefits under the Medicare Savings Program.".

(c) EFFECTIVE DATE RELATING TO MEDICAID AGENCY CONSIDERATION OF LOW-INCOME SUBSIDY APPLICATION AND DATA TRANSMITTAL.—The amendments made by subsections (a) and (b) shall be effective as if included in the enactment of section 113(b) of Public Law 110–275.

(d) TECHNICAL CORRECTION TO SECTION 605 OF CHIPRA.—Section 605 of the Children's Health Insurance Program Reauthorization Act of 2009 (Public Law 111–3) is amended by striking "legal residents" and inserting "lawfully residing in the United States".

(e) TECHNICAL CORRECTION TO SECTION 1905 OF THE SOCIAL SECURITY ACT.—Section 1905(a) of the Social Security Act (42 U.S.C. 1396d(a)) is amended by inserting "or the care and services themselves, or both" before "(if provided in or after".

(f) CLARIFYING AMENDMENT TO SECTION 1115 OF THE SOCIAL SECURITY ACT.—Section 1115(a) of the Social Security Act (42 U.S.C. 1315(a)) is amended by adding at the end the following: "If an experimental, pilot, or demonstration project that relates to title XIX is approved pursuant to any part of this subsection, such project shall be treated as part of the State plan, all medical assistance provided on behalf of any individuals affected by such project shall be medical assistance provided under the State plan, and all provisions of this Act not explicitly waived in approving such project shall remain fully applicable to all individuals receiving benefits under the State plan.".

SEC. 1782. EXTENSION OF QI PROGRAM.

(a) IN GENERAL.—Section 1902(a)(10)(E)(iv) of the Social Security Act (42 U.S.C. 1396b(a)(10)(E)(iv)) is amended—

(1) by striking "sections 1933 and" and by inserting "section"; and

(2) by striking "December 2010" and inserting "December 2012".

(b) ELIMINATION OF FUNDING LIMITATION.—

(1) IN GENERAL.—Section 1933 of such Act (42 U.S.C. 1396u–3) is amended—

(A) in subsection (a), by striking "who are selected to receive such assistance under subsection (b)";

(B) by striking subsections (b), (c), (e), and (g);

(C) in subsection (d), by striking "furnished in a State" and all that follows and inserting "the Federal medical assistance percentage shall be equal to 100 percent."; and

(D) by redesignating subsections (d) and (f) as subsections (b) and (c), respectively.

(2) CONFORMING AMENDMENT.—Section 1905(b) of such Act (42 U.S.C. 1396d(b)) is amended by striking "1933(d)" and inserting "1933(b)".

(3) EFFECTIVE DATE.—The amendments made by paragraph (1) shall take effect on January 1, 2011.

SEC. 1783. OUTREACH AND ENROLLMENT OF MEDICAID AND CHIP ELIGIBLE INDIVIDUALS.

(a) IN GENERAL.—Not later than 12 months after date of enactment of this Act, the Secretary of Health and Human Services shall issue guidance regarding standards and best practices for conducting outreach to inform eligible individuals about healthcare coverage under Medicaid under title XIX of the Social Security Act or for child health assistance under CHIP under title XXI of such Act, providing assistance to such individuals for enrollment in applicable programs, and establishing methods or procedures for eliminating application and enrollment barriers. Such guidance shall include provisions to ensure that outreach, enrollment assistance, and administrative simplification efforts are targeted specifically to vulnerable populations such as children, unaccompanied homeless youth, victims of abuse or trauma, individuals with mental health or substance related disorders, and individuals with HIV/AIDS. Guidance issued pursuant to this section relating to methods to increase outreach and enrollment provided for under titles XIX and XXI of the Social Security Act shall specifically target such vulnerable and underserved populations and shall include, but not be limited to, guidance on outstationing of eligibility workers, express lane eligibility, residence requirements, documentation of income and assets, presumptive eligibility, continuous eligibility, and automatic renewal.

(b) IMPLEMENTATION.—In implementing the requirements under subsection (a), the Secretary may use such authorities as are available under law and may work with such entities as the Secretary deems appropriate to facilitate effective implementation of such programs. Not later than 2 years after the enactment of this Act and annually thereafter, the Secretary shall review and report to Congress on progress in implementing targeted outreach, application and enrollment assistance,

and administrative simplification methods for such vulnerable and underserved populations as are specified in subsection (a).

SEC. 1784. PROHIBITIONS ON FEDERAL MEDICAID AND CHIP PAYMENT FOR UNDOCUMENTED ALIENS.

Nothing in this title shall change current prohibitions against Federal Medicaid and CHIP payments under titles XIX and XXI of the Social Security Act on behalf of individuals who are not lawfully present in the United States.

SEC. 1785. DEMONSTRATION PROJECT FOR STABILIZATION OF EMERGENCY MEDICAL CONDITIONS BY NONPUBLICLY OWNED OR OPERATED INSTITUTIONS FOR MENTAL DISEASES.

(a) AUTHORITY TO CONDUCT DEMONSTRATION PROJECT.—The Secretary of Health and Human Services (in this section referred to as the "Secretary") shall establish a demonstration project under which an eligible State (as described in subsection (c)) shall provide reimbursement under the State Medicaid plan under title XIX of the Social Security Act to an institution for mental diseases that is not publicly owned or operated and that is subject to the requirements of section 1867 of the Social Security Act (42 U.S.C. 1395dd) for the provision of medical assistance available under such plan to an individual who—

(1) has attained age 21, but has not attained age 65;

(2) is eligible for medical assistance under such plan; and

(3) requires such medical assistance to stabilize an emergency medical condition.

(b) IN-STAY REVIEW.—The Secretary shall establish a mechanism for in-stay review to determine whether or not the patient has been stabilized (as defined in subsection (h)(5)). This mechanism shall commence before the third day of the inpatient stay. States participating in the demonstration project may manage the provision of these benefits under the project through utilization review, authorization, or management practices, or the application of medical necessity and appropriateness criteria applicable to behavioral health.

(c) ELIGIBLE STATE DEFINED.—

(1) APPLICATION.—Upon approval of an application submitted by a State described in paragraph (2), the State shall be an eligible State for purposes of conducting a demonstration project under this section.

(2) STATE DESCRIBED.—States shall be selected by the Secretary in a manner so as to provide geographic diversity on the basis of the application to conduct a demonstration project under this section submitted by such States.

(d) LENGTH OF DEMONSTRATION PROJECT.—The demonstration project established under this section shall be conducted for a period of 3 consecutive years.

(e) LIMITATIONS ON FEDERAL FUNDING.—

(1) APPROPRIATION.—

(A) IN GENERAL.—Out of any funds in the Treasury not otherwise appropriated, there is appropriated to carry out this section, $75,000,000 for fiscal year 2010.

(B) BUDGET AUTHORITY.—Subparagraph (A) constitutes budget authority in advance of appropriations Act and represents the obligation of the Federal Government to provide for the payment of the amounts appropriated under that subparagraph.

(2) 3-YEAR AVAILABILITY.—Funds appropriated under paragraph (1) shall remain available for obligation through December 31, 2012.

(3) LIMITATION ON PAYMENTS.—In no case may—

(A) the aggregate amount of payments made by the Secretary to eligible States under this section exceed $75,000,000; or

(B) payments be provided by the Secretary under this section after December 31, 2012.

(4) FUNDS ALLOCATED TO STATES.—The Secretary shall allocate funds to eligible States based on their applications and the availability of funds.

(5) PAYMENTS TO STATES.—The Secretary shall pay to each eligible State, from its allocation under paragraph (4), an amount each quarter equal to the Federal medical assistance percentage of expenditures in the quarter for medical assistance described in subsection (a).

(f) REPORTS.—

(1) ANNUAL PROGRESS REPORTS.—The Secretary shall submit annual reports to Congress on the progress of the demonstration project conducted under this section.

(2) FINAL REPORT AND RECOMMENDATION.—An evaluation shall be conducted of the demonstration project's impact on the functioning of the health and mental health service system and on individuals enrolled in the Medicaid program. This evaluation shall include collection of baseline data for one-year prior to the

initiation of the demonstration project as well as collection of data from matched comparison states not participating in the demonstration. The evaluation measures shall include the following:

(A) A determination, by State, as to whether the demonstration project resulted in increased access to inpatient mental health services under the Medicaid program and whether average length of stays were longer (or shorter) for individuals admitted under the demonstration project compared with individuals otherwise admitted in comparison sites.

(B) An analysis, by State, regarding whether the demonstration project produced a significant reduction in emergency room visits for individuals eligible for assistance under the Medicaid program or in the duration of emergency room lengths of stay.

(C) An assessment of discharge planning by participating hospitals that ensures access to further (non-emergency) inpatient or residential care as well as continuity of care for those discharged to outpatient care.

(D) An assessment of the impact of the demonstration project on the costs of the full range of mental health services (including inpatient, emergency and ambulatory care) under the plan as contrasted with the comparison areas.

(E) Data on the percentage of consumers with Medicaid coverage who are admitted to inpatient facilities as a result of the demonstration project as compared to those admitted to these same facilities through other means.

(F) A recommendation regarding whether the demonstration project should be continued after December 31, 2012, and expanded on a national basis.

(g) WAIVER AUTHORITY.—

(1) IN GENERAL.—The Secretary shall waive the limitation of subdivision (B) following paragraph (28) of section 1905(a) of the Social Security Act (42 U.S.C. 1396d(a)) (relating to limitations on payments for care or services for individuals under 65 years of age who are patients in an institution for mental diseases) for purposes of carrying out the demonstration project under this section.

(2) LIMITED OTHER WAIVER AUTHORITY.—The Secretary may waive other requirements of titles XI and XIX of the Social Security Act (including the requirements of sections 1902(a)(1) (relating to statewideness) and 1902(1)(10)(B) (relating to comparability)) only to extent necessary to carry out the demonstration project under this section.

(h) DEFINITIONS.—In this section:

(1) EMERGENCY MEDICAL CONDITION.—The term "emergency medical condition" means, with respect to an individual, an individual who expresses suicidal or homicidal thoughts or gestures, if determined dangerous to self or others.

(2) FEDERAL MEDICAL ASSISTANCE PERCENTAGE.—The term "Federal medical assistance percentage" has the meaning given that term with respect to a State under section 1905(b) of the Social Security Act (42 U.S.C. 1396d(b)).

(3) INSTITUTION FOR MENTAL DISEASES.—The term "institution for mental diseases" has the meaning given to that term in section 1905(i) of the Social Security Act (42 U.S.C. 1396d(i)).

(4) MEDICAL ASSISTANCE.—The term "medical assistance" has the meaning given to that term in section 1905(a) of the Social Security Act (42 U.S.C. 1396d(a)).

(5) STABILIZED.—The term "stabilized" means, with respect to an individual, that the emergency medical condition no longer exists with respect to the individual and the individual is no longer dangerous to self or others.

(6) STATE.—The term "State" has the meaning given that term for purposes of title XIX of the Social Security Act (42 U.S.C. 1396 et seq.).

[TITLE VIII—REVENUE-RELATED PROVISIONS]

[For title VIII, see text of bill as introduced on July 14, 2009.]

TITLE IX—MISCELLANEOUS PROVISIONS

SEC. 1901. REPEAL OF TRIGGER PROVISION.

Subtitle A of title VIII of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173) is repealed and the provisions of law amended by such subtitle are restored as if such subtitle had never been enacted.

SEC. 1902. REPEAL OF COMPARATIVE COST ADJUSTMENT (CCA) PROGRAM.

Section 1860C–1 of the Social Security Act (42 U.S.C. 1395w–29), as added by section 241(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173), is repealed.

SEC. 1903. EXTENSION OF GAINSHARING DEMONSTRATION.

(a) IN GENERAL.—Subsection (d)(3) of section 5007 of the Deficit Reduction Act of 2005 (Public Law 109-171) is amended by inserting "(or September 30, 2011, in the case of a demonstration project in operation as of October 1, 2008)" after "December 31, 2009".

(b) FUNDING.—

(1) IN GENERAL.—Subsection (f)(1) of such section is amended by inserting "and for fiscal year 2010, $1,600,000," after "$6,000,000,".

(2) AVAILABILITY.—Subsection (f)(2) of such section is amended by striking "2010" and inserting "2014 or until expended".

(c) REPORTS.—

(1) QUALITY IMPROVEMENT AND SAVINGS.—Subsection (e)(3) of such section is amended by striking "December 1, 2008" and inserting "March 31, 2011".

(2) FINAL REPORT.—Subsection (e)(4) of such section is amended by striking "May 1, 2010" and inserting "March 31, 2013".

SEC. 1904. GRANTS TO STATES FOR QUALITY HOME VISITATION PROGRAMS FOR FAMILIES WITH YOUNG CHILDREN AND FAMILIES EXPECTING CHILDREN.

Part B of title IV of the Social Security Act (42 U.S.C. 621–629i) is amended by adding at the end the following:

"Subpart 3—Support for Quality Home Visitation Programs

"SEC. 440. HOME VISITATION PROGRAMS FOR FAMILIES WITH YOUNG CHILDREN AND FAMILIES EXPECTING CHILDREN.

"(a) PURPOSE.—The purpose of this section is to improve the well-being, health, and development of children by enabling the establishment and expansion of high quality programs providing voluntary home visitation for families with young children and families expecting children.

"(b) GRANT APPLICATION.—A State that desires to receive a grant under this section shall submit to the Secretary for approval, at such time and in such manner as the Secretary may require, an application for the grant that includes the following:

"(1) DESCRIPTION OF HOME VISITATION PROGRAMS.—A description of the high quality programs of home visitation for families with young children and families expecting children that will be supported by a grant made to the State under this section, the outcomes the programs are intended to achieve, and the evidence supporting the effectiveness of the programs.

"(2) RESULTS OF NEEDS ASSESSMENT.—The results of a statewide needs assessment that describes—

"(A) the number, quality, and capacity of home visitation programs for families with young children and families expecting children in the State;

"(B) the number and types of families who are receiving services under the programs;

"(C) the sources and amount of funding provided to the programs;

"(D) the gaps in home visitation in the State, including identification of communities that are in high need of the services; and

"(E) training and technical assistance activities designed to achieve or support the goals of the programs.

"(3) ASSURANCES.—Assurances from the State that—

"(A) in supporting home visitation programs using funds provided under this section, the State shall identify and prioritize serving communities that are in high need of such services, especially communities with a high proportion of low-income families or a high incidence of child maltreatment;

"(B) the State will reserve 5 percent of the grant funds for training and technical assistance to the home visitation programs using such funds;

"(C) in supporting home visitation programs using funds provided under this section, the State will promote coordination and collaboration with other home visitation programs (including programs funded under title XIX) and with other child and family services, health services, income supports, and other related assistance;

"(D) home visitation programs supported using such funds will, when appropriate, provide referrals to other programs serving children and families; and

"(E) the State will comply with subsection (i), and cooperate with any evaluation conducted under subsection (j).

"(4) OTHER INFORMATION.—Such other information as the Secretary may require.

"(c) ALLOTMENTS.—

"(1) INDIAN TRIBES.—From the amount reserved under subsection (l)(2) for a fiscal year, the Secretary shall allot to each Indian tribe that meets the requirement of subsection (d), if applicable, for the fiscal year the amount that bears the same ratio to the amount so reserved as the number of children in the Indian tribe whose families have income that does not exceed 200 percent of the poverty line bears to the total number of children in such Indian tribes whose families have income that does not exceed 200 percent of the poverty line.

"(2) STATES AND TERRITORIES.—From the amount appropriated under subsection (m) for a fiscal year that remains after making the reservations required by subsection (l), the Secretary shall allot to each State that is not an Indian tribe and that meets the requirement of subsection (d), if applicable, for the fiscal year the amount that bears the same ratio to the remainder of the amount so appropriated as the number of children in the State whose families have income that does not exceed 200 percent of the poverty line bears to the total number of children in such States whose families have income that does not exceed 200 percent of the poverty line.

"(3) REALLOTMENTS.—The amount of any allotment to a State under a paragraph of this subsection for any fiscal year that the State certifies to the Secretary will not be expended by the State pursuant to this section shall be available for reallotment using the allotment methodology specified in that paragraph. Any amount so reallotted to a State is deemed part of the allotment of the State under this subsection.

"(d) MAINTENANCE OF EFFORT.—Beginning with fiscal year 2011, a State meets the requirement of this subsection for a fiscal year if the Secretary finds that the aggregate expenditures by the State from State and local sources for programs of home visitation for families with young children and families expecting children for the then preceding fiscal year was not less than 100 percent of such aggregate expenditures for the then 2nd preceding fiscal year.

"(e) PAYMENT OF GRANT.—

"(1) IN GENERAL.—The Secretary shall make a grant to each State that meets the requirements of subsections (b) and (d), if applicable, for a fiscal year for which funds are appropriated under subsection (m), in an amount equal to the reimbursable percentage of the eligible expenditures of the State for the fiscal year, but not more than the amount allotted to the State under subsection (c) for the fiscal year.

"(2) REIMBURSABLE PERCENTAGE DEFINED.—In paragraph (1), the term 'reimbursable percentage' means, with respect to a fiscal year—

"(A) 85 percent, in the case of fiscal year 2010;

"(B) 80 percent, in the case of fiscal year 2011; or

"(C) 75 percent, in the case of fiscal year 2012 and any succeeding fiscal year.

"(f) ELIGIBLE EXPENDITURES.—

"(1) IN GENERAL.—In this section, the term 'eligible expenditures'—

"(A) means expenditures to provide voluntary home visitation for as many families with young children (under the age of school entry) and families expecting children as practicable, through the implementation or expansion of high quality home visitation programs that—

"(i) adhere to clear evidence-based models of home visitation that have demonstrated positive effects on important program-determined child and parenting outcomes, such as reducing abuse and neglect and improving child health and development;

"(ii) employ well-trained and competent staff, maintain high quality supervision, provide for ongoing training and professional development, and show strong organizational capacity to implement such a program;

"(iii) establish appropriate linkages and referrals to other community resources and supports;

"(iv) monitor fidelity of program implementation to ensure that services are delivered according to the specified model; and

"(v) provide parents with—

"(I) knowledge of age-appropriate child development in cognitive, language, social, emotional, and motor domains (including knowledge of second language acquisition, in the case of English language learners);

"(II) knowledge of realistic expectations of age-appropriate child behaviors;

"(III) knowledge of health and wellness issues for children and parents;

"(IV) modeling, consulting, and coaching on parenting practices;

"(V) skills to interact with their child to enhance age-appropriate development;

"(VI) skills to recognize and seek help for issues related to health, developmental delays, and social, emotional, and behavioral skills; and

"(VII) activities designed to help parents become full partners in the education of their children;

"(B) includes expenditures for training, technical assistance, and evaluations related to the programs; and

"(C) does not include any expenditure with respect to which a State has submitted a claim for payment under any other provision of Federal law.

"(2) PRIORITY FUNDING FOR PROGRAMS WITH STRONGEST EVIDENCE.—

"(A) IN GENERAL.—The expenditures, described in paragraph (1), of a State for a fiscal year that are attributable to the cost of programs that do not adhere to a model of home visitation with the strongest evidence of effectiveness shall not be considered eligible expenditures for the fiscal year to the extent that the total of the expenditures exceeds the applicable percentage for the fiscal year of the allotment of the State under subsection (c) for the fiscal year.

"(B) APPLICABLE PERCENTAGE DEFINED.—In subparagraph (A), the term 'applicable percentage' means, with respect to a fiscal year—

"(i) 60 percent for fiscal year 2010;

"(ii) 55 percent for fiscal year 2011;

"(iii) 50 percent for fiscal year 2012;

"(iv) 45 percent for fiscal year 2013; or

"(v) 40 percent for fiscal year 2014.

"(g) NO USE OF OTHER FEDERAL FUNDS FOR STATE MATCH.—A State to which a grant is made under this section may not expend any Federal funds to meet the State share of the cost of an eligible expenditure for which the State receives a payment under this section.

"(h) WAIVER AUTHORITY.—

"(1) IN GENERAL.—The Secretary may waive or modify the application of any provision of this section, other than subsection (b) or (f), to an Indian tribe if the failure to do so would impose an undue burden on the Indian tribe.

"(2) SPECIAL RULE.—An Indian tribe is deemed to meet the requirement of subsection (d) for purposes of subsections (c) and (e) if—

"(A) the Secretary waives the requirement; or

"(B) the Secretary modifies the requirement, and the Indian tribe meets the modified requirement.

"(i) STATE REPORTS.—Each State to which a grant is made under this section shall submit to the Secretary an annual report on the progress made by the State in addressing the purposes of this section. Each such report shall include a description of—

"(1) the services delivered by the programs that received funds from the grant;

"(2) the characteristics of each such program, including information on the service model used by the program and the performance of the program;

"(3) the characteristics of the providers of services through the program, including staff qualifications, work experience, and demographic characteristics;

"(4) the characteristics of the recipients of services provided through the program, including the number of the recipients, the demographic characteristics of the recipients, and family retention;

"(5) the annual cost of implementing the program, including the cost per family served under the program;

"(6) the outcomes experienced by recipients of services through the program;

"(7) the training and technical assistance provided to aid implementation of the program, and how the training and technical assistance contributed to the outcomes achieved through the program;

"(8) the indicators and methods used to monitor whether the program is being implemented as designed; and

"(9) other information as determined necessary by the Secretary.

"(j) EVALUATION.—

"(1) IN GENERAL.—The Secretary shall, by grant or contract, provide for the conduct of an independent evaluation of the effectiveness of home visitation pro-

grams receiving funds provided under this section, which shall examine the following:

"(A) The effect of home visitation programs on child and parent outcomes, including child maltreatment, child health and development, school readiness, and links to community services.

"(B) The effectiveness of home visitation programs on different populations, including the extent to which the ability of programs to improve outcomes varies across programs and populations.

"(2) REPORTS TO THE CONGRESS.—

"(A) INTERIM REPORT.—Within 3 years after the date of the enactment of this section, the Secretary shall submit to the Congress an interim report on the evaluation conducted pursuant to paragraph (1).

"(B) FINAL REPORT.—Within 5 years after the date of the enactment of this section, the Secretary shall submit to the Congress a final report on the evaluation conducted pursuant to paragraph (1).

"(k) ANNUAL REPORTS TO THE CONGRESS.—The Secretary shall submit annually to the Congress a report on the activities carried out using funds made available under this section, which shall include a description of the following:

"(1) The high need communities targeted by States for programs carried out under this section.

"(2) The service delivery models used in the programs receiving funds provided under this section.

"(3) The characteristics of the programs, including—

"(A) the qualifications and demographic characteristics of program staff; and

"(B) recipient characteristics including the number of families served, the demographic characteristics of the families served, and family retention and duration of services.

"(4) The outcomes reported by the programs.

"(5) The research-based instruction, materials, and activities being used in the activities funded under the grant.

"(6) The training and technical activities, including on-going professional development, provided to the programs.

"(7) The annual costs of implementing the programs, including the cost per family served under the programs.

"(8) The indicators and methods used by States to monitor whether the programs are being been implemented as designed.

"(l) RESERVATIONS OF FUNDS.—From the amounts appropriated for a fiscal year under subsection (m), the Secretary shall reserve—

"(1) an amount equal to 5 percent of the amounts to pay the cost of the evaluation provided for in subsection (j), and the provision to States of training and technical assistance, including the dissemination of best practices in early childhood home visitation; and

"(2) after making the reservation required by paragraph (1), an amount equal to 3 percent of the amount so appropriated, to pay for grants to Indian tribes under this section.

"(m) APPROPRIATIONS.—Out of any money in the Treasury of the United States not otherwise appropriated, there is appropriated to the Secretary to carry out this section—

"(1) $50,000,000 for fiscal year 2010;

"(2) $100,000,000 for fiscal year 2011;

"(3) $150,000,000 for fiscal year 2012;

"(4) $200,000,000 for fiscal year 2013; and

"(5) $250,000,000 for fiscal year 2014.

"(n) INDIAN TRIBES TREATED AS STATES.—In this section, paragraphs (4), (5), and (6) of section 431(a) shall apply.".

SEC. 1905. IMPROVED COORDINATION AND PROTECTION FOR DUAL ELIGIBLES.

Title XI of the Social Security Act is amended by inserting after section 1150 the following new section:

"IMPROVED COORDINATION AND PROTECTION FOR DUAL ELIGIBLES

"SEC. 1150A. (a) IN GENERAL.—The Secretary shall provide, through an identifiable office or program within the Centers for Medicare & Medicaid Services, for a focused effort to provide for improved coordination between Medicare and Medicaid and protection in the case of dual eligibles (as defined in subsection (e)). The office or program shall—

"(1) review Medicare and Medicaid policies related to enrollment, benefits, service delivery, payment, and grievance and appeals processes under parts A

and B of title XVIII, under the Medicare Advantage program under part C of such title, and under title XIX;

"(2) identify areas of such policies where better coordination and protection could improve care and costs; and

"(3) issue guidance to States regarding improving such coordination and protection.

"(b) ELEMENTS.—The improved coordination and protection under this section shall include efforts—

"(1) to simplify access of dual eligibles to benefits and services under Medicare and Medicaid;

"(2) to improve care continuity for dual eligibles and ensure safe and effective care transitions;

"(3) to harmonize regulatory conflicts between Medicare and Medicaid rules with regard to dual eligibles; and

"(4) to improve total cost and quality performance under Medicare and Medicaid for dual eligibles.

"(c) RESPONSIBILITIES.—In carrying out this section, the Secretary shall provide for the following:

"(1) An examination of Medicare and Medicaid payment systems to develop strategies to foster more integrated and higher quality care.

"(2) Development of methods to facilitate access to post-acute and community-based services and to identify actions that could lead to better coordination of community-based care.

"(3) A study of enrollment of dual eligibles in the Medicare Savings Program (as defined in section 1144(c)(7)), under Medicaid, and in the low-income subsidy program under section 1860D–14 to identify methods to more efficiently and effectively reach and enroll dual eligibles.

"(4) An assessment of communication strategies for dual eligibles to determine whether additional informational materials or outreach is needed, including an assessment of the Medicare website, 1-800-MEDICARE, and the Medicare handbook.

"(5) Research and evaluation of areas where service utilization, quality, and access to cost sharing protection could be improved and an assessment of factors related to enrollee satisfaction with services and care delivery.

"(6) Collection (and making available to the public) of data and a database that describe the eligibility, benefit and cost-sharing assistance available to dual eligibles by State.

"(7) Monitoring total combined Medicare and Medicaid program costs in serving dual eligibles and making recommendations for optimizing total quality and cost performance across both programs.

"(8) Coordination of activities relating to Medicare Advantage plans under 1859(b)(6)(B)(ii) and Medicaid.

"(d) PERIODIC REPORTS.—Not later than 1 year after the date of the enactment of this section and every 3 years thereafter the Secretary shall submit to Congress a report on progress in activities conducted under this section.

"(e) DEFINITIONS.—In this section:

"(1) DUAL ELIGIBLE.—The term 'dual eligible' means an individual who is dually eligible for benefits under title XVIII, and medical assistance under title XIX, including such individuals who are eligible for benefits under the Medicare Savings Program (as defined in section 1144(c)(7)).

"(2) MEDICARE; MEDICAID.—The terms 'Medicare' and 'Medicaid' mean the programs under titles XVIII and XIX, respectively.".

SEC. 1906. STANDARDIZED MARKETING REQUIREMENTS UNDER THE MEDICARE ADVANTAGE AND MEDICARE PRESCRIPTION DRUG PROGRAMS.

(a) MEDICARE ADVANTAGE PROGRAM.—

(1) IN GENERAL.—Section 1856 of the Social Security Act (42 U.S.C. 1395w–26) is amended—

(A) in subsection (b)(1), by inserting "or subsection (c)" after "subsection (a)"; and

(B) by adding at the end the following new subsection:

"(c) STANDARDIZED MARKETING REQUIREMENTS.—

"(1) DEVELOPMENT BY THE NAIC.—

"(A) REQUIREMENTS.—The Secretary shall request the National Association of Insurance Commissioners (in this subsection referred to as the 'NAIC') to—

"(i) develop standardized marketing requirements for Medicare Advantage organizations with respect to Medicare Advantage plans and PDP sponsors with respect to prescription drug plans under part D; and

"(ii) submit a report containing such requirements to the Secretary by not later than the date that is 9 months after the date of the enactment of this subsection.

"(B) PROHIBITED ACTIVITIES.—Such requirements shall include prohibitions on the prohibited activities described in section 1851(j)(1).

"(C) LIMITATIONS.—Such requirements shall establish limitations that include at least the limitations described in section 1851(j)(2), except for those relating to compensation.

"(D) ELECTION FORM.—Such requirements may prohibit a Medicare Advantage organization or a PDP sponsor (or an agent of such an organization or sponsor) from completing any portion of any election form used to carry out elections under section 1851 or 1860D–1 on behalf of any individual.

"(E) AGENT AND BROKER COMMISSIONS AND COMPENSATION.—Such requirements shall establish standards—

"(i) for fair and appropriate commissions for agents and brokers of Medicare Advantage organizations and PDP sponsors, including a prohibition on extra bonuses or incentives;

"(ii) for the disclosure of such commissions; and

"(iii) for the use of compensation for agents and brokers other than such commissions.

Such standards shall ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the Medicare Advantage plan that is intended to best meet their health care needs.

"(F) CERTAIN CONDUCT OF AGENTS.—Such requirements shall address the conduct of agents engaged in on-site promotion at a facility of an organization with which the Medicare Advantage organization or PDP sponsor has a co-branding relationship.

"(G) OTHER STANDARDS.—Such requirements may establish such other standards relating to unfair trade practices and marketing under Medicare Advantage plans and prescription drug plans under part D as the NAIC determines appropriate.

"(2) IMPLEMENTATION OF REQUIREMENTS.—

"(A) ADOPTION OF NAIC DEVELOPED REQUIREMENTS.—If the NAIC develops standardized marketing requirements and submits the report pursuant to paragraph (1), the Secretary shall promulgate regulations for the adoption of such requirements. The Secretary shall ensure that such regulations take effect beginning with the first open enrollment period beginning 12 months after the date of the enactment of this subsection.

"(B) REQUIREMENTS IF NAIC DOES NOT SUBMIT REPORT.—If the NAIC does not develop standardized marketing requirements and submit the report pursuant to paragraph (1), the Secretary shall promulgate regulations for standardized marketing requirements for Medicare Advantage organizations with respect to Medicare Advantage plans and PDP sponsors with respect to prescription drug plans under part D. Such regulations shall meet the requirements of subparagraphs (B) through (F) of paragraph (1), and may establish such other standards relating to marketing under Medicare Advantage plans and prescription drug plans as the Secretary determines appropriate. The Secretary shall ensure that such regulations take effect beginning with the first open enrollment period beginning 12 months after the date of the enactment of this subsection.

"(C) CONSULTATION.—In establishing requirements under this subsection, the NAIC or Secretary (as the case may be) shall consult with a working group composed of representatives of Medicare Advantage organizations and PDP sponsors, consumer groups, and other qualified individuals. Such representatives shall be selected in a manner so as to insure balanced representation among the interested groups.

"(3) STATE REPORTING OF VIOLATIONS OF STANDARDIZED MARKETING REQUIREMENTS.—The Secretary shall request that States report any violations of the standardized marketing requirements under the regulations under subparagraph (A) or (B) of paragraph (2) to national and regional offices of the Centers for Medicare & Medicaid Services.

"(4) REPORT.—The Secretary shall submit an annual report to Congress on the enforcement of the standardized marketing requirements under the regulations under subparagraph (A) or (B) of paragraph (2), together with such recommendations as the Secretary determines appropriate. Such report shall include—

"(A) a list of any alleged violations of such requirements reported to the Secretary by a State, a Medicare Advantage organization, or a PDP sponsor; and

"(B) the disposition of such reported violations.".

(2) STATE AUTHORITY TO ENFORCE STANDARDIZED MARKETING REQUIREMENTS.—

(A) IN GENERAL.—Section 1856(b)(3) of the Social Security Act (42 U.S.C. 1395w–26(b)(3)) is amended—

(i) by striking "or State" and inserting ", State"; and

(ii) by inserting ", or State laws or regulations enacting the standardized marketing requirements under subsection (c)" after "plan solvency".

(B) NO PREEMPTION OF STATE SANCTIONS.—Nothing in title XVIII of the Social Security Act or the provisions of, or amendments made by, this Act, shall be construed to prohibit a State from conducting a market conduct examination or from imposing sanctions against Medicare Advantage organizations, PDP sponsors, or agents or brokers of such organizations or sponsors for violations of the standardized marketing requirements under subsection (c) of section 1856 of the Social Security Act (as added by paragraph (1)) as enacted by that State.

(3) CONFORMING AMENDMENT.—Section 1851(h)(4) of the Social Security Act (42 U.S.C. 1395w–21(h)(4)) is amended by adding at the end the following flush sentence:

"Beginning on the effective date of the implementation of the regulations under subparagraph (A) or (B) of section 1856(c)(2), each Medicare Advantage organization with respect to a Medicare Advantage plan offered by the organization (and agents of such organization) shall comply with the standardized marketing requirements under section 1856(c).".

(b) MEDICARE PRESCRIPTION DRUG PROGRAM.—Section 1860D–4 of the Social Security Act (42 U.S.C. 1395w–104) is amended by adding at the end the following new subsection:

"(m) STANDARDIZED MARKETING REQUIREMENTS.—A PDP sponsor with respect to a prescription drug plan offered by the sponsor (and agents of such sponsor) shall comply with the standardized marketing requirements under section 1856(c).".

SEC. 1907. NAIC RECOMMENDATIONS ON THE ESTABLISHMENT OF STANDARDIZED BENEFIT PACKAGES FOR MEDICARE ADVANTAGE PLANS AND PRESCRIPTION DRUG PLANS.

Not later than 30 days after the date of the enactment of this Act, the Secretary of Health and Human Services shall request the National Association of Insurance Commissioners to establish a committee to study and make recommendations to the Secretary and Congress on—

(1) the establishment of standardized benefit packages for Medicare Advantage plans under part C of title XVIII of the Social Security Act and for prescription drug plans under part D of such Act; and

(2) the regulation of such plans.

SEC. 1908. APPLICATION OF EMERGENCY SERVICES LAWS.

Nothing in this Act shall be construed to relieve any health care provider from providing emergency services as required by State or Federal law, including section 1867 of the Social Security Act (popularly known as "EMTALA").

SEC. 1909. NATIONWIDE PROGRAM FOR NATIONAL AND STATE BACKGROUND CHECKS ON DIRECT PATIENT ACCESS EMPLOYEES OF LONG-TERM CARE FACILITIES AND PROVIDERS.

(a) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the "Secretary"), shall establish a program to identify efficient, effective, and economical procedures for long term care facilities or providers to conduct background checks on prospective direct patient access employees on a nationwide basis (in this subsection, such program shall be referred to as the "nationwide program"). Except for the following modifications, the Secretary shall carry out the nationwide program under similar terms and conditions as the pilot program under section 307 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173; 117 Stat. 2257), including the prohibition on hiring abusive workers and the authorization of the imposition of penalties by a participating State under subsections (b)(3)(A) and (b)(6), respectively, of such section 307:

(1) AGREEMENTS.—

(A) NEWLY PARTICIPATING STATES.—The Secretary shall enter into agreements with each State—

(i) that the Secretary has not entered into an agreement with under subsection (c)(1) of such section 307;

(ii) that agrees to conduct background checks under the nationwide program on a Statewide basis; and

(iii) that submits an application to the Secretary containing such information and at such time as the Secretary may specify.

(B) CERTAIN PREVIOUSLY PARTICIPATING STATES.—The Secretary shall enter into agreements with each State—

(i) that the Secretary has entered into an agreement with under such subsection (c)(1), but only in the case where such agreement did not require the State to conduct background checks under the program established under subsection (a) of such section 307 on a Statewide basis;

(ii) that agrees to conduct background checks under the nationwide program on a Statewide basis; and

(iii) that submits an application to the Secretary containing such information and at such time as the Secretary may specify.

(2) NONAPPLICATION OF SELECTION CRITERIA.—The selection criteria required under subsection (c)(3)(B) of such section 307 shall not apply.

(3) REQUIRED FINGERPRINT CHECK AS PART OF CRIMINAL HISTORY BACKGROUND CHECK.—The procedures established under subsection (b)(1) of such section 307 shall—

(A) require that the long-term care facility or provider (or the designated agent of the long-term care facility or provider) obtain State and national criminal history background checks on the prospective employee through such means as the Secretary determines appropriate that utilize a search of State-based abuse and neglect registries and databases, including the abuse and neglect registries of another State in the case where a prospective employee previously resided in that State, State criminal history records, the records of any proceedings in the State that may contain disqualifying information about prospective employees (such as proceedings conducted by State professional licensing and disciplinary boards and State Medicaid Fraud Control Units), and Federal criminal history records, including a fingerprint check using the Integrated Automated Fingerprint Identification System of the Federal Bureau of Investigation; and

(B) require States to describe and test methods that reduce duplicative fingerprinting, including providing for the development of "rap back" capability by the State such that, if a direct patient access employee of a long-term care facility or provider is convicted of a crime following the initial criminal history background check conducted with respect to such employee, and the employee's fingerprints match the prints on file with the State law enforcement department, the department will immediately inform the State and the State will immediately inform the long-term care facility or provider which employs the direct patient access employee of such conviction.

(4) STATE REQUIREMENTS.—An agreement entered into under paragraph (1) shall require that a participating State—

(A) be responsible for monitoring compliance with the requirements of the nationwide program;

(B) have procedures in place to—

(i) conduct screening and criminal history background checks under the nationwide program in accordance with the requirements of this section;

(ii) monitor compliance by long-term care facilities and providers with the procedures and requirements of the nationwide program;

(iii) as appropriate, provide for a provisional period of employment by a long-term care facility or provider of a direct patient access employee, not to exceed 30 days, pending completion of the required criminal history background check and, in the case where the employee has appealed the results of such background check, pending completion of the appeals process, during which the employee shall be subject to direct on-site supervision (in accordance with procedures established by the State to ensure that a long-term care facility or provider furnishes such direct on-site supervision);

(iv) provide an independent process by which a provisional employee or an employee may appeal or dispute the accuracy of the information obtained in a background check performed under the nationwide program, including the specification of criteria for appeals for direct patient access employees found to have disqualifying information which shall include consideration of the passage of time, extenuating circumstances, demonstration of rehabilitation, and relevancy of the particular disqualifying information with respect to the current employment of the individual;

(v) provide for the designation of a single State agency as responsible for—

(I) overseeing the coordination of any State and national criminal history background checks requested by a long-term care facility or provider (or the designated agent of the long-term care facility or provider) utilizing a search of State and Federal criminal history records, including a fingerprint check of such records;

(II) overseeing the design of appropriate privacy and security safeguards for use in the review of the results of any State or national criminal history background checks conducted regarding a prospective direct patient access employee to determine whether the employee has any conviction for a relevant crime;

(III) immediately reporting to the long-term care facility or provider that requested the criminal history background check the results of such review; and

(IV) in the case of an employee with a conviction for a relevant crime that is subject to reporting under section 1128E of the Social Security Act (42 U.S.C. 1320a–7e), reporting the existence of such conviction to the database established under that section;

(vi) determine which individuals are direct patient access employees (as defined in paragraph (6)(B)) for purposes of the nationwide program;

(vii) as appropriate, specify offenses, including convictions for violent crimes, for purposes of the nationwide program; and

(viii) describe and test methods that reduce duplicative fingerprinting, including providing for the development of "rap back" capability such that, if a direct patient access employee of a long-term care facility or provider is convicted of a crime following the initial criminal history background check conducted with respect to such employee, and the employee's fingerprints match the prints on file with the State law enforcement department—

(I) the department will immediately inform the State agency designated under clause (v) and such agency will immediately inform the facility or provider which employs the direct patient access employee of such conviction; and

(II) the State will provide, or will require the facility to provide, to the employee a copy of the results of the criminal history background check conducted with respect to the employee at no charge in the case where the individual requests such a copy.

(5) PAYMENTS.—

(A) NEWLY PARTICIPATING STATES.—

(i) IN GENERAL.—As part of the application submitted by a State under paragraph (1)(A)(iii), the State shall guarantee, with respect to the costs to be incurred by the State in carrying out the nationwide program, that the State will make available (directly or through donations from public or private entities) a particular amount of non-Federal contributions, as a condition of receiving the Federal match under clause (ii).

(ii) FEDERAL MATCH.—The payment amount to each State that the Secretary enters into an agreement with under paragraph (1)(A) shall be 3 times the amount that the State guarantees to make available under clause (i), except that in no case may the payment amount exceed $3,000,000.

(B) PREVIOUSLY PARTICIPATING STATES.—

(i) IN GENERAL.—As part of the application submitted by a State under paragraph (1)(B)(iii), the State shall guarantee, with respect to the costs to be incurred by the State in carrying out the nationwide program, that the State will make available (directly or through donations from public or private entities) a particular amount of non-Federal contributions, as a condition of receiving the Federal match under clause (ii).

(ii) FEDERAL MATCH.—The payment amount to each State that the Secretary enters into an agreement with under paragraph (1)(B) shall be 3 times the amount that the State guarantees to make available under clause (i), except that in no case may the payment amount exceed $1,500,000.

(6) DEFINITIONS.—Under the nationwide program:

(A) LONG-TERM CARE FACILITY OR PROVIDER.—The term "long-term care facility or provider" means the following facilities or providers which receive payment for services under title XVIII or XIX of the Social Security Act:

(i) A skilled nursing facility (as defined in section 1819(a) of the Social Security Act (42 U.S.C. 1395i–3(a))).

(ii) A nursing facility (as defined in section 1919(a) of such Act (42 U.S.C. 1396r(a))).

(iii) A home health agency.

(iv) A provider of hospice care (as defined in section 1861(dd)(1) of such Act (42 U.S.C. 1395x(dd)(1))).

(v) A long-term care hospital (as described in section 1886(d)(1)(B)(iv) of such Act (42 U.S.C. 1395ww(d)(1)(B)(iv))).

(vi) A provider of personal care services.

(vii) A provider of adult day care.

(viii) A residential care provider that arranges for, or directly provides, long-term care services, including an assisted living facility that provides a level of care established by the Secretary.

(ix) An intermediate care facility for the mentally retarded (as defined in section 1905(d) of such Act (42 U.S.C. 1396d(d))).

(x) Any other facility or provider of long-term care services under such titles as the participating State determines appropriate.

(B) DIRECT PATIENT ACCESS EMPLOYEE.—The term "direct patient access employee" means any individual who has access to a patient or resident of a long-term care facility or provider through employment or through a contract with such facility or provider and has duties that involve (or may involve) one-on-one contact with a patient or resident of the facility or provider, as determined by the State for purposes of the nationwide program. Such term does not include a volunteer unless the volunteer has duties that are equivalent to the duties of a direct patient access employee and those duties involve (or may involve) one-on-one contact with a patient or resident of the long-term care facility or provider.

(7) EVALUATION AND REPORT.—

(A) EVALUATION.—The Inspector General of the Department of Health and Human Services shall conduct an evaluation of the nationwide program.

(B) REPORT.—Not later than 180 days after the completion of the nationwide program, the Inspector General of the Department of Health and Human Services shall submit a report to Congress containing the results of the evaluation conducted under subparagraph (A).

(b) FUNDING.—

(1) NOTIFICATION.—The Secretary of Health and Human Services shall notify the Secretary of the Treasury of the amount necessary to carry out the nationwide program under this section for the period of fiscal years 2010 through 2012, except that in no case shall such amount exceed $160,000,000.

(2) TRANSFER OF FUNDS.—Out of any funds in the Treasury not otherwise appropriated, the Secretary of the Treasury shall provide for the transfer to the Secretary of Health and Human Services of the amount specified as necessary to carry out the nationwide program under paragraph (1). Such amount shall remain available until expended.

SEC. 1910. ESTABLISHMENT OF CENTER FOR MEDICARE AND MEDICAID PAYMENT INNOVATION WITHIN CMS.

(a) IN GENERAL.—Title XI of the Social Security Act is amended by inserting after section 1115 the following new section:

"CENTER FOR MEDICARE AND MEDICAID PAYMENT INNOVATION

"SEC. 1115A. (a) CENTER FOR MEDICARE AND MEDICAID PAYMENT INNOVATION ESTABLISHED.—

"(1) IN GENERAL.—There is created within the Centers for Medicare & Medicaid Services a Center for Medicare and Medicaid Payment Innovation (in this section referred to as the 'CMPI') to carry out the duties described in paragraph (4).

"(2) DIRECTOR.—The CMPI shall be headed by a Director who shall report directly to the Administrator of the Centers for Medicare & Medicaid Services.

"(3) DEADLINE.—The Secretary shall ensure that the CMPI is carrying out the duties described in paragraph (4) by not later than January 1, 2011.

"(4) DUTIES.—The duties described in this paragraph are the following:

"(A) To carry out the duties described in this section.

"(B) Such other duties as the Secretary may specify.

"(5) CONSULTATION.—In carrying out the duties under paragraph (4), the CMPI shall consult representatives of relevant Federal agencies and outside clinical and analytical experts with expertise in medicine and health care man-

agement. The CMPI shall use open door forums or other mechanisms to seek input from interested parties.

"(b) TESTING OF MODELS (PHASE I).—

"(1) IN GENERAL.—The CMPI shall test payment models in accordance with selection criteria under paragraph (2) to determine the effect of applying such models under title XVIII, title XIX, or both titles on program expenditures under such titles and the quality of care received by individuals receiving benefits under such titles.

"(2) SELECTION OF MODELS TO BE TESTED.—

"(A) IN GENERAL.—The Secretary shall give preference to testing models for which, as determined by the professional staff at the Centers for Medicare & Medicaid Services and using such input from outside the Centers as the Secretary determines appropriate, there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. The Secretary shall focus on models expected to reduce program costs under title XVIII, title XIX, or both titles while preserving or enhancing the quality of care received by individuals receiving benefits under such titles.

"(B) APPLICATION TO OTHER DEMONSTRATIONS.—The Secretary shall operate the demonstration programs under sections 1222 and 1236 of the America's Affordable Health Choices Act of 2009 through the CMPI in accordance with the rules applicable under this section, including those relating to evaluations, terminations, and expansions.

"(3) BUDGET NEUTRALITY.—

"(A) INITIAL PERIOD.—The Secretary shall not require as a condition for testing a model under paragraph (1) that the design of the model ensure that the model is budget neutral initially with respect to expenditures under titles XVIII and XIX.

"(B) TERMINATION.—The Secretary shall terminate or modify the design and implementation of a model unless the Secretary determines (and the Chief Actuary of the Centers for Medicare & Medicaid Services, with respect to spending under such titles, certifies), after testing has begun, that the model is expected to—

"(i) improve the quality of patient care (as determined by the Administrator of the Centers for Medicare & Medicaid Services) without increasing spending under such titles;

"(ii) reduce spending under such titles without reducing the quality of patient care; or

"(iii) do both.

Such termination may occur at any time after such testing has begun and before completion of the testing.

"(4) EVALUATION.—The Secretary shall conduct an evaluation of each model tested under this subsection. Such evaluation shall include an analysis of—

"(A) the quality of patient care furnished under the model, including through the use of patient-level outcomes measures; and

"(B) the changes in spending under titles XVIII and XIX by reason of the model.

The Secretary shall make the results of each evaluation under this paragraph available to the public in a timely fashion.

"(c) EXPANSION OF MODELS (PHASE II).—The Secretary may expand the duration and the scope of a model that is being tested under subsection (b) (including implementation on a nationwide basis), to the extent determined appropriate by the Secretary, if—

"(1) the Secretary determines that such expansion is expected—

"(A) to improve the quality of patient care without increasing spending under titles XVIII and XIX;

"(B) to reduce spending under such titles without reducing the quality of patient care; or

"(C) to do both; and

"(2) the Chief Actuary of the Centers for Medicare & Medicaid Services certifies that such expansion would reduce (or not result in any increase in) net program spending under such titles.

"(d) IMPLEMENTATION.—

"(1) WAIVER AUTHORITY.—The Secretary may waive such requirements of title XVIII and of sections 1902(a)(1), 1902(a)(13), and 1903(m)(2)(A)(iii) as may be necessary solely for purposes of carrying out this section with respect to testing models described in subsection (b).

"(2) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of—

"(A) the selection of models for testing or expansion under this section;

"(B) the elements, parameters, scope, and duration of such models for testing or dissemination;

"(C) the termination or modification of the design and implementation of a model under subsection (b)(3)(B); and

"(D) determinations about expansion of the duration and scope of a model under subsection (c) including the determination that a model is not expected to meet criteria described in paragraphs (1) or (2) of such subsection.

"(3) ADMINISTRATION.—Chapter 35 of title 44, United States Code shall not apply to this section and testing and evaluation of models or expansion of such models under this section.

"(4) FUNDING FOR TESTING ITEMS AND SERVICES AND ADMINISTRATIVE COSTS.—There shall be available from the Federal Supplementary Medical Insurance Trust Fund for payments for designing, conducting, and evaluating payment models, as well as for additional benefits for items and services under models tested under subsection (b) not otherwise covered under this title and the evaluation of such models, $350,000,000 for fiscal year 2010 and, for a subsequent fiscal year, the amount determined under this sentence for the preceding fiscal year increased by the annual percentage rate of increase in total expenditures under this title for the previous fiscal year. There are also appropriated, from any amounts in the Treasury not otherwise appropriated, $25,000,000 for each fiscal year (beginning with fiscal year 2010) for administrative costs of administering this section with respect to the Medicaid program under title XIX of the Social Security Act.

"(e) REPORT TO CONGRESS.—Beginning in 2012, and not less than once every other year thereafter, the Secretary shall submit to Congress a report on activities under this section. Each such report shall describe the payment models tested under subsection (b), any models chosen for expansion under subsection (c), and the results from evaluations under subsection (b)(4). In addition, each such report shall provide such recommendations as the Secretary believes are appropriate for legislative action to facilitate the development and expansion of successful payment models.".

(b) MEDICAID CONFORMING AMENDMENT.—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)), as amended by sections 1631(b), 1703(a), 1729, 1753, 1757(a), and 1759(a), is amended—

(1) in paragraph (78), by striking "and" at the end;

(2) in paragraph (79), by striking the period at the end and inserting "; and"; and

(3) by inserting after paragraph (79) the following new paragraph:

"(80) provide for implementation of the payment models specified by the Secretary under section 1115A(c) for implementation on a nationwide basis unless the State demonstrates to the satisfaction of the Secretary that implementation would not be administratively feasible or appropriate to the health care delivery system of the State.".

DIVISION C—PUBLIC HEALTH AND WORKFORCE DEVELOPMENT

SEC. 2001. TABLE OF CONTENTS; REFERENCES.

(a) TABLE OF CONTENTS.—The table of contents of this division is as follows:

Sec. 2001. Table of contents; references.
Sec. 2002. Public Health Investment Fund.

TITLE I—COMMUNITY HEALTH CENTERS

Sec. 2101. Increased funding.

TITLE II—WORKFORCE

Subtitle A—Primary Care Workforce

PART 1—NATIONAL HEALTH SERVICE CORPS

Sec. 2201. National Health Service Corps.
Sec. 2202. Authorizations of appropriations.

PART 2—PROMOTION OF PRIMARY CARE AND DENTISTRY

Sec. 2211. Frontline health providers.
Sec. 2212. Primary care student loan funds.
Sec. 2213. Training in family medicine, general internal medicine, general pediatrics, geriatrics, and physician assistants.
Sec. 2214. Training of medical residents in community-based settings.
Sec. 2215. Training for general, pediatric, and public health dentists and dental hygienists.

Sec. 2216. Authorization of appropriations.
Sec. 2217. Study on effectiveness of scholarships and loan repayments.

Subtitle B—Nursing Workforce

Sec. 2221. Amendments to Public Health Service Act.

Subtitle C—Public Health Workforce

Sec. 2231. Public Health Workforce Corps.
Sec. 2232. Enhancing the public health workforce.
Sec. 2233. Public health training centers.
Sec. 2234. Preventive medicine and public health training grant program.
Sec. 2235. Authorization of appropriations.

Subtitle D—Adapting Workforce to Evolving Health System Needs

PART 1—HEALTH PROFESSIONS TRAINING FOR DIVERSITY

Sec. 2241. Scholarships for disadvantaged students, loan repayments and fellowships regarding faculty positions, and educational assistance in the health professions regarding individuals from disadvantaged backgrounds.
Sec. 2242. Nursing workforce diversity grants.
Sec. 2243. Coordination of diversity and cultural competency programs.

PART 2—INTERDISCIPLINARY TRAINING PROGRAMS

Sec. 2251. Cultural and linguistic competency training for health professionals.
Sec. 2252. Innovations in interdisciplinary care training.

PART 3—ADVISORY COMMITTEE ON HEALTH WORKFORCE EVALUATION AND ASSESSMENT

Sec. 2261. Health workforce evaluation and assessment.

PART 4—HEALTH WORKFORCE ASSESSMENT

Sec. 2271. Health workforce assessment.

PART 5—AUTHORIZATION OF APPROPRIATIONS

Sec. 2281. Authorization of appropriations.

TITLE III—PREVENTION AND WELLNESS

Sec. 2301. Prevention and wellness.

"TITLE XXXI—PREVENTION AND WELLNESS

"Subtitle A—Prevention and Wellness Trust

"Sec. 3111. Prevention and Wellness Trust.

"Subtitle B—National Prevention and Wellness Strategy

"Sec. 3121. National Prevention and Wellness Strategy.

"Subtitle C—Prevention Task Forces

"Sec. 3131. Task Force on Clinical Preventive Services.
"Sec. 3132. Task Force on Community Preventive Services.

"Subtitle D—Prevention and Wellness Research

"Sec. 3141. Prevention and wellness research activity coordination.
"Sec. 3142. Community prevention and wellness research grants.

"Subtitle E—Delivery of Community Prevention and Wellness Services

"Sec. 3151. Community prevention and wellness services grants.

"Subtitle F—Core Public Health Infrastructure

"Sec. 3161. Core public health infrastructure for State, local, and tribal health departments.
"Sec. 3162. Core public health infrastructure and activities for CDC.

"Subtitle G—General Provisions

"Sec. 3171. Definitions.

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Sec. 2565. Licensure pathway for biosimilar biological products.
Sec. 2566. Fees relating to biosimilar biological products.

Subtitle D—Community Living Assistance Services and Supports

Sec. 2571. Establishment of national voluntary insurance program for purchasing community living assistance services and supports.

Subtitle E—Miscellaneous

Sec. 2581. States failing to adhere to certain employment obligations.
Sec. 2582. Study, report, and termination of duplicative grant programs.
Sec. 2583. Health centers under Public Health Service Act; liability protections for volunteer practitioners.
Sec. 2584. Report to Congress on the current state of parasitic diseases that have been overlooked among the poorest Americans.
Sec. 2585. Study of impact of optometrists on access to health care and on availability of support under Federal health programs for optometry.

(b) REFERENCES.—Except as otherwise specified, whenever in this division an amendment is expressed in terms of an amendment to a section or other provision, the reference shall be considered to be made to a section or other provision of the Public Health Service Act (42 U.S.C. 201 et seq.).

SEC. 2002. PUBLIC HEALTH INVESTMENT FUND.

(a) ESTABLISHMENT OF FUNDS.—

(1) IN GENERAL.—There is established a fund to be known as the Public Health Investment Fund (referred to in this section as the "Fund").

(2) FUNDING.—

(A) There shall be deposited into the Fund—

(i) for fiscal year 2010, $4,600,000,000;
(ii) for fiscal year 2011, $5,600,000,000;
(iii) for fiscal year 2012, $6,900,000,000;
(iv) for fiscal year 2013, $7,800,000,000; and
(v) for fiscal year 2014, $9,000,000,000.

(B) Amounts deposited into the Fund shall be derived from general revenues of the Treasury.

(b) AUTHORIZATION OF APPROPRIATIONS FROM THE FUND.—

(1) NEW FUNDING.—

(A) IN GENERAL.—Amounts in the Fund are authorized to be appropriated by the Committees on Appropriations of the House of Representatives and the Senate for carrying out activities under designated public health provisions.

(B) DESIGNATED PROVISIONS.—For purposes of this paragraph, the term "designated public health provisions" means the provisions for which amounts are authorized to be appropriated under section 330(s), 338(c), 338H–1, 799C, 872, or 3111 of the Public Health Service Act, as added by this division.

(2) BASELINE FUNDING.—

(A) IN GENERAL.—Amounts in the Fund are authorized to be appropriated (as described in paragraph (1)) for a fiscal year only if (excluding any amounts in or appropriated from the Fund)—

(i) the amounts specified in subparagraph (B) for the fiscal year involved are equal to or greater than the amounts specified in subparagraph (B) for fiscal year 2008; and

(ii) the amounts appropriated, out of the general fund of the Treasury, to the Prevention and Wellness Trust under section 3111 of the Public Health Service Act, as added by this division, for the fiscal year involved are equal to or greater than the funds—

(I) appropriated under the heading "Prevention and Wellness Fund" in title VIII of division A of the American Recovery and Reinvestment Act of 2009 (Public Law 111–5); and

(II) allocated by the second proviso under such heading for evidence-based clinical and community-based prevention and wellness strategies.

(B) AMOUNTS SPECIFIED.—The amounts specified in this subparagraph, with respect to a fiscal year, are the amounts appropriated for the following:

(i) Community health centers (including funds appropriated under the authority of section 330 of the Public Health Service Act (42 U.S.C. 254b)).

(ii) The National Health Service Corps Program (including funds appropriated under the authority of section 338 of such Act (42 U.S.C. 254k)).

(iii) The National Health Service Corps Scholarship and Loan Repayment Programs (including funds appropriated under the authority of section 338H of such Act (42 U.S.C. 254q)).

(iv) Primary care education programs (including funds appropriated under the authority of sections 736, 740, 741, and 747 of such Act (42 U.S.C. 293, 293d, and 293k)).

(v) Sections 761 and 770 of such Act (42 U.S.C. 294n and 295e).

(vi) Nursing workforce development (including funds appropriated under the authority of title VIII of such Act (42 U.S.C. 296 et seq.)).

(vii) The National Center for Health Statistics (including funds appropriated under the authority of sections 304, 306, 307, and 308 of such Act (42 U.S.C. 242b, 242k, 242l, and 242m)).

(viii) The Agency for Healthcare Research and Quality (including funds appropriated under the authority of title IX of such Act (42 U.S.C. 299 et seq.)).

(3) BUDGETARY IMPLICATIONS.—Amounts appropriated under this section, and outlays flowing from such appropriations, shall not be taken into account for purposes of any budget enforcement procedures including allocations under section 302(a) and (b) of the Balanced Budget and Emergency Deficit Control Act and budget resolutions for fiscal years during which appropriations are made from the Fund.

TITLE I—COMMUNITY HEALTH CENTERS

SEC. 2101. INCREASED FUNDING.

Section 330 of the Public Health Service Act (42 U.S.C. 254b) is amended—

(1) in subsection (r)(1)—

(A) in subparagraph (D), by striking "and" at the end;

(B) in subparagraph (E), by striking the period at the end and inserting "; and"; and

(C) by inserting at the end the following:

"(F) such sums as may be necessary for each of fiscal years 2013 and 2014."; and

(2) by inserting after subsection (r) the following:

"(s) ADDITIONAL FUNDING.—For the purpose of carrying out this section, in addition to any other amounts authorized to be appropriated for such purpose, there are

authorized to be appropriated, out of any monies in the Public Health Investment Fund, the following:

"(1) For fiscal year 2010, $1,000,000,000.

"(2) For fiscal year 2011, $1,500,000,000.

"(3) For fiscal year 2012, $2,500,000,000.

"(4) For fiscal year 2013, $3,000,000,000.

"(5) For fiscal year 2014, $4,000,000,000.".

TITLE II—WORKFORCE

Subtitle A—Primary Care Workforce

PART 1—NATIONAL HEALTH SERVICE CORPS

SEC. 2201. NATIONAL HEALTH SERVICE CORPS.

(a) FULFILLMENT OF OBLIGATED SERVICE REQUIREMENT THROUGH HALF-TIME SERVICE.—

(1) WAIVERS.—Subsection (i) of section 331 (42 U.S.C. 254d) is amended—

(A) in paragraph (1), by striking "In carrying out subpart III" and all that follows through the period and inserting "In carrying out subpart III, the Secretary may, in accordance with this subsection, issue waivers to individuals who have entered into a contract for obligated service under the Scholarship Program or the Loan Repayment Program under which the individuals are authorized to satisfy the requirement of obligated service through providing clinical practice that is half-time.";

(B) in paragraph (2)—

(i) in subparagraphs (A)(ii) and (B), by striking "less than full time" each place it appears and inserting "half time";

(ii) in subparagraphs (C) and (F), by striking "less than full-time service" each place it appears and inserting "half-time service"; and

(iii) by amending subparagraphs (D) and (E) to read as follows:

"(D) the entity and the Corps member agree in writing that the Corps member will perform half-time clinical practice;

"(E) the Corps member agrees in writing to fulfill all of the service obligations under section 338C through half-time clinical practice and either—

"(i) double the period of obligated service that would otherwise be required; or

"(ii) in the case of contracts entered into under section 338B, accept a minimum service obligation of 2 years with an award amount equal to 50 percent of the amount that would otherwise be payable for full-time service; and"; and

(C) in paragraph (3), by striking "In evaluating a demonstration project described in paragraph (1)" and inserting "In evaluating waivers issued under paragraph (1)".

(2) DEFINITIONS.—Subsection (j) of section 331 (42 U.S.C. 254d) is amended by adding at the end the following:

"(5) The terms 'full time' and 'full-time' mean a minimum of 40 hours per week in a clinical practice, for a minimum of 45 weeks per year.

"(6) The terms 'half time' and 'half-time' mean a minimum of 20 hours per week (not to exceed 39 hours per week) in a clinical practice, for a minimum of 45 weeks per year.".

(b) REAPPOINTMENT TO NATIONAL ADVISORY COUNCIL.—Section 337(b)(1) (42 U.S.C. 254j(b)(1)) is amended by striking "Members may not be reappointed to the Council.".

(c) LOAN REPAYMENT AMOUNT.—Section 338B(g)(2)(A) (42 U.S.C. 254l–1(g)(2)(A)) is amended by striking "$35,000" and inserting "$50,000, plus, beginning with fiscal year 2012, an amount determined by the Secretary on an annual basis to reflect inflation,".

(d) TREATMENT OF TEACHING AS OBLIGATED SERVICE.—Subsection (a) of section 338C (42 U.S.C. 254m) is amended by adding at the end the following: "The Secretary may treat teaching as clinical practice for up to 20 percent of such period of obligated service.".

SEC. 2202. AUTHORIZATIONS OF APPROPRIATIONS.

(a) NATIONAL HEALTH SERVICE CORPS PROGRAM.—Section 338 (42 U.S.C. 254k) is amended—

(1) in subsection (a), by striking "2012" and inserting "2014"; and

(2) by adding at the end the following:

"(c) For the purpose of carrying out this subpart, in addition to any other amounts authorized to be appropriated for such purpose, there are authorized to be appropriated, out of any monies in the Public Health Investment Fund, the following:

"(1) $63,000,000 for fiscal year 2010.

"(2) $66,000,000 for fiscal year 2011.

"(3) $70,000,000 for fiscal year 2012.

"(4) $73,000,000 for fiscal year 2013.

"(5) $77,000,000 for fiscal year 2014.".

(b) SCHOLARSHIP AND LOAN REPAYMENT PROGRAMS.—Subpart III of part D of title III of the Public Health Service Act (42 U.S.C. 254l et seq.) is amended—

(1) in section 338H(a)—

(A) in paragraph (4), by striking "and" at the end;

(B) in paragraph (5), by striking the period at the end and inserting "; and"; and

(C) by adding at the end the following:

"(6) for fiscal years 2013 and 2014, such sums as may be necessary."; and

(2) by inserting after section 338H the following:

"SEC. 338H–1. ADDITIONAL FUNDING.

"For the purpose of carrying out this subpart, in addition to any other amounts authorized to be appropriated for such purpose, there are authorized to be appropriated, out of any monies in the Public Health Investment Fund, the following:

"(1) $254,000,000 for fiscal year 2010.

"(2) $266,000,000 for fiscal year 2011.

"(3) $278,000,000 for fiscal year 2012.

"(4) $292,000,000 for fiscal year 2013.

"(5) $306,000,000 for fiscal year 2014.".

PART 2—PROMOTION OF PRIMARY CARE AND DENTISTRY

SEC. 2211. FRONTLINE HEALTH PROVIDERS.

Part D of title III (42 U.S.C. 254b et seq.) is amended by adding at the end the following:

"Subpart XI—Health Professional Needs Areas

"SEC. 340H. IN GENERAL.

"(a) PROGRAM.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall establish a program, to be known as the Frontline Health Providers Loan Repayment Program, to address unmet health care needs in health professional needs areas through loan repayments under section 340I.

"(b) DESIGNATION OF HEALTH PROFESSIONAL NEEDS AREAS.—

"(1) IN GENERAL.—In this subpart, the term 'health professional needs area' means an area, population, or facility that is designated by the Secretary in accordance with paragraph (2).

"(2) DESIGNATION.—To be designated by the Secretary as a health professional needs area under this subpart:

"(A) In the case of an area, the area must be a rational area for the delivery of health services.

"(B) The area, population, or facility must have, in one or more health disciplines, specialties, or subspecialties for the population served, as determined by the Secretary—

"(i) insufficient capacity of health professionals; or

"(ii) high needs for health services, including services to address health disparities.

"(C) With respect to the delivery of primary health services, the area, population, or facility must not include a health professional shortage area (as designated under section 332), except that the area, population, or facility may include such a health professional shortage area in which there is an unmet need for such services.

"(c) ELIGIBILITY.—To be eligible to participate in the Program, an individual shall—

"(1) hold a degree in a course of study or program (approved by the Secretary) from a school defined in section 799B(1)(A) (other than a school of public health);

"(2) hold a degree in a course of study or program (approved by the Secretary) from a school or program defined in subparagraph (C), (D), or (E)(4) of section 799B(1), as designated by the Secretary;

"(3) be enrolled as a full-time student—

"(A) in a school or program defined in subparagraph (C), (D), or (E)(4) of section 799B(1), as designated by the Secretary, or a school described in paragraph (1); and

"(B) in the final year of a course of study or program, offered by such school or program and approved by the Secretary, leading to a degree in a discipline referred to in subparagraph (A) (other than a graduate degree in public health), (C), (D), or (E)(4) of section 799B(1);

"(4) be a practitioner described in section 1842(b)(18)(C) or 1848(k)(3)(B)(iii) or (iv) of the Social Security Act; or

"(5) be a practitioner in the field of respiratory therapy, medical technology, or radiologic technology.

"(d) DEFINITIONS.—In this subpart:

"(1) The term 'health disparities' has the meaning given to the term in section 3171.

"(2) The term 'primary health services' has the meaning given to such term in section 331(a)(3)(D).

"SEC. 340I. LOAN REPAYMENTS.

"(a) LOAN REPAYMENTS.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall enter into contracts with individuals under which—

"(1) the individual agrees—

"(A) to serve as a full-time primary health services provider or as a full-time or part-time provider of other health services for a period of time equal to 2 years or such longer period as the individual may agree to;

"(B) to serve in a health professional needs area in a health discipline, specialty, or a subspecialty for which the area, population, or facility is designated as a health professional needs area under section 340H; and

"(C) in the case of an individual described in section 340H(c)(3) who is in the final year of study and who has accepted employment as a primary health services provider or provider of other health services in accordance with subparagraphs (A) and (B), to complete the education or training and maintain an acceptable level of academic standing (as determined by the educational institution offering the course of study or training); and

"(2) the Secretary agrees to pay, for each year of such service, an amount on the principal and interest of the undergraduate or graduate educational loans (or both) of the individual that is not more than 50 percent of the average award made under the National Health Service Corps Loan Repayment Program under subpart III in that year.

"(b) PRACTICE SETTING.—A contract entered into under this section shall allow the individual receiving the loan repayment to satisfy the service requirement described in subsection (a)(1) through employment in a solo or group practice, a clinic, an accredited public or private nonprofit hospital, or any other health care entity, as deemed appropriate by the Secretary.

"(c) APPLICATION OF CERTAIN PROVISIONS.—The provisions of subpart III of part D shall, except as inconsistent with this section, apply to the loan repayment program under this subpart in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program established under section 338B.

"(d) INSUFFICIENT NUMBER OF APPLICANTS.—If there are an insufficient number of applicants for loan repayments under this section to obligate all appropriated funds, the Secretary shall transfer the unobligated funds to the National Health Service Corps for the purpose of recruiting applicants and entering into contracts with individuals so as to ensure a sufficient number of participants in the National Health Service Corps for the following year.

"SEC. 340J. REPORT.

"The Secretary shall submit to the Congress an annual report on the program carried out under this subpart.

"SEC. 340K. ALLOCATION.

"Of the amount of funds obligated under this subpart each fiscal year for loan repayments—

"(1) 90 percent shall be for physicians and other health professionals providing primary health services; and

"(2) 10 percent shall be for health professionals not described in paragraph (1).".

SEC. 2212. PRIMARY CARE STUDENT LOAN FUNDS.

(a) IN GENERAL.—Section 735 (42 U.S.C. 292y) is amended—

(1) by redesignating subsection (f) as subsection (g); and

(2) by inserting after subsection (e) the following:

"(f) DETERMINATION OF FINANCIAL NEED.—The Secretary—

"(1) may require, or authorize a school or other entity to require, the submission of financial information to determine the financial resources available to any individual seeking assistance under this subpart; and

"(2) shall take into account the extent to which such individual is financially independent in determining whether to require or authorize the submission of such information regarding such individual's family members.".

(b) REVISED GUIDELINES.—The Secretary of Health and Human Services shall—

(1) strike the second sentence of section 57.206(b) of title 42, Code of Federal Regulations; and

(2) make such other revisions to guidelines and regulations in effect as of the date of the enactment of this Act as may be necessary for consistency with the amendments made by paragraph (1).

SEC. 2213. TRAINING IN FAMILY MEDICINE, GENERAL INTERNAL MEDICINE, GENERAL PEDIATRICS, GERIATRICS, AND PHYSICIAN ASSISTANTS.

Section 747 (42 U.S.C. 293k) is amended—

(1) by amending the section heading to read as follows: "**PRIMARY CARE TRAINING AND ENHANCEMENT**";

(2) by redesignating subsection (e) as subsection (g); and

(3) by striking subsections (a) through (d) and inserting the following:

"(a) PROGRAM.—The Secretary shall establish a primary care training and capacity building program consisting of awarding grants and contracts under subsections (b) and (c).

"(b) SUPPORT AND DEVELOPMENT OF PRIMARY CARE TRAINING PROGRAMS.—

"(1) IN GENERAL.—The Secretary shall make grants to, or enter into contracts with, eligible entities—

"(A) to plan, develop, operate, or participate in an accredited professional training program, including an accredited residency or internship program, in the field of family medicine, general internal medicine, general pediatrics, or geriatrics for medical students, interns, residents, or practicing physicians;

"(B) to provide financial assistance in the form of traineeships and fellowships to medical students, interns, residents, or practicing physicians, who are participants in any such program, and who plan to specialize or work in family medicine, general internal medicine, general pediatrics, or geriatrics;

"(C) to plan, develop, operate, or participate in an accredited program for the training of physicians who plan to teach in family medicine, general internal medicine, general pediatrics, or geriatrics training programs including in community-based settings;

"(D) to provide financial assistance in the form of traineeships and fellowships to practicing physicians who are participants in any such programs and who plan to teach in a family medicine, general internal medicine, general pediatrics, or geriatrics training program; and

"(E) to plan, develop, operate, or participate in an accredited program for physician assistant education, and for the training of individuals who plan to teach in programs to provide such training.

"(2) ELIGIBILITY.—To be eligible for a grant or contract under paragraph (1), an entity shall be—

"(A) an accredited school of medicine or osteopathic medicine, public or nonprofit private hospital, or physician assistant training program;

"(B) a public or private nonprofit entity; or

"(C) a consortium of 2 or more entities described in subparagraphs (A) and (B).

"(c) CAPACITY BUILDING IN PRIMARY CARE.—

"(1) IN GENERAL.—The Secretary shall make grants to or enter into contracts with eligible entities to establish, maintain, or improve—

"(A) academic administrative units (including departments, divisions, or other appropriate units) in the specialties of family medicine, general internal medicine, general pediatrics, or geriatrics; or

"(B) programs that improve clinical teaching in such specialties.

"(2) ELIGIBILITY.—To be eligible for a grant or contract under paragraph (1), an entity shall be an accredited school of medicine or osteopathic medicine.

"(d) PREFERENCE.—In awarding grants or contracts under this section, the Secretary shall give preference to entities that have a demonstrated record of the following:

"(1) Training the greatest percentage, or significantly improving the percentage, of health professionals who provide primary care.

"(2) Training individuals who are from underrepresented minority groups or disadvantaged backgrounds.

"(3) A high rate of placing graduates in practice settings having the principal focus of serving in underserved areas or populations experiencing health disparities (including serving patients eligible for medical assistance under title XIX of the Social Security Act or for child health assistance under title XXI of such Act or those with special health care needs).

"(4) Supporting teaching programs that address the health care needs of vulnerable populations.

"(e) REPORT.—The Secretary shall submit to the Congress an annual report on the program carried out under this section.

"(f) DEFINITION.—In this section, the term 'health disparities' has the meaning given the term in section 3171.".

SEC. 2214. TRAINING OF MEDICAL RESIDENTS IN COMMUNITY-BASED SETTINGS.

Title VII (42 U.S.C. 292 et seq.) is amended—

(1) by redesignating section 748 as 749A; and

(2) by inserting after section 747 the following:

"SEC. 748. TRAINING OF MEDICAL RESIDENTS IN COMMUNITY-BASED SETTINGS.

"(a) PROGRAM.—The Secretary shall establish a program for the training of medical residents in community-based settings consisting of awarding grants and contracts under this section.

"(b) DEVELOPMENT AND OPERATION OF COMMUNITY-BASED PROGRAMS.—The Secretary shall make grants to, or enter into contracts with, eligible entities—

"(1) to plan and develop a new primary care residency training program, which may include—

"(A) planning and developing curricula;

"(B) recruiting and training residents and faculty; and

"(C) other activities designated to result in accreditation of such a program; or

"(2) to operate or participate in an established primary care residency training program, which may include—

"(A) planning and developing curricula;

"(B) recruitment and training of residents; and

"(C) retention of faculty.

"(c) ELIGIBLE ENTITY.—To be eligible to receive a grant or contract under subsection (b), an entity shall—

"(1) be designated as a recipient of payment for the direct costs of medical education under section 1886(k) of the Social Security Act;

"(2) be designated as an approved teaching health center under section 1502(d) of the America's Affordable Health Choices Act of 2009 and continuing to participate in the demonstration project under such section; or

"(3) be an applicant for designation described in paragraph (1) or (2) and have demonstrated to the Secretary appropriate involvement of an accredited teaching hospital to carry out the inpatient responsibilities associated with a primary care residency training program.

"(d) PREFERENCES.—In awarding grants and contracts under paragraph (1) or (2) of subsection (b), the Secretary shall give preference to entities that—

"(1) support teaching programs that address the health care needs of vulnerable populations; or

"(2) are a Federally qualified health center (as defined in section 1861(aa)(4) of the Social Security Act) or a rural health clinic (as defined in section 1861(aa)(2) of such Act).

"(e) ADDITIONAL PREFERENCES FOR ESTABLISHED PROGRAMS.—In awarding grants and contracts under subsection (b)(2), the Secretary shall give preference to entities that have a demonstrated record of training—

"(1) a high or significantly improved percentage of health professionals who provide primary care;

"(2) individuals who are from underrepresented minority groups or disadvantaged backgrounds; or

"(3) individuals who practice in settings having the principal focus of serving underserved areas or populations experiencing health disparities (including serving patients eligible for medical assistance under title XIX of the Social Security Act or for child health assistance under title XXI of such Act or those with special health care needs).

"(f) PERIOD OF AWARDS.—

"(1) IN GENERAL.—The period of a grant or contract under this section—

"(A) shall not exceed 3 years for awards under subsection (b)(1); and

"(B) shall not exceed 5 years for awards under subsection (b)(2).

"(2) SPECIAL RULES.—

"(A) An award of a grant or contract under subsection (b)(1) shall not be renewed.

"(B) The period of a grant or contract awarded to an entity under subsection (b)(2) shall not overlap with the period of any grant or contact awarded to the same entity under subsection (b)(1).

"(g) REPORT.—The Secretary shall submit to the Congress an annual report on the program carried out under this section.

"(h) DEFINITIONS.—In this section:

"(1) HEALTH DISPARITIES.—The term 'health disparities' has the meaning given the term in section 3171.

"(2) PRIMARY CARE RESIDENT.—The term 'primary care resident' has the meaning given the term in section 1886(h)(5)(H) of the Social Security Act.

"(3) PRIMARY CARE RESIDENCY TRAINING PROGRAM.—The term 'primary care residency training program' means an approved medical residency training program described in section 1886(h)(5)(A) of the Social Security Act for primary care residents that is—

"(A) in the case of entities seeking awards under subsection (b)(1), actively applying to be accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association; or

"(B) in the case of entities seeking awards under subsection (b)(2), so accredited.".

SEC. 2215. TRAINING FOR GENERAL, PEDIATRIC, AND PUBLIC HEALTH DENTISTS AND DENTAL HYGIENISTS.

Title VII (42 U.S.C. 292 et seq.) is amended—

(1) in section 791(a)(1), by striking "747 and 750" and inserting "747, 749, and 750"; and

(2) by inserting after section 748, as added, the following:

"SEC. 749. TRAINING FOR GENERAL, PEDIATRIC, AND PUBLIC HEALTH DENTISTS AND DENTAL HYGIENISTS.

"(a) PROGRAM.—The Secretary shall establish a training program for oral professionals consisting of awarding grants and contracts under this section.

"(b) SUPPORT AND DEVELOPMENT OF DENTAL TRAINING PROGRAMS.—The Secretary shall make grants to, or enter into contracts with, eligible entities—

"(1) to plan, develop, operate, or participate in an accredited professional training program for oral health professionals;

"(2) to provide financial assistance to oral health professionals who are in need thereof, who are participants in any such program, and who plan to work in general, pediatric, or public health dentistry, or dental hygiene;

"(3) to plan, develop, operate, or participate in a program for the training of oral health professionals who plan to teach in general, pediatric, or public health dentistry, or dental hygiene;

"(4) to provide financial assistance in the form of traineeships and fellowships to oral health professionals who plan to teach in general, pediatric, or public health dentistry or dental hygiene;

"(5) to establish, maintain, or improve—

"(A) academic administrative units (including departments, divisions, or other appropriate units) in the specialties of general, pediatric, or public health dentistry; or

"(B) programs that improve clinical teaching in such specialties;

"(6) to plan, develop, operate, or participate in predoctoral and postdoctoral training in general, pediatric, or public health dentistry programs;

"(7) to plan, develop, operate, or participate in a loan repayment program for full-time faculty in a program of general, pediatric, or public health dentistry; and

"(8) to provide technical assistance to pediatric dental training programs in developing and implementing instruction regarding the oral health status, dental care needs, and risk-based clinical disease management of all pediatric populations with an emphasis on underserved children.

"(c) ELIGIBILITY.—To be eligible for a grant or contract under subsection (a), an entity shall be—

"(1) an accredited school of dentistry, training program in dental hygiene, or public or nonprofit private hospital;

"(2) a training program in dental hygiene at an accredited institution of higher education;

"(3) a public or private nonprofit entity; or

"(4) a consortium of—

"(A) 1 or more of the entities described in paragraphs (1) through (3); and

"(B) an accredited school of public health.

"(d) PREFERENCE.—In awarding grants or contracts under this section, the Secretary shall give preference to entities that have a demonstrated record of the following:

"(1) Training the greatest percentage, or significantly improving the percentage, of oral health professionals who practice general, pediatric, or public health dentistry.

"(2) Training individuals who are from underrepresented minority groups or disadvantaged backgrounds.

"(3) A high rate of placing graduates in practice settings having the principal focus of serving in underserved areas or populations experiencing health disparities (including serving patients eligible for medical assistance under title XIX of the Social Security Act or for child health assistance under title XXI of such Act or those with special health care needs).

"(4) Supporting teaching programs that address the dental needs of vulnerable populations.

"(5) Providing instruction regarding the oral health status, dental care needs, and risk-based clinical disease management of all pediatric populations with an emphasis on underserved children.

"(e) REPORT.—The Secretary shall submit to the Congress an annual report on the program carried out under this section.

"(f) DEFINITIONS.—In this section:

"(1) The term 'health disparities' has the meaning given the term in section 3171.

"(2) The term 'oral health professional' means an individual training or practicing—

"(A) in general dentistry, pediatric dentistry, public health dentistry, or dental hygiene; or

"(B) another oral health specialty, as deemed appropriate by the Secretary.".

SEC. 2216. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—Part F of title VII (42 U.S.C. 295j et seq.) is amended by adding at the end the following:

"SEC. 799C. FUNDING THROUGH PUBLIC HEALTH INVESTMENT FUND.

"(a) PROMOTION OF PRIMARY CARE AND DENTISTRY.—For the purpose of carrying out subpart XI of part D of title III and sections 747, 748, and 749, in addition to any other amounts authorized to be appropriated for such purpose, there are authorized to be appropriated, out of any monies in the Public Health Investment Fund, the following:

"(1) $240,000,000 for fiscal year 2010.

"(2) $253,000,000 for fiscal year 2011.

"(3) $265,000,000 for fiscal year 2012.

"(4) $278,000,000 for fiscal year 2013.

"(5) $292,000,000 for fiscal year 2014.".

(b) EXISTING AUTHORIZATION OF APPROPRIATIONS.—Subsection (g), as so redesignated, of section 747 (42 U.S.C. 293k) is amended by striking "2002" and inserting "2014".

SEC. 2217. STUDY ON EFFECTIVENESS OF SCHOLARSHIPS AND LOAN REPAYMENTS.

Not later than 18 months after the date of the enactment of this Act, the Comptroller General of the United States shall conduct a study to determine the effectiveness of scholarship and loan repayment programs under subparts III and XI of part D of title III of the Public Health Service Act, as amended or added by sections 2201 and 2211, including whether scholarships or loan repayments are more effective in—

(1) incentivizing physicians, and other providers, to pursue careers in primary care specialties;

(2) retaining such primary care providers; and

(3) encouraging such primary care providers to practice in underserved areas.

Subtitle B—Nursing Workforce

SEC. 2221. AMENDMENTS TO PUBLIC HEALTH SERVICE ACT.

(a) DEFINITIONS.—Section 801 (42 U.S.C. 296 et seq.) is amended—

(1) in paragraph (1), by inserting "nurse-managed health centers," after "nursing centers,"; and

(2) by adding at the end the following:

"(16) NURSE-MANAGED HEALTH CENTER.—The term 'nurse-managed health center' means a nurse-practice arrangement, managed by advanced practice nurses, that provides primary care or wellness services to underserved or vulnerable populations and is associated with an accredited school of nursing, Federally qualified health center, or independent nonprofit health or social services agency.".

(b) GRANTS FOR HEALTH PROFESSIONS EDUCATION.—Title VIII (42 U.S.C. 296 et seq.) is amended by striking section 807.

(c) REPORTS.—Part A of title VIII (42 U.S.C. 296 et seq.) is amended by adding at the end the following:

"SEC. 809. REPORTS.

"The Secretary shall submit to the Congress a separate annual report on the activities carried out under each of sections 811, 821, 836, 846A, and 861.".

(d) ADVANCED EDUCATION NURSING GRANTS.—Section 811(f) (42 U.S.C. 296j(f)) is amended—

(1) by striking paragraph (2);

(2) by redesignating paragraph (3) as paragraph (2); and

(3) in paragraph (2), as so redesignated, by striking "that agrees" and all that follows through the end and inserting: "that agrees to expend the award—

"(A) to train advanced education nurses who will practice in health professional shortage areas designated under section 332; or

"(B) to increase diversity among advanced education nurses.".

(e) NURSE EDUCATION, PRACTICE, AND RETENTION GRANTS.—Section 831 (42 U.S.C. 296p) is amended—

(1) in subsection (b), by amending paragraph (3) to read as follows:

"(3) providing coordinated care, quality care, and other skills needed to practice nursing; or"; and

(2) by striking subsection (e) and redesignating subsections (f) through (h) as subsections (e) through (g), respectively.

(f) STUDENT LOANS.—Subsection (a) of section 836 (42 U.S.C. 297b) is amended—

(1) by striking "$2,500" and inserting "$3,300";

(2) by striking "$4,000" and inserting "$5,200";

(3) by striking "$13,000" and inserting "$17,000"; and

(4) by adding at the end the following: "Beginning with fiscal year 2012, the dollar amounts specified in this subsection shall be adjusted by an amount determined by the Secretary on an annual basis to reflect inflation.".

(g) LOAN REPAYMENT.—Section 846 (42 U.S.C. 297n) is amended—

(1) in subsection (a), by amending paragraph (3) to read as follows:

"(3) who enters into an agreement with the Secretary to serve for a period of not less than 2 years—

"(A) as a nurse at a health care facility with a critical shortage of nurses; or

"(B) as a faculty member at an accredited school of nursing;"; and

(2) in subsection (g)(1), by striking "to provide health services" each place it appears and inserting "to provide health services or serve as a faculty member".

(h) NURSE FACULTY LOAN PROGRAM.—Paragraph (2) of section 846A(c) (42 U.S.C. 297n–1(c)) is amended by striking "$30,000" and all that follows through the semicolon and inserting "$35,000, plus, beginning with fiscal year 2012, an amount determined by the Secretary on an annual basis to reflect inflation;".

(i) PUBLIC SERVICE ANNOUNCEMENTS.—Title VIII (42 U.S.C. 296 et seq.) is amended by striking part H.

(j) TECHNICAL AND CONFORMING AMENDMENTS.—Title VIII (42 U.S.C. 296 et seq.) is amended—

(1) by moving section 810 (relating to prohibition against discrimination by schools on the basis of sex) so that it follows section 809, as added by subsection (c);

(2) in sections 835, 836, 838, 840, and 842, by striking the term "this subpart" each place it appears and inserting "this part";

(3) in section 836(h), by striking the last sentence;

(4) in section 836, by redesignating subsection (l) as subsection (k);

(5) in section 839, by striking "839" and all that follows through "(a)" and inserting "839. (a)";

(6) in section 835(b), by striking "841" each place it appears and inserting "871";

(7) by redesignating section 841 as section 871, moving part F to the end of the title, and redesignating such part as part H;

(8) in part G—

(A) by redesignating section 845 as section 851; and

(B) by redesignating part G as part F; and

(9) in part I—

(A) by redesignating section 855 as section 861; and

(B) by redesignating part I as part G.

(k) FUNDING.—

(1) IN GENERAL.—Part H, as redesignated, of title VIII is amended by adding at the end the following:

"SEC. 872. FUNDING THROUGH PUBLIC HEALTH INVESTMENT FUND.

"For the purpose of carrying out this title, in addition to any other amounts authorized to be appropriated for such purpose, there are authorized to be appropriated, out of any monies in the Public Health Investment Fund, the following:

"(1) $115,000,000 for fiscal year 2010.

"(2) $122,000,000 for fiscal year 2011.

"(3) $127,000,000 for fiscal year 2012.

"(4) $134,000,000 for fiscal year 2013.

"(5) $140,000,000 for fiscal year 2014.".

(2) EXISTING AUTHORIZATIONS OF APPROPRIATIONS.—

(A) SECTIONS 831, 846, 846A, AND 861.—Sections 831(g) (as so redesignated), 846(i)(1) (42 U.S.C. 297n(i)(1)), 846A(f) (42 U.S.C. 297n–1(f)), and 861(e) (as so redesignated) are amended by striking "2007" each place it appears and inserting "2014".

(B) SECTION 871.—Section 871, as so redesignated by subsection (j), is amended to read as follows:

"SEC. 871. FUNDING.

"For the purpose of carrying out parts B, C, and D (subject to section 845(g)), there are authorized to be appropriated such sums as may be necessary for each fiscal year through fiscal year 2014.".

Subtitle C—Public Health Workforce

SEC. 2231. PUBLIC HEALTH WORKFORCE CORPS.

Part D of title III (42 U.S.C. 254b et seq.), as amended by section 2211, is amended by adding at the end the following:

"Subpart XII—Public Health Workforce

"SEC. 340L. PUBLIC HEALTH WORKFORCE CORPS.

"(a) ESTABLISHMENT.—There is established, within the Service, the Public Health Workforce Corps (in this subpart referred to as the 'Corps'), for the purpose of ensuring an adequate supply of public health professionals throughout the Nation. The Corps shall consist of—

"(1) such officers of the Regular and Reserve Corps of the Service as the Secretary may designate;

"(2) such civilian employees of the United States as the Secretary may appoint; and

"(3) such other individuals who are not employees of the United States.

"(b) ADMINISTRATION.—Except as provided in subsection (c), the Secretary shall carry out this subpart acting through the Administrator of the Health Resources and Services Administration.

"(c) PLACEMENT AND ASSIGNMENT.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall develop a methodology for placing and assigning Corps participants as public health professionals. Such methodology may allow for placing and assigning such participants in State, local, and tribal health departments and Federally qualified health centers (as defined in section 1861(aa)(4) of the Social Security Act).

"(d) APPLICATION OF CERTAIN PROVISIONS.—The provisions of subpart II shall, except as inconsistent with this subpart, apply to the Public Health Workforce Corps

in the same manner and to the same extent as such provisions apply to the National Health Service Corps established under section 331.

"(e) REPORT.—The Secretary shall submit to the Congress an annual report on the programs carried out under this subpart.

"SEC. 340M. PUBLIC HEALTH WORKFORCE SCHOLARSHIP PROGRAM.

"(a) ESTABLISHMENT.—The Secretary shall establish the Public Health Workforce Scholarship Program (referred to in this section as the 'Program') for the purpose described in section 340L(a).

"(b) ELIGIBILITY.—To be eligible to participate in the Program, an individual shall—

"(1)(A) be accepted for enrollment, or be enrolled, as a full-time or part-time student in a course of study or program (approved by the Secretary) at an accredited graduate school or program of public health; or

"(B) have demonstrated expertise in public health and be accepted for enrollment, or be enrolled, as a full-time or part-time student in a course of study or program (approved by the Secretary) at—

"(i) an accredited graduate school or program of nursing; health administration, management, or policy; preventive medicine; laboratory science; veterinary medicine; or dental medicine; or

"(ii) another accredited graduate school or program, as deemed appropriate by Secretary;

"(2) be eligible for, or hold, an appointment as a commissioned officer in the Regular or Reserve Corps of the Service or be eligible for selection for civilian service in the Corps; and

"(3) sign and submit to the Secretary a written contract (described in subsection (c)) to serve full-time as a public health professional, upon the completion of the course of study or program involved, for the period of obligated service described in subsection (c)(2)(E).

"(c) CONTRACT.—The written contract between the Secretary and an individual under subsection (b)(3) shall contain—

"(1) an agreement on the part of the Secretary that the Secretary will—

"(A) provide the individual with a scholarship for a period of years (not to exceed 4 academic years) during which the individual shall pursue an approved course of study or program to prepare the individual to serve in the public health workforce; and

"(B) accept (subject to the availability of appropriated funds) the individual into the Corps;

"(2) an agreement on the part of the individual that the individual will—

"(A) accept provision of such scholarship to the individual;

"(B) maintain full-time or part-time enrollment in the approved course of study or program described in subsection (b)(1) until the individual completes that course of study or program;

"(C) while enrolled in the approved course of study or program, maintain an acceptable level of academic standing (as determined by the educational institution offering such course of study or program);

"(D) if applicable, complete a residency or internship; and

"(E) serve full-time as a public health professional for a period of time equal to the greater of—

"(i) 1 year for each academic year for which the individual was provided a scholarship under the Program; or

"(ii) 2 years; and

"(3) an agreement by both parties as to the nature and extent of the scholarship assistance, which may include—

"(A) payment of reasonable educational expenses of the individual, including tuition, fees, books, equipment, and laboratory expenses; and

"(B) payment of a stipend of not more than $1,269 (plus, beginning with fiscal year 2011, an amount determined by the Secretary on an annual basis to reflect inflation) per month for each month of the academic year involved, with the dollar amount of such a stipend determined by the Secretary taking into consideration whether the individual is enrolled full-time or part-time.

"(d) APPLICATION OF CERTAIN PROVISIONS.—The provisions of subpart III shall, except as inconsistent with this subpart, apply to the scholarship program under this section in the same manner and to the same extent as such provisions apply to the National Health Service Corps Scholarship Program established under section 338A.

"SEC. 340N. PUBLIC HEALTH WORKFORCE LOAN REPAYMENT PROGRAM.

"(a) ESTABLISHMENT.—The Secretary shall establish the Public Health Workforce Loan Repayment Program (referred to in this section as the 'Program') for the purpose described in section 340L(a).

"(b) ELIGIBILITY.—To be eligible to participate in the Program, an individual shall—

"(1)(A) have a graduate degree from an accredited school or program of public health;

"(B) have demonstrated expertise in public health and have a graduate degree in a course of study or program (approved by the Secretary) from—

"(i) an accredited school or program of nursing; health administration, management, or policy; preventive medicine; laboratory science; veterinary medicine; or dental medicine; or

"(ii) another accredited school or program approved by the Secretary; or

"(C) be enrolled as a full-time or part-time student in the final year of a course of study or program (approved by the Secretary) offered by a school or program described in subparagraph (A) or (B), leading to a graduate degree;

"(2) be eligible for, or hold, an appointment as a commissioned officer in the Regular or Reserve Corps of the Service or be eligible for selection for civilian service in the Corps;

"(3) if applicable, complete a residency or internship; and

"(4) sign and submit to the Secretary a written contract (described in subsection (c)) to serve full-time as a public health professional for the period of obligated service described in subsection (c)(2).

"(c) CONTRACT.—The written contract between the Secretary and an individual under subsection (b)(4) shall contain—

"(1) an agreement by the Secretary to repay on behalf of the individual loans incurred by the individual in the pursuit of the relevant public health workforce educational degree in accordance with the terms of the contract;

"(2) an agreement by the individual to serve full-time as a public health professional for a period of time equal to 2 years or such longer period as the individual may agree to; and

"(3) in the case of an individual described in subsection (b)(1)(C) who is in the final year of study and who has accepted employment as a public health professional, in accordance with section 340L(c), an agreement on the part of the individual to complete the education or training, maintain an acceptable level of academic standing (as determined by the educational institution offering the course of study or training), and serve the period of obligated service described in paragraph (2).

"(d) PAYMENTS.—

"(1) IN GENERAL.—A loan repayment provided for an individual under a written contract under the Program shall consist of payment, in accordance with paragraph (2), on behalf of the individual of the principal, interest, and related expenses on government and commercial loans received by the individual regarding the undergraduate or graduate education of the individual (or both), which loans were made for reasonable educational expenses, including tuition, fees, books, equipment, and laboratory expenses, incurred by the individual.

"(2) PAYMENTS FOR YEARS SERVED.—

"(A) IN GENERAL.—For each year of obligated service that an individual contracts to serve under subsection (c), the Secretary may pay up to $35,000 (plus, beginning with fiscal year 2012, an amount determined by the Secretary on an annual basis to reflect inflation) on behalf of the individual for loans described in paragraph (1).

"(B) REPAYMENT SCHEDULE.—Any arrangement made by the Secretary for the making of loan repayments in accordance with this subsection shall provide that any repayments for a year of obligated service shall be made no later than the end of the fiscal year in which the individual completes such year of service.

"(e) APPLICATION OF CERTAIN PROVISIONS.—The provisions of subpart III shall, except as inconsistent with this subpart, apply to the loan repayment program under this section in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program established under section 338B.".

SEC. 2232. ENHANCING THE PUBLIC HEALTH WORKFORCE.

Section 765 (42 U.S.C. 295) is amended to read as follows:

"SEC. 765. ENHANCING THE PUBLIC HEALTH WORKFORCE.

"(a) PROGRAM.—The Secretary, acting through the Administrator of the Health Resources and Services Administration and in consultation with the Director of the

Centers for Disease Control and Prevention, shall establish a public health workforce training and enhancement program consisting of awarding grants and contracts under subsection (b).

"(b) GRANTS AND CONTRACTS.—The Secretary shall award grants and contracts to eligible entities—

"(1) to plan, develop, operate, or participate in, an accredited professional training program in the field of public health (including such a program in nursing; health administration, management, or policy; preventive medicine; laboratory science; veterinary medicine; or dental medicine) for members of the public health workforce including mid-career professionals;

"(2) to provide financial assistance in the form of traineeships and fellowships to students who are participants in any such program and who plan to specialize or work in the field of public health;

"(3) to plan, develop, operate, or participate in a program for the training of public health professionals who plan to teach in any program described in paragraph (1); and

"(4) to provide financial assistance in the form of traineeships and fellowships to public health professionals who are participants in any program described in paragraph (1) and who plan to teach in the field of public health, including nursing; health administration, management, or policy; preventive medicine; laboratory science; veterinary medicine; or dental medicine.

"(c) ELIGIBILITY.—To be eligible for a grant or contract under subsection (a), an entity shall be—

"(1) an accredited health professions school, including an accredited school or program of public health; nursing; health administration, management, or policy; preventive medicine; laboratory science; veterinary medicine; or dental medicine;

"(2) a State, local, or tribal health department;

"(3) a public or private nonprofit entity; or

"(4) a consortium of 2 or more entities described in paragraphs (1) through (3).

"(d) PREFERENCE.—In awarding grants or contracts under this section, the Secretary shall give preference to entities that have a demonstrated record of the following:

"(1) Training the greatest percentage, or significantly improving the percentage, of public health professionals who serve in underserved communities.

"(2) Training individuals who are from underrepresented minority groups or disadvantaged backgrounds.

"(3) Training individuals in public health specialties experiencing a significant shortage of public health professionals (as determined by the Secretary).

"(4) Training the greatest percentage, or significantly improving the percentage, of public health professionals serving in the Federal Government or a State, local, or tribal government.

"(e) REPORT.—The Secretary shall submit to the Congress an annual report on the program carried out under this section.".

SEC. 2233. PUBLIC HEALTH TRAINING CENTERS.

Section 766 (42 U.S.C. 295a) is amended—

(1) in subsection (b)(1), by striking "in furtherance of the goals established by the Secretary for the year 2000" and inserting "in furtherance of the goals established by the Secretary in the national prevention and wellness strategy under section 3121"; and

(2) by adding at the end the following:

"(d) REPORT.—The Secretary shall submit to the Congress an annual report on the program carried out under this section.".

SEC. 2234. PREVENTIVE MEDICINE AND PUBLIC HEALTH TRAINING GRANT PROGRAM.

Section 768 (42 U.S.C. 295c) is amended to read as follows:

"SEC. 768. PREVENTIVE MEDICINE AND PUBLIC HEALTH TRAINING GRANT PROGRAM.

"(a) GRANTS.—The Secretary, acting through the Administrator of the Health Resources and Services Administration and in consultation with the Director of the Centers for Disease Control and Prevention, shall award grants to, or enter into contracts with, eligible entities to provide training to graduate medical residents in preventive medicine specialties.

"(b) ELIGIBILITY.—To be eligible for a grant or contract under subsection (a), an entity shall be—

"(1) an accredited school of public health or school of medicine or osteopathic medicine;

"(2) an accredited public or private hospital;

"(3) a State, local, or tribal health department; or

"(4) a consortium of 2 or more entities described in paragraphs (1) through (3).

"(c) USE OF FUNDS.—Amounts received under a grant or contract under this section shall be used to—

"(1) plan, develop (including the development of curricula), operate, or participate in an accredited residency or internship program in preventive medicine or public health;

"(2) defray the costs of practicum experiences, as required in such a program; and

"(3) establish, maintain, or improve—

"(A) academic administrative units (including departments, divisions, or other appropriate units) in preventive medicine and public health; or

"(B) programs that improve clinical teaching in preventive medicine and public health.

"(d) REPORT.—The Secretary shall submit to the Congress an annual report on the program carried out under this section.".

SEC. 2235. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—Section 799C, as added by section 2216 of this Act, is amended by adding at the end the following:

"(b) PUBLIC HEALTH WORKFORCE.—For the purpose of carrying out subpart XII of part D of title III and sections 765, 766, and 768, in addition to any other amounts authorized to be appropriated for such purpose, there are authorized to be appropriated, out of any monies in the Public Health Investment Fund, the following:

"(1) $51,000,000 for fiscal year 2010.

"(2) $54,000,000 for fiscal year 2011.

"(3) $57,000,000 for fiscal year 2012.

"(4) $59,000,000 for fiscal year 2013.

"(5) $62,000,000 for fiscal year 2014.".

(b) EXISTING AUTHORIZATION OF APPROPRIATIONS.—Subsection (a) of section 770 (42 U.S.C. 295e) is amended by striking "2002" and inserting "2014".

Subtitle D—Adapting Workforce to Evolving Health System Needs

PART 1—HEALTH PROFESSIONS TRAINING FOR DIVERSITY

SEC. 2241. SCHOLARSHIPS FOR DISADVANTAGED STUDENTS, LOAN REPAYMENTS AND FELLOWSHIPS REGARDING FACULTY POSITIONS, AND EDUCATIONAL ASSISTANCE IN THE HEALTH PROFESSIONS REGARDING INDIVIDUALS FROM DISADVANTAGED BACKGROUNDS.

Paragraph (1) of section 738(a) (42 U.S.C. 293b(a)) is amended by striking "not more than $20,000" and all that follows through the end of the paragraph and inserting: "not more than $35,000 (plus, beginning with fiscal year 2012, an amount determined by the Secretary on an annual basis to reflect inflation) of the principal and interest of the educational loans of such individuals."

SEC. 2242. NURSING WORKFORCE DIVERSITY GRANTS.

Subsection (b) of section 821 (42 U.S.C. 296m) is amended—

(1) in the heading, by striking "GUIDANCE" and inserting "CONSULTATION"; and

(2) by striking "shall take into consideration" and all that follows through "consult with nursing associations" and inserting "shall, as appropriate, consult with nursing associations".

SEC. 2243. COORDINATION OF DIVERSITY AND CULTURAL COMPETENCY PROGRAMS.

(a) IN GENERAL.—Title VII (42 U.S.C. 292 et seq.) is amended by inserting after section 739 the following:

"SEC. 739A. COORDINATION OF DIVERSITY AND CULTURAL COMPETENCY PROGRAMS.

"The Secretary shall, to the extent practicable, coordinate the activities carried out under this part and section 821 in order to enhance the effectiveness of such activities and avoid duplication of effort.".

(b) REPORT.—Section 736 (42 U.S.C. 293) is amended—

(1) by redesignating subsection (h) as subsection (i); and

(2) by inserting after subsection (g) the following:

"(h) REPORT.—The Secretary shall submit to the Congress an annual report on the activities carried out under this section.".

PART 2—INTERDISCIPLINARY TRAINING PROGRAMS

SEC. 2251. CULTURAL AND LINGUISTIC COMPETENCY TRAINING FOR HEALTH PROFESSIONALS.

Section 741 (42 U.S.C. 293e) is amended—

(1) in the section heading, by striking "**GRANTS FOR HEALTH PROFESSIONS EDUCATION**" and inserting "**CULTURAL AND LINGUISTIC COMPETENCY TRAINING FOR HEALTH PROFESSIONALS**";

(2) by redesignating subsection (b) as subsection (h); and

(3) by striking subsection (a) and inserting the following:

"(a) PROGRAM.—The Secretary shall establish a cultural and linguistic competency training program for health professionals, including nurse professionals, consisting of awarding grants and contracts under subsection (b).

"(b) CULTURAL AND LINGUISTIC COMPETENCY TRAINING.—The Secretary shall award grants and contracts to eligible entities—

"(1) to test, develop, and evaluate models of cultural and linguistic competency training (including continuing education) for health professionals; and

"(2) to implement cultural and linguistic competency training programs for health professionals developed under paragraph (1) or otherwise.

"(c) ELIGIBILITY.—To be eligible for a grant or contract under subsection (b), an entity shall be—

"(1) an accredited health professions school or program;

"(2) an academic health center;

"(3) a public or private nonprofit entity; or

"(4) a consortium of 2 or more entities described in paragraphs (1) through (3).

"(d) PREFERENCE.—In awarding grants and contracts under this section, the Secretary shall give preference to entities that have a demonstrated record of the following:

"(1) Addressing, or partnering with an entity with experience addressing, the cultural and linguistic competency needs of the population to be served through the grant or contract.

"(2) Addressing health disparities.

"(3) Placing health professionals in regions experiencing significant changes in the cultural and linguistic demographics of populations, including communities along the United States-Mexico border.

"(4) Carrying out activities described in subsection (b) with respect to more than one health profession discipline, specialty, or subspecialty.

"(e) CONSULTATION.—The Secretary shall carry out this section in consultation with the heads of appropriate health agencies and offices in the Department of Health and Human Services, including the Office of Minority Health.

"(f) DEFINITION.—In this section, the term 'health disparities' has the meaning given to the term in section 3171.

"(g) REPORT.—The Secretary shall submit to the Congress an annual report on the program carried out under this section.".

SEC. 2252. INNOVATIONS IN INTERDISCIPLINARY CARE TRAINING.

Part D of title VII (42 U.S.C. 294 et seq.) is amended by adding at the end the following:

"SEC. 759. INNOVATIONS IN INTERDISCIPLINARY CARE TRAINING.

"(a) PROGRAM.—The Secretary shall establish an innovations in interdisciplinary care training program consisting of awarding grants and contracts under subsection (b).

"(b) TRAINING PROGRAMS.—The Secretary shall award grants to, or enter into contracts with, eligible entities—

"(1) to test, develop, and evaluate health professional training programs (including continuing education) designed to promote—

"(A) the delivery of health services through interdisciplinary and team-based models, which may include patient-centered medical home models, medication therapy management models, and models integrating physical, mental, or oral health services; and

"(B) coordination of the delivery of health care within and across settings, including health care institutions, community-based settings, and the patient's home; and

"(2) to implement such training programs developed under paragraph (1) or otherwise.

"(c) ELIGIBILITY.—To be eligible for a grant or contract under subsection (b), an entity shall be—

"(1) an accredited health professions school or program;

"(2) an academic health center;

"(3) a public or private nonprofit entity (including an area health education center or a geriatric education center); or

"(4) a consortium of 2 or more entities described in paragraphs (1) through (3).

"(d) PREFERENCES.—In awarding grants and contracts under this section, the Secretary shall give preference to entities that have a demonstrated record of the following:

"(1) Training the greatest percentage, or significantly increasing the percentage, of health professionals who serve in underserved communities.

"(2) Broad interdisciplinary team-based collaborations.

"(3) Addressing health disparities.

"(e) REPORT.—The Secretary shall submit to the Congress an annual report on the program carried out under this section.

"(f) DEFINITIONS.—In this section:

"(1) The term 'health disparities' has the meaning given the term in section 3171.

"(2) The term 'interdisciplinary' means collaboration across health professions and specialties, which may include public health, nursing, allied health, and appropriate medical specialties.".

PART 3—ADVISORY COMMITTEE ON HEALTH WORKFORCE EVALUATION AND ASSESSMENT

SEC. 2261. HEALTH WORKFORCE EVALUATION AND ASSESSMENT.

Subpart 1 of part E of title VII (42 U.S.C. 294n et seq.) is amended by adding at the end the following:

"SEC. 764. HEALTH WORKFORCE EVALUATION AND ASSESSMENT.

"(a) ADVISORY COMMITTEE.—The Secretary, acting through the Assistant Secretary for Health, shall establish a permanent advisory committee to be known as the Advisory Committee on Health Workforce Evaluation and Assessment (referred to in this section as the 'Advisory Committee').

"(b) RESPONSIBILITIES.—The Advisory Committee shall—

"(1) not later than 1 year after the date of the establishment of the Advisory Committee, submit recommendations to the Secretary on—

"(A) classifications of the health workforce to ensure consistency of data collection on the health workforce; and

"(B) based on such classifications, standardized methodologies and procedures to enumerate the health workforce;

"(2) not later than 2 years after the date of the establishment of the Advisory Committee, submit recommendations to the Secretary on—

"(A) the supply, diversity, and geographic distribution of the health workforce;

"(B) the retention of the health workforce to ensure quality and adequacy of such workforce; and

"(C) policies to carry out the recommendations made pursuant to subparagraphs (A) and (B); and

"(3) not later than 4 years after the date of the establishment of the Advisory Committee, and every 2 years thereafter, submit updated recommendations to the Secretary under paragraphs (1) and (2).

"(c) ROLE OF AGENCY.—The Secretary shall provide ongoing administrative, research, and technical support for the operations of the Advisory Committee, including coordinating and supporting the dissemination of the recommendations of the Advisory Committee.

"(d) MEMBERSHIP.—

"(1) NUMBER; APPOINTMENT.—The Secretary shall appoint 15 members to serve on the Advisory Committee.

"(2) TERMS.—

"(A) IN GENERAL.—The Secretary shall appoint members of the Advisory Committee for a term of 3 years and may reappoint such members, but the Secretary may not appoint any member to serve more than a total of 6 years.

"(B) STAGGERED TERMS.—Notwithstanding subparagraph (A), of the members first appointed to the Advisory Committee under paragraph (1)—

"(i) 5 shall be appointed for a term of 1 year;

"(ii) 5 shall be appointed for a term of 2 years; and

"(iii) 5 shall be appointed for a term of 3 years.

"(3) QUALIFICATIONS.—Members of the Advisory Committee shall be appointed from among individuals who possess expertise in at least one of the following areas:

"(A) Conducting and interpreting health workforce market analysis, including health care labor workforce analysis.

"(B) Conducting and interpreting health finance and economics research.

"(C) Delivering and administering health care services.

"(D) Delivering and administering health workforce education and training.

"(4) REPRESENTATION.—In appointing members of the Advisory Committee, the Secretary shall—

"(A) include no less than one representative of each of—

"(i) health professionals within the health workforce;

"(ii) health care patients and consumers;

"(iii) employers;

"(iv) labor unions; and

"(v) third-party health payors; and

"(B) ensure that—

"(i) all areas of expertise described in paragraph (3) are represented;

"(ii) the members of the Advisory Committee include members who, collectively, have significant experience working with—

"(I) populations in urban and federally designated rural and nonmetropolitan areas; and

"(II) populations who are underrepresented in the health professions, including underrepresented minority groups; and

"(iii) individuals who are directly involved in health professions education or practice do not constitute a majority of the members of the Advisory Committee.

"(5) DISCLOSURE AND CONFLICTS OF INTEREST.—Members of the Advisory Committee shall not be considered employees of the Federal Government by reason of service on the Advisory Committee, except members of the Advisory Committee shall be considered to be special Government employees within the meaning of section 107 of the Ethics in Government Act of 1978 (5 U.S.C. App.) and section 208 of title 18, United States Code, for the purposes of disclosure and management of conflicts of interest under those sections.

"(6) NO PAY; RECEIPT OF TRAVEL EXPENSES.—Members of the Advisory Committee shall not receive any pay for service on the Committee, but may receive travel expenses, including a per diem, in accordance with applicable provisions of subchapter I of chapter 57 of title 5, United States Code.

"(e) CONSULTATION.—In carrying out this section, the Secretary shall consult with the Secretary of Education and the Secretary of Labor.

"(f) COLLABORATION.—The Advisory Committee shall collaborate with the advisory bodies at the Health Resources and Services Administration, the National Advisory Council (as authorized in section 337), the Advisory Committee on Training in Primary Care Medicine and Dentistry (as authorized in section 749A), the Advisory Committee on Interdisciplinary, Community-Based Linkages (as authorized in section 756), the Advisory Council on Graduate Medical Education (as authorized in section 762), and the National Advisory Council on Nurse Education and Practice (as authorized in section 851).

"(g) FACA.—The Federal Advisory Committee Act (5 U.S.C. App.) except for section 14 of such Act shall apply to the Advisory Committee under this section only to the extent that the provisions of such Act do not conflict with the requirements of this section.

"(h) REPORT.—The Secretary shall submit to the Congress an annual report on the activities of the Advisory Committee.

"(i) DEFINITION.—In this section, the term 'health workforce' includes all health care providers with direct patient care and support responsibilities, including physicians, nurses, physician assistants, pharmacists, oral health professionals (as defined in section 749(f)), allied health professionals, mental and behavioral health professionals, and public health professionals (including veterinarians engaged in public health practice).".

PART 4—HEALTH WORKFORCE ASSESSMENT

SEC. 2271. HEALTH WORKFORCE ASSESSMENT.

(a) IN GENERAL.—Section 761 (42 U.S.C. 294n) is amended—

(1) by redesignating subsection (c) as subsection (e); and

(2) by striking subsections (a) and (b) and inserting the following:

"(a) IN GENERAL.—The Secretary shall, based upon the classifications and standardized methodologies and procedures developed by the Advisory Committee on Health Workforce Evaluation and Assessment under section 764(b)—

"(1) collect data on the health workforce (as defined in section 764(i)), disaggregated by field, discipline, and specialty, with respect to—

"(A) the supply (including retention) of health professionals relative to the demand for such professionals;

"(B) the diversity of health professionals (including with respect to race, ethnic background, and gender); and

"(C) the geographic distribution of health professionals; and

"(2) collect such data on individuals participating in the programs authorized by subtitles A, B, and C and part 1 of subtitle D of title II of division C of the America's Affordable Health Choices Act of 2009.

"(b) GRANTS AND CONTRACTS FOR HEALTH WORKFORCE ANALYSIS.—

"(1) IN GENERAL.—The Secretary may award grants or contracts to eligible entities to carry out subsection (a).

"(2) ELIGIBILITY.—To be eligible for a grant or contract under this subsection, an entity shall be—

"(A) an accredited health professions school or program;

"(B) an academic health center;

"(C) a State, local, or tribal government;

"(D) a public or private entity; or

"(E) a consortium of 2 or more entities described in subparagraphs (A) through (D).

"(c) COLLABORATION AND DATA SHARING.—The Secretary shall collaborate with Federal departments and agencies, health professions organizations (including health professions education organizations), and professional medical societies for the purpose of carrying out subsection (a).

"(d) REPORT.—The Secretary shall submit to the Congress an annual report on the data collected under subsection (a).".

(b) PERIOD BEFORE COMPLETION OF NATIONAL STRATEGY.—Pending completion of the classifications and standardized methodologies and procedures developed by the Advisory Committee on Health Workforce Evaluation and Assessment under section 764(b) of the Public Health Service Act, as added by section 2261, the Secretary of Health and Human Services, acting through the Administrator of the Health Resources and Services Administration and in consultation with such Advisory Committee, may make a judgment about the classifications, methodologies, and procedures to be used for collection of data under section 761(a) of the Public Health Service Act, as amended by this section.

PART 5—AUTHORIZATION OF APPROPRIATIONS

SEC. 2281. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—Section 799C, as added and amended, is further amended by adding at the end the following:

"(c) HEALTH PROFESSIONS TRAINING FOR DIVERSITY.—For the purpose of carrying out sections 736, 737, 738, 739, and 739A, in addition to any other amounts authorized to be appropriated for such purpose, there are authorized to be appropriated, out of any monies in the Public Health Investment Fund, the following:

"(1) $90,000,000 for fiscal year 2010.

"(2) $97,000,000 for fiscal year 2011.

"(3) $100,000,000 for fiscal year 2012.

"(4) $104,000,000 for fiscal year 2013.

"(5) $110,000,000 for fiscal year 2014.

"(d) INTERDISCIPLINARY TRAINING PROGRAMS, ADVISORY COMMITTEE ON HEALTH WORKFORCE EVALUATION AND ASSESSMENT, AND HEALTH WORKFORCE ASSESSMENT.—For the purpose of carrying out sections 741, 759, 761, and 764, in addition to any other amounts authorized to be appropriated for such purpose, there are authorized to be appropriated, out of any monies in the Public Health Investment Fund, the following:

"(1) $87,000,000 for fiscal year 2010.

"(2) $97,000,000 for fiscal year 2011.
"(3) $103,000,000 for fiscal year 2012.
"(4) $105,000,000 for fiscal year 2013.
"(5) $113,000,000 for fiscal year 2014.".

(b) EXISTING AUTHORIZATIONS OF APPROPRIATIONS.—

(1) SECTION 736.—Paragraph (1) of section 736(i) (42 U.S.C. 293(h)), as redesignated, is amended by striking "2002" and inserting "2014".

(2) SECTIONS 737, 738, AND 739.—Subsections (a), (b), and (c) of section 740 are amended by striking "2002" each place it appears and inserting "2014".

(3) SECTION 741.—Subsection (h), as so redesignated, of section 741 is amended—

(A) by striking "and" after "fiscal year 2003,"; and

(B) by inserting ", and such sums as may be necessary for subsequent fiscal years through the end of fiscal year 2014" before the period at the end.

(4) SECTION 761.—Subsection (e)(1), as so redesignated, of section 761 is amended by striking "2002" and inserting "2014".

TITLE III—PREVENTION AND WELLNESS

SEC. 2301. PREVENTION AND WELLNESS.

(a) IN GENERAL.—The Public Health Service Act (42 U.S.C. 201 et seq.) is amended by adding at the end the following:

"TITLE XXXI—PREVENTION AND WELLNESS

"Subtitle A—Prevention and Wellness Trust

"SEC. 3111. PREVENTION AND WELLNESS TRUST.

"(a) DEPOSITS INTO TRUST.—There is established a Prevention and Wellness Trust. There are authorized to be appropriated to the Trust—

"(1) amounts described in section 2002(b)(2)(A)(ii) of the America's Affordable Health Choices Act of 2009 for each fiscal year; and

"(2) in addition, out of any monies in the Public Health Investment Fund—

"(A) for fiscal year 2010, $2,400,000,000;
"(B) for fiscal year 2011, $2,845,000,000;
"(C) for fiscal year 2012, $3,100,000,000;
"(D) for fiscal year 2013, $3,455,000,000; and
"(E) for fiscal year 2014, $3,600,000,000.

"(b) AVAILABILITY OF FUNDS.—Amounts in the Prevention and Wellness Trust shall be available, as provided in advance in appropriation Acts, for carrying out this title.

"(c) ALLOCATION.—Of the amounts authorized to be appropriated in subsection (a)(2), there are authorized to be appropriated—

"(1) for carrying out subtitle C (Prevention Task Forces), $30,000,000 for each of fiscal years 2010 through 2014;

"(2) for carrying out subtitle D (Prevention and Wellness Research)—

"(A) for fiscal year 2010, $100,000,000;
"(B) for fiscal year 2011, $150,000,000;
"(C) for fiscal year 2012, $200,000,000;
"(D) for fiscal year 2013, $250,000,000; and
"(E) for fiscal year 2014, $300,000,000;

"(3) for carrying out subtitle E (Delivery of Community Preventive and Wellness Services)—

"(A) for fiscal year 2010, $1,065,000,000;
"(B) for fiscal year 2011, $1,260,000,000;
"(C) for fiscal year 2012, $1,365,000,000;
"(D) for fiscal year 2013, $1,570,000,000; and
"(E) for fiscal year 2014, $1,600,000,000;

"(4) for carrying out section 3161 (Core Public Health Infrastructure for State, Local, and Tribal Health Departments)—

"(A) for fiscal year 2010, $800,000,000;
"(B) for fiscal year 2011, $1,000,000,000;
"(C) for fiscal year 2012, $1,100,000,000;
"(D) for fiscal year 2013, $1,200,000,000; and
"(E) for fiscal year 2014, $1,265,000,000; and

"(5) for carrying out section 3162 (Core Public Health Infrastructure and Activities for CDC), $350,000,000 for each of fiscal years 2010 through 2014.

"Subtitle B—National Prevention and Wellness Strategy

"SEC. 3121. NATIONAL PREVENTION AND WELLNESS STRATEGY.

"(a) IN GENERAL.—The Secretary shall submit to the Congress within one year after the date of the enactment of this section, and at least every 2 years thereafter, a national strategy that is designed to improve the Nation's health through evidence-based clinical and community prevention and wellness activities (in this section referred to as 'prevention and wellness activities'), including core public health infrastructure improvement activities.

"(b) CONTENTS.—The strategy under subsection (a) shall include each of the following:

"(1) Identification of specific national goals and objectives in prevention and wellness activities that take into account appropriate public health measures and standards, including departmental measures and standards (including Healthy People and National Public Health Performance Standards).

"(2) Establishment of national priorities for prevention and wellness, taking into account unmet prevention and wellness needs.

"(3) Establishment of national priorities for research on prevention and wellness, taking into account unanswered research questions on prevention and wellness.

"(4) Identification of health disparities in prevention and wellness.

"(5) Review of prevention payment incentives, the prevention workforce, and prevention delivery system capacity.

"(6) A plan for addressing and implementing paragraphs (1) through (5).

"(c) CONSULTATION.—In developing or revising the strategy under subsection (a), the Secretary shall consult with the following:

"(1) The heads of appropriate health agencies and offices in the Department, including the Office of the Surgeon General of the Public Health Service, the Office of Minority Health, the Office on Women's Health, and the Substance Abuse and Mental Health Services Administration.

"(2) As appropriate, the heads of other Federal departments and agencies whose programs have a significant impact upon health (as determined by the Secretary).

"(3) As appropriate, nonprofit and for-profit entities.

"(4) The Association of State and Territorial Health Officials and the National Association of County and City Health Officials.

"(5) The Task Force on Community Preventive Services and the Task Force on Clinical Preventive Services.

"Subtitle C—Prevention Task Forces

"SEC. 3131. TASK FORCE ON CLINICAL PREVENTIVE SERVICES.

"(a) IN GENERAL.—The Secretary, acting through the Director of the Agency for Healthcare Research and Quality, shall establish a permanent task force to be known as the Task Force on Clinical Preventive Services (in this section referred to as the 'Task Force').

"(b) RESPONSIBILITIES.—The Task Force shall—

"(1) identify clinical preventive services for review;

"(2) review the scientific evidence related to the benefits, effectiveness, appropriateness, and costs of clinical preventive services identified under paragraph (1) for the purpose of developing, updating, publishing, and disseminating evidence-based recommendations on the use of such services;

"(3) as appropriate, take into account health disparities in developing, updating, publishing, and disseminating evidence-based recommendations on the use of such services;

"(4) identify gaps in clinical preventive services research and evaluation and recommend priority areas for such research and evaluation;

"(5) as appropriate, consult with the clinical prevention stakeholders board in accordance with subsection (f);

"(6) consult with the Task Force on Community Preventive Services established under section 3132; and

"(7) as appropriate, in carrying out this section, consider the national strategy under section 3121.

"(c) ROLE OF AGENCY.—The Secretary shall provide ongoing administrative, research, and technical support for the operations of the Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force.

"(d) MEMBERSHIP.—

"(1) NUMBER; APPOINTMENT.—The Task Force shall be composed of 30 members, appointed by the Secretary.

"(2) TERMS.—

"(A) IN GENERAL.—The Secretary shall appoint members of the Task Force for a term of 6 years and may reappoint such members, but the Secretary may not appoint any member to serve more than a total of 12 years.

"(B) STAGGERED TERMS.—Notwithstanding subparagraph (A), of the members first appointed to serve on the Task Force after the enactment of this title—

"(i) 10 shall be appointed for a term of 2 years;

"(ii) 10 shall be appointed for a term of 4 years; and

"(iii) 10 shall be appointed for a term of 6 years.

"(3) QUALIFICATIONS.—Members of the Task Force shall be appointed from among individuals who possess expertise in at least one of the following areas:

"(A) Health promotion and disease prevention.

"(B) Evaluation of research and systematic evidence reviews.

"(C) Application of systematic evidence reviews to clinical decisionmaking or health policy.

"(D) Clinical primary care in child and adolescent health.

"(E) Clinical primary care in adult health, including women's health.

"(F) Clinical primary care in geriatrics.

"(G) Clinical counseling and behavioral services for primary care patients.

"(4) REPRESENTATION.—In appointing members of the Task Force, the Secretary shall ensure that—

"(A) all areas of expertise described in paragraph (3) are represented; and

"(B) the members of the Task Force include individuals with expertise in health disparities.

"(e) SUBGROUPS.—As appropriate to maximize efficiency, the Task Force may delegate authority for conducting reviews and making recommendations to subgroups consisting of Task Force members, subject to final approval by the Task Force.

"(f) CLINICAL PREVENTION STAKEHOLDERS BOARD.—

"(1) IN GENERAL.—The Task Force shall convene a clinical prevention stakeholders board composed of representatives of appropriate public and private entities with an interest in clinical preventive services to advise the Task Force on developing, updating, publishing, and disseminating evidence-based recommendations on the use of clinical preventive services.

"(2) MEMBERSHIP.—The members of the clinical prevention stakeholders board shall include representatives of the following:

"(A) Health care consumers and patient groups.

"(B) Providers of clinical preventive services, including community-based providers.

"(C) Federal departments and agencies, including—

"(i) appropriate health agencies and offices in the Department, including the Office of the Surgeon General of the Public Health Service, the Office of Minority Health, the National Center on Minority Health and Health Disparities, and the Office on Women's Health; and

"(ii) as appropriate, other Federal departments and agencies whose programs have a significant impact upon health (as determined by the Secretary).

"(D) Private health care payors.

"(3) RESPONSIBILITIES.—In accordance with subsection (b)(5), the clinical prevention stakeholders board shall—

"(A) recommend clinical preventive services for review by the Task Force;

"(B) suggest scientific evidence for consideration by the Task Force related to reviews undertaken by the Task Force;

"(C) provide feedback regarding draft recommendations by the Task Force; and

"(D) assist with efforts regarding dissemination of recommendations by the Director of the Agency for Healthcare Research and Quality.

"(g) DISCLOSURE AND CONFLICTS OF INTEREST.—Members of the Task Force or the clinical prevention stakeholders board shall not be considered employees of the Federal Government by reason of service on the Task Force or the clinical prevention stakeholders board, except members of the Task Force or the clinical prevention

stakeholders board shall be considered to be special Government employees within the meaning of section 107 of the Ethics in Government Act of 1978 (5 U.S.C. App.) and section 208 of title 18, United States Code, for the purposes of disclosure and management of conflicts of interest under those sections.

"(h) NO PAY; RECEIPT OF TRAVEL EXPENSES.—Members of the Task Force or the clinical prevention stakeholders board shall not receive any pay for service on the Task Force, but may receive travel expenses, including a per diem, in accordance with applicable provisions of subchapter I of chapter 57 of title 5, United States Code.

"(i) APPLICATION OF FACA.—The Federal Advisory Committee Act (5 U.S.C. App.) except for section 14 of such Act shall apply to the Task Force to the extent that the provisions of such Act do not conflict with the provisions of this title.

"(j) REPORT.—The Secretary shall submit to the Congress an annual report on the Task Force, including with respect to gaps identified and recommendations made under subsection (b)(4).

"(k) DEFINITION.—In this section, the term 'health disparities' has the meaning given the term in section 3171.

"SEC. 3132. TASK FORCE ON COMMUNITY PREVENTIVE SERVICES.

"(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a permanent task force to be known as the Task Force on Community Preventive Services (in this section referred to as the 'Task Force').

"(b) RESPONSIBILITIES.—The Task Force shall—

"(1) identify community preventive services for review;

"(2) review the scientific evidence related to the benefits, effectiveness, appropriateness, and costs of community preventive services identified under paragraph (1) for the purpose of developing, updating, publishing, and disseminating evidence-based recommendations on the use of such services;

"(3) as appropriate, take into account health disparities in developing, updating, publishing, and disseminating evidence-based recommendations on the use of such services;

"(4) identify gaps in community preventive services research and evaluation and recommend priority areas for such research and evaluation;

"(5) as appropriate, consult with the community prevention stakeholders board in accordance with subsection (f);

"(6) consult with the Task Force on Clinical Preventive Services established under section 3131; and

"(7) as appropriate, in carrying out this section, consider the national strategy under section 3121.

"(c) ROLE OF AGENCY.—The Secretary shall provide ongoing administrative, research, and technical support for the operations of the Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force.

"(d) MEMBERSHIP.—

"(1) NUMBER; APPOINTMENT.—The Task Force shall be composed of 30 members, appointed by the Secretary.

"(2) TERMS.—

"(A) IN GENERAL.—The Secretary shall appoint members of the Task Force for a term of 6 years and may reappoint such members, but the Secretary may not appoint any member to serve more than a total of 12 years.

"(B) STAGGERED TERMS.—Notwithstanding subparagraph (A), of the members first appointed to serve on the Task Force after the enactment of this section—

"(i) 10 shall be appointed for a term of 2 years;

"(ii) 10 shall be appointed for a term of 4 years; and

"(iii) 10 shall be appointed for a term of 6 years.

"(3) QUALIFICATIONS.—Members of the Task Force shall be appointed from among individuals who possess expertise in at least one of the following areas:

"(A) Public health.

"(B) Evaluation of research and systematic evidence reviews.

"(C) Disciplines relevant to community preventive services, including health promotion; disease prevention; chronic disease; worksite health; qualitative and quantitative analysis; and health economics, policy, law, and statistics.

"(4) REPRESENTATION.—In appointing members of the Task Force, the Secretary—

"(A) shall ensure that all areas of expertise described in paragraph (3) are represented;

"(B) shall ensure that such members include sufficient representatives of each of—

"(i) State health officers;

"(ii) local health officers;

"(iii) health care practitioners; and

"(iv) public health practitioners; and

"(C) shall appoint individuals who have expertise in health disparities.

"(e) SUBGROUPS.—As appropriate to maximize efficiency, the Task Force may delegate authority for conducting reviews and making recommendations to subgroups consisting of Task Force members, subject to final approval by the Task Force.

"(f) COMMUNITY PREVENTION STAKEHOLDERS BOARD.—

"(1) IN GENERAL.—The Task Force shall convene a community prevention stakeholders board composed of representatives of appropriate public and private entities with an interest in community preventive services to advise the Task Force on developing, updating, publishing, and disseminating evidence-based recommendations on the use of community preventive services.

"(2) MEMBERSHIP.—The members of the community prevention stakeholders board shall include representatives of the following:

"(A) Health care consumers and patient groups.

"(B) Providers of community preventive services, including community-based providers.

"(C) Federal departments and agencies, including—

"(i) appropriate health agencies and offices in the Department, including the Office of the Surgeon General of the Public Health Service, the Office of Minority Health, the National Center on Minority Health and Health Disparities, and the Office on Women's Health; and

"(ii) as appropriate, other Federal departments and agencies whose programs have a significant impact upon health (as determined by the Secretary).

"(D) Private health care payors.

"(3) RESPONSIBILITIES.—In accordance with subsection (b)(5), the community prevention stakeholders board shall—

"(A) recommend community preventive services for review by the Task Force;

"(B) suggest scientific evidence for consideration by the Task Force related to reviews undertaken by the Task Force;

"(C) provide feedback regarding draft recommendations by the Task Force; and

"(D) assist with efforts regarding dissemination of recommendations by the Director of the Centers for Disease Control and Prevention.

"(g) DISCLOSURE AND CONFLICTS OF INTEREST.—Members of the Task Force or the community prevention stakeholders board shall not be considered employees of the Federal Government by reason of service on the Task Force or the community prevention stakeholders board, except members of the Task Force or the community prevention stakeholders board shall be considered to be special Government employees within the meaning of section 107 of the Ethics in Government Act of 1978 (5 U.S.C. App.) and section 208 of title 18, United States Code, for the purposes of disclosure and management of conflicts of interest under those sections.

"(h) NO PAY; RECEIPT OF TRAVEL EXPENSES.—Members of the Task Force or the community prevention stakeholders board shall not receive any pay for service on the Task Force, but may receive travel expenses, including a per diem, in accordance with applicable provisions of subchapter I of chapter 57 of title 5, United States Code.

"(i) APPLICATION OF FACA.—The Federal Advisory Committee Act (5 U.S.C. App.) except for section 14 of such Act shall apply to the Task Force to the extent that the provisions of such Act do not conflict with the provisions of this title.

"(j) REPORT.—The Secretary shall submit to the Congress an annual report on the Task Force, including with respect to gaps identified and recommendations made under subsection (b)(4).

"(k) DEFINITION.—In this section, the term 'health disparities' has the meaning given the term in section 3171.

"Subtitle D—Prevention and Wellness Research

"SEC. 3141. PREVENTION AND WELLNESS RESEARCH ACTIVITY COORDINATION.

"In conducting or supporting research on prevention and wellness, the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, and the heads of other agencies within the Department of Health

and Human Services conducting or supporting such research, shall take into consideration the national strategy under section 3121 and the recommendations of the Task Force on Clinical Preventive Services under section 3131 and the Task Force on Community Preventive Services under section 3132.

"SEC. 3142. COMMUNITY PREVENTION AND WELLNESS RESEARCH GRANTS.

"(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall conduct, or award grants to eligible entities to conduct, research in priority areas identified by the Secretary in the national strategy under section 3121 or by the Task Force on Community Preventive Services as required by section 3132.

"(b) ELIGIBILITY.—To be eligible for a grant under this section, an entity shall be—

"(1) a State, local, or tribal department of health;

"(2) a public or private nonprofit entity; or

"(3) a consortium of 2 or more entities described in paragraphs (1) and (2).

"(c) REPORT.—The Secretary shall submit to the Congress an annual report on the program of research under this section.

"Subtitle E—Delivery of Community Prevention and Wellness Services

"SEC. 3151. COMMUNITY PREVENTION AND WELLNESS SERVICES GRANTS.

"(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a program for the delivery of community prevention and wellness services consisting of awarding grants to eligible entities—

"(1) to provide evidence-based, community prevention and wellness services in priority areas identified by the Secretary in the national strategy under section 3121; or

"(2) to plan such services.

"(b) ELIGIBILITY.—

"(1) DEFINITION.—To be eligible for a grant under this section, an entity shall be—

"(A) a State, local, or tribal department of health;

"(B) a public or private entity; or

"(C) a consortium of—

"(i) 2 or more entities described in subparagraph (A) or (B); and

"(ii) a community partnership representing a Health Empowerment Zone.

"(2) HEALTH EMPOWERMENT ZONE.—In this subsection, the term 'Health Empowerment Zone' means an area—

"(A) in which multiple community prevention and wellness services are implemented in order to address one or more health disparities, including those identified by the Secretary in the national strategy under section 3121; and

"(B) which is represented by a community partnership that demonstrates community support and coordination with State, local, or tribal health departments and includes—

"(i) a broad cross section of stakeholders;

"(ii) residents of the community; and

"(iii) representatives of entities that have a history of working within and serving the community.

"(c) PREFERENCES.—In awarding grants under this section, the Secretary shall give preference to entities that—

"(1) will address one or more goals or objectives identified by the Secretary in the national strategy under section 3121;

"(2) will address significant health disparities, including those identified by the Secretary in the national strategy under section 3121;

"(3) will address unmet community prevention and wellness needs and avoids duplication of effort;

"(4) have been demonstrated to be effective in communities comparable to the proposed target community;

"(5) will contribute to the evidence base for community prevention and wellness services;

"(6) demonstrate that the community prevention and wellness services to be funded will be sustainable; and

"(7) demonstrate coordination or collaboration across governmental and nongovernmental partners.

"(d) HEALTH DISPARITIES.—Of the funds awarded under this section for a fiscal year, the Secretary shall award not less than 50 percent for planning or implementing community prevention and wellness services whose primary purpose is to achieve a measurable reduction in one or more health disparities, including those identified by the Secretary in the national strategy under section 3121.

"(e) EMPHASIS ON RECOMMENDED SERVICES.—For fiscal year 2013 and subsequent fiscal years, the Secretary shall award grants under this section only for planning or implementing services recommended by the Task Force on Community Preventive Services under section 3122 or deemed effective based on a review of comparable rigor (as determined by the Director of the Centers for Disease Control and Prevention).

"(f) PROHIBITED USES OF FUNDS.—An entity that receives a grant under this section may not use funds provided through the grant—

"(1) to build or acquire real property or for construction; or

"(2) for services or planning to the extent that payment has been made, or can reasonably be expected to be made—

"(A) under any insurance policy;

"(B) under any Federal or State health benefits program (including titles XIX and XXI of the Social Security Act); or

"(C) by an entity which provides health services on a prepaid basis.

"(g) REPORT.—The Secretary shall submit to the Congress an annual report on the program of grants awarded under this section.

"(h) DEFINITIONS.—In this section, the term 'evidence-based' means that methodologically sound research has demonstrated a beneficial health effect, in the judgment of the Director of the Centers for Disease Control and Prevention.

"Subtitle F—Core Public Health Infrastructure

"SEC. 3161. CORE PUBLIC HEALTH INFRASTRUCTURE FOR STATE, LOCAL, AND TRIBAL HEALTH DEPARTMENTS.

"(a) PROGRAM.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention shall establish a core public health infrastructure program consisting of awarding grants under subsection (b).

"(b) GRANTS.—

"(1) AWARD.—For the purpose of addressing core public health infrastructure needs, the Secretary—

"(A) shall award a grant to each State health department; and

"(B) may award grants on a competitive basis to State, local, or tribal health departments.

"(2) ALLOCATION.—Of the total amount of funds awarded as grants under this subsection for a fiscal year—

"(A) not less than 50 percent shall be for grants to State health departments under paragraph (1)(A); and

"(B) not less than 30 percent shall be for grants to State, local, or tribal health departments under paragraph (1)(B).

"(c) USE OF FUNDS.—The Secretary may award a grant to an entity under subsection (b)(1) only if the entity agrees to use the grant to address core public health infrastructure needs, including those identified in the accreditation process under subsection (g).

"(d) FORMULA GRANTS TO STATE HEALTH DEPARTMENTS.—In making grants under subsection (b)(1)(A), the Secretary shall award funds to each State health department in accordance with—

"(1) a formula based on population size; burden of preventable disease and disability; and core public health infrastructure gaps, including those identified in the accreditation process under subsection (g); and

"(2) application requirements established by the Secretary, including a requirement that the State submit a plan that demonstrates to the satisfaction of the Secretary that the State's health department will—

"(A) address its highest priority core public health infrastructure needs; and

"(B) as appropriate, allocate funds to local health departments within the State.

"(e) COMPETITIVE GRANTS TO STATE, LOCAL, AND TRIBAL HEALTH DEPARTMENTS.—In making grants under subsection (b)(1)(B), the Secretary shall give priority to applicants demonstrating core public health infrastructure needs identified in the accreditation process under subsection (g).

"(f) MAINTENANCE OF EFFORT.—The Secretary may award a grant to an entity under subsection (b) only if the entity demonstrates to the satisfaction of the Secretary that—

"(1) funds received through the grant will be expended only to supplement, and not supplant, non-Federal and Federal funds otherwise available to the entity for the purpose of addressing core public health infrastructure needs; and

"(2) with respect to activities for which the grant is awarded, the entity will maintain expenditures of non-Federal amounts for such activities at a level not less than the level of such expenditures maintained by the entity for the fiscal year preceding the fiscal year for which the entity receives the grant.

"(g) ESTABLISHMENT OF A PUBLIC HEALTH ACCREDITATION PROGRAM.—

"(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

"(A) develop, and periodically review and update, standards for voluntary accreditation of State, local, or tribal health departments and public health laboratories for the purpose of advancing the quality and performance of such departments and laboratories; and

"(B) implement a program to accredit such health departments and laboratories in accordance with such standards.

"(2) COOPERATIVE AGREEMENT.—The Secretary may enter into a cooperative agreement with a private nonprofit entity to carry out paragraph (1).

"(h) REPORT.—The Secretary shall submit to the Congress an annual report on progress being made to accredit entities under subsection (g), including—

"(1) a strategy, including goals and objectives, for accrediting entities under subsection (g) and achieving the purpose described in subsection (g)(1); and

"(2) identification of gaps in research related to core public health infrastructure and recommendations of priority areas for such research.

"SEC. 3162. CORE PUBLIC HEALTH INFRASTRUCTURE AND ACTIVITIES FOR CDC.

"(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall expand and improve the core public health infrastructure and activities of the Centers for Disease Control and Prevention to address unmet and emerging public health needs.

"(b) REPORT.—The Secretary shall submit to the Congress an annual report on the activities funded through this section.

"Subtitle G—General Provisions

"SEC. 3171. DEFINITIONS.

"In this title:

"(1) The term 'core public health infrastructure' includes workforce capacity and competency; laboratory systems; health information, health information systems, and health information analysis; communications; financing; other relevant components of organizational capacity; and other related activities.

"(2) The terms 'Department' and 'departmental' refer to the Department of Health and Human Services.

"(3) The term 'health disparities' includes health and health care disparities and means population-specific differences in the presence of disease, health outcomes, or access to health care. For purposes of the preceding sentence, a population may be delineated by race, ethnicity, geographic setting, and other populations or subpopulations determined by the Secretary to experience significant gaps in disease, health outcomes, or access to health care.

"(4) The term 'tribal' refers to an Indian tribe, a Tribal organization, or an Urban Indian organization, as such terms are defined in section 4 of the Indian Health Care Improvement Act.".

(b) TRANSITION PROVISIONS APPLICABLE TO TASK FORCES.—

(1) FUNCTIONS, PERSONNEL, ASSETS, LIABILITIES, AND ADMINISTRATIVE ACTIONS.—All functions, personnel, assets, and liabilities of, and administrative actions applicable to, the Preventive Services Task Force convened under section 915(a) of the Public Health Service Act and the Task Force on Community Preventive Services (as such section and Task Forces were in existence on the day before the date of the enactment of this Act) shall be transferred to the Task Force on Clinical Preventive Services and the Task Force on Community Preventive Services, respectively, established under sections 3121 and 3122 of the Public Health Service Act, as added by subsection (a).

(2) RECOMMENDATIONS.—All recommendations of the Preventive Services Task Force and the Task Force on Community Preventive Services, as in existence on the day before the date of the enactment of this Act, shall be considered

to be recommendations of the Task Force on Clinical Preventive Services and the Task Force on Community Preventive Services, respectively, established under sections 3121 and 3122 of the Public Health Service Act, as added by subsection (a).

(3) MEMBERS ALREADY SERVING.—

(A) INITIAL MEMBERS.—The Secretary of Health and Human Services may select those individuals already serving on the Preventive Services Task Force and the Task Force on Community Preventive Services, as in existence on the day before the date of the enactment of this Act, to be among the first members appointed to the Task Force on Clinical Preventive Services and the Task Force on Community Preventive Services, respectively, under sections 3121 and 3122 of the Public Health Service Act, as added by subsection (a).

(B) CALCULATION OF TOTAL SERVICE.—In calculating the total years of service of a member of a task force for purposes of section 3131(d)(2)(A) or 3132(d)(2)(A) of the Public Health Service Act, as added by subsection (a), the Secretary of Health and Human Services shall not include any period of service by the member on the Preventive Services Task Force or the Task Force on Community Preventive Services, respectively, as in existence on the day before the date of the enactment of this Act.

(c) PERIOD BEFORE COMPLETION OF NATIONAL STRATEGY.—Pending completion of the national strategy under section 3121 of the Public Health Service Act, as added by subsection (a), the Secretary of Health and Human Services, acting through the relevant agency head, may make a judgment about how the strategy will address an issue and rely on such judgment in carrying out any provision of subtitle C, D, E, or F of title XXXI of such Act, as added by subsection (a), that requires the Secretary—

(1) to take into consideration such strategy;

(2) to conduct or support research or provide services in priority areas identified in such strategy; or

(3) to take any other action in reliance on such strategy.

(d) CONFORMING AMENDMENTS.—

(1) Paragraph (61) of section 3(b) of the Indian Health Care Improvement Act (25 U.S.C. 1602) is amended by striking "United States Preventive Services Task Force" and inserting "Task Force on Clinical Preventive Services".

(2) Section 126 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Appendix F of Public Law 106–554) is amended by striking "United States Preventive Services Task Force" each place it appears and inserting "Task Force on Clinical Preventive Services".

(3) Paragraph (7) of section 317D(a) of the Public Health Service Act (42 U.S.C. 247b–5(a)) is amended by striking "United States Preventive Services Task Force" and inserting "Task Force on Clinical Preventive Services".

(4) Section 915 of the Public Health Service Act (42 U.S.C. 299b–4) is amended by striking subsection (a).

(5) Subsections (s)(2)(AA)(iii)(II), (xx)(1), and (ddd)(1)(B) of section 1861 of the Social Security Act (42 U.S.C. 1395x) are amended by striking "United States Preventive Services Task Force" each place it appears and inserting "Task Force on Clinical Preventive Services".

TITLE IV—QUALITY AND SURVEILLANCE

SEC. 2401. IMPLEMENTATION OF BEST PRACTICES IN THE DELIVERY OF HEALTH CARE.

(a) IN GENERAL.—Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) is amended—

(1) by redesignating part D as part E;

(2) by redesignating sections 931 through 938 as sections 941 through 948, respectively;

(3) in section 948(1), as redesignated, by striking "931" and inserting "941"; and

(4) by inserting after part C the following:

"PART D—IMPLEMENTATION OF BEST PRACTICES IN THE DELIVERY OF HEALTH CARE

"SEC. 931. CENTER FOR QUALITY IMPROVEMENT.

"(a) IN GENERAL.—There is established the Center for Quality Improvement (referred to in this part as the 'Center'), to be headed by the Director.

"(b) PRIORITIZATION.—

"(1) IN GENERAL.—The Director shall prioritize areas for the identification, development, evaluation, and implementation of best practices (including innovative methodologies and strategies) for quality improvement activities in the delivery of health care services (in this section referred to as 'best practices').

"(2) CONSIDERATIONS.—In prioritizing areas under paragraph (1), the Director shall consider—

"(A) the priorities established under section 1191 of the Social Security Act; and

"(B) the key health indicators identified by the Assistant Secretary for Health Information under section 1709.

"(3) LIMITATIONS.—In conducting its duties under this subsection, the Center for Quality Improvement shall not develop quality-adjusted life year measures or any other methodologies that can be used to deny benefits to a beneficiary against the beneficiary's wishes on the basis of the beneficiary's age, life expectancy, present or predicted disability, or expected quality of life.

"(c) OTHER RESPONSIBILITIES.—The Director, acting directly or by awarding a grant or contract to an eligible entity, shall—

"(1) identify existing best practices under subsection (e);

"(2) develop new best practices under subsection (f);

"(3) evaluate best practices under subsection (g);

"(4) implement best practices under subsection (h);

"(5) ensure that best practices are identified, developed, evaluated, and implemented under this section consistent with standards adopted by the Secretary under section 3004 for health information technology used in the collection and reporting of quality information (including for purposes of the demonstration of meaningful use of certified electronic health record (EHR) technology by physicians and hospitals under the Medicare program (under sections 1848(o)(2) and 1886(n)(3), respectively, of the Social Security Act)); and

"(6) provide for dissemination of information and reporting under subsections (i) and (j).

"(d) ELIGIBILITY.—To be eligible for a grant or contract under subsection (c), an entity shall—

"(1) be a nonprofit entity;

"(2) agree to work with a variety of institutional health care providers, physicians, nurses, and other health care practitioners; and

"(3) if the entity is not the organization holding a contract under section 1153 of the Social Security Act for the area to be served, agree to cooperate with and avoid duplication of the activities of such organization.

"(e) IDENTIFYING EXISTING BEST PRACTICES.—The Secretary shall identify best practices that are—

"(1) currently utilized by health care providers (including hospitals, physician and other clinician practices, community cooperatives, and other health care entities) that deliver consistently high-quality, efficient health care services; and

"(2) easily adapted for use by other health care providers and for use across a variety of health care settings.

"(f) DEVELOPING NEW BEST PRACTICES.—The Secretary shall develop best practices that are—

"(1) based on a review of existing scientific evidence;

"(2) sufficiently detailed for implementation and incorporation into the workflow of health care providers; and

"(3) designed to be easily adapted for use by health care providers across a variety of health care settings.

"(g) EVALUATION OF BEST PRACTICES.—The Director shall evaluate best practices identified or developed under this section. Such evaluation—

"(1) shall include determinations of which best practices—

"(A) most reliably and effectively achieve significant progress in improving the quality of patient care; and

"(B) are easily adapted for use by health care providers across a variety of health care settings;

"(2) shall include regular review, updating, and improvement of such best practices; and

"(3) may include in-depth case studies or empirical assessments of health care providers (including hospitals, physician and other clinician practices, community cooperatives, and other health care entities) and simulations of such best practices for determinations under paragraph (1).

"(h) IMPLEMENTATION OF BEST PRACTICES.—

"(1) IN GENERAL.—The Director shall enter into arrangements with entities in a State or region to implement best practices identified or developed under this section. Such implementation—

"(A) may include forming collaborative multi-institutional teams; and

"(B) shall include an evaluation of the best practices being implemented, including the measurement of patient outcomes before, during, and after implementation of such best practices.

"(2) PREFERENCES.—In carrying out this subsection, the Director shall give priority to health care providers implementing best practices that—

"(A) have the greatest impact on patient outcomes and satisfaction;

"(B) are the most easily adapted for use by health care providers across a variety of health care settings;

"(C) promote coordination of health care practitioners across the continuum of care; and

"(D) engage patients and their families in improving patient care and outcomes.

"(i) PUBLIC DISSEMINATION OF INFORMATION.—The Director shall provide for the public dissemination of information with respect to best practices and activities under this section. Such information shall be made available in appropriate formats and languages to reflect the varying needs of consumers and diverse levels of health literacy.

"(j) REPORT.—

"(1) IN GENERAL.—The Director shall submit an annual report to the Congress and the Secretary on activities under this section.

"(2) CONTENT.—Each report under paragraph (1) shall include—

"(A) information on activities conducted pursuant to grants and contracts awarded;

"(B) summary data on patient outcomes before, during, and after implementation of best practices; and

"(C) recommendations on the adaptability of best practices for use by health providers.".

(b) INITIAL QUALITY IMPROVEMENT ACTIVITIES AND INITIATIVES TO BE IMPLEMENTED.—Until the Director of the Agency for Healthcare Research and Quality has established initial priorities under section 931(b) of the Public Health Service Act, as added by subsection (a), the Director shall, for purposes of such section, prioritize the following:

(1) HEALTH CARE-ASSOCIATED INFECTIONS.—Reducing health care-associated infections, including infections in nursing homes and outpatient settings.

(2) SURGERY.—Increasing hospital and outpatient perioperative patient safety, including reducing surgical-site infections and surgical errors (such as wrong-site surgery and retained foreign bodies).

(3) EMERGENCY ROOM.—Improving care in hospital emergency rooms, including through the use of principles of efficiency of design and delivery to improve patient flow.

(4) OBSTETRICS.—Improving the provision of obstetrical and neonatal care, including the identification of interventions that are effective in reducing the risk of preterm and premature labor and the implementation of best practices for labor and delivery care.

(5) PEDIATRICS.—Improving the provision of preventive and developmental child health services, including interventions that can reduce child health disparities and reduce the risk of developing chronic health-threatening conditions that affect an individual's life course development.

(c) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Director of the Agency for Healthcare Research and Quality shall submit a report to the Congress on the impact of the nurse-to-patient ratio on the quality of care and patient outcomes, including recommendations for further integration into quality measurement and quality improvement activities.

SEC. 2402. ASSISTANT SECRETARY FOR HEALTH INFORMATION.

(a) ESTABLISHMENT.—Title XVII (42 U.S.C. 300u et seq.) is amended—

(1) by redesignating sections 1709 and 1710 as sections 1710 and 1711, respectively; and

(2) by inserting after section 1708 the following:

"SEC. 1709. ASSISTANT SECRETARY FOR HEALTH INFORMATION.

"(a) IN GENERAL.—There is established within the Department an Assistant Secretary for Health Information (in this section referred to as the 'Assistant Secretary'), to be appointed by the Secretary.

"(b) RESPONSIBILITIES.—The Assistant Secretary shall—

"(1) ensure the collection, collation, reporting, and publishing of information (including full and complete statistics) on key health indicators regarding the Nation's health and the performance of the Nation's health care;

"(2) facilitate and coordinate the collection, collation, reporting, and publishing of information regarding the Nation's health and the performance of the Nation's health care (other than information described in paragraph (1));

"(3)(A) develop standards for the collection of data regarding the Nation's health and the performance of the Nation's health care; and

"(B) in carrying out subparagraph (A)—

"(i) ensure appropriate specificity and standardization for data collection at the national, regional, State, and local levels;

"(ii) include standards, as appropriate, for the collection of accurate data on health and health care by race, ethnicity, primary language, sex, sexual orientation, gender identity, disability, socioeconomic status, rural, urban, or other geographic setting, and any other population or subpopulation determined appropriate by the Secretary;

"(iii) ensure, with respect to data on race and ethnicity, consistency with the 1997 Office of Management and Budget Standards for Maintaining, Collecting and Presenting Federal Data on Race and Ethnicity (or any successor standards); and

"(iv) in consultation with the Director of the Office of Minority Health, and the Director of the Office of Civil Rights, of the Department, develop standards for the collection of data on health and health care with respect to primary language;

"(4) provide support to Federal departments and agencies whose programs have a significant impact upon health (as determined by the Secretary) for the collection and collation of information described in paragraphs (1) and (2);

"(5) ensure the sharing of information described in paragraphs (1) and (2) among the agencies of the Department;

"(6) facilitate the sharing of information described in paragraphs (1) and (2) by Federal departments and agencies whose programs have a significant impact upon health (as determined by the Secretary);

"(7) identify gaps in information described in paragraphs (1) and (2) and the appropriate agency or entity to address such gaps;

"(8) facilitate and coordinate identification and monitoring by the agencies of the Department of health disparities to inform program and policy efforts to reduce such disparities, including facilitating and funding analyses conducted in cooperation with the Social Security Administration, the Bureau of the Census, and other appropriate agencies and entities;

"(9) consistent with privacy, proprietary, and other appropriate safeguards, facilitate public accessibility of datasets (such as de-identified Medicare datasets or publicly available data on key health indicators) by means of the Internet; and

"(10) award grants or contracts for the collection and collation of information described in paragraphs (1) and (2) (including through statewide surveys that provide standardized information).

"(c) KEY HEALTH INDICATORS.—

"(1) IN GENERAL.—In carrying out subsection (b)(1), the Assistant Secretary shall—

"(A) identify, and reassess at least once every 3 years, key health indicators described in such subsection;

"(B) publish statistics on such key health indicators for the public—

"(i) not less than annually; and

"(ii) on a supplemental basis whenever warranted by—

"(I) the rate of change for a key health indicator; or

"(II) the need to inform policy regarding the Nation's health and the performance of the Nation's health care; and

"(C) ensure consistency with the national strategy developed by the Secretary under section 3121 and consideration of the indicators specified in the reports under sections 308, 903(a)(6), and 913(b)(2).

"(2) RELEASE OF KEY HEALTH INDICATORS.—The regulations, rules, processes, and procedures of the Office of Management and Budget governing the review, release, and dissemination of key health indicators shall be the same as the regulations, rules, processes, and procedures of the Office of Management and

Budget governing the review, release, and dissemination of Principal Federal Economic Indicators (or equivalent statistical data) by the Bureau of Labor Statistics.

"(d) COORDINATION.—In carrying out this section, the Assistant Secretary shall coordinate with—

"(1) public and private entities that collect and disseminate information on health and health care, including foundations; and

"(2) the head of the Office of the National Coordinator for Health Information Technology to ensure optimal use of health information technology.

"(e) REQUEST FOR INFORMATION FROM OTHER DEPARTMENTS AND AGENCIES.—Consistent with applicable law, the Assistant Secretary may secure directly from any Federal department or agency information necessary to enable the Assistant Secretary to carry out this section.

"(f) REPORT.—

"(1) SUBMISSION.—The Assistant Secretary shall submit to the Secretary and the Congress an annual report containing—

"(A) a description of national, regional, or State changes in health or health care, as reflected by the key health indicators identified under subsection (c)(1);

"(B) a description of gaps in the collection, collation, reporting, and publishing of information regarding the Nation's health and the performance of the Nation's health care;

"(C) recommendations for addressing such gaps and identification of the appropriate agency within the Department or other entity to address such gaps;

"(D) a description of analyses of health disparities, including the results of completed analyses, the status of ongoing longitudinal studies, and proposed or planned research; and

"(E) a plan for actions to be taken by the Assistant Secretary to address gaps described in subparagraph (B).

"(2) CONSIDERATION.—In preparing a report under paragraph (1), the Assistant Secretary shall take into consideration the findings and conclusions in the reports under sections 308, 903(a)(6), and 913(b)(2).

"(g) PROPRIETARY AND PRIVACY PROTECTIONS.—Nothing in this section shall be construed to affect applicable proprietary or privacy protections.

"(h) CONSULTATION.—In carrying out this section, the Assistant Secretary shall consult with—

"(1) the heads of appropriate health agencies and offices in the Department, including the Office of the Surgeon General of the Public Health Service, the Office of Minority Health, and the Office on Women's Health; and

"(2) as appropriate, the heads of other Federal departments and agencies whose programs have a significant impact upon health (as determined by the Secretary).

"(i) DEFINITION.—In this section:

"(1) The terms 'agency' and 'agencies' include an epidemiology center established under section 214 of the Indian Health Care Improvement Act.

"(2) The term 'Department' means the Department of Health and Human Services.

"(3) The term 'health disparities' has the meaning given to such term in section 3171.".

(b) OTHER COORDINATION RESPONSIBILITIES.—Title III (42 U.S.C. 241 et seq.) is amended—

(1) in paragraphs (1) and (2) of section 304(c) (42 U.S.C. 242b(c)), by inserting ", acting through the Assistant Secretary for Health Information," after "The Secretary" each place it appears; and

(2) in section 306(j) (42 U.S.C. 242k(j)), by inserting ", acting through the Assistant Secretary for Health Information," after "of this section, the Secretary".

SEC. 2403. AUTHORIZATION OF APPROPRIATIONS.

Section 799C, as added and amended, is further amended by adding at the end the following:

"(e) QUALITY AND SURVEILLANCE.—For the purpose of carrying out part D of title IX and section 1709, in addition to any other amounts authorized to be appropriated for such purpose, there are authorized to be appropriated, out of any monies in the Public Health Investment Fund, $300,000,000 for each of fiscal years 2010 through 2014.".

TITLE V—OTHER PROVISIONS

Subtitle A—Drug Discount for Rural and Other Hospitals

SEC. 2501. EXPANDED PARTICIPATION IN 340B PROGRAM.

(a) EXPANSION OF COVERED ENTITIES RECEIVING DISCOUNTED PRICES.—Section 340B(a)(4) (42 U.S.C. 256b(a)(4)) is amended by adding at the end the following:

"(M) A children's hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act which would meet the requirements of subparagraph (L), including the disproportionate share adjustment percentage requirement under subparagraph (L)(ii), if the hospital were a subsection (d) hospital as defined in section 1886(d)(1)(B) of the Social Security Act.

"(N) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act).

"(O) An entity receiving funds under title V of the Social Security Act (relating to maternal and child health) for the provision of health services.

"(P) An entity receiving funds under subpart I of part B of title XIX of the Public Health Service Act (relating to comprehensive mental health services) for the provision of community mental health services.

"(Q) An entity receiving funds under subpart II of such part B (relating to the prevention and treatment of substance abuse) for the provision of treatment services for substance abuse.

"(R) An entity that is a Medicare-dependent, small rural hospital (as defined in section 1886(d)(5)(G)(iv) of the Social Security Act).

"(S) An entity that is a sole community hospital (as defined in section 1886(d)(5)(D)(iii) of the Social Security Act).

"(T) An entity that is classified as a rural referral center under section 1886(d)(5)(C) of the Social Security Act.".

(b) PROHIBITION ON GROUP PURCHASING ARRANGEMENTS.—Section 340B(a) (42 U.S.C. 256b(a)) is amended—

(1) in paragraph (4)(L)—

(A) by adding "and" at the end of clause (i);

(B) by striking "; and" at the end of clause (ii) and inserting a period; and

(C) by striking clause (iii); and

(2) in paragraph (5), by redesignating subparagraphs (C) and (D) as subparagraphs (D) and (E), respectively, and by inserting after subparagraph (B) the following:

"(C) PROHIBITING USE OF GROUP PURCHASING ARRANGEMENTS.—

"(i) A hospital described in subparagraph (L), (M), (N), (R), (S), or (T) of paragraph (4) shall not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement, except as permitted or provided pursuant to clause (ii).

"(ii) The Secretary shall establish reasonable exceptions to the requirement of clause (i)—

"(I) with respect to a covered outpatient drug that is unavailable to be purchased through the program under this section due to a drug shortage problem, manufacturer noncompliance, or any other reason beyond the hospital's control;

"(II) to facilitate generic substitution when a generic covered outpatient drug is available at a lower price; and

"(III) to reduce in other ways the administrative burdens of managing both inventories of drugs obtained under this section and not under this section, if such exception does not create a duplicate discount problem in violation of subparagraph (A) or a diversion problem in violation of subparagraph (B).".

SEC. 2502. EXTENSION OF DISCOUNTS TO INPATIENT DRUGS.

(a) IN GENERAL.—Section 340B (42 U.S.C. 256b) is amended—

(1) in subsection (b)—

(A) by striking "In this section, the terms" and inserting the following: "In this section:

"(1) IN GENERAL.—The terms"; and

(B) by adding at the end the following new paragraph:

"(2) COVERED DRUG.—The term 'covered drug'—

"(A) means a covered outpatient drug (as defined in section 1927(k)(2) of the Social Security Act); and

"(B) includes, notwithstanding the section 1927(k)(3)(A) of such Act, a drug used in connection with an inpatient or outpatient service provided by a hospital described in subparagraph (L), (M), (N), (R), (S), or (T) of subsection (a)(4) that is enrolled to participate in the drug discount program under this section."; and

(2) in paragraphs (5) (other than subparagraph (C)), (7), and (9) of subsection (a), by striking "outpatient" each place it appears.

(b) MEDICAID CREDITS ON INPATIENT DRUGS.—Subsection (c) of section 340B (42 U.S.C. 256b(c)) is amended to read as follows:

"(c) MEDICAID CREDITS ON INPATIENT DRUGS.—

"(1) IN GENERAL.—For the cost reporting period covered by the most recently filed Medicare cost report under title XVIII of the Social Security Act, a hospital described in subparagraph (L), (M), (N), (R), (S), or (T) of subsection (a)(4) and enrolled to participate in the drug discount program under this section shall provide to each State under its plan under title XIX of such Act—

"(A) a credit on the estimated annual costs to such hospital of single source and innovator multiple source drugs provided to Medicaid beneficiaries for inpatient use; and

"(B) a credit on the estimated annual costs to such hospital of noninnovator multiple source drugs provided to Medicaid beneficiaries for inpatient use.

"(2) AMOUNT OF CREDITS.—

"(A) SINGLE SOURCE AND INNOVATOR MULTIPLE SOURCE DRUGS.—For purposes of paragraph (1)(A)—

"(i) the credit under such paragraph shall be equal to the product of—

"(I) the annual value of single source and innovator multiple source drugs purchased under this section by the hospital based on the drugs' average manufacturer price;

"(II) the estimated percentage of the hospital's drug purchases attributable to Medicaid beneficiaries for inpatient use; and

"(III) the minimum rebate percentage described in section 1927(c)(1)(B) of the Social Security Act;

"(ii) the reference in clause (i)(I) to the annual value of single source and innovator multiple source drugs purchased under this section by the hospital based on the drugs' average manufacturer price shall be equal to the sum of—

"(I) the annual quantity of each single source and innovator multiple source drug purchased during the cost reporting period, multiplied by

"(II) the average manufacturer price for that drug;

"(iii) the reference in clause (i)(II) to the estimated percentage of the hospital's drug purchases attributable to Medicaid beneficiaries for inpatient use shall be equal to—

"(I) the Medicaid inpatient drug charges as reported on the hospital's most recently filed Medicare cost report, divided by

"(II) total drug charges reported on the cost report; and

"(iv) the terms 'single source drug' and 'innovator multiple source drug' have the meanings given such terms in section 1927(k)(7) of the Social Security Act.

"(B) NONINNOVATOR MULTIPLE SOURCE DRUGS.—For purposes of paragraph (1)(B)—

"(i) the credit under such paragraph shall be equal to the product of—

"(I) the annual value of noninnovator multiple source drugs purchased under this section by the hospital based on the drugs' average manufacturer price;

"(II) the estimated percentage of the hospital's drug purchases attributable to Medicaid beneficiaries for inpatient use; and

"(III) the applicable percentage as defined in section 1927(c)(3)(B) of the Social Security Act;

"(ii) the reference in clause (i)(I) to the annual value of noninnovator multiple source drugs purchased under this section by the hospital based on the drugs' average manufacturer price shall be equal to the sum of—

"(I) the annual quantity of each noninnovator multiple source drug purchased during the cost reporting period, multiplied by

"(II) the average manufacturer price for that drug;

"(iii) the reference in clause (i)(II) to the estimated percentage of the hospital's drug purchases attributable to Medicaid beneficiaries for inpatient use shall be equal to—

"(I) the Medicaid inpatient drug charges as reported on the hospital's most recently filed Medicare cost report, divided by

"(II) total drug charges reported on the cost report; and

"(iv) the term 'noninnovator multiple source drug' has the meaning given such term in section 1927(k)(7) of the Social Security Act.

"(3) CALCULATION OF CREDITS.—

"(A) IN GENERAL.—Each State calculates credits under paragraph (1) and informs hospitals of amount under section 1927(a)(5)(D) of the Social Security Act.

"(B) HOSPITAL PROVISION OF INFORMATION.—Not later than 30 days after the date of the filing of the hospital's most recently filed Medicare cost report, the hospital shall provide the State with the information described in paragraphs (2)(A)(ii) and (2)(B)(ii). With respect to each drug purchased during the cost reporting period, the hospital shall provide the dosage form, strength, package size, date of purchase, and the number of units purchased.

"(4) PAYMENT DEADLINE.—The credits provided by a hospital under paragraph (1) shall be paid within 60 days after receiving the information specified in paragraph (3)(A).

"(5) OPT OUT.—A hospital shall not be required to provide the Medicaid credit required under paragraph (1) if it can demonstrate to the State that it will lose reimbursement under the State plan resulting from the extension of discounts to inpatient drugs under subsection (b)(2) and that the loss of reimbursement will exceed the amount of the credit otherwise owed by the hospital.

"(6) OFFSET AGAINST MEDICAL ASSISTANCE.—Amounts received by a State under this subsection in any quarter shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1903(a)(1) of the Social Security Act.".

(c) CONFORMING AMENDMENTS.—Section 1927 of the Social Security Act (42 U.S.C. 1396r–8) is amended—

(1) in subsection (a)(5)(A), by striking "covered outpatient drugs" and inserting "covered drugs (as defined in section 340B(b)(2) of the Public Health Service Act)";

(2) in subsection (a)(5), by striking subparagraph (D) and inserting the following:

"(D) STATE RESPONSIBILITY FOR CALCULATING HOSPITAL CREDITS.—The State shall calculate the credits owed by the hospital under paragraph (1) of section 340B(c) of the Public Health Service Act and provide the hospital with both the amounts and an explanation of how it calculated the credits. In performing the calculations specified in paragraphs (2)(A)(ii) and (2)(B)(ii) of such section, the State shall use the average manufacturer price applicable to the calendar quarter in which the drug was purchased by the hospital."; and

(3) in subsection (k)(1)—

(A) in subparagraph (A), by striking "subparagraph (B)" and inserting "subparagraphs (B) and (D)"; and

(B) by adding at the end the following:

"(D) CALCULATION FOR COVERED DRUGS.—With respect to a covered drug (as defined in section 340B(b)(2) of the Public Health Service Act), the average manufacturer price shall be determined in accordance with subparagraph (A) except that, in the event a covered drug is not distributed to the retail pharmacy class of trade, it shall mean the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the acute care class of trade, after deducting customary prompt pay discounts.".

SEC. 2503. EFFECTIVE DATE.

(a) IN GENERAL.—The amendments made by this subtitle shall take effect on July 1, 2010, and shall apply to drugs dispensed on or after such date.

(b) EFFECTIVENESS.—The amendments made by this subtitle shall be effective, and shall be taken into account in determining whether a manufacturer is deemed to meet the requirements of section 340B(a) of the Public Health Service Act (42 U.S.C. 256b(a)) and of section 1927(a)(5) of the Social Security Act (42 U.S.C. 1396r–8(a)(5)), notwithstanding any other provision of law.

Subtitle B—Programs

PART 1—GRANTS FOR CLINICS AND CENTERS

SEC. 2511. SCHOOL-BASED HEALTH CLINICS.

(a) IN GENERAL.—Part Q of title III (42 U.S.C. 280h et seq.) is amended by adding at the end the following:

"SEC. 399Z–1. SCHOOL-BASED HEALTH CLINICS.

"(a) PROGRAM.—The Secretary shall establish a school-based health clinic program consisting of awarding grants to eligible entities to support the operation of school-based health clinics (referred to in this section as 'SBHCs').

"(b) ELIGIBILITY.—To be eligible for a grant under this section, an entity shall—

"(1) be an SBHC (as defined in subsection (l)(4)); and

"(2) submit an application at such time, in such manner, and containing such information as the Secretary may require, including at a minimum—

"(A) evidence that the applicant meets all criteria necessary to be designated as an SBHC;

"(B) evidence of local need for the services to be provided by the SBHC;

"(C) an assurance that—

"(i) SBHC services will be provided in accordance with Federal, State, and local laws;

"(ii) the SBHC has established and maintains collaborative relationships with other health care providers in the catchment area of the SBHC;

"(iii) the SBHC will provide onsite access during the academic day when school is in session and has an established network of support and access to services with backup health providers when the school or SBHC is closed;

"(iv) the SBHC will be integrated into the school environment and will coordinate health services with appropriate school personnel and other community providers co-located at the school; and

"(v) the SBHC sponsoring facility assumes all responsibility for the SBHC administration, operations, and oversight; and

"(D) such other information as the Secretary may require.

"(c) USE OF FUNDS.—Funds awarded under a grant under this section—

"(1) may be used for—

"(A) providing training related to the provision of comprehensive primary health services and additional health services;

"(B) the management and operation of SBHC programs;

"(C) the payment of salaries for health professionals and other appropriate SBHC personnel; and

"(2) may not be used to provide abortions.

"(d) CONSIDERATION OF NEED.—In determining the amount of a grant under this section, the Secretary shall take into consideration—

"(1) the financial need of the SBHC;

"(2) State, local, or other sources of funding provided to the SBHC; and

"(3) other factors as determined appropriate by the Secretary.

"(e) PREFERENCES.—In awarding grants under this section, the Secretary shall give preference to SBHCs that have a demonstrated record of service to the following:

"(1) A high percentage of medically underserved children and adolescents.

"(2) Communities or populations in which children and adolescents have difficulty accessing health and mental health services.

"(3) Communities with high percentages of children and adolescents who are uninsured, underinsured, or eligible for medical assistance under Federal or State health benefits programs (including titles XIX and XXI of the Social Security Act).

"(f) MATCHING REQUIREMENT.—The Secretary may award a grant to an SBHC under this section only if the SBHC agrees to provide, from non-Federal sources, an amount equal to 20 percent of the amount of the grant (which may be provided in cash or in kind) to carry out the activities supported by the grant.

"(g) SUPPLEMENT, NOT SUPPLANT.—The Secretary may award a grant to an SBHC under this section only if the SBHC demonstrates to the satisfaction of the Secretary that funds received through the grant will be expended only to supplement, and not supplant, non-Federal and Federal funds otherwise available to the SBHC for operation of the SBHC (including each activity described in paragraph (1) or (2) of subsection (c)).

"(h) PAYOR OF LAST RESORT.—The Secretary may award a grant to an SBHC under this section only if the SBHC demonstrates to the satisfaction of the Secretary that funds received through the grant will not be expended for any activity to the extent that payment has been made, or can reasonably be expected to be made—

"(1) under any insurance policy;

"(2) under any Federal or State health benefits program (including titles XIX and XXI of the Social Security Act); or

"(3) by an entity which provides health services on a prepaid basis.

"(i) REGULATIONS REGARDING REIMBURSEMENT FOR HEALTH SERVICES.—The Secretary shall issue regulations regarding the reimbursement for health services provided by SBHCs to individuals eligible to receive such services through the program under this section, including reimbursement under any insurance policy or any Federal or State health benefits program (including titles XIX and XXI of the Social Security Act).

"(j) TECHNICAL ASSISTANCE.—The Secretary shall provide (either directly or by grant or contract) technical and other assistance to SBHCs to assist such SBHCs to meet the requirements of this section. Such assistance may include fiscal and program management assistance, training in fiscal and program management, operational and administrative support, and the provision of information to the SBHCs of the variety of resources available under this title and how those resources can be best used to meet the health needs of the communities served by the SBHCs.

"(k) EVALUATION; REPORT.—The Secretary shall—

"(1) develop and implement a plan for evaluating SBHCs and monitoring quality performances under the awards made under this section; and

"(2) submit to the Congress on an annual basis a report on the program under this section.

"(l) DEFINITIONS.—In this section:

"(1) COMPREHENSIVE PRIMARY HEALTH SERVICES.—The term 'comprehensive primary health services' means the core services offered by SBHCs, which shall include the following:

"(A) PHYSICAL.—Comprehensive health assessments, diagnosis, and treatment of minor, acute, and chronic medical conditions and referrals to, and followup for, specialty care.

"(B) MENTAL HEALTH.—Mental health assessments, crisis intervention, counseling, treatment, and referral to a continuum of services including emergency psychiatric care, community support programs, inpatient care, and outpatient programs.

"(C) OPTIONAL SERVICES.—Additional services, which may include oral health, social, and age-appropriate health education services, including nutritional counseling.

"(2) MEDICALLY UNDERSERVED CHILDREN AND ADOLESCENTS.—The term 'medically underserved children and adolescents' means a population of children and adolescents who are residents of an area designated by the Secretary as an area with a shortage of personal health services and health infrastructure for such children and adolescents.

"(3) SCHOOL-BASED HEALTH CLINIC.—The term 'school-based health clinic' means a health clinic that—

"(A) is located in, or is adjacent to, a school facility of a local educational agency;

"(B) is organized through school, community, and health provider relationships;

"(C) is administered by a sponsoring facility;

"(D) provides, at a minimum, comprehensive primary health services during school hours to children and adolescents by health professionals in accordance with State and local laws and regulations, established standards, and community practice; and

"(E) does not perform abortion services.

"(4) SPONSORING FACILITY.—The term 'sponsoring facility' is—

"(A) a hospital;

"(B) a public health department;

"(C) a community health center;

"(D) a nonprofit health care agency;

"(E) a local educational agency; or

"(F) a program administered by the Indian Health Service or the Bureau of Indian Affairs or operated by an Indian tribe or a tribal organization under the Indian Self-Determination and Education Assistance Act, a Native Hawaiian entity, or an urban Indian program under title V of the Indian Health Care Improvement Act.

"(m) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this section, there are authorized to be appropriated $50,000,000 for fiscal year 2010 and such sums as may be necessary for each of the fiscal years 2011 through 2014.".

(b) EFFECTIVE DATE.—The Secretary of Health and Human Services shall begin awarding grants under section 399Z–1 of the Public Health Service Act, as added by subsection (a), not later than July 1, 2010, without regard to whether or not final regulations have been issued under section 399Z–1(i) of such Act.

SEC. 2512. NURSE-MANAGED HEALTH CENTERS.

Title III (42 U.S.C. 241 et seq.) is amended by adding at the end the following:

"PART S—NURSE-MANAGED HEALTH CENTERS

"SEC. 399GG. NURSE-MANAGED HEALTH CENTERS.

"(a) PROGRAM.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall establish a nurse-managed health center program consisting of awarding grants to entities under subsection (b).

"(b) GRANT.—The Secretary shall award grants to entities—

"(1) to plan and develop a nurse-managed health center; or

"(2) to operate a nurse-managed health center.

"(c) USE OF FUNDS.—Amounts received as a grant under subsection (b) may be used for activities including the following:

"(1) Purchasing or leasing equipment.

"(2) Training and technical assistance related to the provision of comprehensive primary care services and wellness services.

"(3) Other activities for planning, developing, or operating, as applicable, a nurse-managed health center.

"(d) ASSURANCES APPLICABLE TO BOTH PLANNING AND OPERATION GRANTS.—

"(1) IN GENERAL.—The Secretary may award a grant under this section to an entity only if the entity demonstrates to the Secretary's satisfaction that—

"(A) nurses, in addition to managing the center, will be adequately represented as providers at the center; and

"(B) not later than 90 days after receiving the grant, the entity will establish a community advisory committee composed of individuals, a majority of whom are being served by the center, to provide input into the nurse-managed health center's operations.

"(2) MATCHING REQUIREMENT.—The Secretary may award a grant under this section to an entity only if the entity agrees to provide, from non-Federal sources, an amount equal to 20 percent of the amount of the grant (which may be provided in cash or in kind) to carry out the activities supported by the grant.

"(3) PAYOR OF LAST RESORT.—The Secretary may award a grant under this section to an entity only if the entity demonstrates to the satisfaction of the Secretary that funds received through the grant will not be expended for any activity to the extent that payment has been made, or can reasonably be expected to be made—

"(A) under any insurance policy;

"(B) under any Federal or State health benefits program (including titles XIX and XXI of the Social Security Act); or

"(C) by an entity which provides health services on a prepaid basis.

"(4) MAINTENANCE OF EFFORT.—The Secretary may award a grant under this section to an entity only if the entity demonstrates to the satisfaction of the Secretary that—

"(A) funds received through the grant will be expended only to supplement, and not supplant, non-Federal and Federal funds otherwise available to the entity for the activities to be funded through the grant; and

"(B) with respect to such activities, the entity will maintain expenditures of non-Federal amounts for such activities at a level not less than the lesser of such expenditures maintained by the entity for the fiscal year preceding the fiscal year for which the entity receives the grant.

"(e) ADDITIONAL ASSURANCE FOR PLANNING GRANTS.—The Secretary may award a grant under subsection (b)(1) to an entity only if the entity agrees—

"(1) to assess the needs of the medically underserved populations proposed to be served by the nurse-managed health center; and

"(2) to design services and operations of the nurse-managed health center for such populations based on such assessment.

"(f) ADDITIONAL ASSURANCES FOR OPERATION GRANTS.—The Secretary may award a grant under subsection (b)(2) to an entity only if the entity assures that the nurse-managed health center will provide—

"(1) comprehensive primary care services, wellness services, and other health care services deemed appropriate by the Secretary;

"(2) care without respect to insurance status or income of the patient; and

"(3) direct access to client-centered services offered by advanced practice nurses, other nurses, physicians, physician assistants, or other qualified health professionals.

"(g) TECHNICAL ASSISTANCE.—The Secretary shall provide (either directly or by grant or contract) technical and other assistance to nurse-managed health centers to assist such centers in meeting the requirements of this section. Such assistance may include fiscal and program management assistance, training in fiscal and program management, operational and administrative support, and the provision of information to nurse-managed health centers regarding the various resources available under this section and how those resources can best be used to meet the health needs of the communities served by nurse-managed health centers.

"(h) REPORT.—The Secretary shall submit to the Congress an annual report on the program under this section.

"(i) DEFINITIONS.—

"(1) COMPREHENSIVE PRIMARY CARE SERVICES.—The term 'comprehensive primary care services' has the meaning given to the term 'required primary health services' in section 330(b)(1).

"(2) MEDICALLY UNDERSERVED POPULATION.—The term 'medically underserved population' has the meaning given to such term in section 330(b)(3).

"(3) NURSE-MANAGED HEALTH CENTER.—The term 'nurse-managed health center' has the meaning given to such term in section 801.

"(4) WELLNESS SERVICES.—The term 'wellness services' means any health-related service or intervention, not including primary care, which is designed to reduce identifiable health risks and increase healthy behaviors intended to prevent the onset of disease or lessen the impact of existing chronic conditions by teaching more effective management techniques that focus on individual self-care and patient-driven decisionmaking.".

SEC. 2513. FEDERALLY QUALIFIED BEHAVIORAL HEALTH CENTERS.

(a) BLOCK GRANTS REGARDING MENTAL HEALTH AND SUBSTANCE ABUSE.—Section 1913 (42 U.S.C. 300x–3) is amended—

(1) in subsection (a)(2)(A), by striking "community mental health services" and inserting "behavioral health services";

(2) in subsection (b)—

(A) by striking paragraph (1) and inserting the following:

"(1) services under the plan will be provided only through appropriate, qualified community programs (which may include federally qualified behavioral health centers, child mental health programs, psychosocial rehabilitation programs, mental health peer-support programs, and mental health primary consumer-directed programs); and"; and

(B) in paragraph (2), by striking "community mental health centers" and inserting "federally qualified behavioral health centers"; and

(3) by striking subsection (c) and inserting the following:

"(c) CRITERIA FOR FEDERALLY QUALIFIED BEHAVIORAL HEALTH CENTERS.—

"(1) IN GENERAL.—The Administrator shall certify, and recertify at least every 5 years, federally qualified behavioral health centers as meeting the criteria specified in this subsection.

"(2) REGULATIONS.—Not later than 18 months after the date of the enactment of the America's Affordable Health Choices Act of 2009, the Administrator shall issue final regulations for certifying centers under paragraph (1).

"(3) CRITERIA.—The criteria referred to in subsection (b)(2) are that the center performs each of the following:

"(A) Provide services in locations that ensure services will be available and accessible promptly and in a manner which preserves human dignity and assures continuity of care.

"(B) Provide services in a mode of service delivery appropriate for the target population.

"(C) Provide individuals with a choice of service options where there is more than one efficacious treatment.

"(D) Employ a core staff of clinical staff that is multidisciplinary and culturally and linguistically competent.

"(E) Provide services, within the limits of the capacities of the center, to any individual residing or employed in the service area of the center.

"(F) Provide, directly or through contract, to the extent covered for adults in the State Medicaid plan and for children in accordance with section 1905(r) of the Social Security Act regarding early and periodic screening, diagnosis, and treatment, each of the following services:

"(i) Screening, assessment, and diagnosis, including risk assessment.

"(ii) Person-centered treatment planning or similar processes, including risk assessment and crisis planning.

"(iii) Outpatient clinic mental health services, including screening, assessment, diagnosis, psychotherapy, substance abuse counseling, medication management, and integrated treatment for mental illness and substance abuse which shall be evidence-based (including cognitive behavioral therapy, dialectical behavioral therapy, motivational interviewing, and other such therapies which are evidence-based).

"(iv) Outpatient clinic primary care services, including screening and monitoring of key health indicators and health risk (including screening for diabetes, hypertension, and cardiovascular disease and monitoring of weight, height, body mass index (BMI), blood pressure, blood glucose or HbA1C, and lipid profile).

"(v) Crisis mental health services, including 24-hour mobile crisis teams, emergency crisis intervention services, and crisis stabilization.

"(vi) Targeted case management (services to assist individuals gaining access to needed medical, social, educational, and other services and applying for income security and other benefits to which they may be entitled).

"(vii) Psychiatric rehabilitation services including skills training, assertive community treatment, family psychoeducation, disability self-management, supported employment, supported housing services, therapeutic foster care services, multisystemic therapy, and such other evidence-based practices as the Secretary may require.

"(viii) Peer support and counselor services and family supports.

"(G) Maintain linkages, and where possible enter into formal contracts with, inpatient psychiatric facilities and substance abuse detoxification and residential programs.

"(H) Make available to individuals served by the center, directly, through contract, or through linkages with other programs, each of the following:

"(i) Adult and youth peer support and counselor services.

"(ii) Family support services for families of children with serious mental disorders.

"(iii) Other community or regional services, supports, and providers, including schools, child welfare agencies, juvenile and criminal justice agencies and facilities, housing agencies and programs, employers, and other social services.

"(iv) Onsite or offsite access to primary care services.

"(v) Enabling services, including outreach, transportation, and translation.

"(vi) Health and wellness services, including services for tobacco cessation.".

(b) CONFORMING AMENDMENTS.—

(1) BLOCK GRANTS FOR BEHAVIORAL HEALTH SERVICES.—Subpart I of part B of title XIX (42 U.S.C. 300x–1 et seq.) is amended—

(A) in the subpart heading, by striking "**Community Mental Health Services**" and inserting "**Behavioral Mental Health Services**";

(B) in the heading of section 1912, by striking "**COMMUNITY MENTAL HEALTH SERVICES**" and inserting "**BEHAVIORAL MENTAL HEALTH SERVICES**"; and

(C) in sections 1912(a)(1), 1912(b), 1915(b)(1), and 1918(a)(8), by striking the term "community mental health services" each place it appears and inserting "behavioral mental health services".

(2) CENTER FOR MENTAL HEALTH SERVICES.—Paragraph (13) of section 520(b) (42 U.S.C. 290bb–31) is amended by striking "community mental health centers" and inserting "federally qualified behavioral health centers".

(3) GRANTS FOR EMERGENCY MENTAL HEALTH CENTERS.—Subsection (b) of section 520F (42 U.S.C. 290bb–37) is amended by striking "community mental health centers" and inserting "federally qualified behavioral health centers".

PART 2—OTHER GRANT PROGRAMS

SEC. 2521. COMPREHENSIVE PROGRAMS TO PROVIDE EDUCATION TO NURSES AND CREATE A PIPELINE TO NURSING.

(a) PURPOSES.—It is the purpose of this section to authorize grants to—

(1) address the projected shortage of nurses by funding comprehensive programs to create a career ladder to nursing (including certified nurse assistants, licensed practical nurses, licensed vocational nurses, and registered nurses) for incumbent ancillary health care workers;

(2) increase the capacity for educating nurses by increasing both nurse faculty and clinical opportunities through collaborative programs between staff nurse organizations, health care providers, and accredited schools of nursing; and

(3) provide training programs through education and training organizations jointly administered by health care providers and health care labor organizations or other organizations representing staff nurses and frontline health care workers, working in collaboration with accredited schools of nursing and academic institutions.

(b) GRANTS.—Not later than 6 months after the date of the enactment of this Act, the Secretary of Labor (referred to in this section as the "Secretary") shall establish a partnership grant program to award grants to eligible entities to carry out comprehensive programs to provide education to nurses and create a pipeline to nursing for incumbent ancillary health care workers who wish to advance their careers, and to otherwise carry out the purposes of this section.

(c) ELIGIBILITY.—To be eligible for a grant under this section, an entity shall be—

(1) a health care entity that is jointly administered by a health care employer and a labor union representing the health care employees of the employer and that carries out activities using labor management training funds as provided for under section 302(c)(6) of the Labor Management Relations Act, 1947 (29 U.S.C. 186(c)(6));

(2) an entity that operates a training program that is jointly administered by—

(A) one or more health care providers or facilities, or a trade association of health care providers; and

(B) one or more organizations which represent the interests of direct care health care workers or staff nurses and in which the direct care health care workers or staff nurses have direct input as to the leadership of the organization;

(3) a State training partnership program that consists of nonprofit organizations that include equal participation from industry, including public or private employers, and labor organizations including joint labor-management training programs, and which may include representatives from local governments, worker investment agency one-stop career centers, community-based organizations, community colleges, and accredited schools of nursing; or

(4) a school of nursing (as defined in section 801 of the Public Health Service Act (42 U.S.C. 296)).

(d) ADDITIONAL REQUIREMENTS FOR HEALTH CARE EMPLOYER DESCRIBED IN SUBSECTION (c).—To be eligible for a grant under this section, a health care employer described in subsection (c) shall demonstrate that it—

(1) has an established program within its facility to encourage the retention of existing nurses;

(2) provides wages and benefits to its nurses that are competitive for its market or that have been collectively bargained with a labor organization; and

(3) supports programs funded under this section through 1 or more of the following:

(A) The provision of paid leave time and continued health coverage to incumbent health care workers to allow their participation in nursing career ladder programs, including certified nurse assistants, licensed practical nurses, licensed vocational nurses, and registered nurses.

(B) Contributions to a joint labor-management training fund which administers the program involved.

(C) The provision of paid release time, incentive compensation, or continued health coverage to staff nurses who desire to work full- or part-time in a faculty position.

(D) The provision of paid release time for staff nurses to enable them to obtain a bachelor of science in nursing degree, other advanced nursing degrees, specialty training, or certification program.

(E) The payment of tuition assistance which is managed by a joint labor-management training fund or other jointly administered program.

(e) OTHER REQUIREMENTS.—

(1) MATCHING REQUIREMENT.—

(A) IN GENERAL.—The Secretary may not make a grant under this section unless the applicant involved agrees, with respect to the costs to be incurred by the applicant in carrying out the program under the grant, to make available non-Federal contributions (in cash or in kind under subparagraph (B)) toward such costs in an amount equal to not less than $1 for each $1 of Federal funds provided in the grant. Such contributions may be made directly or through donations from public or private entities, or may be provided through the cash equivalent of paid release time provided to incumbent worker students.

(B) DETERMINATION OF AMOUNT OF NON-FEDERAL CONTRIBUTION.—Non-Federal contributions required in subparagraph (A) may be in cash or in kind (including paid release time), fairly evaluated, including equipment or services (and excluding indirect or overhead costs). Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(2) REQUIRED COLLABORATION.—Entities carrying out or overseeing programs carried out with assistance provided under this section shall demonstrate collaboration with accredited schools of nursing which may include community colleges and other academic institutions providing associate, bachelor's, or advanced nursing degree programs or specialty training or certification programs.

(f) USE OF FUNDS.—Amounts awarded to an entity under a grant under this section shall be used for the following:

(1) To carry out programs that provide education and training to establish nursing career ladders to educate incumbent health care workers to become nurses (including certified nurse assistants, licensed practical nurses, licensed vocational nurses, and registered nurses). Such programs shall include one or more of the following:

(A) Preparing incumbent workers to return to the classroom through English-as-a-second language education, GED education, precollege counseling, college preparation classes, and support with entry level college classes that are a prerequisite to nursing.

(B) Providing tuition assistance with preference for dedicated cohort classes in community colleges, universities, and accredited schools of nursing with supportive services including tutoring and counseling.

(C) Providing assistance in preparing for and meeting all nursing licensure tests and requirements.

(D) Carrying out orientation and mentorship programs that assist newly graduated nurses in adjusting to working at the bedside to ensure their retention postgraduation, and ongoing programs to support nurse retention.

(E) Providing stipends for release time and continued health care coverage to enable incumbent health care workers to participate in these programs.

(2) To carry out programs that assist nurses in obtaining advanced degrees and completing specialty training or certification programs and to establish incentives for nurses to assume nurse faculty positions on a part-time or full-time basis. Such programs shall include one or more of the following:

(A) Increasing the pool of nurses with advanced degrees who are interested in teaching by funding programs that enable incumbent nurses to return to school.

(B) Establishing incentives for advanced degree bedside nurses who wish to teach in nursing programs so they can obtain a leave from their bedside position to assume a full- or part-time position as adjunct or full-time faculty without the loss of salary or benefits.

(C) Collaboration with accredited schools of nursing which may include community colleges and other academic institutions providing associate, bachelor's, or advanced nursing degree programs, or specialty training or certification programs, for nurses to carry out innovative nursing programs which meet the needs of bedside nursing and health care providers.

(g) PREFERENCE.—In awarding grants under this section the Secretary shall give preference to programs that—

(1) provide for improving nurse retention;

(2) provide for improving the diversity of the new nurse graduates to reflect changes in the demographics of the patient population;

(3) provide for improving the quality of nursing education to improve patient care and safety;

(4) have demonstrated success in upgrading incumbent health care workers to become nurses or which have established effective programs or pilots to increase nurse faculty; or

(5) are modeled after or affiliated with such programs described in paragraph (4).

(h) EVALUATION.—

(1) PROGRAM EVALUATIONS.—An entity that receives a grant under this section shall annually evaluate, and submit to the Secretary a report on, the activities carried out under the grant and the outcomes of such activities. Such outcomes may include—

(A) an increased number of incumbent workers entering an accredited school of nursing and in the pipeline for nursing programs;

(B) an increasing number of graduating nurses and improved nurse graduation and licensure rates;

(C) improved nurse retention;

(D) an increase in the number of staff nurses at the health care facility involved;

(E) an increase in the number of nurses with advanced degrees in nursing;

(F) an increase in the number of nurse faculty;

(G) improved measures of patient quality (which may include staffing ratios of nurses, patient satisfaction rates, and patient safety measures); and

(H) an increase in the diversity of new nurse graduates relative to the patient population.

(2) GENERAL REPORT.—Not later than 2 years after the date of the enactment of this Act, and annually thereafter, the Secretary of Labor shall, using data and information from the reports received under paragraph (1), submit to the Congress a report concerning the overall effectiveness of the grant program carried out under this section.

(i) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary.

SEC. 2522. MENTAL AND BEHAVIORAL HEALTH TRAINING.

Part E of title VII (42 U.S.C. 294n et seq.) is amended by adding at the end the following:

"Subpart 3—Mental and Behavioral Health Training

"SEC. 775. MENTAL AND BEHAVIORAL HEALTH TRAINING PROGRAM.

"(a) PROGRAM.—The Secretary shall establish an interdisciplinary mental and behavioral health training program consisting of awarding grants and contracts under subsection (b).

"(b) SUPPORT AND DEVELOPMENT OF MENTAL AND BEHAVIORAL HEALTH TRAINING PROGRAMS.—The Secretary shall make grants to, or enter into contracts with, eligible entities—

"(1) to plan, develop, operate, or participate in an accredited professional training program for mental and behavioral health professionals to promote—

"(A) interdisciplinary training; and

"(B) coordination of the delivery of health care within and across settings, including health care institutions, community-based settings, and the patient's home;

"(2) to provide financial assistance to mental and behavioral health professionals, who are participants in any such program, and who plan to work in the field of mental and behavioral health;

"(3) to plan, develop, operate, or participate in an accredited program for the training of mental and behavioral health professionals who plan to teach in the field of mental and behavioral health; and

"(4) to provide financial assistance in the form of traineeships and fellowships to mental and behavioral health professionals who are participants in any such program and who plan to teach in the field of mental and behavioral health.

"(c) ELIGIBILITY.—To be eligible for a grant or contract under subsection (b), an entity shall be—

"(1) an accredited health professions school, including an accredited school or program of psychology, psychiatry, social work, marriage and family therapy, professional mental health and substance abuse counseling, or addiction medicine;

"(2) an accredited public or nonprofit private hospital;

"(3) a public or private nonprofit entity; or

"(4) a consortium of 2 or more entities described in paragraphs (1) through (3).

"(d) PREFERENCE.—In awarding grants or contracts under this section, the Secretary shall give preference to entities that have a demonstrated record of the following:

"(1) Training the greatest percentage, or significantly improving the percentage, of health professionals who serve in underserved communities.

"(2) Supporting teaching programs that address the health care needs of vulnerable populations.

"(3) Training individuals who are from underrepresented minority groups or disadvantaged backgrounds.

"(4) Training individuals who serve geriatric populations with an emphasis on underserved elderly.

"(5) Training individuals who serve pediatric populations with an emphasis on underserved children.

"(e) REPORT.—The Secretary shall submit to the Congress an annual report on the program under this section.

"(f) DEFINITION.—In this section:

"(1) The term 'health disparities' has the meaning given the term in section 3171.

"(2) The term 'mental and behavioral health professional' means an individual training or practicing—

"(A) in psychology; general, geriatric, child or adolescent psychiatry; social work; marriage and family therapy; professional mental health and substance abuse counseling; or addiction medicine; or

"(B) another mental and behavioral health specialty, as deemed appropriate by the Secretary.

"(3) The term 'interdisciplinary' means collaboration across health professions, specialties, and subspecialties, which may include public health, nursing, allied health, and appropriate medical specialties.

"(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $60,000,000 for each of fiscal years 2010 through 2014. Of the amounts appropriated to carry out this section for a fiscal year, not less than 15 percent shall be used for training programs in psychology.".

SEC. 2523. PROGRAMS TO INCREASE AWARENESS OF ADVANCE CARE PLANNING ISSUES.

Title III (42 U.S.C. 241 et seq.), as amended, is amended by adding at the end the following:

"PART T—PROGRAMS TO INCREASE AWARENESS OF ADVANCE CARE PLANNING ISSUES

"SEC. 399HH. ADVANCE CARE PLANNING EDUCATION CAMPAIGNS AND INFORMATION PHONE LINE AND CLEARINGHOUSE.

"(a) ADVANCE CARE PLANNING EDUCATION CAMPAIGN.—The Secretary shall, directly or through grants awarded under subsection (c), conduct a national public education campaign—

"(1) to raise public awareness of the importance of planning for care near the end of life;

"(2) to improve the public's understanding of the various situations in which individuals may find themselves if they become unable to express their health care wishes;

"(3) to explain the need for readily available legal documents that express an individual's wishes through—

"(A) advance directives (including living wills, comfort care orders, and durable powers of attorney for health care); and

"(B) other planning tools, such as a physician's orders for life-sustaining treatment (POLST); and

"(4) to educate the public about the availability of hospice care and palliative care.

"(b) INFORMATION PHONE LINE AND CLEARINGHOUSE.—The Secretary, directly or through grants awarded under subsection (c), shall provide for the establishment of a national, toll-free, information telephone line and a clearinghouse that the public and health professionals may access to find out about State-specific and other information regarding advance directive and end-of-life decisions.

"(c) GRANTS.—

"(1) IN GENERAL.—The Secretary shall use funds appropriated under subsection (d) for the purpose of awarding grants to public or nonprofit private en-

tities (including States or political subdivisions of a State), or a consortium of any of such entities, for the purpose of conducting education campaigns under subsection (a).

"(2) LIMITATION ON ELIGIBILITY.—Any grant awarded under this Act shall not go to any governmental or nongovernmental organization that promotes suicide, assisted suicide, or the active hastening of death. Nothing in the previous clause shall be construed to prohibit palliative or hospice care.

"(3) PERIOD.—Any grant awarded under paragraph (1) shall be for a period of 3 years.

"(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated—

"(1) for purposes of carrying out subsection (b), $5,000,000 for fiscal year 2010 and each subsequent year; and

"(2) for purposes of making grants under subsection (c), $10,000,000 for fiscal year 2010, to remain available until expended.".

SEC. 2524. REAUTHORIZATION OF TELEHEALTH AND TELEMEDICINE GRANT PROGRAMS.

(a) TELEHEALTH NETWORK AND TELEHEALTH RESOURCE CENTERS GRANT PROGRAMS.—Section 330I (42 U.S.C. 254c–14) is amended—

(1) in subsection (a)—

(A) by striking paragraph (3) (relating to frontier communities); and

(B) by inserting after paragraph (2) the following:

"(3) HEALTH DISPARITIES.—The term 'health disparities' has the meaning given such term in section 3171.";

(2) in subsection (d)(1)—

(A) in subparagraph (B), by striking "and" at the end;

(B) in subparagraph (C), by striking the period at the end and inserting "; and"; and

(C) by adding at the end the following:

"(D) reduce health disparities.";

(3) in subsection (f)(1)(B)(iii)—

(A) in subclause (VII), by inserting ", including skilled nursing facilities" before the period at the end;

(B) in subclause (IX), by inserting ", including county mental health and public mental health facilities" before the period at the end; and

(C) by adding at the end the following:

"(XIII) Renal dialysis facilities.";

(4) by amending subsection (i) to read as follows:

"(i) PREFERENCES.—

"(1) TELEHEALTH NETWORKS.—In awarding grants under subsection (d)(1) for projects involving telehealth networks, the Secretary shall give preference to eligible entities meeting the following:

"(A) NETWORK.—The eligible entity is a health care provider in, or proposing to form, a health care network that furnishes services in a medically underserved area or a health professional shortage area.

"(B) BROAD GEOGRAPHIC COVERAGE.—The eligible entity demonstrates broad geographic coverage in the rural or medically underserved areas of the State or States in which the entity is located.

"(C) HEALTH DISPARITIES.—The eligible entity demonstrates how the project to be funded through the grant will address health disparities.

"(D) LINKAGES.—The eligible entity agrees to use the grant to establish or develop plans for telehealth systems that will link rural hospitals and rural health care providers to other hospitals, health care providers, and patients.

"(E) EFFICIENCY.—The eligible entity agrees to use the grant to promote greater efficiency in the use of health care resources.

"(F) VIABILITY.—The eligible entity demonstrates the long-term viability of projects through—

"(i) availability of non-Federal funding sources; or

"(ii) institutional and community support for the telehealth network.

"(G) SERVICES.—The eligible entity provides a plan for coordinating system use by eligible entities and prioritizes use of grant funds for health care services over nonclinical uses.

"(2) TELEHEALTH RESOURCE CENTERS.—In awarding grants under subsection (d)(2) for projects involving telehealth resource centers, the Secretary shall give preference to eligible entities meeting the following:

"(A) PROVISION OF A BROAD RANGE OF SERVICES.—The eligible entity has a record of success in the provision of a broad range of telehealth services to medically underserved areas or populations.

"(B) PROVISION OF TELEHEALTH TECHNICAL ASSISTANCE.—The eligible entity has a record of success in the provision of technical assistance to providers serving medically underserved communities or populations in the establishment and implementation of telehealth services.

"(C) COLLABORATION AND SHARING OF EXPERTISE.—The eligible entity has a demonstrated record of collaborating and sharing expertise with providers of telehealth services at the national, regional, State, and local levels.";

(5) in subsection (j)(2)(B), by striking "such projects for fiscal year 2001" and all that follows through the period and inserting "such project for fiscal year 2009.";

(6) in subsection (k)(1)—

(A) in subparagraph (E)(i), by striking "transmission of medical data" and inserting "transmission and electronic archival of medical data"; and

(B) by amending subparagraph (F) to read as follows:

"(F) developing projects to use telehealth technology—

"(i) to facilitate collaboration between health care providers;

"(ii) to promote telenursing services; or

"(iii) to promote patient understanding and adherence to national guidelines for chronic disease and self-management of such conditions;";

(7) in subsection (q), by striking "Not later than September 30, 2005" and inserting "Not later than 1 year after the date of the enactment of the America's Affordable Health Choices Act of 2009, and annually thereafter";

(8) by striking subsection (r);

(9) by redesignating subsection (s) as subsection (r); and

(10) in subsection (r) (as so redesignated)—

(A) in paragraph (1)—

(i) by striking "and" before "such sums"; and

(ii) by inserting ", $10,000,000 for fiscal year 2010, and such sums as may be necessary for each of fiscal years 2011 through 2014" before the semicolon; and

(B) in paragraph (2)—

(i) by striking "and" before "such sums"; and

(ii) by inserting ", $10,000,000 for fiscal year 2010, and such sums as may be necessary for each of fiscal years 2011 through 2014" before the period.

(b) TELEMEDICINE; INCENTIVE GRANTS REGARDING COORDINATION AMONG STATES.—Subsection (b) of section 330L (42 U.S.C. 254c–18) is amended by inserting ", $10,000,000 for fiscal year 2010, and such sums as may be necessary for each of fiscal years 2011 through 2014" before the period at the end.

SEC. 2525. NO CHILD LEFT UNIMMUNIZED AGAINST INFLUENZA: DEMONSTRATION PROGRAM USING ELEMENTARY AND SECONDARY SCHOOLS AS INFLUENZA VACCINATION CENTERS.

(a) PURPOSE.—The Secretary of Health and Human Services, in consultation with the Secretary of Education and the Secretary of Labor, shall award grants to eligible partnerships to carry out demonstration programs designed to test the feasibility of using the Nation's elementary schools and secondary schools as influenza vaccination centers.

(b) IN GENERAL.—The Secretary shall coordinate with the Secretary of Labor, the Secretary of Education, State Medicaid agencies, State insurance agencies, and private insurers to carry out a program consisting of awarding grants under subsection (c) to ensure that children have coverage for all reasonable and customary expenses related to influenza vaccinations, including the costs of purchasing and administering the vaccine incurred when influenza vaccine is administered outside of the physician's office in a school or other related setting.

(c) PROGRAM DESCRIPTION.—

(1) GRANTS.—From amounts appropriated pursuant to subsection (l), the Secretary shall award grants to eligible partnerships to be used to provide influenza vaccinations to children in elementary and secondary schools, in coordination with school nurses, school health care programs, community health care providers, State insurance agencies, or private insurers.

(2) ACIP RECOMMENDATIONS.—The program under this section shall be designed to administer vaccines consistent with the recommendations of the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) for the annual vaccination of all children 5 through 19 years of age.

(3) PARTICIPATION VOLUNTARY.—Participation by a school or an individual shall be voluntary.

(d) USE OF FUNDS.—Eligible partnerships receiving a grant under this section shall ensure the maximum number of children access influenza vaccinations as follows:

(1) COVERED CHILDREN.—To the extent to which payment of the costs of purchasing and administering the influenza vaccine for children is not covered through other federally funded programs or through private insurance, eligible partnerships receiving a grant shall use funds to purchase and administer influenza vaccinations.

(2) CHILDREN COVERED BY OTHER FEDERAL PROGRAMS.—For children who are eligible under other federally funded programs for payment of the costs of purchasing and administering the influenza vaccine, eligible partnerships receiving a grant shall not use funds provided under this section for such costs.

(3) CHILDREN COVERED BY PRIVATE HEALTH INSURANCE.—For children who have private insurance, eligible partnerships receiving a grant shall offer assistance in accessing coverage for vaccinations administered through the program under this section.

(e) PRIVACY.—The Secretary shall ensure that the program under this section adheres to confidentiality and privacy requirements of section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note) and section 444 of the General Education Provisions Act (20 U.S.C. 1232g; commonly referred to as the "Family Educational Rights and Privacy Act of 1974").

(f) APPLICATION.—An eligible partnership desiring a grant under this section shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(g) DURATION.—Eligible partnerships receiving a grant shall administer a demonstration program funded through this section over a period of 2 consecutive school years.

(h) CHOICE OF VACCINE.—The program under this section shall not restrict the discretion of a health care provider to administer any influenza vaccine approved by the Food and Drug Administration for use in pediatric populations.

(i) AWARDS.—The Secretary shall award—

(1) a minimum of 10 grants in 10 different States to eligible partnerships that each include one or more public schools serving primarily low-income students; and

(2) a minimum of 5 grants in 5 different States to eligible partnerships that each include one or more public schools located in a rural local education agency.

(j) REPORT.—Not later than 90 days following the completion of the program under this section, the Secretary shall submit to the Committees on Education and Labor, Energy and Commerce, and Appropriations of the House of Representatives and to the Committees on Health, Education, Labor, and Pensions and Appropriations of the Senate a report on the results of the program. The report shall include—

(1) an assessment of the influenza vaccination rates of school-age children in localities where the program is implemented, compared to the national average influenza vaccination rates for school-aged children, including whether school-based vaccination assists in achieving the recommendations of the Advisory Committee on Immunization Practices for annual influenza vaccination of all children 6 months to 18 years of age;

(2) an assessment of the utility of employing elementary schools and secondary schools as a part of a multistate, community-based pandemic response program that is consistent with existing Federal and State pandemic response plans;

(3) an assessment of the feasibility of using existing Federal and private insurance funding in establishing a multistate, school-based vaccination program for seasonal influenza vaccination;

(4) an assessment of the number of education days gained by students as a result of seasonal vaccinations based on absenteeism rates;

(5) a determination of whether the program under this section—

(A) increased vaccination rates in the participating localities; and

(B) was implemented for sufficient time for gathering enough valid data; and

(6) a recommendation on whether the program should be continued, expanded, or terminated.

(k) DEFINITIONS.—In this section:

(1) ELIGIBLE PARTNERSHIP.—The term "eligible partnership" means a local public health department, or another health organization defined by the Secretary as eligible to submit an application, and one or more elementary and secondary schools.

(2) ELEMENTARY SCHOOL.—The terms "elementary school'" and "secondary school" have the meanings given such terms in section 9101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(3) LOW-INCOME.—The term "low-income" means a student, age 5 through 19, eligible for free or reduced-price lunch under the National School Lunch Act (42 U.S.C. 1751 et seq.).

(4) RURAL LOCAL EDUCATIONAL AGENCY.—The term "rural local educational agency" means an eligible local educational agency described in section 6211(b)(1) of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7345(b)(1)).

(5) SECRETARY.—Except as otherwise specified, the term "Secretary" means the Secretary of Health and Human Services.

(l) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated such sums as may be necessary.

SEC. 2526. EXTENSION OF WISEWOMAN PROGRAM.

Section 1509 of the Public Health Service Act (42 U.S.C. 300n–4a) is amended—

(1) in subsection (a)—

(A) by striking the heading and inserting "IN GENERAL.—"; and

(B) in the matter preceding paragraph (1), by striking "may make grants" and all that follows through "purpose" and inserting the following: "may make grants to such States for the purpose"; and

(2) in subsection (d)(1), by striking "there are authorized" and all that follows through the period and inserting "there are authorized to be appropriated $70,000,000 for fiscal year 2010, $73,500,000 for fiscal year 2011, $77,000,000 for fiscal year 2012, $81,000,000 for fiscal year 2013, and $85,000,000 for fiscal year 2014.".

SEC. 2527. HEALTHY TEEN INITIATIVE TO PREVENT TEEN PREGNANCY.

Part B of title III (42 U.S.C. 243 et seq.) is amended by inserting after section 317T the following:

"SEC. 317U. HEALTHY TEEN INITIATIVE TO PREVENT TEEN PREGNANCY.

"(a) PROGRAM.—To the extent and in the amount of appropriations made in advance in appropriations Acts, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a program consisting of making grants, in amounts determined under subsection (c), to each State that submits an application in accordance with subsection (d) for an evidence-based education program described in subsection (b).

"(b) USE OF FUNDS.—Amounts received by a State under this section shall be used to conduct or support evidence-based education programs (directly or through grants or contracts to public or private nonprofit entities, including schools and community-based and faith-based organizations) to reduce teen pregnancy or sexually transmitted diseases.

"(c) DISTRIBUTION OF FUNDS.—The Director shall, for fiscal year 2010 and each subsequent fiscal year, make a grant to each State described in subsection (a) in an amount equal to the product of—

"(1) the amount appropriated to carry out this section for the fiscal year; and

"(2) the percentage determined for the State under section 502(c)(1)(B)(ii) of the Social Security Act.

"(d) APPLICATION.—To seek a grant under this section, a State shall submit an application at such time, in such manner, and containing such information and assurance of compliance with this section as the Secretary may require. At a minimum, an application shall to the satisfaction of the Secretary—

"(1) describe how the State's proposal will address the needs of at-risk teens in the State;

"(2) identify the evidence-based education program or programs selected from the registry developed under subsection (g) that will be used to address risks in priority populations;

"(3) describe how the program or programs will be implemented and any adaptations to the evidence-based model that will be made;

"(4) list any private and public entities with whom the State proposes to work, including schools and community-based and faith-based organizations, and demonstrate their capacity to implement the proposed program or programs; and

"(5) identify an independent entity that will evaluate the impact of the program or programs.

"(e) EVALUATION.—

"(1) REQUIREMENT.—As a condition on receipt of a grant under this section, a State shall agree—

"(A) to arrange for an independent evaluation of the impact of the programs to be conducted or supported through the grant; and

"(B) submit reports to the Secretary on such programs and the results of evaluation of such programs.

"(2) FUNDING LIMITATION.—Of the amounts made available to a State through a grant under this section for any fiscal year, not more than 10 percent may be used for such evaluation.

"(f) RULE OF CONSTRUCTION.—This section shall not be construed to preempt or limit any State law regarding parental involvement and decisionmaking in children's education.

"(g) REGISTRY OF ELIGIBLE PROGRAMS.—The Secretary shall develop not later than 180 days after the date of the enactment of the America's Affordable Health Choices Act of 2009, and periodically update thereafter, a publicly available registry of programs described in subsection (b) that, as determined by the Secretary—

"(1) meet the definition of the term 'evidence-based' in subsection (i);

"(2) are medically and scientifically accurate; and

"(3) provide age-appropriate information.

"(h) MATCHING FUNDS.—The Secretary may award a grant to a State under this section for a fiscal year only if the State agrees to provide, from non-Federal sources, an amount equal to $1 (in cash or in kind) for each $4 provided through the grant to carry out the activities supported by the grant.

"(i) DEFINITION.—In this section, the term 'evidence-based' means based on a model that has been found, in methodologically sound research—

"(1) to delay initiation of sex;

"(2) to decrease number of partners;

"(3) to reduce teen pregnancy;

"(4) to reduce sexually transmitted infection rates; or

"(5) to improve rates of contraceptive use.

"(j) APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $50,000,000 for each of the fiscal years 2010 through 2014.".

SEC. 2528. NATIONAL TRAINING INITIATIVE ON AUTISM SUPPLEMENTAL GRANTS AND TECHNICAL ASSISTANCE.

Part R of title III (42 U.S.C. 280i et seq.) is amended—

(1) by inserting after the header for part R the following:

"Subpart 1—Surveillance and Research Program; Education, Early Detection, and Intervention; and Reporting";

(2) in section 399AA(d), by striking "part" and inserting "subpart"; and

(3) by adding at the end the following:

"Subpart 2—National Training Initiative

"SEC. 399FF. NATIONAL TRAINING INITIATIVE.

"(a) NATIONAL TRAINING INITIATIVE SUPPLEMENTAL GRANTS AND TECHNICAL ASSISTANCE.—

"(1) SUPPLEMENTAL GRANTS.—

"(A) IN GENERAL.—The Secretary shall award, in consultation with the Interagency Autism Coordinating Committee, multiyear national training initiative supplemental grants to University Centers for Excellence in Developmental Disabilities authorized by the Developmental Disabilities Assistance and Bill of Rights Act of 2000, public or private nonprofit entities, and other comparable interdisciplinary service, training, and academic entities to provide interdisciplinary training, continuing education initiatives, technical assistance, dissemination, and services to address the unmet needs of children and adults with autism spectrum disorders and related developmental disabilities, and their families.

"(B) REQUIREMENTS.—A University Center for Excellence in Developmental Disabilities that desires to receive a grant under this paragraph shall submit to the Secretary an application containing such agreements and information as the Secretary may require, including agreements that the training program shall—

"(i) provide trainees with an appropriate balance of interdisciplinary academic and community-based experiences;

"(ii) have a demonstrated capacity to provide training and technical assistance in evidence-based practices to evaluate, and provide effective

interventions, treatment, services, and supports to children and adults with autism and related developmental disabilities, and their families;

"(iii) have a demonstrated capacity to include persons with autism spectrum disorders, parents, and family members as part of the training program to ensure that a person and family-centered approach is used;

"(iv) provide to the Secretary, in the manner prescribed by the Secretary, data regarding the number of persons who have benefitted and outcomes of the provision of training and technical assistance;

"(v) demonstrate a capacity to share and disseminate materials and practices that are developed and evaluated to be effective in the provision of training and technical assistance;

"(vi) provide assurances that training, technical assistance, dissemination, and services performed under grants made pursuant to this paragraph shall be consistent with the goals of the Developmental Disabilities Act of 1984, the Americans with Disabilities Act of 1990, the Individuals with Disabilities Education Act, and the No Child Left Behind Act of 2001 and conducted in coordination with other relevant State agencies, other institutions of higher education, and service providers; and

"(vii) have a demonstrated capacity to provide training, technical assistance, supports, and services under this section statewide.

"(C) ACTIVITIES.—A University Center for Excellence in Developmental Disabilities, or other eligible entity that receives a grant under this paragraph shall expand and develop interdisciplinary training and continuing education initiatives for parents, health, allied health, vocational, educational, and other professionals and develop model services and supports that demonstrate evidence-based practices, by engaging in the following activities:

"(i) Training health, allied health, vocational, and educational professionals to identify, evaluate the needs, and develop treatments, interventions, services, and supports for children and adults with, autism spectrum disorder and related developmental disabilities.

"(ii) Developing systems and products that allow for the interventions, services and supports to be evaluated for fidelity of implementation.

"(iii) Working to expand the availability of evidence-based, lifelong interventions, educational, employment, and transition services, and community supports.

"(iv) Providing statewide technical assistance in collaboration with relevant State agencies, other institutions of higher education, autism spectrum disorder advocacy groups, and community-based service providers.

"(v) Working to develop comprehensive systems of supports and services for individuals with autism and related developmental disabilities and their families, including seamless transitions between educational and health systems across the lifespan.

"(vi) Promoting training, technical assistance, dissemination, supports, and services.

"(vii) Developing mechanisms to provide training and technical assistance, including for-credit courses, intensive summer institutes, continuing education programs, distance based programs, and Web-based information dissemination strategies.

"(viii) Promoting activities that support community-based family and individual services and enable individuals with autism and related developmental disabilities to fully participate in society and achieve good quality of life outcomes.

"(ix) Collecting data on the outcomes of training and technical assistance programs to meet statewide needs for the expansion of services to children and adults with autism spectrum disorders and related developmental disabilities.

"(2) TECHNICAL ASSISTANCE.—The Secretary shall reserve 2 percent of the appropriated funds to make a grant to a national organization with demonstrated capacity for proving training and technical assistance to University Centers for Excellence in Developmental Disabilities to—

"(A) assist in national dissemination of specific information, including evidence-based best practices, from interdisciplinary training programs, and when appropriate, other entities whose findings would inform the work performed by entities awarded grants;

"(B) compile and disseminate strategies and materials that prove to be effective in the provision of training and technical assistance so that the entire network can benefit from the models, materials, and practices developed in individual centers;

"(C) assist in the coordination of activities of grantees under this section;

"(D) develop a Web portal that will provide linkages to each of the individual training initiatives and provide access to training modules, promising training, and technical assistance practices and other materials developed by grantees;

"(E) serve as a research-based resource for Federal and State policymakers on information concerning the provision of training and technical assistance for the assessment, and provision of supports and services for children and adults with autism spectrum disorders and related developmental disabilities;

"(F) convene experts from multiple interdisciplinary training programs, individuals with autism spectrum disorders, and their families to discuss and make recommendations with regard to training issues related to the assessment, and treatment, interventions, supports, and services for children and adults with autism spectrum disorders and related developmental disorders; and

"(G) undertake any other functions that the Secretary determines to be appropriate.

"(3) AUTHORIZATION OF APPROPRIATIONS.—

"(A) IN GENERAL.—Subject to subparagraph (B), there is authorized to be appropriated to carry out this subsection $17,000,000 for fiscal year 2011 to be equally divided among existing University Centers for Excellence in Developmental Disabilities and such sums for fiscal years 2012 through 2015 in the case of University Centers for Excellence in Developmental Disabilities located in American Samoa or the Commonwealth of the Northern Mariana Islands, supplemental grants of not less than $100,000.

"(B) APPROPRIATIONS LESS THAN $17,000,000.—With respect to any fiscal year in which the amount appropriated under subsection (A) to carry out this section is less than $17,000,000, the Secretary shall make competitive grants from such amount to individual University Centers for Excellence in Developmental Disabilities but would not be less than $250,000 per individual grant, in the case of University Centers for Excellence for Developmental Disabilities located in American Samoa or the Commonwealth of the Northern Mariana Islands, supplemental grants of not less than $100,000.

"(C) RESERVATION.—Not more than 2 percent of the amount appropriated under subparagraphs (A) or (B) shall be reserved to carry out paragraph (2).

"(b) EXPANSION OF THE NUMBER OF UNIVERSITY CENTERS FOR EXCELLENCE IN DEVELOPMENTAL DISABILITIES RESEARCH, EDUCATION, AND SERVICES.—

"(1) PURPOSE.—The Secretary shall award up to four additional grants for the University Centers for Excellence in Developmental Disabilities for the purpose of expanding the capacity of existing national network and enhance the number of training facilities serving minority institutions with a primary focus on autism spectrum disorder and related developmental disabilities. Such centers shall—

"(A) train health, allied health, and educational professionals to identify, diagnose, treat, and provide services for individuals with autism spectrum disorders;

"(B) provide services, including early identification, diagnosis, and intervention for individuals with autism spectrum disorders; and

"(C) provide other training and technical assistance, as necessary.

"(2) PRIORITY.—The Secretary shall give priority to establishing such centers in—

"(A) minority-serving institutions that have demonstrated capacity to meet the requirements to qualify as a University Center for Excellence in Developmental Disabilities and provide services to individuals with autism spectrum disorders; or

"(B) States with underserved populations.

"(3) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection $2,000,000 for each of the fiscal years 2011 through 2015.".

SEC. 2529. IMPLEMENTATION OF MEDICATION MANAGEMENT SERVICES IN TREATMENT OF CHRONIC DISEASES.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary"), acting through the Director of the Agency for Health

Care Research and Quality, shall establish a program to provide grants to eligible entities to implement medication management services (referred to in this section as "MTM services") provided by licensed pharmacists, as a part of a collaborative, multidisciplinary, interprofessional approach to the treatment of chronic diseases for targeted individuals, to improve the quality of care and reduce overall cost in the treatment of such diseases. The Secretary shall commence the grant program not later than May 1, 2010.

(b) ELIGIBLE ENTITIES.—To be eligible to receive a grant under subsection (a), an entity shall—

(1) provide a setting appropriate for MTM services, as recommended by the experts described in subsection (e);

(2) submit to the Secretary a plan for achieving long-term financial sustainability;

(3) where applicable, submit a plan for coordinating MTM services with other local providers and where applicable, through or in collaboration with the Medicare Medical Home Pilot program as established by section 1866F of the Social Security Act, as added by section 1302(a) of this Act;

(4) submit a plan for meeting the requirements under subsection (c); and

(5) submit to the Secretary such other information as the Secretary may require.

(c) MTM SERVICES TO TARGETED INDIVIDUALS.—The MTM services provided with the assistance of a grant awarded under subsection (a) shall, as allowed by State law (including applicable collaborative pharmacy practice agreements), include—

(1) performing or obtaining necessary assessments of the health and functional status of each patient receiving such MTM services;

(2) formulating a medication treatment plan according to therapeutic goals agreed upon by the prescriber and the patient or caregiver or authorized representative of the patient;

(3) selecting, initiating, modifying, recommending changes to, or administering medication therapy;

(4) monitoring, which may include access to, ordering, or performing laboratory assessments, and evaluating the response of the patient to therapy, including safety and effectiveness;

(5) performing an initial comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events, quarterly targeted medication reviews for ongoing monitoring, and additional follow–up interventions on a schedule developed collaboratively with the prescriber;

(6) documenting the care delivered and communicating essential information about such care (including a summary of the medication review) and the recommendations of the pharmacist to other appropriate health care providers of the patient in a timely fashion;

(7) providing education and training designed to enhance the understanding and appropriate use of the medications by the patient, caregiver, and other authorized representative;

(8) providing information, support services, and resources and strategies designed to enhance patient adherence with therapeutic regimens;

(9) coordinating and integrating MTM services within the broader health care management services provided to the patient; and

(10) such other patient care services as are allowed under the scopes of practice for pharmacists for purposes of other Federal programs.

(d) TARGETED INDIVIDUALS.—MTM services provided by licensed pharmacists under a grant awarded under subsection (a) shall be offered to targeted individuals who—

(1) take 4 or more prescribed medications (including over-the-counter and dietary supplements);

(2) take any high-risk medications;

(3) have 2 or more chronic diseases, as identified by the Secretary; or

(4) have undergone a transition of care, or other factors, as determined by the Secretary, that are likely to create a high risk of medication-related problems.

(e) CONSULTATION WITH EXPERTS.—In designing and implementing MTM services provided under grants awarded under subsection (a), the Secretary shall consult with Federal, State, private, public-private, and academic entities, pharmacy and pharmacist organizations, health care organizations, consumer advocates, chronic disease groups, and other stakeholders involved with the research, dissemination, and implementation of pharmacist-delivered MTM services, as the Secretary determines appropriate. The Secretary, in collaboration with this group, shall determine whether it is possible to incorporate rapid cycle process improvement concepts in use in other Federal programs that have implemented MTM services.

(f) REPORTING TO THE SECRETARY.—An entity that receives a grant under subsection (a) shall submit to the Secretary a report that describes and evaluates, as requested by the Secretary, the activities carried out under subsection (c), including quality measures, as determined by the Secretary.

(g) EVALUATION AND REPORT.—The Secretary shall submit to the relevant committees of Congress a report which shall—

(1) assess the clinical effectiveness of pharmacist-provided services under the MTM services program, as compared to usual care, including an evaluation of whether enrollees maintained better health with fewer hospitalizations and emergency room visits than similar patients not enrolled in the program;

(2) assess changes in overall health care resource of targeted individuals;

(3) assess patient and prescriber satisfaction with MTM services;

(4) assess the impact of patient-cost-sharing requirements on medication adherence and recommendations for modifications;

(5) identify and evaluate other factors that may impact clinical and economic outcomes, including demographic characteristics, clinical characteristics, and health services use of the patient, as well as characteristics of the regimen, pharmacy benefit, and MTM services provided; and

(6) evaluate the extent to which participating pharmacists who maintain a dispensing role have a conflict of interest in the provision of MTM services, and if such conflict is found, provide recommendations on how such a conflict might be appropriately addressed.

(h) GRANT TO FUND DEVELOPMENT OF PERFORMANCE MEASURES.—The Secretary may award grants or contracts to eligible entities for the purpose of funding the development of performance measures that assess the use and effectiveness of medication therapy management services.

SEC. 2530. POSTPARTUM DEPRESSION.

(a) EXPANSION AND INTENSIFICATION OF ACTIVITIES.—

(1) CONTINUATION OF ACTIVITIES.—The Secretary is encouraged to expand and intensify activities on postpartum conditions.

(2) PROGRAMS FOR POSTPARTUM CONDITIONS.—In carrying out paragraph (1), the Secretary is encouraged to continue research to expand the understanding of the causes of, and treatments for, postpartum conditions, including conducting and supporting the following:

(A) Basic research concerning the etiology and causes of the conditions.

(B) Epidemiological studies to address the frequency and natural history of the conditions and the differences among racial and ethnic groups with respect to the conditions.

(C) The development of improved screening and diagnostic techniques.

(D) Clinical research for the development and evaluation of new treatments.

(E) Information and education programs for health professionals and the public, which may include a coordinated national campaign that—

(i) is designed to increase the awareness and knowledge of postpartum conditions;

(ii) may include public service announcements through television, radio, and other means; and

(iii) may focus on—

(I) raising awareness about screening;

(II) educating new mothers and their families about postpartum conditions to promote earlier diagnosis and treatment; and

(III) ensuring that such education includes complete information concerning postpartum conditions, including its symptoms, methods of coping with the illness, and treatment resources.

(b) REPORT BY THE SECRETARY.—

(1) STUDY.—The Secretary shall conduct a study on the benefits of screening for postpartum conditions.

(2) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Secretary shall complete the study required by paragraph (1) and submit a report to the Congress on the results of such study.

(c) SENSE OF CONGRESS REGARDING LONGITUDINAL STUDY OF RELATIVE MENTAL HEALTH CONSEQUENCES FOR WOMEN OF RESOLVING A PREGNANCY.—

(1) SENSE OF CONGRESS.—It is the sense of the Congress that the Director of the National Institute of Mental Health may conduct a nationally representative longitudinal study (during the period of fiscal years 2009 through 2018) on the relative mental health consequences for women of resolving a pregnancy (intended and unintended) in various ways, including carrying the pregnancy to term and parenting the child, carrying the pregnancy to term and placing the

child for adoption, miscarriage, and having an abortion. This study may assess the incidence, timing, magnitude, and duration of the immediate and long-term mental health consequences (positive or negative) of these pregnancy outcomes.

(2) REPORT.—Beginning not later than 3 years after the date of the enactment of this Act, and periodically thereafter for the duration of the study, such Director may prepare and submit to the Congress reports on the findings of the study.

(d) DEFINITIONS.—In this section:

(1) The term "postpartum condition" means postpartum depression or postpartum psychosis.

(2) The term "Secretary" means the Secretary of Health and Human Services.

(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, in addition to any other amounts authorized to be appropriated for such purpose, there are authorized to be appropriated such sums as may be necessary for fiscal years 2010 through 2012.

SEC. 2531. GRANTS TO PROMOTE POSITIVE HEALTH BEHAVIORS AND OUTCOMES.

Part P of title III (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

"SEC. 399V. GRANTS TO PROMOTE POSITIVE HEALTH BEHAVIORS AND OUTCOMES.

"(a) GRANTS AUTHORIZED.—The Secretary, in collaboration with the Director of the Centers for Disease Control and Prevention and other Federal officials determined appropriate by the Secretary, is authorized to award grants to eligible entities to promote positive health behaviors for populations in medically underserved communities through the use of community health workers.

"(b) USE OF FUNDS.—Grants awarded under subsection (a) shall be used to support community health workers—

"(1) to educate, guide, and provide outreach in a community setting regarding health problems prevalent in medically underserved communities, especially racial and ethnic minority populations;

"(2) to educate, guide, and provide experiential learning opportunities that target behavioral risk factors including—

"(A) poor nutrition;

"(B) physical inactivity;

"(C) being overweight or obese;

"(D) tobacco use;

"(E) alcohol and substance use;

"(F) injury and violence;

"(G) risky sexual behavior;

"(H) untreated mental health problems;

"(I) untreated dental and oral health problems; and

"(J) understanding informed consent;

"(3) to educate and provide guidance regarding effective strategies to promote positive health behaviors within the family;

"(4) to educate and provide outreach regarding enrollment in health insurance including the State Children's Health Insurance Program under title XXI of the Social Security Act, Medicare under title XVIII of such Act, and Medicaid under title XIX of such Act;

"(5) to educate and refer underserved populations to appropriate health care agencies and community-based programs and organizations in order to increase access to quality health care services, including preventive health services, and to eliminate duplicative care; or

"(6) to educate, guide, and provide home visitation services regarding maternal health and prenatal care.

"(c) APPLICATION.—

"(1) IN GENERAL.—Each eligible entity that desires to receive a grant under subsection (a) shall submit an application to the Secretary, at such time, in such manner, and accompanied by such information as the Secretary may require.

"(2) CONTENTS.—Each application submitted pursuant to paragraph (1) shall—

"(A) describe the activities for which assistance is sought under this section;

"(B) contain an assurance that, with respect to each community health worker program receiving funds under the grant, such program will provide training and supervision to community health workers to enable such workers to provide authorized program services;

"(C) contain an assurance that the applicant will evaluate the effectiveness of community health worker programs receiving funds under the grant;

"(D) contain an assurance that each community health worker program receiving funds under the grant will provide services in the cultural context most appropriate for the individuals served by the program;

"(E) contain a plan to document and disseminate project descriptions and results to other States and organizations as identified by the Secretary; and

"(F) describe plans to enhance the capacity of individuals to utilize health services and health-related social services under Federal, State, and local programs by—

"(i) assisting individuals in establishing eligibility under the programs and in receiving the services or other benefits of the programs; and

"(ii) providing other services as the Secretary determines to be appropriate, that may include transportation and translation services.

"(d) PRIORITY.—In awarding grants under subsection (a), the Secretary shall give priority to applicants that—

"(1) propose to target geographic areas—

"(A) with a high percentage of residents who are eligible for health insurance but are uninsured or underinsured;

"(B) with a high percentage of residents who suffer from chronic diseases including pulmonary conditions, hypertension, heart disease, mental disorders, diabetes, and asthma; and

"(C) with a high infant mortality rate;

"(2) have experience in providing health or health-related social services to individuals who are underserved with respect to such services; and

"(3) have documented community activity and experience with community health workers.

"(e) COLLABORATION WITH ACADEMIC INSTITUTIONS.—The Secretary shall encourage community health worker programs receiving funds under this section to collaborate with academic institutions, especially those that graduate a disproportionate number of health and health care students from underrepresented racial and ethnic minority backgrounds. Nothing in this section shall be construed to require such collaboration.

"(f) EVIDENCE-BASED INTERVENTIONS.—The Secretary shall encourage community health worker programs receiving funding under this section to implement an outcome-based payment system that rewards community health workers for connecting underserved populations with the most appropriate services at the most appropriate time. Nothing in this section shall be construed to require such payment.

"(g) QUALITY ASSURANCE AND COST EFFECTIVENESS.—The Secretary shall establish guidelines for assuring the quality of the training and supervision of community health workers under the programs funded under this section and for assuring the cost-effectiveness of such programs.

"(h) MONITORING.—The Secretary shall monitor community health worker programs identified in approved applications under this section and shall determine whether such programs are in compliance with the guidelines established under subsection (g).

"(i) TECHNICAL ASSISTANCE.—The Secretary may provide technical assistance to community health worker programs identified in approved applications under this section with respect to planning, developing, and operating programs under the grant.

"(j) REPORT TO CONGRESS.—

"(1) IN GENERAL.—Not later than 4 years after the date on which the Secretary first awards grants under subsection (a), the Secretary shall submit to Congress a report regarding the grant project.

"(2) CONTENTS.—The report required under paragraph (1) shall include the following:

"(A) A description of the programs for which grant funds were used.

"(B) The number of individuals served under such programs.

"(C) An evaluation of—

"(i) the effectiveness of such programs;

"(ii) the cost of such programs; and

"(iii) the impact of the programs on the health outcomes of the community residents.

"(D) Recommendations for sustaining the community health worker programs developed or assisted under this section.

"(E) Recommendations regarding training to enhance career opportunities for community health workers.

"(k) DEFINITIONS.—In this section:

"(1) COMMUNITY HEALTH WORKER.—The term 'community health worker' means an individual who promotes health or nutrition within the community in which the individual resides—

"(A) by serving as a liaison between communities and health care agencies;

"(B) by providing guidance and social assistance to community residents;

"(C) by enhancing community residents' ability to effectively communicate with health care providers;

"(D) by providing culturally and linguistically appropriate health or nutrition education;

"(E) by advocating for individual and community health, including oral and mental, or nutrition needs; and

"(F) by providing referral and followup services or otherwise coordinating care.

"(2) COMMUNITY SETTING.—The term 'community setting' means a home or a community organization located in the neighborhood in which a participant resides.

"(3) MEDICALLY UNDERSERVED COMMUNITY.—The term 'medically underserved community' means a community identified by a State, United States territory or possession, or federally recognized Indian tribe—

"(A) that has a substantial number of individuals who are members of a medically underserved population, as defined by section 330(b)(3); and

"(B) a significant portion of which is a health professional shortage area as designated under section 332.

"(4) SUPPORT.—The term 'support' means the provision of training, supervision, and materials needed to effectively deliver the services described in subsection (b), reimbursement for services, and other benefits.

"(5) ELIGIBLE ENTITY.—The term 'eligible entity' means a public or nonprofit private entity (including a State or public subdivision of a State, a public health department, or a federally qualified health center), or a consortium of any of such entities, located in the United States or territory thereof.

"(l) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $30,000,000 for each of fiscal years 2010, 2011, 2012, 2013, and 2014.".

PART 3—EMERGENCY CARE-RELATED PROGRAMS

SEC. 2541. TRAUMA CARE CENTERS.

(a) GRANTS FOR TRAUMA CARE CENTERS.—Section 1241 (42 U.S.C. 300d–41) is amended to read as follows:

"SEC. 1241. GRANTS FOR CERTAIN TRAUMA CENTERS.

"(a) IN GENERAL.—The Secretary shall establish a trauma center program consisting of awarding grants under section (b).

"(b) GRANTS.—The Secretary shall award grants as follows:

"(1) EXISTING CENTERS.—Grants to public, private nonprofit, Indian Health Service, Indian tribal, and urban Indian trauma centers—

"(A) to further the core missions of such centers; or

"(B) to provide emergency relief to ensure the continued and future availability of trauma services by trauma centers—

"(i) at risk of closing or operating in an area where a closing has occurred within their primary service area; or

"(ii) in need of financial assistance following a natural disaster or other catastrophic event, such as a terrorist attack.

"(2) NEW CENTERS.—Grants to local governments and public or private nonprofit entities to establish new trauma centers in urban areas with a substantial degree of trauma resulting from violent crimes.

"(c) MINIMUM QUALIFICATIONS OF TRAUMA CENTERS.—

"(1) PARTICIPATION IN TRAUMA CARE SYSTEM OPERATING UNDER CERTAIN PROFESSIONAL GUIDELINES.—

"(A) LIMITATION.—Subject to subparagraph (B), the Secretary may not award a grant to an existing trauma center under this section unless the center is a participant in a trauma care system that substantially complies with section 1213.

"(B) EXEMPTION.—Subparagraph (A) shall not apply to trauma centers that are located in States with no existing trauma care system.

"(2) DESIGNATION.—The Secretary may not award a grant under this section to an existing trauma center unless the center is—

"(A) verified as a trauma center by the American College of Surgeons; or

"(B) designated as a trauma center by the applicable State health or emergency medical services authority.".

(b) CONSIDERATIONS IN MAKING GRANTS.—Section 1242 (42 U.S.C. 300d–42) is amended to read as follows:

"SEC. 1242. CONSIDERATIONS IN MAKING GRANTS.

"(a) CORE MISSION AWARDS.—

"(1) IN GENERAL.—In awarding grants under section 1241(b)(1)(A), the Secretary shall—

"(A) reserve a minimum of 25 percent of the amount allocated for such grants for level III and level IV trauma centers in rural or underserved areas;

"(B) reserve a minimum of 25 percent of the amount allocated for such grants for level I and level II trauma centers in urban areas; and

"(C) give preference to any application made by a trauma center—

"(i) in a geographic area where growth in demand for trauma services exceeds capacity;

"(ii) that demonstrates the financial support of the State or political subdivision involved;

"(iii) that has at least 1 graduate medical education fellowship in trauma or trauma-related specialties, including neurological surgery, surgical critical care, vascular surgery, and spinal cord injury, for which demand is exceeding supply; or

"(iv) that demonstrates a substantial commitment to serving vulnerable populations.

"(2) FINANCIAL SUPPORT.—For purposes of paragraph (1)(C)(ii), financial support may be demonstrated by State or political subdivision funding for the trauma center's capital or operating expenses (including through State trauma regional advisory coordination activities, Medicaid funding designated for trauma services, or other governmental funding). State funding derived from Federal support shall not constitute State or local financial support for purposes of preferential treatment under this subsection.

"(3) USE OF FUNDS.—The recipient of a grant under section 1241(b)(1)(A) shall carry out, consistent with furthering the core missions of the center, one or more of the following activities:

"(A) Providing 24-hour-a-day, 7-day-a-week trauma care availability.

"(B) Reducing overcrowding related to throughput of trauma patients.

"(C) Enhancing trauma surge capacity.

"(D) Ensuring physician and essential personnel availability.

"(E) Trauma education and outreach.

"(F) Coordination with local and regional trauma care systems.

"(G) Such other activities as the Secretary may deem appropriate.

"(b) EMERGENCY AWARDS; NEW CENTERS.—In awarding grants under paragraphs (1)(B) and (2) of section 1241(b), the Secretary shall—

"(1) give preference to any application submitted by an applicant that demonstrates the financial support (in accordance with subsection (a)(2)) of the State or political subdivision involved for the activities to be funded through the grant for each fiscal year during which payments are made to the center under the grant; and

"(2) give preference to any application submitted for a trauma center that—

"(A) is providing or will provide trauma care in a geographic area in which the availability of trauma care has either significantly decreased as a result of a trauma center in the area permanently ceasing participation in a system described in section 1241(c)(1) as of a date occurring during the 2-year period preceding the fiscal year for which the trauma center is applying to receive a grant, or in geographic areas where growth in demand for trauma services exceeds capacity;

"(B) will, in providing trauma care during the 1-year period beginning on the date on which the application for the grant is submitted, incur substantial uncompensated care costs in an amount that renders the center unable to continue participation in such system and results in a significant decrease in the availability of trauma care in the geographic area;

"(C) operates or will operate in rural areas where trauma care availability will significantly decrease if the center is forced to close or downgrade service and substantial costs are contributing to a likelihood of such closure or downgradation;

"(D) is in a geographic location substantially affected by a natural disaster or other catastrophic event such as a terrorist attack; or

"(E) will establish a new trauma service in an urban area with a substantial degree of trauma resulting from violent crimes.

"(c) DESIGNATIONS OF LEVELS OF TRAUMA CENTERS IN CERTAIN STATES.—In the case of a State which has not designated 4 levels of trauma centers, any reference in this section to—

"(1) a level I or level II trauma center is deemed to be a reference to a trauma center within the highest 2 levels of trauma centers designated under State guidelines; and

"(2) a level III or IV trauma center is deemed to be a reference to a trauma center not within such highest 2 levels.".

(c) CERTAIN AGREEMENTS.—Section 1243 (42 U.S.C. 300d–43) is amended to read as follows:

"SEC. 1243. CERTAIN AGREEMENTS.

"(a) COMMITMENT REGARDING CONTINUED PARTICIPATION IN TRAUMA CARE SYSTEM.—The Secretary may not award a grant to an applicant under section 1241(b) unless the applicant agrees that—

"(1) the trauma center involved will continue participation, or in the case of a new center will participate, in the system described in section 1241(c)(1), except as provided in section 1241(c)(1)(B), throughout the grant period beginning on the date that the center first receives payments under the grant; and

"(2) if the agreement made pursuant to paragraph (1) is violated by the center, the center will be liable to the United States for an amount equal to the sum of—

"(A) the amount of assistance provided to the center under section 1241; and

"(B) an amount representing interest on the amount specified in subparagraph (A).

"(b) MAINTENANCE OF FINANCIAL SUPPORT.—With respect to activities for which funds awarded through a grant under section 1241 are authorized to be expended, the Secretary may not award such a grant unless the applicant agrees that, during the period in which the trauma center involved is receiving payments under the grant, the center will maintain access to trauma services at levels not less than the levels for the prior year, taking into account—

"(1) reasonable volume fluctuation that is not caused by intentional trauma boundary reduction;

"(2) downgrading of the level of services; and

"(3) whether such center diverts its incoming patients away from such center 5 percent or more of the time during which the center is in operation over the course of the year.

"(c) TRAUMA CARE REGISTRY.—The Secretary may not award a grant to a trauma center under section 1241(b)(1) unless the center agrees that—

"(1) not later than 6 months after the date on which the center submits a grant application to the Secretary, the center will establish and operate a registry of trauma cases in accordance with guidelines developed by the American College of Surgeons; and

"(2) in carrying out paragraph (1), the center will maintain information on the number of trauma cases treated by the center and, for each such case, the extent to which the center incurs uncompensated costs in providing trauma care.".

(d) GENERAL PROVISIONS.—Section 1244 (42 U.S.C. 300d–44) is amended to read as follows:

"SEC. 1244. GENERAL PROVISIONS.

"(a) LIMITATION ON DURATION OF SUPPORT.—The period during which a trauma center receives payments under a grant under section 1241(b)(1) shall be for 3 fiscal years, except that the Secretary may waive such requirement for the center and authorize the center to receive such payments for 1 additional fiscal year.

"(b) ELIGIBILITY.—The acquisition of, or eligibility for, a grant under section 1241(b) shall not preclude a trauma center's eligibility for another grant described in such section.

"(c) FUNDING DISTRIBUTION.—Of the total amount appropriated for a fiscal year under section 1245—

"(1) 90 percent shall be used for grants under paragraph (1)(A) of section 1241(b); and

"(2) 10 percent shall be used for grants under paragraphs (1)(B) and (2) of section 1241(b).

"(d) REPORT.—Beginning 2 years after the date of the enactment of the America's Affordable Health Choices Act of 2009, and every 2 years thereafter, the Secretary shall biennially—

"(1) report to Congress on the status of the grants made pursuant to section 1241;

"(2) evaluate and report to Congress on the overall financial stability of trauma centers in the United States;

"(3) report on the populations using trauma care centers and include aggregate patient data on income, race, ethnicity, and geography; and

"(4) evaluate the effectiveness and efficiency of trauma care center activities using standard public health measures and evaluation methodologies.".

(e) AUTHORIZATION OF APPROPRIATIONS.—Section 1245 (42 U.S.C. 300d–45) is amended to read as follows:

"SEC. 1245. AUTHORIZATION OF APPROPRIATIONS.

"(a) IN GENERAL.—For the purpose of carrying out this part, there are authorized to be appropriated $100,000,000 for fiscal year 2010, and such sums as may be necessary for each of fiscal years 2011 through 2015. Such authorization of appropriations is in addition to any other authorization of appropriations or amounts that are available for such purpose.

"(b) REALLOCATION.—The Secretary shall reallocate for grants under section 1241(b)(1)(A) any funds appropriated for grants under paragraph (1)(B) or (2) of section 1241(b), but not obligated due to insufficient applications eligible for funding.".

SEC. 2542. EMERGENCY CARE COORDINATION.

(a) IN GENERAL.—Subtitle B of title XXVIII (42 U.S.C. 300hh–10 et seq.) is amended by adding at the end the following:

"SEC. 2816. EMERGENCY CARE COORDINATION.

"(a) EMERGENCY CARE COORDINATION CENTER.—

"(1) ESTABLISHMENT.—The Secretary shall establish, within the Office of the Assistant Secretary for Preparedness and Response, an Emergency Care Coordination Center (in this section referred to as the 'Center'), to be headed by a director.

"(2) DUTIES.—The Secretary, acting through the Director of the Center, in coordination with the Federal Interagency Committee on Emergency Medical Services, shall—

"(A) promote and fund research in emergency medicine and trauma health care;

"(B) promote regional partnerships and more effective emergency medical systems in order to enhance appropriate triage, distribution, and care of routine community patients; and

"(C) promote local, regional, and State emergency medical systems' preparedness for and response to public health events.

"(b) COUNCIL OF EMERGENCY CARE.—

"(1) ESTABLISHMENT.—The Secretary, acting through the Director of the Center, shall establish a Council of Emergency Care to provide advice and recommendations to the Director on carrying out this section.

"(2) COMPOSITION.—The Council shall be comprised of employees of the departments and agencies of the Federal Government who are experts in emergency care and management.

"(c) REPORT.—

"(1) SUBMISSION.—Not later than 12 months after the date of the enactment of the America's Affordable Health Choices Act of 2009, the Secretary shall submit to the Congress an annual report on the activities carried out under this section.

"(2) CONSIDERATIONS.—In preparing a report under paragraph (1), the Secretary shall consider factors including—

"(A) emergency department crowding and boarding; and

"(B) delays in care following presentation.

"(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated such sums as may be necessary for fiscal years 2010 through 2014.".

(b) FUNCTIONS, PERSONNEL, ASSETS, LIABILITIES, AND ADMINISTRATIVE ACTIONS.—All functions, personnel, assets, and liabilities of, and administrative actions applicable to, the Emergency Care Coordination Center, as in existence on the day before the date of the enactment of this Act, shall be transferred to the Emergency Care Coordination Center established under section 2816(a) of the Public Health Service Act, as added by subsection (a).

SEC. 2543. PILOT PROGRAMS TO IMPROVE EMERGENCY MEDICAL CARE.

Part B of title III (42 U.S.C. 243 et seq.) is amended by inserting after section 314 the following:

"SEC. 315. REGIONALIZED COMMUNICATION SYSTEMS FOR EMERGENCY CARE RESPONSE.

"(a) IN GENERAL.—The Secretary, acting through the Assistant Secretary for Preparedness and Response, shall award not fewer than 4 multiyear contracts or competitive grants to eligible entities to support demonstration programs that design, implement, and evaluate innovative models of regionalized, comprehensive, and accountable emergency care systems.

"(b) ELIGIBLE ENTITY; REGION.—

"(1) ELIGIBLE ENTITY.—In this section, the term 'eligible entity' means a State or a partnership of 1 or more States and 1 or more local governments.

"(2) REGION.—In this section, the term 'region' means an area within a State, an area that lies within multiple States, or a similar area (such as a multicounty area), as determined by the Secretary.

"(c) DEMONSTRATION PROGRAM.—The Secretary shall award a contract or grant under subsection (a) to an eligible entity that proposes a demonstration program to design, implement, and evaluate an emergency medical system that—

"(1) coordinates with public safety services, public health services, emergency medical services, medical facilities, and other entities within a region;

"(2) coordinates an approach to emergency medical system access throughout the region, including 9-1-1 public safety answering points and emergency medical dispatch;

"(3) includes a mechanism, such as a regional medical direction or transport communications system, that operates throughout the region to ensure that the correct patient is taken to the medically appropriate facility (whether an initial facility or a higher level facility) in a timely fashion;

"(4) allows for the tracking of prehospital and hospital resources, including inpatient bed capacity, emergency department capacity, on-call specialist coverage, ambulance diversion status, and the coordination of such tracking with regional communications and hospital destination decisions; and

"(5) includes a consistent regionwide prehospital, hospital, and interfacility data management system that—

"(A) complies with the National EMS Information System, the National Trauma Data Bank, and others;

"(B) reports data to appropriate Federal and State databanks and registries; and

"(C) contains information sufficient to evaluate key elements of prehospital care, hospital destination decisions, including initial hospital and interfacility decisions, and relevant outcomes of hospital care.

"(d) APPLICATION.—

"(1) IN GENERAL.—An eligible entity that seeks a contract or grant described in subsection (a) shall submit to the Secretary an application at such time and in such manner as the Secretary may require.

"(2) APPLICATION INFORMATION.—Each application shall include—

"(A) an assurance from the eligible entity that the proposed system—

"(i) has been coordinated with the applicable State office of emergency medical services (or equivalent State office);

"(ii) is compatible with the applicable State emergency medical services system;

"(iii) includes consistent indirect and direct medical oversight of prehospital, hospital, and interfacility transport throughout the region;

"(iv) coordinates prehospital treatment and triage, hospital destination, and interfacility transport throughout the region;

"(v) includes a categorization or designation system for special medical facilities throughout the region that is—

"(I) consistent with State laws and regulations; and

"(II) integrated with the protocols for transport and destination throughout the region; and

"(vi) includes a regional medical direction system, a patient tracking system, and a resource allocation system that—

"(I) support day-to-day emergency care system operation;

"(II) can manage surge capacity during a major event or disaster; and

"(III) are integrated with other components of the national and State emergency preparedness system;

"(B) an agreement to make available non-Federal contributions in accordance with subsection (e); and

"(C) such other information as the Secretary may require.

"(e) MATCHING FUNDS.—

"(1) IN GENERAL.—With respect to the costs of the activities to be carried out each year with a contract or grant under subsection (a), a condition for the receipt of the contract or grant is that the eligible entity involved agrees to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is not less than 25 percent of such costs.

"(2) DETERMINATION OF AMOUNT CONTRIBUTED.—Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

"(f) PRIORITY.—The Secretary shall give priority for the award of the contracts or grants described in subsection (a) to any eligible entity that serves a medically underserved population (as defined in section 330(b)(3)).

"(g) REPORT.—Not later than 90 days after the completion of a demonstration program under subsection (a), the recipient of such contract or grant described in such subsection shall submit to the Secretary a report containing the results of an evaluation of the program, including an identification of—

"(1) the impact of the regional, accountable emergency care system on patient outcomes for various critical care categories, such as trauma, stroke, cardiac emergencies, and pediatric emergencies;

"(2) the system characteristics that contribute to the effectiveness and efficiency of the program (or lack thereof);

"(3) methods of assuring the long-term financial sustainability of the emergency care system;

"(4) the State and local legislation necessary to implement and to maintain the system; and

"(5) the barriers to developing regionalized, accountable emergency care systems, as well as the methods to overcome such barriers.

"(h) EVALUATION.—The Secretary, acting through the Assistant Secretary for Preparedness and Response, shall enter into a contract with an academic institution or other entity to conduct an independent evaluation of the demonstration programs funded under subsection (a), including an evaluation of—

"(1) the performance of the eligible entities receiving the funds; and

"(2) the impact of the demonstration programs.

"(i) DISSEMINATION OF FINDINGS.—The Secretary shall, as appropriate, disseminate to the public and to the appropriate committees of the Congress, the information contained in a report made under subsection (h).

"(j) AUTHORIZATION OF APPROPRIATIONS.—

"(1) IN GENERAL.—There is authorized to be appropriated to carry out this section $12,000,000 for each of fiscal years 2010 through 2015.

"(2) RESERVATION.—Of the amount appropriated to carry out this section for a fiscal year, the Secretary shall reserve 3 percent of such amount to carry out subsection (h) (relating to an independent evaluation).".

SEC. 2544. ASSISTING VETERANS WITH MILITARY EMERGENCY MEDICAL TRAINING TO BECOME STATE-LICENSED OR CERTIFIED EMERGENCY MEDICAL TECHNICIANS (EMTS).

(a) IN GENERAL.—Part B of title III (42 U.S.C. 243 et seq.), as amended, is amended by inserting after section 315 the following:

"SEC. 315A. ASSISTING VETERANS WITH MILITARY EMERGENCY MEDICAL TRAINING TO BECOME STATE-LICENSED OR CERTIFIED EMERGENCY MEDICAL TECHNICIANS (EMTS).

"(a) PROGRAM.—The Secretary shall establish a program consisting of awarding grants to States to assist veterans who received and completed military emergency medical training while serving in the Armed Forces of the United States to become, upon their discharge or release from active duty service, State-licensed or certified emergency medical technicians.

"(b) USE OF FUNDS.—Amounts received as a grant under this section may be used to assist veterans described in subsection (a) to become State-licensed or certified emergency medical technicians as follows:

"(1) Providing training.

"(2) Providing reimbursement for costs associated with—

"(A) training; or

"(B) applying for licensure or certification.

"(3) Expediting the licensing or certification process.

"(c) ELIGIBILITY.—To be eligible for a grant under this section, a State shall demonstrate to the Secretary's satisfaction that the State has a shortage of emergency medical technicians.

"(d) REPORT.—The Secretary shall submit to the Congress an annual report on the program under this section.

"(e) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated such sums as may be necessary for fiscal years 2010 through 2014.".

(b) GAO STUDY AND REPORT.—The Comptroller General of the United States shall—

(1) conduct a study on the barriers experienced by veterans who received training as medical personnel while serving in the Armed Forces of the United States and, upon their discharge or release from active duty service, seek to become licensed or certified in a State as civilian health professionals; and

(2) not later than 2 years after the date of the enactment of this Act, submit to the Congress a report on the results of such study, including recommendations on whether the program established under section 315A of the Public Health Service Act, as added by subsection (a), should be expanded to assist veterans seeking to become licensed or certified in a State as health providers other than emergency medical technicians.

SEC. 2545. DENTAL EMERGENCY RESPONDERS: PUBLIC HEALTH AND MEDICAL RESPONSE.

(a) NATIONAL HEALTH SECURITY STRATEGY.—Section 2802(b)(3) (42 U.S.C. 300hh–1(b)(3)) is amended—

(1) in the matter preceding subparagraph (A), by inserting "dental and" before "mental health facilities"; and

(2) in subparagraph (D), by inserting "and dental" after "medical".

(b) ALL-HAZARDS PUBLIC HEALTH AND MEDICAL RESPONSE CURRICULA AND TRAINING.—Section 319F(a)(5)(B) (42 U.S.C. 247d–6(a)(5)(B)) is amended by striking "public health or medical" and inserting "public health, medical, or dental".

SEC. 2546. DENTAL EMERGENCY RESPONDERS: HOMELAND SECURITY.

(a) NATIONAL RESPONSE FRAMEWORK.—Paragraph (6) of section 2 of the Homeland Security Act of 2002 (6 U.S.C. 101) is amended by inserting "and dental" after "emergency medical".

(b) NATIONAL PREPAREDNESS SYSTEM.—Subparagraph (B) of section 653(b)(4) of the Post-Katrina Emergency Management Reform Act of 2006 (6 U.S.C. 753(b)(4)) is amended by striking "public health and medical" and inserting "public health, medical, and dental".

(c) CHIEF MEDICAL OFFICER.—Paragraph (5) of section 516(c) of the Homeland Security Act of 2002 (6 U.S.C. 321e(c)) is amended by striking "medical community" and inserting "medical and dental communities".

PART 4—PAIN CARE AND MANAGEMENT PROGRAMS

SEC. 2551. INSTITUTE OF MEDICINE CONFERENCE ON PAIN.

(a) CONVENING.—Not later than June 30, 2010, the Secretary of Health and Human Services shall seek to enter into an agreement with the Institute of Medicine of the National Academies to convene a Conference on Pain (in this section referred to as "the Conference").

(b) PURPOSES.—The purposes of the Conference shall be to—

(1) increase the recognition of pain as a significant public health problem in the United States;

(2) evaluate the adequacy of assessment, diagnosis, treatment, and management of acute and chronic pain in the general population, and in identified racial, ethnic, gender, age, and other demographic groups that may be disproportionately affected by inadequacies in the assessment, diagnosis, treatment, and management of pain;

(3) identify barriers to appropriate pain care, including—

(A) lack of understanding and education among employers, patients, health care providers, regulators, and third-party payors;

(B) barriers to access to care at the primary, specialty, and tertiary care levels, including barriers—

(i) specific to those populations that are disproportionately undertreated for pain;

(ii) related to physician concerns over regulatory and law enforcement policies applicable to some pain therapies; and

(iii) attributable to benefit, coverage, and payment policies in both the public and private sectors; and

(C) gaps in basic and clinical research on the symptoms and causes of pain, and potential assessment methods and new treatments to improve pain care; and

(4) establish an agenda for action in both the public and private sectors that will reduce such barriers and significantly improve the state of pain care research, education, and clinical care in the United States.

(c) OTHER APPROPRIATE ENTITY.—If the Institute of Medicine declines to enter into an agreement under subsection (a), the Secretary of Health and Human Services may enter into such agreement with another appropriate entity.

(d) REPORT.—A report summarizing the Conference's findings and recommendations shall be submitted to the Congress not later than June 30, 2011.

(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated $500,000 for each of fiscal years 2010 and 2011.

SEC. 2552. PAIN RESEARCH AT NATIONAL INSTITUTES OF HEALTH.

Part B of title IV (42 U.S.C. 284 et seq.) is amended by adding at the end the following:

"SEC. 409J. PAIN RESEARCH.

"(a) RESEARCH INITIATIVES.—

"(1) IN GENERAL.—The Director of NIH is encouraged to continue and expand, through the Pain Consortium, an aggressive program of basic and clinical research on the causes of and potential treatments for pain.

"(2) ANNUAL RECOMMENDATIONS.—Not less than annually, the Pain Consortium, in consultation with the Division of Program Coordination, Planning, and Strategic Initiatives, shall develop and submit to the Director of NIH recommendations on appropriate pain research initiatives that could be undertaken with funds reserved under section 402A(c)(1) for the Common Fund or otherwise available for such initiatives.

"(3) DEFINITION.—In this subsection, the term 'Pain Consortium' means the Pain Consortium of the National Institutes of Health or a similar trans-National Institutes of Health coordinating entity designated by the Secretary for purposes of this subsection.

"(b) INTERAGENCY PAIN RESEARCH COORDINATING COMMITTEE.—

"(1) ESTABLISHMENT.—The Secretary shall establish not later than 1 year after the date of the enactment of this section and as necessary maintain a committee, to be known as the Interagency Pain Research Coordinating Committee (in this section referred to as the 'Committee'), to coordinate all efforts within the Department of Health and Human Services and other Federal agencies that relate to pain research.

"(2) MEMBERSHIP.—

"(A) IN GENERAL.—The Committee shall be composed of the following voting members:

"(i) Not more than 7 voting Federal representatives as follows:

"(I) The Director of the Centers for Disease Control and Prevention.

"(II) The Director of the National Institutes of Health and the directors of such national research institutes and national centers as the Secretary determines appropriate.

"(III) The heads of such other agencies of the Department of Health and Human Services as the Secretary determines appropriate.

"(IV) Representatives of other Federal agencies that conduct or support pain care research and treatment, including the Department of Defense and the Department of Veterans Affairs.

"(ii) 12 additional voting members appointed under subparagraph (B).

"(B) ADDITIONAL MEMBERS.—The Committee shall include additional voting members appointed by the Secretary as follows:

"(i) 6 members shall be appointed from among scientists, physicians, and other health professionals, who—

"(I) are not officers or employees of the United States;

"(II) represent multiple disciplines, including clinical, basic, and public health sciences;

"(III) represent different geographical regions of the United States; and

"(IV) are from practice settings, academia, manufacturers, or other research settings; and

"(ii) 6 members shall be appointed from members of the general public, who are representatives of leading research, advocacy, and service organizations for individuals with pain-related conditions.

"(C) NONVOTING MEMBERS.—The Committee shall include such nonvoting members as the Secretary determines to be appropriate.

"(3) CHAIRPERSON.—The voting members of the Committee shall select a chairperson from among such members. The selection of a chairperson shall be subject to the approval of the Director of NIH.

"(4) MEETINGS.—The Committee shall meet at the call of the chairperson of the Committee or upon the request of the Director of NIH, but in no case less often than once each year.

"(5) DUTIES.—The Committee shall—

"(A) develop a summary of advances in pain care research supported or conducted by the Federal agencies relevant to the diagnosis, prevention, and treatment of pain and diseases and disorders associated with pain;

"(B) identify critical gaps in basic and clinical research on the symptoms and causes of pain;

"(C) make recommendations to ensure that the activities of the National Institutes of Health and other Federal agencies, including the Department of Defense and the Department of Veteran Affairs, are free of unnecessary duplication of effort;

"(D) make recommendations on how best to disseminate information on pain care; and

"(E) make recommendations on how to expand partnerships between public entities, including Federal agencies, and private entities to expand collaborative, cross-cutting research.

"(6) REVIEW.—The Secretary shall review the necessity of the Committee at least once every 2 years.".

SEC. 2553. PUBLIC AWARENESS CAMPAIGN ON PAIN MANAGEMENT.

Part B of title II (42 U.S.C. 238 et seq.) is amended by adding at the end the following:

"SEC. 249. NATIONAL EDUCATION OUTREACH AND AWARENESS CAMPAIGN ON PAIN MANAGEMENT.

"(a) ESTABLISHMENT.—Not later than June 30, 2010, the Secretary shall establish and implement a national pain care education outreach and awareness campaign described in subsection (b).

"(b) REQUIREMENTS.—The Secretary shall design the public awareness campaign under this section to educate consumers, patients, their families, and other caregivers with respect to—

"(1) the incidence and importance of pain as a national public health problem;

"(2) the adverse physical, psychological, emotional, societal, and financial consequences that can result if pain is not appropriately assessed, diagnosed, treated, or managed;

"(3) the availability, benefits, and risks of all pain treatment and management options;

"(4) having pain promptly assessed, appropriately diagnosed, treated, and managed, and regularly reassessed with treatment adjusted as needed;

"(5) the role of credentialed pain management specialists and subspecialists, and of comprehensive interdisciplinary centers of treatment expertise;

"(6) the availability in the public, nonprofit, and private sectors of pain management-related information, services, and resources for consumers, employers, third-party payors, patients, their families, and caregivers, including information on—

"(A) appropriate assessment, diagnosis, treatment, and management options for all types of pain and pain-related symptoms; and

"(B) conditions for which no treatment options are yet recognized; and

"(7) other issues the Secretary deems appropriate.

"(c) CONSULTATION.—In designing and implementing the public awareness campaign required by this section, the Secretary shall consult with organizations representing patients in pain and other consumers, employers, physicians including physicians specializing in pain care, other pain management professionals, medical device manufacturers, and pharmaceutical companies.

"(d) COORDINATION.—

"(1) LEAD OFFICIAL.—The Secretary shall designate one official in the Department of Health and Human Services to oversee the campaign established under this section.

"(2) AGENCY COORDINATION.—The Secretary shall ensure the involvement in the public awareness campaign under this section of the Surgeon General of the

Public Health Service, the Director of the Centers for Disease Control and Prevention, and such other representatives of offices and agencies of the Department of Health and Human Services as the Secretary determines appropriate.

"(e) UNDERSERVED AREAS AND POPULATIONS.—In designing the public awareness campaign under this section, the Secretary shall—

"(1) take into account the special needs of geographic areas and racial, ethnic, gender, age, and other demographic groups that are currently underserved; and

"(2) provide resources that will reduce disparities in access to appropriate diagnosis, assessment, and treatment.

"(f) GRANTS AND CONTRACTS.—The Secretary may make awards of grants, cooperative agreements, and contracts to public agencies and private nonprofit organizations to assist with the development and implementation of the public awareness campaign under this section.

"(g) EVALUATION AND REPORT.—Not later than the end of fiscal year 2012, the Secretary shall prepare and submit to the Congress a report evaluating the effectiveness of the public awareness campaign under this section in educating the general public with respect to the matters described in subsection (b).

"(h) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this section, there are authorized to be appropriated $2,000,000 for fiscal year 2010 and $4,000,000 for each of fiscal years 2011 and 2012.".

Subtitle C—Food and Drug Administration

PART 1—IN GENERAL

SEC. 2561. NATIONAL MEDICAL DEVICE REGISTRY.

(a) REGISTRY.—

(1) IN GENERAL.—Section 519 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i) is amended—

(A) by redesignating subsection (g) as subsection (h); and

(B) by inserting after subsection (f) the following:

"National Medical Device Registry

"(g)(1) The Secretary shall establish a national medical device registry (in this subsection referred to as the 'registry') to facilitate analysis of postmarket safety and outcomes data on each device that—

"(A) is or has been used in or on a patient; and

"(B) is—

"(i) a class III device; or

"(ii) a class II device that is implantable, life-supporting, or life-sustaining.

"(2) In developing the registry, the Secretary shall, in consultation with the Commissioner of Food and Drugs, the Administrator of the Centers for Medicare & Medicaid Services, the head of the Office of the National Coordinator for Health Information Technology, and the Secretary of Veterans Affairs, determine the best methods for—

"(A) including in the registry, in a manner consistent with subsection (f), appropriate information to identify each device described in paragraph (1) by type, model, and serial number or other unique identifier;

"(B) validating methods for analyzing patient safety and outcomes data from multiple sources and for linking such data with the information included in the registry as described in subparagraph (A), including, to the extent feasible, use of—

"(i) data provided to the Secretary under other provisions of this chapter; and

"(ii) information from public and private sources identified under paragraph (3);

"(C) integrating the activities described in this subsection with—

"(i) activities under paragraph (3) of section 505(k) (relating to active postmarket risk identification);

"(ii) activities under paragraph (4) of section 505(k) (relating to advanced analysis of drug safety data); and

"(iii) other postmarket device surveillance activities of the Secretary authorized by this chapter; and

"(D) providing public access to the data and analysis collected or developed through the registry in a manner and form that protects patient privacy and

proprietary information and is comprehensive, useful, and not misleading to patients, physicians, and scientists.

"(3)(A) To facilitate analyses of postmarket safety and patient outcomes for devices described in paragraph (1), the Secretary shall, in collaboration with public, academic, and private entities, develop methods to—

"(i) obtain access to disparate sources of patient safety and outcomes data, including—

"(I) Federal health-related electronic data (such as data from the Medicare program under title XVIII of the Social Security Act or from the health systems of the Department of Veterans Affairs);

"(II) private sector health-related electronic data (such as pharmaceutical purchase data and health insurance claims data); and

"(III) other data as the Secretary deems necessary to permit postmarket assessment of device safety and effectiveness; and

"(ii) link data obtained under clause (i) with information in the registry.

"(B) In this paragraph, the term 'data' refers to information respecting a device described in paragraph (1), including claims data, patient survey data, standardized analytic files that allow for the pooling and analysis of data from disparate data environments, electronic health records, and any other data deemed appropriate by the Secretary.

"(4) Not later than 36 months after the date of the enactment of this subsection, the Secretary shall promulgate regulations for establishment and operation of the registry under paragraph (1). Such regulations—

"(A)(i) in the case of devices that are described in paragraph (1) and sold on or after the date of the enactment of this subsection, shall require manufacturers of such devices to submit information to the registry, including, for each such device, the type, model, and serial number or, if required under subsection (f), other unique device identifier; and

"(ii) in the case of devices that are described in paragraph (1) and sold before such date, may require manufacturers of such devices to submit such information to the registry, if deemed necessary by the Secretary to protect the public health;

"(B) shall establish procedures—

"(i) to permit linkage of information submitted pursuant to subparagraph (A) with patient safety and outcomes data obtained under paragraph (3); and

"(ii) to permit analyses of linked data;

"(C) may require device manufacturers to submit such other information as is necessary to facilitate postmarket assessments of device safety and effectiveness and notification of device risks;

"(D) shall establish requirements for regular and timely reports to the Secretary, which shall be included in the registry, concerning adverse event trends, adverse event patterns, incidence and prevalence of adverse events, and other information the Secretary determines appropriate, which may include data on comparative safety and outcomes trends; and

"(E) shall establish procedures to permit public access to the information in the registry in a manner and form that protects patient privacy and proprietary information and is comprehensive, useful, and not misleading to patients, physicians, and scientists.

"(5) To carry out this subsection, there are authorized to be appropriated such sums as may be necessary for fiscal years 2010 and 2011.".

(2) EFFECTIVE DATE.—The Secretary of Health and Human Services shall establish and begin implementation of the registry under section 519(g) of the Federal Food, Drug, and Cosmetic Act, as added by paragraph (1), by not later than the date that is 36 months after the date of the enactment of this Act, without regard to whether or not final regulations to establish and operate the registry have been promulgated by such date.

(3) CONFORMING AMENDMENT.—Section 303(f)(1)(B)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 333(f)(1)(B)(ii)) is amended by striking "519(g)" and inserting "519(h)".

(b) ELECTRONIC EXCHANGE AND USE IN CERTIFIED ELECTRONIC HEALTH RECORDS OF UNIQUE DEVICE IDENTIFIERS.—

(1) RECOMMENDATIONS.—The HIT Policy Committee established under section 3002 of the Public Health Service Act (42 U.S.C. 300jj–12) shall recommend to the head of the Office of the National Coordinator for Health Information Technology standards, implementation specifications, and certification criteria for the electronic exchange and use in certified electronic health records of a unique device identifier for each device described in section 519(g)(1) of the Federal Food, Drug, and Cosmetic Act, as added by subsection (a).

(2) STANDARDS, IMPLEMENTATION CRITERIA, AND CERTIFICATION CRITERIA.—The Secretary of the Health Human Services, acting through the head of the Office of the National Coordinator for Health Information Technology, shall adopt standards, implementation specifications, and certification criteria for the electronic exchange and use in certified electronic health records of a unique device identifier for each device described in paragraph (1), if such an identifier is required by section 519(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360i(f)) for the device.

SEC. 2562. NUTRITION LABELING OF STANDARD MENU ITEMS AT CHAIN RESTAURANTS AND OF ARTICLES OF FOOD SOLD FROM VENDING MACHINES.

(a) TECHNICAL AMENDMENTS.—Section 403(q)(5)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)(A)) is amended—

(1) in subclause (i), by inserting "except as provided in clause (H)(ii)(III)," after "(i)" ; and

(2) in subclause (ii), by inserting "except as provided in clause (H)(ii)(III)," after "(ii)".

(b) LABELING REQUIREMENTS.—Section 403(q)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)) is amended by adding at the end the following:

"(H) RESTAURANTS, RETAIL FOOD ESTABLISHMENTS, AND VENDING MACHINES.—

"(i) GENERAL REQUIREMENTS FOR RESTAURANTS AND SIMILAR RETAIL FOOD ESTABLISHMENTS.—Except for food described in subclause (vii), in the case of food that is a standard menu item that is offered for sale in a restaurant or similar retail food establishment that is part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items, the restaurant or similar retail food establishment shall disclose the information described in subclauses (ii) and (iii).

"(ii) INFORMATION REQUIRED TO BE DISCLOSED BY RESTAURANTS AND RETAIL FOOD ESTABLISHMENTS.—Except as provided in subclause (vii), the restaurant or similar retail food establishment shall disclose in a clear and conspicuous manner—

"(I)(aa) in a nutrient content disclosure statement adjacent to the name of the standard menu item, so as to be clearly associated with the standard menu item, on the menu listing the item for sale, the number of calories contained in the standard menu item, as usually prepared and offered for sale; and

"(bb) a succinct statement concerning suggested daily caloric intake, as specified by the Secretary by regulation and posted prominently on the menu and designed to enable the public to understand, in the context of a total daily diet, the significance of the caloric information that is provided on the menu;

"(II)(aa) in a nutrient content disclosure statement adjacent to the name of the standard menu item, so as to be clearly associated with the standard menu item, on the menu board, including a drive-through menu board, the number of calories contained in the standard menu item, as usually prepared and offered for sale; and

"(bb) a succinct statement concerning suggested daily caloric intake, as specified by the Secretary by regulation and posted prominently on the menu board, designed to enable the public to understand, in the context of a total daily diet, the significance of the nutrition information that is provided on the menu board;

"(III) in a written form, available on the premises of the restaurant or similar retail establishment and to the consumer upon request, the nutrition information required under clauses (C) and (D) of subparagraph (1); and

"(IV) on the menu or menu board, a prominent, clear, and conspicuous statement regarding the availability of the information described in item (III).

"(iii) SELF-SERVICE FOOD AND FOOD ON DISPLAY.—Except as provided in subclause (vii), in the case of food sold at a salad bar, buffet line, cafeteria line, or similar self-service facility, and for self-service beverages or food that is on display and that is visible to customers, a restaurant or similar retail food establishment shall place adjacent to each food offered a sign that lists calories per displayed food item or per serving.

"(iv) REASONABLE BASIS.—For the purposes of this clause, a restaurant or similar retail food establishment shall have a reasonable basis for its nutrient content disclosures, including nutrient databases, cookbooks, laboratory analyses, and other reasonable means, as described in section 101.10 of title 21,

Code of Federal Regulations (or any successor regulation) or in a related guidance of the Food and Drug Administration.

"(v) MENU VARIABILITY AND COMBINATION MEALS.—The Secretary shall establish by regulation standards for determining and disclosing the nutrient content for standard menu items that come in different flavors, varieties, or combinations, but which are listed as a single menu item, such as soft drinks, ice cream, pizza, doughnuts, or children's combination meals, through means determined by the Secretary, including ranges, averages, or other methods.

"(vi) ADDITIONAL INFORMATION.—If the Secretary determines that a nutrient, other than a nutrient required under subclause (ii)(III), should be disclosed for the purpose of providing information to assist consumers in maintaining healthy dietary practices, the Secretary may require, by regulation, disclosure of such nutrient in the written form required under subclause (ii)(III).

"(vii) NONAPPLICABILITY TO CERTAIN FOOD.—

"(I) IN GENERAL.—Subclauses (i) through (vi) do not apply to—

"(aa) items that are not listed on a menu or menu board (such as condiments and other items placed on the table or counter for general use);

"(bb) daily specials, temporary menu items appearing on the menu for less than 60 days per calendar year, or custom orders; or

"(cc) such other food that is part of a customary market test appearing on the menu for less than 90 days, under terms and conditions established by the Secretary.

"(II) WRITTEN FORMS.—Clause (C) shall apply to any regulations promulgated under subclauses (ii)(III) and (vi).

"(viii) VENDING MACHINES.—In the case of an article of food sold from a vending machine that—

"(I) does not permit a prospective purchaser to examine the Nutrition Facts Panel before purchasing the article or does not otherwise provide visible nutrition information at the point of purchase; and

"(II) is operated by a person who is engaged in the business of owning or operating 20 or more vending machines,

the vending machine operator shall provide a sign in close proximity to each article of food or the selection button that includes a clear and conspicuous statement disclosing the number of calories contained in the article.

"(ix) VOLUNTARY PROVISION OF NUTRITION INFORMATION.—

"(I) IN GENERAL.—An authorized official of any restaurant or similar retail food establishment or vending machine operator not subject to the requirements of this clause may elect to be subject to the requirements of such clause, by registering biannually the name and address of such restaurant or similar retail food establishment or vending machine operator with the Secretary, as specified by the Secretary by regulation.

"(II) REGISTRATION.—Within 120 days of the enactment of this clause, the Secretary shall publish a notice in the Federal Register specifying the terms and conditions for implementation of item (I), pending promulgation of regulations.

"(III) RULE OF CONSTRUCTION.—Nothing in this subclause shall be construed to authorize the Secretary to require an application, review, or licensing process for any entity to register with the Secretary, as described in such item.

"(x) REGULATIONS.—

"(I) PROPOSED REGULATION.—Not later than 1 year after the date of the enactment of this clause, the Secretary shall promulgate proposed regulations to carry out this clause.

"(II) CONTENTS.—In promulgating regulations, the Secretary shall—

"(aa) consider standardization of recipes and methods of preparation, reasonable variation in serving size and formulation of menu items, space on menus and menu boards, inadvertent human error, training of food service workers, variations in ingredients, and other factors, as the Secretary determines; and

"(bb) specify the format and manner of the nutrient content disclosure requirements under this subclause.

"(III) REPORTING.—The Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a quarterly report that describes the Secretary's progress toward promulgating final regulations under this subparagraph.

"(xi) DEFINITION.—In this clause, the term 'menu' or 'menu board' means the primary writing of the restaurant or other similar retail food establishment from which a consumer makes an order selection.".

(c) NATIONAL UNIFORMITY.—Section 403A(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343–1(a)(4)) is amended by striking "except a requirement for nutrition labeling of food which is exempt under subclause (i) or (ii) of section 403(q)(5)(A)" and inserting "except that this paragraph does not apply to food that is offered for sale in a restaurant or similar retail food establishment that is not part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items unless such restaurant or similar retail food establishment complies with the voluntary provision of nutrition information requirements under section 403(q)(5)(H)(ix)".

(d) RULE OF CONSTRUCTION.—Nothing in the amendments made by this section shall be construed—

(1) to preempt any provision of State or local law, unless such provision establishes or continues into effect nutrient content disclosures of the type required under section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (b)) and is expressly preempted under section 403A(a)(4) of such Act;

(2) to apply to any State or local requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food; or

(3) except as provided in section 403(q)(5)(H)(ix) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (b)), to apply to any restaurant or similar retail food establishment other than a restaurant or similar retail food establishment described in section 403(q)(5)(H)(i) of such Act.

SEC. 2563. PROTECTING CONSUMER ACCESS TO GENERIC DRUGS.

(a) IN GENERAL.—Section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is amended by adding at the end the following:

"(w) PROTECTING CONSUMER ACCESS TO GENERIC DRUGS.—

"(1) UNFAIR AND DECEPTIVE ACTS AND PRACTICES RELATED TO NEW DRUG APPLICATIONS.—

"(A) CONDUCT PROHIBITED.—It shall be unlawful for any person to directly or indirectly be a party to any agreement resolving or settling a patent infringement claim in which—

"(i) an ANDA filer receives anything of value; and

"(ii) the ANDA filer agrees to limit or forego research, development, manufacturing, marketing, or sales, for any period of time, of the drug that is to be manufactured under the ANDA involved and is the subject of the patent infringement claim.

"(B) EXCEPTIONS.—Notwithstanding subparagraph (A)(i), subparagraph (A) does not prohibit a resolution or settlement of a patent infringement claim in which the value received by the ANDA filer includes no more than—

"(i) the right to market the drug that is to be manufactured under the ANDA involved and is the subject of the patent infringement claim, before the expiration of—

"(I) the patent that is the basis for the patent infringement claim; or

"(II) any other statutory exclusivity that would prevent the marketing of such drug; and

"(ii) the waiver of a patent infringement claim for damages based on prior marketing of such drug.

"(C) ENFORCEMENT.—

"(i) IN GENERAL.—A violation of subparagraph (A) shall be treated as an unfair and deceptive act or practice and an unfair method of competition in or affecting interstate commerce prohibited under section 5 of the Federal Trade Commission Act and shall be enforced by the Federal Trade Commission in the same manner, by the same means, and with the same jurisdiction as though all applicable terms and provisions of the Federal Trade Commission Act were incorporated into and made a part of this subsection.

"(ii) INAPPLICABILITY.—Subchapter A of chapter VII shall not apply with respect to this subsection.

"(D) DEFINITIONS.—In this subsection:

"(i) AGREEMENT.—The term 'agreement' means anything that would constitute an agreement under section 5 of the Federal Trade Commission Act.

"(ii) AGREEMENT RESOLVING OR SETTLING.—The term 'agreement resolving or settling', in reference to a patent infringement claim, in-

cludes any agreement that is contingent upon, provides a contingent condition for, or is otherwise related to the resolution or settlement of the claim.

"(iii) ANDA.—The term 'ANDA' means an abbreviated new drug application for the approval of a new drug under section (j).

"(iv) ANDA FILER.—The term 'ANDA filer' means a party that has filed an ANDA with the Food and Drug Administration.

"(v) PATENT INFRINGEMENT.—The term 'patent infringement' means infringement of any patent or of any filed patent application, extension, reissuance, renewal, division, continuation, continuation in part, reexamination, patent term restoration, patent of addition, or extension thereof.

"(vi) PATENT INFRINGEMENT CLAIM.—The term 'patent infringement claim' means any allegation made to an ANDA filer, whether or not included in a complaint filed with a court of law, that its ANDA or drug to be manufactured under such ANDA may infringe any patent.

"(2) FTC RULEMAKING.—The Federal Trade Commission may, by rule promulgated under section 553 of title 5, United States Code, exempt certain agreements described in paragraph (1) from the requirements of this subsection if the Commission finds such agreements to be in furtherance of market competition and for the benefit of consumers. Consistent with the authority of the Commission, such rules may include interpretive rules and general statements of policy with respect to the practices prohibited under paragraph (1).".

(b) NOTICE AND CERTIFICATION OF AGREEMENTS.—

(1) NOTICE OF ALL AGREEMENTS.—Section 1112(c)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. 3155 note) is amended by—

(A) striking "the Commission the" and inserting the following: "the Commission—

"(A) the";

(B) striking the period at the end and inserting "; and"; and

(C) adding at the end the following:

"(B) any other agreement the parties enter into within 30 days of entering into an agreement covered by subsection (a) or (b).".

(2) CERTIFICATION OF AGREEMENTS.—Section 1112 of such Act is amended by adding at the end the following:

"(d) CERTIFICATION.—The chief executive officer or the company official responsible for negotiating any agreement required to be filed under subsection (a), (b), or (c) shall execute and file with the Assistant Attorney General and the Commission a certification as follows: 'I declare under penalty of perjury that the following is true and correct: The materials filed with the Federal Trade Commission and the Department of Justice under section 1112 of subtitle B of title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, with respect to the agreement referenced in this certification: (1) represent the complete, final, and exclusive agreement between the parties; (2) include any ancillary agreements that are contingent upon, provide a contingent condition for, or are otherwise related to, the referenced agreement; and (3) include written descriptions of any oral agreements, representations, commitments, or promises between the parties that are responsive to subsection (a) or (b) of such section 1112 and have not been reduced to writing.'.".

(c) GAO STUDY.—

(1) STUDY.—Beginning 2 years after the date of enactment of this Act, and each year for a period of 4 years thereafter, the Comptroller General shall conduct a study on the litigation in United States courts during the period beginning years prior to the date of enactment of this Act relating to patent infringement claims involving generic drugs, the number of patent challenges initiated by manufacturers of generic drugs, and the number of settlements of such litigation. The Comptroller General shall transmit to Congress a report of the findings of such a study and an analysis of the effect of the amendments made by subsections (a) and (b) on such litigation, whether such amendments have had an effect on the number and frequency of claims settled, and whether such amendments resulted in earlier or delayed entry of generic drugs to market, including whether any harm or benefits to consumers has resulted.

(2) DISCLOSURE OF AGREEMENTS.—Notwithstanding any other law, agreements filed under section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (21 U.S.C. 355 note), or unaggregated information from such agreements, shall be disclosed to the Comptroller General for purposes of the study under paragraph (1) within 30 days of a request by the Comptroller General.

PART 2—BIOSIMILARS

SEC. 2565. LICENSURE PATHWAY FOR BIOSIMILAR BIOLOGICAL PRODUCTS.

(a) LICENSURE OF BIOLOGICAL PRODUCTS AS BIOSIMILAR OR INTERCHANGEABLE.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended—

(1) in subsection (a)(1)(A), by inserting "under this subsection or subsection (k)" after "biologics license"; and

(2) by adding at the end the following:

"(k) LICENSURE OF BIOLOGICAL PRODUCTS AS BIOSIMILAR OR INTERCHANGEABLE.—

"(1) IN GENERAL.—Any person may submit an application for licensure of a biological product under this subsection.

"(2) CONTENT.—

"(A) IN GENERAL.—

"(i) REQUIRED INFORMATION.—An application submitted under this subsection shall include information demonstrating that—

"(I) the biological product is biosimilar to a reference product based upon data derived from—

"(aa) analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;

"(bb) animal studies (including the assessment of toxicity); and

"(cc) a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and potency in 1 or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product;

"(II) the biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product;

"(III) the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product;

"(IV) the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product; and

"(V) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

"(ii) DETERMINATION BY SECRETARY.—The Secretary may determine, in the Secretary's discretion, that an element described in clause (i)(I) is unnecessary in an application submitted under this subsection.

"(iii) ADDITIONAL INFORMATION.—An application submitted under this subsection—

"(I) shall include publicly available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent; and

"(II) may include any additional information in support of the application, including publicly available information with respect to the reference product or another biological product.

"(B) INTERCHANGEABILITY.—An application (or a supplement to an application) submitted under this subsection may include information demonstrating that the biological product meets the standards described in paragraph (4).

"(3) EVALUATION BY SECRETARY.—Upon review of an application (or a supplement to an application) submitted under this subsection, the Secretary shall license the biological product under this subsection if—

"(A) the Secretary determines that the information submitted in the application (or the supplement) is sufficient to show that the biological product—

"(i) is biosimilar to the reference product; or

"(ii) meets the standards described in paragraph (4), and therefore is interchangeable with the reference product; and

"(B) the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

"(4) SAFETY STANDARDS FOR DETERMINING INTERCHANGEABILITY.—Upon review of an application submitted under this subsection or any supplement to such application, the Secretary shall determine the biological product to be interchangeable with the reference product if the Secretary determines that the information submitted in the application (or a supplement to such application) is sufficient to show that—

"(A) the biological product—

"(i) is biosimilar to the reference product; and

"(ii) can be expected to produce the same clinical result as the reference product in any given patient; and

"(B) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

"(5) GENERAL RULES.—

"(A) ONE REFERENCE PRODUCT PER APPLICATION.—A biological product, in an application submitted under this subsection, may not be evaluated against more than 1 reference product.

"(B) REVIEW.—An application submitted under this subsection shall be reviewed by the division within the Food and Drug Administration that is responsible for the review and approval of the application under which the reference product is licensed.

"(C) RISK EVALUATION AND MITIGATION STRATEGIES.—The authority of the Secretary with respect to risk evaluation and mitigation strategies under the Federal Food, Drug, and Cosmetic Act shall apply to biological products licensed under this subsection in the same manner as such authority applies to biological products licensed under subsection (a).

"(D) RESTRICTIONS ON BIOLOGICAL PRODUCTS CONTAINING DANGEROUS INGREDIENTS.—If information in an application submitted under this subsection, in a supplement to such an application, or otherwise available to the Secretary shows that a biological product—

"(i) is, bears, or contains a select agent or toxin listed in section 73.3 or 73.4 of title 42, section 121.3 or 121.4 of title 9, or section 331.3 of title 7, Code of Federal Regulations (or any successor regulations); or

"(ii) is, bears, or contains a controlled substance in schedule I or II of section 202 of the Controlled Substances Act, as listed in part 1308 of title 21, Code of Federal Regulations (or any successor regulations);

the Secretary shall not license the biological product under this subsection unless the Secretary determines, after consultation with appropriate national security and drug enforcement agencies, that there would be no increased risk to the security or health of the public from licensing such biological product under this subsection.

"(6) EXCLUSIVITY FOR FIRST INTERCHANGEABLE BIOLOGICAL PRODUCT.—Upon review of an application submitted under this subsection relying on the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, the Secretary shall not make a determination under paragraph (4) that the second or subsequent biological product is interchangeable for any condition of use until the earlier of—

"(A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;

"(B) 18 months after—

"(i) a final court decision on all patents in suit in an action instituted under subsection (l)(5) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

"(ii) the dismissal with or without prejudice of an action instituted under subsection (l)(5) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

"(C)(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (l)(5) and such litigation is still ongoing within such 42-month period; or

"(ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued under subsection (l)(5).

For purposes of this paragraph, the term 'final court decision' means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken.

"(7) EXCLUSIVITY FOR REFERENCE PRODUCT.—

"(A) EFFECTIVE DATE OF BIOSIMILAR APPLICATION APPROVAL.—Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).

"(B) FILING PERIOD.—An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a).

"(C) FIRST LICENSURE.—Subparagraphs (A) and (B) shall not apply to a license for or approval of—

"(i) a supplement for the biological product that is the reference product; or

"(ii) a subsequent application filed by the same sponsor or manufacturer of the biological product that is the reference product (or a licensor, predecessor in interest, or other related entity) for—

"(I) a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

"(II) a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

"(8) PEDIATRIC STUDIES.—

"(A) EXCLUSIVITY.—If, before or after licensure of the reference product under subsection (a) of this section, the Secretary determines that information relating to the use of such product in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the applicant or holder of the approved application agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act the period referred to in paragraph (7)(A) of this subsection is deemed to be 12 years and 6 months rather than 12 years.

"(B) EXCEPTION.—The Secretary shall not extend the period referred to in subparagraph (A) of this paragraph if the determination under section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act is made later than 9 months prior to the expiration of such period.

"(C) APPLICATION OF CERTAIN PROVISIONS.—The provisions of subsections (a), (d), (e), (f), (h), (j), (k), and (l) of section 505A of the Federal Food, Drug, and Cosmetic Act shall apply with respect to the extension of a period under subparagraph (A) of this paragraph to the same extent and in the same manner as such provisions apply with respect to the extension of a period under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act.

"(9) GUIDANCE DOCUMENTS.—

"(A) IN GENERAL.—The Secretary may, after opportunity for public comment, issue guidance in accordance, except as provided in subparagraph (B)(i), with section 701(h) of the Federal Food, Drug, and Cosmetic Act with respect to the licensure of a biological product under this subsection. Any such guidance may be general or specific.

"(B) PUBLIC COMMENT.—

"(i) IN GENERAL.—The Secretary shall provide the public an opportunity to comment on any proposed guidance issued under subparagraph (A) before issuing final guidance.

"(ii) INPUT REGARDING MOST VALUABLE GUIDANCE.—The Secretary shall establish a process through which the public may provide the Secretary with input regarding priorities for issuing guidance.

"(C) NO REQUIREMENT FOR APPLICATION CONSIDERATION.—The issuance (or non-issuance) of guidance under subparagraph (A) shall not preclude the review of, or action on, an application submitted under this subsection.

"(D) REQUIREMENT FOR PRODUCT CLASS-SPECIFIC GUIDANCE.—If the Secretary issues product class-specific guidance under subparagraph (A), such guidance shall include a description of—

"(i) the criteria that the Secretary will use to determine whether a biological product is highly similar to a reference product in such product class; and

"(ii) the criteria, if available, that the Secretary will use to determine whether a biological product meets the standards described in paragraph (4).

"(E) CERTAIN PRODUCT CLASSES.—

"(i) GUIDANCE.—The Secretary may indicate in a guidance document that the science and experience, as of the date of such guidance, with respect to a product or product class (not including any recombinant protein) does not allow approval of an application for a license as provided under this subsection for such product or product class.

"(ii) MODIFICATION OR REVERSAL.—The Secretary may issue a subsequent guidance document under subparagraph (A) to modify or reverse a guidance document under clause (i).

"(iii) NO EFFECT ON ABILITY TO DENY LICENSE.—Clause (i) shall not be construed to require the Secretary to approve a product with respect to which the Secretary has not indicated in a guidance document that the science and experience, as described in clause (i), does not allow approval of such an application.

"(10) NAMING.—The Secretary shall ensure that the labeling and packaging of each biological product licensed under this subsection bears a name that uniquely identifies the biological product and distinguishes it from the reference product and any other biological products licensed under this subsection following evaluation against such reference product.

"(l) PATENT NOTICES; RELATIONSHIP TO FINAL APPROVAL.—

"(1) DEFINITIONS.—For the purposes of this subsection, the term—

"(A) 'biosimilar product' means the biological product that is the subject of the application under subsection (k);

"(B) 'relevant patent' means a patent that—

"(i) expires after the date specified in subsection (k)(7)(A) that applies to the reference product; and

"(ii) could reasonably be asserted against the applicant due to the unauthorized making, use, sale, or offer for sale within the United States, or the importation into the United States of the biosimilar product, or materials used in the manufacture of the biosimilar product, or due to a use of the biosimilar product in a method of treatment that is indicated in the application;

"(C) 'reference product sponsor' means the holder of an approved application or license for the reference product; and

"(D) 'interested third party' means a person other than the reference product sponsor that owns a relevant patent, or has the right to commence or participate in an action for infringement of a relevant patent.

"(2) HANDLING OF CONFIDENTIAL INFORMATION.—Any entity receiving confidential information pursuant to this subsection shall designate one or more individuals to receive such information. Each individual so designated shall execute an agreement in accordance with regulations promulgated by the Secretary. The regulations shall require each such individual to take reasonable steps to maintain the confidentiality of information received pursuant to this subsection and use the information solely for purposes authorized by this subsection. The obligations imposed on an individual who has received confidential information pursuant to this subsection shall continue until the individual returns or destroys the confidential information, a court imposes a protective order that governs the use or handling of the confidential information, or the party providing the confidential information agrees to other terms or conditions regarding the handling or use of the confidential information.

"(3) PUBLIC NOTICE BY SECRETARY.—Within 30 days of acceptance by the Secretary of an application filed under subsection (k), the Secretary shall publish a notice identifying—

"(A) the reference product identified in the application; and

"(B) the name and address of an agent designated by the applicant to receive notices pursuant to paragraph (4)(B).

"(4) EXCHANGES CONCERNING PATENTS.—

"(A) EXCHANGES WITH REFERENCE PRODUCT SPONSOR.—

"(i) Within 30 days of the date of acceptance of the application by the Secretary, the applicant shall provide the reference product sponsor

with a copy of the application and information concerning the biosimilar product and its production. This information shall include a detailed description of the biosimilar product, its method of manufacture, and the materials used in the manufacture of the product.

"(ii) Within 60 days of the date of receipt of the information required to be provided under clause (i), the reference product sponsor shall provide to the applicant a list of relevant patents owned by the reference product sponsor, or in respect of which the reference product sponsor has the right to commence an action of infringement or otherwise has an interest in the patent as such patent concerns the biosimilar product.

"(iii) If the reference product sponsor is issued or acquires an interest in a relevant patent after the date on which the reference product sponsor provides the list required by clause (ii) to the applicant, the reference product sponsor shall identify that patent to the applicant within 30 days of the date of issue of the patent, or the date of acquisition of the interest in the patent, as applicable.

"(B) EXCHANGES WITH INTERESTED THIRD PARTIES.—

"(i) At any time after the date on which the Secretary publishes a notice for an application under paragraph (3), any interested third party may provide notice to the designated agent of the applicant that the interested third party owns or has rights under 1 or more patents that may be relevant patents. The notice shall identify at least 1 patent and shall designate an individual who has executed an agreement in accordance with paragraph (2) to receive confidential information from the applicant.

"(ii) Within 30 days of the date of receiving notice pursuant to clause (i), the applicant shall send to the individual designated by the interested third party the information specified in subparagraph (A)(i), unless the applicant and interested third party otherwise agree.

"(iii) Within 90 days of the date of receiving information pursuant to clause (ii), the interested third party shall provide to the applicant a list of relevant patents which the interested third party owns, or in respect of which the interested third party has the right to commence or participate in an action for infringement.

"(iv) If the interested third party is issued or acquires an interest in a relevant patent after the date on which the interested third party provides the list required by clause (iii), the interested third party shall identify that patent within 30 days of the date of issue of the patent, or the date of acquisition of the interest in the patent, as applicable.

"(C) IDENTIFICATION OF BASIS FOR INFRINGEMENT.—For any patent identified under clause (ii) or (iii) of subparagraph (A) or under clause (iii) or (iv) of subparagraph (B), the reference product sponsor or the interested third party, as applicable—

"(i) shall explain in writing why the sponsor or the interested third party believes the relevant patent would be infringed by the making, use, sale, or offer for sale within the United States, or importation into the United States, of the biosimilar product or by a use of the biosimilar product in treatment that is indicated in the application;

"(ii) may specify whether the relevant patent is available for licensing; and

"(iii) shall specify the number and date of expiration of the relevant patent.

"(D) CERTIFICATION BY APPLICANT CONCERNING IDENTIFIED RELEVANT PATENTS.—Not later than 45 days after the date on which a patent is identified under clause (ii) or (iii) of subparagraph (A) or under clause (iii) or (iv) of subparagraph (B), the applicant shall send a written statement regarding each identified patent to the party that identified the patent. Such statement shall either—

"(i) state that the applicant will not commence marketing of the biosimilar product and has requested the Secretary to not grant final approval of the application before the date of expiration of the noticed patent; or

"(ii) provide a detailed written explanation setting forth the reasons why the applicant believes—

"(I) the making, use, sale, or offer for sale within the United States, or the importation into the United States, of the biosimilar product, or the use of the biosimilar product in a treatment indicated in the application, would not infringe the patent; or

"(II) the patent is invalid or unenforceable.

"(5) ACTION FOR INFRINGEMENT INVOLVING REFERENCE PRODUCT SPONSOR.—If an action for infringement concerning a relevant patent identified by the reference product sponsor under clause (ii) or (iii) of paragraph (4)(A), or by an interested third party under clause (iii) or (iv) of paragraph (4)(B), is brought within 60 days of the date of receipt of a statement under paragraph (4)(D)(ii), and the court in which such action has been commenced determines the patent is infringed prior to the date applicable under subsection (k)(7)(A) or (k)(8), the Secretary shall make approval of the application effective on the day after the date of expiration of the patent that has been found to be infringed. If more than one such patent is found to be infringed by the court, the approval of the application shall be made effective on the day after the date that the last such patent expires.".

(b) DEFINITIONS.—Section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)) is amended—

(1) by striking "In this section, the term 'biological product' means" and inserting the following: "In this section:

"(1) The term 'biological product' means";

(2) in paragraph (1), as so designated, by inserting "protein (except any chemically synthesized polypeptide)," after "allergenic product,"; and

(3) by adding at the end the following:

"(2) The term 'biosimilar' or 'biosimilarity', in reference to a biological product that is the subject of an application under subsection (k), means—

"(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and

"(B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

"(3) The term 'interchangeable' or 'interchangeability', in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

"(4) The term 'reference product' means the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k).".

(c) PRODUCTS PREVIOUSLY APPROVED UNDER SECTION 505.—

(1) REQUIREMENT TO FOLLOW SECTION 351.—Except as provided in paragraph (2), an application for a biological product shall be submitted under section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act).

(2) EXCEPTION.—An application for a biological product may be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) if—

(A) such biological product is in a product class for which a biological product in such product class is the subject of an application approved under such section 505 not later than the date of enactment of this Act; and

(B) such application—

(i) has been submitted to the Secretary of Health and Human Services (referred to in this Act as the "Secretary") before the date of enactment of this Act; or

(ii) is submitted to the Secretary not later than the date that is 10 years after the date of enactment of this Act.

(3) LIMITATION.—Notwithstanding paragraph (2), an application for a biological product may not be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) if there is another biological product approved under subsection (a) of section 351 of the Public Health Service Act that could be a reference product with respect to such application (within the meaning of such section 351) if such application were submitted under subsection (k) of such section 351.

(4) DEEMED APPROVED UNDER SECTION 351.—An approved application for a biological product under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) shall be deemed to be a license for the biological product under such section 351 on the date that is 10 years after the date of enactment of this Act.

(5) DEFINITIONS.—For purposes of this subsection, the term "biological product" has the meaning given such term under section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act).

SEC. 2566. FEES RELATING TO BIOSIMILAR BIOLOGICAL PRODUCTS.

Subparagraph (B) of section 735(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g(1)) is amended by inserting ", including licensure of a biological product under section 351(k) of such Act" before the period at the end.

Subtitle D—Community Living Assistance Services and Supports

SEC. 2571. ESTABLISHMENT OF NATIONAL VOLUNTARY INSURANCE PROGRAM FOR PURCHASING COMMUNITY LIVING ASSISTANCE SERVICES AND SUPPORTS.

(a) IN GENERAL.—The Public Health Service Act (42 U.S.C. 201 et seq.), as amended, is amended by adding at the end the following:

"TITLE XXXII—COMMUNITY LIVING ASSISTANCE SERVICES AND SUPPORTS

"SEC. 3201. IN GENERAL.

"The Secretary shall establish a national voluntary insurance program to be known as the CLASS Independence Benefit Plan for purchasing community living assistance services and supports. Such program shall—

"(1) provide individuals who have functional limitations with tools that will allow them—

"(A) to maintain their personal and financial independence; and

"(B) to live in the community through a new financing strategy for community living assistance services and supports;

"(2) establish an infrastructure that will help address the Nation's community living assistance services and supports needs;

"(3) alleviate burdens on family caregivers; and

"(4) address institutional bias by providing a financing mechanism that supports personal choice and independence to live in the community.

"SEC. 3202. DEVELOPMENT AND MANAGEMENT OF PROGRAM.

"The Secretary shall develop the CLASS Independence Benefit Plan in an actuarially sound manner and—

"(1) set criteria for participation in the CLASS Independence Benefit Plan that do not restrict eligibility based on underwriting;

"(2) establish criteria for eligibility for benefits;

"(3) establish benefit levels;

"(4) establish mechanisms for collecting and distributing payments;

"(5) provide mechanisms to assist beneficiaries in the use of benefits;

"(6) promulgate such regulations as are necessary to carry out the CLASS program in accordance with this title; and

"(7) take any other action appropriate to develop, manage, and maintain the CLASS Independence Benefit Plan, including making adjustments to benefits paid out and premiums collected in order to—

"(A) maintain program solvency; and

"(B) ensure the program remains deficit neutral.

"SEC. 3203. REPORT.

"The Secretary shall submit to the Congress an annual report on the program under this title.".

(b) EFFECTIVE DATE.—Title XXXII of the Public Health Service Act, as added by subsection (a), shall take effect on the effective date of a statute establishing a voluntary payroll deduction under the Internal Revenue Code of 1986 to support the program authorized by such title.

Subtitle E—Miscellaneous

SEC. 2581. STATES FAILING TO ADHERE TO CERTAIN EMPLOYMENT OBLIGATIONS.

A State is eligible for Federal funds under the provisions of the Public Health Service Act (42 U.S.C. 201 et seq.) only if the State—

(1) agrees to be subject in its capacity as an employer to each obligation under division A of this Act and the amendments made by such division applicable to persons in their capacity as an employer; and

(2) assures that all political subdivisions in the State will do the same.

SEC. 2582. STUDY, REPORT, AND TERMINATION OF DUPLICATIVE GRANT PROGRAMS.

(a) STUDY.—The Secretary of Health and Human Services (in this section referred to as the "Secretary") shall conduct a study to determine if any grant program established by this division, or any amendment made by this division, is duplicative of one or more other Federal grant programs under the authority of the Secretary in existence as of the date of the enactment of this Act.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall submit to Congress and make available to the public a report that contains the results of the study required under subsection (a).

(c) TERMINATION OF DUPLICATIVE GRANT PROGRAMS.—If the Secretary determines under subsection (a) that any grant program established by this division, or any amendment made by this division, is duplicative of one or more other Federal grant programs under the authority of the Secretary, the Secretary shall, to maximum extent appropriate, terminate such other Federal grant programs not later than 180 days after the date of the submission of the report under subsection (b).

SEC. 2583. HEALTH CENTERS UNDER PUBLIC HEALTH SERVICE ACT; LIABILITY PROTECTIONS FOR VOLUNTEER PRACTITIONERS.

(a) IN GENERAL.—Section 224 (42 U.S.C. 233) is amended—

(1) in subsection (g)(1)(A)—

(A) in the first sentence, by striking "or employee" and inserting "employee, or (subject to subsection (k)(4)) volunteer practitioner"; and

(B) in the second sentence, by inserting "and subsection (k)(4)" after "subject to paragraph (5)"; and

(2) in each of subsections (g), (i), (j), (l), and (m), by striking the term "employee, or contractor" each place such term appears and inserting "employee, volunteer practitioner, or contractor";

(3) in subsection (g)(1)(H), by striking the term "employee, and contractor" each place such term appears and inserting "employee, volunteer practitioner, and contractor";

(4) in subsection (l), by striking the term "employee, or any contractor" and inserting "employee, volunteer practitioner, or contractor"; and

(5) in subsections (h)(3) and (k), by striking the term "employees, or contractors" each place such term appears and inserting "employees, volunteer practitioners, or contractors".

(b) APPLICABILITY; DEFINITION.—Section 224(k) (42 U.S.C. 233(k)) is amended by adding at the end the following paragraph:

"(4)(A) Subsections (g) through (m) apply with respect to volunteer practitioners beginning with the first fiscal year for which an appropriations Act provides that amounts in the fund under paragraph (2) are available with respect to such practitioners.

"(B) For purposes of subsections (g) through (m), the term 'volunteer practitioner' means a practitioner who, with respect to an entity described in subsection (g)(4), meets the following conditions:

"(i) The practitioner is a licensed physician, a licensed clinical psychologist, or other licensed or certified health care practitioner.

"(ii) At the request of such entity, the practitioner provides services to patients of the entity, at a site at which the entity operates or at a site designated by the entity. The weekly number of hours of services provided to the patients by the practitioner is not a factor with respect to meeting conditions under this subparagraph.

"(iii) The practitioner does not for the provision of such services receive any compensation from such patients, from the entity, or from third-party payors (including reimbursement under any insurance policy or health plan, or under any Federal or State health benefits program).".

SEC. 2584. REPORT TO CONGRESS ON THE CURRENT STATE OF PARASITIC DISEASES THAT HAVE BEEN OVERLOOKED AMONG THE POOREST AMERICANS.

Not later than 12 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall report to Congress on the epidemiology of, impact of, and appropriate funding required to address neglected diseases of poverty, including neglected parasitic diseases identified as Chagas Disease, cysticercosis, toxocariasis, toxoplasmosis, trichomoniasis, the soil-transmitted helminths, and others. The report should provide the information necessary to enhance health policy to accurately evaluate and address the threat of these diseases.

SEC. 2585. STUDY OF IMPACT OF OPTOMETRISTS ON ACCESS TO HEALTH CARE AND ON AVAILABILITY OF SUPPORT UNDER FEDERAL HEALTH PROGRAMS FOR OPTOMETRY.

(a) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the "Secretary") shall conduct a study with respect to optometrists and optometry to determine—

(1) whether there is a current and projected role for, and the impact of, optometrists in increasing access to primary eye and vision care to underserved, rural, and senior populations;

(2) the role and impact of optometrists in the early diagnosis and treatment of glaucoma, cataract, diabetes, and other conditions;

(3) whether there is a need for optometrists to be recognized and supported as primary care providers;

(4) whether there is an existence of, and the extent of, any barriers to recruitment and participation of underrepresented minorities in optometry, including the potential role played by the lack of eligibility of optometrists, optometry students, and facilities for certain Federal health programs; and

(5) the scope of Federal support for clinical optometric education and options for enhancing that support—

(A) to address barriers to underrepresented minority recruitment and participation in optometry; and

(B) to improve access to primary eye and vision care, especially in underserved and rural areas.

(b) COMMENT ON MATTERS STUDIED.—In carrying out the study under subsection (a), the Secretary shall seek the comments of appropriate public and private entities.

(c) REPORT TO CONGRESS.—Not later than 18 months after the date of the enactment of this Act, the Secretary shall submit to the Congress a report containing—

(1) the results of the study under subsection (a);

(2) a summary of comments received from public and private entities under subsection (b); and

(3) recommendations for such legislation and administrative action as the Secretary determines to be appropriate regarding the issues studied under subsection (a).

PURPOSE AND SUMMARY

The purpose of H.R. 3200, the "America's Affordable Health Choices Act of 2009", is to provide affordable, quality health care for all Americans and to reduce the growth in health care costs.

It does that in a manner consistent with President Obama's principles for health reform: building on what works in today's healthcare system while repairing aspects that are broken. It provides for comprehensive reform in three key areas:

- Affordable Health Care Choices
- Medicare and Medicaid Improvements
- Public Health and Workforce Development

AFFORDABLE HEALTH CARE CHOICES

H.R. 3200 reforms the health system by ensuring more affordable health care choices for all Americans. It provides for:

• *Strong insurance market reforms:* Pre-existing condition exclusions are prohibited; guarantee issue and renewal is required of all health insurance; and discrimination in coverage and premium rating based on health status, gender, or any other personal characteristics is prohibited. Premiums can vary only by geographic area and by age, with a limit of 2:1 variation in rate variation by age. There are limits on the maximum out-of-pocket payments for covered benefits, and no annual or lifetime limits on benefits.

• *A new national health insurance exchange:* Individuals and small groups can purchase health benefits, with a choice among

private insurers and a new public option competing on a level playing field.

• *Affordability:* Medicaid coverage expansions and new sliding scale affordability credits make premiums and cost sharing more affordable for those with income below 400% of the federal poverty level.

• *Shared responsibility among individuals, employers and government:* Individuals are required to have health coverage; employers (except for small employers) are required to either offer qualified health benefits or make a contribution toward the costs of health care; and new insurance reforms and oversight by the federal and state governments create a marketplace to foster choice and competition, while ensuring that coverage is affordable for those who need assistance.

MEDICARE AND MEDICAID IMPROVEMENTS

H.R. 3200 improves and strengthens Medicare and Medicaid, provides for substantial savings and fosters long-term delivery system reforms through those programs. It provides for:

• *Modernization of Medicare:* Major delivery system reforms include innovative concepts such as accountable care organizations, medical homes, and bundling of acute and post-acute care services. Payment incentives decrease preventable hospital readmissions. Physician payments are improved, with a complete reform of the sustainable growth rate formula (eliminating the prospect of immediate, deep cuts in physician payments), along with payment improvements for primary care services.

• *Benefit improvements:* The Medicare Part D "donut hole" is phased out, financed by re-imposing rebates on the drugs purchased for individuals eligible for both Medicare and Medicaid; cost-sharing on preventive services is eliminated, and the low income subsidy programs in Medicare improved.

• *Fraud and abuse protections:* New tools are provided to combat waste, fraud, and abuse in Medicare and Medicaid, as well as in the new public option.

• *Payment accuracy:* Overpayments to Medicare Advantage plans are phased out, and payment systems and updates are made more accurate for providers in Medicare, following the recommendations of the Medicare Payment Advisory Commission and the President's budget. In total, the changes in Medicare will put the program on a much more solid financial growth pattern in the future and extend the life of the Medicare Hospital Insurance Trust Fund by five years.

• *Medicaid improvements:* In addition to the Medicaid coverage expansion, primary care payments are phased up to Medicare levels to enhance beneficiary access to services, and recommended preventive services are covered without cost-sharing.

PUBLIC HEALTH AND WORKFORCE DEVELOPMENT

H.R. 3200 addresses critical health care access, public health, and enhancements in the health care workforce. It provides for:

• *Community health centers:* A significant expansion in community health centers to foster access to needed services.

• *Workforce investments:* Increased funding for the National Health Service Corps, and for training for primary care physicians,

nurses, and public health professionals, with special attention to workforce diversity and the needs of health care shortage areas.

• *Preventive services:* Improvements in research and adoption of policy improvements in both clinical and community preventive services, including elimination of cost-sharing on recommended preventive services.

• *Public health and wellness:* Investments in state, territorial, and local public health infrastructure.

BACKGROUND AND NEED FOR LEGISLATION

Rising costs, declining insurance coverage and suboptimal quality are evident in the U.S. healthcare system. National healthcare spending now is approximately $2.4 trillion, or about 17% of the gross domestic product (GDP). The U.S. Census Bureau estimates that more than 45.7 million people were uninsured in 2007, representing more than one-seventh of the population. Although the United States spends substantially more on health care per person than other industrialized countries, it scores only average or somewhat worse on many quality-of-care indicators.

HEALTH CARE COSTS

Escalating healthcare costs are a significant public policy concern and key driver of calls to reform the healthcare system. The United States spends a large and growing share of national income on health care. In 2008, national health spending was approximately $2.4 trillion and accounted for nearly 17% of GDP. We spend substantially more than other developed countries on health care, both per capita and as a share of GDP. That strains the budgets of families, business, and government.

Health insurance coverage is expensive and premiums have been growing rapidly. For private-sector employer plans in 2008, the average premium for self-only and family coverage was $4,386 and $12,298, respectively. Moreover, from 1996 to 2006, health insurance premiums grew a cumulative 107% for self-only coverage and 130% for family coverage. In contrast, workers' earnings have grown more slowly. For example, over the same time period, the average weekly earnings of private-sector workers increased by 47%.

To attract and maintain a qualified workforce, many businesses provide health benefits for their employees. As the cost of insurance rises, employers face a growing challenge paying for health benefits while managing labor costs to succeed in a competitive market. Given that health insurance premiums have been rising and employers on average pay a majority of those costs, the amount that employers pay for health insurance has been increasing both absolutely and as a share of labor costs. For example, in 1996, private-sector employers contributed an average of $1,650 towards the premium for self-only coverage. By 2006, that average had grown to $3,330; a 102% increase. In response to such conditions, some employers offer insurance to fewer workers or stop offering it altogether; ask employees to pay more for coverage; and reduce benefits.

In addition, health care costs place significant pressure on the federal and state budgets—both directly, through spending on

Medicare, Medicaid, and other programs, and indirectly, through tax expenditures for health insurance and expenses. The Congressional Budget Office (CBO) expects federal outlays for Medicare and Medicaid to exceed $700 billion in FY2009, representing about 5% of GDP. CBO projects that federal spending on Medicare and Medicaid combined will grow from roughly 5% of GDP today to almost 10% by 2035 and to more than 17% by 2080.

Even prior to the recent economic downturn, the Medicaid program's financing represented a growing share of federal and state budgets. The weakening economy is likely to exacerbate the issue. A poor economy affects how much money states can dedicate to the program while at the same time has the potential to vastly increase the number of individuals who meet the income eligibility thresholds that make them eligible for coverage.

Underlying health care cost growth is a health care delivery system in the United States that is highly fragmented, with this fragmentation oftentimes reflected in a lack of coordinated, timely, effective, or efficient care. The system for delivering health services has arisen incrementally and has been shaped by a range of factors, including financing mechanisms and patterns in the supply and distribution of resources such as health care providers.

In its June 2009 report to Congress, the Medicare Payment Advisory Commission (MedPAC) concluded that fundamental changes are needed in health care delivery in the United States, and in Medicare. The Commission recommended Medicare reforms that would, among other things, increase value, promote accountability and care coordination, change incentives to encourage efficiency and high quality, and set more accurate payment rates.

In calling for action, the Council of Economic Advisors reported in June 2009 that genuine health reform that ultimately slowed the annual growth rate in health care costs by just 1.5 percentage points annually would:

- Increase GDP by nearly 8% in 2030;
- Increase income for a typical family of four by nearly $10,000 by 2030;
- Prevent disastrous increases in the federal budget deficit.

COVERAGE

Americans obtain health insurance in different settings and through a variety of methods. Those aged 65 and older are generally covered by the Medicare program, so most assessments of coverage issues and options focus on the population under age 65. For this population, the two dominant sources of coverage are employment-based coverage and government programs, largely Medicaid and the Children's Health Insurance Program (CHIP). There is also a relatively small "non-group" or individual health insurance market.

In 2007, approximately 177 million people had employment-based health insurance. Employers who choose to offer health coverage may either purchase insurance from a state-licensed insurer or choose to self-fund health benefits for their employees (most larger employers self-fund benefits).

Approximately 99% of large employers (200 or more workers) offer health benefits to at least some of their employees. Large employers are generally able to obtain lower premiums for a given

health insurance package than small employers and individuals. The result is that the vast majority of large firms typically can find and provide health insurance in the private market, in contrast with small firms and individuals.

Less than half of all small employers (less than 50 employees) offer health insurance coverage to their employees. These pools are generally considered to be less stable than larger pools, as one or two employees moving in or out of the pool (or developing an illness) would have a greater impact on the average per-person cost of health care than they would in a larger pool. Also, small groups lack the economies of scale and leveraging ability available to large employers. Thus, small employers face greater difficulties in obtaining health insurance in the private market than large employers.

Other individuals obtain coverage on their own in the non-group market. Depending on the applicable state laws, individuals who purchase health insurance in the non-group market may be rejected or face premiums that reflect their health status, which can make premiums lower for the healthy but higher for the sick. Even when these individuals are issued a health insurance policy, the insurer may be allowed to exclude coverage for pre-existing health conditions. Some health insurers have undertaken so-called post-claims underwriting practices, whereby the initial applications of individuals are re-examined after a claim is filed. If errors or omissions, even minor ones unrelated to the claim filed, are discovered the individual may be subject to a denial of coverage or a rescission of the policy.

In August 2008, the U.S. Census Bureau estimated that 45.7 million people had no health insurance in 2007 through employers, individual policies or government programs. The millions of uninsured, and underinsured, individuals in the United States present significant challenges to public policymakers and this lack of comprehensive coverage has served as an impetus for reform for decades.

In calling for action, the Institute of Medicine (IOM) of the National Academies reported in 2009 that:

- Coverage is declining and will continue to decline;
- Health insurance is integral to personal well-being and health—For people without health insurance, there is a chasm between health care needs and access to services, despite the availability of some safety net services;
- High levels of uninsured in communities may undermine health care for the insured population.

Further, the University of Washington Medical School found that a lack of health insurance causes more than 44,000 deaths each year, after adjusting for age, gender, education, employment status, smoking, and other factors. In addition, the Council of Economic Advisors reported in June 2009 that expanding insurance coverage to the uninsured would increase net economic well-being by roughly $100 billion a year, or about two-thirds of a percent of GDP.

QUALITY

Despite our spending far more than any other nation on health care, the U.S. health care system is characterized by systemic quality shortcomings.

In a 1999 study, the IOM reported that between 44,000 and 98,000 people die each year due to preventable medical errors at a cost of between 17 and 29 billion dollars per year. Serious adverse medication events are estimated to occur in up to 15% of hospitalized patients and more than 100,000 deaths are attributed annually to such reactions.

With respect to the problems of overuse, misuse, and underuse of health care services, a study conducted by the Midwest Business Group on Health in 2003 found that approximately "30 percent of all direct health care outlays are the result of poor-quality care, consisting primarily of overuse, misuse and waste." Another study found that as many as 20% to 30% of patients received contraindicated care. A 2007 RAND study found that only 46.5% of children receive care recommended by evidence-based guidelines and a similar RAND study conducted in 2003 concluded that adults receive only 55% of indicated care. Taken together, these findings evidence significant shortfalls in the quality of care provided in the United States.

Over the past decade, there have been numerous efforts to improve quality of care in the United States that have engaged a wide range of stakeholders. These efforts have generally focused on improving and refining metrics for measuring the quality of care delivered in a number of settings; publicly reporting comparative information on quality performance; and, in some cases, using metrics as the basis for payment policies to demand provider accountability (value-based purchasing).

Despite observable progress, the most recent National Healthcare Quality Report (2008) indicated that health care quality is suboptimal and continues to improve at a slow pace. Among the challenges to making further improvements are disagreements about the utility or appropriateness of some measures (including concerns about how the public might interpret them), the fragmented nature of the American health care system, and barriers to access for some groups that complicate the work of providers.

In calling for action at the Committee's hearing in June, 2009, the Secretary of Health and Human Services, Kathleen Sebelius, testified:

> Despite the best efforts of business purchasers and private quality improvement initiatives and the development of standards, both government and private, recent reports indicate that the quality of care has actually declined in recent years. We will not be able to achieve the quality we need without the major reforms the President seeks. It will take a comprehensive approach to provide the leverage needed to improve care.

HEALTH SERVICES DELIVERY REFORM

The health reform debate has embraced a number of proposals to improve the delivery of health care services as the vehicle for improving value in care. MedPAC's call for fundamental delivery reform through Medicare is noted above. Further, the call for delivery reforms include initiatives to improve the health care workforce; to encourage individuals to adopt healthier lifestyles; and to

change the way that physicians and other providers treat and manage disease.

Policymakers have considered leveraging federal dollars to selectively augment health care resources and improve the functioning of the delivery system, targeting areas such as emergency care, pain management, and the support of various programs, clinics, and centers. Finally, the need for reliable, comprehensive, and robust health data, and the federal government's role in ensuring access to this data, has been an important component of efforts that aim to reform the delivery system.

PAYMENT FOR HEALTH CARE SERVICES

The inefficiencies resulting from fee-for-service payment arrangements in American health care are well documented. Most common in payment for physician and practitioner services, fee-for-service rewards the provision of a high volume of services without regard to the value of each service to a patient's health or a patient's preferences. Overtreatment can be harmful to a patient's health and leads to increased health spending for the patient, businesses, and employers. Fee-for-service also does not encourage physicians and other professionals to collaborate to manage a patient's health needs over time.

Proposals have been offered to reform and replace fee-for-service payments in Medicare and private health insurance. Reformed payment methods focus on encouraging care coordination and the provision of high-quality, rather than high-volume, care.

In testimony before the Committee, chairman of MedPAC Glenn Hackbarth noted:

> The health care delivery system we see today is not a true system: Care coordination is rare, specialist care is favored over primary care, quality of care is often poor, and costs are high and increasing at an unsustainable rate. Part of the problem is that Medicare's fee-for-service (FFS) payment systems reward more care, and more complex care, without regard to the value of that care. In addition, Medicare's payment systems create separate payment "silos" (e.g., inpatient hospitals, physicians, post-acute care providers) and do not encourage coordination among providers within a silo or across the silos. We must address those limitations—creating new payment methods that will reward efficient use of our limited resources and encourage the effective integration of care.

WORKFORCE

The health workforce consists of a number of providers including physicians, physician assistants, nurses—including nurse practitioners, nurse-midwives, registered nurses, licensed practical or vocational nurses—pharmacists, dentists, and allied health professionals, such as audiologists and nutritionists. There are also a number of direct care workers who provide health and custodial services to the institutionalized population, and public health workers who work in government agencies and state and local health departments.

Policymakers and experts have expressed concerns about the size, specialty mix, and geographic distribution of the healthcare workforce. Although quantifying the size of these healthcare provider shortages is a difficult endeavor, there is agreement that certain geographic areas, such as inner cities and rural areas, experience significant healthcare provider shortages. For example, HHS estimates that an additional 7,000 physicians are needed in health professions shortage areas. Shortages of specific healthcare providers such as primary care physicians—physicians trained in the fields of family medicine, general internal medicine, and pediatric medicine—and nurses also exist at present. There is also broad consensus among experts and advisory groups that there will be further healthcare provider shortages in the future. For example, the Health Resources and Services Administration (HRSA)—the agency that administers the majority of health workforce programs—estimated that by 2020 there will be shortages in a number of physician specialties and nearly 67,000 too few primary care physicians. Additionally, a federal advisory group on the nursing workforce estimates that as of 2000 there was a 6% shortage of nurses and that this shortage is expected to grow to 20% in 2020.

The federal government has a long-standing role in supporting workforce-related programs. Much of this support is through grants, contracts, and loan programs authorized in the Public Health Service Act (PHSA). PHSA Title III authorizes the National Health Service Corps, which provides scholarship and loan repayment to practitioners who agree to provide care in medically underserved areas. PHSA Title VII supports the training of health professionals, such as physicians, dentists, physician assistants, and public health workers, through various grants, contracts, and loan programs. PHSA Title VII also includes programs to encourage diversity in the healthcare workforce. PHSA Title VIII authorizes several programs to support nursing workforce development including grant, contract, scholarship, and loan programs to train nurses, support nursing faculty development, and increase diversity in the nursing workforce.

Another major source of federal workforce support is through federal support of medical residency and fellowship training. Specifically, Medicare, through Graduate Medical Education (GME) payments to hospitals, provides more than $9 billion to educate and train about 90,000 residents, and the U.S. Department of Veterans Affairs sponsors and funds residency training.

Beyond these programs, the federal government supports the healthcare workforce in a variety of other ways. For example, Medicaid funds residency training, the armed forces offers residencies for enlisted physicians, and the U.S. Department of Education supports federally subsidized student loan programs to encourage students to enter health professions.

In calling for action at the Subcommittee on Health's hearing in March 2009, Dr. Jeffrey Harris, President of the American College of Physicians, testified:

> A fundamental goal of delivery system reform should be to recognize and support the value of primary care in improving outcomes; reducing preventable overutilization of emergency rooms, hospitals and testing facilities; and achieving overall cost savings.

WELLNESS AND PREVENTION

In the context of health, "prevention" may refer to a range of activities, from a plan for a more walkable community to an immunization, to a colonoscopy, to a diabetes management program. Prevention activities span a continuum of stages often referred to as primary, secondary and tertiary prevention. Primary prevention measures are those that prevent the risk of illness or injury entirely, or at a very early stage. These include public health (i.e. population-based) measures such as anti-smoking campaigns and nutrition and exercise guidelines. Secondary measures detect health problems at an early stage, when they are most amenable to cure. These include clinical preventive services such as cancer screenings. Tertiary measures are remedial, mitigating the effects of an illness or injury once a problem has occurred. Chronic disease management programs are sometimes referred to as tertiary prevention measures. Workplace "wellness" programs may incorporate activities at each stage of the prevention continuum.

There is increasing concern that the prevalence of chronic diseases in the United States is on the rise, and that this development contributes both to a growing burden of illness among individuals, and to challenges in curbing cost growth in health care. According to the Centers for Disease Control and Prevention (CDC):

> Chronic diseases—such as heart disease, cancer, and diabetes—are the leading causes of death and disability in the United States. Chronic diseases account for 70% of all deaths in the U.S., which is 1.7 million each year. These diseases also cause major limitations in daily living for almost 1 out of 10 Americans or about 25 million people. Although chronic diseases are among the most common and costly health problems, they are also among the most preventable. Adopting healthy behaviors such as eating nutritious foods, being physically active and avoiding tobacco use can prevent or control the devastating effects of these diseases.

Efforts to reform the nation's health system often include discussion of the role of prevention in reducing the burden of chronic diseases. Current federal law addresses prevention in several ways, including through (1) coverage of certain clinical preventive services under Medicare and Medicaid; (2) community-based research, disease prevention, and health promotion programs, which may be funded through federal grants; (3) support of evidence reviews to determine whether specific clinical and community prevention interventions are effective; and (4) regulation of certain employer-provided wellness programs in order to strike a balance between flexibility and compliance with current federal privacy, civil rights, and other laws.

Many chronic diseases such as obesity and heart disease are worsened by unhealthy behaviors, and may not be amenable to successful management or cure unless such behaviors can be addressed. The federal government's role in encouraging healthy behaviors is varied, and includes developing and disseminating information for public health and medical professionals and the general public. This includes the work of the U.S. Preventive Services Task Force that is administered by the Agency for Healthcare Research

and Quality and that provides recommendations about which preventive services (e.g. cancer screenings) should be incorporated into primary care practice.

Through a variety of programs, the federal government also provides funding and technical assistance to state, local, and tribal health authorities and others to support community, or population-based, prevention activities. In addition, the CDC supports the Task Force on Community Preventive Services, which evaluates the effectiveness of primary prevention measures, and recommends the use of those interventions shown to be effective. For example, work by the Task Force has identified a number of population-based strategies that are effective in reducing tobacco use, promoting physical activity, and improving diabetes management, among many others.

HHS Secretary Sebelius, at the Committee on Energy and Commerce's June 2009 hearing, called for comprehensive action on prevention and wellness:

> We must make important investments in prevention and wellness. The old adage is true: an ounce of prevention truly is worth a pound of cure. But for too long, we've sunk all our resources into cures and short-changed prevention. Preventing disease and controlling its effects over time must be the foundation of our health care system.

HEALTH DATA COLLECTION

Currently a wide range of public and private data systems are used to monitor the nation's health, access to care, and cost and quality of that care. Key federal tracking initiatives include HealthyPeople 2010 (which tracks health promotion and disease prevention), Health U.S. (which tracks the health status of the nation), and the National Healthcare Quality and National Healthcare Disparities Reports (which track the quality of health care in the United States and disparities related to quality of, and access to, health care).

Each of these efforts draws from a combination of administrative data, vital records, population-based data, provider-based data, surveillance data, and special studies. For example, 190 data systems are used to track HealthyPeople 2010 objectives. Many, but not all, of these data systems and sources are sponsored by the Department of Health and Human Services, but others (such as population estimates used to calculate rates or data on specific populations such as Native Americans) are supported by other federal agencies (such as the Census Bureau or the Indian Health Service). Private and global data sources comprise other measures in the nation's health tracking efforts. For example, comparative international data may come from the World Health Organization or the Organization for Economic Cooperation and Development while pharmaceutical data or data on the managed care population may come from private sources.

There are a large and growing number of public and private data sources that help inform our understanding of health, health care, and the potential effects of proposed policies. At present time, there is no central source of information at HHS or elsewhere, and no central repository for health data. While there are a number of ef-

forts to coordinate federal data (such as interagency working groups or coordinating efforts through the Paperwork Reduction Act) and efforts to standardize the collection and reporting of data (through OMB data standards and the efforts of advisory groups such as the National Committee on Vital and Health Statistics), achieving full coordination at the national level remains a challenge.

In calling for action at the Subcommittee on Health's hearing in June, 2009, Jeffrey Levi of the Trust for America's Health testified on the need for better use of information and data:

> As we enter a reformed health care system, harnessing the power of health information technology for public health purposes as well as health care is going to be essential. Assuring that the American people have a true sense of our progress . . . will require a commitment to collecting, analyzing, and releasing in an accessible manner, a full range of data about our nation's health.

LEGISLATIVE HISTORY

H.R. 3200 was introduced on July 14, 2009, by Committee on Energy and Commerce Chairman Emeritus Dingell, Chairman Waxman, Subcommittee on Health Chairman Pallone, as well as Chairman Rangel and Subcommittee Chairman Stark of the Committee on Ways and Means, and Chairman Miller of California and Subcommittee Chairman Andrews from the Committee on Education and Labor. H.R. 3200 was referred primarily to the Committee on Energy and Commerce, and in addition to the Committees on Ways and Means, Education and Labor, Oversight and Government Reform, and the Budget.

During the 110th Congress, there were 17 hearings held by the Subcommittee on Health on issues relating to healthcare access and problems of those who are uninsured. These hearings also explored areas of health delivery systems, cost containment, and protecting health coverage during an economic downturn.

In the first session of the 111th Congress, the Subcommittee on Health held five days of oversight hearings focused on making health care work for American families. Hearings were held on Tuesday, March 10, 2009; Tuesday, March 17, 2009; Tuesday, March 24, 2009; Tuesday, March 31, 2009; and Thursday, April 2, 2009.

A Discussion Draft of comprehensive health reform legislation was circulated by the Committee to the Members of the Committee and the public on June 19, 2009. The same Discussion Draft was also issued by the Committee on Ways and Means and the Committee on Education and Labor.

The Committee on Energy and Commerce and its Subcommittee on Health held three days of legislative hearings on the Discussion Draft. Hearings by the Subcommittee on Health were held on Tuesday, June 23, 2009; Wednesday, June 24, 2009; and Thursday, June 25, 2009. The full Committee held a hearing on Wednesday, June 24, 2009, to receive testimony from the Secretary of Health and Human Services, the Hon. Kathleen Sebelius.

COMMITTEE CONSIDERATION

The Committee on Energy and Commerce met in open markup session for five days to consider amendments to H.R. 3200. The Committee met on July 16, 17, 20, 30, and 31, 2009. The Committee adopted 78 amendments to the legislation. H.R. 3200 was ordered favorably reported to the House, amended, by a roll call vote of 31 to 28.

COMMITTEE VOTES

Clause 3(b) of rule XIII of the Rules of the House of Representatives requires the Committee to list the record votes on the motion to report legislation and amendments and motions thereto. The Committee agreed to a motion by Mr. Dingell to order H.R. 3200 favorably reported to the House, amended, by a record vote of 31 yeas and 28 nays. The following is the recorded votes taken during Committee consideration, including the names of those Members voting for and against:

COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 69

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mr. Sullivan, # 1D, to add at the end of title V of division C a new Subtitle F entitled "Termination of Duplicative Grant Programs".

DISPOSITION: **AGREED TO** by a roll call vote of 29 yeas to 27 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey		X		Mr. Upton	X		
Mr. Boucher				Mr. Stearns	X		
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon				Mr. Whitfield	X		
Mr. Rush		X		Mr. Shimkus	X		
Ms. Eshoo		X		Mr. Shadegg	X		
Mr. Stupak	X			Mr. Blunt			
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle		X		Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick	X		
Mr. Inslee		X		Mr. Sullivan	X		
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross	X			Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson	X			Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon	X						
Mr. Barrow	X						
Mr. Hill	X						
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space	X						
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

07/17/2009

COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 70

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mr. Deal, # 1F, in title V of division C, strike subtitle E entitled "States Failing to Adhere to Certain Employment Obligations".

DISPOSITION: **NOT AGREED TO** by a roll call vote of 20 yeas to 35 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey		X		Mr. Upton	X		
Mr. Boucher				Mr. Stearns			
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon		X		Mr. Whitfield	X		
Mr. Rush		X		Mr. Shimkus	X		
Ms. Eshoo		X		Mr. Shadegg	X		
Mr. Stupak		X		Mr. Blunt			
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle		X		Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick			
Mr. Inslee		X		Mr. Sullivan	X		
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross		X		Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson		X		Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon		X					
Mr. Barrow		X					
Mr. Hill		X					
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

07/20/2009

COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 71

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mr. Gingrey, # 1H, to add a new subsection (k) at the end of section 2401 that nothing in this section shall be construed to allow any federal employee or political appointee to dictate how a medical provider practices medicine.

DISPOSITION: **NOT AGREED TO** by a roll call vote of 24 yeas to 33 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey		X		Mr. Upton	X		
Mr. Boucher				Mr. Stearns	X		
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon		X		Mr. Whitfield	X		
Mr. Rush		X		Mr. Shimkus	X		
Ms. Eshoo		X		Mr. Shadegg	X		
Mr. Stupak		X		Mr. Blunt	X		
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle		X		Mr. Walden	X		
Ms. Harman				Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick	X		
Mr. Inslee		X		Mr. Sullivan	X		
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross		X		Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson		X		Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon		X					
Mr. Barrow	X						
Mr. Hill		X					
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

07/20/2009

COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 72

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Ms. Sutton, # 1M, to insert after section 2301 of title III in division C a new section 2302 entitled "Grants to Promote Positive Health Behaviors and Outcomes."

DISPOSITION: **AGREED TO** by a roll call vote of 36 yeas to 23 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman	X			Mr. Barton		X	
Mr. Dingell	X			Mr. Hall		X	
Mr. Markey	X			Mr. Upton		X	
Mr. Boucher	X			Mr. Stearns		X	
Mr. Pallone	X			Mr. Deal		X	
Mr. Gordon	X			Mr. Whitfield		X	
Mr. Rush	X			Mr. Shimkus		X	
Ms. Eshoo	X			Mr. Shadegg		X	
Mr. Stupak	X			Mr. Blunt		X	
Mr. Engel	X			Mr. Buyer		X	
Mr. Green	X			Mr. Radanovich		X	
Ms. DeGette	X			Mr. Pitts		X	
Mrs. Capps	X			Ms. Bono Mack		X	
Mr. Doyle	X			Mr. Walden		X	
Ms. Harman	X			Mr. Terry		X	
Ms. Schakowsky	X			Mr. Rogers		X	
Mr. Gonzalez	X			Mrs. Myrick		X	
Mr. Inslee	X			Mr. Sullivan		X	
Ms. Baldwin	X			Mr. Murphy of PA		X	
Mr. Ross	X			Mr. Burgess		X	
Mr. Weiner	X			Ms. Blackburn		X	
Mr. Matheson	X			Mr. Gingrey		X	
Mr. Butterfield	X			Mr. Scalise		X	
Mr. Melancon	X						
Mr. Barrow	X						
Mr. Hill	X						
Ms. Matsui	X						
Mrs. Christensen	X						
Ms. Castor	X						
Mr. Sarbanes	X						
Mr. Murphy of CT	X						
Mr. Space	X						
Mr. McNerney	X						
Ms. Sutton	X						
Mr. Braley	X						
Mr. Welch	X						

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 73

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mr. Rogers of Michigan, # 1N, adding in title III division C a new paragraph in section 3131 (L) entitled "Comparative effectiveness research not to be used for coverage determinations or reimbursement levels."

DISPOSITION: **NOT AGREED TO** by a roll call vote of 23 yeas to 35 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey		X		Mr. Upton	X		
Mr. Boucher		X		Mr. Stearns	X		
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon				Mr. Whitfield	X		
Mr. Rush		X		Mr. Shimkus	X		
Ms. Eshoo		X		Mr. Shadegg	X		
Mr. Stupak		X		Mr. Blunt	X		
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle		X		Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick	X		
Mr. Inslee		X		Mr. Sullivan	X		
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross		X		Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson		X		Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon		X					
Mr. Barrow		X					
Mr. Hill		X					
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 74

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mrs. Capps, # 1O, adding at the end of title V of division C a new subtitle entitled "Healthy Teen Initiative to Prevent Teen Pregnancy".

DISPOSITION: **AGREED TO** by a roll call vote of 33 yeas to 23 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman	X			Mr. Barton		X	
Mr. Dingell	X			Mr. Hall	X		
Mr. Markey	X			Mr. Upton			
Mr. Boucher	X			Mr. Stearns		X	
Mr. Pallone	X			Mr. Deal		X	
Mr. Gordon				Mr. Whitfield		X	
Mr. Rush				Mr. Shimkus		X	
Ms. Eshoo	X			Mr. Shadegg		X	
Mr. Stupak		X		Mr. Blunt		X	
Mr. Engel	X			Mr. Buyer	X		
Mr. Green	X			Mr. Radanovich		X	
Ms. DeGette	X			Mr. Pitts		X	
Mrs. Capps	X			Ms. Bono Mack		X	
Mr. Doyle	X			Mr. Walden		X	
Ms. Harman	X			Mr. Terry		X	
Ms. Schakowsky	X			Mr. Rogers		X	
Mr. Gonzalez	X			Mrs. Myrick		X	
Mr. Inslee	X			Mr. Sullivan		X	
Ms. Baldwin	X			Mr. Murphy of PA		X	
Mr. Ross		X		Mr. Burgess		X	
Mr. Weiner	X			Ms. Blackburn		X	
Mr. Matheson	X			Mr. Gingrey		X	
Mr. Butterfield	X			Mr. Scalise		X	
Mr. Melancon		X					
Mr. Barrow	X						
Mr. Hill	X						
Ms. Matsui	X						
Mrs. Christensen	X						
Ms. Castor	X						
Mr. Sarbanes	X						
Mr. Murphy of CT	X						
Mr. Space	X						
Mr. McNerney	X						
Ms. Sutton	X						
Mr. Braley	X						
Mr. Welch	X						

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 75

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mr. Terry, # 1P, striking section 1732 of title VII division B and inserting a new section 1732 entitled "Extension of transitional Medical Assistance and Abstinence Education Program."

DISPOSITION: **NOT AGREED TO** by a roll call vote of 26 yeas to 29 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey		X		Mr. Upton	X		
Mr. Boucher		X		Mr. Stearns	X		
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon				Mr. Whitfield	X		
Mr. Rush				Mr. Shimkus	X		
Ms. Eshoo		X		Mr. Shadegg	X		
Mr. Stupak	X			Mr. Blunt	X		
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle		X		Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick	X		
Mr. Inslee		X		Mr. Sullivan	X		
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross		X		Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson		X		Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon	X						
Mr. Barrow	X						
Mr. Hill							
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley							
Mr. Welch		X					

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 76

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mr. Terry, No. 1V, adding in title III of division C a condition on the availability of funds in the Prevention and Wellness Trust.

DISPOSITION: **NOT AGREED TO** by a roll call vote of 23 yeas to 33 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey		X		Mr. Upton	X		
Mr. Boucher		X		Mr. Stearns	X		
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon				Mr. Whitfield	X		
Mr. Rush				Mr. Shimkus	X		
Ms. Eshoo		X		Mr. Shadegg	X		
Mr. Stupak		X		Mr. Blunt	X		
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle		X		Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick	X		
Mr. Inslee		X		Mr. Sullivan	X		
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross		X		Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson		X		Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon		X					
Mr. Barrow		X					
Mr. Hill							
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 77

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mr. Burgess, # 1X, to strike section 1121 in Division B and insert a new section 1121 relating to resetting the base year for applying the sustainable growth rates formula of payment for physician services and formula elimination and transition .

DISPOSITION: **NOT AGREED TO** by a roll call vote of 20 yeas to 32 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey		X		Mr. Upton	X		
Mr. Boucher				Mr. Stearns	X		
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon				Mr. Whitfield	X		
Mr. Rush		X		Mr. Shimkus	X		
Ms. Eshoo		X		Mr. Shadegg	X		
Mr. Stupak		X		Mr. Blunt	X		
Mr. Engel				Mr. Buyer			
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle				Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick			
Mr. Inslee		X		Mr. Sullivan			
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross		X		Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson		X		Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon		X					
Mr. Barrow		X					
Mr. Hill		X					
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 78

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mr. Deal, # 1Z, adding at the end of subtitle F or title II of division B a new section 1761 on verification requirements to prevent unauthorized aliens from receiving Medicaid benefits.

DISPOSITION: **NOT AGREED TO** by a roll call vote of 28 yeas to 29 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey		X		Mr. Upton	X		
Mr. Boucher				Mr. Stearns	X		
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon		X		Mr. Whitfield	X		
Mr. Rush		X		Mr. Shimkus	X		
Ms. Eshoo		X		Mr. Shadegg	X		
Mr. Stupak		X		Mr. Blunt	X		
Mr. Engel				Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle		X		Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick	X		
Mr. Inslee		X		Mr. Sullivan	X		
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross	X			Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson	X			Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon	X						
Mr. Barrow	X						
Mr. Hill	X						
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 79

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mr. Barton, # 1DD, adding a section at the end of title IX of division B entitled "Study Savings from Division."

DISPOSITION: **NOT AGREED TO** by a roll call vote of 25 yeas to 33 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey		X		Mr. Upton	X		
Mr. Boucher				Mr. Stearns	X		
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon		X		Mr. Whitfield	X		
Mr. Rush		X		Mr. Shimkus	X		
Ms. Eshoo		X		Mr. Shadegg	X		
Mr. Stupak		X		Mr. Blunt	X		
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle		X		Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick	X		
Mr. Inslee		X		Mr. Sullivan	X		
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross		X		Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson		X		Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon	X						
Mr. Barrow	X						
Mr. Hill		X					
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 80

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mr. Barton, # 1FF, adding at the end of title VII of division B a new subtitle I on beneficiary choice under Medicaid and SCHIP.

DISPOSITION: **NOT AGREED TO** by a roll call vote of 21 yeas to 33 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell				Mr. Hall	X		
Mr. Markey		X		Mr. Upton	X		
Mr. Boucher				Mr. Stearns			
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon		X		Mr. Whitfield	X		
Mr. Rush				Mr. Shimkus			
Ms. Eshoo		X		Mr. Shadegg	X		
Mr. Stupak		X		Mr. Blunt	X		
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle		X		Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick	X		
Mr. Inslee		X		Mr. Sullivan	X		
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross		X		Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson		X		Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon		X					
Mr. Barrow		X					
Mr. Hill		X					
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 81

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mr. Burgess, # 1KK, to add at the end of title XIX of division B a new section 1906 on liability protections.

DISPOSITION: **NOT AGREED TO** by a roll call vote of 23 yeas to 32 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell				Mr. Hall	X		
Mr. Markey		X		Mr. Upton	X		
Mr. Boucher		X		Mr. Stearns	X		
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon	X			Mr. Whitfield	X		
Mr. Rush		X		Mr. Shimkus			
Ms. Eshoo		X		Mr. Shadegg	X		
Mr. Stupak		X		Mr. Blunt	X		
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle		X		Mr. Walden	X		
Ms. Harman		X		Mr. Terry			
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick	X		
Mr. Inslee		X		Mr. Sullivan	X		
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross		X		Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson	X			Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon		X					
Mr. Barrow		X					
Mr. Hill		X					
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley							
Mr. Welch		X					

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 82

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mr. Rogers of Michigan, # 1OO, to add a section at the end of part 2 of subtitle D of title I of division B on protecting current Medicare Advantage plan coverage of seniors.

DISPOSITION: **NOT AGREED TO** by a roll call vote of 20 yeas to 34 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey		X		Mr. Upton	X		
Mr. Boucher				Mr. Stearns			
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon		X		Mr. Whitfield	X		
Mr. Rush				Mr. Shimkus			
Ms. Eshoo		X		Mr. Shadegg			
Mr. Stupak		X		Mr. Blunt	X		
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle		X		Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick	X		
Mr. Inslee		X		Mr. Sullivan	X		
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross		X		Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson		X		Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon		X					
Mr. Barrow		X					
Mr. Hill		X					
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

07/30/2009

COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 83

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mr. Weiner, # 1PP, to section 1906 at the end of title IX of division B to eliminate eligibility and benefits under parts B, C, and D of Medicare.

DISPOSITION: **NOT AGREED TO** by a roll call vote of 0 yeas to 57 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton		X	
Mr. Dingell		X		Mr. Hall			
Mr. Markey		X		Mr. Upton		X	
Mr. Boucher		X		Mr. Stearns		X	
Mr. Pallone		X		Mr. Deal		X	
Mr. Gordon		X		Mr. Whitfield		X	
Mr. Rush		X		Mr. Shimkus		X	
Ms. Eshoo		X		Mr. Shadegg		X	
Mr. Stupak		X		Mr. Blunt		X	
Mr. Engel		X		Mr. Buyer		X	
Mr. Green		X		Mr. Radanovich		X	
Ms. DeGette		X		Mr. Pitts		X	
Mrs. Capps		X		Ms. Bono Mack		X	
Mr. Doyle		X		Mr. Walden		X	
Ms. Harman		X		Mr. Terry		X	
Ms. Schakowsky		X		Mr. Rogers		X	
Mr. Gonzalez		X		Mrs. Myrick		X	
Mr. Inslee		X		Mr. Sullivan		X	
Ms. Baldwin		X		Mr. Murphy of PA		X	
Mr. Ross				Mr. Burgess		X	
Mr. Weiner		X		Ms. Blackburn		X	
Mr. Matheson		X		Mr. Gingrey		X	
Mr. Butterfield		X		Mr. Scalise		X	
Mr. Melancon		X					
Mr. Barrow		X					
Mr. Hill		X					
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 84

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mr. Deal, # 1QQ, adding section 1159 at the end of subtitle C of title I of division B on protection for physician services in emergency departments.

DISPOSITION: **NOT AGREED TO** by a roll call vote of 23 yeas to 35 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey		X		Mr. Upton	X		
Mr. Boucher		X		Mr. Stearns	X		
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon	X			Mr. Whitfield	X		
Mr. Rush		X		Mr. Shimkus			
Ms. Eshoo		X		Mr. Shadegg	X		
Mr. Stupak		X		Mr. Blunt	X		
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle		X		Mr. Walden	X		
Ms. Harman		X		Mr. Terry		X	
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick	X		
Mr. Inslee		X		Mr. Sullivan	X		
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross		X		Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson	X			Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon		X					
Mr. Barrow		X					
Mr. Hill		X					
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 85

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mrs. Capps, # 1RR, concerning rules relating to abortion services.

DISPOSITION: **AGREED TO** by a roll call vote of 30 yeas to 28 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman	X			Mr. Barton		X	
Mr. Dingell	X			Mr. Hall		X	
Mr. Markey	X			Mr. Upton		X	
Mr. Boucher	X			Mr. Stearns		X	
Mr. Pallone	X			Mr. Deal		X	
Mr. Gordon	X			Mr. Whitfield		X	
Mr. Rush	X			Mr. Shimkus		X	
Ms. Eshoo	X			Mr. Shadegg		X	
Mr. Stupak		X		Mr. Blunt		X	
Mr. Engel	X			Mr. Buyer		X	
Mr. Green	X			Mr. Radanovich		X	
Ms. DeGette	X			Mr. Pitts		X	
Mrs. Capps	X			Ms. Bono Mack		X	
Mr. Doyle	X			Mr. Walden		X	
Ms. Harman	X			Mr. Terry		X	
Ms. Schakowsky	X			Mr. Rogers		X	
Mr. Gonzalez	X			Mrs. Myrick		X	
Mr. Inslee	X			Mr. Sullivan		X	
Ms. Baldwin	X			Mr. Murphy of PA			
Mr. Ross		X		Mr. Burgess		X	
Mr. Weiner	X			Ms. Blackburn		X	
Mr. Matheson		X		Mr. Gingrey		X	
Mr. Butterfield	X			Mr. Scalise		X	
Mr. Melancon		X					
Mr. Barrow		X					
Mr. Hill		X					
Ms. Matsui	X						
Mrs. Christensen	X						
Ms. Castor	X						
Mr. Sarbanes	X						
Mr. Murphy of CT	X						
Mr. Space	X						
Mr. McNerney	X						
Ms. Sutton	X						
Mr. Braley	X						
Mr. Welch	X						

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 86

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mr. Pitts, # 1SS, to insert in division A at the appropriate place a section regarding limitation on abortion mandates. *(See later vote when Committee reconsidered this amendment.)*

DISPOSITION: **AGREED TO** by a roll call vote of 31 yeas to 27 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman	X			Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey		X		Mr. Upton	X		
Mr. Boucher		X		Mr. Stearns	X		
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon	X			Mr. Whitfield	X		
Mr. Rush		X		Mr. Shimkus	X		
Ms. Eshoo		X		Mr. Shadegg	X		
Mr. Stupak	X			Mr. Blunt	X		
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle		X		Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick	X		
Mr. Inslee		X		Mr. Sullivan	X		
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross	X			Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson	X			Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon	X						
Mr. Barrow	X						
Mr. Hill	X						
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space							
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 87

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mr. Burgess, # 1UU, to amend division A to prohibit the establishment of a federally-funded qualified health benefits plan.

DISPOSITION: **NOT AGREED TO** by a roll call vote of 24 yeas to 35 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey		X		Mr. Upton	X		
Mr. Boucher	X			Mr. Stearns	X		
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon		X		Mr. Whitfield	X		
Mr. Rush		X		Mr. Shimkus	X		
Ms. Eshoo		X		Mr. Shadegg	X		
Mr. Stupak		X		Mr. Blunt	X		
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle		X		Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick	X		
Mr. Inslee		X		Mr. Sullivan	X		
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross		X		Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson		X		Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon		X					
Mr. Barrow		X					
Mr. Hill		X					
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 88

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mr. Stearns, # 1XX, to amend section 102 in division A regarding protections for keeping current health benefit plan coverage.

DISPOSITION: **NOT AGREED TO** by a roll call vote of 26 yeas to 32 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey		X		Mr. Upton	X		
Mr. Boucher		X		Mr. Stearns	X		
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon		X		Mr. Whitfield	X		
Mr. Rush		X		Mr. Shimkus	X		
Ms. Eshoo		X		Mr. Shadegg	X		
Mr. Stupak		X		Mr. Blunt	X		
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle		X		Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick	X		
Mr. Inslee		X		Mr. Sullivan	X		
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross		X		Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson				Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon	X						
Mr. Barrow	X						
Mr. Hill	X						
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 89

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

MOTION: A motion by Mr. Dingell to table a Buyer motion to appeal the ruling of the Chair that the Blunt amendment, # 1YY, was not germane under the Committee's jurisdiction of H.R. 3200.

DISPOSITION: **AGREED TO** by a roll call vote of 36 yeas to 22 nays, with 1 member voting "Present."

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman	X			Mr. Barton			X
Mr. Dingell	X			Mr. Hall		X	
Mr. Markey	X			Mr. Upton		X	
Mr. Boucher	X			Mr. Stearns		X	
Mr. Pallone	X			Mr. Deal		X	
Mr. Gordon	X			Mr. Whitfield		X	
Mr. Rush	X			Mr. Shimkus		X	
Ms. Eshoo	X			Mr. Shadegg		X	
Mr. Stupak	X			Mr. Blunt		X	
Mr. Engel	X			Mr. Buyer		X	
Mr. Green	X			Mr. Radanovich		X	
Ms. DeGette	X			Mr. Pitts		X	
Mrs. Capps	X			Ms. Bono Mack		X	
Mr. Doyle	X			Mr. Walden		X	
Ms. Harman	X			Mr. Terry		X	
Ms. Schakowsky	X			Mr. Rogers		X	
Mr. Gonzalez	X			Mrs. Myrick		X	
Mr. Inslee	X			Mr. Sullivan			
Ms. Baldwin	X			Mr. Murphy of PA		X	
Mr. Ross	X			Mr. Burgess		X	
Mr. Weiner	X			Ms. Blackburn		X	
Mr. Matheson	X			Mr. Gingrey		X	
Mr. Butterfield	X			Mr. Scalise		X	
Mr. Melancon	X						
Mr. Barrow	X						
Mr. Hill	X						
Ms. Matsui	X						
Mrs. Christensen	X						
Ms. Castor	X						
Mr. Sarbanes	X						
Mr. Murphy of CT	X						
Mr. Space	X						
Mr. McNerney	X						
Ms. Sutton	X						
Mr. Braley	X						
Mr. Welch	X						

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 90

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

MOTION: A motion by Mr. Waxman to reconsider the vote on the Pitts amendment, # 1SS.

DISPOSITION: **AGREED TO** by a roll call vote of 35 yeas to 24 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman	X			Mr. Barton		X	X
Mr. Dingell	X			Mr. Hall		X	
Mr. Markey	X			Mr. Upton		X	
Mr. Boucher	X			Mr. Stearns		X	
Mr. Pallone	X			Mr. Deal		X	
Mr. Gordon	X			Mr. Whitfield		X	
Mr. Rush	X			Mr. Shimkus		X	
Ms. Eshoo	X			Mr. Shadegg		X	
Mr. Stupak		X		Mr. Blunt		X	
Mr. Engel	X			Mr. Buyer		X	
Mr. Green	X			Mr. Radanovich		X	
Ms. DeGette	X			Mr. Pitts		X	
Mrs. Capps	X			Ms. Bono Mack		X	
Mr. Doyle	X			Mr. Walden		X	
Ms. Harman	X			Mr. Terry		X	
Ms. Schakowsky	X			Mr. Rogers		X	
Mr. Gonzalez	X			Mrs. Myrick		X	
Mr. Inslee	X			Mr. Sullivan		X	
Ms. Baldwin	X			Mr. Murphy of PA		X	
Mr. Ross	X			Mr. Burgess		X	
Mr. Weiner	X			Ms. Blackburn		X	
Mr. Matheson	X			Mr. Gingrey		X	
Mr. Butterfield	X			Mr. Scalise		X	
Mr. Melancon	X						
Mr. Barrow	X						
Mr. Hill	X						
Ms. Matsui	X						
Mrs. Christensen	X						
Ms. Castor	X						
Mr. Sarbanes	X						
Mr. Murphy of CT	X						
Mr. Space	X						
Mr. McNerney	X						
Ms. Sutton	X						
Mr. Braley	X						
Mr. Welch	X						

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 91

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mr. Pitts, # 1SS, to insert in division A at the appropriate place a section regarding limitation on abortion mandates.

DISPOSITION: **NOT AGREED TO** by a roll call vote of 29 yeas to 30 nays, *the Committee having agreed to reconsider the vote taken earlier on this amendment.*

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey		X		Mr. Upton	X		
Mr. Boucher		X		Mr. Stearns	X		
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon		X		Mr. Whitfield	X		
Mr. Rush		X		Mr. Shimkus	X		
Ms. Eshoo		X		Mr. Shadegg	X		
Mr. Stupak	X			Mr. Blunt	X		
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle		X		Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick	X		
Mr. Inslee		X		Mr. Sullivan	X		
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross	X			Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson	X			Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon	X						
Mr. Barrow	X						
Mr. Hill	X						
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 92

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mr. Shadegg, # 1ZZ, amending sections 223 and 224 relating to negotiation of payment rates for the public health insurance option and not using negotiated payment rates of any other government program.

DISPOSITION: **NOT AGREED TO** by a roll call vote of 29 yeas to 29 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey		X		Mr. Upton	X		
Mr. Boucher	X			Mr. Stearns	X		
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon	X			Mr. Whitfield	X		
Mr. Rush		X		Mr. Shimkus	X		
Ms. Eshoo		X		Mr. Shadegg	X		
Mr. Stupak		X		Mr. Blunt	X		
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle		X		Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick	X		
Mr. Inslee		X		Mr. Sullivan	X		
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross				Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson	X			Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon	X						
Mr. Barrow	X						
Mr. Hill		X					
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space	X						
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 93

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mr. Barton, # 1BBb, striking subtitle B of title II of division A relating to the public health insurance option and inserting a new subtitle "Protecting Affordability through Reinsurance or High Risk Pooling."

DISPOSITION: **NOT AGREED TO** by a roll call vote of 22 yeas to 35 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey		X		Mr. Upton	X		
Mr. Boucher				Mr. Stearns	X		
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon		X		Mr. Whitfield	X		
Mr. Rush		X		Mr. Shimkus	X		
Ms. Eshoo		X		Mr. Shadegg	X		
Mr. Stupak		X		Mr. Blunt	X		
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle		X		Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick	X		
Mr. Inslee		X		Mr. Sullivan	X		
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross		X		Mr. Burgess			
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson		X		Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon		X					
Mr. Barrow		X					
Mr. Hill		X					
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

07/31/2009

COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 94

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mr. Buyer, # 1KKk, inserting at the end of subtitle D of title I of division A section 128 relating to programs of health promotion or disease prevention.

DISPOSITION: **NOT AGREED TO** by a roll call vote of 24 yeas to 34 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey		X		Mr. Upton	X		
Mr. Boucher		X		Mr. Stearns	X		
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon		X		Mr. Whitfield	X		
Mr. Rush		X		Mr. Shimkus	X		
Ms. Eshoo		X		Mr. Shadegg	X		
Mr. Stupak		X		Mr. Blunt	X		
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle		X		Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez				Mrs. Myrick	X		
Mr. Inslee		X		Mr. Sullivan	X		
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross		X		Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson		X		Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon		X					
Mr. Barrow		X					
Mr. Hill		X					
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney	X						
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

07/31/2009

COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 95

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mr. Rogers of Michigan, # 1QQq, adding at the end of section 201(c) that health benefit plans offered in conjunction with a health savings account shall be treated as qualified health benefit plans that may be offered through the Health Insurance Exchange.

DISPOSITION: **NOT AGREED TO** by a roll call vote of 26 yeas to 33 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey		X		Mr. Upton	X		
Mr. Boucher		X		Mr. Stearns	X		
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon		X		Mr. Whitfield	X		
Mr. Rush		X		Mr. Shimkus	X		
Ms. Eshoo		X		Mr. Shadegg	X		
Mr. Stupak		X		Mr. Blunt	X		
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle		X		Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick	X		
Mr. Inslee		X		Mr. Sullivan	X		
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross		X		Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson	X			Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon	X						
Mr. Barrow		X					
Mr. Hill	X						
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 96

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mr. Terry, # 1OOo, striking subtitles A and B of title II of division A and inserting a new subtitle that entitles certain U.S. citizens to enroll in a qualified health benefits plan having the same terms and conditions as government employees under chapter 89 of title 5, U.S.C.

DISPOSITION: **NOT AGREED TO** by a roll call vote of 28 yeas to 31 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey		X		Mr. Upton	X		
Mr. Boucher		X		Mr. Stearns	X		
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon		X		Mr. Whitfield	X		
Mr. Rush		X		Mr. Shimkus	X		
Ms. Eshoo		X		Mr. Shadegg	X		
Mr. Stupak	X			Mr. Blunt	X		
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle		X		Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick	X		
Mr. Inslee		X		Mr. Sullivan	X		
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross		X		Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson	X			Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon	X						
Mr. Barrow	X						
Mr. Hill		X					
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space	X						
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 97

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mr. Stupak, # 1UUu, to insert a new section in division A regarding limitation of abortion funding authorized under this Act.

DISPOSITION: **NOT AGREED TO** by a roll call vote of 27 yeas to 31 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey		X		Mr. Upton	X		
Mr. Boucher		X		Mr. Stearns	X		
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon		X		Mr. Whitfield	X		
Mr. Rush		X		Mr. Shimkus		X	
Ms. Eshoo		X		Mr. Shadegg	X		
Mr. Stupak	X			Mr. Blunt	X		
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle		X		Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick	X		
Mr. Inslee		X		Mr. Sullivan	X		
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross	X			Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson	X			Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon	X						
Mr. Barrow	X						
Mr. Hill							
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 98

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mr. Radanovich, # 1VVv, adding to section 221 of Division A that the Secretary shall have the public health insurance option comply with the same requirements as are applied to any private qualified health benefit plan offered through the Health Insurance Exchange.

DISPOSITION: **NOT AGREED TO** by a roll call vote of 23 yeas to 32 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey		X		Mr. Upton	X		
Mr. Boucher				Mr. Stearns	X		
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon				Mr. Whitfield	X		
Mr. Rush		X		Mr. Shimkus	X		
Ms. Eshoo		X		Mr. Shadegg	X		
Mr. Stupak		X		Mr. Blunt			
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle		X		Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick	X		
Mr. Inslee		X		Mr. Sullivan	X		
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross		X		Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson	X			Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon		X					
Mr. Barrow		X					
Mr. Hill							
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 99

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Ms. Eshoo, # 1XXx, to add at the end of title V of division C a subtitle entitled "Pathway for Biosimilars".

DISPOSITION: **AGREED TO** by a roll call vote of 47 yeas to 11 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey	X			Mr. Upton	X		
Mr. Boucher	X			Mr. Stearns	X		
Mr. Pallone		X		Mr. Deal		X	
Mr. Gordon	X			Mr. Whitfield	X		
Mr. Rush	X			Mr. Shimkus	X		
Ms. Eshoo	X			Mr. Shadegg	X		
Mr. Stupak	X			Mr. Blunt			
Mr. Engel	X			Mr. Buyer	X		
Mr. Green	X			Mr. Radanovich	X		
Ms. DeGette	X			Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle	X			Mr. Walden	X		
Ms. Harman	X			Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez	X			Mrs. Myrick	X		
Mr. Inslee	X			Mr. Sullivan	X		
Ms. Baldwin	X			Mr. Murphy of PA	X		
Mr. Ross	X			Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson	X			Mr. Gingrey	X		
Mr. Butterfield	X			Mr. Scalise	X		
Mr. Melancon	X						
Mr. Barrow	X						
Mr. Hill	X						
Ms. Matsui	X						
Mrs. Christensen	X						
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT	X						
Mr. Space	X						
Mr. McNerney	X						
Ms. Sutton		X					
Mr. Braley	X						
Mr. Welch		X					

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 100

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mr. Gingrey, # 1AAaa, adding at the end of title IX of division B a new section that requires the Secretary to ensure any savings to the Medicare program resulting from this division shall be used solely for improving affordability of health care for Medicare beneficiaries.

DISPOSITION: **NOT AGREED TO** by a roll call vote of 23 yeas to 35 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey		X		Mr. Upton	X		
Mr. Boucher		X		Mr. Stearns			
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon		X		Mr. Whitfield	X		
Mr. Rush		X		Mr. Shimkus	X		
Ms. Eshoo		X		Mr. Shadegg	X		
Mr. Stupak		X		Mr. Blunt	X		
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle		X		Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick	X		
Mr. Inslee		X		Mr. Sullivan	X		
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross		X		Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson		X		Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon	X						
Mr. Barrow		X					
Mr. Hill		X					
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 101

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mr. Ross, # 1EEee, reducing affordability credits, helping more small employers; establishing a Center for Medicare and Medicaid Payment Innovation within CMS; and that enrollment in public health insurance option is voluntary.

DISPOSITION: **AGREED TO** by a roll call vote of 33 yeas to 26 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman	X			Mr. Barton		X	
Mr. Dingell	X			Mr. Hall		X	
Mr. Markey	X			Mr. Upton		X	
Mr. Boucher	X			Mr. Stearns		X	
Mr. Pallone	X			Mr. Deal		X	
Mr. Gordon	X			Mr. Whitfield		X	
Mr. Rush	X			Mr. Shimkus		X	
Ms. Eshoo	X			Mr. Shadegg		X	
Mr. Stupak		X		Mr. Blunt		X	
Mr. Engel		X		Mr. Buyer		X	
Mr. Green	X			Mr. Radanovich		X	
Ms. DeGette	X			Mr. Pitts		X	
Mrs. Capps	X			Ms. Bono Mack		X	
Mr. Doyle	X			Mr. Walden		X	
Ms. Harman		X		Mr. Terry		X	
Ms. Schakowsky	X			Mr. Rogers		X	
Mr. Gonzalez	X			Mrs. Myrick		X	
Mr. Inslee	X			Mr. Sullivan		X	
Ms. Baldwin	X			Mr. Murphy of PA		X	
Mr. Ross	X			Mr. Burgess		X	
Mr. Weiner	X			Ms. Blackburn		X	
Mr. Matheson	X			Mr. Gingrey		X	
Mr. Butterfield	X			Mr. Scalise		X	
Mr. Melancon	X						
Mr. Barrow	X						
Mr. Hill	X						
Ms. Matsui	X						
Mrs. Christensen	X						
Ms. Castor	X						
Mr. Sarbanes	X						
Mr. Murphy of CT	X						
Mr. Space	X						
Mr. McNerney	X						
Ms. Sutton	X						
Mr. Braley	X						
Mr. Welch	X						

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 102

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Ms. Baldwin, # 1GGgg, to establish a prescription drug formulary under the public option, pharmacy benefit managers transparency requirements, and pilot programs for state accountable care organizations, and to expand electronic transactions in Medicare.

DISPOSITION: **AGREED TO** by a roll call vote of 32 yeas to 26 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman	X			Mr. Barton		X	
Mr. Dingell	X			Mr. Hall		X	
Mr. Markey	X			Mr. Upton		X	
Mr. Boucher	X			Mr. Stearns		X	
Mr. Pallone	X			Mr. Deal		X	
Mr. Gordon	X			Mr. Whitfield		X	
Mr. Rush	X			Mr. Shimkus		X	
Ms. Eshoo	X			Mr. Shadegg		X	
Mr. Stupak	X			Mr. Blunt		X	
Mr. Engel	X			Mr. Buyer		X	
Mr. Green	X			Mr. Radanovich		X	
Ms. DeGette	X			Mr. Pitts		X	
Mrs. Capps	X			Ms. Bono Mack		X	
Mr. Doyle	X			Mr. Walden		X	
Ms. Harman	X			Mr. Terry		X	
Ms. Schakowsky	X			Mr. Rogers		X	
Mr. Gonzalez				Mrs. Myrick		X	
Mr. Inslee	X			Mr. Sullivan		X	
Ms. Baldwin	X			Mr. Murphy of PA		X	
Mr. Ross	X			Mr. Burgess		X	
Mr. Weiner	X			Ms. Blackburn		X	
Mr. Matheson		X		Mr. Gingrey		X	
Mr. Butterfield	X			Mr. Scalise		X	
Mr. Melancon		X					
Mr. Barrow		X					
Mr. Hill	X						
Ms. Matsui	X						
Mrs. Christensen	X						
Ms. Castor	X						
Mr. Sarbanes	X						
Mr. Murphy of CT	X						
Mr. Space	X						
Mr. McNerney	X						
Ms. Sutton	X						
Mr. Braley	X						
Mr. Welch	X						

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 103

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mr. Shadegg, # 1HHhh, inserting a new section 138 in Division A where if the 5-year breast cancer survival rate in the US declined by .01% or more, women and families with at least 1 woman would be permitted to choose a health benefit plan with no mandated minimum benefits and still be eligible for affordability credits.

DISPOSITION: **NOT AGREED TO** by a roll call vote of 22 yeas to 36 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey		X		Mr. Upton	X		
Mr. Boucher		X		Mr. Stearns	X		
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon		X		Mr. Whitfield	X		
Mr. Rush		X		Mr. Shimkus	X		
Ms. Eshoo		X		Mr. Shadegg	X		
Mr. Stupak		X		Mr. Blunt	X		
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle		X		Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick	X		
Mr. Inslee		X		Mr. Sullivan			
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross		X		Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson		X		Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon		X					
Mr. Barrow		X					
Mr. Hill		X					
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space		X					
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 104

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Ms. Schakowsky, # 1IIii, relating to contingent adjustments for additional savings, limitation on premium increases under Exchange-participating health benefits plans and negotiation of lower covered part D drug prices for Medicare beneficiaries.

DISPOSITION: **AGREED TO** by a roll call vote of 32 yeas to 23 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman	X			Mr. Barton		X	
Mr. Dingell	X			Mr. Hall		X	
Mr. Markey	X			Mr. Upton		X	
Mr. Boucher	X			Mr. Stearns		X	
Mr. Pallone	X			Mr. Deal		X	
Mr. Gordon				Mr. Whitfield		X	
Mr. Rush	X			Mr. Shimkus		X	
Ms. Eshoo	X			Mr. Shadegg		X	
Mr. Stupak	X			Mr. Blunt		X	
Mr. Engel	X			Mr. Buyer		X	
Mr. Green	X			Mr. Radanovich			
Ms. DeGette	X			Mr. Pitts		X	
Mrs. Capps	X			Ms. Bono Mack		X	
Mr. Doyle	X			Mr. Walden		X	
Ms. Harman	X			Mr. Terry		X	
Ms. Schakowsky	X			Mr. Rogers			
Mr. Gonzalez	X			Mrs. Myrick		X	
Mr. Inslee	X			Mr. Sullivan		X	
Ms. Baldwin	X			Mr. Murphy of PA		X	
Mr. Ross	X			Mr. Burgess		X	
Mr. Weiner	X			Ms. Blackburn		X	
Mr. Matheson		X		Mr. Gingrey		X	
Mr. Butterfield	X			Mr. Scalise		X	
Mr. Melancon							
Mr. Barrow	X						
Mr. Hill		X					
Ms. Matsui	X						
Mrs. Christensen	X						
Ms. Castor	X						
Mr. Sarbanes	X						
Mr. Murphy of CT	X						
Mr. Space	X						
Mr. McNerney	X						
Ms. Sutton	X						
Mr. Braley	X						
Mr. Welch	X						

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COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 105

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

AMENDMENT: An amendment to the Waxman amendment in the nature of a substitute offered by Mr. Hall, # 1JJjj, to amend section 1161 of division B relating to phase-in of reduction in payment for Medicare Advantage plans.

DISPOSITION: **NOT AGREED TO** by a roll call vote of 27 yeas to 31 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman		X		Mr. Barton	X		
Mr. Dingell		X		Mr. Hall	X		
Mr. Markey		X		Mr. Upton	X		
Mr. Boucher				Mr. Stearns	X		
Mr. Pallone		X		Mr. Deal	X		
Mr. Gordon		X		Mr. Whitfield	X		
Mr. Rush		X		Mr. Shimkus	X		
Ms. Eshoo		X		Mr. Shadegg	X		
Mr. Stupak		X		Mr. Blunt	X		
Mr. Engel		X		Mr. Buyer	X		
Mr. Green		X		Mr. Radanovich	X		
Ms. DeGette		X		Mr. Pitts	X		
Mrs. Capps		X		Ms. Bono Mack	X		
Mr. Doyle		X		Mr. Walden	X		
Ms. Harman		X		Mr. Terry	X		
Ms. Schakowsky		X		Mr. Rogers	X		
Mr. Gonzalez		X		Mrs. Myrick	X		
Mr. Inslee		X		Mr. Sullivan	X		
Ms. Baldwin		X		Mr. Murphy of PA	X		
Mr. Ross		X		Mr. Burgess	X		
Mr. Weiner		X		Ms. Blackburn	X		
Mr. Matheson	X			Mr. Gingrey	X		
Mr. Butterfield		X		Mr. Scalise	X		
Mr. Melancon	X						
Mr. Barrow		X					
Mr. Hill	X						
Ms. Matsui		X					
Mrs. Christensen		X					
Ms. Castor		X					
Mr. Sarbanes		X					
Mr. Murphy of CT		X					
Mr. Space	X						
Mr. McNerney		X					
Ms. Sutton		X					
Mr. Braley		X					
Mr. Welch		X					

07/31/2009

COMMITTEE ON ENERGY AND COMMERCE – 111TH CONGRESS
ROLL CALL VOTE # 106

BILL: **H.R. 3200**, the "America's Affordable Health Choices Act of 2009".

MOTION: A Motion by Mr. Dingell to order H.R. 3200 favorably reported to the House, amended. (Final Passage)

DISPOSITION: **AGREED TO** by a roll call vote of 31 yeas to 28 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Waxman	X			Mr. Barton		X	
Mr. Dingell	X			Mr. Hall		X	
Mr. Markey	X			Mr. Upton		X	
Mr. Boucher		X		Mr. Stearns		X	
Mr. Pallone	X			Mr. Deal		X	
Mr. Gordon	X			Mr. Whitfield		X	
Mr. Rush	X			Mr. Shimkus		X	
Ms. Eshoo	X			Mr. Shadegg		X	
Mr. Stupak		X		Mr. Blunt		X	
Mr. Engel	X			Mr. Buyer		X	
Mr. Green	X			Mr. Radanovich		X	
Ms. DeGette	X			Mr. Pitts		X	
Mrs. Capps	X			Ms. Bono Mack		X	
Mr. Doyle	X			Mr. Walden		X	
Ms. Harman	X			Mr. Terry		X	
Ms. Schakowsky	X			Mr. Rogers		X	
Mr. Gonzalez	X			Mrs. Myrick		X	
Mr. Inslee	X			Mr. Sullivan		X	
Ms. Baldwin	X			Mr. Murphy of PA		X	
Mr. Ross	X			Mr. Burgess		X	
Mr. Weiner	X			Ms. Blackburn		X	
Mr. Matheson		X		Mr. Gingrey		X	
Mr. Butterfield	X			Mr. Scalise		X	
Mr. Melancon		X					
Mr. Barrow		X					
Mr. Hill	X						
Ms. Matsui	X						
Mrs. Christensen	X						
Ms. Castor	X						
Mr. Sarbanes	X						
Mr. Murphy of CT	X						
Mr. Space	X						
Mr. McNerney	X						
Ms. Sutton	X						
Mr. Braley	X						
Mr. Welch	X						

07/31/2009

COMMITTEE OVERSIGHT FINDINGS AND RECOMMENDATIONS

In compliance with clause 3(c)(1) of rule XIII and clause 2(b)(1) of rule X of the Rules of the House of Representatives, the Committee's oversight findings and recommendations are reflected in the body of this report.

NEW BUDGET AUTHORITY AND CONGRESSIONAL BUDGET OFFICE ESTIMATE

With respect to the requirements of clause 3(c)(2) of House rule XIII and section 308(a) of the Congressional Budget Act of 1974 and with respect to requirements of clause 3(c)(3) of House rule XIII and section 402 of the Congressional Budget Act of 1974, the Committee anticipates that a CBO cost estimate letter on H.R. 3200 will address these issues when the bill proceeds to consideration on the House floor. CBO is unable to provide a cost estimate prior to the reconciliation of the versions of the bill as amended and reported by the three committees of jurisdiction.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

In accordance with clause 3(c) of House rule XIII, the Committee finds that the goal of H.R. 3200 is to increase access to affordable quality health coverage and contain costs.

CONSTITUTIONAL AUTHORITY STATEMENT

Pursuant to clause 3(d)(1) of rule XIII of the Rules of the House of Representatives, the Committee finds that the constitutional authority for H.R. 3200 is provided in clauses 1, 3, and 18 of Article I, section 8 of the United States Constitution.

EARMARKS AND TAX AND TARIFF BENEFITS

H.R. 3200 does not contain any congressional earmarks, limited tax benefits, or limited tariff benefits as defined in clause 9 of rule XXI of the Rules of the House of Representatives.

ADVISORY COMMITTEE STATEMENT

The Committee finds that the legislation establishes or authorizes the establishment of advisory committees within the definition of 5 U.S.C. App., Section 5(b). Section 123 of the bill establishes a Health Benefits Advisory Committee. The Committee finds this committee is needed to make recommendations on covered benefits and essential, enhanced, and premium plans. Section 1191 establishes a Telehealth Advisory Committee. The Committee finds this committee is needed to advise the Secretary of Health and Human Services on policies of the Centers for Medicare and Medicaid Services regarding telehealth services. Section 1401 establishes a Comparative Effectiveness Research Commission, which the Committee finds is necessary to oversee and evaluate the activities of the Center for Comparative Effectiveness Research established by the bill.

In addition, section 2261 establishes an Advisory Committee on Health Workforce Evaluation and Assessment. The Committee finds this entity is needed to make recommendations to the Secretary of Health and Human Services regarding classifications of

the health workforce; standardized methodologies and procedures to enumerate the health workforce; the supply, diversity, and geographic distribution of the health workforce; retention of the health workforce; and policies to carry out these recommendations. Section 2310 establishes a Task Force on Clinical Preventive Services, which the Committee finds is necessary to assist the Secretary of Health and Human Services in the review of scientific evidence related to costs, benefits, effectiveness, and appropriateness of clinical preventive services, gaps in such services, and other issues relating to clinical preventive services. Section 2310 also establishes a Task Force on Community Preventive Services, which the Committee finds is necessary to assist the Secretary of Health and Human Services in the review of scientific evidence related to costs, benefits, effectiveness, and appropriateness of community preventive services, gaps in such services, and other issues relating to community preventive services. Section 2552 establishes the Interagency Pain Research Coordinating Committee. The Committee finds this entity is needed to coordinate all efforts within the Department of Health and Human Services and other federal agencies that relate to pain research.

APPLICABILITY OF LAW TO THE LEGISLATIVE BRANCH

Section 102(b)(3) of Public Law 104–1, the Congressional Accountability Act, requires a description of the application of this bill to the legislative branch. The Committee has determined that the bill would apply to the legislative branch and its employees in the same way it would apply to employers and employees in the private sector.

FEDERAL MANDATES STATEMENT

Section 423 of the Congressional Budget and Impoundment Act (as amended by section 101(a)(2) of the Unfunded Mandates Reform Act, P.L. 104–4) requires a statement of whether the provisions of the reported bill include unfunded mandates. The Committee anticipates that this issue will be addressed in a CBO cost estimate letter for the bill when it proceeds to consideration on the House floor.

COMMITTEE COST ESTIMATE

Clause 3(d) of rule XIII of the Rules of the House of Representatives requires an estimate and comparison of the costs that would be incurred in carrying out H.R. 3200. The Committee anticipates that a CBO cost estimate letter will address these issues when the bill proceeds to consideration on the House floor.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

Sec. 1. Short Title; Table of Divisions, Titles, and Subtitles

The short title may be cited as the America's Affordable Health Choices Act of 2009 . The section also provides a table of contents for the divisions, titles, and subtitles of the bill. This Act is divided into divisions, titles, and subtitles as follows:

DIVISION A—AFFORDABLE HEALTH CARE CHOICES

Sec. 100. Purpose; Table of Contents of Division; General Definitions

Purpose

The purpose of this division is to provide affordable, quality health care for all Americans and reduce the growth in health care spending. This division achieves this purpose by building on what works in today's health care system, while repairing the aspects that are broken by:

- Enacting strong insurance market reforms;
- Creating a new Health Insurance Exchange, with a public health insurance option alongside private plans;
- Including sliding scale affordability credits; and
- Initiating shared responsibility among workers, employers, and the government.

This division institutes health delivery system reforms both to increase quality and to reduce growth in health spending so that health care becomes more affordable for businesses, families, and government.

General Definitions (Created within this Act)

- *Acceptable Coverage.*—a qualified health benefit plan coverage, coverage under a grandfathered health insurance coverage or current group health plan, Medicare Part A, Medicaid, Military Health System, Veteran's Health Care Program (VA), and other coverage the Secretary of HHS in coordination with the Health Choices Commissioner sees fit.
- *Basic Plan.*—a plan that offers the essential benefits package's minimum requirements to be a qualified health benefits plan approximately 70% of the actuarial value of the benefits provided.
- *Cost-sharing.*—includes deductibles, coinsurance, copayments, and similar charges but does not include premiums or any network payment differential for covered services or spending for non-covered services.
- *Employment-Based Health Plan.*—the term given to group health plans (as defined in section 733(a)(1) of ERISA as an employee welfare benefit plan to the extent that plan provides medical care to employees or their dependents, either directly, through insurance or otherwise)—and is comprised of federal and state government plans, tribal plans and church plans.
- *Enhanced Plan.*—a plan that offers, in addition to the level of benefits under a basic plan, a lower level of cost-sharing equivalent to approximately 85% of the actuarial value of the benefits provided.
- *Essential Benefits Package.*—health benefits coverage, consistent with the standards set forth by the Secretary no later than 18 months after enactment of this Act.
- *Health Benefits Plan.*—health insurance coverage and a group health plan, including the public health insurance option.
- *Health Insurance Exchange.*—created by this bill to facilitate access of individuals and employers, through a transparent process, to a variety of choices of affordable, quality health insurance coverage, including a public health insurance option.

• *Premium Plan*.—a plan that offers, in addition to the level of benefits under a basic plan, a lower level of cost-sharing equivalent to approximately 95% of the actuarial value of the benefits provided.

• *Premium Plus Plan*.—a premium plan that also offers additional benefits, such as oral health and vision care, all of which is approved by the Commissioner.

• *Qualified Health Benefits Plan (QHBP)*.—a health benefits plan that meets the requirements set forth in Title I (by the Secretary) including the public health insurance option and cooperatives.

• *QHBP Offering Entity*.—an entity can be any of the following: a health benefits plan (that is a group health plan) in which the employer is the main source of financing, health insurance coverage which the insurance issuer is offering the coverage (to include cooperatives), the public health insurance option, a non-federal government plan established by the state or political subdivision of a state, and a federal government plan.

• *Public Health Insurance Option*.—a public plan (only available through the Health Insurance Exchange) with payment rates negotiated by the Secretary. The public option would be required to offer basic, enhanced, and premium plans, and would be allowed to offer premium-plus plans.

• *Service Area, Premium Rating Area*.—with respect to health insurance coverage: (1) if not within the Health Insurance Exchange, an area established by a QHBP offering entity of such coverage in accordance with applicable state law or (2) within the Health Insurance Exchange, an area established by such entity in accordance with state law and applicable rules set forth by the Commissioner for Exchange-participating health benefits plans.

• *State*.—the 50 states and the District of Columbia.

• *Y1, Y2, ETC*.—are numbered terms that mean 2013, 2014, and subsequent years.

TITLE I—PROTECTIONS AND STANDARDS FOR QUALIFIED HEALTH BENEFITS PLANS

Subtitle A—General Standards

Sec. 101. Requirements reforming health insurance marketplace

Current Law

Regulation of the private health insurance market is primarily done at the state level. State regulatory authority is broad in scope and includes requirements related to the issuance and renewal of coverage, benefits, rating, consumer protections, and other issues. Federal regulation of the private market is more narrow in scope and applicable mostly to employer-sponsored health insurance (i.e., through the Employee Retirement Income Security Act of 1974 (ERISA)) and through established federal minimum standards (i.e., through the Genetic Information Nondiscrimination Act of 2008 and the Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008, etc.).

Proposed Law

This provision would require Qualified Health Benefits Plans (QHBPs) to meet the new federal health insurance standards specified in subtitles B (relating to affordable coverage), C (relating to essential benefits) and D (relating to consumer protection) of Title I. The section also provides terminology for the phrases "enrollment in employment-based health plans" and "individual and group health insurance coverage."

Sec. 102. Protecting the choice to keep current coverage

Current Law

See description under Section 101.

Proposed Law

"Grandfathered health insurance coverage" would be defined as individual health insurance coverage that is in effect before the first day of Y1, as long as the insurance carrier does not (1) enroll new individuals on or after the first day of Y1 (would not affect subsequent enrollment of a dependent); (2) change any terms or conditions of the individual coverage, except as required by law; and (3) vary the percentage increase in premiums for a risk group of enrollees without changing the premium for all enrollees in the same risk group at the same rate, as specified by the Commissioner. The Commissioner would establish a 5-year grace period beginning Y1 for existing group health plans to transition to the new federal health insurance standards applied to QHBPs. Limited benefits plans specified in the provision, such as dental only, vision only, flexible spending arrangements, and others, are unaffected by these reforms and may continue to be sold to new applicants irrespective of other reforms.

Individual health insurance coverage that is not grandfathered may only be offered after the first day of Y1 as an Exchange plan. Excepted benefits (e.g., accident or disability insurance) could be offered as long as they are offered and priced separately from health insurance coverage.

For purposes of the individual mandate (established under title III of Division A), an individual would be required to have "acceptable coverage." In order for an individual health insurance policy to be considered acceptable coverage, the policy would be either grandfathered health insurance coverage, in effect prior to Y1, or offered through the Exchange (established under title II of Division A). Group health coverage provided during the grace period would be considered acceptable coverage.

Nothing in Division A of this bill would prevent the offering of stand-alone dental and vision plans under state law. The requirements of qualified health benefits plans would not apply to a stand-alone plan that was offered and priced separately from a qualified health benefits plan.

Subtitle B—Standards Guaranteeing Access to Affordable Coverage

Sec. 111. Prohibiting pre-existing condition exclusions

Current Law

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), which amended ERISA, limits the duration that issuers in the group market may exclude coverage for pre-existing health conditions for "HIPAA eligible" individuals, among other provisions. Group plans may impose pre-existing condition exclusions for no longer than 12 months (18 months in the case of a late enrollee), and must decrease that exclusion period by the number of months an enrollee had prior "creditable coverage." HIPAA outright prohibits issuers in the individual market from excluding coverage for pre-existing conditions for certain HIPAA eligible individuals.

All states require health issuers to reduce the period of time when coverage for pre-existing health conditions may be excluded, in compliance with HIPAA. As of January 2009 in the small group market, 21 states had pre-existing condition exclusion rules that provided consumer protection above the federal standard. And, as of December 2008, 42 states limit the period of time when coverage for pre-existing health conditions may be excluded for non-HIPAA eligible enrollees in the individual market.

Proposed Law

This provision would prohibit a qualified health benefits plan from excluding coverage for pre-existing health conditions, or otherwise limit or condition such coverage with respect to an individual or dependent based on any health status-related factors. Such factors include health status, medical condition (including both physical and mental illnesses), claims experience, receipt of health care, medical history, genetic information, evidence of insurability (including conditions arising out of acts of domestic violence) and disability.

Sec. 112. Guaranteed issue and renewal for insured plans

Current Law

HIPAA requires that coverage sold to small groups (2–50 employees) must be sold on a guaranteed issue basis. That is, the issuer must accept every small employer that applies for coverage. (Guaranteed issue rules do not address premiums.) HIPAA also guarantees that each issuer in the individual market make at least two policies available ("guaranteed availability") to all HIPAA eligible individuals. In addition, HIPAA guarantees renewal or continuation of group coverage at the option of the plan sponsor (e.g., employer) and individual coverage at the option of the individual, with some exceptions. Insurers may not renew coverage under specified circumstances, such as nonpayment of premiums or fraud.

All states require issuers to offer policies to firms with 2–50 workers on a guaranteed issue basis, in compliance with HIPAA. As of January 2009 in the small group market, 13 states also require issuers to offer policies on a guaranteed issue basis to self-employed "groups of one." And, as of December 2008, 15 states require issuers in the individual market to offer some or all of their

insurance products on a guaranteed issue basis to non-HIPAA eligible individuals.

Proposed Law

This provision would require issuers to offer all health insurance coverage on a guaranteed issue and renewal basis beginning in Y1, whether offered through the Exchange (established under subtitle A of Title II), through any employment-based health plan, or otherwise. Rescissions of coverage would be prohibited, except in cases of fraud.

Sec. 113. Insurance rating rules

Current Law

There are no federal rating rules applicable to the private health insurance market. However, many states currently impose rating rules on insurance carriers in the small group and individual markets. Existing state rating rules restrict an insurer's ability to price insurance policies according to the risk of the person or group seeking coverage, and vary considerably from state to state. Such restrictions may specify the case characteristics (or risk factors) that may or may not be considered when setting a premium, such as age. The spectrum of existing state rating limitations ranges from pure community rating, to adjusted (or modified) community rating to rate bands. Some states have no limits on rating practices which permits insurance companies to charge unlimited amounts. Pure community rating means that premiums cannot vary based on any characteristic related to a person's or group's risk, including health. Adjusted community rating means that premiums cannot vary based on health, but may vary based on other key risk factors, such as gender or industry of work. Rate bands allow premium variation based on health and/or age, but such variation is limited according to a range specified by the state. For each characteristic, the state typically specifies the amount of allowable variation. As of January 2009 in the small group market, one state has pure community rating rules, eleven have adjusted community rating rules, and 35 have rate bands. As of December 2008 in the individual market, two states have pure community rating rules, five have adjusted community rating rules, and eleven have rate bands.

There are no federally-established rating areas in the private health insurance market. However, some states have enacted rating rules that include geographic location as a factor on which premiums may vary. In these cases, the state has established rating areas. Typically, states use counties or zip codes to define those areas.

Proposed Law

This provision would impose a new federal floor on rating rules for qualified health benefits plans. QHBP premiums would at most vary by age (by no more than a 2:1 ratio within age categories specified by the Commissioner (established under section 141)), premium rating area (as permitted by state regulators or, in the case of an Exchange plan, as specified by the Commissioner), and family enrollment (as specified under state law and consistent with Commissioner rules).

The Commissioner, in coordination with the Secretaries of Health and Human Services (HHS) and Labor, would conduct a study of the large group market to examine (1) characteristics of employers who purchase fully-insured health insurance products and employers who self-fund health benefits, including characteristics related to bearing risk and solvency, and (2) the extent to which rating rules cause adverse selection in the large group market or encourage small and mid-size employers to self-insure health benefits. The Commissioner would submit this report to Congress and the applicable agencies no later than 18 months after enactment, and include any recommendations to ensure that the law does not provide incentives for small and mid-size employers to self-insure or create adverse selection in the risk pools of large group insurers and self-insured employers.

Subsection (b) deals with a specific issue about calculating the actuarial value of insurance coverage of abortion services in plans that choose to cover them. This provision is discussed in detail below, in the section titled "Abortion-Related Language in Division A."

Sec. 114. Nondiscrimination in benefits

Current Law

HIPAA established federal rules regarding non-discrimination based on health status-related factors. Group issuers are prohibited from establishing rules for eligibility and premium contributions based on health status-related factors. Those factors include health status, medical condition (including both physical and mental illnesses), claims experience, receipt of health care, medical history, genetic information, evidence of insurability (including conditions arising out of acts of domestic violence) and disability. In addition, the Genetic Information Nondiscrimination Act of 2008 prohibits issuers in the individual health insurance market from establishing eligibility rules (including continued eligibility) based on an individual's genetic information. The Mental Health Parity Act of 1996, as amended, establishes parity by prohibiting the placement of a dollar limit (either annual or aggregate lifetime) on mental health benefits that is less than such a limit for medical/surgical benefits for groups with more than 50 employees.

Proposed Law

This provision would require QHBPs to comply with new nondiscrimination standards regarding health benefits or benefit structures established by the Commissioner, building on existing federal nondiscrimination rules in ERISA, the Public Health Service Act (PHSA), and the Internal Revenue Code of 1986. These standards would apply to plans offered to individuals and groups of all sizes in QHBPs, not just groups with over 50 employees. This provision would apply existing mental health parity rules regardless of whether coverage is offered in the individual or group market and size of employer.

Sec. 115. Ensuring adequacy of provider networks

Current Law

HIPAA established special rules for plans that develop a network of providers. It allows small group issuers to (1) limit the employers that apply for coverage to those firms with eligible individuals who live or work in the network service area, and (2) deny coverage to small employers if the issuer demonstrates (if required) to the state that it has limited provider capacity due to obligations to existing enrollees and it is applying this decision uniformly without regard to claims experience or health status-related factors. HIPAA also prohibits a small group issuer that has denied coverage in any service area to offer small group coverage in that area for 180 days after the denial.

Proposed Law

This provision would require QHBPs that use provider networks to meet provider network standards that may be established by the Commissioner to ensure the adequacy of networks, and transparency in the cost-sharing differences between in- and out-of-network coverage. The term "provider network" means the providers with respect to covered benefits, treatments, and services available under a health benefit plan.

Sec. 116. Ensuring value and lower premiums

Current Law

Medical loss ratio is the share of total premium revenue spent on medical claims. Medigap insurance policies are private supplemental health care policies that Medicare beneficiaries can purchase to help cover some items, services, and cost sharing not covered under Medicare. Medigap plans are required to have a minimum medical loss ratio of 65% for individual policies and 75% for group policies. In addition, some states impose medical loss ratios or related requirements on insurers in the individual and/or small group health insurance markets. As of June 2008, minimum ratios required by states ranged from 55% to 80%.

Proposed Law

This provision would require QHBPs to comply with a medical loss ratio standard to be determined by the Commissioner. For any QHBP that does not meet such a standard, it would be required to provide rebates to enrollees, in a manner specified by the Commissioner, in sufficient amounts to meet such a loss ratio. To establish the medical loss ratio standard, the Commissioner would build on the definition and methodology, developed by the HHS Secretary under Section 161, for determining how to calculate such a ratio. The methodology would set the highest ratio possible to ensure adequate QHBP participation, competition both in and out of the Exchange, and value for consumers so that their premium payments are used predominately for medical claims.

Subtitle C—Standards Guaranteeing Access to Essential Benefits

Sec. 121. Coverage of essential benefits package

Current Law

There are very limited federal benefit mandates for health insurance. These standards were added to HIPAA and are described in the discussion of Section 122. There are more than 2,000 state-level benefit mandates that vary across the country.

Proposed Law

This provision would require a QHBP to cover at least an "essential benefit package." QHBPs could be offered in or outside of an Exchange. QHBPs offered outside of an Exchange would be allowed to offer additional benefits beyond those specified in the essential benefits package. For QHBPs offered through the Exchange, a plan offering a premium-plus level of benefits (established under Section 203) could also provide additional benefits.

The requirements under Division A would not affect the offering of limited-purpose or "excepted" benefit plans, including policies covering dental or vision treatment, long-term care, workers' compensation, and other similar benefits, if such benefit plans are offered under a separate policy, contract, or certificate of insurance.

A QHBP would not be allowed to impose coverage restrictions (except cost sharing) unrelated to the clinical appropriateness of the health care items and services.

Sec. 122. Essential benefit package defined

Current Law

There are very few federally mandated benefits. The laws that provide guidance are found in the Employee Retirement Income Security Act (ERISA covers employer-sponsored plans), the Public Health Service Act (PHSA covers insurance plans and state and local government plans), and the Internal Revenue Code (IRC covers church plans in certain circumstances). There is no federal requirement that employers offer health insurance, or that any plans that are offered cover any specific benefits. However, the mandates that do exist require that if a plan (governed by ERISA, PHSA, or IRC) covers a particular service that is addressed in the statutes, then that benefit must be designed in a certain way. Those mandates include:

- The Paul Wellstone and Pete Domenici Mental Health Parity and Addiction Equity Act of 2008 (MHPA) (P.L. 110–343) requires a large group health plan to offer parity in mental health and substance use disorder benefits and medical and surgical benefits with regard to annual and lifetime limits, financial requirements and treatment limitations, but does not require a plan to cover mental health benefits.
- The Newborns' and Mothers' Health Protection Act of 1996 (NMHPA) (P.L. 104–204) requires plans that offer maternity coverage to pay for at least a 48-hour hospital stay following childbirth (96-hour stay in the case of a cesarean section).
- The Women's Health and Cancer Rights Act of 1998 (P.L. 105–277) contains protections for patients who elect breast reconstruction in connection with a mastectomy. For plan participants and

beneficiaries receiving benefits in connection with a mastectomy, plans offering coverage for a mastectomy must also cover reconstructive surgery and other benefits related to a mastectomy.

• The Genetic Information Nondiscrimination Act of 2008 (GINA) (P.L. 110–233) prohibits discrimination based on genetic information by health insurers and employers. Broadly, GINA prohibits health insurers from engaging in three practices: (1) using genetic information about an individual to adjust a group plan's premiums, or, in the case of individual plans, to deny coverage, adjust premiums, or impose a pre-existing condition exclusion; (2) requiring or requesting genetic testing; and (3) requesting, requiring, or purchasing genetic information for underwriting purposes. It also prohibits employers from making hiring or firing decisions based on genetic information.

• Michelle's Law (P.L. 110–381) ensures that dependent post secondary education students who take a medically necessary leave of absence do not lose health insurance coverage. The law provides that a group health plan may not terminate a college student's health coverage simply because the student takes a medically necessary leave of absence from school or changes to part-time status. The leave of absence must be medically necessary, begin while the student is suffering from a serious illness or injury and would otherwise result in a loss of coverage.

Although current federal law provides only a limited number of service and coverage mandates, it does provide some guidance toward the definition of preventive services for use by public programs and private insurance. The U.S. Preventive Services Task Force (USPSTF), administered by the Agency for Healthcare Research and Quality (AHRQ), reviews scientific evidence and makes recommendations to the health care community regarding the use of clinical preventive services, based on evidence of effectiveness and any harm associated with specific services. The USPSTF grades services as "A" through "D," or notes that there is insufficient evidence to support a recommendation. Clinical services graded "A" or "B" by the USPSTF are recommended for use in clinical practice.

Similarly, the Advisory Committee on Immunization Practices (ACIP), administered by the Centers for Disease Control and Prevention (CDC), reviews scientific evidence and makes recommendations to the Secretary and the CDC Director for the routine administration of vaccines to children, adolescents, and adults in the U.S. civilian population. The ACIP is not explicitly authorized; rather, it is based in general authorities of the Secretary in Titles II and III of the PHSA.

"Actuarial value" is a summary measure of a health insurance plan's benefit generosity. It is expressed as the percentage of medical expenses estimated to be paid by the insurer for a standard population and set of allowed charges. Two plans that have the same actuarial value are "actuarially equivalent." Because these are summary measures, two plans that are actuarially equivalent may not provide the same benefits for any two individuals. State health insurance regulations may include requirements expressed in terms of actuarial value.

Proposed Law

This provision would require the essential benefits package to cover specified items and services, limit cost sharing, prohibit annual and lifetime limits on covered services, ensure the adequacy of provider networks, and be equivalent (as certified by the Office of the Actuary of the Centers for Medicare and Medicaid Services) to the average prevailing employer-sponsored coverage.

The essential benefits package would be required to cover the following items and services:

- Hospitalization;
- Outpatient hospital and clinic services, including emergency department services;
- Services of physicians and other health professionals;
- Services, equipment, and supplies incident to the services of a physician or health professional in appropriate settings;
- Prescription drugs;
- Rehabilitative and "habilitative" services (i.e., services to maintain or prevent the deterioration of the physical, intellectual, emotional, and social functioning of developmentally delayed individuals);
- Mental health and substance use disorder services, including behavioral health treatments;
- Preventive services, include those graded "A" or "B" by the Task Force on Clinical and Preventive Services, as established by this Act, and those vaccines recommended by the Director of the CDC;
- Maternity care; and
- Well-baby and well-child care; treatment of a congenital or developmental deformity, disease, or injury; and oral health, vision, and hearing services, equipment, and supplies for those under age 21.

A qualified health benefits plan offering entity has the option of subcontracting with other entities to provide select benefits as is often the case currently, such as dental, vision, and mental health benefits.

Mental health and substance use disorder services include medically necessary and appropriate treatments, items and services for disorders and conditions listed in the Diagnostic and Statistical Manual of Mental Disorders (DSM) published by the American Psychiatric Association.

Services recommended with a grade A or B grade by the Task Force on Clinical Preventive Services (formerly the U.S. Preventive Services Task Force) and vaccines recommended for use by the Director of the Centers for Disease Control and Prevention constitute a floor for preventive services in the essential benefits package. The Health Benefits Advisory Committee has discretion to also consider recommendations of specialty medical associations, patient advocacy groups, and scientific societies in making recommendations to the Secretary of covered treatments, items and services within the essential benefits package.

The essential benefits package would be subject to various requirements concerning cost-sharing. The package would be required to provide preventive items and services without cost-sharing (including well-baby and well-child care). The annual out-of-pocket limit in Y1 would be $5,000 for an individual and $10,000

for a family. These limits would be annually adjusted for inflation using the Consumer Price Index for all Urban Consumers (CPI-U). The Secretary could consider establishing a lower limit on cost-sharing for prescription drugs that would be included within the global cost-sharing cap. All out-of-pocket spending on prescription drugs would count toward both the lower, drug-specific limit and the global limit on all cost-sharing. The drug-specific cap could be helpful for chronically ill patients that rely on medications to remain healthy and avoid hospitalizations and other acute health care services. The Secretary in setting a drug-specific limit could do so at a level that will support medication adherence.

To the extent possible, the Benefits Advisory Committee and the Secretary of HHS would establish cost-sharing levels using copayments (a flat dollar fee) and not coinsurance (a percentage fee). Cost-sharing for the Essential Benefits Package would result in coverage equal to approximately 70% of the actuarial value of the benefits if there were no cost-sharing imposed.

This provision would also prohibit the requirement of abortion services as a minimum benefit in any plan. Each plan is to decide voluntarily on whether abortion is a covered benefit; in the case of the public option, the Secretary is to make that decision. This provision is discussed in detail below in the section titled "Abortion-Related Language in Division A."

Adults 21 and over would not be required to receive separately priced stand-alone vision-only or dental-only coverage (as defined in Section 102(c)(3)).

Sec. 123. Health Benefits Advisory Committee

Current Law

No provision.

Proposed Law

A Health Benefits Advisory Committee would be established to recommend covered benefits and cost-sharing parameters and the essential, enhanced, and premium plans. The Committee would be chaired by the Surgeon General. The Committee membership would be comprised of:

- Nine members, appointed by the President, who are neither federal employees nor officers;
- Nine members, appointed by the Comptroller General, who are neither federal employees nor officers; and
- An even number, up to eight members, appointed by the President, who are federal employees and officers.

The initial appointments would be made within 60 days of enactment. Each Committee member would serve a three-year term, except the terms of the initial appointments would be adjusted to provide for staggered years of appointment. The members would reflect the interests of the many diverse groups of stakeholders so that no single interest would unduly influence the Committee's recommendations. At a minimum, Committee membership would reflect physicians and other health care providers, consumer representatives, employers, labor, health insurance issuers, experts in health care delivery, and experts in health disparities, and government agencies. At least one Committee member would be a prac-

ticing physician or health professional, and another member would be an expert on children's health. Finally, at least 25% of the Committee members would have to be health care practitioners who practiced in a rural area for at least the five years preceding the appointment.

The Committee's recommendations to the Secretary on the essential benefits package (as defined in Section 122), cost-sharing levels for the enhanced plans and premium plans (as defined in Section 203), and periodic updates of the package would be required to incorporate innovation in health care. The Committee members would also be required to consider how the package would reduce health disparities, and would allow for public input as part of developing its recommendations. The Committee's initial benefit recommendations must be made to the Secretary within one year of enactment.

In developing standards for the basic, enhanced and premium plans, the Committee would be required to calculate cost-sharing such that the enhanced plan would have benefits that are actuarially equivalent to about 85% of the actuarial value of the benefits provided in the essential benefits package, and the premium plans would have benefits that are actuarially equivalent to about 95% of the actuarial value of the benefits provided in the essential benefits package.

Committee members would serve without pay, but would receive federal travel expenses, including per diem expenses. In addition, the Committee would be subject to the Federal Advisory Committee Act (which provides sunshine and transparency over advisory committee actions).

The Secretary would be required to publish all recommendations developed pursuant to this Section in the Federal Register and on the HHS website.

Sec. 124. Process for adoption of recommendations; adoption of benefit standards

Current Law

No provision.

Proposed Law

This section proposes a timeline under which the Secretary must choose whether to adopt the recommendations of the Committee established under section 123 of this bill. Within 45 days of receiving the Committee's recommendations regarding the essential benefits package, the Secretary would be required either to adopt the benefit standards as written or not adopt the benefit standards. If the Secretary does not wish to adopt the recommendations, the Secretary shall notify the Committee of the reasons for this decision, and provide an opportunity for the Committee to revise and resubmit its recommendations.

The Secretary would be required to adopt an initial set of benefit standards within 18 months of enactment. The Secretary would be required to publish all determinations under this section in the Federal Register. The Secretary would be required to periodically update the benefit standards. However, an essential benefits pack-

age that does not meet the essential benefits requirements specified in section 122 could not be adopted.

Sec. 125. Prohibition of discrimination in health care services based on religious or spiritual content

Current Law

No provision.

Proposed Law

The Commissioner and insurance issuers offering health insurance coverage through the Health Insurance Exchange shall not discriminate in approving or covering a health care service based on its religious or spiritual content if the services are deductible as an eligible medical expense, as defined in the Internal Revenue Code.

Subtitle D—Additional Consumer Protections

Sec. 131. Requiring fair marketing practices by health insurers

Current Law

States have established fair marketing standards to regulate insurers' marketing activities.

Proposed Law

This provision would require the Commissioner to establish uniform marketing standards for QHBPs.

Sec. 132. Requiring fair grievance and appeals mechanisms

Current Law

ERISA does not require an employer to offer health benefits, but does mandate compliance to certain standards if an employer chooses to offer health benefits, such as procedures for appealing denied benefit claims. In addition, as of February 2008, 44 states and the District of Columbia mandate the independent review of benefit denials by an entity outside of the health plan ("external review").

Proposed Law

This provision would require QHBPs to provide for timely grievance and appeals mechanisms as established by the Commissioner consistent with sections 139 through 139B.

Sec. 133. Requiring information transparency and plan disclosure

Current Law

ERISA requires applicable health plans (as well as other "welfare benefit" plans) to disclose and report certain plan information to enrollees and regulators. For example, plan administrators must provide to enrollees a written summary plan description (SPD) that contains the terms of the plan and the benefits offered, including any material modifications, and the SPD must be written in a manner that can be understood by the average enrollee. Certain plans must file an annual report with the Department of Labor, con-

taining information about the operation, funding, assets, and investments of those plans.

Proposed Law

This provision would require QHBPs to comply with disclosure standards established by the Commissioner concerning plan terms and conditions, claims payment policies, plan finances, claims denials, and other information as determined appropriate by the Commissioner. The Commissioner would require such disclosure to be provided in plain language. QHBPs would be required to comply with standards established by the Commissioner to ensure transparency to a provider regarding reimbursements between the plan and such health care provider. A change in a QHBP could not be made without reasonable and timely advance notice to enrollees about the change.

The purpose of the pharmacy benefit managers transparency provision is to provide the Commissioner and QHBPs additional information on several aspects of the performance of pharmacy benefit managers: the spread between the price PBMs pay to pharmacies and the ultimate cost to the PBM of drugs; the extent to which PBMs are successful at switching patients to less costly generic drugs; the extent and reasons for switching patients to more expensive drugs; and the ability of PBMs to obtain—and pass through to QHPBs—discounts, rebates, and price concessions from drug manufacturers. Under the provision, a QHBP would be allowed to contract with a pharmacy benefit manager (PBM) to manage prescription drug coverage offered under the health plan, or control costs related to such coverage, only if as a condition of the contract the PBM is required to annually provide to the Commissioner and QHBP, in a form and manner to be determined by the Commissioner, certain information on the performance of the PBM under the contract, including the volume of prescriptions filled; aggregate average payments made to pharmacists by the PBM, and paid to the PBM by the QHBP, per prescription for mail order and retail sales; discounts, rebates, and price concessions received from drug manufacturers; volume of generic drugs dispensed; number of instances when enrollees switched from a less expensive prescribed drug to a more expensive prescription and the rationale for such switches, and other information. Information disclosed by a PBM to the Commissioner and QHBP would be considered confidential, and the disclosure of information in a form which discloses the identity of a specific PBM or a specific retailer, manufacturer, or wholesaler would be prohibited from disclosure by the Commissioner or QHBP except for specified purposes. The intent of these confidentiality provisions is to provide the same general level of confidentiality for this information as is given to Medicaid drug rebate data reported by manufactures under Section 1927 of the Social Security Act. The Commissioner would be allowed to publish industry-wide aggregate or average information to be used by the Commissioner, by QHBPs, and by members of the public in assessing the overall impact of PBMs on prescription drug prices and spending.

Sec. 134. Application to qualified health benefits plans not offered through the Health Insurance Exchange

Current Law

No provision.

Proposed Law

The previous disclosure and other standards would apply to QHBPs offered outside of the Exchange only to the extent specified by the Commissioner.

Sec. 135. Timely payment of claims

Current Law

Under Medicare Advantage (MA), private health plans are paid a per-person amount to provide all Medicare-covered benefits (except hospice) to beneficiaries who enroll in their plans. MA plans include health maintenance organizations (HMOs) and private fee-for-service (PFFS) plans, among other plan types. MA PFFS plans—that generally do not currently contract with providers—are required to pay 95% of "clean claims" within 30 days of receipt. The Centers for Medicare and Medicaid Services (CMS) defines a clean claim as a claim that has no defect or impropriety, and is submitted with all the required documentation. The 30-day rule also applies to claims submitted to any MA organization by a provider who does not have a written contract with the plan. MA organizations are required to pay interest on clean claims that are not paid within 30 days. All other claims from non-contracted providers must be paid within 60 days. MA organizations that contract with providers (i.e., HMOs and PPOs) must include a prompt payment provision in their contracts.

Proposed Law

This provision would require QHBPs to comply with the prompt pay requirements applicable to Medicare Advantage plans.

Sec. 136. Standardized rules for coordination and subrogation of benefits

Current Law

While there are no federal statutes specifying primary and secondary payment rules for multiple insurers in the private market, Section 1862(b) of the Social Security Act authorizes the Medicare Secondary Payer (MSP) program, which identifies specific conditions under which another party has primary responsibility for payment and Medicare is only responsible for qualified secondary payments. The statute authorizes several methods to identify cases when an insurer other than Medicare is the primary payer and to facilitate recoveries when incorrect Medicare payments have been made. Under certain conditions, the law makes Medicare the secondary payer to insurance plans and programs for beneficiaries covered through (1) a group health plan based on either their own or a spouse's current employment; (2) auto and other liability insurance; (3) no-fault liability insurance; and (4) workers' compensation situations, including the Black Lung program. Additionally, the Medicare statutes exclude Medicare coverage for items and

services paid for directly or indirectly by a government entity, subject to certain limitations. This includes the Department of Veterans Affairs, among others.

Proposed Law

The Commissioner would establish standards for the coordination of benefits and reimbursement of payments in cases involving individual and multiple plan coverage.

Sec. 137. Application of administrative simplification

Current Law

To support the growth of electronic record keeping and claims processing, HIPAA's Administrative Simplification provisions instructed the Secretary to adopt electronic format and data standards for several routine administrative and financial transactions between health care providers and health plans/payers. The standards apply to health care providers (who transmit any health information in electronic form in connection with a HIPAA-specified transaction), health plans, and health care clearinghouses.

Proposed Law

This provision would require QHBP-offering entities (as defined in the bill) to comply with existing and new administrative simplification standards under Title 11 of the Social Security Act and adopted under Section 163 (discussed below).

Sec. 138. Information on end-of-life planning

Current Law

No provision.

Proposed Law

This provision would require QHBP offering entities to provide for the dissemination of information related to end-of-life planning to individuals seeking enrollment in Exchange-participating plans. The QHBP would be prohibited from promoting suicide, assisted suicide, or the active hastening of death. Moreover, the information presented would not presume the withdrawal of treatment and would be required to include end-of-life planning information that would maintain all or most medical interventions. Nothing in this provision would be construed to (1) require an individual to complete an advanced directive, physician's order for life sustaining treatment, or other end-of-life planning document; (2) require an individual to consent to restrictions on the amount, duration, or scope of medical benefits otherwise covered under a QHBP; or (3) encourage the hastening of death or the promotion of assisted suicide. An "advance directive" would be defined to include a living will, a comfort care order, or a durable power of attorney for health care.

Sec. 139. Utilization review activities

Current Law

Section 503 of ERISA requires every employee benefit plan to "provide adequate notice in writing to every participant or bene-

ficiary whose claim for benefits under the plan has been denied, setting forth the specific reasons for such denial, written in a manner calculated to be understood by the participant" and to "afford a reasonable opportunity to any participant whose claim for benefits has been denied for a full and fair review by the appropriate named fiduciary of the decision denying the claim." Regulations accompanying this section of ERISA set out specific periods of time for private employment-based plans to evaluate a claim and inform an individual of its decision. While these limits do not govern when the benefits must be paid or provided, plans are required to pay or provide benefits within a reasonable time after a claim is approved.

Urgent care claims must be decided as soon as possible, taking into account the medical needs of the patient, but no later than 72 hours after the plan receives the claim. The plan must inform an individual within 24 hours if more information is needed; and they have no less than 48 hours to respond. Then the plan must decide the claim within 48 hours after the missing information is supplied or the time to supply it has elapsed. The plan must provide notice that a claim has been granted or denied before the end of the time allotted for the decision.

Pre-service claims must be decided within a reasonable period of time appropriate to the medical circumstances, but no later than 15 days after the plan has received the claim. The plan may extend the time period up to an additional 15 days if, for reasons beyond the plan's control, the decision cannot be made within the first 15 days. If more information is requested, the individual has at least 45 days to supply it. The plan then must decide the claim no later than 15 days after they are supplied with the additional information or after the period of time allowed to supply additional information ends, whichever comes first.

Post-service health claims must be decided within a reasonable period of time, but not later than 30 days after the plan has received the claim. If, because of reasons beyond the plan's control, more time is needed to review a request, the plan may extend the time period up to an additional 15 days. However, the plan administrator has to let the individual know before the end of the first 30-day period, explaining the reason for the delay, requesting any additional information needed, and advising when a final decision is expected. If more information is requested, the individual has at least 45 days to supply it. The claim then must be decided no later than 15 days after it has been supplied with the additional information or the period of time given by the plan to do so ends, whichever comes first. The plan must give notice that a claim has been denied in whole or in part before the end of the time allotted for the decision.

Proposed Law

A QHBP and a QHBP offering entity that offers a plan would be required to conduct utilization review (UR) activities meeting the requirements of this section. UR could be contracted out. Those activities include procedures to monitor or evaluate the use of coverage, clinical necessity, appropriateness, efficacy, or efficiency of healthcare services, procedures or settings, and include prospective review, concurrent review, second opinions, case management, discharge planning, and retrospective review. The UR program would

include written clinical review criteria, based on valid clinical evidence, directed specifically at meeting the needs of at-risk populations and covered individuals with chronic conditions or severe illnesses. Once a service has been specifically pre-authorized for an enrollee, it could not be changed by a retrospective review. UR programs must be administered by qualified health care professionals who oversee review decisions.

The UR program would be conducted by trained personnel, who could not be offered compensation to encourage claims denials, and could not be conducted by the practitioner who provided services to the individual in question, among other restrictions. UR activities involving prior authorization of services would be made as soon as possible in accordance with the medical exigencies of the case, but no later than 14 days after the request and no later than 3 business days after the date of receipt of information necessary to make a determination. An extension could be requested for additional information, within 5 business days of receiving the initial request. The deadline would then be extended to 14 days after receiving the additional information, but no later than 28 days after the request for prior authorization. For expedited cases (where the individual's life, health, or ability to regain maximum function was in jeopardy, or for continuity of care) the deadline would be 72 hours after the request. No prior authorization would be required for emergency services.

For concurrent review of ongoing care, the decision must be provided no later than 1 business day after the date of receipt of necessary information, with sufficient time for an appeal before the service is reduced or eliminated. Plans would not be required to provide coverage that exceeded their limitations. In the case of UR for previously provided services, the decision would have to be provided within 30 days of the date of receipt of necessary information, but no later than 60 days after the request.

Failure by a QHBP or QHBP entity to make a timely determination would be treated as a claims denial. Denials would have to be provided in writing, along with the reasons, instructions on how to initiate an appeal, and the availability, upon request, of the clinical criteria used, and other information. Claims for benefits would mean any request for coverage, for eligibility, or payment for items or services under a QHBP.

Sec. 139A. Internal appeals procedures

Current Law

Under ERISA regulations, an individual covered by a private employment-based health plan has at least 180 days to file an appeal following an adverse benefit determination. The plan must provide claimants, on request and free of charge, copies of documents, records, and other information relevant to the claim for benefits. The plan also must identify, upon request, any medical or vocational expert whose advice was obtained by the plan.

On appeal, claims must be reviewed by someone new who looks at all of the information submitted and consults with qualified medical professionals if a medical judgment is involved. This reviewer cannot be a subordinate of the person who made the initial decision and must give no consideration to that decision.

Plans have specific periods of time within which to review an appeal, depending on the type of claim. Urgent care claims must be reviewed as soon as possible, taking into account the medical needs of the patient, but not later than 72 hours after the plan receives a request to review a denied claim. Pre-service claims must be reviewed within a reasonable period of time appropriate to the medical circumstances, but not later than 30 days after the plan receives a request to review a denied claim. Post-service claims must be reviewed within a reasonable period of time, but not later than 60 days after the plan receives a request to review a denied claim.

There are two exceptions to these time limits. In general, single-employer collectively bargained plans may use a collectively bargained grievance process for their claims appeal procedure if it has provisions on filing, determination, and review of benefit claims. Multi-employer collectively bargained plans are given special timeframes to allow them to schedule reviews on appeal of post-service claims and disability claims for the regular quarterly meetings of their boards of trustees.

Plans can require two levels of review of a denied health claim to finish the plan's claims process. If two levels of review are required, the maximum time for each review generally is half of the time limit permitted for one review.

Once the decision on a claim is made following review, the plan must provide to the claimant a written or electronic notification of the decision. The notice must be in plain language that can be understood by participants in the plan. It must include all the specific reasons for the denial of the claim on appeal, refer the individual to the plan provisions on which the decision is based, provide information on any additional voluntary levels of appeal, explain the right to receive documents that are relevant to the benefit claim free of charge, and describe rights to seek judicial review of the plan's decision.

Proposed Law

Each QHBP and each QHPB offering entity that offers a plan would be required to provide adequate written notice to individuals (participants, beneficiaries and enrollees) who are denied a claim for benefits. The notice would include specific reasons for the denial and rights to further review or appeal. Individuals would have no less than 180 days to file for a full and fair review. Reviews of denied claims would be made by a physician (for cases involving a medical judgment) or a specialist (in the case of limited scope coverage) who is selected by the plan and did not make the initial denial. The QHBP offering entity would be required to complete the review and either affirm, reverse or modify the original denial. If the decision did not reverse the denial, the plan or issuer would transmit a written notice stating the reason for the decision, including a description of rights to any further appeal. Failure to issue such a decision by the deadline would be treated as final decision denying the claim.

Generally, the deadline would be 14 days after the date of receipt of the request for internal review. An extension for additional necessary information would be allowed if the requestor was notified within 5 business days. The deadline would then be extended to 14 days after receiving the additional information, but no later than

28 days after the request for internal review. For expedited cases (where the individual's life, health, or ability to regain maximum function was in jeopardy, or for continuity of care) the deadline would be 72 hours after the request, or for ongoing care, before the end of the approved period of care. A plan or entity could waive its right for internal review, and in such cases the individual could proceed directly to any applicable external appeals process.

Sec. 139B. External appeals procedures

Current Law

No specific provision in federal law. As of February 2008, however, 44 States and the District of Columbia mandate the independent review of benefit denials by an entity outside of the health plan ("external review").

Proposed Law

A QHBP and a QHPB entity would be required to provide for an external appeals process. An externally appealable decision would be defined as a denial of claims based in whole or in part on a decision that the item or service is not medically necessary or appropriate, is investigational or experimental, or in which the decision as to whether the benefit is covered involved a medical judgment. It would also include a failure to meet the applicable deadline for internal review. It would not include specific exclusions or express limitations on the amount, duration or scope of coverage that do not involve medical judgment, or a decision regarding whether an individual is a participant beneficiary or enrollee under the plan. A plan or entity may require that external review only be conducted after a final decision is made on internal review (except in cases where the internal review decision is not made within necessary deadlines). A filing fee may be required, of no more than $25, except in cases where the individuals certify to the Secretary that they cannot afford the fee. The fee would be refunded if the external appeal entity reverses or modifies the denial.

The external appeal process would be conducted under a contract between the plan or issuer and one or more qualified external appeal entities. Procedures would be implemented to ensure that the external appeal entity did not have incentives to make biased decisions. There would be a sample audit of decisions. The Secretary would establish other terms and conditions. A state could designate an entity to provide external review activities.

The standards for external review would include at least the following: (1) fair, de novo determinations; (2) determinations of whether the decision was in accordance with the medical needs of the patient; (3) consideration of language in the plan or coverage documents relating to the definition of terms, such as medical necessity; and (4) evidence from the internal review, any personal health and medical information supplied by the individual, the opinion of the treating physician or health care professional. The external entity could also take into consideration other information such as results of studies and professional consensus. The external appeals entity would determine whether the claim was externally appealable and whether the decision should be expedited.

Each party could submit information. The decision would be made no later than 21 days after the date (or 72 hours for expedited review) of the request for an external appeal, and written in layperson language. The appeals entity would also inform the participant of any rights, including review by courts. If the decision was to reverse or modify the denial, the plan would be required to authorize benefits, take action to provide benefits in a timely manner, and submit information documenting compliance.

External appeals entities would have to be independent, use a panel of at least 3 clinical peers, have sufficient medical legal and other expertise, and meet other requirements. The entity must be certified, and periodically recertified, as specified by the bill. Reviewers exercising due care would not be criminally or civilly liable for performance of their duties.

The decision by the external appeals entity would be binding on the plan. If the plan did not follow the decision, it would be subject to a civil money penalty of up to $1,000 per day, until it adhered to the decision. An additional civil monetary penalty could be assessed against a person acting in the capacity of authorizing benefits determined by an external review entity for any pattern or practice of repeated refusal to authorize such benefits or for any pattern or practice of repeated violations of requirements of this section. The penalty would not exceed the lesser of 25% of the aggregate value of denied benefits or $500,000.

This Act would not alter or eliminate any cause of action or legal rights or remedies of participants, beneficiaries, enrollees, and others under state or federal law. The provisions of this section would apply to all acceptable coverage in the same manner as such provisions apply with respect to QHBPs.

Subtitle E—Governance

Sec. 141. Health Choices Administration; Health Choices Commissioner

Current Law

No provision.

Proposed Law

This provision would establish an independent agency in the executive branch of the United States called the Health Choices Administration ("Administration"). The Administration would be headed by a Health Choices Commissioner ("Commissioner"), who would be appointed by the President, with advice and consent of the Senate. Section 702 of the Social Security Act (detailing compensation, terms, general powers, rule-making, and delegation as applied to the Commissioner of Social Security and the Social Security Administration) would apply to the Commissioner.

Sec. 142. Duties and authority of Commissioner

Current Law

No provision.

Proposed Law

This provision would make the Commissioner responsible for carrying out the following functions:

• *Qualified Plan Standards*.—Establishing QHBP standards, including the enforcement of such standards in coordination with state insurance regulators and the Secretaries of Labor and the Treasury.

• *Health Insurance Exchange*.—Establishing and operating the Health Insurance Exchange.

• *Individual Affordability Credits*.—Administering individual affordability credits, including the determination of eligibility for such credits.

• *Promoting Accountability*.—Undertaking activities in accordance with this section to promote accountability of QHBP offering entities in meeting federal health insurance requirements, regardless of whether such accountability is with respect to qualified health benefit plans offered through or outside the Health Insurance Exchange.

• *Compliance Examination and Audits*.—Coordinating with states to conduct audits of qualified health benefits plans compliance with federal requirements. These audits could include random compliance audits and targeted audits in response to complaints or other suspected non-compliance.

• *Recoupment of Costs in Connection with Examination and Audits*.—Authorizing the Commissioner to recoup from qualified health benefits plans reimbursement for costs of such examinations and audit of such QHBP offering entities.

• *Data Collection*.—Collecting data for the purposes of carrying out the Commissioner's duties, including promoting quality and value, protecting consumers, and addressing disparities in health and health care; the Commissioner may share such data with Secretary of Health and Human Services.

• *Sanctions Authority*.—Providing any of the following remedies (in addition to any other authorized by law) in coordination with state insurance regulators and the Secretary of Labor if it is determined that a QHBP offering entity violates a requirement:

1. Civil money penalties of not more than the amount applicable under similar circumstances for similar violations under Medicare;

2. Suspension of plan enrollment of individuals under such plan after the date the Commissioner notifies the entity of a decision until rectification of violation;

3. In the case of an Exchange-participating health benefits plan, suspension of payment under the Health Insurance Exchange for individuals enrolled in the plan after the date the Commissioner notifies the entity of such decision and until corrective action is taken; or

4. Work with state insurance regulators to terminate plans for repeated failure by the QHBP offering entity to meet this title's requirements.

• *Standard Definitions of Insurance and Medical Terms*.—Providing the development of standards for defining terms used in health insurance coverage, including insurance-related terms.

• *Efficiency in Administration*.—Issuing regulations for the effective and efficient administration of the Health Insurance Exchange and affordability credits including:

1. The determination of eligibility for affordability credits.
2. The use of personnel to carry out the duties of the Commissioner.

Sec. 143. Consultation and coordination

Current Law

No provision.

Proposed Law

The Commissioner, as appropriate, would be required to consult with, at a minimum, the National Association of Insurance Commissioners (including for purposes of using model guidelines), state attorneys general, and state insurance regulators concerning the standards and enforcement for insured qualified health benefits plans described in this title. Concurrently, the Commissioner would be required to consult with, at a minimum, Indian tribes and tribal organizations, appropriate federal agencies, and appropriate state agencies concerning affordability credits and the offering of Exchange-participating health benefits plans to Medicaid eligible individuals.

The Commissioner would be required to work in coordination with existing federal and state entities to the maximum extent feasible and in a manner preventing conflicts of interest. Concurrently, the Commissioner would seek to achieve uniform standards that sufficiently protect consumers in a manner that does not unreasonably affect employers and insurers.

Sec. 144. Health Insurance Ombudsman

Current Law

The Department of Health and Human Services houses various complaint handling and client-assistance ombudsmen:

• *Food and Drug Administration (FDA) Ombudsman*.—Reviews marketing or investigational applications; provides information on import or export issues, ensures a fair hearing of claims of unfair or unequal treatment; also determines the jurisdiction of a product.

• *Long-Term Care Ombudsman*.—Mandated by Older Americans Act of 1965, consists of 1,000 paid individuals and 14,000 volunteers who identify, investigate, and resolve complaints made by, or on the behalf, of residents. They have a blend of federal and state oversight.

• *Medicare Beneficiary Ombudsman*.—Created by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. 108–173), is intended to ensure those eligible for Medicare have reliable and current information about their benefits, rights and protections under the Medicare program, and the procedures for getting problems and disputes resolved. The Ombudsman is to aid Medicare recipients in filing appeals if their insurance did not pay proper amounts for their medical services or those services were denied.

• *Specialized Jurisdictional Ombudsmen*.—The FDA also has four additional ombudsmen who serve as the points of contact for

specific public complaints connected to the subject of their jurisdiction. They are located at the Center for Biologics Evaluation and Research, Center for Drug Evaluation and Research, Center for Devices and Radiological Health, and Center for Veterinary Medicine. If any of the above cannot resolve or rectify a complaint, the issue is then sent to the FDA Office of Ombudsman.

• *State Health Insurance Ombudsman*.—Several states (including VT, MN, and IL) have created State health insurance ombudsmen, with the core responsibilities of rectifying concerns encompassing access to care, billing problems, and access to health insurance. The Ombudsman provides information on state and federal programs that may be available, explains continuation rights under an existing health plan, provides help on how to shop for health insurance, and assists in appealing decisions made by their health insurance.

Proposed Law

The Commissioner would appoint within the Health Choices Administration a Qualified Health Benefits Ombudsman (with experience and expertise in the fields of health care and education). The Ombudsman would be required to perform the following duties:

• Receive and provide assistance with complaints, grievances, and requests for information submitted by individuals. The assistance would be provided more specifically in instances such as helping individuals determine relevant information for an appeal, assisting with any problems arising from disenrollment, choosing a qualified health benefits plan in which to enroll, and presenting information relevant to affordability credits.

• Submit annual reports to Congress and the Commissioner describing the activities of the Ombudsman, including recommendations for improvement in the Administration of this Division, as determined appropriate. The Ombudsman would not serve as an advocate for any increases in payments or new coverage of services, but would identify issues and problems in payment or coverage policies.

Subtitle F—Relation to Other Requirements; Miscellaneous

Sec. 151. Relation to other requirements

Coverage Not Offered Through Exchange.—The requirements of this provision would not supersede specified federal and state laws with respect to the health insurance coverage not offered through the Health Insurance Exchange (whether or not offered in connection with an employment-based health plan). Such laws encompass applicable requirements under the Public Health Service Act for certain group health plans and state and local employee requirements for health insurance coverage, group health plan standards and requirements under ERISA, or other applicable federal or state laws. Nothing in this subsection would prevent application of state laws creating private rights of action with remedies or affect the application preemption (under Section 514 of ERISA).

Coverage Offered Through the Exchange.—The requirements under this title would not supersede any requirements relating to genetic information nondiscrimination and mental health for such health insurance coverage (as long as those related do not prevent

the application of requirements detailed in this division; as determined by the Commissioner). Concurrently, individual rights and remedies under state laws would apply. Nothing detailed in this paragraph would be construed as preventing the application of rights and remedies under state laws with respect to any referred requirement.

Sec. 152. Prohibiting discrimination in health care

Current Law

HIPAA established federal rules regarding nondiscrimination based on health status-related factors. It prohibits group issuers from establishing rules for eligibility and premium contributions based on health status-related factors. Those factors include health status, medical condition (including both physical and mental illnesses), claims experience, receipt of health care, medical history, genetic information, evidence of insurability (including conditions arising out of acts of domestic violence) and disability. In addition, the Genetic Information Nondiscrimination Act of 2008 (GINA, P.L. 110–233) prohibits issuers in the individual health insurance market from establishing eligibility rules (including continued eligibility) based on an individual's genetic information. The Mental Health Parity Act of 1996, as amended, establishes parity in treatment limitations, financial requirements including annual or lifetime limits between mental health and substance use disorder benefits and medical and surgical benefits.

Proposed Law

Unless explicitly permitted within this Act and subsequent related regulations, all health care and related services (including insurance coverage and public health activities) covered by this Act would be provided regardless of personal characteristics extraneous to the provision of high quality health care or related services. Within 18 months of enactment, the Secretary would be required to ensure that all health care and related services would be provided without regard for extraneous personal characteristics.

Sec. 153. Whistleblower protection

No employer may discharge (or otherwise discriminate against) any employee with respect to his compensation, terms, conditions, or other privileges of employment because the employee (or an individual acting at the request of the employee):

- Provides or causes to provide to the employer, federal government, the attorney general of a relevant state, information relating to any violation of, or any act or omission the employee reasonably believes to be a violation of any provision, order, rule, or regulation promulgated under this Act.
- Testifies or is about to testify in a proceeding concerning such violation.
- Assists, participates or is about to assist or participate in such a proceeding.
- Objects to, or refuses to participate in any activity, policy, practice, or assigned task that the employee reasonably believes to be in violation of any provision, order, rule or regulation promulgated under this Act.

Enforcement Action.—An employee covered by this section who alleges discrimination by an employer in violation may bring an action governed by the rules, procedures, legal burden of proof, and remedies detailed in section 40(b) of the Consumer Product Safety Act.

Employer Defined.—The term employer in this section means any person (including one or more individuals, partnerships, associations, corporations, trusts, professional membership organization including a certification, disciplinary, or other professional body, unincorporated organizations, nongovernmental organizations, or trustees) engaged in profit or nonprofit business or industry whose activities are governed by this Act, and any agent, contractor, subcontractor, grantee, or consultant of such person.

Rule of Construction.—The rule of construction set forth concerning employee protections in the United States Code would apply to this section.

Sec. 154. Construction regarding collective bargaining

Nothing in this division would be construed to alter or supersede any statutory authority (or other obligation) to engage in collective bargaining over the terms and conditions of employment related to health care.

Sec. 155. Severability

If any provision of this Act, or the application thereof toward any person or circumstance, is held unconstitutional, the application of the remaining provisions would not be affected.

Sec. 156. Application of State and Federal laws regarding abortion

Current Law

The performance of abortions is regulated by both state and federal laws.

Proposed Law

This provision would ensure that state laws regarding the prohibition or requirement of coverage or funding for abortions, and state laws involving abortion-related procedural requirements are not preempted. The provision similarly provides that federal conscience protection and abortion-related antidiscrimination laws would not be affected by the bill. The rights and obligations of employees and employers under title VII of the Civil Rights Act of 1964 would also not be affected by the bill.

This provision is discussed in detail below in the section entitled "Abortion-Related Language in Division A."

Sec. 157. Non-discrimination on abortion and respect for rights of conscience

Current Law

Under Section 245 of the Public Health Service Act, federal, state, and local governments are prohibited from discriminating against health care entities that refuse to undergo abortion training, provide such training, perform abortions, or provide referrals for the relevant training for abortions. Under the so-called Weldon Amendment, which has been included in the annual appropriations

measure for the Departments of Labor, Health and Human Services (HHS), and Education since 2004, appropriated funds may not be made available to a federal agency or program, or to a state or local government, that subjects any institutional or individual health care entity to discrimination on the basis that the entity does not provide, pay for, provide coverage of, or refer for abortions.

Proposed Law

This provision would prohibit a federal agency or program, or state or local government that receives federal financial assistance under the bill, from subjecting any individual or institutional health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions. The provision would also prohibit a federal agency or program, or state or local government that receives federal financial assistance under the bill from requiring any health plan created or regulated under the bill to subject any individual or institutional health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions. The HHS Office of Civil Rights would be designated to receive and coordinate the investigation of such complaints. This provision is discussed in detail below in the section titled "Abortion-Related Language in Division A."

Subtitle G—Early Investments

Sec. 161. Ensuring value and lower premiums

Current Law

Medical loss ratio is the share of total premium revenue spent on medical claims. Some states impose medical loss ratios or related requirements on insurers in the individual and/or small group health insurance markets. As of June 2008, minimum ratios required by states ranged from 55% to 80%. In addition, Medigap insurance policies are private supplemental health care policies that Medicare beneficiaries can purchase to help cover some items, services, and cost sharing not covered under Medicare. Medigap plans are required to have a minimum medical loss ratio of 65% for individual policies and 75% for group policies.

Proposed Law

Each health insurance issuer that offers health insurance coverage in the small or large group market would be required to provide rebates to enrollees if the coverage provided had a medical loss ratio below a level specified by the Secretary, for any plan year. The amount of the rebate would be sufficient to meet such loss ratio. The methodology would be set at the highest level medical loss ratio possible designed to ensure adequate participation by issuers, competition in the health insurance market, and value for consumers so that their premiums would be used for services. The Secretary would establish a uniform definition and a methodology for determining medical loss ratio, taking into account special circumstances of plans such as size, type, and longevity of the plan. These same provisions would also apply to health insurance coverage offered in the individual market. This provision would be effective for plan years beginning on or after January 1, 2011.

Sec. 162. Ending health insurance rescission abuse

Current Law

In the individual health insurance market, HIPAA guarantees renewal or continuation of individual health coverage at the option of the individual, except under specified circumstances. Those circumstances include nonpayment of premiums, fraud (including intentional misrepresentation of material fact) on the part of the enrollee, plan termination of coverage in the individual market, movement of enrollee outside of the network service area, or enrollee membership in an association ending (in the case of association sponsored coverage).

Proposed Law

This provision would clarify that the existing guaranteed renewability rules under HIPAA include prohibition of rescissions. An issuer would be allowed to rescind policies only upon clear and convincing evidence of fraud. No later than July 1, 2010, the Secretary would issue guidance on implementing this requirement. In order for a rescission to take effect, the issuer would be required to provide notice to the enrollee of the proposed rescission and give that enrollee the opportunity for a review of the determination by an independent, external third party under procedures specified by the Secretary. The health coverage for an enrollee who requests such a review would remain in effect until the third party determines such coverage may be rescinded under Secretarial guidance. The requirements related to external review would apply on and after October 1, 2010 to all health insurance coverage, regardless of date of issue.

Sec. 163. Ending health insurance denials and delays of necessary treatment for children with deformities

Current Law

See description under Section 122.

Proposed Law

This provision would require issuers of group coverage and individual coverage that includes coverage for surgical benefits to provide coverage for outpatient and inpatient diagnosis and treatment of a child's congenital or developmental deformity, disease, or injury. Any such coverage would be subject to pre-authorization or pre-certification as required under the health plan, and include any surgical treatment deemed by the treating physician as medically necessary to approximate a normal appearance. The provision would define treatment and make conforming amendments. These requirements would apply to group health plans for plan years beginning on or after January 1, 2010, and to individual health plans offered, sold, issued, renewed, in effect or operated on or after January 1, 2010.

Sec. 164. Administrative simplification

Current Law

HIPAA's Administrative Simplification provisions required the Secretary to adopt electronic format and data standards for nine

specified administrative and financial transactions, including those related to enrollment in a health plan, eligibility for a plan, and health care payment and remittance. In addition, HIPAA directed the Secretary to adopt a standard for transferring standard data elements among health plans for the coordination of benefits and the sequential processing of claims. In 2000, CMS issued an initial set of standards for seven of the nine specified transactions and for the coordination of benefits. As required under HIPAA, CMS published an updated version of the standards in early 2009. The compliance date for implementing those updated standards is January 1, 2012.

In September 2005, CMS published a proposed rule on a standard for electronic health care claims attachments, one of the two remaining transactions standards required to be adopted. A claims attachment transaction is used to request and supply additional data necessary to adjudicate a claim and typically includes specific clinical information that a plan needs in order to decide whether a service should be covered. This type of transaction is a key bridge between administrative transactions and clinical data. The claims attachment standard has yet to be finalized.

HIPAA's Administrative Simplification provisions also instructed the Secretary to develop security standards to safeguard electronic health information from unauthorized access, use, and disclosure, and to issue standards to protect the privacy of patient information. The HIPAA privacy rule, which took effect in 2003, established a set of patient rights, including the right of access to one's medical information, and placed certain limitations of when and how health plans and health care providers may use and disclose patient information. The Health Information Technology for Economic and Clinical Health (HITECH) Act, enacted earlier this year as part of the Recovery Act, included a series of privacy and security provisions that amended and expanded the current HIPAA requirements. The HIPAA Administrative Simplification standards do not apply to the use and disclosure of information by financial institutions that are responsible for authorizing, processing, clearing, billing, transferring or collecting payments for premiums or health care.

Proposed Law

This provision would amend the HIPAA Administrative Simplification provisions by adding a new section requiring the Secretary, within two years of implementation of the updated HIPAA electronic transactions standards (i.e., by January 2014), to adopt an additional set of financial and administrative transactions standards to help clarify, complete, and expand the existing requirements. The goal would be for the standards to be unique (with no conflicting or redundant standards), authoritative, and comprehensive, requiring minimal augmentation by paper transactions. In addition, the standards would describe all data elements in unambiguous terms and not permit optional fields. They would enable real-time (or near real-time) determination of a patient's financial responsibility at the point of service and adjudication of claims, and harmonize all common data elements across transactions standards. Finally, the standards would have to support electronic funds transfers as well as timely and transparent claim and denial man-

agement processes, enable providers to quickly and efficiently enroll with a health plan so as to conduct other electronic transactions, and provide for other requirements related to administrative simplification as identified by the Secretary.

In developing the standards, the Secretary would be required to build upon existing and planned standards and regularly update the new standards. Within six months of enactment, the Secretary would be required to submit to Congress a plan for implementing and enforcing the new standards within five years of enactment. The plan would have to include a timetable for developing and regularly updating the new standards, implementation programs to help rural and other providers, an estimate of the funding needed to ensure timely completion of the implementation plan, and an enforcement process including timely investigation of complaints, random audits, and a fair and reasonable appeals process. The Secretary would have to ensure that all data collected pursuant to the new standards meets the HIPAA privacy and security requirements, as modified by the HITECH Act.

The provision would require the Secretary, within one year of enactment, to issue a final rule to establish a standard for health claims attachment transactions. It also would clarify that the HIPAA standards do not apply to the use and disclosure of information by financial institutions that process payments unless they are business associates of health plans and healthcare providers.

Sec. 165. Expansion of electronic transactions in Medicare

Current Law

Generally, Medicare statute prohibits payment to providers for Part A and B claims that are not submitted electronically. However, the Secretary is required to allow providers to submit paper claims if they have no method for submitting claims electronically or if they meet the definition of a small provider or supplier. "A" small provider is defined as a provider with fewer than 25 full-time employees or a physician, practitioner, facility, or supplier with fewer than 10 full-time employees. The Secretary also has the discretion to waive the electronic claims submission requirement in unusual cases that it deems appropriate.

Proposed Law

By January 1, 2015, the Secretary would be prohibited from paying Medicare Part A and B claims that are not submitted through electronic funds transfer or in electronic form as specified in ASC X12 835 Health Care Payment and Remittance Advice or subsequent standards. The exemption for providers that have no method for submitting claims electronically, for small providers or suppliers, and for unusual cases deemed appropriate by the Secretary would remain in effect.

Sec. 166. Reinsurance program for retirees

Current Law

No provision in current law. Average per capita health spending among the near elderly (55- to 64-year-olds) in 2004 was $7,787, or 50% more than spending among 45- to 54-year-olds ($5,210), and more than double that of 19- to 44-year olds ($3,370). These spend-

ing levels carry over into health insurance costs for these age groups. In the non-group market, average premiums for the near elderly were nearly $1,200 more than 45- to 54-year-olds and triple that for 25- to 34-year olds. The near elderly were more likely than their younger adult counterparts to spend more than 10% of their after-tax income on health care and health insurance premiums.

Proposed Law

No later than 90 days after enactment, the Secretary would establish a temporary reinsurance program, to provide reimbursement to assist participating employment-based plans with the cost of providing health benefits to eligible retirees who are 55 and older and their dependents, including eligible and surviving spouses. Health benefits would be required to include medical, surgical, hospital, prescription drug, and other benefits determined by the Secretary. An eligible employment-based plan would submit an application to the Secretary, as required. A participating employment-based program would submit claims for reimbursement to the Secretary, documenting the actual cost of items and services for each claim. Each claim would be based on the actual amount expended by the participant. The participating employment-based plan would take into account any negotiated price concessions, such as discounts, subsides, and rebates. The cost of deductibles and cost-sharing would be included in the cost of the claim, along with the amounts paid by the plan. For any valid claim, the Secretary would reimburse the plan for 80% of the portion of costs above $15,000 and below $90,000. This amount would be adjusted annually based on the percent increase in the medical care component of the Consumer Price Index, rounded to the nearest multiple of $1,000. Amounts paid to a participating employment-based plan would be used to lower cost directly to participants and beneficiaries in the form of premiums, co-payments, deductible, co-insurance, or other out-of-pocket costs, but would not be used to reduce the costs of an employer maintaining the employment-based plan. The Secretary would establish an appeals process for denied claims, procedures to protect against fraud, waste, and abuse, and would conduct annual audits of claims date.

The Retiree Reserve Trust Fund would be established consisting of such amounts as appropriated or credited to the Fund to enable the Secretary to carry out the reinsurance program. The Secretary could request such sums as necessary to carry out this section, not to exceed $10 billion. Amounts appropriated and outlays from such appropriation would not be taken into account for purpose of any budget enforcement procedures, thus exempting the Fund from the framework of the budget resolution and the points of order which enforce that framework. The Secretary would have the authority to stop taking applications or take other steps to reduce expenditures to ensure that expenditures did not exceed available funds.

Sec. 167. Limitations on pre-existing condition exclusions in group health plans and health insurance coverage in the group and individual markets in advance of applicability of new prohibition of pre-existing condition exclusions

Current Law

See description under Section 111.

Proposed Law

This provision would decrease the amount of time that issuers of group coverage would be allowed to exclude coverage for pre-existing health conditions, in advance of the effective date of the wholesale prohibition against any such coverage exclusions (established under Section 111). It would allow group health plans to impose pre-existing condition exclusions for no longer than 3 months (9 months in the case of a late enrollee). Also, it would allow issuers to review only the past 30-day period for evidence of a pre-existing health condition, as opposed to the current look-back period of six months.

Such changes would apply to group health plans beginning after the first six months following enactment. In the case of a collective bargaining agreement, such changes would apply either at the date on which the last collective bargaining agreement ends or three years after enactment, whichever is earlier.

This provision also would prohibit coverage exclusions for pre-existing health conditions in the individual health insurance market, except to the extent that such exclusions could be applied consistent with the rules relating to group coverage, in advance of the effective date of the wholesale prohibition against any such coverage exclusions. It would specify the circumstances under which an issuer of individual coverage may impose a pre-existing health condition exclusion, and limit the duration of such exclusions to a maximum of three months. These changes would apply to individual coverage offered, sold, issued, renewed, in effect, or operated beginning after the first six months following enactment.

These rules imposed on group and individual coverage would cease to apply once such plans become subject to the requirements under Section 111 that prohibit any exclusions for pre-existing health conditions.

TITLE II—HEALTH INSURANCE EXCHANGE AND RELATED PROVISIONS

Subtitle A—Health Insurance Exchange

Current Law

No provision in federal law. The Health Insurance Exchange proposal, however, has some components that are similar to the Massachusetts Connector as an intermediary that assists individuals in acquiring health insurance.

Proposed Law

Sec. 201. Establishment of Health Insurance Exchange; outline of duties; definitions

A Health Insurance Exchange ("Exchange") would be established to facilitate access of individuals and employers to a variety of choices of affordable, quality health insurance coverage, including a public health insurance option. The Exchange would exist within the Health Choices Administration under the direction of the Health Choices Commissioner (described above in Sections 141 and 142). As described in greater detail in the following sections, regarding the Exchange, the Commissioner would (1) establish standards for, accept bids from, and negotiate and enter into contracts with entities seeking to offer qualified health benefits plans (QHBPs) through the Exchange, (2) facilitate outreach and enrollment of Exchange-eligible individuals and employers, and (3) conduct appropriate activities related to the Exchange, including establishment of a risk pooling mechanism and consumer protections.

Sec. 202. Exchange-eligible individuals and employers

Beginning in Y1, all individuals generally would be eligible to obtain coverage through the Exchange, unless they were enrolled in the following:

- a group plan through a full-time employee (including a self-employed person with at least one employee) for which the employer makes an adequate contribution (described below in Section 312);
- Medicare;
- Medicaid (except in certain cases, discussed below).

Those enrolled in Tricare and veterans healthcare are eligible to obtain coverage through the Exchange. Regarding Medicaid, individuals could still participate in the Exchange if their Medicaid eligibility was related to COBRA continuation coverage, tuberculosis, or breast or cervical cancer. As described in greater detail in Section 1701, Medicaid would be expanded to cover individuals up to 133?% FPL who are not eligible under current state Medicaid programs—called "non-traditional Medicaid eligible individuals" per Section 205. A non-traditional Medicaid eligible individual could be Exchange-eligible if the individual was enrolled in a qualified health benefits plan, grandfathered health insurance coverage, or current group health plan during the six months before the individual became a non-traditional Medicaid eligible individual. During the period in which such an individual had chosen to enroll in an Exchange plan, the individual would be ineligible for regular Medicaid.

Except for the Medicaid exception described above, individuals would lose eligibility for Exchange coverage once they become eligible for Medicare Part A, Medicaid (although in this case, the Commissioner could permit continued Exchange eligibility for such limited time as the Commissioner determines it is administratively feasible and consistent with minimizing disruption in the individual's access to health care), and other circumstances as the Commissioner provides. Besides those cases, once individuals enroll in an Exchange plan, they would continue to be eligible until they are no longer enrolled.

Exchange-eligible employers could meet the requirements of the employer responsibility (Section 312) by offering and contributing adequately toward employees' enrollment through the Exchange. Those employees would be able to choose any of the available Exchange plans. Once employers are Exchange eligible and enroll their employees through the Exchange, they would continue to be Exchange eligible, unless they decided to then offer their own qualified health benefits plan(s).

In Y1, only employers with 10 or fewer employees would be Exchange-eligible. In Y2, employers with 20 or fewer employees would be Exchange-eligible. Beginning in Y3, the Commissioner could permit larger employers to participate in the Exchange. These additional employers could be phased in or made eligible based on the number of full-time employees or other considerations the Commissioner deems appropriate. Employer and other employment-related definitions would be defined by the Commissioner.

The Commissioner would have the authority to establish rules to deal with special situations with regard to uninsured individuals participating as Exchange-eligible individuals and employers, such as transition periods for individuals and employers who gain, or lose, Exchange-eligible participation status, and to establish grace periods for premium payment.

The Commissioner would be required to provide for periodic surveys of Exchange-eligible individuals and employers concerning their satisfaction with the Exchange and its plans.

The Commissioner would conduct an Exchange Access Study—a study of access to the Health Insurance Exchange for individuals and for employers, including individuals such as Medicaid recipients and employers who are not eligible and enrolled in Exchange plans. The goal of the study would be to determine if there are significant groups and types of individuals and employers who are not Exchange eligible but who would have improved benefits and affordability if made eligible. The study also would examine the terms, conditions, and affordability of group health coverage offered by employers and QHBP-offering insurers outside of the Exchange compared to Exchange-participating health benefits plans, as well as the affordability test standard for access of certain employed individuals to coverage in the Health Insurance Exchange. The Commissioner would submit the study to Congress by January 1 of Y3, Y6, and thereafter, and would include in the report recommendations regarding changes in standards for Exchange eligibility for individuals and employers.

This section shall not be construed as affecting any authority under title 38 of the U.S. Code, Veterans benefits, or Chapter 55 of title 10 of the U.S. Code, Armed Forces.

By December 31, 2011, the Secretary would submit a report to Congress comparing the benefit package offered in 2011 for an average Children's Health Insurance Program (CHIP) plan to the benefit standards adopted for the essential benefits package and the affordability credits discussed under Subtitle C. No child eligible for CHIP coverage could be enrolled in an Exchange plan until the Secretary has certified, based on the report and any resulting changes (if any), that QHBP coverage meeting the essential benefits package is at least comparable to average CHIP coverage available in 2011.

Sec. 203. Benefits package levels

The Commissioner would specify the benefits to be made available under Exchange plans during each plan year, consistent with this section and sections 121–134 above. The Commissioner could not enter into a contract with an entity wanting to offer coverage through the Exchange in a service area(s), unless the following requirements are met:

- The entity offers one Basic plan in a service area.
- If the entity offers a Basic plan in a service area, the entity may offer one Enhanced plan for the service area.
- If the entity offers an Enhanced plan in a service area, the entity may offer one Premium plan for the area.
- If the entity offers a Premium plan for a service area, the entity may offer one or more Premium-Plus plans for the area.

All such plans could be offered under a single contract with the Commissioner.

Consistent with the standards in sections 101–164 above, the Commissioner would also establish standards for the three primary levels of Exchange plans—Basic, Enhanced, and Premium—and for additional benefits that may be offered in Premium-Plus plans. Besides offering the essential benefits package (Section 122 above) for a QHBP, Basic plan benefit packages would be modified to provide for reduced cost-sharing for individuals eligible for the "affordability cost-sharing credit," described below in Section 244. Excluding the credit, the benefit package of a Basic plan would have an actuarial value representing payment for approximately 70% of all the covered items and services in the essential benefits package (Section 122 above). Enhanced plans would have lower cost-sharing than Basic plans, representing approximately 85% of the actuarial value of all the covered items and services in the essential benefits package. Premium plans would have lower cost-sharing than Enhanced plans, representing approximately 95% of the actuarial value of all the covered items and services in the essential benefits package. Premium-Plus plans would be Premium plans that also provide additional benefits not otherwise covered approved by the Commissioner, such as adult oral health and adult vision care. The portion of the premium that is attributable to such additional benefits would be separately specified.

The Commissioner would establish a permissible range of variation of cost-sharing for the Basic, Enhanced, and Premium plans. Such variation would permit variations up to 10% in cost-sharing within specific benefit categories (Section 122); for example, with respect to a standard that provides for 20% coinsurance, the permissible variation would be between 18% and 22% coinsurance. This would not prohibit a greater differential in cost sharing between different benefit categories or benefit tiers within a category such as between generic drugs and brand name drugs.

If a state requires health insurers to offer benefits beyond the essential benefits package, such requirements would continue to apply to Exchange plans, but only if the state has entered into an arrangement satisfactory to the Commissioner to reimburse the Commissioner for the amount of any resulting net increase in affordability premium credits (Section 243).

The Commissioner would assure that in each premium rating area of the Exchange, at least one Exchange plan provides coverage

of both abortions for which federal funds appropriated for the Department of Health and Human Services are permitted and abortions for which such funds are not permitted under the Hyde Amendment. The Commissioner would also assure that in each premium rating area of the Exchange, at least one Exchange plan does not provide coverage of elective abortions. If a qualified health benefits plan did provide coverage of elective abortions, it would have to provide assurances to the Commissioner that affordability credits were not used to pay for such abortions, and only premium amounts attributable to the actuarial value described in section 113(b) were used for such purpose. This section is discussed in detail below in the section titled "Abortion-Related Language in Division A."

Sec. 204. Contracts for the offering of Exchange-participating health benefits plans

The Commissioner would establish standards, described below, for Exchange-participating entities and their health benefits plans. The Commissioner would certify entities and plans if the standards are met. The Commissioner would solicit and review bids from QHBP-offering entities for offering Exchange plans, negotiate with the entities, and enter into contracts with the entities for offering plans through the Exchange under terms negotiated between the Exchange and the entities.

The Federal Acquisition Regulation (the principal set of rules that govern the contracting process for the federal government) would not apply to contracts between the Commissioner and QHBP-offering entities for offering Exchange plans.

The standards for Exchange-participating entities would consist of the following requirements:

- The entity must be licensed to offer health insurance coverage under state law for each state in which it offers coverage.
- The entity must provide for reporting data/information specified by the Commissioner, including information necessary to administer the risk pooling mechanism in Section 206 and information to address disparities in health and health care.
- The entity must provide for implementation of the affordability credits provided for enrollees (described in Sections 241–246 below).
- The entity must accept all applicable enrollment via the Exchange, subject to such exceptions (such as capacity limitations) in accordance with the federal requirements for QHBPs (discussed under Title I), and would notify the Commissioner if it projects or anticipates reaching a capacity that would result in a limitation in enrollment.
- The entity must participate in the pooling mechanism as established by the Commissioner (described in Section 206 below).
- Regarding the Basic plan offered by the entity, the entity must contract for outpatient services with certain federally supported health care providers. The Commissioner would also specify how this requirement would apply to Health Maintenance Organizations (HMOs).
- The entity must provide culturally and linguistically appropriate communication and health services.

• The entity must comply with other applicable requirements of this title specified by the Commissioner, which would include standards regarding billing and collection practices for premiums and grace periods and which may include standards to ensure that the entity does not use coercive practices to force providers not to contract with other entities offering coverage through the Exchange.

For the contracting process, entities' bids would have to contain the information required by the Commissioner. Contracts would last at least one year, but could be automatically renewed in the absence of notice of termination by either party. The contract would provide that if the Commissioner determines that a plan's provider network is not adequate, then the cost-sharing charged to a person who received out-of-network care would be the same as if the care had been provided in-network.

In coordination with state insurance regulators, the Commissioner would establish processes to oversee, monitor, and enforce applicable requirements on Exchange-participating entities and QHBPs, including plan marketing. In conjunction with state insurance regulators, the Commissioner would establish a process for individuals and employers to file complaints concerning violations. The Commissioner could terminate a contract with an entity if it fails to comply with the requirements of this title; the Commissioner could also impose one or more intermediate sanctions.

Any determination by the Commissioner to terminate a contract would be made in accordance with formal investigation and compliance procedures established by the Commissioner under which (a) the Commissioner provides the entity with the reasonable opportunity to develop and implement a corrective action plan to correct the deficiencies that were the basis of the Commissioner's determination; and (b) the Commissioner provides the entity with reasonable notice and opportunity for hearing (including the right to appeal an initial decision) before terminating the contract. However, these procedures need not apply if the Commissioner determined that a delay in termination would pose an imminent and serious risk to the health of individuals enrolled under the plan.

Exchange plans would be prohibited from discriminating against any individual health care provider or health care facility because of its willingness or unwillingness to provide, pay for, provide coverage of, or refer for abortions. This provision is discussed in detail below in the section titled "Abortion-Related Language in Division A."

Sec. 205. Outreach and enrollment of Exchange-eligible individuals and employers in Exchange-participating health benefits plan

Outreach. The Commissioner would conduct outreach activities to inform and educate individuals and employers about the Exchange and its participating health plans. Such outreach would include outreach specific to vulnerable populations, such as children, individuals with disabilities, individuals with mental illness, and individuals with other cognitive impairments.

The Commissioner could work with other entities, such as community-based, non-profit organizations with experience working with people who are low-income, uninsured, or from diverse communities. The Commissioner may support and contract with com-

munity-based non-profits to provide these services. The Commissioner's required outreach activities would include the following:

- broadly disseminate information on Exchange-participating plans, provided in a comparative manner and including information on benefits, premiums, cost-sharing, quality, provider networks, and consumer satisfaction;
- provide assistance to Exchange-eligible individuals and employers via a toll-free telephone hotline and an Internet website;
- develop and disseminate information to Exchange-eligible enrollees on their rights and responsibilities;
- assist Exchange-eligible individuals in selecting plans and obtaining benefits; and
- ensure the information is developed using plain language (described in Section 133 above).

Enrollment. The Commissioner would be required to make timely determinations of whether individuals and employers are eligible for Exchange coverage and to establish and carry out an enrollment process, including at community locations. Enrollment would be permitted by mail, telephone, electronically, or in person.

Open enrollment for individuals and employers to enroll in an Exchange plan and affordability credits (described in Sections 241–245 below) would be at least 30 days and would be during September through November of each year before benefits would begin, or such other time that would maximize the timeliness of income verification. However, the Commissioner would also provide for special enrollment periods to take into account special circumstances of individuals and employers, such as an individual who loses acceptable coverage, experiences a change in marital or other dependent status, moves outside the plan's service area, or experiences a significant change in income. The Commissioner, potentially with other appropriate entities, would be required to broadly disseminate information on the enrollment process, including before each enrollment period.

The Commissioner would establish a process to automatically enroll the following individuals into an appropriate Exchange plan (potentially involving a random assignment or some other form of assignment that takes into account the health care providers used by the individual, or such other relevant factors specified by the Commissioner):

- Those who have applied for affordability credits, been determined eligible, have not opted out from receiving such credit, and do not enroll in another Exchange plan; and
- Those enrolled in an Exchange plan that is terminated who do not enroll in another Exchange plan.

Under the enrollment process, individuals enrolled in an Exchange plan would pay such plans directly, not through the Commissioner or the Exchange.

Special provisions apply to newborns born in the United States without acceptable coverage at birth. Until other acceptable coverage begins, the child would be considered a non-traditional Medicaid-eligible individual (for whom the state would be paid 100% federal reimbursement) and would be deemed as having elected Medicaid coverage. This coverage would end no later than the end of the month 60 days after the child's birth; at the end of that pe-

riod, if the child still does not have acceptable coverage, the child is deemed a traditional Medicaid-eligible individual, for whom the state receives the regular Medicaid federal matching rate.

As of the day before the first day of Y1, CHIP-eligible children, including targeted low-income children in a Medicaid-expansion CHIP program, would be deemed to be Exchange eligible. The Commissioner would notify each state in Y1 whether the Exchange could support enrollment of these children.

A "traditional Medicaid eligible individual" is a Medicaid-eligible individual *excluding* (1) those who are eligible because of the expansion of Medicaid in Section 1701 of this legislation to individuals up to 133⅓% FPL and (2) a childless adult who would not otherwise be classified as categorically needy (as per current Medicaid statute, Section 1902(a)(10)(A)) or medically needy (as per current Medicaid statute, Section 1902(a)(10)(C)) as in effect as of the day before the date of enactment of this Act. A "non-traditional Medicaid-eligible individual" is a Medicaid-eligible individual who is not a traditional Medicaid-eligible individual. Section 202 of the legislation includes provisions so that a non-traditional Medicaid eligible individual could be Exchange-eligible if the individual was enrolled in a qualified health benefits plan, grandfathered health insurance coverage, or current group health plan during the six months before the individual became a non-traditional Medicaid eligible individual. Under this section, the Commissioner would provide these individuals with the option to enroll in Medicaid rather than an Exchange plan and to change that election during open enrollment periods described earlier in this section.

An Exchange-eligible individual could apply for a Medicaid-eligibility determination. If the individual is determined to be eligible, the Commissioner would provide for the individual's enrollment under the state Medicaid plan in accordance with the Medicaid memorandum of understanding. In the case of such an enrollment, the state would provide for the same periodic redetermination of eligibility under Medicaid that would apply if the individual had directly applied to the state Medicaid agency. The legislation would require the Commissioner, in consultation with the HHS Secretary, to enter into a memorandum of understanding with each state with respect to coordinating enrollment of individuals in Exchange plans and under state Medicaid programs, and to otherwise coordinate the implementation of these provisions with respect to the Medicaid program. This memorandum would permit the exchange of information consistent with limitations specified in Medicaid statute with respect to providing safeguards that restrict the use or disclosure of information concerning applicants and recipients to purposes directly connected with the administration of the state Medicaid plan, and at state's option, the exchange of information necessary to verify eligibility for other federal programs (e.g., for free and reduced price school lunches). None of these provisions could be construed as permitting such memorandum to modify or vitiate any requirement of a state Medicaid plan.

In carrying out this section, the Commissioner would establish effective methods for communicating in plain language and a culturally and linguistically appropriate manner.

Nothing in this division could be construed to affect the role of enrollment agents and brokers under state law, including with re-

gard to the enrollment of individuals and employers in QHBPs, including the public health insurance option. This section preserves the ability of agents and brokers to assist employers and individuals in selecting health insurance available through an exchange and to enroll individuals and employers in qualified health benefits plans, including Exchange-participating health benefits plans and the public health insurance option, under terms determined between the agents and brokers and the plan. "[E]nrollment agents or brokers" include individuals and private health exchanges licensed as agents or brokers under state law to sell health insurance. Persons or employers enrolling in qualified health benefits plans through agents and brokers should not be discriminated against by HHS, the Health Choices Administration, and the Internal Revenue Service; including individuals accessing affordability credits or fulfilling their obligations under section 401 or employers fulfilling their obligations under Section 312 of this Act.

Sec. 206. Other functions

The Commissioner would be required to coordinate the distribution of affordability premium and cost-sharing credits (described below in Sections 243–244) to the Exchange plans. The Commissioner would also be required to establish a risk-pooling mechanism, to adjust premium payments to Exchange plans to take into account (in a manner specified by the Commissioner) the differences in the risk characteristics of individuals and employers enrolled under the Exchange plans.

An Office of the Special Inspector General for the Exchange would be established, headed by a Special Inspector General appointed by the President and confirmed by the Senate. The Special Inspector General's nomination would be made as soon as practicable after the establishment of the Exchange.

The duties of the Special Inspector General would consist of the following:

- Conduct, supervise, and coordinate audits, evaluations and investigations of the Health Insurance Exchange to protect the integrity of the Exchange as well as the health and welfare of participants in the Exchange;
- Report both to the Commissioner and to the Congress regarding program and management problems and recommendations to correct them;
- Related to the duties above, have other duties described as applying to the Special Inspector General of the Troubled Asset Relief Program (TARP), per paragraphs (2) and (3) of Section 121 of P.L. 110–343; and
- In carrying out these duties, have the authorities of inspectors general in Section 6 of the Inspector General Act of 1978.

Other provisions of the TARP Special Inspector General would also be applied, regarding the basis of the Special Inspector General's appointment, how s/he might be removed, his/her salary, and available personnel, facilities and other resources.

Not later than one year after the confirmation of the Special Inspector General, and annually thereafter, the Special Inspector General would submit to the appropriate committees of Congress a report summarizing the activities of the Special Inspector Gen-

eral during the one year period ending on the date the report is submitted.

The Office of the Special Inspector General would terminate five years after the date of the enactment of this Act.

Sec. 207. Health Insurance Exchange Trust Fund

A "Health Insurance Exchange Trust Fund" would be created within the U.S. Treasury, consisting of such amounts as may be appropriated or credited to the fund. The Commissioner would pay from the Trust Fund amounts as determined necessary to make payments to operate the Exchange, including affordability credits.

Dedicated payments to the Trust Fund would include the following:

- taxes on individuals not obtaining acceptable coverage (Section 401);
- taxes on employers electing to not provide health benefits (Section 412); and
- excise tax on employers who fail to satisfy health coverage participation requirements (Section 411).

Such additional sums as necessary would be appropriated. General provisions in the Internal Revenue Code regarding federal government trust funds would apply.

Sec. 208. Optional operation of State-based health insurance exchanges

If a state (or group of states, subject to the Commissioner's approval) applied to the Commissioner for approval of a state-based Health Insurance Exchange, and if the Commissioner approves such state-based Exchange, then the state-based Exchange would operate instead of the federal Exchange in that state(s).

The Commissioner could not approve a state-based Exchange unless the following requirements were met (and would be required to approve it if the conditions were met):

- The state-based Exchange must demonstrate the capacity to and provide assurances satisfactory to the Commissioner that it could carry out the functions specified for the federal Exchange in the state(s) including:
  - negotiating and contracting with qualified plans;
  - enrolling Exchange-eligible individuals and employers in plans;
  - establishing sufficient local offices to meet the needs of Exchange-eligible individuals and employers;
  - administering premium and cost-sharing credits (described below in Sections 241–246) using the same methodologies, and at least the same income verification methods, as would otherwise apply and at a cost to the federal government that is not greater than what would otherwise apply; and
  - enforcement activities consistent with federal requirements.
- There is no more than one Exchange in operation in any one state.
- The state provides assurances satisfactory to the Commissioner that approval of such an Exchange would not result in any net increase in expenditures to the federal government.

• The state provides for reporting of such information as the Commissioner determines and assurances satisfactory to the Commissioner that it will vigorously enforce violations of applicable requirements.

• Such other requirements as the Commissioner may specify.

If a state was operating an "Exchange" prior to January 1, 2010, and sought to operate a state-based Exchange under this section, the Commissioner would presume the Exchange meets the required standards. The Commissioner would be required to establish a process to work with such a state, but could determine, after working with the state, that the state does not comply with such standards.

A state-based Exchange could, at the option of the state, and only after providing timely and reasonable notice to the Commissioner, cease operation. In this case, the federal Exchange would be operational in the state(s).

The Commissioner could terminate the approval (for some or all functions) of a state-based Exchange if the Commissioner determined that it no longer met the requirements listed above or was no longer capable of carrying out such functions. In lieu of terminating the state-based Exchange's approval, the Commissioner could temporarily assume some or all functions of the state-based Exchange until the Commissioner determined that it met the applicable requirements and was capable of carrying out those functions. The ceasing or termination of a state-based Exchange would be effective in such time and manner as the Commissioner would specify.

Enforcement authorities of the Commissioner would be retained by the Commissioner. The Commissioner could specify functions of the federal Exchange that may not be performed by a state-based Exchange or that could be performed by both the Commissioner and the state-based Exchange.

In the case of a state-based Exchange, except as the Commissioner may otherwise specify, any references to the "Exchange" or to the "Commissioner" in the area in which the state-based Exchange operates would be deemed a reference to the state-based Exchange and the head of that Exchange.

In the case of a state-based Exchange, funding assistance would be provided for its operation in the form of a matching grant, with a state share of expenditures required.

This provision would also enable a state to receive an incentive payment if it enacts and implements an alternative medical liability law that complies with the bill. The Secretary would determine that a state law is compliant if she is satisfied that the State has enacted and is currently implementing the law, and finds the law to be "effective." To determine the effectiveness of a law, the Secretary would consider whether it makes the medical liability system more reliable through the prevention of or prompt and fair resolution of disputes, it encourages the disclosure of health care errors, and it maintains access to affordable liability insurance. The state law would be required to provide for an "early offer" system, a "certificate of merit" program, or a combination of both. In general, an early offer system permits a defendant to offer to a claimant within 180 days after a claim is filed, periodic payment of the claimant's economic losses. If an early offer is not made, the in-

jured party can proceed with a normal tort claim for both economic and noneconomic damages. However, if an early offer is made and the claimant declines the offer, both the standard of misconduct and standard of proof are raised. A certificate of merit program requires claimants, when a medical malpractice suit is first filed, to include testimony from a qualified medical expert that establishes that there is merit to the claim. A state that receives an incentive payment would have to use it to improve health care in the state. The Secretary may provide technical assistance to those states that apply for or are awarded an incentive payment. Not later than one year after the date of enactment, the Secretary shall submit to Congress an annual report on the progress states have made in adopting and implementing alternative medical liability laws that comply with this provision.

Sec. 209. Limitation on premium increases under Exchange-participating health benefits plans

This provision would limit Exchange plans' premium increases to 150% of annual medical inflation, unless the plan receives one of two exceptions (none of which would preempt existing State prior-approval laws): (1) the plan must offer additional benefits required by the Commissioner, or (2) the plan demonstrates to the Commissioner (or, if determined appropriate by the Commissioner, the State insurance commissioner) that the premium limitation would threaten its financial viability or its ability to provide timely benefits to plan participants.

Subtitle B—Public Health Insurance Option

Sec. 221. Establishment and administration of a public health insurance option as an Exchange-qualified health benefits plan

Current Law

There is no federal public option available for the non-disabled population under age 65. Medicare is an example of a federal public health insurance program for the aged and disabled. Under Medicare, Congress and the Department of Health and Human Services (HHS), Centers for Medicare and Medicaid Services (CMS) determine many parameters of the program including eligibility rules, financing (including determination of payroll taxes, and premiums), required benefits, payments to health care providers, and cost-sharing amounts. However, even within this public plan, CMS subcontracts with private companies to carry out much of the administration of the program.

Proposed Law

The provision would require the Secretary of Health and Human Services (Secretary) to provide for the offering of a public health insurance option through the Exchange starting Y1. The Secretary would be required to ensure that the public option provided choice, competition, and stability of affordable, high-quality coverage throughout the United States. The Secretary's primary responsibility would be to create a low-cost plan without compromising quality or access to care.

The public option would only be available through the Health Insurance Exchange. The public option would be required to comply

with requirements applicable to Exchange-participating health benefit plans, including requirements related to benefits, benefit levels, provider networks, notices, consumer protections, and cost sharing. The public option would be required to offer Basic, Enhanced, and Premium plans, and would be allowed to offer Premium-Plus plans.

The Secretary would be allowed to enter into contracts for the administration of the public option in the same manner as the Secretary is allowed to enter into contracts for the administration of the Medicare program. These administrative functions include, subject to restrictions, determination of payment amounts, making payments, beneficiary education and assistance, provider consultative services, communication with providers, and provider education and technical assistance. This includes contracting with appropriate non-profit entities, including Medicare's Quality Improvement Organizations, quality improvement entities created under Section 2401 of this Act, or other appropriate organizations, to assist providers to improve their performance. The provision would prohibit contracts that involve the transfer of insurance risk.

The Secretary would be required to establish an office of the ombudsman for the public health insurance option which would have duties similar to those of the Medicare Beneficiary Ombudsman.

The Secretary would be required to collect data necessary to establish premiums and payment rates and for other purposes, including improving quality and reducing racial, ethnic, and other disparities in health and health care.

With respect to the public health insurance option, the Secretary would be treated as an entity offering a Quality Health Benefit Plan through the Exchange.

The provisions relating to access to federal courts for enforcement of rights under Medicare would apply to the public option and individuals enrolled under the public option in the same manner that they apply to Medicare and Medicare beneficiaries.

Sec. 222. Premiums and financing

The Secretary would be required to establish geographically-adjusted premiums for the public option in a manner that complies with the premium rules established by the Commissioner for Exchange-participating health benefit plans and at a level sufficient to fully finance the cost of health benefits and administration for the public option. Premiums would be required to include an appropriate amount for a contingency margin of not less than 90 days of estimated claims. Starting in 2015, the Secretary would be required to solicit recommendations from the American Academy of Actuaries prior to setting the amount of the contingency margin.

The provision would establish an account in the Treasury for receipts and disbursements attributable to the public option, including start-up funding. The start-up funding would be equal to the sum of $2 billion for the establishment of the public option, and such sums as may be necessary to cover 90 days worth of reserves based on projected enrollment. These amounts would be authorized to be appropriated to the Secretary out of any funds in the Treasury not otherwise appropriated. The Secretary would be required to provide for repayment of the start-up funding in an amortized manner over a 10-year period starting in Y1. The provision specifies that nothing in this section could be construed as authorizing

any additional appropriations to the account, other than amounts otherwise provided with respect to other Exchange-participating plans. As under the Medicare Advantage program, states could not impose a premium tax or similar tax with respect to the public option. In no case shall the public health insurance option receive any Federal funds for purposes of insolvency in any manner similar to the manner in which entities receive Federal funding under the Troubled Assets Relief Program.

Sec. 223. Payment rates for items and services

The Secretary would be required to establish payment rates for services and health care providers under the public option consistent with the modernized payment initiatives and payment reforms specified in Section 224.

The Secretary would be required to negotiate rates in a manner that resulted in payment rates not lower, in aggregate, than rates under Medicare and not higher, in aggregate, than the average rates paid by other qualified health benefits plan offering entities for services and health care providers. The provision specifies that nothing would prevent the use of innovative payment methodologies such as those described in Section 224 in connection with the negotiation of payment rates. As introduced and reported, H.R. 3200 would allow the Secretary discretion to establish a prescription drug formulary, and use other methods, including those used by private sector pharmacy benefit managers, to reduce prescription drug costs under the public health insurance option, and the Committee expects that the Secretary would implement such a formulary. Section 223(a)(4), as added by the Committee, would require that the Secretary establish a particular formulary for prescription drugs under the public health insurance option. Health care providers participating in Medicare would be participating providers in the public health insurance option unless they opted out in a process established by the Secretary. Not later than 18 months before the first day of 2013, the Secretary would be required to promulgate rules for the opt out process. Under the opt out process, (a) providers would be provided at least a 1–year period prior to the first day of 2013 to opt out, (b) no provider would be penalized for opting out, (c) the Secretary would be required to include information on how providers participating in Medicare who choose to opt out of participating in the public option may opt back in, and (d) there would be an annual enrollment period in which providers may decide whether to participate in the public option.

The provision would prohibit administrative or judicial review of a payment or methodology established under this section, or Section 244 on modernized payment initiatives and delivery system reform.

Sec. 224. Modernized payment initiatives and delivery system reform

Beginning in the first year of the public option, the Secretary would be given the authority to use innovative payment mechanisms and policies to determine payments for items and services under the public option. The payment mechanisms and policies may include the following: patient-centered medical home, other

care management payments, accountable care organizations, value-based purchasing, bundling of services, differential payment rates, performance or utilization based payments, partial capitation, and direct contracting with providers. The Secretary would be required to design and implement the payment mechanisms and policies in a way that promotes care that is integrated, patient-centered, efficient and of quality, and that seeks to either (a) improve health outcomes, (b) reduce health disparities, (c) address geographic variation in the provision of health services, (d) prevent or manage chronic illness, or (e) provide efficient and affordable care. To the extent allowed under the rules for Exchange-participating plans, the provision would allow cost-sharing and payment rates under the public option to be modified to encourage the use of services that promote health and value.

The Secretary shall monitor and evaluate the progress and payment of delivery system reforms under this section and shall seek to implement such reforms on as large a geographic scale as practical and economical in so much that the Secretary finds such reforms are successful in improving quality and reducing costs. The Secretary may delay the implementation of such reforms in a geographic area in which such implementation would place the public health insurance option at a competitive disadvantage. The Secretary may also prioritize such a reform in a high cost geographic area in order to reduce total program costs or to promote high value care. The provision specifies that nothing in the subtitle would prevent the Secretary from varying payments based on different payment structure models for different geographic areas.

Sec. 225. Provider participation

Current Law

No provision.

Proposed Law

The Secretary would be required to establish conditions of participation for health care providers under the public option. The Secretary would be prohibited from allowing a health care provider to participate unless appropriately licensed or certified under state law. A health care provider that was excluded from participation in a federal health care program (as defined in Section 1128(f) of the Social Security Act), would be prohibited from participating under the public option.

Sec. 226. Application of fraud and abuse provisions

Current Law

Title XVIII of the SSA, the Medicare statutes, requires activities that prevent, detect, investigate, and prosecute health care fraud and abuse. In general, initiatives designed to fight fraud, waste, and abuse are considered program integrity activities. Program integrity is considered a component of the effective and efficient administration of government programs, which are entrusted with ensuring that taxpayer dollars are spent wisely. Efforts to ensure Medicare program integrity encompass a wide range of activities and require coordination among multiple private and public entities. This includes processes directed at reducing payment errors to

Medicare providers, as well as activities to prevent, detect, investigate, and ultimately prosecute health care fraud and abuse.

Proposed Law

The provisions of law (other than criminal law) identified by the Secretary by regulation, in consultation with the Inspector General, that impose sanctions with respect to waste, fraud, and abuse under Medicare would also apply to the public health insurance option. The Secretary shall not be given discretion as to whether criminal laws apply, but rather criminal laws apply regardless of the Secretary.

Sec. 227. Application of HIPAA insurance requirements

Current Law

HIPAA established federal rules regarding insurance in the individual and group markets. These include rules on non-discrimination based on health status-related factors, pre-existing condition exclusions, provisions on renewal and termination of coverage, the Genetic Information Nondiscrimination Act of 2008, the Mental Health Parity Act of 1996, as amended and other requirements.

Proposed Law

The requirements of the Public Health Service Act sections 2701 to 2792 apply to the public health insurance option in the same manner they apply to health insurance coverage offered by a health issuer in the individual market.

Sec. 228. Application of health information privacy, security, and electronic transaction requirements

Current Law

HIPAA established federal privacy and security rules in 1996. In addition, it established rules for standardized electronic transactions such as eligibility and claims payment.

Proposed Law

Part C of title XI of the Social Security Act applies to the public health insurance option in the same manner it applies to health insurance coverage offered by a health issuer in the individual market.

Sec. 229. Enrollment in public health insurance option is voluntary

The provision would clarify that enrollment in the public health insurance option is voluntary and nothing in the division would require anyone to enroll in it.

Subtitle C—Individual Affordability Credits

Sec. 241. Availability through Health Insurance Exchange

Current Law

No provision.

Proposed Law

This provision would provide premium and cost-sharing credits to "affordable credit eligible individuals" (defined in Section 242) for certain individuals enrolled in coverage through the Exchange. The Commissioner would pay each QHBP participating in the Exchange the aggregate amount of credits for all eligible individuals enrolled in that plan.

An Exchange-eligible individual could apply to the Commissioner, through the Exchange or another entity under an arrangement made with the Commissioner, in a form and manner specified by the Commissioner. The Commissioner, through the Health Insurance Exchange or through another public entity under an arrangement made with the Commissioner, would make a determination as to eligibility of an individual for affordability credits. The Commissioner would establish a process whereby, on the basis of information otherwise available, individuals may be deemed eligible for credits. The Commissioner would also establish effective methods that ensure that individuals with limited English proficiency are able to apply for affordability credits.

If the Commissioner determines that a state Medicaid agency has the capacity to make a determination of eligibility for affordability credits under the same standards as used by the Commissioner under the Medicaid memorandum of understanding (described above in Section 205), the state Medicaid agency is authorized to conduct such determinations for any Exchange-eligible individual who requests such a determination, and the Commissioner would reimburse the state Medicaid agency for the costs of conducting such determinations.

In addition, there would be a Medicaid screen-and-enroll obligation, that when individuals apply for affordability credits, a determination would be made as to whether they are eligible for Medicaid. If they are determined eligible for Medicaid, the Commissioner, through the Medicaid memorandum of understanding, would provide for their enrollment under the state Medicaid plan, and the state would provide for the same periodic redetermination of eligibility under Medicaid as would otherwise apply.

During the first two years of implementation, credits would be allowed for coverage under a Basic plan only. Beginning in the third year, credits would be allowed for coverage under Enhanced or Premium plans by a process established by the Commissioner. The individual would be responsible for any difference between the premium for an Enhanced or Premium plan and the credit amount based on a Basic plan applicable to that enrollee.

Under subsection (c)(3) an affordability credit is specifically prohibited from being used for payment for abortion services. This provision is discussed in detail below in the section titled "Abortion-Related Language in Division A."

The Commissioner would be authorized to request from the Treasury Secretary information that may be required to carry out this subtitle (regarding individual affordability credits), consistent with existing rules regarding confidentiality and disclosure of tax return information. Individuals who are eligible to receive credits would not receive them in the form of cash payments.

Sec. 242. Affordable credit eligible individual

This provision would define an "affordable credit eligible individual" as an individual who (1) is lawfully present in a state in the United States (other than a nonimmigrant, with some exceptions), (2) is enrolled in an Exchange plan and is not enrolled through an employer plan that meets the employer responsibility to contribute toward employee and dependent coverage (described below in Section 312), (3) has family income below 400% FPL, and (4) who is not a Medicaid-eligible individual (other than some exceptions described above in Section 202). Family members who are eligible for credits will be treated as a single affordable credit eligible individual.

Credits would not be available to full-time employees of an employer offering coverage consistent with the employer contribution rules described in Section 312. The Commissioner would make exceptions to this rule for divorced or separated individuals, or dependents of employees who would otherwise be eligible for credits. Exceptions would also be made, beginning in Y2, for full-time employees whose premium costs under a group health plan exceed 12% of family income.

Income would be defined as "modified adjusted gross income" (MAGI), per the new section 59B of the Internal Revenue Code, added in Section 401. The Commissioner would conduct a study to examine the application of income disregards for the purposes of the affordability credits. The Commissioner would submit a report to Congress of such a study, including recommendations as the Commissioner determines appropriate. Affordability credits would not be treated as a federal means-tested public benefit for eligibility purposes for qualified aliens under the Personal Responsibility and Work Opportunity Reconciliation Act of 1996.

In the introduced bill, employers with payrolls under $250,000 were exempt from the employer responsibility requirements, and those with payrolls between $250,000 and $400,000 had phased in responsibility requirements. The Committee adopted an amendment that reflects the Committee's view that this employer responsibility exemption should apply to employers with payrolls under $500,000 instead of $250,000, with phased-in responsibility for those with payrolls between $500,000 and $750,000 instead of $250,000 and $400,000.

Sec. 243. Affordable premium credit

This section would establish the rules for determining the amount of the premium credit provided to eligible individuals enrolled in an Exchange plan. The "affordability premium credit" would be an amount equal to the lesser of (1) the amount by which the enrollee's premium exceeds a specified level that is considered affordable ("affordable premium amount"), or (2) the amount by which the "reference premium" (the average premium of the three least expensive Basic plans in the individual's premium rating area) exceeds the "affordable premium amount". In calculating the reference premium, the Commissioner may exclude plans with extremely limited enrollments.

The affordable premium credit amount would be calculated on a monthly basis, based on the following table, to limit individuals'

premium payments to a percentage of family income (MAGI) relative to the poverty level, as specified in the table below.

Federal poverty level (FPL)	Premium payment limit, as a percent of income
133% or less	1.5
150%	3
200%	5.5
250%	8
300%	10
350%	11
400%	12

The Commissioner would establish premium percentage limits so that for individuals whose family income is between the income tiers specified in the table, the percentage limits would increase on a linear sliding scale. Beginning in 2014, the Commissioner would adjust the percentages in the table so that the percentage of premiums paid by the government versus enrollees in each income tier remains the same as in 2013.

Every year, beginning before January 1, 2014, the Chief Actuary of the Centers for Medicare and Medicaid Services (CMS) would estimate the cost savings in the previous year from the provisions listed below and would report the estimate to the Commissioner, who would provide for an appropriate increase in the table above so that those cost savings could be reflected in increased affordability credits:

- formulary provisions under the public option (Section 223(a)(4));
- pharmacy benefit managers (PBM) transparency (Section 133(d));
- accountable care organizations in Medicaid (Section 1730);
- administration simplifications (Sections 163–164);
- limitations on Exchange plan premium increases (Section 209); and
- the authority of the Secretary to negotiate lower Part D prescription drug prices (Section 1186).

Sec. 244. Affordability cost-sharing credit

The affordability cost-sharing credit under this section would be available to those enrolled in an Exchange plan whose income is less than 400% FPL. The Commissioner would specify reductions in cost-sharing amounts and the annual limitation (out-of-pocket maximum) on cost-sharing under a Basic plan so that the average percentage of covered benefits paid by the plan (as estimated by the Commissioner) is equal to the percentages (actuarial values) in the table for each income tier.

Federal poverty level (FPL)	Actuarial value percentage
150% or less	97
200%	93
250%	85
300%	78
350%	72
400%	70

The Commissioner would provide payments to QHBP-offering entities in an amount equivalent to the increased actuarial value of benefits resulting from the cost-sharing reductions.

Sec. 245. Income determinations

This provision would use an individual's adjusted gross income in the most recent taxable year for determination of a credit under this subtitle. The Commissioner would take steps as may be appropriate to ensure the accuracy of determinations and redeterminations under this subtitle. The Commissioner would request information from the Treasury Secretary as may be permitted to verify income information submitted in applications for credits. The Commissioner would establish procedures for verification of income if no tax return is available for the most recent completed tax year. The Commissioner would establish special rules for cases when an individual's income is expected (in a manner specified by the Commissioner) to be significantly different from the income submitted for application for and determination of a credit. The Commissioner would establish rules under which an individual would be required to inform the Commissioner when there is a significant change in income. Such mechanism would provide for guidelines that specify the circumstances that qualify as a significant change, the verifiable information required to document such a change, and the process for submission of such information. If the Commissioner receives new information from an individual regarding the family income of the individual, the Commissioner would provide for a redetermination of the individual's eligibility to be an affordable credit eligible individual.

An individual who intentionally misrepresents family income or fails to disclose to the Commissioner a significant change in family income would be liable for repayment of any improperly received credit and, in the case of intentional misrepresentation, may be required to pay an additional penalty as imposed by the Commissioner.

For a CHIP-eligible child deemed to be eligible for coverage through the Exchange, during the first year of implementation the Commissioner would establish rules under which family income of the child is deemed to be no greater than the family income of that child as most recently determined by the State under CHIP. The Commissioner would examine the feasibility and implication of adjusting the application of the federal poverty level in this subtitle to take into account geographic differences, in order to reflect cost-of-living variations across the country. The Commissioner would ensure that the study covers the territories (Puerto Rico, U.S. Virgin Islands, Guam, Northern Mariana Islands and any other territory or possession of the United States), paying special attention to the disparity that exists among poverty levels and the cost of living in the territories and the impact of such disparities on efforts to expand health coverage and ensure health care. The Commissioner would submit a report to Congress, no later than the first day of the second year of implementation, on such a study and make recommendations as appropriate.

Sec. 246. No Federal payment for undocumented aliens

No credits are permitted for individuals who are not lawfully present in the country. The Commissioner will have to establish a process to enforce this federal requirement and ensure no undocumented persons receive affordability credits.

Subtitle D—Health Insurance Cooperatives

Sec. 251. Establishment

Sec. 252. Start-up and solvency grants and loans

Sec. 253. Definitions

Current Law

Some states have laws and regulations applicable to a specific type of multiple employer welfare arrangement (MEWA), a health insurance cooperative, a non-profit arrangement which allows small businesses to join as members and obtain health benefits offered through the cooperative. While ERISA gives the Department of Labor some authority to regulate MEWAs, States are the primary regulators.

Proposed Law

This provision would require the Commissioner, in consultation with the Treasury Secretary, to establish a program to provide grants and loans for the establishment and initial operation of health insurance cooperatives. The program would be established within six months after enactment. Such cooperatives would provide insurance through the Exchange (established under Section 201) or state-based exchange (established under Sec 208), but would not substitute for the public health insurance option. A state is not required to establish a health cooperative.

Within 36 months after enactment, the Commissioner may make (1) loans to cooperatives to assist them with start-up costs, and (2) grants to cooperatives to assist them in meeting applicable state solvency requirements. The cooperative would need to meet specified criteria in order to be awarded such a grant or loan. Such criteria include the requirements that the cooperative be run as a non-profit, member-run organization, not be sponsored by the state, be licensed in the state which it offers insurance, and other requirements. This provision would allow cooperatives in different states to integrate their administrative, insurance, and other functions. Cooperatives that violate the terms of the grant and loan program and fails to make corrections would be required to repay the total amount received. This provision would authorize a total of $5 billion in appropriations for the period of FY2010 to FY2014 for grants and loans under this section.

With respect to cooperatives, the definition of a "state" would refer to the 50 states and the District of Columbia. And the definition of a "member" would refer to an individual who, after the cooperative offers health insurance, is enrolled in such coverage.

TITLE III—SHARED RESPONSIBILITY

Subtitle—Individual Responsibility

Sec. 301. Individual responsibility

Current Law

No provision.

Proposed Law

The provision cross-references the shared responsibility provisions of section 59B of the Code (as added by section 401 of the bill) which provides for a tax on individuals (or a husband and wife in the case of a joint return) who do not maintain coverage under acceptable health insurance for themselves and each of their qualifying children. The provision is effective for taxable years beginning after December 31, 2012.

Subtitle B—Health Coverage Participation Requirements

PART 1—HEALTH COVERAGE PARTICIPATION REQUIREMENTS

Sec. 311. Health coverage participation requirements

Current Law

Currently, it is optional whether employers contribute to the costs of health insurance for their employees' health insurance. For employers who choose to offer coverage to their employees, the cost to an employer of providing health coverage for its employees, including the cost of employer contributions towards health coverage premiums, is generally deductible as an ordinary and necessary business expense for employee compensation. In addition, compensation in the form of employer-provided health insurance is not subject to payroll taxes.

The Employee Retirement Income Security Act of 1974 ("ERISA") preempts state law relating to certain employee benefit plans, including employer-sponsored health plans. While ERISA specifically provides that its preemption rule does not exempt or relieve any person from any state law which regulates insurance, ERISA also provides that an employee benefit plan is not deemed to be engaged in the business of insurance for purposes of any state law regulating insurance companies or insurance contracts. As a result of this ERISA preemption, self-insured employer-sponsored health plans need not provide benefits that are mandated under state insurance law.

While ERISA does not require an employer to offer health benefits, it does require compliance with certain rules if an employer chooses to offer health benefits, such as compliance with plan fiduciary standards, reporting and disclosure requirements, and procedures for appealing denied benefit claims. ERISA was amended (as well as the Public Health Service Act[1] and the Internal Revenue Code) in the Consolidated Omnibus Budget Reconciliation Act of 1985 ("COBRA") and the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), adding other federal requirements for health plans, including rules for health care continuation

[1] 42 U.S.C. 6A.

coverage, limitations on exclusions from coverage based on preexisting conditions, and a few benefit requirements such as minimum hospital stay requirements for mothers following the birth of a child.

Under Medicaid, states may establish "premium assistance" programs, which pay a Medicaid beneficiary's share of premiums for employer-sponsored health coverage. Besides being available to the beneficiary through his or her employer, the coverage must be comprehensive and cost-effective for the State. A 2007 U.S. Department of Health and Human Services, Center for Medicare and Medicaid Services analysis titled "The State Children's Health Insurance Program" showed that 12 states had Medicaid premium assistance programs as authorized under current law.

Proposed Law

An employer has a responsibility requirement. To fulfill the requirement, employers offering health benefit plans are required to offer individual and family coverage under a qualified health benefits plan (or under certain grandfathered plans). They are required to make contributions to help discharge the coverage costs of employees enrolled in the employer-provided plan.

Beginning in the second year after the general effective date of the market reforms of the bill, employers are required to make contributions to the Health Insurance Exchange (the "Exchange") for employees who decline employer-provided coverage and instead enroll in an Exchange-participating plan pursuant to an affordability waiver. However, contributions are not required if the employee declines coverage because the employee is enrolled in family coverage in the Exchange as a spouse or dependent of another insured. The provision is effective for periods beginning after December 31, 2012.

Sec. 312. Employer responsibility to contribute towards employee and dependant coverage

Employers that offer health benefit plans are required to offer individual and family coverage under a qualified health benefit plan (or certain grandfathered health insurance plans). For a plan to be a "qualified health benefits plan" it needs to meet certain minimum coverage requirements, minimum benefit requirements, and has specific requirements such as a prohibition on annual and lifetime limits, but it need not be offered through the Exchange. They are required to make contributions to help discharge the coverage costs of employees (and their spouses and qualifying children, if any) enrolled in the employer-provided plan.

For full time employees, the contribution amount is required to be at least 72.5% of the lowest cost plan offered by the employer which meets the requirements of the essential benefits package. This employer contribution amount is 65% for eligible employees electing family coverage. The essential benefits bans annual or life time limits on covered health care items or services and certain specified minimum services, it has a set out of pocket maximum, it imposes certain requirements as to network adequacy as determined by the Health Choices Commissioner, and other protections.

For part-time employees, the contribution amount is a fraction or prorated amount of the minimum contributions made for full time

employees, with such fraction being equal to a ratio of the average weekly hours worked by the employee compared to the minimum weekly hours specified by the Health Choices Commissioner. The coverage offered to non full time employees can be a less generous coverage package but the coverage package must meet the essential benefits requirements at a minimum.

An employer cannot satisfy the minimum contribution requirement through a salary reduction arrangement with the employee.

An employer that elects to offer health benefit plans must provide each employee with a 30-day opt-out period after the employee becomes eligible for employer-provided coverage in which to either decline coverage entirely or affirmatively enroll in a health plan. At the end of the 30-day period, if the employee does not make an affirmative election with respect to health coverage, the employer must automatically enroll the employee for individual (not family) coverage in the employer-sponsored health benefit plan with the lowest applicable employee premium.

Employers are required, within a reasonable period before the beginning of each plan year, to provide employees with written notice of employees' rights and obligations relating to automatic enrollment. The notice must be both comprehensive in scope (for example, it must explain opt-out and affirmative election rights) and easily understood by the average employee to whom it pertains. Specifically, the notice must explain an employee's right to make an affirmative election as to health coverage rather than being automatically enrolled; and, if more than one level of benefits or employee premium is offered by the employer, the notice must explain in which level of benefits and employee premium the employee will be automatically enrolled absent an affirmative election.

Employers that offer health benefit plans are required to provide the Health Choices Commissioner, and the Secretaries of Labor, Health and Human Services, and the Treasury with information required by the Health Choices Commissioner to ascertain compliance with the provision's requirements.

The provision is effective for periods beginning after December 31, 2012.

Sec. 313. Employer contributions in lieu of coverage

Beginning in 2014, employers are required to make contributions to the Health Insurance Exchange for employees who decline employer-provided coverage and instead enroll in an Exchange-participating plan. The contribution amount is equal to 8% of the average wages paid by the employer to its employee during the time the employee was enrolled in the non-employer-provided plan. However, contributions are not required if the employee declines coverage because the employee is enrolled in family coverage as a spouse or dependent of another insured. Additionally, such contributions are not required if an employee declines coverage for any reason and does not enroll in the exchange, including receiving coverage through Medicare, Medicaid, as a spouse or dependent of another's plan, or chooses to not be covered.

Employers with annual payrolls not exceeding $250,000 during the preceding calendar year are not subject to the tax. Employers with annual payrolls between $250,000 and $400,000 during the preceding calendar year are subject to a reduced rate. Employer

contributions are paid to the Health Choices Commissioner and deposited into the Health Insurance Exchange Trust Fund. The contributions are not tied to a particular employee (i.e., the contribution does not subsidize an employee's premium liability). This contribution requirement parallels the payroll tax equal to 8% of wages that applies to non-electing employers. The provision is effective for periods beginning after December 31, 2012.

Sec. 314. Authority related to improper steering

The Health Choices Commissioner (in coordination with the Secretaries of Labor, Health and Human Services, and the Treasury) has the authority to set standards for determining whether employers, in the course of offering coverage, are undertaking any actions to affect the risk pool within the Health Insurance Exchange by inducing sicker or older employees to enroll in Exchange-participating health plans rather than in employer-provided plans. An employer found to be violating these standards is treated as not meeting the provision's coverage requirements. The provision is effective for periods beginning after December 31, 2012.

Part 2—Satisfaction of Health Coverage Participation Requirements

Sec. 323. Satisfaction of health coverage participation requirements under the Public Health Service Act

Under the provision, employers are required to make an affirmative election regarding whether to offer health benefit plans to employees. Employers electing to offer health benefit plans are required to have their plans meet certain minimum coverage requirements. Employers electing to offer health benefit plans are treated as having established and maintained a group health plan for purposes of ERISA, and the provision's health coverage participation requirements are deemed to be part of the terms and conditions of the employer-provided plan.

The Secretary of Health and Human Services is required to conduct periodic audits of a representative sampling of employers and employer-provided group health plans in order to discover noncompliance. The Secretary of Health and Human Services must share findings of noncompliance with the Secretary of the Treasury and the Health Choices Commissioner, and must take timely enforcement action as appropriate to achieve compliance.

Separate elections may be made with regard to full time employees and those who are not full time employees. Coverage offered each need not be equivalent, but both must be offered coverage that meets the essential benefits package at a minimum.

The Secretary of Health and Human Services (in coordination with the Health Choices Commissioner) may terminate an employer's election (and thus subject the employer to the payroll tax imposed on employers that do not offer coverage) if the Secretary determines that the employer was substantially noncompliant with the health coverage participation requirements. The Secretary is permitted to promulgate regulations to carry out the provisions of these coverage requirements, and may issue interim final rules as appropriate.

Employers who elect to provide coverage but whose health benefit plans fail to meet the provision's minimum health coverage participation requirements are subject to penalties of $100 per day for each employee to whom the failure applies. The provision permits the penalties to be assessed through an excise tax or a civil penalty under the Public Health Service Act. Penalties for any particular failure may not be duplicated, however. The Secretary of Health and Human Services is required to give advance written notification of failure to employers prior to the assessment of a penalty.

The penalties do not apply to (1) periods during which an employer used reasonable diligence but did not discover any failures, and (2) failures that were corrected within 30 days of discovery (but only if such failures were due to reasonable cause and not willful neglect). Penalties imposed on employers for unintentional failures (i.e., due to reasonable cause and not willful neglect) are to be limited to the lesser of 10 percent of the aggregate amount paid or incurred by the employer during the preceding taxable year for group health plans, or $500,000.

The provision is effective for periods beginning after December 31, 2012.

Sec. 324. Additional rules relating to health coverage participation requirements

The Health Choices Commissioner and the Secretaries of Labor, Health and Human Services, and the Treasury are required to execute an interagency memorandum of understanding to ensure coordination with respect to regulations, rulings, interpretations, and enforcement of the employer responsibility requirements relating to the offering of health insurance set forth in the Code and the parallel provisions in ERISA and the Public Health Service Act. The interagency memorandum must provide that in the case of multiemployer group health plans the health coverage participation requirements apply to the plan sponsor and the contributing sponsors of the plan. A multiemployer plan is a collectively bargained plan maintained by more than one employer, usually within the same or related industries, and a labor union. ERISA section 3(37). The provision is effective for periods beginning after December 31, 2012.

ABORTION-RELATED LANGUAGE IN DIVISION A

Current Law

Abortion is widely covered by private insurance. One study concluded that, of surveyed insurance plans, 87% covered abortion services.[2] Another study found that, of surveyed insurance plans, 46% covered abortion services.[3] A comparison of the two studies examined the different methodologies used by each (e.g., who was surveyed, definition of plans), and concluded that, "The actual answer is probably somewhere in between, meaning that most Ameri-

[2] Sonfield, et al., "U.S. Insurance Coverage of Contraceptives and the Impact Of Contraceptive Coverage Mandates," *Perspectives on Sexual and Reproductive Health* (2002) (available at *http://www.guttmacher.org/pubs/psrh/full/3607204.pdf*).

[3] Claxton, et al., "Employer Health Benefits: 2003," Kaiser Family Foundation (2003) (available at *http://www.kff.org/insurance/upload/Kaiser-Family-Foundation-2003-Employer-Health-Benefits-Survey-Full-Report.pdf*).

cans with employer-based insurance currently have coverage for abortion."[4]

Some states impose restrictions on what abortion services private insurance may cover. Currently, four states restrict insurance coverage only to instances in which pregnancy endangers the life of the woman; in those states abortion coverage is only available through a separate rider at additional cost.[5] Additional states impose restrictions on insurance for public employees.[6]

Federal health programs (including Medicaid) are prohibited from using federal funds to pay for abortion services by an amendment added annually since 1977 to the Labor/HHS/Appropriations bill.[7] That amendment (popularly known as the "Hyde Amendment") in its current form prohibits the use of federal funds for any abortion unless the pregnancy is the result of rape or incest or is life-endangering.[8] The amendment affirmatively adds, however, that it does not prohibit the expenditure of private funds by a state, locality, entity, or private person.[9] Indeed, while federal funds may not be used to provide abortion services through Medicaid, seventeen states pay for all or most medically necessary abortions with their own funds and another six states use state funds to pay for a limited group of abortions beyond the Hyde Amendment.[10]

Proposed Law

The legislation makes no changes to the Hyde Amendment. All funds appropriated through the Labor/HHS Appropriations bill each year will continue to be covered by its restrictions, as they have for more than 30 years. But, with the exception of those programs in Division C, most funds in this legislation are not to be subject to annual appropriations and will not be subject to the Hyde Amendment. The bill as originally introduced was silent on abortion services, providing only a broad list of health benefit categories and leaving the determination of specific benefits to the Health Benefits Advisory Committee and the Secretary. If no changes had been made to the bill, it would have been possible to construe the legislation to allow federal funds to be used to pay for abortion services.

For this reason, the Committee adopted an amendment offered by Congresswoman Capps (and already popularly known as the "Capps Amendment"). That amendment places a number of restrictions on abortion in health reform, which are discussed in detail below. Most notably, it prohibits the use of Affordability Credits

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[4] "Guttmacher Memo on Insurance Coverage of Abortion," Guttmacher Institute (July 22, 2009; updated Sept. 18, 2009) (available at *http://www.guttmacher.org/media/inthenews/2009/07/22/index.html*).

[5] "State Policies in Brief: Restricting Insurance Coverage of Abortion," Guttmacher Institute (Oct. 1, 2009) (available at *http://www.guttmacher.org/statecenter/spibs/spib_RICA.pdf*).

[6] Ibid.

[7] Shimabukuro "Abortion: Legislative Response," CRS Report for Congress (Apr. 10, 2009).

[8] Cf. Secs. 506 and 507 of H.R. 3293 ("An Act making appropriations for the Departments of Labor, Health and Human Services, and Education, and related agencies for the fiscal year ending September 30, 2010, and for other purposes")(111th Congress, 1st Session)(2009) (available at *http://thomas.loc.gov/cgi-bin/query/C?c111:./temp/~c111gEfpRH*).

[9] Sec. 507(b) of H.R. 3293 ("An Act making appropriations for the Departments of Labor, Health and Human Services, and Education, and related agencies for the fiscal year ending September 30, 2010, and for other purposes")(111th Congress, 1st Session)(2009) (available at *http://thomas.loc.gov/cgi-bin/query/C?c111:./temp/~c111gEfpRH*).

[10] "State Policies in Brief: State Funding of Abortion Under Medicaid," Guttmacher Institute (October 1, 2009) (available at *http://www.guttmacher.org/statecenter/spibs/spib_SFAM.pdf*).

(the federal funds in the bill that assist people to purchase health insurance) to pay for abortions that are not allowed by the Hyde Amendment. It also prohibits all parties with decision-making authority (i.e., the Secretary of HHS, the Commissioner of the Exchange, and the Benefits Advisory Committee) from requiring that abortion coverage be made a minimum benefit in health insurance; the decision whether or not to cover abortion is to be made individually by each plan in the Exchange. A detailed description follows.

Under the terms of the bill, abortion cannot be made a required minimum benefit; the bill notes every party that might have a role in such a decision (i.e., the Secretary, the Benefits Advisory Committee, and the Commissioner of the Exchange) and prohibits each from requiring that abortion services be made a minimum benefit. Instead, each private insurance plan is allowed to decide on its own whether to cover abortion. In the case of the public option, the Secretary of HHS must decide if abortion will be covered. As such decisions are made, the Commissioner (who administers the workings of the Insurance Exchange) must assure that every region has at least one plan that covers abortion and one plan that does not. (It should be noted that Commissioner may designate as the plan that does not cover abortion a plan that covers all of the Hyde exceptions (i.e., rape, incest, or life-endangerment), some of the Hyde exceptions, or none of them.)

Plans (including the public option) that do choose to cover abortion may not pay for abortions beyond those permitted by the Hyde Amendment with federal funds; those permitted by the Hyde Amendment may be paid for with Federal funds. Inasmuch as the Hyde Amendment is an annual decision by the Congress as part of its appropriations process and has, over its history, varied in its exceptions,[11] the bill does not incorporate the statutory language of the Hyde Amendment. Rather, the bill adopts by cross-reference the Hyde Amendment to the Labor/HHS Appropriations legislation as it is in force in any future year. Thus, if the Hyde Amendment were amended to return to its original form (i.e., including an exception only for life-endangerment but not for rape or incest), the allowable use of federal funds in plans in the Exchange would automatically be restricted in the same way. Conversely, if the Hyde Amendment were amended to include a new exception (e.g., fetal abnormality, an exception included in a number of state laws[12]), then the allowable use of federal funds in plans in the Exchange would automatically be expanded in the same way. The Committee has made this cross-reference in an attempt to keep the use of federal funds for abortions consistent across programs: Medicaid and other appropriated programs will be governed by the annual Hyde Amendment; inasmuch as many beneficiaries will likely move from Medicaid to the Exchange (or vice versa) during a year, the Committee believes insurance coverage through the Exchange should be parallel to coverage in Medicaid. If abortion restrictions change in Medicaid, it will be simpler for the beneficiary, her health care providers, and program administration if the restrictions in the Exchange are automatically the same. The Committee emphasizes

[11] Shimabukuro, "Abortion: Legislative Response," CRS Report for Congress, p. 13 (Apr. 10, 2009).

[12] "State Policies in Brief: State Funding of Abortion Under Medicaid," Guttmacher Institute, p. 2 (Oct. 1, 2009) (available at *http://www.guttmacher.org/statecenter/spibs/spib_SFAM.pdf*).

that this cross-reference itself makes no change in the Hyde Amendment itself or in its application to any federal funds.

Under the legislation, the Commissioner of the Exchange is required to estimate the actuarial cost of abortion coverage beyond that allowed under the Hyde Amendment under a basic plan. In a routine actuarial estimate of health services, one might consider the cost offsets of such coverage; for instance, in the case of abortion, the estimator might calculate the foregone insurance costs of labor, delivery, and postnatal care. In this case, however, the legislation forbids the Commissioner from taking such offsets into account. The Committee has taken these extra steps to ensure that the full estimated cost is one that is covered solely by private dollars and that federal funds are not used to pay for abortion services.

After the Commissioner has estimated the actuarial cost of abortion coverage, those plans that have voluntarily chosen to include such coverage (including the public option, if the Secretary chooses to have it cover abortion) must segregate sufficient policyholder premium dollars to pay for abortion services beyond those allowed by the Hyde Amendment. As with the Hyde Amendment, no federal funding (meaning no general revenue funds, no taxpayer funds, no public dollars, etc.) may be used for this purpose. Premium dollars, however, are money that comes directly from the insured person and goes directly to their insurance plan; the funds are not deposited in the Treasury, they do not come through Washington, and they do not pass through the tax system. It is factually, legally, and theoretically wrong to characterize these funds as federal funds. Similar prohibitions on the use of federal funds by an agency have widespread precedent: For example, federal contractors may not use federal funds to lobby, and religious organizations receiving federal assistance for a secular purpose may not use federal funds to promote religion. These prohibitions are successfully and routinely carried out with accounting procedures and audits by both the administering agencies and, in some instances, the Government Accountability Office.

The legislation also affirmatively states that the bill does not preempt any state laws regarding abortion (including parental consent, waiting periods, etc.). In considering the applicability of other aspects of health reform to the insurance that state and local governments provide to their employees, the Committee specifically discussed the limitations that some states have imposed on abortion coverage. The Committee was explicit that these limitations will be preserved under the legislation and that similar limitations and restrictions are to be allowed to continue.

The legislation also explicitly continues a variety of laws popularly known as Abortion Conscience Clauses (i.e., permission for providers to refuse to provide abortions and not to be discriminated against on that basis).[13] Some of these laws are permanent (e.g., the Church Amendment, adopted in 1973); others are annual (e.g., the amendments to the Labor/HHS Appropriations Acts, popularly known as the Weldon Amendment).

[13] For a discussion of such laws, see Shimabukuro, "The History and Effect of Abortion Conscience Clause Laws," CRS Report for Congress (Apr. 7, 2009).

In addition to the Capps Amendment, which continues existing Abortion Conscience Clauses that already exist, the Committee also adopted another amendment, authored by Congressman Stupak, to create a new conscience clause specifically for this legislation. This provision would prohibit any public entity (federal, state, or local) that receives funding under this Act (or an amendment made by this Act) from discriminating against a health care entity on the basis of that entity's unwillingness to provide, pay for, provide coverage for, or refer for abortions.

DIVISION B—MEDICARE AND MEDICAID IMPROVEMENTS

TITLE I—IMPROVING HEALTH CARE VALUE

Subtitle A—Provisions Relating to Medicare Part A

PART 1—MARKET BASKET UPDATES

PART 2—OTHER MEDICARE PART A PROVISIONS

Subtitle B—Provisions Related to Part B

PART 1—PHYSICIANS' SERVICES

Sec. 1121. Sustainable growth rate reform

Current Law

Medicare payments for services of physicians and certain nonphysician practitioners are made on the basis of a fee schedule. The fee schedule assigns relative values to services that reflect physician work (i.e., time, skill, and intensity it takes to provide the service), practice expenses, and malpractice costs. The relative values are adjusted for geographic variation in costs. The adjusted relative values are then converted into a dollar payment amount by a conversion factor. The law specifies a formula, commonly referred to as the sustainable growth rate (SGR) system, for calculating the annual update to the conversion factors and the resultant fees.

If cumulative physician expenditures are below the expenditure target, then an annual update is calculated based on several variables including the Medicare Economic Index (MEI). (Created in 1975, the MEI is an inflation index similar to the Consumer Price Index that includes the prices of inputs required for the production of physician services including the physician's time, the cost of hiring employees such as technicians and clerical staff, rent, medical equipment, supplies, and drugs.) However, when cumulative physician expenditures exceed the expenditure target, the SGR system reduces the annual update factor (and therefore, all physician reimbursements under the fee schedule) to attempt to bring cumulative expenditures in line with the target.

Reductions resulting from application of the SGR have been frequently overridden by legislation. Section 101 of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (P. L. 110–173, MMSEA) increased the update to the conversion factor for Medicare physician payment by 0.5% compared with 2007 rates for the first six months of 2008. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, P.L. 110–275) extended the 0.5% increase in the physician fee schedule that was set to expire

on June 30, 2008, through the end of 2008 and set the update to the conversion factor to 1.1% for 2009. The conversion factor for 2010 and subsequent years will be computed as if this modification had never applied, so unless further legislation is passed, the update formula will require a 21% reduction in physician fees beginning January 1, 2010 and by additional amounts annually for at least several years thereafter.

The calculation of the expenditure target has been criticized for including items that are not reimbursed under the Medicare physician fee schedule. Specifically, MedPAC and various physician organizations have suggested removing Part B drugs from the calculation of the baseline and growth targets. In its proposed rule for payment for physicians' services in 2010, CMS proposed removing Part B drugs from those targets.

Proposed Law

For the past several years, Congress has failed to make substantive changes to the SGR mechanism.

Since 2002, Congress has enacted a series of short-term fixes that have avoided payment reductions called for by the SGR, but failed to address the fundamental flaws with the formula. Meanwhile, the projected budgetary cost of comprehensive reform to the SGR has soared and the depth of required payment rate reductions has deepened.

The Committee has long recognized that the current update methodology is unsustainable and must be replaced. This legislation makes needed reforms that reflect more realistic allowances for growth in spending on physician services, while still holding physicians accountable for overall spending on the services they provide.

Instead of grouping all physician expenditures together in the calculation of the annual update to the fee schedule under the SGR system, the bill would establish separate target growth rates for evaluation and management services and for all other services. This will help counteract the historical undervaluation of those services. The bill would also rebase the SGR baseline to 2009 expenditures for calculating future expenditure targets.

Future update adjustments would be calculated against a new baseline; the allowed expenditures for 2009 would be the amount of the actual expenditures for physicians' services during 2009. Instead of setting the expenditure target using physician expenditures since April 1, 1996, increased according to the SGR system, the proposal would rebase the physician expenditure target using physician expenditures beginning January 1, 2009, with future targets determined under a new formula. The proposal would also limit the services included in the target growth rate computation to services covered under the physician fee schedule.

The bill would modify how updates to the fee schedule would be determined. For 2010, the update to the single conversion factor would be the percentage increase in the MEI. To calculate future updates, separate target growth rates would be established for 2 categories of services: evaluation and management services and all other services. Evaluation and management services would include procedure codes for Medicare covered services in the category designated Evaluation and Management in the Health Care Common

Procedure Coding and Medicare-covered preventive services. The service categories would apply without regard to the specialty of the physician providing the service. The calculation of the update factors would be based on physician expenditures in these categories beginning January 1, 2009.

The application of multiple conversion factors would begin with 2011. The initial conversion factors for 2011 would be based upon the single conversion factor for 2010 multiplied by the update factors for such category for 2011. To update the conversion factors for the two service categories in subsequent years, the conversion factor for each category for the previous year would be adjusted by the update established for the category.

In determining the allowed expenditures for 2010, total 2009 actual expenditures for all services included in the SGR computation for each service category would be increased by the growth rate to obtain 2010 allowed expenditures for each service category. In subsequent years, the amount of allowed expenditures for such category would be the allowed expenditures for the preceding year increased by the target growth rate (as described below) for such category and year.

Each category would have a separate target growth rate. The target growth rate for a year, beginning with 2010, would be computed and applied separately for each service category as defined above and would be computed using the same method for computing the target growth rate except that the update to the conversion factor for evaluation and management services as well as Medicare covered preventive services would be allowed to increase by the percentage growth rate of GDP per capita plus 2 percentage points, while the increase for all other physicians' services would be allowed to grow at the percentage rate of increase in GDP per capita plus 1 percentage point. The Secretary would publish the target growth rate for such succeeding year and each of the 2 preceding years by November 1 of each year.

Creating two separate expenditure targets and allowing higher growth for evaluation and management and preventive services infuses additional resources into these services to encourage their use. Furthermore, removing labs, drugs, and other "incident to" services from the calculation will result in the targets being more closely aligned with actual spending for physician services, rather than drug price inflation. Where the current system imposes a growth target of per capita GDP, the provision will allow spending to grow at GDP + 2 or GDP + 1 for each category, a target more in line with expected and historical growth in medical spending. A more realistic target will create a more stable payment system while still maintaining spending restraints in payments for physician services.

Providers participating in the accountable care organization (ACO) pilot program would have the option of pursuing separate target growth amounts applicable only that organization. No later than January 1, 2012, the Secretary would develop a method that would (1) allow each ACO to have its own Medicare Part B expenditure targets and updates that would be consistent with the methodologies described above, and (2) provide that the target growth rate applicable to other physicians would not apply to physicians to the extent that their services are furnished through the ACO.

This method would apply beginning with 2012. In determining the expenditure targets and updates for physicians in the ACO pilot program, the Secretary could apply the difference in the update on a claim-by-claim or lump sum basis and such a payment would be taken into account under the pilot program. Allowing accountable care organizations to have their own unique spending targets will increase the incentive for physicians to form or join such organizations. Physicians who participate in ACOs and choose to have their own spending targets will be held harmless from growth of physicians outside the ACO, further incentivizing those physicians to participate in an ACO arrangement.

Sec. 1122. Misvalued codes under the physician fee schedule

Current Law

The Medicare physician fee schedule is based on assigning relative weights to each of the approximately 7,500 physician service codes used to bill Medicare. The relative value for a service compares the relative work involved in performing one service with the work involved in providing other physicians' services. The scale used to compare the value of one service with another is known as a resource-based relative value scale (RBRVS).

The Centers for Medicare and Medicaid Services (CMS), which is responsible for maintaining and updating the fee schedule, continually modifies and refines the methodology for estimating relative value units (RVUs). CMS relies on advice and recommendations from the American Medical Association/Specialty Society Relative Value Scale Update Committee (RUC) in its assessments. In general, as currently implemented, increases in RVUs for a service or number of services lowers the resultant fees for other physician services. One consequence has been that the payments for evaluation and management codes, whose RVUs typically are not increased over time, have fallen relative to other codes whose RVUs have increased as a consequence of new technologies that have been introduced into coverage with relatively high RVUs. CMS is required to review the RVUs no less than every five years.

In determining adjustments to RVUs used as the basis for calculating Medicare physician reimbursement under the fee schedule, the Secretary has authority to adjust the number of RVUs for any service code to take into account changes in medical practice, coding changes, new data on relative value components, or the addition of new procedures. The Secretary is required to publish an explanation of the basis for such adjustments.

These adjustments are subject to a budget neutrality condition. With the exception of certain expenditures that are exempt by statute, the adjustments may not cause the amount of expenditures made under the Medicare physician fee schedule to differ from year to year by more than $20,000,000 from the expenditures that would have been incurred without such an adjustment.

Under current law, the Secretary appoints 15 physicians (nominated by physicians organizations) to form the Practicing Physicians Advisory Council, including both participating and nonparticipating physicians and physicians practicing in rural areas and underserved urban areas. This council meets each quarter to discuss certain proposed changes in regulations and carrier manual

instructions related to physician services identified by the Secretary.

Proposed Law

Traditionally the five-year review has led to more increases in work RVUs than decreases. MedPAC and other observers have stated that more attention needs to be given to the accurate valuation of services in order to maintain the integrity of the fee schedule.

The provision gives clearer direction to the Secretary to maintain accurate valuation of services and prioritizes identification of potentially misvalued codes. The provision also addresses concerns that CMS does not have the resources or administrative authority to conduct such reviews by providing funding to the agency. Providing additional resources will promote collection of more timely and accurate data that can be used to improve valuation of services.

The Secretary would periodically identify and make appropriate adjustments to the relative values for the services identified as being potentially misvalued. The Secretary would examine the following, as appropriate: (1) codes (and families of codes as appropriate) for which there has been the fastest growth; (2) codes (and families of codes as appropriate) that have experienced substantial changes in practice expenses; (3) codes for new technologies or services within an appropriate period (such as three years) after the relative values are initially established for such codes; (4) multiple codes that are frequently billed in conjunction with furnishing a single service; (5) codes with low relative values, particularly those that are often billed multiple times for a single treatment; (6) codes that have not been subject to review since the implementation of the RBRVS (the so-called Harvard-valued codes"); and (7) such other codes determined to be appropriate by the Secretary.

In conducting the review and adjustments (1) the Secretary could use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services; (2) the Secretary could conduct surveys, other data collection activities, studies, or other analyses as appropriate to facilitate the review and appropriate adjustment; (3) the Secretary could use analytic contractors to identify and analyze potentially misvalued services identified, conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of services; (4) the Secretary could coordinate the review and appropriate adjustment with the existing periodic (no less often than every 5 years) review of the relative values; (5) the Secretary could make appropriate coding revisions (including using existing processes for consideration of coding changes) that could include consolidation of individual services into bundled codes for payment under the fee schedule; and (6) the Secretary would apply the existing budget neutrality condition that applies to relative value adjustments to this proposal.

The Secretary would establish a process to validate relative value units under the fee schedule. The evaluation process could include validation of work elements (such as time, mental effort and professional judgment, technical skill and physical effort, and stress due to risk) involved with furnishing a service and could include valida-

tion of the pre, post, and intra-service components of work. The validation of work relative value units would include a sampling of codes for services that is the same as the potentially misvalued codes described above.

The Secretary could conduct the validation using methods described above to identify potentially misvalued services, as the Secretary determines to be appropriate. Following the evaluation, the Secretary would make appropriate adjustments to the work relative value units under the fee schedule. The same budget neutrality provision would apply to adjustments to relative value units made as a result of the evaluation.

For FY2010 and each subsequent fiscal year, $20 million would be appropriated to the CMS Program Management Account to carry out the provisions described above. The amounts appropriated for a fiscal year would be available until expended.

The provision also clarifies how certain existing statutes might pertain to the proposals contained in this section. Chapter 35 of title 44 of the United States Code, pertaining to the Coordination of Federal Information Policy, and the provisions of the Federal Advisory Committee Act (5 U.S.C. App.) would not apply to the modifications proposed in this section. Notwithstanding any other provision of law, the Secretary could implement the proposed modifications in order to identify, adjust, and evaluate potentially misvalued codes by program instruction or otherwise. Section 4505(d) of BBA, which placed requirements on how the Secretary developed the practice expense RVUs, would be repealed. Except for provisions related to confidentiality of information, the provisions of the Federal Acquisition Regulation would not apply to this section or the amendment made by this section. Finally, the statute establishing the Practicing Physicians Advisory Council would be repealed.

Sec. 1123. Payments for efficient areas

Current Law

Medicare uses a fee schedule to reimburse physicians for the services they provide. In certain circumstances, physicians receive an additional payment to encourage targeted activities. These bonuses, typically a percentage increase above the Medicare fee schedule amounts, can be awarded for a number of activities including demonstrating quality achievements, participating in electronic prescribing, or practicing in underserved areas.

Proposed Law

The proposal would create new incentive payments for "efficient" areas. Providers delivering services on or after January 1, 2011, and before January 1, 2013, who practice in an area identified as an "efficient" area would receive an additional payment (on a monthly or quarterly basis) equal to 5% of the payment amount for the Medicare Part B services.

Based upon available data, the Secretary would identify those counties or equivalent areas in the United States in the lowest fifth percentile of utilization based on per capita spending for Medicare part A and part B services provided in the most recent year for which data are available as of the date of the enactment. The Sec-

retary would standardize per capita spending to eliminate the effect of geographic adjustments in payment rates.

For purposes of the additional payment for providers in "efficient" areas, if the Secretary were to use the 5–digit postal ZIP Code where the service is furnished, the dominant county of the postal ZIP Code would be used to determine whether the postal ZIP Code is in a county described as an "efficient" area. There would be no administrative or judicial review respecting (1) the identification of a county or other area as an efficient area; or (2) the assignment of a postal ZIP Code to a county or other area designated as an efficient area.

The Secretary would identify counties or areas designated as "efficient" as part of the proposed and final rule to implement the physician fee schedule for the applicable year. The Secretary would post the list of counties identified as efficient on the CMS website.

Sec. 1124. Modifications to the Physician Quality Reporting Initiative (PQRI)

Current Law

The Tax Relief and Health Care Act of 2006 (TRHCA, P.L. 109–432) required the establishment of a physician quality reporting system that would include an incentive payment, based on a percentage of the allowed Medicare charges for all such covered professional services, to eligible professionals who satisfactorily report data on quality measures. CMS named this program the Physician Quality Reporting Initiative (PQRI). The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, P.L. 110–275) made this program permanent and extended the bonuses through 2010; the incentive payment was increased from 1.5% of total allowable charges under the physician fee schedule in 2007 and 2008 to 2% in 2009 and 2010.

Providers that successfully report for services provided in calendar year 2009 will receive an incentive payment of two percent of total allowable charges for the physician fee schedule. Providers may choose claims-based reporting or registry-based reporting. For claims-based reporting, providers seeking incentive payments for the entire calendar year may meet the requirement by reporting on one measures group for a sample of 30 consecutive Medicare part B fee-for-service patients (FFS), or report for one measures group for 80% of applicable Medicare part B FFS. For providers seeking to report for the six-month period beginning July 1, 2009, similar criteria apply for those that report through CMS approved registries.

Proposed Law

The PQRI program has the potential to be a valuable tool measuring the quality of services furnished by physicians to Medicare beneficiaries. However, its potential usefulness has been limited by problems with the way the initiative has been implemented. This provision addresses those problems, extends the payment initiative for two years, and improves the program by integrating it with the incentive program for the adoption and use of health information technology.

Not later than January 1, 2011, the Secretary would develop and implement a mechanism to provide timely feedback to eligible professionals on the performance of the eligible professional with respect to satisfactorily submitting data on quality measures under the PQRI program.

Not later than January 1, 2011, the Secretary would establish and have in place an informal process for eligible professionals to appeal the determination that an eligible professional did not satisfactorily submit data on quality measures for the PQRI program.

The bill would integrate physician quality reporting under the PQRI and EHR reporting relating to the meaningful use of EHR. The integration would consist of the following: (1) the development of measures that would both demonstrate meaningful use of an electronic health record for purposes of EHR reporting and provide information on the clinical quality of the care furnished to an individual; (2) the collection of health data to identify deficiencies in the quality and coordination of care for Medicare beneficiaries; and (3) other activities as specified by the Secretary. The Secretary would develop such a plan no later than January 1, 2012.

Incentive payments under the PQRI program would be extended by two years, through 2012; for each of the years 2009 through 2012, the bonus would be 2% of Part B payments.

Sec. 1125. Adjustment to Medicare payment localities

Current Law

The Medicare fee schedule pays providers differently according to the geographic location, known as a Medicare physician payment locality, in which the provider practices. By construction, the costs of providing physician services were relatively consistent within each payment locality at the time when they were defined; sub-regions of a state were designated as separate payment localities only if the data showed a marked difference between the costs in that area compared with the rest of the state.

Each year, the Centers for Medicare and Medicaid Services (CMS) uses data from a number of sources to calculate separate geographic practice cost indices (GPCIs) for each payment locality for each of three component inputs required to produce physician services (physician work, practice expense, and medical malpractice insurance). For each locality, these 3 GPCIs are then combined to produce a weighted average index of relative costs, called the geographic adjustment factor (GAF).

In constructing the payment localities, the Health Care Financing Administration (HCFA, now CMS) used an iterative criteria that compared the relative cost of a potentially distinct locality with the GAFs in the rest of the state. Localities that had GAFs at least 5% higher than the rest of the state were designated as a separate locality; this process was repeated until this condition was not met, whereupon the remaining regions of the state were combined into one locality. In 1996, HCFA reduced the number of Medicare localities for physician payment by aggregating several existing contiguous localities with similar costs and combining other localities to create a single payment area for the entire state. As a result, there are currently 89 Medicare physician payment localities based on counties or aggregates of counties across the 50

states; some localities are the entirety of the state while other states may have several payment localities. None of the payment localities cross state lines.

Economic conditions have affected parts of the country differently in the years since the payment localities were created. If localities were to be created based on data from recent years using the original methodology, the resulting number and composition of the payment localities might not be the same as the ones that currently exist.

Proposed Law

A GAO report issued July 2007 confirmed significant problems with inaccurate pricing that result from current methodology used to establish Medicare's payment localities. While the problem is not limited to California, during the last 15 years that state has experienced some of the largest economic and demographic shifts, leading to large disparities between local costs and geographic price adjustments. Revising and updating the state's payment localities to reflect costs at the Metropolitan Statistical Area (MSA) level will achieve a balance between price accuracy and administrative feasibility. In order to minimize the effect of resources shifting from one area of the state to another that result from this change, the provision provides temporary relief to counties in California that would be adjusted downward. The payment localities used as the basis for the geographic adjustment of Medicare physician payments under the fee schedule would be changed in the state of California. Under the proposal, payments to California physicians would transition from a system based on the current localities to one based on MSAs. For services furnished on or after January 1, 2011, the Secretary would revise the Medicare physician payment areas for the State of California to be based on MSAs.

The methodology for constructing the new payment areas would be similar to the original methodology, but the Core-Based Statistical Areas-Metropolitan Statistical Areas, as defined by the Office of Management and Budget (OMB), would be used as the geographic units for comparing GAFs. First, the Secretary would list all MSAs within California by their GAFs in descending order. In the first iteration, the Secretary would compare the GAF of the highest-cost MSA in the state to the weighted-average GAF of the group of remaining MSAs in the state. If the ratio of the GAF of the highest-cost MSA to the weighted-average GAF of the rest of state is 1.05 or greater then the highest-cost MSA becomes a separate fee schedule area. In each subsequent iteration, the Secretary would compare the MSA of the next-highest GAF to the weighted-average GAF of the group of remaining MSAs. If the ratio of the next-highest MSA's GAF to the weighted-average of the remaining lower-cost MSAs is 1.05 or greater, that MSA would become a separate fee schedule area. The iterative process would continue until the ratio of the GAF of the highest-cost remaining MSA to the weighted-average of the remaining lower-cost MSAs is less than 1.05, and the remaining group of lower-cost MSAs would form a single fee schedule area. If two MSAs were to have identical GAFs, they would be combined in that step of the iterative comparison.

The provision would require that no GPCIs be reduced during the first 5 years of the transition from the former county-based

payment localities to the MSA-based fee schedule areas. For services furnished in California on or after January 1, 2011, and before January 1, 2016, the Secretary would increase any such index to the county-based fee schedule area value on December 31, 2009, if the index under the new calculation would be less than the value on January 1, 2010.

The new fee schedule areas would be subject to periodic review and adjustments. Not less often than every 3 years, the Secretary would review and update the California Rest-of-State fee schedule area using MSAs as defined by the OMB applying the iterative methodology described above. This revision would be made effective concurrently with the application of the periodic review of the adjustment factors required under current law for California for 2012 and subsequent periods and would be linked to the review of the GPCIs for all fee schedule areas that occurs not less often than every 3 years. Upon request, the Secretary would make any county-level or MSA derived data used to calculate the geographic practice cost index available to the public.

Sec. 1126. Resource-based feedback program for physicians in Medicare

Current Law

Both MedPAC and the Government Accountability Office (GAO) have suggested that CMS provide information to physicians on their resource use with the expectation that physicians who are outliers would alter their practice patterns as a result. MedPAC asserts that physicians would be able to assess their practice styles, evaluate whether they tend to use more resources than their peers, evaluate what evidence-based research (if available) recommends, and revise practice styles as appropriate. MedPAC notes that in certain instances, the private sector use of feedback has led to a small downward trend in resource use. The GAO notes that certain public and private health care purchasers routinely evaluate physicians in their networks using measures of efficiency and other factors and that the purchasers it studied linked their evaluation results to a range of incentives to encourage efficiency.

Section 131(c) of MIPPA established such a physician feedback program, which CMS initiated before January, 2009. The Physician Feedback Program uses Medicare claims data and other data to provide confidential feedback reports to physicians (and as determined appropriate by the Secretary, to groups of physicians) that measure the resources involved in furnishing care to Medicare beneficiaries. CMS initially called this effort the Physician Resource Use Feedback Program, but has renamed this initiative the "Physician Resource Use Measurement and Reporting Program." The program would consist of multiple phases. The interim final rules for phase I of the program include the following parameters: (1) the program will use both per capita and episode of care methodologies to measure resource use; (2) the program will include a cost of service category analysis (for example, imaging services or inpatient admissions); (3) four calendar years of claims data will be used; (4) the feedback program will focus on high cost and/or high volume conditions; (5) feedback will also include reporting to physician specialties relevant to the selected focal conditions; (6) the pro-

gram will focus on physicians practicing in certain geographic areas, and (7) the program will establish low, median, and high cost benchmarks.

MIPPA also requires the GAO to conduct a study of the Physician Feedback Program as described above, including the implementation of the Program, and to submit a report to Congress by March 1, 2011, containing the results of the study, together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

Proposed Law

The proposal would expand and strengthen the existing physician feedback program. The feedback reports would include measures of the utilization of services under the Medicare program based on claims data and would include quality data under the existing physician quality reporting initiative (PQRI) as well as other information determined to be appropriate. These reports would be provided confidentially to physicians and other practitioners (those who furnish services for which payment is made under Medicare and for which such payment would be made if furnished by a physician).

No later than December 31, 2010, in consultation with physicians and others as appropriate, the Secretary would develop an episode grouper or other resource analysis tool that could be used to measure physician resource use. The Secretary could update the grouper from time to time as appropriate.

The feedback reports would include information allowing the comparison of a physician's resource use pattern to the use patterns of peers. These reports could include resource use data on a per capita basis, a per episode basis, or both. The reports would include information regarding nationwide groups of similarly situated physicians (taking into consideration specialty, practice setting, and such other criteria as the Secretary finds appropriate) and comparing the pattern of services of each physician in the group to the group average pattern of services. In the reports, the Secretary would include details about the services, procedures, and relevant clinical information to identify factors that could account for significant variation of a physician from national norms, such as high rates of elective surgeries, diagnostic services, or other utilization attributable to the judgment of the physician.

The Secretary would disseminate feedback reports and would seek to establish the reports' validity and credibility to physicians. The Secretary would experiment with communications methods such as the following: (1) direct meetings between contracted physicians, facilitated by the Secretary, to discuss the contents of feedback reports, including any reasons for divergence from national averages; (2) contracts with local, non-profit entities engaged in quality improvement efforts at the community level, who would use the feedback reports or equivalent tools as specified by the Secretary, where any data exchanged would be protected by appropriate privacy safeguards; (3) mailings or other methods of communication that facilitate large-scale dissemination; or (4) other methods specified by the Secretary.

During 2011, the Secretary would evaluate the efficacy of the feedback methods with regard to changing practice patterns to im-

prove quality and decrease costs. Taking into account the cost of each method, the Secretary would expand the program by developing a plan to disseminate feedback reports in a significant manner in the regions and cities of the country with the highest utilization of services under Medicare. The Secretary would disseminate, to the extent practicable, feedback reports in a manner consistent with the following: (A) during 2011, at least 1,000 reports; (B) during 2012, at least 10,000 reports; (C) during 2013, at least 25,000 reports; (D) during 2014 and subsequent years, reports to the physicians with utilization within the highest 5 percent of physicians, subject to the following authority to focus efforts. The Secretary could focus the program and the dissemination of feedback reports on appropriate subsets of physicians, such as physicians who (1) practice in geographic areas that account for unusually high rates of spending per capita, (2) treat conditions that have a high cost or volume under Medicare, (3) use a high amount of resources compared to other physicians, or (4) treat at least a minimum number of Medicare beneficiaries.

The Secretary would establish a process by which a physician could opt not to receive feedback reports under this program. Chapter 35 of title 44, United States Code would not apply to this section. Notwithstanding any other provision of law, the Secretary could implement this feedback program through program instruction or otherwise.

PART 2—MARKET BASKET UPDATES

Sec. 1131. Incorporating productivity improvements into market basket updates that do not already incorporate such improvements

Current Law

Medicare pays for hospital outpatient department services under its outpatient prospective payment system (OPPS). Generally, Medicare's OPPS base payment amount is increased each year by an annual update that is linked to projected changes in specific market basket (MB) indices which are designed to measure the change in the price of goods and services purchased by the provider. Starting in CY2009, hospitals paid under OPPS that do not submit required quality data will have the applicable MB percentage reduced by two percentage points. The reduction would apply for that year and would not be taken into account in subsequent years.

Ambulance services are paid on the basis of a national fee schedule, which is being phased in. The national fee schedule is fully phased-in for air ambulance services. For ground ambulance services, payments through 2009 are equal to the greater of the national fee schedule or a blend of the national and regional fee schedule amounts. The portion of the blend based on national rates is 80% for 2007–2009. In 2010 and subsequently, the payments in all areas will be based on the national fee schedule amount. The fee schedule amounts are updated each year by the consumer price index for all urban consumers (CPI–U).

Since January 1, 2008, Medicare pays for surgery-related facility services provided in an ambulatory surgery center (ASC) using a payment system based on the hospital OPPS. The new payment

system will be implemented over a four-year transition period. Beginning in CY2010, the ASC conversion factor will be updated annually using the CPI–U. This update will be subject to a 2 percentage point reduction if required quality data are not provided.

Clinical lab services are paid on the basis of area-wide fee schedules. The fee schedule amounts are periodically updated. The annual clinical laboratory test fee schedule update adjustment for 2009–2013 will be the percentage increase or decrease in the CPI–U minus 0.5 percentage points.

Except in Competitive Acquisition Areas where payments for items and services are to be based on suppliers' bids, Medicare pays for durable medical equipment (DME) on the basis of fee schedules. Items are classified into five groups for determining the fee schedules and making payments: (1) inexpensive or other routinely purchased equipment (defined as items costing less than $150 or which are purchased at least 75% of the time); (2) items requiring frequent and substantial servicing; (3) customized items; (4) oxygen and oxygen equipment; and (5) other items referred to as capped rental items. In general, fee schedule rates are established locally and are subject to national limits. In general, fee schedule amounts are updated annually by the CPI–U. Updates were eliminated for 1998–2000; payments were increased by the CPI–U for 2001; and payments were frozen for 2002. MMA eliminated the updates for 2004–2008. In 2009, for items and services selected before July 1, 2008 to be part of a Competitive Acquisition Program for durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS), the update was a decrease of 9.5 percent. This decrease applied across geographic areas and was not restricted to Competitive Acquisition Areas. This adjustment allowed provisions in the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, P.L. 110–275) delaying the implementation of the Competitive Acquisition Program to be budget neutral. For items and services that had not been selected before July 1, 2008, to be part of the Competitive Acquisition Program, the payment update for 2009 was the CPI–U. For 2010 through 2013, the updates are to be the CPI–U. In 2014, if an item received a payment decrease in 2009, the update is to be equal to the CPI–U plus 2 percentage points, otherwise the update is to be the CPI–U. Starting in 2015, the update is to be the CPI–U. Payment updates for DME do not include an adjustment for productivity.

Proposed Law

The annual update to the Medicare physician fee schedule already incorporates adjustments for gains in productivity. This provision creates uniformity across Medicare providers by creating a productivity adjustment for other Part B providers. This adjustment will encourage greater efficiency in health care provision, hold Medicare providers accountable for achieving productivity gains on par with the overall economy, and more accurately align Medicare payments with provider costs.

The productivity adjustment would equal the percentage change in the 10-year moving average of annual economy-wide private nonfarm business multi-factor productivity. The estimate used would be that published before the promulgation of the regulation establishing increases in the Medicare rates for the year or period.

The productivity adjustment would be included in annual updates for OPPS, ambulance services, clinical laboratory services, and certain durable medical equipment years beginning in CY2010. The productivity adjustment would be the same as that applied to providers in Part A established under Section 1103 of the bill.

Starting in CY2010, to the extent an annual percentage change factor applies to ASC services, it would include the productivity adjustment.

PART 3—OTHER PROVISIONS

Sec. 1141. Rental and purchase of power-driven wheelchairs

Current Law

Wheelchairs, including power-driven wheelchairs, are covered by Medicare Part B under the capped-rental category of the durable medical equipment (DME) benefit. Medicare pays for power-driven wheelchairs in one of two ways: either Medicare will pay the supplier a monthly rental amount during the beneficiary's period of medical need (though payments are not to exceed 13 continuous months), or, payment is made on a lump-sum basis at the time the supplier furnishes the chair, if the beneficiary chooses the lump-sum payment option. The same payment choice applies to replacement power-driven wheelchairs as well.

Medicare covers over 600 power wheelchair models under 42 procedure codes (Healthcare Common Procedure Coding System, HCPCS). Power wheelchairs are further classified into 3 broad groups based on their reported performance in categories such as speed, range of travel and the height of the vertical obstruction they can climb. Group 3 must meet the highest performance standards. Group 2 and Group 1 must meet intermediate and the lowest performance requirements, respectively. For example, a Group 3 wheelchair must be able to travel a minimum of 12 miles on a single charge of its batteries, while the minimum travel requirements for Group 2 and Group 1 chairs are 7 and 5 miles, respectively.

The Secretary is required to establish a competitive acquisition program for specified durable medical equipment; the competitive acquisition program would replace the Medicare fee schedule payments. The program is to be phased-in, starting in 10 of the largest metropolitan statistical areas (MSAs) in 2009; expanding to 80 of the largest MSAs in 2011 and remaining areas after 2011. The Secretary is permitted to phase-in first items and services with the highest cost and highest volume, or those items and services that the Secretary determines to have the largest savings potential first, which includes power-driven wheelchairs in the initial round of bidding.

Proposed Law

This provision would restrict the "lump-sum" payment provision for new and replacement power-driven wheelchairs to those recognized by the Secretary as classified within Group 3 or higher. The provision would be effective for chairs furnished on or after January 1, 2010, but would not apply to competitive bidding areas where bids had been submitted before October 1, 2010.

There are a sizeable number of wheelchairs purchased by Medicare during the first month of use that are not used beyond the 13

month rental period. By eliminating the first month full purchase option, the provision reduces waste in the Medicare program. This change protects beneficiaries from the burden of paying the cost-sharing associated with the wheelchair in one lump sum.

The practical requirements of patients with complex conditions such as quadriplegia and Louis Gehrig's disease usually justify the outright purchase of mobility devices rather than rentals. These special needs patients require wheelchairs that are highly customized, use complex technologies, and are in use for very long periods—if not the rest of the patient's lifetime. As such, the provision continues to allow for first-month purchase of complex mobility devices classified as Group 3 or higher.

Sec. 1141A. Election to take ownership, or to decline ownership, of a certain item of complex durable medical equipment after the 13-month capped rental period ends

Current Law

Pressure reducing support surfaces are used for the care or prevention of pressure ulcers. A pressure ulcer, also known as a bedsore, is an area of the skin that breaks down when the person stays in one position for too long without shifting his or her weight. Pressure reducing support surfaces are covered by Medicare Part B under the capped-rental category of the durable medical equipment (DME) benefit. For beneficiaries that fulfill coverage criteria for a pressure reducing support surface, Medicare will pay the supplier a monthly rental amount during the beneficiary's period of medical need (though payments are not to exceed 13 continuous months). On the first day after the thirteenth continuous month of rental payments, the supplier of the item is required to transfer title of the item to the beneficiary.

After the supplier transfers title to the beneficiary, Medicare pays for maintenance and servicing for parts and labor not otherwise covered under a manufacturer's warranty if the Secretary determines that payments are reasonable and necessary. Payment amounts for such maintenance and services are determined by the Secretary.

Support surfaces come in different categories. A Group 3 support surface is a complete bed system known as air-fluidized beds. It simulates the movement of fluid by circulating filtered air through silicone-coated ceramic beads.

Proposed Law

This provision would eliminate the automatic transfer of title of group 3 support surfaces to beneficiaries after 13 months of continuous use. Effective upon enactment, this provision would require DME suppliers, during the tenth continuous month of rental, to offer the beneficiary the option to accept or reject the transfer of title to a Group 3 support surface after the thirteenth month of rental. The beneficiary would be deemed to reject the title, unless it was accepted within one month of the offer.

If the individual accepted the title, it would be transferred on the first day that begins after the thirteenth month of continuous rental; reasonable and necessary maintenance and servicing not otherwise covered by a manufacturer's warranty would be covered by

Medicare, as under current law. If the beneficiary did not accept the title, payments for maintenance and servicing would be as follows: no maintenance and serving payment during the first 6 months following the 13 continuous months of rental payments; during the first month of each succeeding 6 month period, a maintenance and servicing payment could be made, (for parts and labor not covered by the supplier's or manufacturer's warranty as determined by the Secretary, to be appropriate for Group 3 support surfaces) and in an amount equal to the lower of (a) a reasonable and necessary maintenance and servicing fee or fees established by the Secretary, or (b) 10% of the total purchase price, as specified.

Sec. 1142. Extension of payment rule for brachytherapy

Current Law

The Medicare Prescription Drug, Improvement and Modernization Act (MMA, P.L. 108–173) required Medicare's outpatient prospective payment system to make separate payments for specified brachytherapy sources. As mandated by the Tax Relief and Health Care Act of 2006 (TRHCA, P.L. 109–432), this separate payment was made using hospitals' charges adjusted to their costs until January 1, 2008. The Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA, P.L. 110–173) extended cost reimbursement for brachytherapy services until July 1, 2008. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, P.L. 110–275) extended cost reimbursement for brachytherapy until January 1, 2010.

Proposed Law

The provision would extend cost reimbursement for brachytherapy until January 1, 2012.

Sec. 1143. Home infusion therapy report to Congress

Current Law

Infusion therapy involves the administration of medication through a needle or a catheter. If a physician determines that it is medically appropriate for a particular patient, some infusion therapies may be provided in a patient's home. Infusion therapies that can be provided in the home include treatments such as antibiotic therapy, chemotherapy, pain management, and hydration therapy.

Infusion drugs administered in a patient's home are covered under the Medicare Part D drug benefit and in some cases when such drugs are furnished incident to covered durable medical equipment. Medicare Part D does not, however, cover supplies, equipment, or professional services associated with home infusion therapy.

Proposed Law

The Committee is exploring options to promote home and community-based care to allow beneficiaries to remain healthy and independent. Expanded Medicare coverage of home infusion therapy has the potential to achieve these results for the Medicare program and for beneficiaries. It is possible that if infusion therapy was more widely available in the home setting, Medicare bene-

ficiaries could avoid the higher costs associated with being admitted to hospitals and nursing homes for this treatment. They also could avoid the serious risk of healthcare-acquired infections, which is a growing problem in institutional settings. The Committee directs the Medicare Payment Advisory Commission to assess the potential benefits of complete coverage of home infusion therapy under Medicare and provide recommendations to Congress as to whether and how the Medicare program can efficiently and effectively provide such coverage, after considering how home infusion is covered and paid for by private health plans and Medicare Advantage plans.

The provision would require the Medicare Payment Advisory Committee (MedPAC) to submit a report to Congress not later than 12 months after the date of enactment. The report would be required to include (a) an analysis of the scope of coverage for home infusion therapy services (and the scope of services provided) in traditional Medicare, Medicare Advantage, the Veterans Health Administration, and among private payers; (b) the benefits and costs of providing such coverage under the Medicare program, including a calculation of the potential savings achieved through avoided or shortened hospital or nursing home stays; (c) an assessment of data on home infusion therapy that might be used to construct payment mechanisms under Medicare and (d) recommendations, if any, on the structure of a payment system under the Medicare program for home infusion therapy services, including an analysis of MA and private plan payment methodologies for home infusion therapy and their applicability to the Medicare program.

Sec. 1144. Require Ambulatory Surgical Centers (ASCs) to submit cost data and other data

Current Law

Ambulatory surgery centers (ASCs) must meet certain health, safety, and other specified standards in order to participate in Medicare. The Centers for Medicare and Medicaid Services implemented a new payment system for ASCs on January 1, 2008. The new payment system, which is being phased-in over a 4–year period, uses the ambulatory payment classification groups that are the basis for Medicare's outpatient prospective payment system (OPPS) for hospital outpatient departments. ASCs have never been required to submit cost reports. In March 2009, the Medicare Payment Advisory Commission recommended that Congress require ASCs to submit cost data and quality data that would allow for an effective evaluation of the adequacy of Medicare's payment rates.

The number of Medicare-certified ASCs has grown substantially in recent years, growing at an annual rate of 6.7 percent from 2002 to 2007. Spending per beneficiary also increased substantially during that time period, growing at an average annual rate of 8.4 percent, and receiving $2.9 billion in payments from Medicare and beneficiary cost-sharing in 2007. Ninety-one percent of ASCs have at least one physician-owner and MedPAC has pointed out that the presence of physician ownership of ASCs may influence referral patterns.

Proposed Law

MedPAC uses cost data to analyze the adequacy of Medicare payments in many areas. However, cost data are not available for ASCs, limiting MedPAC's ability to assess payment adequacy. This provision instructs the Secretary to require ASCs to submit reports on their facility costs as a condition for agreeing to participate in Medicare. That data will allow MedPAC to properly assess Medicare's payment adequacy for ASCs. The specifications for the cost report data would take into account the requirements for hospital cost data. No later than 3 years from enactment, an ASC cost reporting form would be developed. The ASC cost reports would be periodically audited. The requirements would apply to agreements applicable to cost reporting periods beginning 18 months after the date the Secretary develops the cost reporting form.

This provision also follows MedPAC's recommendation to require reporting of quality data. Beginning in 2012, the Secretary would require ASCs to report quality data, including data on health care associated infections.

Sec. 1145. Treatment of certain cancer hospitals

Current Law

Eleven cancer hospitals are exempt from the inpatient prospective payment system (IPPS) used to pay inpatient hospital services provided by acute care hospitals. Historically, they have been paid on a reasonable cost basis, subject to certain payment limitations and incentives. These hospitals are also held harmless under the outpatient prospective payment system (OPPS) and will not receive less from Medicare under this payment system than under the prior outpatient payment system. Under OPPS, Medicare pays for outpatient services using as defined by ambulatory payment classification (APC) groups.

Proposed Law

The provision requires the Secretary to determine if the costs incurred by cancer hospitals with respect to APCs exceed those costs incurred by other hospitals reimbursed under OPPS. If the costs in cancer hospitals exceed the costs incurred by other hospitals, the Secretary would be required to provide for an appropriate adjustment for cancer hospitals for outpatient services furnished starting January 1, 2011.

The provision addresses concerns that the cost of outpatient services at PPS-exempt cancer hospitals is greater than that at other outpatient hospitals and that these higher costs are not currently reflected and adequately reimbursed under the current payment system. This provision directs CMS to assess whether such a cost differential exists, and if so, to remedy it. This provision supplements the existing hold harmless provision under 1833(t)(7)(D)(ii) of the Social Security Act as the hold harmless will continue to apply in the situation where the combination of existing payments and any payment change under this section results in a payment less than the pre-BBA amount.

Sec. 1146. Medicare Improvement Fund

Current Law

Section 188 of MIPPA established the Medicare Improvement Fund (MIF), available to the Secretary to make improvements under the original fee-for-service program under Parts A and B for Medicare beneficiaries. Under current law, $22.29 billion are available to the Secretary for this purpose for services furnished during FY2014. For fiscal year 2020 and in each subsequent fiscal year, the amount in the fund would be the Secretary's estimate, as of July 1 of the fiscal year, of the aggregate savings in Medicare expenditures due to payment reductions resulting from payment reductions imposed on various Medicare providers as an incentive for the adoption and meaningful use of certified EHR technology.

Proposed Law

Over the course of several years, money has been set aside in the MIF to fund policies that would improve and modernize the Medicare program. This provision would fulfill this intent by using the MIF to offset important investments in Medicare made by this bill. The remaining $8 billion will be available to fund increases in payment rates implemented under section 1158, regarding Medicare geographic payment adjustments. Any amount not spent under that section would remain in the MIF through 2019.

Sec. 1147. Payment for Imaging Services

Current Law

Under the Medicare fee schedule, some services have separate payments for the technical component and the professional component. For example, imaging procedures generally have two parts: the actual taking of the image (the technical component), and the interpretation of the image (the professional component). Medicare pays for each of these components separately when the technical component is furnished by one provider and the professional component by another. When both components are furnished by one provider, Medicare makes a single global payment that is equal to the sum of the payment for each of the components.

CMS's method for calculating the Medicare fee schedule reimbursement rate for advanced imaging services assumes that imaging machines are operated 25 hours per week, or 50% of the time that practices are open for business. Setting the equipment use factor at a lower rather than at a higher rate has led to higher payment for these services. Citing evidence showing that the utilization rate is 90%, rather than the 50% currently assumed, MedPAC has recommended CMS to use the higher utilization rate in the calculation of fee schedule payments for advanced imaging services.

According to MedPAC and the Government Accountability Office (GAO), there are opportunities to improve the efficiency of the Medicare fee schedule. In 2005, MedPAC recommended reducing certain fees to account for efficiencies and savings from the technical preparation and supplies achieved when multiple imaging services are furnished sequentially on contiguous body parts during the same visit. Starting January 1, 2006, physicians receive the full technical component fee for the highest paid imaging service in a

visit, but technical component fees for additional imaging services are reduced by 25%.

The work relative value units in the Medicare physician fee schedule were and are developed with input from the physician community. Refinements in existing values and the establishment of values for new services are included in the annual fee schedule updates. The refinement and update process is based in part on recommendations made by the American Medical Association's Specialty Society Relative Value Update Committee (RUC), which receives input from many physician specialty societies. Current law requires a review of the relative values every five years.

Section 1834(e)(1)(B) defines advanced diagnostic imaging services to include diagnostic magnetic resonance imaging, computed tomography, and nuclear medicine (including positron emission tomography), and other diagnostic imaging services as specified by the Secretary in consultation with physician specialty organizations and other stakeholders.

Proposed Law

The utilization rate for calculating the payment for advanced diagnostic imaging equipment as defined under current law would be increased from 50% to 75%. For single session imaging involving continuous body parts, the proposal would reduce the technical component fees for additional imaging services to 50%. These modifications would apply to services furnished on or after January 1, 2011.

Recent MedPAC analysis found problems with the current calculation of practice expenses for imaging providers. Low assumptions about equipment use artificially inflate the price Medicare pays for imaging services. MedPAC has recommended increasing the utilization assumption for advanced imaging equipment to more accurately reflect actual utilization rates.

MedPAC has also recommended reducing the technical component for a second image on a contiguous body part. When a second image on an adjacent body part is taken, the clerical time, preparation, and supplies needed for the second image are significantly reduced. In 2006, CMS administratively proposed to reduce payment for the second image by 50 percent, but eventually implemented a smaller 25 percent discount. By increasing the discount to 50 percent, this provision would reflect economies arising from studies on multiple body parts and bring Medicare payment policy in line with private payers.

Sec. 1148. Durable medical equipment program improvements

Current Law

The Secretary is prohibited from issuing or renewing a provider number for payment of Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) claims for a supplier unless the supplier provides the Secretary with a surety bond of not less than $50,000. The Secretary may waive this requirement in the case of a supplier that provides a comparable surety bond under state law. The final regulation exempts certain individuals from the surety bond requirement, including certain physicians and non-physician practitioners, physical and occupational therapists,

state-licensed orthotic and prosthetic personnel, and government-owned suppliers.

Medicare Part B pays for certain items of durable medical equipment (DME) including oxygen and oxygen equipment. The Deficit Reduction Act (DRA, P.L. 109–171) changed how long Medicare would make rental payments for oxygen equipment. It changed from the entire period of medical need, to a rental period of 36-months. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, P.L. 110–275) requires suppliers to continue furnishing the equipment during any period of medical need for the remainder of the reasonable useful lifetime of the equipment, which is defined by the Secretary as 5 years (or 60 months).

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, P.L. 108–173) required the Secretary to establish and implement quality and accreditation requirements for Medicare suppliers of DMEPOS. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, P.L. 110–275) exempted a group of health care professionals from having to become accredited unless the Secretary determined the standards were designed specifically to be applied to those professionals. The Secretary was given authority to exempt certain professionals from the accreditation requirement if the Secretary determined that licensing, accreditation, or other mandatory quality requirements applied to those professionals. The provision identified some of the professionals subject to the provision, including: physicians; physical or occupational therapists; physicians assistants; nurse practitioners; clinical nurse specialists; orthotists; and prosthetists.

For a description of DME payment policies, see section 1131 of this legislation.

Proposed Law

This section will make a number of technical changes to the durable medical equipment program that will improve the program for beneficiaries.

Surety Bond: This provision would waive the surety bond requirement for a pharmacy that (1) supplies durable medical equipment, prosthetics, orthotics, and supplies, (2) has been issued a provider number for at least 5 years, and (3) has not received an adverse action, as defined in the Code of Federal Regulations.

Oxygen Equipment: This provision would modify the time period during which the supplier would be required to furnish medically necessary oxygen and oxygen equipment. As of the twenty-seventh month of the 36 month rental period, the supplier furnishing the equipment would be required to continue furnishing the equipment (either directly or through arrangements with other suppliers) during any subsequent period of medical need for the remainder of the reasonable useful lifetime of the equipment, as determined by the Secretary, regardless of the location of the individual, unless another supplier accepted the responsibility to furnish equipment during the remainder of the period. This provision would be effective upon enactment and would apply to equipment furnished to individuals for whom the twenty-seventh month of a continuous period of use occurred on or after July 1, 2010.

This provision would also allow a beneficiary to begin a new 36-month rental period if the supplier who had been furnishing oxy-

gen and oxygen equipment to the beneficiary was declared bankrupt and its assets were liquidated and at the time of the declaration and liquidation more than 24 months of rental payments had been made.

Accreditation: This provision would exempt pharmacies enrolled as Medicare DMEPOS suppliers from the accreditation requirement for the purposes of supplying diabetic testing supplies, canes, and crutches. Any supplier that had submitted an application for accreditation before August 1, 2009, would be deemed as meeting applicable standards and accreditation requirements under the subparagraph until the independent accreditation organization took action on the supplier's application.

Payment Adjustment: The provision would reduce the fee-schedule update amount for covered items of durable medical equipment for 2010, 2011, 2012, and 2013. The amount of the update would be reduced by 0.5%. (The fee schedule update for covered DME would also be subject to a productivity improvement adjustment as described in Section 1131 of this bill.)

Sec. 1149. MedPAC study and report on bone mass measurement

Current Law

No current law.

Proposed Law

The Medicare Payment Advisory Commission would be instructed to conduct a study regarding bone mass measurement, including computed tomography, dual-energy x-ray absorptriometry, and vertebral fracture assessment. The study would focus on the following: (1) an assessment of the adequacy of Medicare payment rates for such services, taking into account costs of acquiring the necessary equipment, professional work time, and practice expense costs; (2) the impact of Medicare payment changes since 2006 on beneficiary access to bone mass measurement benefits in general and in rural and minority communities specifically; (3) a review of the clinically appropriate and recommended use among Medicare beneficiaries and how usage rates among such beneficiaries compares to such recommendations; and (4) in conjunction with the findings under (3), recommendations, if necessary, regarding methods for reaching appropriate use of bone mass measurement studies among Medicare beneficiaries. Not later than 9 months after enactment, the Commission would submit a report to the Congress containing a description of the results of the aforementioned study and the conclusions and recommendations, if any, regarding each of the issues described above.

Sec. 1149A. Exclusion of customary prompt pay discounts extended to wholesalers from manufacturer's average sales price for payments for drugs and biologicals under Medicare part B

Current Law

Medicare Part B pays for a small number of drugs in certain circumstances such as drugs administered to patients in physician offices and outpatient departments. The Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA, P.L. 108–173) established a Part B drug reimbursement methodology based on

the Average Sales Price (ASP) of drugs; since January 2005, Medicare has paid for most physician administered drugs based on 106% of the volume-weighted ASP for each drug code. MMA defines ASP as the average manufacturer's sales of a drug to all purchasers in the United States in a given quarter. The ASP is net of any price concessions provided by the manufacturer to the purchaser (e.g. the wholesaler, group purchasing organization or provider) such as prompt pay discounts, volume discounts, and rebates other than those obtained through the Medicaid drug rebate program.

Proposed Law

This provision would exclude customary prompt pay discounts, to the extent such discounts do not exceed 2% of the product's wholesale acquisition cost, extended to wholesalers from the calculation of ASP for drugs or biologicals sold on or after January 1, 2011, and before January 1, 2016. The term "wholesale acquisition cost" means, with respect to a drug or biological, the manufacturer's list price for the drug or biological to wholesalers or direct purchasers in the United States, not including prompt pay or other discounts, rebates or reductions in price, for the most recent month for which the information is available, as reported in wholesale price guides or other publications of drug or biological pricing data.

Sec. 1149B. Timely access to post-mastectomy items

Current Law

Under Medicare Part B a breast prosthesis is covered for a patient who has *had* a mastectomy. An external breast prosthesis garment, with mastectomy form is covered for use in the post-operative period prior to a permanent breast prosthesis or as an alternative to a mastectomy bra and breast prosthesis. The breast prosthesis and garment are not covered by Medicare prior to the mastectomy or breast cancer surgery as there is no medical need for the items.

Proposed Law

Upon enactment, the provision would specify that payment for post-mastectomy external breast prosthesis garments would be made regardless of whether the items are supplied to the beneficiary prior to or after the mastectomy procedure or other breast cancer surgical procedure. The Secretary would be required to develop policies to ensure appropriate beneficiary access and utilization safeguards.

Sec. 1149C. Moratorium on Medicare reductions in payment rates for certain interventional pain management procedures covered under the ASC fee schedule

Current Law

The Centers for Medicare and Medicaid Services implemented a new payment system for ASCs starting on January 1, 2008. The new payment system is being phased in over a 4-year period and uses the ambulatory payment classification groups that are the basis for Medicare's outpatient prospective payment system (OPPS) for hospital outpatient departments. Under the new payment sys-

tem, Medicare's payments for certain services will increase and those for other services will decrease relative to payment amounts in use prior to 2008.

Proposed Law

Medicare payments for interventional pain management services provided in ASCs starting January 1, 2010, and before January 1, 2010, would be increased to be not less than the payment rate in effect as of January 1, 2007, under the prior payment system. This interventional pain services included under this provision would be epidural injections, facet joint injections, and sacroiliac joint injections.

Sec. 1149D. Medicare coverage of services of qualified respiratory therapists performed under the general supervision of a physician

Current Law

Under current law, respiratory therapists cannot be reimbursed independently under the Medicare fee schedule, as they are not included in the definition of physicians and other providers. Thus, services provided by respiratory therapists outside of hospital settings are generally covered as services "incident to a physician's professional service." Accordingly, the physician must directly supervise the service (meaning the physician must be physically present) when the physician is not the one providing the service.

Proposed Law

The definition of "medical and other health services" would be amended to add a new subparagraph addressing respiratory therapy and respiratory therapists. For purposes of the Medicare program, respiratory therapy services would include those services that are performed by a respiratory therapist under the general (not direct) supervision of a physician for the diagnosis and treatment of respiratory illnesses (and would be physicians' services if furnished by a physician). These services would be paid for under the Medicare fee schedule, but only if no facility or other provider charges are paid with respect to the furnishing of such services. The term "respiratory therapist" would mean an individual who (1) is credentialed by a national credentialing board recognized by the Secretary, (2) is licensed to practice respiratory therapy in the state in which the respiratory therapy services are performed, or in the case of an individual in a state which does not provide for such licensure, is legally authorized to perform respiratory therapy services (in the state in which the individual performed such services) under state law or the state regulatory mechanism provided by state law, (3) is a registered respiratory therapist; and (4) holds a bachelor's degree.

Payment for these respiratory services furnished by a respiratory therapist would be the amount equal to 80% of the lesser of the actual charge for the services or 85% of the Medicare fee schedule amount provided for the same services if furnished by a physician. This change applies to services furnished on or after January 1, 2010.

Subtitle C—Provisions Related to Medicare Parts A and B

Sec. 1151. Reducing potentially preventable hospital readmissions

Current Law

Medicare pays for most acute care hospital stays using a prospectively determined payment for each discharge. Payment also depends on the relative resource use associated with a patient classification group, referred to as the Medicare Severity diagnosis related groups (MS–DRGs), to which the patient is assigned based on an estimate of the relative resources needed to care for a patient with a specific diagnosis and set of care needs. Medicare's inpatient prospective payment system (IPPS) includes adjustments that reflect certain characteristics of the hospital. For instance, a hospital with an approved resident training program would qualify for an indirect medical education (IME) adjustment; hospitals that serve a sufficient number of poor Medicare or Medicaid patients would receive higher Medicare payments because of their disproportionate share hospital (DSH) adjustment. Hospitals in Maryland are not paid using IPPS; rather they receive Medicare payments based on a state-specific Medicare reimbursement system.

Critical Access Hospitals (CAHs) are limited-service facilities that are located more than 35 miles from another hospital (15 miles in certain circumstances) or designated by the state as a necessary provider of health care; offer 24-hour emergency care; have no more than 25 acute care inpatient beds; and have a 96-hour average length of stay. Medicare pays CAHs on the basis of 101% of the reasonable costs of the facility for inpatient and outpatient services. Certain aspects of the CAH payment system are not subject to administrative or judicial review.

According to Medicare Payment Advisory Commission's (MedPAC) analysis of 2005 Medicare data, 6.2% of hospitalizations of Medicare beneficiaries resulted in readmission within 7 days and 17.6% of hospitalizations resulted in readmission within 30 days. The 17.6% of hospital readmission accounts for $15 billion in Medicare spending. These readmission rates reflect the total number of readmissions, including those that may not have been related to the initial diagnosis and may not have been preventable. MedPAC, CMS, and others have expressed concern that providers do not have financial incentives to reduce potentially preventable readmissions. In addition, MedPAC, in its June 2008 report, recommended that Medicare's payments to hospitals with relatively high readmission rates for select conditions be reduced.

Proposed Law

Hospital readmissions for Medicare beneficiaries are costly and prevalent. Studies have demonstrated that almost 20% of Medicare beneficiaries who had been discharged from a hospital were rehospitalized within 30 days and accounted for almost $15 billion in spending in a year. A number of interventions at the time of discharge have been shown to decrease readmissions. Researchers have suggested that supportive palliative care and increased efforts to coordinate prompt and reliable follow-up care with primary care physicians by hospital providers would reduce readmissions and increase patient satisfaction.

To reduce readmission rates, enhance quality of care and improve coordination during discharge planning, policies for the reduction of readmission rates have been recommended by MedPAC. This section takes into account the recommendations set forth by MedPAC regarding payment policies pegged to readmission rates. The policy adjusts payments for hospitals, critical access hospitals and hospitals paid under 1814(b)(3) based on the dollar value of each hospital's percentage of potentially preventable Medicare readmissions for 3 conditions with measures that have been endorsed by NQF as risk-adjusted readmission measures. It also directs the Secretary to expand the policy to additional conditions in future years and authorizes the Secretary to modify the adjustment based on a hospital's performance in readmissions compared to a ranking of hospitals nationally.

In addition, because care received after a discharge can be a primary contributor to preventable readmission, the policy incorporates penalties for post-acute care providers and directs the Secretary to study whether similar penalties should be applied to physicians.

Penalties for Hospitals. IPPS hospitals and those hospitals in Maryland paid under a state-specific Medicare payment system would receive reduced payments for potentially preventable hospital readmissions occurring on or after October 1, 2011. Under this proposal, hospitals with lower potentially preventable readmission rates would receive smaller payment reductions while hospitals with higher potentially preventable readmission rates would receive higher payment reductions. Certain components of Medicare hospital payments would be exempt from these payment reductions.

Reduced hospital payments for readmissions would be calculated by multiplying the base operating DRG payment amount by an adjustment amount. The base operating DRG payment amount is the base amount that would have been paid under IPPS reduced by payments associated with IME and DSH. In the case of hospitals in Maryland, the base amount would be the payment amount under their state system.

The adjustment factor for a hospital in a fiscal year would be the greater of (1) a floor adjustment factor equal to a reduced percentage of the discharge payment or (2) the excess readmissions ratio for the applicable fiscal year. The floor adjustment factor would be 0.99 of the discharge payments in FY2012, 0.98 of the discharge in FY 2013, 0.97 in FY 2014, or 0.95 in subsequent fiscal years. The excess readmissions ratio would equal 1 minus the ratio of the aggregate payments for excess readmissions for the hospital divided by the aggregate payments for all discharges.

Aggregate payments for excess readmissions for a hospital for a fiscal year would be the sum of the applicable conditions of the product of the base operating DRG payment for each applicable condition multiplied by the number of admissions for each condition multiplied by the excess readmissions ratio minus one. The excess readmissions ratio is the ratio of the risk adjusted readmissions based on actual readmissions divided by the risk adjusted expected readmissions. This number would not be less than one. The ratio would be calculated for each applicable condition for a hospital for the applicable period. The aggregate payments for all dis-

charges would be calculated as the sum of the hospital's base operating DRG payments for all discharges for all conditions for such a fiscal year.

Excess readmissions would be prohibited from including conditions for which there are fewer than a certain minimum number (as determined by the Secretary) of discharges within a certain time period. To encourage hospitals to continue to reduce their potentially preventable readmission rates over time, beginning with discharges for FY2014, the Secretary would be able to determine the excess readmissions ratio based on a ranking of hospitals by readmission ratios (from lower to higher readmissions) normalized to a benchmark that is lower than the 50th percentile.

An applicable condition would be defined as a condition or procedure that represents high volume or high expenditures for Medicare or meets other specified criteria that also satisfies certain measures of readmissions. These measures of readmission would be those that have been endorsed by a consensus based entity with a performance measurement contract under section 1890 of the Social Security Act, excluding readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital). Readmission would be defined as an admission to the hospital of an individual who had been discharged from either the same or another applicable hospital within a time period from the date of discharge as specified by the Secretary.

Starting in FY2012, the Secretary would select 3 applicable conditions that have been endorsed by the consensus based entity as of the date of enactment. Beginning with FY2013, the Secretary would be required to expand the list of applicable conditions for such readmissions to include 4 conditions identified by the MedPAC in its June 2007 Report to Congress. The Secretary would also be able to include an appropriate all-condition measure of readmissions. In expanding the list of conditions, the Secretary would be required to seek the endorsement by a consensus-based entity, but would be able to apply such conditions without such endorsement.

The Secretary would be required to monitor activities of applicable hospitals to determine if such hospitals took the steps to avoid patients at risk to reduce the likelihood of increasing readmissions for applicable conditions. If the Secretary determines that such a hospital had taken such steps, the Secretary could impose an appropriate sanction after having provided notice to the hospital and the opportunity for that hospital to alleviate such steps.

For fiscal years beginning on or after FY2011, the Secretary would be required to increase DSH payments to targeted hospitals that received $10 million or more in disproportionate share payments in their most recently settled cost report. These targeted hospitals would be required to provide satisfactory assurances that the increased payments would be used for transitional care activities. These would be activities designed to address the patient noncompliance issues that result in higher than normal readmission rates, such as one or more of the following: (1) providing care coordination services to assist in transitions from the targeted hospital to another setting; (2) hiring translators and interpreters; (3) increasing services offered by discharge planners; (4) ensuring that individuals receive a summary of care and medication orders upon

discharge; (5) developing a quality improvement plan to assess and remedy preventable readmission rates; (6) assigning discharged individuals to a medical home; and (7) doing other activities as determined by the Secretary.

The Secretary would estimate the percent of the DSH increase subject to aggregate and hospital-specific caps. In the aggregate, increases would not exceed 5% of the estimated savings that would occur in a fiscal year from hospital readmissions policies described above. For specific hospitals, DSH increases would not exceed the estimated difference in spending that would occur in a fiscal year for a hospital due to the application of the excess readmissions policy. The Secretary would make these additional DSH payments on a lump sum basis, a periodic basis, a claim by claim basis or in any other form deemed appropriate. Not later than 3 years after funds are first made available, GAO would be required to submit a report on the use of such funds.

No administrative or judicial review could be conducted of the determination of the base operating DRG amounts; the methodology for determining the adjustment factor and its various components (excess readmissions ratio, aggregate payments for excess readmissions and aggregate payments for all discharges, applicable conditions, and applicable periods); measures of readmissions; the determination of a targeted hospital for additional DSH payments, the increase in DSH payments, the aggregate DSH cap, the hospital-specific DSH limit, and the form of DSH payment.

Application to Critical Access Hospitals (CAHs). CAHs would receive reduced payments for preventable hospital readmissions starting for cost reporting periods beginning in FY2012 and in subsequent fiscal years. The adjustment factor for acute care hospitals would be applied. The methodology for determining the adjustment factor, including the determination of aggregate payments for actual and expected readmissions, applicable periods, applicable conditions, and measures of readmission would not be subject to administrative or judicial review.

Application to Post-Acute Care Providers. The proposal would also reduce Medicare payments on claims from post-acute care providers (skilled nursing facilities, inpatient rehabilitation facilities, home health agencies, and long-term care hospitals) for patients readmitted to an applicable hospital or a CAH within 30 days of an initial discharge from a hospital or a CAH. Payments to post-acute providers would be reduced by 0.996 for the fiscal year or rate year 2012; 0.993 for the fiscal or rate year 2013; and 0.99 for fiscal or rate year 2014. This policy would apply to the discharges or services furnished on or after the first day of the fiscal or rate year, beginning on or after October 1, 2011.

The Secretary would be required to develop appropriate measures of readmissions rates for post-acute care providers and to submit such measures for endorsement through a consensus-based entity, such as the National Quality Forum. The Secretary would be required to adopt, expand, and apply such measures, in the same manner as for applicable hospitals established earlier in the legislation. To the extent such measures would be adopted, the Secretary would adopt similar payment policies for post-acute providers on or after October 1, 2014, that have been established for applicable hospitals and CAHs. Post-acute providers would also be

subject to the monitoring and penalties established for applicable hospitals and CAHs elsewhere in this legislation.

Physicians. The Secretary would be required to conduct a study to determine how this readmissions policy could be applied to physicians and issue a public report no later than one year after enactment. Such approaches would be required to be considered: (1) creating a code (or codes) and budget neutral payment amount(s) under the fee schedule for services furnished by an appropriate physician who sees an individual within the first week after discharge from a hospital or CAH; (2) developing measures of readmissions rates for individuals treated by physicians; (3) applying a payment reduction for physicians who treat the patient during the initial admissions that results in a readmission; and (4) methods for attributing payments or payment reductions to the appropriate physician or physicians.

Funding. In addition to funds otherwise available, out of any funds in the Treasury not otherwise appropriated, there would be appropriated, to the CMS Program Management Account, $25 million for each fiscal year beginning with 2010. Amounts appropriated for a fiscal year would be required to be available until expended.

Sec. 1152. Post-acute care services payment reform plan and bundling pilot program

Current Law

Medicare pays for most post-acute care (PAC) services, including skilled nursing facilities (SNF), long-term care hospitals (LTCH), inpatient rehabilitation facilities (IRF), and home health, under prospective payment systems (PPS) established for each type of provider. Under each PPS, a predetermined rate is paid for each unit of service, such as a hospital discharge, or a payment classification group. As some Medicare beneficiaries with complex health conditions and multiple co-morbidities move between hospital stays and a range of PAC providers, Medicare makes separate payments to each provider for covered services. Payments across PAC settings may differ considerably even though the clinical characteristics of the patient and the services delivered may be very similar.

The Deficit Reduction Act of 2005 (P.L. 109–171) required the Centers for Medicare and Medicaid Services (CMS) to develop a Post-Acute Care Payment Reform Demonstration (PAC demonstration). The goal of this initiative is to standardize patient assessment information from PAC settings and to use these data to guide payment policy in the Medicare program. This demonstration began in 2008 and a report is expected to be submitted to Congress by the Secretary in 2011. CMS has also established a 3-year Acute Care Episode (ACE) Demonstration to test the effects of using a bundled payment for inpatient hospital and physician services for a set of 9 orthopedic and 28 cardiovascular conditions. There are 5 participants in the ACE demonstration, which began early in 2009.

The Medicare Payment Advisory Commission (MedPAC), among others, has expressed concern that providers do not have financial incentives to coordinate across episodes of care nor to evaluate the full spectrum of care a patient may receive. In its June 2008 re-

port, MedPAC recommended that a bundled payment system for an episode of care be explored in a pilot program. Under this voluntary program, a single provider entity would receive a bundled payment intended to cover the costs of the full range of care needed over the hospitalization episode, including 30 days post-discharge. MedPAC recommended that the pilot program should have clearly established guidelines for determining whether it should be discontinued or expanded to the entire Medicare program

Proposed Law

Fee-for-service payment systems reward high patient and procedure volume and do not encourage care coordination delivered across an episode of care. Ideally, the payment system should incentivize hospitals, post-acute institutions, and physicians to collaborate in coordinating care for Medicare beneficiaries and to work efficiently together.

Currently, hospitals are paid in a single amount based on the patient's diagnosis to cover all hospital costs associated with the stay except for physician services. Surgeons are paid a bundled fee called a global surgical fee that includes the post-surgical follow up visits. MedPAC suggests that while these payment innovations may have improved providers' efficiency (e.g., shorter length of stay) during the episode of care, they apply to only one provider and therefore have a limited effect in reducing the aggregate volume of services paid for by Medicare.

Health policy experts have recommended that under a bundled payment structure, Medicare would pay a single provider entity an amount intended to cover the costs of providing a full range of care needed over a hospitalization episode that would include the acute care and the post-acute care setting. However, a bundled payment system has significant implications for the future delivery of care for Medicare beneficiaries. Such a broad policy change requires significant research and planning to implement in order to protect the quality of care received by beneficiaries and the integrity of the program.

The Secretary would be required to develop a detailed plan to reform payment for Medicare's PAC services, including specifications for a bundled payment to improve their coordination, quality, and efficiency, and to improve outcomes for individuals. For this plan, PAC services would include those services provided by SNFs, IRFs, LTCHs, hospital based outpatient rehabilitation facilities, and home health agencies to individuals after discharge from a hospital and such other services as determined appropriate by the Secretary.

The plan would be required to include consideration of the following issues: (1) the nature of payments under a PAC bundle, including the type of provider or entity to whom payment should be made, the scope of activities and services included in the bundle, whether payment for physicians' services would be included, and the period covered by the bundle; (2) whether the payment should be consolidated with the payment under the inpatient prospective system or a separate payment established for such bundle, and if a separate payment is established, whether it should be made only upon use of PAC services or for every discharge; (3) whether the bundle should be applied across all categories of providers of inpa-

tient services and PAC services or whether it should be limited to certain categories of providers, services, or discharges, such as high volume or high cost MS–DRGs; (4) the extent to which payment rates could be established to achieve offsets for efficiencies that could be expected to be achieved with a bundled payment, whether such rates should be established on a national basis or for different geographic areas, whether such rates should vary according to discharge, case mix, outliers, and geographic differences; (5) the nature of protections needed for individuals under a system of bundled payments to ensure that individuals receive quality care, are furnished the level and amount of services needed, as determined by an appropriate assessment instrument, and the extent to which transitional care services would improve quality of care for individuals and the functioning of a bundled post-acute system; (6) the nature of relationships that may be required between hospitals and providers of PAC services to facilitate bundled payments, including the application of gainsharing, anti-referral, anti-kickback, and anti-trust laws; (7) quality measures that would be appropriate for reporting by hospitals and post-acute providers; (8) how cost-sharing for a PAC bundle should be treated relative to current rules for cost-sharing for inpatient hospital, home health, skilled nursing facility, and other services; (9) how other programmatic issues should be treated in a PAC bundle; and (10) such other issues as the Secretary would deem appropriate.

In the development of this plan, the Secretary would be required to consult relevant stakeholders and to consider experience with such research studies and demonstrations that the Secretary determines appropriate. In addition, the Secretary would be required to analyze the impacts (including geographic impacts) of PAC reform approaches, including the effect on beneficiaries, hospitals, PAC providers, and physicians; use existing data (such as data submitted on claims) and collect such data as the Secretary would determine appropriate; and if patient functional status measures are appropriate for the analysis, to the extent practical, build upon the Continuity Assessment Record and Evaluation (CARE) tool being developed to measure the health and functional status of Medicare acute discharges and changes in severity and other outcomes for Medicare PAC patients under CMS' PAC demonstration plan.

Out of any funds in the Treasury not otherwise appropriated, there would be appropriated to the Secretary for the CMS Program Management Account $15 million for each of the fiscal years 2010 through 2012. These amounts appropriated for the fiscal years would be available until expended.

The Secretary would be required to issue interim public reports on a periodic basis and, not later than 3 years after enactment, issue a final public report on this plan and its impact.

Conversion of Acute Care Episode Demonstration to Pilot Program and Expansion to Include Post-Acute Services. This provision would require the Secretary, by no later than January 1, 2011, and for the purpose of promoting bundled payments to promote efficient and high quality delivery of care, to convert the acute care episode demonstration into a pilot program and expand it to include post-acute services and such other services the Secretary determines to be appropriate (which may include transitional services).

The Secretary would be required to set specific goals for the number of acute and post-acute bundling test sites under the pilot program to ensure that it is of sufficient size and scope to: (1) test the approaches under the pilot program in a variety of settings, including urban, rural, and underserved areas; (2) include geographic areas and additional conditions that account for significant program spending, as defined by the Secretary; and (3) disseminate the pilot program rapidly on a national basis if appropriate. To the extent that the Secretary finds the inpatient and post-acute care bundling to be successful in improving quality and reducing costs, the Secretary would be required to implement such mechanisms and reforms under the pilot program on as large a geographic scale as practical and economical. The Secretary would be required to only expand the pilot program if the CMS' Chief Actuary certifies that the demonstration and pilot programs maintain or increase the quality of care received by individuals and such demonstration program and that the pilot program reduces program expenditures. Participation in this pilot program would be voluntary.

Sec. 1153. Home health payment update for 2010

Current Law

Home health agencies (HHAs) are paid under a prospective payment system (PPS) that began on October 1, 2000. Payment is based on 60-day episodes of care for beneficiaries, subject to several adjustments, with unlimited episodes of care in a year. The payment covers skilled nursing, therapy, medical social services, aide visits, medical supplies, and other services. Durable medical equipment is not included in the home health PPS. The base payment amount, or national standardized 60-day episode rate, is increased annually by an update factor that is determined, in part, by the projected increase in the home health market basket (MB) index. This index measures changes in the costs of goods and services purchased by HHAs. Since 2007, HHAs are required to submit to the Secretary health care quality data. An HHA that does not submit the required quality data will receive an update of the MB minus two percentage points. This reduction only applies to the payment year in question.

Proposed Law

This section implements a MedPAC recommendation to maintain payment rates for home health agencies (HHAs) for CY2010 at their levels in 2009. Home health agencies would still be subject to the data quality provision for subsequent years.

Sec. 1154. Payment adjustments for home health care

Current Law

Home health agencies (HHAs) are paid under a prospective payment system (PPS) that began on October 1, 2000. Payment is based on 60-day episodes of care for beneficiaries, subject to several adjustments, with unlimited episodes of care in a year. The payment covers skilled nursing, therapy, medical social services, aide visits, medical supplies, and other services. Durable medical equipment is not included in the home health PPS. The base payment amount, or national standardized 60-day episode rate, is increased

annually by an update factor that is determined, in part, by the projected increase in the home health market basket (MB) index. This index measures changes in the costs of goods and services purchased by HHAs. Since 2007, HHAs are required to submit to the Secretary health care quality data. An HHA that does not submit the required quality data will receive an update of the MB minus two percentage points. This reduction only applies to the payment year in question.

In calendar year (CY) 2008, CMS made refinements to the home health (HH) PPS. These refinements included a reduction in the national standardized 60-day episode payment rate, phased-in over 4 years, to account for changes in case mix that are not related to HH patients' actual clinical conditions; changes to the case-mix model to account differently for comorbidities and the differing health characteristics of longer-stay patients, including increasing the number of HH resource groups from 80 to 153; changes to the way the PPS accounts for the impact of rehabilitation services on resource use to reduce the impact of financial incentives on the delivery of therapy visits; and an increased payment for low utilization payment adjustment (LUPA) episodes that occur as the only episode or the first episode during a period of HH; and other changes. These refinements resulted in payment changes described in Federal Regulation § 484.220 issued on Aug. 29, 2007 (72 FR 49879).

This regulation established changes to the HHA case-mix index to account for the relative resource utilization of different patients. These changes modified the coding or classification of different units of service that do not reflect real changes in case-mix. As a result, the national prospective 60-day episode payment rate was adjusted downward by 2.75% for CY2008–2010; then by 2.71% for CY2011.

Proposed Law

Pursuant to a MedPAC recommendation, the provision would accelerate the case-mix adjustments described in 42 FR § 484.220 by implementing both the planned CY2011 adjustment of 2.71% and the planned CY2010 adjustment of 2.75% at the same time in CY2010, for a total FY2010 downward adjustment of 5.46%. The amounts of these adjustments would not be limited if more recent data were to indicate that a greater adjustment would be appropriate.

One source of Medicare overpayments to HHAs is the use of outdated data in payment rates. The prospective payment system for home health services developed in 1998 is based on agencies providing an average of 32 visits per 60-day episode. However, since that time, the number of visits per episode has dropped by 30 percent, to an average of 22 visits. This provision incorporates those changes into the payment system.

Starting in 2011, HH prospective payment amounts would be adjusted by a uniform percentage determined appropriate by the Secretary and based on analysis of factors such as changes in the average number and types of visits in an episode since the implementation of the PPS, changes in the intensity of visits in an episode, growth in cost per episodes, and other factors that the Secretary would consider to be relevant. For years after 2011, such amounts

would be required to be equal to the amount paid for the previous year updated by the HH market basket.

If the Secretary is not able to compute the changed prospective payment amounts for 2011 on a timely basis, then the Secretary would be required to pay 95% of what the prospective payment amount would have been had this provision not applied. And, under such circumstances, the Secretary would be required to compare, before July 1, 2011, amounts paid to the amount that would have been paid had the Secretary been able to compute the adjustment on a timely basis. For 2012, the Secretary would be required to decrease or increase the prospective payment amount (or at the Secretary's discretion, over a period of several years beginning with 2012), by the amount (if any) by which the amount applied is greater or less, respectively, than the amount that should have been applied.

Sec. 1155. Incorporating productivity improvements into market basket update for home health services

Current Law

Home health agencies (HHAs) are paid under a prospective payment system (PPS) that began on October 1, 2000. Payment is based on 60-day episodes of care for beneficiaries, subject to several adjustments, with unlimited episodes of care in a year. The payment covers skilled nursing, therapy, medical social services, aide visits, medical supplies, and other services. Durable medical equipment is not included in the home health PPS. The base payment amount, or national standardized 60-day episode rate, is increased annually by an update factor that is determined, in part, by the projected increase in the home health market basket (MB) index. This index measures changes in the costs of goods and services purchased by HHAs. Since 2007, HHAs are required to submit to the Secretary health care quality data. A HHA that does not submit the required quality data will receive an update of the MB minus two percentage points. This reduction only applies to the payment year in question.

Each year, the Medicare Payment Advisory Commission (MedPAC) makes payment update recommendations for the different payment systems. In its view, Medicare's payment systems should encourage efficiency: providers should be able to reduce the quantity of inputs to produce a unit of service while maintaining quality. Accordingly, MedPAC begins its update deliberations with an assumption that all providers can achieve efficiency gains similar to the economy and examines the Bureau of Labor Statistics' estimate of the 10-year moving average rate of past growth in total factor productivity for the economy as a whole. This policy target links Medicare's expectations for efficiency improvements to the productivity gains achieved by firms and workers who pay taxes that fund Medicare. MedPAC's annual update recommendation depends on its overall assessment of the circumstances of a given set of providers in any year.

Proposed Law

The annual update to the Medicare physician fee schedule already incorporates adjustments for gains in productivity. This pro-

vision creates uniformity across Medicare providers by creating a productivity adjustment for home health agencies. This adjustment will encourage greater efficiency in health care provision, hold Medicare providers accountable for achieving productivity gains on par with the overall economy, and more accurately align Medicare payments with provider costs.

The provision would make annual updates by the HH MB subject to a productivity adjustment as long as the annual update would not be less than zero. The productivity adjustment would equal the 10-year moving average of changes in annual economy-wide private non-farm business multi-factor productivity. The estimate used would be that published before the promulgation of the regulation establishing the Medicare rates for the year or period. This provision would be required to apply to home health market basket percentage increases for years beginning with 2010.

Sec. 1156. Limitation on Medicare exception to the prohibition on certain physician referrals for hospitals

Current Law

Physicians are generally prohibited from referring Medicare patients for certain services to facilities in which they (or their immediate family members) have financial interests. However, among other exceptions, physicians are not prohibited from referring patients to hospitals in which they have ownership or investment interests that include the hospital's entire business (the so-called whole hospital exception). Providers that furnish substantially all of its designated health services to individuals residing in rural areas are exempt as well.

Entities receiving Medicare payment for covered items and services are required to provide the information on the entities' ownership, investment, and compensation arrangements. This information includes the covered items and services provided by the entity, and the names and unique physician identification numbers of all physicians (or those whose immediate relatives) who have an ownership or investment interest, or certain compensation arrangements.

Proposed Law

The provision prohibits new physician-owned hospitals from participating in Medicare. The provision addresses concerns about the strong incentive self-referral exerts on physician decision-making and the potential negative implications of that conflict of interest for patient safety and the volume of services in Medicare.

Under this provision, only hospitals meeting certain requirements would be exempt from the prohibition on self-referral. Hospitals (including rural providers) that have physician ownership and a provider agreement in operation on January 1, 2009, and that meet other specified reporting and disclosure requirements would be exempt from this self-referral ban. Hospitals would be allowed to maintain the percentage of the total ownership or investment held in the hospital (or in an entity whose assets include the hospital) by physician owners or investors in the aggregate at the level that existed as of date of enactment. Hospitals would be allowed to expand the number of operating rooms, procedure rooms,

or beds of the hospital if certain criteria are met. The exempted hospital could not have converted from an ambulatory surgical center to a hospital after enactment.

To qualify for the exemption, entities receiving Medicare payment for covered items and services would be required to provide the information on the entities' ownership, investment, and compensation arrangements. This information includes the covered items and services provided by the entity, and the names and unique physician identification numbers of all physicians (or those with immediate relatives) who have an ownership or investment interest, or certain compensation arrangements. Such information would be provided in the form, manner, and at such times as specified. This requirement would not apply to designated health services provided outside of the United States or to entities deemed to provide services infrequently paid by Medicare.

An exempt entity would also be (1) required to submit an initial report and periodic updates at specified intervals that contained a detailed description of the identity of each physician owner and investor as well as any other owners and investors in the hospital; and any other information on the nature and extent of all ownership interests in the hospital; (2) required to provide to all patients a disclosure relating to any referring physician owner's ownership interest in the hospital and, if applicable, any such ownership interest of the treating physician (by a time that permits the patient to make a meaningful decision regarding the receipt of care) ; and (3) required to disclose the fact that the hospital is partially or wholly owned by one or more physician investors on any public website for the hospital and in any public advertising for the hospital. This requirement would not apply to designated health services provided outside of the United States or to entities deemed to provide services infrequently paid by Medicare. Information provided by hospitals would be published and periodically updated on the Internet website of the Centers for Medicare and Medicaid Services (CMS). Any person who fails to meet required reporting and disclosure requirements are subject to a civil monetary penalty of not more than $10,000 for each day for which reporting is required to have been made or for each case in which disclosure is required to have been made.

Exempt hospitals would ensure bona fide ownership and investment by meeting the following requirements: (1) any ownership or investment interest offered to a physician could not be offered on more favorable terms than those offered to a person who is not in a position to refer patients or otherwise generate hospital business; (2) the hospital (or investors in the hospital) could not directly or indirectly provide loans or financing for physician owners or investors in the hospital; (3) the hospital or its investors could not guarantee a loan, make a payment toward a loan, or otherwise subsidize a loan to any individual physician owner, investor, group of physician owners or investors that is related to acquiring an ownership or investment interest in the hospital; (4) ownership or investment returns must be distributed to investors in the hospital in an amount that is directly proportional to the investment or ownership by the hospital investor; (5) the investment interest of the owner or investor is directly proportional to the capital contributions made at the time the ownership or investment interest is ob-

tained; (6) physician owners and investors do not receive any guaranteed receipt or right to purchase other business related interests in the hospital, including the purchase or lease of any property under the control of other investors in the hospital or located near the premises of the hospital; (7) the hospital does not offer a physician owner the opportunity to purchase or lease any property under hospital control on more favorable terms than those offered to others and (8) the hospital does not condition any physician ownership or investment interests on the physician making or influencing referrals to the hospital or generating business for the hospital.

To ensure patient safety, those exempt hospitals that do not offer emergency services would have to have the capacity to (1) provide assessment and initial treatment for medical emergencies; and (2) refer and transfer the patient with the medical emergency to the hospital with the required capability if it lacks the capabilities to treat the involved emergency. Those hospitals that do not have any physician available on the premises 24 hours per day, 7 days a week must disclose such fact to the patient before admitting the patient. Following such a disclosure, the hospital would receive a signed acknowledgement from the patient that the patient understands that fact. The Secretary would retain the ability to terminate a hospital's provider agreement if the hospital is not in compliance with Medicare's conditions of participation.

Exempt hospitals would be permitted to increase the number of operating rooms, procedure rooms or beds after the date of enactment under certain criteria. A procedure room includes a room in which catheterizations, angiographies, angiograms, and endoscopies are furnished. This would not include emergency rooms or departments (except for rooms in which catheterizations, angiographies, angiograms, and endoscopies are furnished). Hospitals meeting certain criteria would be allowed to expand, with these criteria including (1) a hospital that is located in a county where the population increased during the most recent 5-year period at a rate that is at least 150% of the state's population increase; (2) a hospital whose Medicaid inpatient admission percentage is equal to or greater than the average percentage for all hospitals located in the county; (3) a hospital that does not discriminate against beneficiaries of federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries; (4) a hospital that is located in a state with an average bed capacity less than the national average; (5) a hospital that has an average bed occupancy rate that is greater than the state average bed occupancy rate; and (6) meets other established requirements.

This capacity increase would be limited to facilities on the main campus of the hospital and could not exceed 200% of the number of operating rooms, procedure rooms and beds at the time of enactment. Any increase would only be permitted in facilities on the main campus of the hospital. The process for expansion should allow the opportunity for community input and should permit an applicable hospital to apply for the expansion exception up to once every two years. The Secretary would be required to promulgate regulations establishing the appeal process no later than the first day of the month beginning 18 months after the date of enactment. The appeal process would be implemented one month after the date

of regulations are promulgated. These regulations would be able to be issued as interim final regulations. The final decision regarding an expansion request will be posted on the CMS website no later than 120 days after a complete application is received. There shall be no administrative or judicial review of this process.

The Secretary would be required to establish policies and procedures to ensure compliance with these requirements. The enforcement efforts may include unannounced site reviews of hospitals. In addition to funds otherwise available, starting in FY2010, $5 million would be appropriated in each fiscal year from not otherwise appropriated funds in the Treasury for purposes of carrying out this section. Appropriated funds would be available until expended. Certain federal laws with respect to the coordination of federal information policy established by Chapter 35 of Title 44 of the United States Code would not apply to these requirements.

Sec. 1157. Institute of Medicine study of geographic adjustment factors under Medicare

Current Law

Generally, Medicare's payment systems include adjustment factors to account for the geographic differences in the costs of providing health care services. For example, Medicare's physician fee schedule (which with modifications is used to reimburse other health care practitioners in Medicare) uses the geographic practice cost index (GPCI) for this purpose; Medicare's inpatient prospective payment system (IPPS) uses a hospital wage index to adjust payments for acute care hospitals. With modifications, the IPPS wage index is used to calculate payments for inpatient rehabilitation hospitals, inpatient psychiatric hospitals, long term care hospitals, skilled nursing facilities, and home health agencies.

Proposed Law

This provision addresses concerns that have been raised about the methodology and data used to geographically adjust Medicare payment rates.

The Secretary would enter into a contract with the Institutes of Medicine (IOM) of the National Academies to conduct a comprehensive empirical study with appropriate recommendations on the accuracy of the geographic adjustment factors established for Medicare's physician fee schedule and for Medicare's IPPS. The study would include an evaluation of the empirical validity of the adjustments; methodology used to determine the adjustments, and measures used for the adjustments. The latter would take into account the timeliness of the data and frequency of data revisions; data sources and validity, and operational costs of participating providers. The study would also examine the effect of the adjustment factors on the level and distribution of the health workforce within the United States. This would include recruitment and retention accounting for workforce mobility between urban and rural areas; ability of hospital and other facilities to maintain an adequate and skilled workforce; patient access to providers and needed medical technology. The study would also examine the effect of the adjustment factors on population health and quality of care and the ability of providers to furnish efficient, high value care. The IOM re-

port would be submitted to the Secretary and to Congress no later than one year from enactment. Necessary funds would be authorized to be appropriated to carry out this study.

Sec. 1158. Revision of Medicare payment systems to address geographic inequities

Current Law

Generally, Medicare's payment systems include adjustment factors to account for the geographic differences in the costs of providing health care services. Section 1157 requires the IOM to conduct a study of the geographic practice cost index (GPCI) used to adjust Medicare's physician fee schedule and the hospital wage index used in Medicare's inpatient prospective payment system (IPPS).

Generally, the Centers for Medicare and Medicare Services promulgates changes to Medicare's physician fee schedule and IPPS through an annual rulemaking process where proposed changes and a notice of a public comment period are published in the Federal Register. Subsequently, a final rule establishing the payment polices and responding to public comments is published in the Federal Register. Medicare's IPPS and physician payments are on different payment years and therefore rulemaking schedules. Generally the new IPPS payment rates are effective October 1 of each year and new physician fee schedule is effective as of January 1 of each year.

Proposed Law

The Secretary would be required to take into account the IOM recommendations included in the report on the adequacy of Medicare's geographic adjustments established in the previous section. Appropriate proposals to revise the respective geographic adjustments would be included in the proposed rules applicable to the rulemaking process for Medicare's payments for physicians' services and IPPS hospitals. The proposals would be included in the next applicable rulemaking cycle after submission of the IOM report to the Secretary. The Secretary would be able to change the geographic adjustments accordingly, but could not reduce an adjustment below that which applied in the payment system in the prior payment year. These adjustments for services furnished before January 1, 2014, could not exceed the amounts in the Medicare Improvement Fund as amended in this legislation. No more than half of that $8 billion would be available in any one payment year.

Subtitle D—Medicare Advantage Reforms

PART 1—PAYMENT AND ADMINISTRATION

Sec. 1161. Phase-in of payment based on fee-for-service costs

Current Law

Most Medicare beneficiaries (about 75%) receive their care through the original Medicare program, often called fee-for-service Medicare (FFS). Medicare Advantage (MA) is an alternative way for Medicare beneficiaries to receive covered benefits. Under MA,

private health plans are paid a per-person amount to provide all Medicare-covered benefits (except hospice) to beneficiaries who enroll in their plan. Beginning in 2006, the Secretary began determining MA payment rates by comparing plan bids to a benchmark. Each bid represents the plan's estimated revenue requirement for providing required Parts A and B Medicare services to an average Medicare beneficiary. The benchmark amounts represent the maximum amount the federal government will pay a plan for providing required Medicare benefits. If a plan's bid is less than the benchmark, its payment equals its bid plus a rebate of 75% of the difference between the benchmark and the bid. The rebate must be used to provide additional benefits, reduce enrollees' Medicare cost sharing expenses, or reduce enrollees' monthly Part B, Part D, or supplemental premiums (for services beyond required Medicare benefits). The remaining 25% of the difference is retained by the federal government. If a plan's bid is equal to or above the benchmark, its payment is equal to the benchmark amount, and each enrollee in that plan will pay an additional premium equal to the amount by which the bid exceeds the benchmark.

In general, the MA benchmarks in each local area (county) are updated annually by the overall growth in Medicare expenditures, otherwise known as the National MA Growth Percentage. In certain years (known as rebasing years), plan payments are updated by the greater of the growth percentage or 100% of fee-for-service (FFS) costs, with adjustments. Beginning in 2010, the benchmarks will be adjusted to phase-out the value of indirect medical education costs. Payments for the indirect costs of medical education will continue to be made directly to hospitals.

MA benchmarks are based, in part, on historical Medicare private plan payment rates. The Balanced Budget Act of 1997 (P.L. 105–33, BBA) increased payments to private plans above rates of per person FFS costs in some areas. Subsequent legislation also increased payment rates to private plans. The historical payment rates were used as the basis for the benchmark amounts, as specified in the Medicare Prescription Drug, Improvements, and Modernization Act of 2003, (P.L. 108–173, MMA). As a result, current MA benchmarks exceed per capita FFS costs in virtually all areas, in some cases substantially.

Proposed Law

Private plans were initially included in the Medicare program to test whether managed care would improve efficiency and innovation and reduce costs, especially in parts of the county where traditional, or fee-for-service (FFS), Medicare was an inefficient purchaser. Reflecting this goal, Medicare Health Maintenance Organizations were originally paid at 95 percent of the average adjusted per capita costs (AAPCC) in fee-for-service Medicare at the county level. New Medicare policies enacted in 1997, 2000 and 2003 now result in overpayments to Medicare Advantage (MA) plans. MedPAC estimates that, on average, payments to plans were 14% higher than costs in fee-for-service Medicare, on average.

Starting in 2011, the provision would phase-in MA payment based on per person FFS spending each county. Starting 2013, MA benchmarks would be equal to per capita FFS spending in each county. In no event would a benchmark be less than per capita

FFS spending. This provision would not apply to Programs of All-Inclusive Care for the Elderly (PACE). Phasing MA payments down to FFS costs in each county over three years gives MA plans time to adjust, if necessary, to the new payment rates.

The phase-down of MA payments to FFS costs applies equally to all 50 states and the territories; however, Puerto Rico is a unique situation that the Committee expects that the Secretary will use authority under current law to examine. Specifically, very few Medicare beneficiaries in Puerto Rico choose to enroll in Part B; instead, MA plans buy down the Part B premium for enrollees and therefore many Medicare beneficiaries enroll in MA to receive all of their Medicare services. With only a small population enrolled in Part B through traditional Medicare, the county FFS expenditures calculated by the Secretary are low and unstable from year-to-year. Therefore, the Committee expects that when calculating county FFS rates for Puerto Rico, the Secretary will use utilization and expenditure data from MA plans under current authority and adjust these rates and risk scores appropriately.

Sec. 1162. Quality bonus payments

Current Law

Payments to MA plans are not contingent on the quality of care provided to Medicare beneficiaries. However, all MA organizations are required to have a quality improvement program before January 1, 2010. As part of the quality improvement program, plans must collect, analyze, and report data to measure health outcomes and other indices. Plans are also required to report quality data to CMS, with some exceptions.

The Medicare Improvements for Patients and Providers Act of 2008 (P.L. 110–275, MIPPA) required for Medicare Payment Advisory Commission (MedPAC) to conduct a study on how comparable quality measures of performance and patient experience can be collected and reported by 2011 for MA and original Medicare. The report is to be submitted to Congress not later than March 31, 2010.

Payments to MA plans are determined by comparing plan bids to a benchmark. Each bid represents the plan's estimated revenue requirement for providing required Medicare services to an average Medicare beneficiary. The benchmark is the maximum amount Medicare will pay a plan. If the plan bid is below the benchmark, the plan payment is the bid plus 75% of the difference between the bid and the benchmark. If the bid is above the benchmark, the plan payment is equal to the benchmark and each plan enrollee must pay a premium equal to the difference between the bid and the benchmark.

Proposed Law

This provision creates a pay-for-quality program in Medicare Advantage. Today, plans that deliver poor quality care are paid as much as plans that provide high quality care. This situation provides no incentive for plans to focus on improving the quality of care received by their enrollees. By changing the payment incentives facing plans this provision will drive Medicare Advantage plans to focus on providing services that improve the health of their enrollees.

For plan years starting with 2011, MA plans identified as high quality plans or improved quality plans would receive an increase in their benchmark amounts. For high quality plans, the increase would be 1% in 2011, 2% in 2012 and 3% in subsequent years. For improved quality plans, the increase would be 0.33% in 2011, 0.66% in 2012, and 1% in subsequent years.

The Secretary would be required to compute a quality performance score for each MA plan for each year beginning in 2010. The calculation of quality scores for MA plans would change over time. For years before 2014, the quality score would be equal to a blend (as designated by the Secretary) of the plan's Healthcare Effectiveness Data and Information Set (HEDIS) scores, Consumer Assessment of Health Care Providers and Systems (CAHPS) scores, and such other measures of clinical quality as the Secretary specifies. The measures would be risk-adjusted as deemed appropriate by the Secretary. By 2013, the Secretary would be required to implement new reporting requirements for quality measures that reflect the outcomes of care experienced by MA enrollees. These measures may include (a) measures of rates of admission and readmission to a hospital, (b) measures of prevention quality, such as those established by the Agency for Healthcare Research and Quality, (c) measures of patient mortality and morbidity following surgery, (d) measures of health functioning such as limitations on activities of daily living and survival for patients with chronic diseases, (e) measures of patient safety, and (f) other measures as determined by the Secretary. The measures would be risk-adjusted as the Secretary deemed appropriate. In determining the quality measures to be used, the Secretary would be required to consider the MedPAC recommendations presented in their report to Congress mandated under MIPPA. The Secretary would be required to provide preferential consideration to measures of quality collected on, or comparable to measures of quality under Medicare Parts A and B. The Secretary would be required to follow specified rules for selection of quality measures. Specifically, the Secretary would be required to provide preference to clinical quality measures that have been endorsed by a consensus-based entity under contract with the Secretary. The Secretary would also be required to publish the measures in the Federal Register and provide for public comment on those measures prior to their selection. For 2014 and 2015, the Secretary would have the authority to compute quality performance scores based on a blend of the HEDIS/CAHPS scores and the new quality reporting measures. For years beginning in 2016, the preponderance of measures used to calculate MA plan quality would be required to be the new quality reporting measures.

The provision would specify which year's data would be used to calculate quality measures. For payments in 2011, quality measure data for 2009 would be used. Starting in 2012, payments would be based on quality measures for the second preceding year. Each MA organization would be required to report quality data to the Secretary for the determination of quality performance scores under this part, in a time and manner specified by the Secretary.

Based on the quality performance scores, each plan would be ranked to determine which are "high quality MA plans" and "improved quality MA plans" and thus receive the corresponding benchmark increases. The Secretary would be required to rank

plans from highest to lowest based on absolute scores and projected enrollment, and from highest to lowest based on percentage improvement in score and projected enrollment for the plan from the previous year. A plan which does not report quality data would be counted as having the lowest plan performance and lowest percentage improvement. Based on the quality performance scores, and the estimated proportion of enrollment, the Secretary would be required to identify the MA plans with the highest scores that are projected to include 20 percent of the aggregate projected enrollment for the year. These plans will be identified as "high quality MA plans." The same methodology would be used to determine "improved quality MA plans." Starting in 2011, the Secretary would be required to notify "high quality plans" and "improved quality plans" of their status and the corresponding payment adjustment for the year. The Secretary is to notify these plans through the annual announcement of benchmark rates and through publication on the website for the Medicare program. The Secretary would be given the authority to disqualify an MA plan from receiving a quality bonus if the Secretary identifies deficiencies in the plan's compliance with rules under this part.

Sec. 1163. Extension of secretarial coding intensity adjustment authority

Current Law

In general, Medicare payments to MA plans are risk-adjusted to account for the variation in the cost of providing care to enrollees of varying health status. Risk adjustment is designed to compensate plans for the increased cost of treating older and sicker beneficiaries, and thus discourage plans from preferential enrollment of healthier individuals. The Medicare risk adjustment models take into account the variation in expected medical expenditures of the Medicare population associated with demographic characteristics (age, sex, current Medicaid eligibility, original Medicare eligibility due to a disability), as well as medical diagnoses. The Deficit Reduction Act of 2005 (P.L. 109–171, DRA) required the Secretary, when risk adjusting payments to MA plans during 2008, 2009, and 2010, to adjust for patterns of diagnosis coding differences between MA plans and providers under parts A and B of Medicare, to the extent that the Secretary identified such differences based on an analysis of data submitted for 2004 and subsequent years.

Proposed Law

This provision would allow CMS to continue making appropriate adjustments to Medicare Advantage payments to account for any "upcoding" identified by the agency.

Sec. 1164. Simplification of annual beneficiary election periods

Current Law

Medicare beneficiaries may enroll in or change their enrollment in MA from November 15 to December 31 each year (the annual, coordinated election period). Changes go into effect on January 1 of the next year. During the first three months of the year, beneficiaries can enroll in an MA plan, and individuals enrolled in an

MA plan can either switch to a different MA plan or return to original Medicare. This period is known as the continuous open enrollment and disenrollment period. However, during the three-month period, beneficiaries cannot change their drug coverage but can change prescription drug plans.

Proposed Law

The current annual election period, from November 15 through December 31, gives MA and Part D plans very little, if any, time to process enrollment requests and ensure that on January 1, each beneficiary is properly enrolled in the plan. Allowing for a two-week processing period between the end of the annual election period and the start of the plan year better ensures that enrollees do not experience any gaps in coverage, and that plans are able to process enrollments in time for the start of the plan year.

The provision would move the annual, coordinated election period to 15 days earlier in the year—November 1 to December 15, rather than from November 15 to December 30. The provision would also eliminate the continuous open enrollment and disenrollment period (during the first three months of the year.) The change would simplify enrollment options so that beneficiaries select drug plans and the mode of receiving parts A and B benefits at the same time.

Sec. 1165. Extension of reasonable cost contracts

Current Law

Reasonable Cost plans are MA plans that are reimbursed by Medicare for the actual cost of providing services to enrollees. Cost plans were created in the Tax Equity and Fiscal Responsibility Act (P.L. 97–248, TEFRA) of 1982. The Balanced Budget Act of 1997 (P.L. 105–33, BBA) included a provision to phase-out the reasonable cost contracts, however, the phase-out has been delayed over the years by legislation. These plans are allowed to operate indefinitely, unless two other plans of the same type (i.e., either 2 local or 2 regional plans) offered by different organizations operate for the entire year in the cost contract's service area. After January 1, 2010, the Secretary may not extend or renew a reasonable cost contract for a service area if (1) during the entire previous year there were either two or more MA regional plans *or* two or more MA local plans in the service area offered by different MA organizations; *and* (2) these regional or local plans meet minimum enrollment requirements.

Proposed Law

This provision would extend for two years—from January 1, 2010, to January 1, 2012—the length of time reasonable cost plans could continue operating regardless of any other MA plans serving the area. The provision would modify the minimum enrollment requirement used as one of the criteria the Secretary considers when determining whether to renew or extend a reasonable cost plan. The enrollment criteria would apply to the portion of the MA regional or local plan's service area for the year that it was within the service area of the reasonable cost contract (and not the total service area of the MA regional or local plan).

Sec. 1166. Limitation of waiver authority for employer group plans

Current Law

The Secretary has the authority to waive or modify requirements that hinder the design of, the offering of, or the enrollment in employer or union sponsored MA plans. Such plans can be offered either under contracts between the union or employer group and a Medicare Advantage organization, or directly by the employer or union group.

Proposed Law

The MMA gave broad authority to CMS many requirements in order to encourage employers to provide retiree coverage through Medicare Advantage. While some requirements of MA plans marketing in the individual market may not be applicable to employers contracting with or offering an MA plan, and can appropriately be waived, it is crucial that retirees enrolling in such a MA plan have adequate access to a provider network. Requiring that MA plans offer local plans alongside employer group plans ensures that they are meeting network adequacy requirements and enrollees are protected.

For employers or unions that sponsor an MA plan directly (and not through a contract with a private MA organization), the Secretary would only have authority to waive or modify MA requirements for the plan if 90% of eligible individuals enrolled in the plan live in a county in which the MA organization offers an MA local plan. This provision would apply to plan years on or after January 1, 2011. The provision would not apply to plans in effect as of December 31, 2010.

Sec. 1167. Improving risk adjustment for payments

Current Law

In general, Medicare payments to MA plans are risk-adjusted to account for the variation in the cost of providing care to enrollees of varying health status. Risk adjustment is designed to compensate plans for the increased cost of treating older and sicker beneficiaries, and thus discourage plans from preferential enrollment of healthier individuals. The Medicare risk adjustment models take into account the variation in expected medical expenditures of the Medicare population associated with demographic characteristics (age, sex, current Medicaid eligibility, original Medicare eligibility due to a disability), as well as medical diagnoses, and differences in coding practices between MA and providers under Medicare Part A and B.

Proposed Law

The provision would require the Secretary to continue to refine the risk adjustment system used for Medicare Advantage payments to ensure its accuracy with regard to populations with high health needs, particularly beneficiaries with low incomes and chronic conditions.

Not later than 1 year after enactment, the Secretary would be required to submit a report to Congress evaluating the adequacy of the Medicare Advantage risk adjustment system at predicting costs

for beneficiaries with chronic or co-morbid conditions, beneficiaries dually-eligible for Medicare and Medicaid, and non-Medicaid eligible low-income beneficiaries. The report would be required to also address the need and feasibility of including further gradations of diseases or conditions and multiple years of beneficiary data. Taking this report into account, not later than January 1, 2012, the Secretary would be required to implement necessary improvements to the MA risk adjustment system.

Sec. 1168. Elimination of the MA regional plan stabilization fund

Current Law

The MMA created MA regional preferred provider organizations and established the MA Regional Plan Stabilization Fund to encourage plans to enter into and/or remain in the MA Regional Program. The fund was originally set at $10 billion with additional money added to the fund from savings in the bidding process. Funds were to be available from 2007 through the end of 2013. Subsequent legislation decreased the amount of funds available and delayed their availability. Most recently, MIPPA reduced the initial funding of the program to one dollar. Money from the regional plan bidding process continues to flow into the Fund. Expenditures from the Fund are delayed until 2014.

Proposed Law

Regional PPOs are no longer new products so this fund is no longer necessary.

The provision would eliminate the MA Regional Plan Stabilization Fund. Any amounts contained in the Fund would be transferred to the Federal Supplementary Medical Insurance Trust Fund.

Sec. 1169. Study regarding the effects of calculating Medicare Advantage payment rates on a regional average of Medicare fee for service rates

Current Law

No current law.

Proposed Law

The provision would require the Administrator of the Centers for Medicare and Medicaid Services to conduct a study to determine the potential effects of calculating MA rates on a more aggregated geographic basis, rather than using county boundaries. The Administrator would be required to consider whether the alternatives would result in (a) improvements in quality of care, (b) greater equity among providers, and (c) more predictable benchmark amounts. In conducting the study, the Administrator would be required to consult with (a) experts in health financing, (b) representatives of foundations and other nonprofit entities that have conducted research on Medicare financing issues, (c) Medicare Advantage plans, and (d) such other entities or people as determined by the Secretary. Not later than one year after the date of enactment, the Administrator would be required to submit a report to Congress with a detailed statement of findings and conclusions of the

study, together with recommendations for legislation and administrative action.

PART 2—BENEFICIARY PROTECTIONS AND ANTI-FRAUD

Sec. 1171. Limitation on cost-sharing for individual health services

Current Law

Each MA plan must provide all required Part A and B Medicare benefits (other than hospice) to individuals entitled to Medicare Part A and enrolled in Part B. The aggregate amount of cost sharing in a MA plan must be equal to the aggregate amount of cost sharing in original Medicare. Cost sharing per enrollee (excluding premiums) for covered services cannot be more than the actuarial value of the deductibles, coinsurance, and co-payments under traditional Medicare.

Dual eligibles are persons also entitled to the full range of benefits under their state's Medicaid program. Qualified Medicare beneficiaries (QMBs) are those aged or disabled individuals that are entitled to have some of their Medicare cost sharing and Part B premiums paid by the federal-state Medicaid program, but are not entitled to coverage of Medicaid services.

Proposed Law

Using a standard of actuarial equivalence across cost sharing for all services leaves an opportunity for MA plans to increase cost sharing for infrequently-used services that enrollees may not scrutinize—like home health or cancer drugs—while lowering cost sharing for more commonly used services, like physician visits. While this may be attractive for enrollees who are relatively healthy, it has potentially serious out-of-pocket cost implications for those enrollees who fall sick. MA plans that receive a rebate, because their bid is below the county benchmark, can use this rebate to lower cost sharing for certain services, either to attract enrollment or to encourage use of certain services (e.g. visits to a primary care physician). Setting a maximum cost sharing that does not exceed cost sharing under traditional Medicare ensures that no beneficiary will have higher out-of-pocket costs because they choose to receive Medicare services through a private plan.

For plan years beginning on or after January 1, 2011, this provision would prohibit MA plans from offering benefits with cost sharing requirements that are greater than the cost sharing requirements imposed under the traditional Medicare program. The "actuarially equivalent" standard in the statute would be eliminated. Medicare private plans would not be prohibited from using flat copayments or per diem rates in lieu of the cost sharing amounts imposed under Part A and B Medicare, as long as they did not exceed the level of cost sharing under traditional Medicare. This provision would also prohibit plans from imposing cost-sharing for dual-eligible individuals or qualified Medicare beneficiaries enrolled in a Medicare MA plan that exceeds the cost-sharing amounts permitted under the Medicare and Medicaid statutes.

Sec. 1172. Continuous open enrollment for enrollees in plans with enrollment suspension

Current Law

Special Election Periods (SEPs) allow beneficiaries the option to discontinue or change their enrollment in a MA plan outside of the annual coordinated election period. The circumstances in which an enrollee can exercise this option include (1) an MA plan terminates its participation in the MA program or in a specific area, (2) an individual's place of residence changes, (3) the MA plan violates a provision of its contract or misrepresents the plan's provisions in marketing the plan, or (4) other exceptional conditions as provided by the Secretary.

Proposed Law

This provision would expand the categories of beneficiaries eligible to participate in a SEP to include beneficiaries enrolled in private plans that have been suspended for not meeting the terms of their contract. This provision would require the Secretary to take into account the health or well-being of an individual when determining what constitutes eligibility for a SEP.

Sec. 1173. Information for beneficiaries on MA plan administrative costs

Current Law

The Secretary must provide for the dissemination of information to current and prospective Medicare beneficiaries about MA plans, including, but not limited to benefits, cost sharing, service areas, access to providers, out-of-area coverage, emergency coverage, and supplemental benefits.

By the first Monday in June, each local MA plan must submit to the Secretary an aggregate monthly bid amount (which includes separate bids for required services, any offered supplemental benefits, and any offered drug benefits) for each MA plan it intends to offer in the upcoming calendar year. The bid is based on the average revenue requirements in the payment area for an enrollee with a national average risk profile. The Secretary has the authority to evaluate and negotiate the plan's bid amounts and its proposed benefit packages.

Proposed Law

This provision would require Medicare Advantage plans to meet minimal standards of efficiency, consistent with requirements being placed on qualifying health benefits plans in the non-Medicare sector under this legislation.

This provision would require the publication of administrative cost information, including the medical loss ratio (MLR), for MA plans. Plans that fail to meet a minimum MLR would be subject to sanctions, such as enrollment suspension and potential termination.

Beginning in 2011, the Secretary would be required to publish the MLR for the previous year by November 1 for each MA plan contract. The definition of MLR would be defined by the Secretary, taking into account the definition adopted by the Health Choices

Commissioner under Section116 of this Act. Each MA plan would be required to submit to the Secretary, in a manner and form specified by the Secretary, the necessary data for publishing MLR information on a timely basis. For 2010 and 2011, the data submitted would be required to be consistent in content with the data reported as part of the MA plan bid in June 2009 for 2010.

For contract years beginning in 2010, the Secretary would be required to develop and implement standardized elements and definitions for reporting the data necessary to calculate a MLR. The elements and definitions would be developed in consultation with the Health Choices Commissioner, representatives of MA organizations, experts on health plan accounting systems, and representatives of the National Association of Insurance Commissioners. The Secretary would be required to publish a report describing the elements and definitions no later than December 31, 2010.

Beginning in 2014, if the Secretary determines that a MA plan failed to have a MLR of at least 0.85, the plan would be required provide enrollees with a rebate of their Part C premiums (or Part B or D, if applicable) by the amount necessary to meet a MLR of at least 0.85. The Secretary would also be required to restrict enrollment in the MA plan if the plan failed to meet the MLR requirement for 3 consecutive years and terminate the plan's contract if the plan failed to meet the MLR requirements for 5 consecutive years.

Sec. 1174. Strengthening audit authority

Current Law

The Secretary is required to provide for the annual auditing of the financial records of at least ⅓ of MA plans. Each contract with a MA plan is required to provide that the Secretary has the right to inspect or evaluate the quality, appropriateness and timeliness of services performed under the contract. Contracts must also provide the Secretary with the right to audit any plan's books and records related to the plan's ability to bear risk, the services delivered, or any amounts payable under the contract.

By the first Monday in June, each local MA plan must submit to the Secretary an aggregate monthly bid amount (which includes separate bids for required services, any offered supplemental benefits, and any offered drug benefits) for each MA plan it intends to offer in the upcoming calendar year. The bid is based on the average revenue requirements in the payment area for an enrollee with a national average risk profile. The Secretary has the authority to evaluate and negotiate the plan's bid amounts and its proposed benefit packages.

Proposed Law

This provision strengthens the ability of the Secretary to act on findings from audits of MA plans and Prescription Drug Plans (PDPs).

Each contract with a MA plan would be required to include a provision that the Secretary have the authority to take necessary action, including the pursuit of financial recoveries, to address deficiencies identified during an annual audit. The provision would apply to Part D PDPs in the same manner as certain other MA

contract provisions apply to PDP plans. The provision would apply to audits conducted for contract years beginning on or after January 1, 2011.

Sec. 1175. Authority to deny plan bids

Current Law

By the first Monday in June, each local MA plan must submit to the Secretary an aggregate monthly bid amount (which includes separate bids for required services, any offered supplemental benefits, and any offered drug benefits) for each MA plan it intends to offer in the upcoming calendar year. The bid is based on the average revenue requirements in the payment area for an enrollee with a national average risk profile. The Secretary has the authority to evaluate and negotiate the plan's bid amounts and its proposed benefit packages.

Potential PDP sponsors are also required to submit bids by the first Monday in June of the year prior to the plan benefit year. The following information must be included with the bid: (1) coverage to be provided; (2) actuarial value of qualified prescription drug coverage in the region for a beneficiary with a national average risk profile; (3) information on the bid, including the basis for the actuarial value, the portion of the bid attributable to basic coverage and, if applicable, the portion attributable to enhanced coverage, and assumptions regarding the reinsurance subsidy; and (4) service area. The bid also includes costs (including administrative costs and return on investment/profit) for which the plan is responsible. The bid must exclude costs paid by enrollees, payments expected to be made by CMS for reinsurance, and any other costs for which the sponsor is not responsible.

Proposed Law

Under current law, the Secretary has the authority to negotiate bids with most MA plans and PDPs. So that the Secretary can hold plans wishing to participate in Part C to a high standard, this provision clarifies that the Secretary may reject plan bids.

Sec. 1176. Limitation on enrollment outside open enrollment period of individuals into chronic care specialized MA plans for special needs individuals

Current Law

Under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, P.L. 108–173), Congress created a new type of Medicare Advantage (MA) coordinated care plan focused on individuals with special needs. Special needs plans (SNPs) are allowed to target enrollment to one or more types of special needs individuals identified by Congress as (1) institutionalized; (2) dually eligible; and/or (3) individuals with severe or disabling chronic conditions.

Congress has since passed additional legislation affecting SNPs. The original SNP authority established by MMA was to expire on December 31, 2008. Passage of the Medicare, Medicaid, and SCHIP Extension Act of 2007 (MMSEA, P.L. 110–173) authorized the SNP program through December 31, 2009, but also established a moratorium on the creation of SNPs after January 1, 2008, although ex-

isting plans could continue to enroll qualified individuals. More recently, the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, P.L. 110–275), extended the moratorium on designation of new SNPs until January 1, 2011, and authorized the SNP program through the same date. MIPPA also required SNPs to collect, analyze, and report data on their models of care before January 1, 2010.

In addition to legislative changes affecting SNPs, the CMS has issued regulatory guidance on recent legislative changes. CMS' guidance included an interim final rule that, among other issues, required data to be reported that demonstrates compliance with 10 quality indicators. Most recently, CMS issued a Final Rule in the January 12, 2009, Federal Register.

The number of SNPs has increased dramatically since 2004, the first year of operation. In 2004, CMS approved 11 SNPs, but by January 2008, CMS had approved 787 SNPs, including 442 dual-eligible SNPs, 256 chronic care SNPs, and 89 institutional SNPs. In September 2008, there were 1.2 million beneficiaries in SNPs.

Medicare beneficiaries may enroll in or change their enrollment in Medicare Advantage from November 15 to December 31 each year. Changes go into effect January 1 of the next year. During the first three months of the year, beneficiaries can enroll in an MA plan, and individuals enrolled in an MA plan can either switch to a different MA plan or return to original Medicare. Beneficiaries may also enroll in MA or switch their enrollment if they qualify for a Special Election Period (SEP) as defined in statutes or by the Secretary. One SEP specified by the Secretary in the Medicare Managed Care Manual allows individuals with severe or disabling chronic conditions to enroll in a SNP designed for individuals with those conditions. This SEP only applies as long as the individual has the qualifying condition and ends once the beneficiary enrolls in a SNP. Once the SEP ends, that individual may make enrollment changes only during applicable MA election periods.

Proposed Law

The current SEP for beneficiaries eligible for a chronic condition SNP encourages aggressive marketing by plans and is confusing for beneficiaries accustomed to annual enrollment periods. The new SEP will be more narrowly targeted to the time around a beneficiary's diagnosis, but the provision gives authority to the Secretary to determine how long after a diagnosis the beneficiary is permitted to elect a SNP. This should be a length of time sufficient for the beneficiary to understand the consequences of a diagnosis and learn about options for specialized plans.

This provision would require that beginning on January 1, 2011, SNPs serving beneficiaries with severe or disabling conditions could only enroll eligible individuals during an annual, coordinated open enrollment period or at the time of diagnosis of the disease or condition that would qualify an individual for a chronic care SNP.

Sec. 1177. Extension of authority of special needs plans to restrict enrollment

Current Law

Prior to January 1, 2011, SNPs may restrict enrollment to those who are in one or more classes of special needs individuals. Starting January 1, 2010, new SNP enrollment must be limited exclusively to individuals that meet the criteria for which the SNP is designated: those dually eligible for Medicare and Medicaid, chronic care, or institutional care. Further, MIPPA required that dual eligible SNPs contract with state Medicaid agencies to provide medical assistance services (Medicaid), which may include long-term care services. If SNPs do not have contracts with Medicaid agencies by January 1, 2010, then they can continue to operate, but are prohibited from expanding their service areas. However, state Medicaid agencies are not required to enter into contracts with SNPs.

Proposed Law

Congress and the Secretary have taken legislative and regulatory steps to ensure that SNPs offer specialized services for the populations enrolled. The provision extends SNP authority for a limited number of years in order to allow plans to meet these requirements.

A small subset of SNPs that have fully integrated Medicare and Medicaid services for dually eligible beneficiaries would receive a longer extension.

This Section would extend the time period, from January 1, 2011, to January 1, 2013, during which SNPs may restrict enrollment to individuals who meet the definition of the respective SNP. In addition, certain SNPs that had contracts with states would be grandfathered so that they would be permitted to restrict enrollment to beneficiaries who meet the definition of special needs individuals through January 1, 2016. To be grandfathered SNPs would be required to have had contracts with states where the state had a CMS-approved integrated Medicare-Medicaid program as of January 1, 2004.

The Secretary would be required to contract with an independent health services evaluation organization to evaluate the grandfathered SNPs in terms of their impact on cost, quality of care, patient satisfaction, and other subjects as specified by the Secretary. The Secretary would be required to submit to Congress by December 31, 2011, a report on the analysis of the grandfathered SNPs. The report would include recommendations on the treatment of the grandfathered SNPs as deemed appropriate by the Secretary.

Subtitle E—Improvements to Medicare Part D

Sec. 1181. Elimination of coverage gap

Current Law

Medicare law sets out a defined standard benefit structure under the Part D prescription drug benefit. In 2009, the standard benefit includes a $295 deductible and a 25% coinsurance until the enrollee reaches $2,700 in total covered drug spending. After this initial coverage limit is reached, there is a gap in coverage in which the enrollee is responsible for the full cost of the drugs until total

costs hit the catastrophic threshold, $6,153.75 in 2009. Each year, the deductible, co-payments, and coverage thresholds are increased by the annual percentage increase in average per-capita aggregate expenditures for covered outpatient drugs for Medicare beneficiaries for the 12–month period ending in July of the previous year.

Part D plan sponsors are allowed to offer plans that differ in benefit design, but are actuarially equivalent, or they may offer "enhanced" plans that offer more generous coverage. Currently, almost all plans include a coverage gap in their benefit designs. CMS estimates that 31.7% (8.3 million) of Part D enrollees reached the initial coverage limit of their drug plans in 2007.

Some beneficiaries with limited income and resources may qualify for assistance with a portion of their Part D premiums, cost-sharing, and other out-of-pocket expenses. Medicare beneficiaries who qualify for Medicaid based on their income and assets (dual eligibles) are automatically deemed eligible for the full low-income subsidy. Prior to the implementation of the Medicare Part D outpatient prescription drug benefit, established by the Medicare Prescription Drug Improvement and Modernization Act of 2003 (MMA, P.L. 108–173), Medicaid was the primary payer for drugs for full-benefit dual-eligible beneficiaries.

The Omnibus Budget Reconciliation Act of 1990 (P.L. 101–508) requires drug manufacturers who wish to have their drugs available for Medicaid enrollees to enter into rebate agreements with the Secretary of HHS, on behalf of the states. Under the agreements, pharmaceutical manufacturers must provide state Medicaid programs with rebates on drugs paid for Medicaid beneficiaries. The formulas used to compute the rebates are intended to ensure that Medicaid pays the lowest price that the manufacturers offer for the drugs. In return for entering into agreements with the Secretary, state Medicaid programs are required to cover all of the drugs marketed by those manufacturers (with possible exceptions for the 11 categories of drugs that states are allowed to exclude from coverage).

The rebates are computed and remitted by pharmaceutical manufacturers each quarter based on utilization information supplied by the state programs. States collect the rebates from the manufacturers. The federal share of the rebates are subtracted from states' claims for their federal share of program costs. In setting the amount of required rebates, the law distinguishes between two classes of drugs. The first includes single source drugs (generally, those still under patent) and "innovator" multiple source drugs (drugs originally marketed under a patent or original new drug application (NDA) but for which generic competition now exists). The second class includes all other, "non-innovator" multiple source drugs (generics).

Manufacturers are required to pay state Medicaid programs a basic rebate for single source and innovator multiple source drugs. Basic rebate amounts are determined by comparing the Average Manufacturer Price (AMP) for a drug to the "best price," which is the lowest price that is offered by the manufacturer in the same period to any wholesaler, retailer, nonprofit, or public entity. The basic rebate is the greater of 15.1% of the AMP or the difference between the AMP and the best price. For non-innovator multiple

source drugs, basic rebates are equal to 11% of the AMP. Manufacturers are also required to pay an additional Medicaid inflation rebate for single source drugs. This rebate is equal to the amount by which the increase in the AMP of the single source drug exceeds the increase in the consumer price index.

Proposed Law

This provision closes the coverage gap (commonly called the "doughnut hole" in Part D prescription drug benefits and institutes a rebate in Medicare for prescription drugs covered under Part D.

Funds received from the new rebate requirement will be used to pay for the elimination of the Part D coverage gap. Since the program's inception, this mid-year gap in benefits has plagued millions of beneficiaries who continue to pay their monthly premium, yet also have to pay 100 percent of the cost of their drugs out-of-pocket. This section would eliminate the gap over time, ensuring that beneficiaries are insured against the full cost of drugs throughout the entire benefit year.

Coverage Gap. This provision would phase in an elimination of the coverage gap. For each year beginning with 2011, the Secretary would progressively increase the initial coverage limit and decrease the annual out-of-pocket threshold until there is a continuation of coverage from the initial coverage limit up to the expenditure threshold at which catastrophic coverage begins. Starting in 2011, the initial coverage limit for each year, as determined using current annual percentage increase methodology, would be increased by one-half of the cumulative phase-in percentage (the sum of the annual phase-in percentage for the year and the annual phase-in percentages for each previous year) times the out-of-pocket gap amount (the amount by which the annual out-of-pocket threshold for the year exceeds the sum of the annual deductible for the year and one-fourth the amount by which the initial coverage limit for the year exceeds the annual deductible). Also beginning in 2011, the annual out-of-pocket threshold would be decreased by one-half of the cumulative phase-in percentage of the out-of pocket gap amount for the year multiplied by 1.75.

The annual phase in percentage would be 13% for 2011; 5% for years 2012 through 2015; 7.5% for years 2016 through 2018, and 10% for 2019 and each subsequent year.

The combined effect of those changes would be to eliminate about $500 of the coverage gap in 2011 and additional amounts thereafter until it is closed in 2023. The closure of the coverage gap is split even between increases in the initial coverage limit and decreases in the catastrophic threshold.

Requiring Drug Manufacturers to Provide Rebates for Full-Benefit Dual Eligibles. When prescription drug coverage for six million dually eligible beneficiaries was switched from Medicaid to Medicare Part D in 2006, drug manufacturers received a windfall amounting to almost $4 billion in just the first two years of the program. While Medicaid rebates are statutorily required at a certain level, rebates in the Part D program are entirely negotiated between plans and manufacturers, giving the federal government and taxpayers—who pay for the Part D program—no control over the level of rebate provided. Requiring that rebates from drug manufacturers in the Part D program match the rebates required under

Medicaid ensures that for the same beneficiary, manufacturers are not permitted to charge higher prices to the government under Part D than under Medicaid. Manufacturers will continue to enter into rebate agreements with the Part D plans. However, if that rebate amount does not equal the Medicaid rebate amount for a particular drug, the manufacturer would be required to make up the difference in rebate payments directly to the federal government.

Under this provision, drug manufacturers would be required to provide the Secretary a rebate for any covered Part D drug of the manufacturer dispensed after December 31, 2010, to any full-benefit dual eligible individual for which payment was made by a prescription drug plan (PDP) sponsor or a Medicare Advantage (MA) organization.

The amount of the rebate for a rebate period would be equal to the product of the total number of units of such dosage form and strength of the drug dispensed and the amount, if any, by which the Medicaid rebate, as modified by this statute, and including both the basic and inflation rebate, for such form, strength, and period, exceeds the average Medicare drug program full-benefit dual eligible rebate amount for such form, strength, and period.

The average Medicare drug program full-benefit dual eligible rebate amount means with respect to each dosage form and strength of a covered outpatient drug provided by a manufacturer for a rebate period, the sum for all PDP sponsors and MA organizations administering a Medicare Advantage drug plan (MA–PD), of the product for each such sponsor or organization of: the sum of all rebates, discounts, or other price concessions, calculated on a per unit basis (but only to the extent that any such rebate, discount, or other price concession applies equally to drugs dispensed to full-benefit dual eligible Medicare drug plan enrollees and drugs dispensed to PDP and MA–PD enrollees who are not full-benefit dual eligible enrollees) and the number of units of such dosage and strength of the drug dispensed during the rebate period to full-benefit dual eligible enrollees, divided by the total number of units of the drug dispensed during the rebate period to all full-benefit dual eligible PDP and MA–PD enrollees.

In general, a rebate agreement would be effective for an initial period of not less than 1 year and would be automatically renewed for a period of not less than 1 year. The Secretary would be required to establish other terms and conditions of the rebate agreement including terms and conditions related to compliance.

For contract years beginning on or after January 1, 2011, each drug plan contract entered into with a PDP sponsor or a MA organization would require that the sponsor or organization report to each manufacturer not later than 60 days after the end of each rebate period, information on the total number of units of each dosage, form, and strength of each drug the manufacturer dispensed to full-benefit dual eligible Medicare drug plan enrollees under any PDPs or MA–PDs operated by the sponsor during the rebate period; information on the price discounts, price concessions, and rebates for such drugs for such form, strength, and period; information on the extent to which such price discounts, price concessions, and rebates apply equally to full-benefit dual eligible Medicare drug plan enrollees and enrollees who are not full-benefit dual eligible plan enrollees; and any additional information that the Sec-

retary determines is necessary to enable the Secretary to calculate the average Medicare drug program full-benefit dual eligible rebate amount. The report would be in a form consistent with a standard reporting format established by the Secretary, and a copy of the information would be reported to the Secretary for the purpose of oversight and evaluation. The information submitted would be treated as confidential. The rebate would be paid by the manufacturer to the Secretary not later than 30 days after the date of receipt of this information.

The provision would allow the Medicare Payment Advisory Commission, the Congressional Budget Office, and the GAO, access to the information, and the information reported may be used by the HHS Office of Inspector General for audits, investigations, and evaluations. Additional confidentiality provisions (with the exception of clause iv) from the Medicaid rebate section (1927(b)(3)) of the Social Security Act also apply to the Medicare Part D rebate data reported under this section.

With respect to GAO, the confidentiality provision that incorporates section 1927(b)(3) of the Social Security Act is intended to reflect and confirm GAO's existing right to access Part D information in light of its broad authority at 31 U.S.C. 716.

In cases where information was not submitted timely or if false information is submitted, penalties would be imposed. PDP sponsors and MA organizations would be subject to a civil money penalty in the amount of $10,000 for each day in which such information has not been provided. If the sponsor or organization knowingly provides false information, the sponsor or organization would be subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information. Such penalties would be in addition to any other civil money penalties as may be prescribed by law.

The rebates for full-benefit dual eligible Medicare drug plan enrollees would be paid into the Medicare Prescription Drug Account in the Supplementary Medical Insurance Trust Fund and used to pay for all or part of the gradual elimination of the coverage gap.

Sec. 1182. Discounts for certain Part D drugs in original coverage gap

Current Law

None.

Proposed Law

In June 2009, the trade association representing brand-name pharmaceutical manufacturers—PhRMA—pledged to provide a 50% discount to seniors in the Part D coverage gap to alleviate the high costs that seniors currently faced. This section would enact that promise into law.

Manufacturers of prescription drugs would, as a condition of allowing any of the drugs they manufacture to be treated as covered drugs under Medicare Part D, be required to enter into agreements with Medicare Part D drug plan sponsors to provide discounts on drugs provided to plan enrollees in the coverage gap period. This provision would be applicable to drugs dispensed after December 31, 2010.

Under a discount agreement, a drug manufacturer would be required to provide to each PDP or MA–PD a discount for qualifying drugs of the manufacturer dispensed to a qualifying enrollee when in the original Part D coverage gap. A qualifying drug would be defined as a drug that is produced under an original new drug application approved by the FDA, or a drug that was initially marketed under such an application, or a biological product approved under Section 351(a) of the Public Health Service Act, and that is covered under the plan's formulary and is dispensed to an individual who is in the original gap in coverage.

The Secretary would establish the terms and conditions of the discount agreement, including those relating to compliance, similar to the terms and conditions for rebate agreements between states and drug manufacturers for drugs provided to Medicaid recipients. However, the discounts would be applied to PDP and MA–PDs rather than to state plans, PDP sponsors and MA organizations, instead of states, would be required to provide the necessary utilization information to drug manufacturers; and PDP sponsors and MA organizations would be responsible for reporting information on drug-component negotiated prices instead of other manufacturer prices used in calculating Medicaid rebates.

The amount of the discount for a discount period for a plan would be equal to 50% of the amount of the negotiated price for qualifying drugs, excluding any dispensing fee for the period involved. The sponsor or plan would provide the discount to the enrollee at the time the enrollee pays for the drug if the enrollee is in the actual gap in coverage, and in such cases the amount of the discount, in addition to the amount actually paid by the enrollee, would count toward costs incurred by the plan enrollee. If the enrollee is in the portion of the original gap in coverage that is not in the actual gap in coverage, the discount shall not be applied against the negotiated price for the purpose of calculating the beneficiary payment.

A qualifying enrollee is defined as an individual who is enrolled in a PDP or an MA–PD plan who is not a subsidy-eligible individual as defined in section 1860D–14(a)(3). The original gap in coverage is defined as the gap that would occur between the initial coverage limit and the out-of-pocket threshold if the phase-out of the coverage gap described in Section 1181 did not apply. The actual gap in coverage refers to the gap between the initial coverage limit and the out-of-pocket threshold as modified by Section 1181.

With regard to payments to pharmacists, discounts under this section are to be treated in a similar fashion to any other discounts, rebates, or price concessions provided to PDP sponsors, and payments to pharmacists in conjunction with these discounts are to be made consistent with prompt payment requirements under Section 1860D–12(b)(4), with the pharmacist to be fully reimbursed for clean claims within 14 days.

Sec. 1183. Repeal of provision relating to submission of claims by pharmacies located in or contracting with long-term care facilities

Current Law

Section 172 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA; P.L. 110–275) provided for a new set of requirements for contracts between Part D drug plan sponsors and pharmacies located in or contracting with long-term care facilities for plan years beginning on or after January 1, 2010. Under that section, each contract entered into with a PDP sponsor or MA–PD plan is required to provide that a pharmacy located in or having a contract with a long-term care facility would have between 30 and 90 days to submit claims for reimbursement.

Proposed Law

This provision repeals Section 172 of the MIPPA to allow long-term pharmacies and nursing homes more time to coordinate with state Medicaid programs.

This provision would be applicable for contract years beginning with 2010.

Sec. 1184. Including costs incurred by AIDS drug assistance programs and Indian Health Service in providing prescription drugs toward the annual out-of-pocket threshold under part D

Current Law

Under a standard Medicare part D plan design, beneficiaries must incur a certain level of out-of-pocket costs ($4,350 in 2009) before catastrophic protection begins. These include costs that are incurred for the deductible, cost-sharing, or benefits not paid because they fall in the coverage gap. Costs are counted as incurred, and thus treated as true out-of-pocket (TrOOP) costs only if they are paid by the individual (or by another family member on behalf of the individual), paid on behalf of a low-income individual under the subsidy provisions, or paid under a State Pharmaceutical Assistance Program. Incurred costs do not include amounts for which no benefits are provided—for example, because a drug is excluded under a particular plan's formulary. Additional payments that do not count toward TrOOP include part D premiums and coverage by other insurance, including group health plans, workers' compensation, Part D plans' supplemental or enhanced benefits, or other third parties.

Proposed Law

This requires the Secretary to count contributions from other programs designed to help beneficiaries with their drug costs for the purpose of assessing when a beneficiary reaches the catastrophic cap. This change will lower prescription drug costs for beneficiaries who receive assistance from other sources.

The provision would treat as incurred those costs that are borne or paid by the Indian Health Service, Indian tribe or tribal organization or an urban Indian organization (as defined in Section 4 of the Indian Health Care Improvement Act) to count toward the out-of-pocket threshold. Costs paid under an AIDS Drug Assistance

Program under part B of title XXVI of the Public Health Service Act would also count toward the out-of-pocket threshold. The provision would apply to costs incurred on or after January 1, 2011.

Sec. 1185. Permitting mid-year changes in enrollment for formulary changes that adversely impact an enrollee

Current Law

Part D plans are permitted to operate formularies—lists of drugs that a plan chooses to cover and the terms under which they are covered. By law part D plans may not change the therapeutic categories and classes in a formulary other than at the beginning of each plan year except as the Secretary may permit to take into account new therapeutic uses and newly approved covered part D drugs. The law further stipulates that any removal of a covered part D drug from a formulary and any change in the preferred or tiered cost-sharing status of such a drug shall take effect only after appropriate notice is made available to the Secretary, affected enrollees, physicians, pharmacies, and pharmacists.

Under current regulations, a part D sponsor may not remove a covered part D drug from its part D plan's formulary or make any change in the preferred or tiered cost-sharing status of a covered part D drug on its plan's formulary between the beginning of the open enrollment period and 60 days after the beginning of the contract year associated with that open enrollment period except under certain circumstances, for example, when a covered drug has been deemed unsafe by the FDA or removed from the market by its manufacturer. After March 1 of a given plan year, part D sponsors may make maintenance changes to their formularies, such as replacing brand name drugs with new generic drugs or modifying formularies as a result of new information on drug safety or effectiveness. According to CMS policy, if part D sponsors remove part D drugs from their formularies, move covered part D drugs to a less preferred tier status, or add utilization management requirements, these changes must be approved by CMS and sponsors may make such changes only if enrollees currently taking the affected drug are exempt from the formulary change for the remainder of the contract year. Part D sponsors may expand formularies by adding drugs to their formularies, reducing copayments or coinsurance by placing a drug on a lower cost-sharing tier, or deleting utilization management requirements at any time during the year.

Proposed Law

Beneficiaries choose prescription drug plans based on a number of factors, including whether a plan covers the drugs they are currently taking. Though CMS has imposed certain restrictions on plan formulary changes, there is no protection for beneficiaries who are nonetheless harmed by a mid-year formulary change. This provision will allow adversely affected beneficiaries to choose a new plan, and will discourage plans from making mid-year formulary changes for highly prescribed drugs.

The provision would establish a special open enrollment period for an individual to change plans during a period other than during the annual open enrollment period. The provision would apply to an individual enrolled in a prescription drug plan (or an MA-PD

plan) who has been prescribed a drug and is using the drug while enrolled in the plan in the case where the formulary of the plan materially changed (other than at the end of the contract year) such as to reduce coverage or increase the cost-sharing of the drug. The provision would not apply in cases where the drug was removed from the formulary because of a recall or withdrawal issued by the Food and Drug Administration (FDA) or because the drug was replaced with a therapeutically equivalent generic drug. The provision would also not apply in instances where utilization management was applied for drugs for which FDA required a boxed warning or drugs subject to a Risk Evaluation and Management Strategy under subsection (f) of section 505–1 of the Federal Food, Drug, and Cosmetic Act. The provision would apply to contract years beginning on or after January 1, 2011.

Sec. 1186. Negotiation of lower covered part D drug prices on behalf of Medicare beneficiaries

Current Law

Part D plan sponsors (or the pharmaceutical benefit managers (PBMs) they have contracted with) negotiate prices with drug manufacturers, wholesalers, and pharmacies and are required to provide beneficiaries with access to these negotiated prices for covered part D drugs. The law specifically states that the Secretary may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors. Further, the Secretary may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs. This is known as the non-interference provision (SSA 1860D–11(i)).

Proposed Law

The 2003 Medicare Modernization Act specifically banned the HHS Secretary from negotiating with drug manufacturers for lower drug prices on behalf of Part D enrollees. A series of investigations in 2006, 2007, and 2008 by the House Oversight Committee has found that the private plans that run the part D program are unable to effectively negotiate with drug manufacturers, resulting in higher drug prices for part D enrollees and higher taxpayer costs for the part D program. This provision overturns the negotiating ban, and requires that the Secretary negotiate with drug manufacturers for lower part D prices.

This provision would strike section 1860D–11(i), and in its place, add language that would require the Secretary to negotiate with pharmaceutical manufacturers' prescription drug prices (including discounts, rebates and other price concessions) that may be charged to PDP sponsors and MA organizations. The provision allows prescription drug plans to obtain discounts or price reductions below those negotiated by the Secretary. The provision would also maintain the prohibition against the establishment of a formulary by the Secretary; however, there would no longer be an explicit prohibition of the institution of a price structure. Not later than June 1, 2011, and every six months thereafter, the Secretary would be required to submit to the House Committees on Ways and Means, Energy and Commerce, and Oversight and Government Reform and to the Senate Finance Committee a report on the prices and

discounts achieved as a result of the negotiations. The provision would take effect on the date of enactment and would first apply to negotiations and prices for plan years beginning on January 1, 2011.

PDP sponsors and MA organizations serve as third-party payers for drugs, reimbursing pharmacies for drugs that the pharmacies purchase from drug wholesalers or directly from drug manufacturers. The intent of this section is to reduce the prices charged by drug manufacturers via the ability of the Secretary to negotiate with these manufacturers for discounts, rebates, and price concessions. This section shall not be construed to require negotiation between the Secretary and retail or mail-order pharmacies.

Sec. 1187. State certification prior to waiver of licensure requirements under Medicare prescription drug program

Current Law

Medicare part D participants must obtain coverage through a part D sponsor—a private insurer or other entity that has contracted with Medicare to provide prescription drug benefits. According to section 1860D–12 of the Social Security Act, a sponsor of a prescription drug plan is required to be organized and licensed under state law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each state it offers a prescription drug plan. Under certain circumstances, a sponsor may apply to the Centers for Medicare and Medicaid Services (CMS) for a waiver of this requirement. For example, if CMS determines, based on the application and other evidence presented, that a state did not process a sponsor's substantially complete application for licensure within 90 days of receipt, did not approve the licensing application based on grounds other than those required under federal law, or does not have a PDP sponsor licensing process in place, the licensure requirement may be waived. In such instances, the sponsor must obtain certification from the state that the organization meets a level of financial solvency or other standards required by the state.

The National Association of Insurance Commissioners (NAIC) has noted instances in which PDP sponsors have been granted waivers from state licensure requirements but did not have fully completed applications for licensure pending at the time the waiver had been granted.

Proposed Law

This provision would ensure that prescription drug plans are in compliance with applicable state laws relating to insurance licensure.

The provision would amend section 1860D–12 of the Social Security Act to require that CMS may only grant a waiver of licensure for a particular state if it has received a certification from the state insurance commissioner that the prescription drug plan has a substantially complete application pending in that state. Additionally, the waiver could be revoked if the state insurance commissioner submits a certification to CMS that the sponsor committed fraud with respect to the waiver, did not made a good faith effort to satisfy state licensing requirements, or was determined by the state

to be ineligible for licensure. The requirements would be effective for plan years beginning January 1, 2010.

Subtitle F—Medicare Rural Access Protections

Sec. 1191. Telehealth expansion and enhancements

Current Law

Medicare covers certain services including professional consultations, office and other outpatient visits, individual psychotherapy, pharmacological management, psychiatric diagnostic interview examinations, neurobehavioral status exams, and end stage renal disease related services delivered via an eligible telecommunications system. An interactive telecommunications system is required as a condition of payment. The originating site (the location of the beneficiary receiving the telehealth service) can be a physician or practitioner's office, a critical access hospital, a rural health clinic, a federally qualified health center, a hospital-based renal dialysis center, a skilled nursing facility, a community mental health center or a hospital. The originating site must be in a rural health professional shortage area or in a county that is not in a metropolitan statistical area or at an entity that participates in a specified federal telemedicine demonstration project.

Proposed Law

This provision expands Medicare's telehealth benefit and ensures that CMS benefits from valuable outside expertise in the administration of the benefit.

The provision specifies that a renal dialysis facility would be included as a covered originating site for telehealth services effective for services starting January 1, 2011.

The Secretary would appoint a Telehealth Advisory Committee to make policy recommendations regarding telehealth services including the appropriate addition or deletion of covered services and procedure codes for authorized payments.

The Advisory Committee would be composed of 9 members: 5 would be practicing physicians; 2 would be practicing non-physician healthcare practitioners, and 2 shall be administrators of telehealth programs. In appointing the committee members, the Secretary would be required to ensure that each member has prior experience with the practice of telemedicine or telehealth; would give preference to individuals who are currently providing telemedicine or telehealth services or who are involved in telemedicine or telehealth programs; would ensure that committee membership represents a balance of specialties and geographic regions; and would take into account the recommendations of stakeholders.

The Telehealth Advisory Committee would meet at least twice each calendar year and at other times provided by the Secretary. The committee members would serve for the term specified by the Secretary. An advisory committee member would not be able to participate in a particular matter considered in meeting if such a member (or an immediate family member) had a financial interest that could be affected by the advice given to the Secretary. Section 14 of the Federal Advisory Committee Act governing termination, renewal and continuation of committees would not apply. The Secretary would establish this committee regardless of any limitation

that would apply to the number of advisory committees that may be established with the Department of Health and Human Services or otherwise.

In making determinations with respect to covered services, the Secretary would be required to take into account the recommendations of the Telehealth Advisory Committee. If the Secretary does not implement a recommendation, the Secretary would publish a statement providing the reason for such decision in the *Federal Register*.

Sec. 1192. Extension of outpatient hold harmless provision

Current Law

Small rural hospitals (with no more than 100 beds) that are not sole community hospitals (SCHs) can receive additional Medicare payments if their outpatient payments under the prospective payment system are less than under the prior reimbursement system. For calendar year CY2006, these hospitals received 95% of the difference between payments under the prospective payment system and those that would have been made under the prior reimbursement system. The hospitals receive 90% of the difference in CY2007 and 85% of the difference in CY2008 and CY2009. Sole community hospitals with not more than 100 beds receive 85% of the payment difference for covered Hospital Outpatient Department (HOPD) services furnished on or after January 1, 2009, and before January 1, 2010.

Proposed Law

This provision protects small rural hospitals from the financial losses they would face under the outpatient prospective payment system. Eligible hospitals will receive a partial hold harmless payment until the end of CY2011.

Small rural hospitals and sole community hospitals with not more than 100 beds would receive 85% of the payment difference for covered HOPD services furnished until January 1, 2012.

Sec. 1193. Extension of section 508 hospital reclassifications

Current Law

Section 508 of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (MMA, P.L. 108–173) provided $900 million for a one-time, 3 year geographic reclassification of certain hospitals that were otherwise unable to qualify for administrative reclassification to areas with higher wage index values. These reclassifications were extended from March 31, 2006, to September 30, 2007, by the Tax Relief and Health Care Act of 2006 (P.L. 109–432). The Medicare, Medicaid and SCHIP Extension Act (P.L. 110–173) extended the reclassifications to September 30, 2008. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, P.L. 110–275) extended the reclassifications until September 30, 2009. These extensions are exempt from any budget neutrality requirements.

Proposed Law

The section 508 reclassifications would be extended until September 30, 2011.

Sec. 1194. Extension of geographic floor for work

Current Law

The Medicare fee schedule is adjusted geographically for three factors to reflect differences in the cost of resources needed to produce physician services: physician work, practice expense, and medical malpractice insurance. The geographic adjustments are indices that reflect how each area compares to the national average for a "market basket" of goods. A geographic practice cost index (GPCI) with a value of 1.00 represents the average across all areas. A series of bills set a temporary floor value of 1.00 on the physician work index beginning January 2004; most recently, section 134 of the MIPPA extended the application of this floor when calculating Medicare physician reimbursement through December 2009. The other geographic indices (for practice expense and medical malpractice) were not modified by these Acts.

Proposed Law

Rural physicians put in as much time, skill, and intensity into their work as physicians in urban areas. This provision ensures that rural physicians are paid at least the average rate for their work. Adjustments for practice expense and malpractice, reflecting the differing costs in operating practices and purchasing malpractice insurance across the country, are not affected by this provision.

The proposal would extend the 1.00 floor for the geographic index for physician work for an additional 2 years through December, 2011.

Sec. 1195. Extension of payment for technical component of certain physician pathology services

Current Law

Legislation enacted in 1997 specified that independent labs that had agreements with hospitals on July 22, 1999, to bill directly for the technical component of pathology services could continue to do so in 2001 and 2002. The provision has been periodically extended, most recently through December 31, 2009 by MIPPA.

Proposed Law

This provision is needed in order to continue allowing direct billing for the technical component for independent labs that have agreements with hospitals. Without this extension, hospitals will incur an additional cost that is not included in the payment rate under the prospective payment system. This provision protects rural beneficiaries' access to laboratory services.

The bill would extend this provision through 2011.

Sec. 1196. Extension of ambulance add-ons

Current Law

Ambulance services are paid on the basis of a national fee schedule, which is being phased in. The fee schedule establishes seven categories of ground ambulance services and two categories of air ambulance services. The national fee schedule is fully phased in for air ambulance services. For ground ambulance services, payments

through 2009 are equal to the greater of the national fee schedule or a blend of the national and regional fee schedule amounts. The portion of the blend based on national rates is 80% for 2007–2009. In 2010 and subsequently, the payments in all areas will be based on the national fee schedule amount.

The fee schedule payment for an ambulance service equals a base rate for the level of service plus payment for mileage. Geographic adjustments are made to a portion of the base rate. For the period July 2004 to December 2009, mileage payments are increased for ground ambulance services originating in rural low population density areas. For the period July 1, 2004 until December 31, 2008, there is a 25% bonus on the mileage rate for trips of 51 miles and more. Payments for ground transports originating in rural areas or rural census tracts are increased by 3% for the period of October 1, 2008, through December 31, 2009.

MIPPA specifies that any area designated as rural for the purposes of making payments for air ambulance services on December 31, 2006, will be treated as rural for the purpose of making air ambulance payments during the period July 1, 2008 until December 31, 2009.

Proposed Law

This provision helps to cover the cost of providing ambulance services in rural areas.

The provision would maintain the 3% higher payments for ground transports originating in rural areas or rural census tracts until December 31, 2011. The MIPPA provision maintaining the designation of certain areas as rural for the purposes of Medicare's payments for air ambulance services would be maintained until December 31, 2011.

Sec. 1197. Ensuring proportional representation of interests in rural areas on MedPAC

Current Law

The Balanced Budget Act of 1997 established the Medicare Payment Advisory Commission (MedPAC) to advise Congress on issues impacting the Medicare program. The Commission is composed of 17 members appointed for three-year terms by the Comptroller General. Represented on the Commission are a mix of health care providers, health researchers, insurance organization officials, employers, representatives from prescription drug benefit programs, and consumers, among others. Specifically, the Medicare statute indicates that individuals appointed to MedPAC should be nationally recognized for their expertise in health finance and economics, actuarial science, health facility management, health plans and integrated delivery systems, reimbursement of health facilities, allopathic and osteopathic physicians, and other providers of health services.

Proposed Law

The provision requires that the proportion of MedPAC commissioners who would represent the interests of health care providers and beneficiaries located in rural areas would be no less than the proportion of total number of Medicare beneficiaries who live in

rural areas. This provision would apply to appointments to MedPAC made after enactment.

DIVISION B—MEDICARE AND MEDICAID IMPROVEMENTS

TITLE II—MEDICARE BENEFICIARY IMPROVEMENTS

Subtitle A—Improving and Simplifying Financial Assistance for Low-Income Medicare Beneficiaries

Sec. 1201. Improving assets tests for Medicare savings program and low-income subsidy program

Current Law

Federal assistance is provided to certain low-income persons to help them meet Medicare Part D premium and cost-sharing charges. To qualify for the part D low-income subsidy, Medicare beneficiaries must have resources no greater than the income and resource limits established by the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L.108–173, MMA).

Individuals may qualify for the full subsidy in two ways: (1) if they are eligible for Medicaid or one of the Medicare Savings Programs (Qualified Medicare Beneficiary (QMB), Specified Low Income Medicare Beneficiary (SLMB), or Qualifying Individual (QI)), or are recipients of Supplemental Security Income (SSI) benefits, they are deemed automatically eligible; or (2) if they apply for the benefit, through their State Medicaid agency or through the Social Security Administration (SSA) and are determined to have an annual income below 135% of the federal poverty level (FPL) and have resources below a certain limit (in 2009, $6,600 for an individual or $9,910 if married). Beneficiaries may qualify for a partial subsidy if they apply and are determined to have an annual income below 150% of the FPL and whose resources do not exceed a certain limit (in 2009, $11,010 for individuals or $22,010 if married). (When determining whether a beneficiary qualifies for the Medicare Part D low-income subsidy, $1,500 per person in resources are excluded from consideration if the beneficiary indicates that he/she expects to use resources for burial expenses; otherwise $1,500 should be added to the above asset limits for an individual and $3,000 for a couple.)

Federal assistance is also provided to individuals to assist with premium and cost sharing arising under Parts A and B of Medicare (the Medicare Savings Programs). QMBs are entitled to receive payments (on their behalf) for their Medicare Part B premium and cost-sharing for services under Parts A and B. SLMBs and QIs are entitled to payments for Part B premiums. Each category of beneficiary is subject to an income test and an asset test of $4,000 for an individual and $6,000 for a couple in 2009.

Proposed Law

This section harmonizes the asset tests for eligibility for all LIS eligible individuals—full and partial Part D subsidy—and the MSP to simplify the test, and raises the maximum level to prevent seniors with nest eggs from being disqualified from receiving the subsidy.

Under this provision, the maximum resource levels used to determine eligibility for the low income subsidy would be increased. In 2012, the level would be $17,000 for an individual and $34,000 for a couple. In subsequent years, the asset level would be increased by the annual percent increase in the Consumer Price Index (all items, U.S. city average) as of September of the previous year.

These maximum resources levels would also apply for determining eligibility for Medicare Savings programs, beginning January 1, 2012.

Sec. 1202. Elimination of part D cost-sharing for certain non-institutionalized full-benefit dual eligible individuals

Current Law

Cost-sharing subsides for Low-Income Subsidy (LIS) enrollees are linked to the standard prescription drug coverage. Full-subsidy eligibles have no deductible, minimal cost sharing during the initial coverage period and coverage gap, and no cost-sharing over the catastrophic threshold.

Full-benefit dual eligibles who are residents of medical institutions or nursing facilities have no cost-sharing. Other full-benefit dual-eligible individuals with incomes up to 100% of poverty have cost-sharing, for all costs up to the out-of-pocket threshold, of $1.10 in 2009 for a generic drug prescription or preferred multiple source drug prescription and $3.20 in 2009 for any other drug prescription. All other full-subsidy-eligible individuals have cost-sharing for all costs up to the out-of-pocket threshold, of $2.40 in 2009 for a generic drug or preferred multiple source drug and $6.00 in 2009 for any other drug.

Proposed Law

Under this provision, cost-sharing would not apply to persons who are full benefit dual eligibles and for whom a determination was made that but for the provision of home- and community-based care, the individual would require the level of care provided in a hospital or a nursing facility or intermediate care facility for the mentally retarded and such care would be paid for by Medicaid. Such home- and community-based care would be that provided under Section 1915 or 1932 of the SSA or under a waiver under Section 1115 of the Act. The provision would apply to drugs dispensed on or after January 1, 2011.

Extending the protection against cost-sharing to dually eligible beneficiaries who are eligible to be institutionalized in a hospital or facility for the mentally retarded ensures that these beneficiaries are not penalized for choosing to receive care in a home or community-based setting.

Sec. 1203. Eliminating barriers to enrollment

Current Law

In general, states administer eligibility determinations for the Medicare Savings Program (MSP), a set of cost-sharing and premium subsidies available to certain low-income Medicare beneficiaries. Currently, states may require income and asset documentation through self-declaration or through other procedures. State policies on this issue vary based on the eligibility group, but

a considerable amount of paper-based documentation may be required to determine whether an individual meets financial eligibility requirements for Medicaid.

Under the low-income subsidy program under Medicare Part D, full-benefit dual eligibles, those receiving assistance through Medicare Savings Programs, and recipients of SSI are deemed subsidy-eligible individuals for up to one year; other persons, or their personal representatives, have to apply for assistance. Applicants may apply either at state Medicaid offices or Social Security offices. Applicants are required to provide information from financial institutions, as requested, to support information in the application, and to certify as to the accuracy of the information provided.

Proposed Law

Medicare beneficiaries applying for a low-income subsidy under the prescription drug program would be permitted to apply on the basis of self-certification of income and resources. The information provided would be subject to administrative verification; however, and except in extraordinary situations as determined by the Commissioner of SSA, the individual would not be required to provide additional documentation. Verification would be accomplished through data-sharing between the SSA and the Internal Revenue Service described under existing authority. This provision would be effective beginning January 1, 2010.

Sec. 1204. Enhanced oversight relating to reimbursements for retroactive low-income subsidy enrollment

Current Law

Certain groups of Medicare beneficiaries automatically qualify (and are deemed eligible) for the full low-income subsidy. Dual eligibles who qualify for Medicaid based on their income and assets are automatically deemed eligible for Medicare prescription drug low-income subsidies. Additionally, those who receive premium and/or cost-sharing assistance from Medicaid through the Medicare savings programs, plus those eligible for SSI cash assistance, are automatically deemed eligible for low-income subsidies and need not apply for them. CMS deems individuals automatically eligible for LIS effective as of the first day of the month that the individual attains the qualifying status (e.g., becomes eligible for Medicaid, MSP, or SSI). The end date is, at a minimum, through the end of the calendar year within which the individual becomes eligible.

For individuals who are newly full-benefit dual eligibles, their Medicaid prescription drug coverage ceases as soon as the individual is eligible for part D, regardless of whether the individual is enrolled in a Part D plan. This creates the risk of coverage gaps for these individuals. To prevent coverage gaps between the end of Medicaid prescription drug coverage and the start of Medicare prescription drug coverage, CMS regulation specifies that auto-enrollment is effective the month in which the person becomes full-benefit dual eligible. Because Medicaid eligibility is often retroactive, CMS randomly auto-enrolls new full-benefit dual eligibles into Part D plans retroactively to the start of their full dual status.

Other individuals with limited income and resources who do not automatically qualify may apply for the low-income subsidy and

have their eligibility determined by either the SSA or their state Medicaid agency. An individual who applies and is determined eligible for the LIS is eligible effective the first day of the month in which the individual submitted an application. In most cases, this means that LIS status is applied retroactively. If a beneficiary is already enrolled in a Part D plan, the Part D sponsor must take steps to ensure that the beneficiary has been reimbursed for any premiums or cost-sharing the member had paid that should have been covered by the subsidy.

CMS issued a request for proposals (RFP) on February 17, 2009, to solicit a contractor (a national prescription drug plan sponsor) to cover Part D prescription drug claims for retroactive periods of coverage for full-benefit dual eligible and SSI-eligible individuals, as well as point of sale coverage at a pharmacy for certain individuals with the Part D low-income subsidy who are not yet enrolled in a Part D plan. Beginning in 2010, CMS has the demonstration authority to test a revised approach for providing retroactive and immediate need coverage. Under the demonstration, CMS will contract with a single Medicare Part D plan (PDP) sponsor to pay for all claims for retroactive auto-enrollment periods plus current and immediate need claims for all LIS eligibles. CMS will modify its auto and facilitated enrollment process so that all those with retroactive effective dates are assigned to the demonstration for those retroactive periods, but continue to be randomly assigned for prospective periods to standard LIS PDPs.

Proposed Law

Through existing authority under current law, the Secretary has established a requirement that Part D plans make appropriate retroactive reimbursements to beneficiaries and third parties. This provision would codify and clarify that process. It also would implement oversight procedures of the retroactive reimbursement process to allow the Secretary to better determine whether the payments for this retroactive coverage from CMS to the Part D plans are accurately and consistently reimbursed to beneficiaries and third parties.

In the case of a retroactive LIS enrollment, the beneficiary, or a third party that is owed payment on behalf of the beneficiary, would be entitled to be reimbursed for covered drug costs incurred by the beneficiary during the retroactive coverage period. The retroactive coverage period is defined as the period beginning on the effective date of LIS assistance for which the individual is eligible and ending on the date the plan effectuates the status of such individual as eligible. Covered drug costs would be defined as the amount by which the costs incurred by the beneficiary for covered part D drugs, premiums and cost sharing exceeds such costs that would have been incurred if the beneficiary had been receiving low-income subsidy to which the individual was entitled.

The reimbursement would be made automatically by the Part D plan sponsor upon appropriate notice that the beneficiary is eligible for assistance and no further information would need to be submitted to the plan by the beneficiary. For each such reimbursement, the PDP or a Medicare Advantage Prescription Drug Plan (MA–PD) would be required to include a line-item description of the items for which the reimbursement is made. Additionally, the

provision would require that reimbursement be submitted not later than 45 days after the date on which the plan receives notice from the Secretary that the beneficiary is eligible for assistance or the date on which the beneficiary files the claim with the plan.

A retroactive LIS enrollment beneficiary would be defined as an individual who is enrolled in a PDP or an MA–PD and subsequently becomes eligible as a full-benefit dual eligible individual, Medicare Savings Program eligible, or eligible for SSI, or is a full-benefit dual eligible individual who is automatically enrolled in such a plan. Beneficiaries who enrolled in a plan whose sponsor entered into a contract with the Secretary, pursuant to CMS's RFP issued on February 17, 2009, relating to Medicare part D retroactive coverage for certain low income beneficiaries, or a similar subsequent request for such proposals, would not be included in this definition.

Sec. 1205. Intelligent assignment in enrollment

Current Law

Special enrollment rules apply to individuals eligible for the Part D low income subsidy. Generally, there is a two-step process for low-income persons to gain Part D coverage. First, a determination must be made that they qualify for the assistance; second, they must enroll, or be enrolled, in a specific Part D plan.

According to Section 1860D–14 of the Social Security Act (SSA), full-benefit dual-eligible individuals who have not elected a Part D plan are to be auto-enrolled into one by CMS. If there is more than one plan available that has a monthly beneficiary premium that does not exceed the premium assistance amount under the low-income subsidy, the beneficiary is to be enrolled on a random basis among all such plans in the PDP region. The individual has the option of declining or changing such enrollment.

Some dual eligibles may find that they are auto-enrolled in a plan that may not best meet their needs. For example, it is possible that the specific drug(s) that a beneficiary is currently taking is not covered by the new plan. For this reason, beneficiaries are able to change enrollment at any time, with the new coverage effective the following month.

Proposed Law

The Medicare Modernization Act prohibited CMS from using any methodology other than random assignment when automatically enrolling full benefit dual eligibles into Part D plans. While this process results in beneficiaries enrolled in the lowest cost plans based on monthly premium, it does not take into consideration whether this vulnerable population is enrolled in quality plans that cover the beneficiaries' necessary medications. While dual eligibles have the option of enrolling in a different plan, this is a particularly frail population that may not have the capacity to evaluate and choose among all of the available plans. The provision instructs CMS to evaluate methodologies for intelligently assigning dual eligibles to Part D plans based on cost—but also on formulary coverage for beneficiaries' needed prescriptions, use of prior authorization and other restrictions, and quality measures—and to implement if the Secretary determines that a methodology could both

minimize cost to the program and maximize access of dual eligibles to needed prescription drugs.

The Secretary would be given the option to use an "intelligent assignment" process as an alternative to the random assignment process. The intelligent assignment process would be designed to maximize the access of full-benefit dual eligibles to necessary prescription drugs while minimizing costs to the individual and to the program to the greatest extent possible. The process would be required to take into account the extent to which prescription drugs necessary for the individual are covered, the use of prior authorization or other restrictions on access to coverage of drugs, and the overall quality of a prescription drug plan as measured by quality ratings established by the Secretary.

The provision would take effect for contract years beginning with 2012.

Sec. 1206. Special enrollment period and automatic enrollment process for certain subsidy eligible individuals

Current Law

In general, a Medicare beneficiary who does not enroll in Part D during his or her initial enrollment period may enroll only during the annual open enrollment period, which occurs from November 15 to December 31 each year. Coverage begins the following January 1. Beneficiaries already enrolled in a Part D plan may change their plans during the annual open enrollment period.

There are a few additional, limited occasions when an individual may enroll in or disenroll from a Part D plan or switch from one Part D plan to another, called special enrollment periods. For example, special enrollment periods are allowed for individuals who (1) move to a new geographic area, (2) involuntarily lose creditable coverage, (3) receive inadequate information on creditable coverage status, (4) are subject to a federal error, or (5) are enrolled in a PDP that has failed or been terminated.

Proposed Law

Under current statutory authority, the Secretary has established a continuous SEP whereby upon becoming eligible for Part D, the Secretary automatically enrolls full benefit dual eligibles into a Part D plan; the individual retains the right to decline or change enrollment in any month. The Secretary has also expanded this SEP to include all individuals who are eligible for the Part D low-income subsidy (LIS). This provision codifies CMS's interpretation of current law with regard to allowing an SEP and automatic enrollment process for all LIS-eligible beneficiaries. It also requires the Secretary to use an automatic assignment process to enroll low-income beneficiaries who failed to enroll in a prescription drug plan or MA–PD plan during the special enrollment period. This assignment process would be identical to that used for full-benefit dual eligibles. The individual would have the option of declining or changing such enrollment.

The provision would apply with respect to subsidy determination made for months beginning with January 2011.

Sec. 1207. Application of MA premiums prior to rebate in calculation of low income subsidy benchmark

Current Law

The federal government pays up to 100% of the Part D premiums for LIS beneficiaries who are enrolled in benchmark plans. A Part D plan qualifies as a benchmark plan if it offers basic Part D coverage with premiums equal to or lower than the regional low-income premium subsidy amount. The regional low-income benchmark premium amount, calculated annually, is the weighted average of all premiums in each of the 34 prescription drug plan (PDP) regions for basic prescription drug coverage, or the actuarial value of basic prescription drug coverage for plans that offer enhanced coverage options, or for Medicare Advantage Prescription Drug plans (MA–PD), the portion of the premium attributable to basic prescription drug benefits.

Under the Medicare Advantage program (Part C), plans bid to offer Parts A and B coverage to beneficiaries. CMS bases the Medicare payment for a MA plan on the relationship between its bid and a benchmark (different from the LIS benchmark). The MA benchmark represents the maximum amount the federal government will pay a plan for providing required Medicare benefits. If a plan's bid is less than the benchmark, its payment equals its bid plus a rebate of 75% of the difference between the benchmark and the bid. The rebate must be used to provide additional benefits to enrollees, reduce Medicare cost sharing expenses, or reduce a beneficiary's monthly Part B, prescription drug, or supplemental premium (for services beyond the required Medicare benefits).

MA plans offering prescription drug coverage submit a separate bid for the Part D portion. Payment for the portion of the premium attributable to basic prescription drug benefits is calculated in the same way as that for stand-alone PDPs; however the MA plan may choose to apply some of its Part C rebate payments to lower the Part D premium. Any contribution by an MA plan of its rebate amount towards the Part D premium will lower the Part D benchmark premium amount and, typically, reduce the number of stand-alone PDPs qualifying as full-subsidy plans.

Proposal

The statute would be modified to exclude the Part C rebate amounts from the MA–PDP premium bids when calculating the low-income regional benchmark for subsidy determinations made for months beginning with January 2011.

Excluding the rebate portion of the premium from the calculation of the LIS benchmark will decrease the number of beneficiaries who have to switch plans each year because their plan's premium exceeds the LIS benchmark.

Subtitle B—Reducing Health Disparities

Sec. 1221. Ensuring effective communication in Medicare

Current Law

Federal civil rights policy (Section 601 of Title VI of the Civil Rights Act of 1964, 42 U.S.C. 2000d) requires most health care providers to make interpretation services available to limited English

proficiency (LEP) patients. Health and Human Services (HHS) regulations promulgated pursuant to section 602 forbid recipients from utiliz[ing] criteria or methods of administration which have the effect of subjecting individuals to discrimination because of their race, color, or national origin, or have the effect of defeating or substantially impairing accomplishment of the objectives of the program with respect to individuals of a particular race, color, or national origin. 45 CFR 80.3(b)(2).

HHS regulations (45 CFR 80.3(b)(2)) require all recipients of federal financial assistance from HHS to provide meaningful access to LEP persons. Recipients of HHS assistance may include (but are not limited to) hospitals, nursing homes, home health agencies, managed care organizations, universities, state, county, and local health agencies, Medicaid agencies, public and private contractors, vendors, physicians, and other providers. Providers who only receive Medicare Part B payments are not considered recipients of HHS assistance (45 CFR 80.2).

Research has demonstrated that Medicare beneficiaries with limited English proficiency have a harder time accessing health care than LEP seniors covered by Medicaid. Some authors have argued that this difference may be attributed to the fact that federal civil rights policies require Medicaid health care providers to offer language assistance, while physicians serving only Medicare patients are not subject to the same requirements. Although all providers are bound by Civil Rights Act of 1964 which obligates health care professionals to make interpreters available to LEP patients, studies have suggested that a lack of reimbursement for language services and poor enforcement of Title VI has sometimes made it difficult for LEP Medicare beneficiaries to access translation services.

Proposed Law

This provision directs the Secretary to evaluate the effectiveness of culturally and linguistically appropriate care by directing the Secretary to conduct a study that examines the extent to which Medicare providers utilize, offer or make available language services for beneficiaries who are limited English proficient. The study will also evaluate ways that Medicare should develop payment systems for language services.

The provision would require the Secretary of the Department of Health and Human Services to conduct a study to examine the extent to which Medicare providers utilize, offer, or make available language services for beneficiaries who are limited English proficient and ways that Medicare should develop payment systems for language services. The study would include an analysis of: ways to develop and structure appropriate payment systems for language services for Medicare providers; the feasibility of adopting a payment methodology for on-site interpreters; the feasibility of Medicare contracting directly with agencies that provide off-site interpretation, including telephonic and video interpretation; the feasibility of modifying the existing Medicare resource-based relative value scale by using adjustments when a patient is LEP; and how each of these options would be funded. The study would also include an analysis of the extent to which providers under Medicare Parts A, B, C, and D utilize, offer, or make available language services for beneficiaries with LEP; and the nature and type of lan-

guage services provided by states for Medicaid recipients, and the extent to which such services could be utilized by Medicare providers.

The potential payment systems included in the analysis could allow variations based on types of service providers, available delivery methods, and costs for providing language services. Factors could include: the type of language service provided, such as the provision of health care or health care related services directly in a non-English language by a bilingual provider or use of an interpreter; the type of interpretation provided, such as in-person, telephonic, video interpretation; the methods and costs of providing language services, including the costs of providing language services with internal staff and/or through contract with external independent contractors or agencies; providing services for languages not frequently encountered in the United States; and providing services in rural areas.

The Secretary would be required to submit a report to appropriate committees of Congress not later than 12 months after the date of enactment of this Act. The Paperwork Reduction Act would not apply for purposes of carrying out this study. The necessary funds to conduct the study would be authorized to be appropriated.

This provision also would authorize the Secretary to apply sanctions, such as civil money penalties, suspension of enrollment, and suspension or payments, to Medicare Advantage organizations that substantially fail to provide required language services to LEP beneficiaries enrolled in their plans.

Sec. 1222. Demonstration to promote access for Medicare beneficiaries with limited-English proficiency by providing reimbursement for culturally and linguistically appropriate services

Current Law

Refer to current law under Section 1221.

Proposed Law

Although recipients of federal funds are required to offer language services, Medicare does not reimburse for these services. Testing alternative methods of delivering culturally and linguistically appropriate services will enable Medicare to apply best practices and improve both access to and quality of services to beneficiaries with limited English proficiency.

Not later than 6 months after the completion of the study described in section 1221, the Secretary, acting through the CMS, would be required to carry out a demonstration program under which the Secretary would award no fewer than 24 three-year grants to eligible Medicare providers to improve effective communication between providers and Medicare beneficiaries living in communities where racial and ethnic minorities, including populations that face language barriers, are underserved with respect to such services. Using the results of the completed study, the Secretary would adjust, as appropriate, the distribution of grants to target Medicare beneficiaries who are in the greatest need of language services. Grants would be limited to $500,000 or less over three years for any grantee.

To be eligible to receive a grant, an entity would be required to be a Medicare provider of services under Parts A or B, a Medicare Advantage organization offering a Medicare part C plan, or a sponsor of a part D prescription drug plan (PDP). To the extent feasible, the Secretary would award at least 6 grants each to part A providers, part B providers, part C organizations, and to prescription drug sponsors. The Secretary would be required to give priority to applicants that have developed partnerships with community organizations or agencies with experience in language access. The Secretary would also need to ensure that grantees represent variations in types of language services, languages needed and their frequency of use, urban and rural settings, at least two geographic regions as defined by the Secretary, and at least two large urban areas with diverse populations.

The grantee would be required to use the grant funds to pay for the provision of competent language services to LEP Medicare beneficiaries. Such services may be provided through on-site interpretation, telephonic interpretation, video interpretation, or direct provision of health care or health care-related services by a bilingual health care provider. The grantee may also use bilingual providers, staff, or contract interpreters. The grantee may use up to 10% of the grant funds to pay for administrative costs associated with the provision of competent language services and for required reporting. Grantees that are part C organizations or PDP sponsors would be required to ensure that their network providers, including physicians and pharmacies, receive at least 50% of the grant funds to pay for the provision of language services.

The payments to grantees would be calculated based on the estimated numbers of LEP Medicare beneficiaries in a grantee's service area, using the most recently available data from the Bureau of Census or other state-based study on the number of individuals served by the grantee who speak English less than "very well," or using the grantee's own data on Medicare beneficiaries' primary language if the Secretary determines such data to be reliable. Payment would only be provided to grantees that report their costs of providing language services and may be modified annually at the discretion of the Secretary. If the grantee does not provide the reports for the first year of a grant, the Secretary would be able to terminate the grant and to solicit applications from new grantees to participate in the subsequent two years of the demonstration program.

Payments would only be provided to grantees that utilize competent bilingual staff or competent interpreter or translation services which meet the state standards currently in effect if the grantee operates in a state that has statewide health care interpreter standards. For grantees operating in states without such standards, the grantee would be required to utilize interpreters who follow the National Council on Interpreting in Health Care's Code of Ethics and Standards of Practice. This requirement would not apply if a beneficiary requests the use of family, friends, or other persons untrained in interpretation and the grantee documents the request in the beneficiary's record. This requirement would also not apply in the case of a medical emergency where the delay associated with obtaining an interpreter would jeopardize the health of the patient. Emergency rooms and other entities that regularly pro-

vide health care services in medical emergencies, would, however not be exempt from the requirement to provide interpreter and translation services without undue delay.

Grantees would also be required to: ensure that appropriate clinical and support staff receive ongoing education and training in linguistically appropriate service delivery; ensure the linguistic competence of bilingual providers; offer and provide appropriate language services at no additional charge to each LEP patient at all points of contact, in a timely manner during all hours of operation; notify Medicare beneficiaries of their right to receive language services in their primary language; post signage in the languages of the commonly encountered group or groups present in the organization's service area; and ensure that primary language data are collected for recipients of language services (if the recipient of language services is a minor or is incapacitated, the primary language of the parent or legal guardian would be collected and utilized).

Grantees would be required to provide the Secretary with reports at the end of each year of the grant. The report would include (1) the number of Medicare beneficiaries to whom language services are provided; (2) the languages of those Medicare beneficiaries; (3) the types of language services provided; (4) the type of interpretation; (5) the methods of providing language services; (6) the length of time for each interpretation encounter; and (7) the costs of providing language services.

LEP Medicare beneficiaries would not be required to pay cost-sharing or co-pays for language services provided under this demonstration.

The Secretary would be required to conduct an evaluation of the demonstration program and submit a report to the appropriate committees of Congress not later than 1 year after the completion of the program. The report would include an analysis of the patient outcomes and costs of furnishing care to the LEP Medicare beneficiaries participating in the project compared to those not participating; the effect of delivering culturally and linguistically appropriate services on beneficiary access to care, utilization of services, efficiency and cost-effectiveness of health care delivery, patient satisfaction, and health outcomes; and recommendations regarding the extension of the project to the entire Medicare program.

This provision would not limit existing obligations of recipients of federal financial assistance under title VI of the Civil Rights Act of 1964. An amount of $16 million would be authorized to be appropriated for each fiscal year of the demonstration program.

Sec. 1223. IOM report on impact of language access services

Current Law

Refer to current law under Section 1221.

Proposed Law

Under this provision, the Secretary of HHS would be required to enter into an arrangement with the Institute of Medicine (IOM) under which the IOM would prepare a report on the impact of language access services on the health and health care of limited English proficient populations. The report would be issued not later than 3 years after the date of the enactment of the Act.

The report would include recommendations on the development and implementation of policies and practices by health care organizations and providers for limited English proficient patient populations, a description of the effect of providing language access services on quality of health care and access to care and reduced medical error, and a description of the costs associated with, or savings related to, the provision of language access services.

Sec. 1224. Definitions

Current Law

None.

Proposed Law

This provision provides the following definitions to be applied in sections 1221 through 1223.

The term *bilingual* would mean a person who has a sufficient degree of proficiency in two languages and can ensure that effective communication can occur in both languages.

The term *competent interpreter services* would be defined as a trans-language rendition of a spoken message in which the interpreter comprehends the source language and can speak comprehensively in the target language to convey the intended meaning. The interpreter would be required to know health and health-related terminology.

The term *competent translation services* would mean a trans-language rendition of a written document in which the translator comprehends the source language and can write comprehensively in the target language to convey the meaning intended in the source language. The translator would be required to know health and health-related terminology.

The term *effective communication* would mean an exchange of information between the provider of health care or health care-related services and the LEP recipient of such services that enables the LEP individual to access, understand, and benefit from health care or health care-related services.

The terms *interpreting/interpretation* would be defined as the transmission of a spoken message from one language into another, faithfully, accurately, and objectively.

The term *health care services* would mean services that address physical as well as mental health conditions in all care settings.

The term *health care-related services* would be defined as human or social services, programs or activities that provide access, referrals or links to health care.

The term *language access* would mean the provision of language services to an LEP individual designed to enhance that individual's access to, understanding of or benefit from health care or health care-related services.

The term *language services* would be defined as the provision of health care services directly in a non-English language, interpretation, translation, and non-English signage.

The term *limited-English proficient (LEP)* would be defined as an individual who speaks a primary language other than English and who cannot speak, read, write or understand the English language at a level that permits the individual to effectively communicate

with clinical or nonclinical staff at an entity providing health care or health care related services.

The term *Medicare beneficiary* would mean an individual entitled to benefits under Medicare part A or enrolled in Medicare part B.

The term *Medicare program* would mean the programs under parts A through D of title XVIII of the Social Security Act (SSA).

The term *service provider* would be defined as all suppliers, providers of services, or entities under contract to provide coverage, items or services under any part of title XVIII of the SSA.

Subtitle C—Miscellaneous Improvements

Sec. 1231. Extension of therapy caps exceptions process

Current Law

Current law places two annual per beneficiary payment limits for all outpatient therapy services provided by non-hospital providers. For 2009, the annual limit on the allowed amount for outpatient physical therapy and speech-language pathology combined is $1,840. There is a separate limit for occupational therapy of $1,840. The Secretary was required to implement an exceptions process for 2006, 2007, and the first half of 2008 for cases in which the provision of additional therapy services was determined to be medically necessary. Section 141 of the Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, P.L. 110–275) extended the exceptions process for therapy caps through December 31, 2009.

Proposed Law

The provision would extend the exceptions process for therapy caps for 2 years, through December 31, 2011.

Sec. 1232. Extended months of coverage of immunosuppressive drugs for kidney transplant patients and other renal dialysis provisions

Current Law

To be eligible for Medicare, one must be (1) 65 years or older and eligible to receive Social Security; (2) under 65, permanently disabled, and have received Social Security disability insurance payments for at least 2 years; (3) have Amyotrophic Lateral Sclerosis (ALS-Lou Gehrig's disease); or (4) have end-stage renal disease (ESRD).

Coverage for beneficiaries with ESRD generally begins in the fourth month of dialysis treatments or the month of a kidney transplant. After receiving a kidney transplant, individuals are prescribed immunosuppressive drugs to reduce the risk of their immune system rejecting the new organ. These drugs generally need to be taken for the rest of the individual's life.

Under Medicare Secondary Payer (MSP) rules, Medicare is prohibited from making payments for any item or service when payment has been made or can reasonably be expected to be made by a third party payer. For individuals with Medicare entitlement based solely on ESRD, MSP rules apply for those covered by an employer-sponsored group plan, regardless of the employer size or current employment status. Any group health plan coverage these beneficiaries receive through their employer or their spouse's em-

ployer is the primary payer for the first 30 months of ESRD benefit eligibility. After 30 months, Medicare becomes the primary insurer.

If a beneficiary already had Medicare because of age or disability before the onset of end-stage renal disease, or if an individual became eligible for Medicare because of age or disability after receiving a transplant paid for by Medicare, Medicare will continue to pay for immunosuppressive drugs with no time limit. However, if a beneficiary qualifies for Medicare only because of kidney failure, Medicare, together with coverage of the immunosuppressive drugs, ends 36 months after the month of the successful transplant. After that period, kidney recipients must pay for immunosuppressive drugs through private insurance, public or pharmaceutical programs, or pay out-of-pocket until they reach 65 and qualify for Medicare because of age.

Individuals with ESRD are eligible for all Part B Services. Part B covers their dialysis services, drugs, and biologicals, including erythropoiesis stimulating agents, diagnostic laboratory tests, and other items and services furnished to individuals for the treatment of ESRD.

Dialysis services are offered in three outpatient settings: hospital-based facilities, independent facilities, and the patient's home. There are two methods for payment. Under Method I, facilities are paid a prospectively set amount, known as the composite rate, for each dialysis session, regardless of whether services are provided at a facility or in the patient's home. Beneficiaries electing home dialysis may choose not to be associated with a facility and may make independent arrangements with a supplier for equipment, supplies, and support services. Payment to these suppliers, known as Method II, is made on the basis of reasonable charges.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, P.L. 110–275) requires the Secretary to implement a bundled payment system, making a single payment for Medicare renal dialysis services, to be phased in over 4 years beginning January 1, 2011. The bundled payment will include (1) items and services included in the composite rate as of December 31, 2010; (2) erythropoiesis stimulating agents for the treatment of ESRD; (3) injectable biologicals and medications that were paid for separately under Part B (before bundling) and any oral equivalent to such medications; and (4) diagnostic laboratory tests and other items and services furnished to individuals for the treatment of ESRD. Dialysis facilities will have the opportunity to opt out of the phase-in and be paid under the new bundled system starting in 2011. The new law also creates a quality incentive payment program that ties payments to certain quality measures including anemia management, dialysis adequacy, patient satisfaction, and bone mineral metabolism.

Proposed Law

Patients who receive a kidney transplant must continue taking immunosuppressive drugs for the rest of their lives in order to avoid rejecting the new organ. Once a patient stops taking the drugs, his or her body will almost immediately reject the transplanted kidney and the patient either needs another kidney transplant or requires dialysis treatments for the rest of his or her life. Because a recurrence of kidney failure again entitles the bene-

ficiary to Medicare, these costs are incurred by the Medicare program. To remedy this problem, and to improve the quality of life of these patients, this provision removes the 36–month limit on entitlement to Medicare with respect to immunosuppressive therapies to ensure that transplant patients continue to receive the drugs they need.

This provision would amend SSA title II (Old Age, Survivors and Disability Insurance) to (1) continue entitlement to prescription drugs used in immunosuppressive therapy furnished to an individual who receives a kidney transplant for which payment is made under Medicare, and (2) extend Medicare secondary payer requirements for ESRD beneficiaries.

It would also amend title XVIII (Medicare) of SSA to apply special rules to kidney transplant recipients who receive additional coverage for immunosuppressive drugs whose eligibility for benefits would end but for application of this section. Such individuals would be deemed to be enrolled under Medicare Part B and would be responsible for the full amount of the applicable premiums, deductibles, and co-insurance payments that are not covered under the Medicare savings program.

This section also includes a technical clarification that oral drugs furnished to individuals for treatment of ESRD are included in the bundled payment. This authority exists under current law.

The provision specifies that oral drugs that are not the oral equivalent of an intravenous drug would be included in the drugs and biologicals provided as part of the renal dialysis services covered by Medicare. The provision also would allow providers of renal dialysis services to make an election with respect to 2011, 2012, or 2013, prior to the first date of such year, to be excluded from the phase in of the prospective rate (or the remainder of the phase in) and be paid entirely based on the prospective rate. Additionally, the provision changes the performance standards of ESRD providers from the "lesser of" to the "greater of" the performance of such provider or facility or a performance standard based on the national performance rates for such measures in a period determined by the Secretary.

Sec. 1233. Advance care planning consultation

Current Law

Section 1866(f) of Title XVIII of the SSA requires certain institutional providers and prepaid plans that participate in Medicare to follow specified policies and procedures in regard to advance directives. Specifically, it requires such entities to furnish written information regarding an individual's rights under state law to make decisions concerning medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advance directives; to furnish the written policies of the entity respecting the implementation of such rights; to document in a prominent part of the individual's medical record whether or not the individual executed an advance directive; not to condition the provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advance directive; to ensure compliance with requirements of state law (whether statutory or as recognized by the courts of the state) re-

specting advance directives at facilities of the provider or organization; and to provide (individually or with others) for education for staff and the community on issues concerning advance directives.

Hospitals and nursing homes must provide this information to individuals at the time of admission; home health agencies must provide it in advance of the individual coming under the care of such agencies; hospice providers must provide this information at the time of the initial receipt of hospice care; and prepaid health plans must provide it to individuals upon enrollment. Medicare-certified providers that do not comply with these requirements may have payments withheld by the Secretary. State laws that allow for an objection on the basis of conscience for any health care provider or any agent of such provider which, as a matter of conscience, cannot implement an advance directive, supersede these requirements.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, P.L. 110–275) added end-of-life planning to the initial preventive physical exam that Medicare beneficiaries receive upon enrollment in Medicare. MIPPA also defines "end-of-life" planning to mean verbal or written information regarding: an individual's ability to prepare an advance directive in the case that an injury or illness causes the individual to be unable to make health care decisions; and whether or not the physician is willing to follow the individual's wishes as expressed in an advance directive.

The Physician Quality Reporting Initiative (PQRI), the voluntary individual reporting program that provides an incentive payment to eligible professionals (EPs) who satisfactorily report data on quality measures for covered Medicare Physician Fee Schedule (PFS) services, is established by section 1848(k)(1) of the SSA. PQRI requires eligible professionals to report on certain quality measures in order to receive an incentive payment equal to 2.0% of covered professional services. Participation in PQRI is voluntary. The PQRI program is not specific to end-of-life care, but it does include several geriatrics measures, including one measure which specifically addresses advance care plans. This measure aims to assess whether a patient has an advance care plan or surrogate decision maker documented in their medical record.

CMS was mandated by the Balanced Budget Act of 1997 (P.L. 105–33) to develop and organize activities to educate beneficiaries about the Medicare program. Specifically, the Act mandated that CMS establish a toll-free helpline, mail written information to beneficiaries on Medicare and their options to enroll in private plans, create a Medicare website, and support a community outreach program to help beneficiaries and their caregivers make informed health care decisions. CMS conducts these activities as part of its National Medicare and You Education Program (NMEP). The Medicare & You Handbook is one component of the agency's NMEP program. The Handbook, which is produced in English and Spanish, is updated on an annual basis and mailed to beneficiaries every fall. Handbooks are mailed monthly to newly eligible beneficiaries.

Proposed Law

This provision adds an advanced care planning consultation as a Medicare benefit and makes other changes intended to promote patient-centered decision-making about medical care options. Ad-

vanced planning consultations are designed to assist patients make informed decisions about the full range of life sustaining treatment options available and to ensure that treating physicians are fully aware of patients' wishes. The provision does not require any beneficiary to receive such consultations and does not prescribe or restrict the advanced care treatment options available to any beneficiary.

The provision would amend Section 1861 of Title XVIII of the SSA under Medicare to add new language concerning an advance care planning consultation and add a new subsection describing these consultations. It would amend Section 1848(j)(3) to provide payment to physicians for an advance care planning consultation under Medicare. The provision would also expand the physician quality reporting initiative for end of life care. The Medicare & You Handbook would be updated to include an explanation of various end-of-life care planning terms and resources.

The term "advance care planning consultation" would mean a consultation between the individual and an individual's physician, nurse practitioner or physician assistant as specified regarding advance care planning. Such consultation would be covered not more than once every five years, with some exceptions. Medicare's initial preventative physical examination would not be considered an advance care planning consultation for purposes of applying the 5–year limitation. Such consultation would be authorized to be conducted more frequently if there is a significant change in an individual's health.

Such a consultation would be required to include an explanation by the practitioner of advance care planning; advance directives and their uses; role and responsibilities of a health care proxy; the continuum of end-of-life care services and supports available and Medicare benefits that are available. Practitioners would be required to provide a list of national and state-specific resources to assist consumers and their families with advance care planning. The advance care planning consultation would also be required to include an explanation of orders regarding life sustaining treatment or similar orders as specified. This requirement would apply to consultations furnished in a state in which all legal barriers for such orders have been addressed and that has a program in effect as specified. Such consultation is authorized to include the formulation of an order regarding life sustaining treatment or similar order.

The term "order regarding life sustaining treatment" would mean, with respect to an individual, an actionable medical order relating to the treatment of that individual that (1) is signed and dated by a physician or another health care professional as specified and is in a form that permits it to stay with the individual and be followed by health care professionals and providers across the continuum of care; (2) effectively communicates the individual's preferences regarding life sustaining treatment; (3) is uniquely identifiable and standardized within a given locality, region, or state (as identified by the Secretary); and (4) may incorporate any advance directive if executed by the individual.

The level of life treatment indicated may range from an indication for full treatment to an indication to limit some or all or specified interventions. The provision would modify Section 1848(j)(3) of

the SSA (concerning definitions for physicians' services) to include Medicare payment for physicians' services with respect to an advance care planning consultation. It would amend Section 1862(a)(1) of the SSA (concerning exclusions from coverage and Medicare as secondary payer) to add that no Medicare payment would be authorized for expenses incurred in the case of an advance care planning consultation which is performed more frequently than covered under such section.

The provision would amend Section 1848(k)(2) of the SSA to add new language that would require the Secretary, for the purposes of reporting data on quality measures for covered professional services furnished during 2011 and any subsequent year, to include quality measures on end of life care and advanced care planning that have been adopted or endorsed by a consensus-based organization, if available and appropriate. Such measures would be required to measure both creation and adherence to orders for life-sustaining treatment. The Secretary would be required to publish these proposed measures in the *Federal Register* and provide for a period of public comment before finalization.

No later than 1 year after the date of enactment, the Secretary would be required to update the online version of the Medicare & You Handbook to include an explanation of advance care planning and advance directives, including living wills, durable power of attorney, orders of life-sustaining treatment, and health care proxies. It would also be updated to include a description of federal and state resources available to assist individuals and their families with advance care planning and advance directives, including available state legal service organizations to assist individuals with advance care planning, including those organizations that receive funding pursuant to the Older Americans Act of 1965; website links or addresses for state-specific advance directive forms; and any additional information, as determined by the Secretary. The Secretary would also be required to include the above information in all paper and electronic versions of the Medicare & You Handbook that are published on or after the date that is 1 year after the date of enactment.

Sec. 1234. Part B special enrollment period and waiver of limited enrollment penalty for Tricare beneficiaries

Current Law

Since 2001, military retirees and their eligible dependents become eligible for Tricare for Life at the same time they become eligible for Medicare. Tricare for Life functions similarly to a supplemental insurance policy to Medicare and provides coverage for authorized services not covered by Medicare. Enrollment in Medicare Part B is required for access to Tricare for Life. Prior to the legislation creating Tricare for Life, many retirees had not enrolled in Part B, believing that they would always have access to military medical facilities. With the establishment of Tricare for Life and the concomitant need to enroll in Medicare Part B, there was concern over the potential imposition of significant penalties for late enrollment in Part B. Subsequent legislation (Section 625 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, P.L. 108–173) waived the Part B enrollment penalty

for eligible retirees who enrolled in Part B prior to December 31, 2004.

Proposed Law

The provision will simplify enrollment in Medicare for retired members of the armed forces and provide a grace period for such individuals who have not yet enrolled in Medicare.

This provision creates a special 12–month enrollment period in which military retirees (or their eligible dependents) who have not yet enrolled in Medicare Part B can enroll in Part B, thus becoming eligible for Tricare for Life, without incurring a late enrollment penalty. The provision would apply to elections made on or after the date of enactment of the Act.

This provision would also require the Secretary of HHS to establish a method for providing rebates for late enrollment penalties that were charged to certain disabled and end-stage renal disease (ESRD) beneficiaries who enrolled during or after January 2005 and before the month of enactment of this Act.

Sec. 1235. Exception for use of more recent tax year in case of gains from sale of primary residence in computing part B income-related premium

Current Law

Physician and outpatient services provided under Part B are financed through a combination of beneficiary premiums, deductibles, and federal general revenues. In general, Part B beneficiary premiums equal 25% of estimated program costs for the aged, with federal general revenues accounting for the remaining 75%.

Beginning in 2007, higher-income enrollees pay a higher percentage of Part B costs according to a sliding scale. Beneficiaries with incomes above $85,000 for and individual (and $170,000 for a couple) pay 35% to 80% of the standardized Part B costs depending on their income reported to the IRS.

For purposes of determining the income-related premium, beneficiaries experiencing major life events may apply to use a more recent tax year for determination of the income-related premium.

Proposed Law

This provision treats the sale of a primary residence as a major life event for purposes of qualifying for the use of a more recent tax year. This modification would apply to premiums and payments for years beginning with 2011.

Sec. 1236. Demonstration program on use of patient decisions aids

Current Law

Current law does not explicitly address patient decision aids, which are information tools to help patients understand health care options, and make informed choices that take into account their lifestyle, preferences, and beliefs. A related concept is shared decision making (referred to by many other names as well), meaning the cooperation of providers and patients in making health care decisions.

Section 646 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, P.L. 108–173) requires the Secretary to carry out a Medicare quality demonstration program, which would, among other things, encourage shared decision making. Eligible entities include physician groups, integrated health systems, or regional coalitions of the same. Projects approved under this demonstration are expected to achieve significant improvements in safety, effectiveness, efficiency, patient-centeredness (i.e., shared decision making), timeliness, and equity, the six aims for quality improvement identified by the Institute of Medicine. Two demonstrations have been approved and will begin in 2009. Two others are in the final review process.

In addition, under their general authorities, the Agency for Healthcare Research and Quality (AHRQ) and Centers for Disease Control and Prevention (CDC) conduct research on the application and use of shared decision making, including the use of patient decision aids.

Proposed Law

This provision would require the Secretary to conduct a Medicare demonstration program to determine if using patient decision aids would improve beneficiaries' understanding of their medical treatment options. The program would enroll not more than 30 eligible providers, with preference given to providers that have documented experience, and the necessary information technology infrastructure and training, in using patient decision aids. Eligible providers would be required to provide follow-up counseling visits after beneficiaries have viewed decision aids, to address questions about subsequent medical care and the beneficiary's preferences. The Secretary would have to provide for the development of one or more billing codes and reimbursement for the follow-up counseling. Eligible providers would be responsible for the costs of selecting, purchasing, and delivering patient decision aids, and reporting data on quality and outcome measures.

To carry out the program, the Secretary would be required to use funds from the Federal Supplementary Medical Insurance Trust Fund, and would be authorized to waive requirements under SSA Titles XI (general and administrative provisions) and XVIII (Medicare). Within 12 months of program completion, the Secretary would be required to report to Congress regarding the effects of the program on health quality, utilization of health care services, and quality of life; and any recommendations for legislation and administrative action.

Eligible providers would be (a) a primary care practice; (b) a specialty practice; (c) a multispecialty group practice; (d) a hospital; (e) a rural health clinic; (f) a Federally Qualified Health Center (FQHC); (g) an integrated delivery system; (h) a state cooperative entity that includes the state government and at least one other health care provider which is set up for the purpose of testing shared decision making and patient decision aids. The provision would define "patient decision aid" to mean "an educational tool (such as the Internet, a video, or a pamphlet) that helps patients (or, if appropriate, the family caregiver of the patient) understand and communicate their beliefs and preferences related to their treatment options, and to decide with their health care provider

what treatments are best for them based on their treatment options, scientific evidence, circumstances, beliefs, and preferences"; and "shared decision making" would be defined to mean "a collaborative process between patient and clinician that engages the patient in decision making, provides patients with information about trade-offs among treatment options, and facilitates the incorporation of patient preferences and values into the medical plan."

TITLE III—PROMOTING PRIMARY CARE, MENTAL HEALTH SERVICES AND COORDINATING CARE

Sec. 1301. Accountable care organization pilot program

Current Law

No current provision. In April 2005, the Centers for Medicare and Medicaid Services (CMS) initiated the Physician Group Practice demonstration, which offers 10 large practices the opportunity to earn performance payments for improving the quality and cost-efficiency of health care delivered to beneficiaries in fee-for-service Medicare.

Proposed Law

The Physician Group Practice (PGP) demonstration program has shown promise in incentivizing physicians and other providers to reduce health care costs and improve quality. The ACO pilot program in the legislation builds on progress that has been made to date in the PGP demonstration and gives CMS a flexible platform on which to continue to test, adjust, and expand the shared savings concept as an alternative to fee-for-service payment.

A new section 1866E would be added to the Social Security Act (SSA) to establish the accountable care organization (ACO) pilot program. The Secretary would conduct a pilot program to test different payment incentive models intended to reduce growth in Medicare costs while improving health outcomes. The pilot would promote accountability for services provided to a Medicare patient population, coordinate Medicare's Part A and B items and services, encourage investment in infrastructure and the redesign of care processes, and reward high quality, efficient physician practices.

The Secretary would set specific goals for the number of ACOs, participating practitioners, and patient served in the initial tests under the pilot program to ensure that the program has sufficient size and scope to test the approach in a variety of settings, including urban, rural and underserved areas and, subject to certain qualifications, disseminate the approach rapidly under a national basis. To the extent that the Secretary finds a qualifying ACO to be successful in improving quality and reducing costs, the Secretary would attempt to attract at least 10% of all eligible providers to act as ACOs and implement such mechanisms and reforms within 5 years of enactment. If the Secretary further finds such ACO models to be successful, the Secretary would seek to implement such mechanisms and reforms on as large a geographic scale as practical and economical.

A qualifying accountable care organization (qualifying ACO) would be a group of physicians who are organized, at least in part, for the purpose of providing physician services and meet other specified standards. A qualifying ACO could include other practi-

tioners such as nurse practitioners or physician assistants, a hospital or multiple hospitals, or any other provider or supplier (furnishing Medicare covered services) that are affiliated with the ACO under an arrangement structured to coordinate patient care. A qualifying ACO would meet the following requirements: (1) have a legal structure that would allow the group to receive and distribute incentive payments; (2) include a sufficient number of primary care physicians (as determined by the Secretary); (3) report on required quality measures in the specified form, manner, and frequency (which may be for the group, for providers of services, and suppliers or both); (4) report required data to monitor and evaluate the pilot program; (5) provide notice to applicable beneficiaries regarding the pilot program; (6) contribute to a best practices network or website to share strategies on quality improvement, care coordination, and efficiency; (7) utilize patient-centered processes of care, and (8) meet other criteria determined to be appropriate by the Secretary.

Organizations qualifying as ACOs may include independent practice association or other medical practice arrangements which already provide services to Medicare beneficiaries through fee-for-service Medicare or Medicare Advantage. An ACO may continue to provide services to Medicare Advantage enrollees in addition to providing services to enrollees in fee-for-service Medicare through the ACO program.

Specific payment incentive models to be tested include: a performance target model, a partial capitation model, and other payment models.

Under the performance target model, a qualifying ACO would receive an incentive payment if expenditures for applicable beneficiaries are less than a target spending level or a target rate of growth. The incentive payment would be made only if savings are greater than would result from normal variation in Medicare expenditures for Part A and B items and services. In general the Secretary would establish a base amount increased to the current year by an adjustment factor. The base amount would equal the average total payments (or allowed charges) under Parts A and B for applicable beneficiaries for whom the qualifying ACO furnishes items and services. The base amount may include Medicare Part D drugs and services if deemed appropriate. The adjustment factor would equal an annual per capita amount that reflects changes in expenditures from the base period to the current year. The factor could be determined as an amount or rate, determined on a national, regional, local or organization-specific basis, and may be determined on a per capita basis. It could also include a risk adjustment factor as determined by the Secretary. The base amount would be periodically recalculated.

A qualifying ACO that meets or exceeds annual quality and performance targets for a year would receive an incentive payment equal to a portion of the amount by which Medicare payments are estimated to be below the performance target (i.e., Medicare savings). The Secretary could establish a cap on incentive payments for a year for a qualifying ACO. Incentive payments to qualifying ACOs would be limited to ensure that the aggregate expenditures do not exceed the amount that the Secretary estimates would be

expended for such ACO for such beneficiaries if the pilot program were not implemented.

The Secretary would be able to incorporate reporting requirements, incentive payments, and penalties related to the physician quality reporting initiative (PQRI), electronic prescribing, electronic health records, and other similar physician payment initiatives under section 1848 of the SSA. Alternative criteria than would otherwise apply could be used when determining whether to make these payments so as to streamline administration of the overlapping monitoring and reporting requirements for ACOs and fee-for-service Medicare. Also, these incentive payments would not be included in the aggregate expenditure test described previously or in the performance target model.

Under a partial capitation model, a qualifying ACO would be at financial risk for some, but not all, of the Part A and B items and services. The Secretary would be able to limit a partial capitation model to ACOs that are highly integrated systems of care and to ACOs capable of bearing risk. Payments under the partial capitation model would be established in a manner that does not result in spending more for such ACO for such beneficiaries than would otherwise be expended if the pilot were not implemented. Partial capitation would not constrain beneficiaries' to seeing any particular provider; beneficiaries would retain the ability to choose their doctor or practitioner and could leave the ACO at any time.

The Secretary may develop other payment models that meet the goals of this pilot program to improve quality and efficiency. Payments under these models would be established in a manner that does not result in spending more for such ACO for such beneficiaries than would otherwise be expended if the pilot were not implemented.

An applicable beneficiary would be an individual is enrolled under part B and entitled to Part A benefits; is not enrolled in a Medicare Advantage plan under part C or a PACE (Program of All-Inclusive Care for the Elderly) program under Section 1894 of the SSA; and meets other appropriate criteria.

The Secretary would monitor data on Medicare expenditures and quality of services including a period of time after an applicable beneficiary discontinues receiving services through a qualifying ACO.

The pilot program would begin no later than January 1, 2012. An agreement with a qualifying ACO under this pilot would cover a multi-year period of between 3 and 5 years. The Secretary would be able to waive Medicare provisions and the general provisions established under Title XI of the SSA only insofar as necessary for implementation of this section.

The Secretary would be required to report performance results to qualifying ACOs under the pilot program at least annually. There would be no administrative or judicial review of the (1) elements, parameters, scope, and duration of the pilot program; (2) the selection of qualifying ACOs for the pilot program; (3) the establishment of targets, measurement of performance, determinations with respect to whether savings have been achieved and the amount of savings; (4) determinations regarding whether, to whom, and in what amounts incentive payments are paid; and (5) decisions about the extension of the program with successful ACOs, expansion of

the program to additional ACOs or transitional extension of the existing physician group practice demonstration project. Also, Chapter 35 of Title 44 of the United States Code (concerning the coordination of federal information policy) would not apply to this pilot.

The Secretary would evaluate the payment incentive model for each qualifying ACO to assess the pilot's impact on beneficiaries, providers of services, suppliers and the program. The evaluation would be publicly available within 60 days of the date of completion of such report. The OIG would monitor the operation of ACOs under the pilot program with regard to violations of the Stark self referral prohibition (Section 1877 of the SSA).

No later than 2 years after the date the first pilot agreement is established, and every 2 years thereafter for six years, the Secretary would report to Congress on the use of authorities under the pilot program and its impact on expenditures, access, and quality. Subject to monitoring of the qualifying ACO, the Secretary would be able to extend the duration of the agreement if (1) the ACO receives incentive payments with respect to any of the first 4 years of the pilot agreement and is consistently meeting quality standards or (2) the ACO is consistently exceeding quality standards and is not increasing spending under the program. The Secretary would be able to terminate an agreement if the ACO did not receive incentive payments or consistently failed to meet quality standards in any of the first 3 years under the program.

Subject to the evaluation of the pilot, the Secretary would be able to enter into agreements with additional qualifying ACOs to further test and refine payment incentive models. The Secretary would be able issue regulations to implement on a permanent basis the components of the pilot program that are beneficial to Medicare. However, to do so, the Chief Actuary of the CMS would be required to certify that the expansion of the program's components would result in estimated spending that would be less than what spending would otherwise be estimated to be in the absence of such expansion.

The Secretary would be able to enter into an agreement with an organization participating in the physician group practice demonstration as a qualifying ACO. Participation as a qualifying ACO would be subject to rebasing and other appropriate modifications, until the pilot program under this section is operational.

The Secretary would be able to create separate incentive arrangements (including using multiple years of data, varying thresholds, varying shared savings amounts, and varying shared savings limits) for different categories of qualifying ACOs to reflect natural variations in data availability, variation in average annual attributable expenditures, program integrity, and other matters the Secretary deems appropriate.

The Secretary would be able to limit a qualifying ACO's exposure to high cost patients in order to encourage the participation of smaller accountable care organizations in the pilot.

Nothing in this section would be construed as preventing a qualified ACO from entering into an arrangement with an Independence at Home medical practice or for providing home based services for the treatment of beneficiaries who are eligible for that program. Nothing in this section would be construed as preventing qualifying

ACOs participating in the pilot program from negotiating similar contracts with private payers.

The Secretary would not be able to enter into an agreement with an entity to provide health care items or services under the pilot program, or with an entity to administer the program, unless such entity guarantees that it will not deny, limit, or condition the coverage or provision of benefits under the program, for individuals eligible to be enrolled under such program, based on any health status-related factor described in section 2702(a)(1) of the Public Health Service Act, including health status, medical condition, claims experience, receipt of health care, medical history, genetic information, evidence of insurability, and disability.

Providers participating in the accountable care organization (ACO) pilot program would have the option of pursuing separate target growth rate for purposes of Medicare's physician fee schedule (as amended under Section 1121) that is applicable only that organization. No later than January 1, 2012, the Secretary would develop a method that would (1) allow each ACO to have its own Medicare Part B expenditure targets and updates that would be consistent with the methodologies described above, and (2) provide that the target growth rate applicable to other physicians would not apply to physicians to the extent that their services are furnished through the ACO. This method would apply beginning with 2012. In determining the expenditure targets and updates for physicians in the ACO pilot program, the Secretary could apply the difference in the update on a claim-by-claim or lump sum basis and such a payment would be taken into account under the pilot program.

Nothing in this section would be construed to compel an organization to use that organization-specific target growth rate methodology.

The program management account of CMS would be appropriated $25 million for FY2010 through FY2014 and $20 million in FY2015 for the purposes of administering and carrying out the pilot program, but not for payments for Medicare covered items and services or for incentive payments.

Sec. 1302. Medical home pilot program

Current Law

The Tax Relief and Health Care Act of 2006 (P.L. 109–432), as modified by the Medicare Improvements for Patients and Providers Act of 2008 requires the Secretary to establish a three-year demonstration in up to 8 states (with urban, rural and underserved areas) to redesign the health care delivery system to provide targeted, accessible, continuous and coordinated family-centered care to high need Medicare populations with chronic or prolonged illnesses requiring regular medical monitoring, advising, or treatment.

Over 83% of Medicare beneficiaries have a chronic illness and over 95% of total spending in Medicare is linked to chronically ill patients. The medical home concept envisions a health care system where patient care is coordinated and integrated through a provider-guided multidisciplinary team enabled by a transformed practice setting. The practice would manage patient-centered care

across a variety of settings according to the needs of the patient through the promotion of continuous care relationships as well as application of the chronic care model, use of evidence based-medicine, care coordination, and patient empowerment. The idea has been described as early as 1967 by the American Academy of Pediatrics' Council on Pediatric Practice. The model has proven to be successful in improving outcomes for patients with chronic illnesses through improved care-coordination. Many demonstration programs have demonstrated long term cost-savings as well.

Proposed Law

This provision establishes a pilot program that builds on the current medical home model program, as modified by MIPPA, and allows for a broader paradigm beyond the model proposed by the National Committee for Quality Assurance (NCQA). It directs the Secretary to establish "a community-based medical home model" in addition to the "independent patient-centered medical home model." Studies have demonstrated that such alternative models using community care teams within the medical home can achieve cost savings and quality improvements.

A new section 1866E would be added to SSA to establish the medical home pilot program for the purpose of evaluating the feasibility and advisability of reimbursing qualified patient-centered medical homes for furnishing medical home services to high need beneficiaries in a variety of areas, including urban, rural, and underserved areas.

The pilot program would evaluate two medical home models (1) the independent patient-centered medical home model and (2) the community-based medical home model.

Independent Patient-Centered Medical Home. Patient-centered medical home services would be those services that (1) provide beneficiaries with direct, ongoing access to primary care or principal care provided by a physician or nurse practitioner; (2) coordinate the care provided to a beneficiary by a team of individuals at the practice level across office, institutional and home settings led by a primary care or principal physician or nurse practitioner; (3) provide for all the patient's health care needs or take responsibility for appropriately arranging care with other qualified providers for all stages of life; (4) provide continuous access to care and communication with participating beneficiaries; (5) provide support for patient self-management, proactive, and regular patient monitoring, support for family caregivers, and coordination with community resources; (6) integrate readily accessible, clinically useful information on participating patients; and (7) implement evidence-based guidelines and apply such guidelines to the identified needs of beneficiaries over time and with the intensity needed by such beneficiaries.

"Primary care" would mean health care that is provided by a physician or nurse practitioner who practices in the field of family medicine, general internal medicine, geriatric medicine, or pediatric medicine. "Principal care" means integrated, accessible health care that is provided by a physician who is a medical subspecialist that addresses the majority of the personal health care needs of patients with chronic conditions and for whom the subspecialist assumes care management.

Nothing in this provision would prevent a nurse practitioner or a physician assistant from leading or participating in a patient centered medical home so long as all of the pilot program requirements are met and the nurse practitioner or physician assistant is acting consistently with state law.

Under the independent patient-centered medical home model, the Secretary would make payments for medical home services furnished by an independent patient-centered medical home to targeted high need beneficiaries. An independent patient-centered medical home would be a physician-directed or nurse-practitioner-directed practice that is qualified to provide beneficiaries with patient-centered medical home services and meets such other requirements as the Secretary may specify. A targeted high need beneficiary would be a high need beneficiary who, based on a chronic disease risk score as specified by the Secretary, is generally within the upper 50th percentile of Medicare beneficiaries.

The Secretary would be required to determine an appropriate method of ensuring that beneficiaries have agreed to participate in the pilot program. The pilot program would begin no later than 6 months after the date of the enactment of this section. The Secretary would review alternative models for standard setting and qualification and develop a process that (1) establishes standards to enable medical practices to qualify as patient-centered medical homes; and (2) provides for the review and certification of medical practices as meeting such standards.

The Secretary would establish a methodology for the payment for medical home services furnished by independent patient-centered medical homes. Under the payment methodology, the Secretary would adjust payments to medical homes based on beneficiary risk scores to ensure that higher payments are made for higher risk beneficiaries. Moreover, the Secretary shall pay independent patient-centered medical homes a monthly fee for each targeted high need beneficiary who receives medical home services through such medical home. The monthly fee would be paid on a prospective basis. The amount of the monthly fee would depend upon the clinical work and practice expenses involved in providing the service; allow for differential payments based on capabilities of the independent patient-centered medical home; and use appropriate risk-adjustment in determining the per beneficiary per monthly payment in a manner that ensures that higher payments are made for higher risk beneficiaries.

The pilot program would be designed to include the participation of physicians in practices with fewer than 10 full-time equivalent physicians, as well as physicians in larger practices, particularly in underserved and rural areas, as well as federally qualified community health centers, and rural health centers. A physician in a group practice that participates in the Accountable Care Organizations pilot program established in section 1866D would not be eligible to participate in this pilot program, unless the pilot program is expanded and made permanent.

Community-Based Medical Home. Under the community-based medical home model (the "CBMH model"), the Secretary would make payments for the furnishing of medical home services by a community-based medical home to a high need beneficiary. A CBMH would be an appropriately certified nonprofit community-

based or state-based organization that provides beneficiaries with medical home services under the supervision of and in close collaboration with the primary care or principal care physician or nurse practitioner or physician assistant designated by the beneficiary as his or her community-based medical home provider. A CBMH would employ community health workers, including nurses or other non-physician practitioners, lay health workers, or other appropriate persons that assist the primary or principal care physician or nurse practitioner or physician assistant in chronic care management activities, such as teaching self-care skills, providing transitional care services, and developing care plans. A CBMH would meet such other requirements as the Secretary may specify. For this model, a "high need beneficiary" would be an individual with multiple chronic illnesses who requires regular medical monitoring, advising, or treatment. The Secretary would establish a process (1) to determine the necessary qualifications for community-based or state-based organizations to function as community-based medical homes; and (2) to provide for the review and assessment of these qualifications pursuant to criteria to be established by the Secretary.

The CBMH pilot program would start no later than 2 years after the date of the enactment of this section. Each demonstration site under the pilot program would operate for a period of up to 5 years after the initial implementation phase. In selecting sites for the CBMH model, the Secretary would give preference to applications from geographic areas that propose to coordinate health care services for chronically ill beneficiaries across a variety of health care settings, practices with fewer than 10 physicians, rural health clinics, and rural health clinics. Preference may also be given to applications for models that include the collaboration of other payors to provide medical homes services; or to states that propose to use the medical home model to coordinate health care services for chronically ill individuals enrolled under Title XIX of the Social Security Act across a variety of health care settings.

The Secretary would establish a methodology for the payment for medical home services furnished under the CBMH model. Under such payment methodology, the Secretary would make two separate monthly payments for each high need beneficiary as follows: one monthly payment to a community-based or state-based organization and one monthly payment to the primary or principal care practice for such beneficiary. The payments would be made on a prospective basis. The amount of the monthly fee would depend upon the clinical work and practice expenses involved in providing the service and would include an appropriate risk-adjustment to determine the monthly per beneficiary payment amount.

The Secretary would be able to make available initial implementation funding to a community-based or state-based organization or a state participating in the pilot. The entity would provide a detailed implementation plan that includes how such funds will be used.

The Secretary would evaluate the pilot program to determine the extent to which medical homes result in improvements in the quality and coordination of health care services; reduction in health disparities; reductions in preventable hospitalizations; prevention of readmissions; reductions in emergency room visits; improvement in

health outcomes; increased patient satisfaction; improved efficiency of care; and reductions in health care expenditures. The evaluation would also examine the feasibility and advisability of reimbursing medical homes for medical home services under Medicare on a permanent basis. No later than 60 days after the date of completion of the evaluation, the Secretary would submit to Congress and make available to the public a report on the findings of the evaluation.

Subject to the results of the evaluation, the Secretary would be able to issue regulations to implement, on a permanent basis, one or more models, if, and to the extent that such model or models, are beneficial to Medicare beneficiaries. The Secretary would not be able to issue such regulations unless the Chief Actuary of CMS certifies that the expansion of the components of the pilot program would result in estimated Medicare spending that would be no more than the level of spending that the Secretary estimates would otherwise be spent in the absence of such expansion.

During any month, the Secretary would not be able to make payments under more than one model or through more than one medical home under any model for the furnishing of medical home services to an individual. Also, payments made under this pilot are in addition to, and have no effect on the amount of, payment for evaluation and management services made under this title.

Chapter 35 of Title 44, United States Code would not apply to the pilot.

For purposes of operational costs associated with the pilot program (including the design, implementation, technical assistance for and evaluation of such program), in addition to funds otherwise available, $6 million for each of fiscal years 2010 through 2014 would be transferred from the Federal Supplementary Medical Insurance Trust Fund (Part B trust fund) to the CMS Program Management Account. Amounts appropriated under this paragraph for a fiscal year would be available until expended. In addition to funds otherwise available, $200 million for each fiscal year 2010 through 2014 for payments for patient centered medical home services and $125 million for each fiscal year 2012 through 2016 for CBMH services would be available for CMS from the Part B trust fund. Amounts available under this paragraph for a fiscal year would be available until expended.

In addition to funds otherwise available, $2.5 million for each of fiscal years 2010 through 2012 would be available to CMS from the Part B trust fund for initial implementation costs. Amounts available under this paragraph for a fiscal year would be available until expended.

In addition to funds otherwise available for payment of medical home services, there would also be available the amount established for the existing Medicare Medical Home Demonstration for the independent patient-centered medical home model. The Medicare Medical Home Demonstration project is repealed. The amendment made by this section would apply to services furnished on or after the date of the enactment of this Act.

Sec. 1303. Independence at home pilot program

Current Law

The Department of Veterans Affairs has been implementing a Home Based Primary Care (HBPC) program since 1972. HBPC provides comprehensive, interdisciplinary primary care in the homes of veterans with complex medical, social, and behavioral conditions for whom routine clinic-based care is not effective. HBPC targets frail, chronically ill veterans who require interdisciplinary health care teams, continuity, coordination of care, and the integration of diverse services to cover their complex medical, social, rehabilitative, and behavioral care needs. These veterans need comprehensive, longitudinal home care services as they age to maximize function, minimize institutionalization, and maintain quality of life. HBPC currently operates at over 130 locations in 48 states and Puerto Rico, and has shown substantial reductions in hospital days, nursing home days, and total costs of care.

Proposed Law

The Secretary would be required to conduct a Medicare pilot program, beginning no later than January 1, 2012, to test a payment incentive and service delivery model that utilizes physician- and nurse-practitioner-directed home-based primary care teams designed to reduce expenditures and improve health outcomes in the provision of items and services to certain high-cost, chronically ill Medicare beneficiaries. The pilot would test whether such a model, which is accountable for providing comprehensive, coordinated, continuous, and accessible care to high-need populations at home and coordinating health care across all treatment settings, would result in reductions in preventable hospitalizations; reductions in preventable readmissions; reductions in emergency room visits; improvements in health outcomes; improvements in the efficiency of care, such as by reducing duplicative diagnostic and laboratory tests; reductions in Medicare costs; and improvements in beneficiary and family caregiver satisfaction, among others.

The Secretary would enter into agreements with qualifying Independence at Home Medical Practices, legal entities comprised of an individual physician or nurse practitioner or group of physicians and nurse practitioners who are certified or have experience and training in providing home-based primary care services to high cost chronically ill beneficiaries. The provision would not prohibit Practices from including participating practitioners that are affiliated with the medical practice under an arrangement structured so that such provider or practitioner would participate in the pilot program and share in any of its savings.

Practice teams, comprised of physicians, nurses, physician assistants, pharmacists, and other health and social services staff, as appropriate, would make in-home visits and carry out plans of care tailored to the beneficiary's chronic conditions to achieve the pilot program's objectives. The teams would also report the clinical and quality of care outcomes as determined by the Secretary. The Secretary would design the pilot program to include the participation of physician and nurse practitioner practices with fewer than 10 full-time equivalent physicians, as well as physicians in larger practices, particularly in underserved rural areas. A home-based

primary care team could be led by a nurse practitioner or physician assistant, if he or she complies with the requirements of this provision and acts consistently with state law.

Practices would be expected to spend at least 5% less than a target spending level or a target rate of growth. A practice could receive 80% of savings in excess of 5% if Medicare expenditures for applicable beneficiaries are at least 5% greater than would result from normal variation in expenditures for items and services covered under Medicare parts A and B (and part D to the extent the Secretary decides to include such costs). Target spending levels, savings thresholds, and limits on shared savings amounts for each practice may be established by the Secretary, and would be based upon the size of the practice, characteristics of the enrolled individuals, and other factors the Secretary would determine to be appropriate.

Practices could receive interim payments for geriatric assessments and monthly care coordination services, as determined by the Secretary. But those payments, or a fraction of them, may be recouped by the Secretary in the event that the practice does not achieve the required savings so as to ensure that no practice receives more payments under the pilot program than Medicare otherwise would have paid for the services in the absence of the pilot program. To participate, a practice would be required to demonstrate to the Secretary that it is able to assume financial risk for the 5% savings requirement. The Secretary must limit payments for shared savings to each practice so that aggregate expenditures for applicable beneficiaries, including shared savings payments, would not exceed the amount that would have been expended for such practice if the pilot program had not been implemented.

An applicable beneficiary would be defined as an individual who:

(A) Is enrolled under Medicare part B and entitled to benefits under part A;

(B) Is not enrolled in a Medicare Advantage plan C or a Program for All-Inclusive Care for the Elderly program;

(C) Is in the top 20% of Medicare patient health risk scores;

(D) Has two or more chronic illnesses, including congestive heart failure, pulmonary disease, ischemic heart disease, stroke, Alzheimer's disease, among others specified in the provision, which would result in high Medicare costs when in combination with one or more of the specified diseases;

(E) Had a non-elective hospital admission within the past 12 months;

(F) Has received acute or subacute rehabilitation services;

(G) Has two or more functional dependencies requiring the assistance of another person (e.g., bathing, dressing, toileting, walking, or feeding); and

(H) Fulfills other criteria as the Secretary determines appropriate.

The Secretary would be required to publish eligibility requirements for beneficiaries that are sufficiently clear to be understood by beneficiaries and the individuals providing services to them, and the Secretary would be required to determine a method to ensure that beneficiaries' agreement to participate in a Practice is voluntarily. Beneficiaries who do agree to participate do not relinquish

access to any Medicare benefits as a condition of receiving services from a practice.

Agreements with practices under the program could cover a 3-year period. No physician or nurse practitioner participating in the accountable-care organization pilot program or the medical home pilot program would be eligible to participate in this pilot program.

The Secretary would be required to give preference, in selecting practices, to medical practices in high costs areas of the country, that have experience in furnishing health care services to applicable beneficiaries in the home, and that use electronic medical records, health information technology, and individualized plans of care. The Secretary could waive certain provisions in the Social Security Act to implement this pilot program.

To the extent practicable, at least two unaffiliated practices would be established in the 13 highest cost states and the District of Columbia, and in 13 additional states that are representative of other regions of the United States and include medically underserved rural and urban areas, as determined by the Secretary.

The Secretary would be required to provide an annual evaluation of each practice, which it would be required to make publicly available within 60 days of the completion of the report, to assess whether it achieved the minimum savings of 5% and other goals of the program, and can terminate an agreement with a practice if the practice did not meet those goals.

The Secretary would also be required to submit to Congress and make publicly available, no more than 2 years after the date the first agreement is entered into, and every second year thereafter during the pilot program, a report on best practices under the pilot program, and the impact of best practices on expenditures, access, and quality.

Subject to the evaluation, the Secretary may enter into additional agreements with practices to further test and refine models with respect to qualifying practices. If the practice models are beneficial to Medicare, as determined by the Secretary, and if the Chief Actuary of the CMS certifies that the model would result in estimated spending that would be less than without the expansion, the Secretary may issue regulations to implement, on a permanent basis, the independence at home practice model.

For purposes of administering and carrying out the pilot program, the provision would appropriate to the Secretary for the CMS Program Management Account $5 million for each of fiscal years 2010 through 2014 to administer and carry out the pilot program (other than for payments for items and services furnished under Medicare, shared savings and monthly fees, or other related payments such as interim payments).

Sec. 1304. Payment incentive for selected primary care services

Current Law

Section 1833(m) of the Social Security Act provides bonus payments for physicians who furnish medical care services in geographic areas that are designated by the Health Resources and Services Administration (HRSA) as primary medical care health professional shortage areas (HPSAs) under section 332(a)(1)(A) of the Public Health Service (PHS) Act. In addition, for claims with

dates of service on or after July 1, 2004, psychiatrists furnishing services in mental health HPSAs are also eligible to receive bonus payments.

The bonus payment equals 10% of what would otherwise be paid under the fee schedule. HPSAs may be designated as having a shortage of primary medical care, dental or mental health providers. They may be urban or rural areas, population groups or medical or other public facilities.

Proposed Law

The provision would establish payment incentives in Medicare to promote primary care furnished by primary care practitioners. For such services furnished on or after January 1, 2011, by a primary care practitioner, a payment incentive of 5% would be allowed (or 10% if the practitioner provides the services predominately in an area that is designated as a primary care health professional shortage area) and would be paid from the Supplementary Medical Insurance Trust Fund.

Primary care services would be defined to mean physicians' services as defined in section 1848(j)(5)(A) as well as services furnished by another health care professional that would be described above if furnished by a physician. A primary care practitioner would be defined as (1) a physician or other health care practitioner (including a nurse practitioner) who specializes in family medicine, general internal medicine, general pediatrics, geriatrics, or obstetrics and gynecology and has allowed charges for primary care services that account for at least 50% of the physician's or practitioner's total allowed charges under section 1848, as determined by the Secretary for the most recent period for which data are available, or (2) a physician assistant who is under the supervision of a practitioner described above.

There would be no administrative or judicial review respecting (1) any determination or designation of the primary care services payment incentive; (2) the identification of services as primary care services for the purpose of this payment incentive; or (3) the identification of a practitioner as a primary care practitioner for the purposes of this payment incentive.

The primary care services incentive payments would not be taken into account in determining the additional payments for physicians in health professions shortage areas or in physician scarcity areas. Furthermore, any bonus payment to physicians in health professions shortage areas or physician scarcity areas would not be taken into account in computing incentive payments for primary care services, nor would the primary care incentive payments be taken into account in determining the amounts that would otherwise be paid to physicians providing outpatient critical access hospital (CAH) services.

Sec. 1305. Increased reimbursement rate for certified nurse-midwives

Current Law

In general, Medicare pays 80% of the reasonable charges (the lesser of the actual charge for the services or the amount determined by the fee schedule) for physician services covered under

Medicare Part B. However, Medicare payments for services performed by certified nurse-midwives to Medicare beneficiaries are currently limited to no more than 65% of the fee schedule amount for the same service performed by a physician.

Proposed Law

In order to increase access to women's health services for Medicare beneficiaries, the provision increases the reimbursement for nurse-midwife services from 65% of the fee schedule to 100%. The modification would apply to services furnished on or after January 1, 2011.

Sec. 1306. Coverage and waiver of cost-sharing for preventive services

Current Law

In general, Medicare law authorizes the Secretary to cover services for the diagnosis and treatment of illness, while coverage of preventive services (i.e., services provided in the absence of illness) has required legislation. Section 1861 of the SSA requires coverage of a number of specified preventive services under Part B (often with specified conditions for coverage) in language interspersed throughout the section. There is no definition of "preventive services" in the law that refers to them collectively. Also, in Section 101 of the Medicare Improvements for Patients and Providers Act of 2008 (P.L. 110–275), Congress provided administrative authority for the Secretary to add coverage of new preventive services, under certain conditions.

Section 1833(a) of the SSA establishes coinsurance for the beneficiary, requiring Medicare to cover 80% of the costs of covered services under Part B, with specified exceptions. Section 1833(b) establishes an annual deductible for which the beneficiary is responsible. These sections have been amended over the years to waive coinsurance and/or the deductible for many, but not all, covered preventive services.

Proposed Law

In order to increase access to and utilization of preventive services in Medicare, this section eliminates co-insurance and the application of any deductible for such services. Subsection (a) of this section would add a new subsection to SSA Section 1861, which would define Medicare covered preventive services to mean a specified list of currently covered services, and colorectal cancer screening services regardless of the code applied, as provided in Section 1307 of this bill. The list would also include any new services that were covered under the Secretary's administrative authority. Coverage would be subject to all conditions and limitations that apply to each listed service under current law.

With respect to Medicare covered preventive services (as defined by this bill), subsection (b) of this section would amend Section 1833(a) of the SSA to require Medicare to pay 100% of their allowed charges. It would also amend several additional SSA sections to require the waiver of coinsurance for specified sigmoidoscopy and colonoscopy services, and, in outpatient hospital settings, for diagnostic mammograms and Medicare clinical preventive services.

This subsection would also amend Section 1833(b) of the SSA to waive the application of the deductible for Medicare covered preventive services. Finally, it would amend the SSA to remove the authority of providers to charge coinsurance when providing Medicare covered preventive services.

The amendments made by this section would apply to services furnished on or after January 1, 2011. The Secretary would be required, within 12 months of enactment, to report to Congress regarding barriers faced by beneficiaries in accessing abdominal aortic aneurysm screening and other recommended preventive services, and to provide educational resources to patients and physicians regarding risk factors for abdominal aortic aneurysm.

Sec. 1307. Waiver of deductible for colorectal cancer screening tests regardless of coding, subsequent diagnosis, or ancillary tissue removal

Current Law

Section 1833(a) of the SSA establishes coinsurance for the beneficiary, requiring Medicare to cover 80% of the costs of covered services under Part B, with specified exceptions. Section 1833(b) of the SSA requires the application of an annual deductible, for which the beneficiary is responsible, for some Part B services. Under current law, coinsurance is applied to colorectal cancer screening services, but the deductible is not.

Proposed Law

Current law prohibits the application of the Medicare Part B deductible for screening colonoscopies. If, however, a patient has a screening colonoscopy and the physician finds polyps that need to be removed during the screening exam, it is relabeled a diagnostic procedure and the deductible is applied. This provision would amend Sections 1833(a) and 1833(b) of the SSA (as amended by Section 1306 of this bill) to ensure that a screening colonoscopy avoids the deductible and the coinsurance regardless of whether the procedure becomes diagnostic. This provision would apply to items and services furnished on or after January 1, 2011.

Sec. 1308. Excluding clinical social worker services from coverage under the Medicare skilled nursing facility prospective payment system and consolidated payment

Current Law

The majority of services provided to beneficiaries in a Medicare covered skilled nursing facility (SNF) stay are included in the bundled prospective payment made to the SNF. Certain services have been specifically excluded from SNF consolidated billing. In these instances, Medicare will pay the entity or practitioner providing the service directly. Currently, the items and services provided by a clinical social worker are included in the SNF consolidated billing.

Proposed Law

In order to improve access to mental health services for Medicare beneficiaries in nursing facilities, items and services provided by clinical social workers to Medicare beneficiaries in a SNF would re-

ceive separate Medicare payment on or after July 1, 2011. This treatment would be equivalent to the billing rules for psychiatrists and psychologists employed under current law.

Sec. 1309. Coverage of marriage and family therapist services and mental health counselor services

Current Law

Section 1861(s)(2) of the SSA (42 U.S.C. 1395x(s)(2)) defines services covered under the term "medical and other health services." These services include medical supplies, hospital services, diagnostic services, outpatient physical therapy services, rural health clinic services, home dialysis services and supplies, antigens and physician assistant and nurse practitioner services. Marriage and family therapists and mental health counselors are not included under current law.

Proposed Law

In states that have licensed or certified marriage and family therapists and mental health counselors, these practitioners provide mental health services to people under age 65. Few states did so when Medicare was first created in 1965. This provision updates Medicare coverage by allowing them to treat Medicare beneficiaries as well, subject to state law.

The proposal would add two subcategories of services to be covered under the term "medical and health services." These are (1) marriage and family therapists, and (2) mental health counselors.

The proposal would stipulate the required qualifications for a marriage and family therapist, and mental health counselor in Medicare. It would define these providers' services as the diagnosis and treatment of mental illnesses, as permitted by his or her state license, if no other provider or facility is also paid for those services. The proposal would add a payment provision for marriage and family therapists, and mental health counselors. The amount paid would be 80% of the lesser of the actual charge for services or 75% of the amount that would be paid for a psychologist's services. The proposal would require the Secretary to consider confidentiality issues while developing criteria allowing for direct payment of the therapist and medical information sharing with the patient's primary care physician or nurse practitioner. The proposal would exclude marriage and family therapists and mental health counselors from the prospective payment system for skilled nursing facilities. The proposal would include marriage and family therapy services and mental health counseling services in the scope of services that rural health clinics and federally qualified health centers can provide to Medicare beneficiaries.

Sec. 1310. Extension of physician fee schedule mental health add-on

Current Law

By law, every five years CMS examines Medicare billing codes under the physician fee schedule to determine whether they are overvalued or undervalued. Subsequent to the most recent evaluation, Medicare increased the rates for the codes used by physicians to bill for "evaluation and management" (E/M) services (face-to-face

visits with patients), effective January 1, 2007. To maintain budget neutrality, rates for certain other codes, including some used to bill for psychotherapy services, were reduced.

The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA; P.L. 110–275) increased Medicare payments under the fee-schedule for psychotherapy services by 5% beginning on July 1, 2008, and ending on December 31, 2009. Psychiatric therapeutic procedures that involve insight oriented, behavior modifying, or supportive psychotherapy or interactive psychotherapy furnished in an office or other outpatient facility setting or in an inpatient hospital or residential care facility are paid at this higher amount.

Proposed Law

In order to maintain access to mental health services in Medicare, this proposal would extend the increased payments provided by MIPPA for psychotherapy services for an additional two years (ending December 31, 2011).

Sec. 1311. Expanding access to vaccines

Current Law

Medicare Part B covers influenza, pneumococcal, and, for individuals at increased risk, hepatitis B vaccinations. This coverage includes both the costs of these vaccines and their administration by recognized providers. Medicare Part D covers all vaccines licensed by the FDA, and their administration, when prescribed by recognized providers.

This split coverage arrangement is burdensome for patients and providers and potentially dangerous. For vaccines covered by Part D, beneficiaries may have to fill the vaccine prescription at the pharmacy and carry it to the physicians' office for administration.

Proposed Law

This provision transfers coverage for all vaccines to Part B, simplifying the program and improving access for beneficiaries.

Under this provision, coverage of vaccines currently covered by Part D would be transferred to Medicare Part B. Part B coverage vaccine coverage would include all federally recommended vaccines, defined as any licensed vaccine that is recommended by the Advisory Committee on Immunization Practices (an advisory committee established by the Secretary, acting through the Director of the Centers for Disease Control and Prevention). The provision would also include all federally recommended vaccines in the suite of Medicare covered preventive services defined under section 1306 of this Act. The provision would apply to vaccines administered on or after January 1, 2011. Payment rates for vaccines under Medicare Part B would be based on 106% of the vaccines' Average Sales Price, with the exception of influenza vaccine. Payment rates for influenza vaccine would remain unchanged from current law, at 95% of the Average Wholesale Price.

Sec. 1312. Recognition of certified diabetes educators as certified providers for purposes of Medicare diabetes outpatient self-management training services

Current Law

Diabetes Self Management Training (DSMT) is covered under Medicare Part B pursuant to Section 1861(qq) of the SSA. DSMT means educational and training services furnished to an individual with diabetes by a "certified provider," in an outpatient setting, by an individual or entity who meets specified quality standards. Certification of the need for such services is required by the treating physician or qualified non-physician practitioner. A certified provider for the purpose of providing DSMT services is a physician, or other individual or entity designated by the Secretary that, in addition to providing diabetes outpatient self-management training services, provides other items or services for which payment may be made under this title.

Proposed Law

Diabetes self-management training teaches patients how to manage diabetes to avoid and minimize subsequent health problems. This proposal would amend Section 1861(qq) of the SSA to designate certain certified diabetes educators as certified providers of covered DSMT services.

Under the proposal, a "certified diabetes educator" is an individual who: (1) is licensed or registered as a health care professional by the state in which the services are performed; (2) specializes in teaching individuals with diabetes to develop the necessary skills and knowledge to manage the individual's diabetic condition; and (3) is certified as a diabetes educator by a recognized certifying body. A "recognized certifying body" means (1) the National Certification Board for Diabetes Educators, or (2) a certifying body for diabetes educators that is recognized by the Secretary as authorized to grant certification of diabetes educators for purposes of this proposal, pursuant to standards established by the Secretary, if the Secretary determines that such board or body meets the following requirements: (1) it is incorporated and registered to do business in the United States; and (2) it requires, as a condition of certification, that an individual: (A) has a qualifying credential in a specified health care profession; (B) has professional practice experience in DSMT that includes a minimum number of hours and years of experience in such training; (C) has successfully completed a national certification examination offered by such entity; and (D) periodically renews certification status following initial certification.

Amendments made by this proposal would apply to outpatient DSMT services furnished on or after the first day of the first calendar year that is at least six months after the date of enactment.

TITLE IV—QUALITY

Subtitle A—Comparative Effectiveness Research

Sec. 1401. Comparative effectiveness research

Current Law

The need for more and better information about which clinical strategies work best and under what conditions has been widely recognized by clinicians, patients, researchers and policy makers. Most recently, comparative effectiveness research was addressed in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, P.L. 108–173) and the American Recovery and Reinvestment Act (ARRA, P.L. 111–5). Section 1013 of the MMA authorizes the Agency for Healthcare Research and Quality (AHRQ) to conduct and support research on the outcomes, comparative clinical effectiveness, and appropriateness of health care items and services. In ARRA Congress provided $1.1 billion for comparative effectiveness research, with $400 million going to the National Institutes of Health and $300 million to the Agency for Health Care Research and Quality to support comparative effectiveness research efforts at those agencies and $400 million to the Office of the Secretary to (1) conduct, support, or synthesize research that compares the clinical outcomes, effectiveness, and appropriateness of items, services, and procedures that are used to prevent, diagnose, or treat diseases, disorders, and other health conditions; and (2) encourage the development and use of clinical registries, clinical data networks, and other forms of electronic health data that can be used to generate or obtain outcomes data.

Proposed Law

The provision would establish a Center for Comparative Effectiveness Research within the Agency for Healthcare Research and Quality under title XI of the Social Security Act. The Center would conduct, support, and synthesize research with respect to the outcomes, effectiveness, and appropriateness of health care services and procedures in order to identify the manner in which diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically.

The duties of the Center would be to (1) conduct, support, and synthesize research relevant to the comparative effectiveness of the full spectrum of health care items, services, and systems, including pharmaceuticals, medical devices, medical and surgical procedures, and other medical interventions; (2) conduct and support systematic reviews of clinical research, including original research conducted subsequent to the date of the enactment of this section; (3) continuously develop rigorous scientific methodologies for conducting comparative effectiveness studies, and use such methodologies appropriately; (4) submit to the Comparative Effectiveness Research Commission (see below), the Secretary, and Congress relevant reports produced by the Center or a grantee or contractor of the Center; and (5) encourage, as appropriate, the development and use of clinical registries and the development of clinical effectiveness research data networks from electronic health records, post-

marketing drug and medical device surveillance efforts, and other forms of electronic health data.

The Center could secure information necessary to enable it to carry out its duties directly from any department or agency of the United States. Upon request of the Center, the head of that department or agency would furnish the information to the Center on an agreed upon schedule. In order to carry out its functions, the Center would (1) utilize existing information, both published and unpublished, where possible, collected and assessed either by its own staff or under other arrangements; (2) carry out, or award grants or contracts for, original research and experimentation, where existing information is inadequate; and (3) adopt procedures allowing any interested party to submit information for the Center or the Commission's to use in making reports and recommendations. The Comptroller General would have unrestricted access to all deliberations, records, and nonproprietary data of the Center and Commission, immediately upon request, and both the Center and the Commission would be subject to periodic audit by the Comptroller General.

The Secretary would establish an independent Comparative Effectiveness Research Commission to oversee and evaluate the activities carried out by the Center to ensure that the Center's activities result in highly credible research and information produced from such research. The duties of the Commission would include the following:

(1) Determine national priorities for research to be conducted, supported or synthesized by the center, and in making such determinations consult with a broad array of public and private stakeholders, including patients and health care providers and payers;

(2) Monitor the appropriateness of use of the Comparative Effectiveness Research Trust Fund (CERTF) (described below) with respect to the timely production of comparative effectiveness research determined to be a national priority;

(3) Identify highly credible research methods and standards of evidence for such research to be considered by the Center;

(4) Review the methodologies developed by the Center;

(5) Not later than one year after the date of the enactment, enter into an arrangement under which the Institute of Medicine of the National Academy of Sciences would conduct an evaluation and report on standards of evidence for such comparative effectiveness research;

(6) Support forums to increase stakeholder awareness and permit stakeholder feedback on the efforts of the Center to advance methods and standards that promote highly credible research;

(7) Make recommendations for policies that would allow for public access of data produced under this section, in accordance with appropriate privacy and proprietary practices, while ensuring that the information produced through such data is timely and credible;

(8) Appoint a clinical perspective advisory panel for each national research priority, which would consult with patients and advise the Center on research questions, methods and evidence gaps in terms of clinical outcomes for the specific research in-

quiry to be examined with respect to such priority to ensure that the information produced from such research is clinically relevant to decisions made by clinicians and patients at the point of care;

(9) Make recommendations for the priority for periodic reviews of previous comparative effectiveness research and studies conducted by the Center;

(10) Routinely review processes of the Center with respect to such research to confirm that the information produced by such research is objective, credible, consistent with standards of evidence established under this section, and developed through a transparent process that includes consultations with appropriate stakeholders; and

(11) Make recommendations to the Center for the broad dissemination of the findings of research conducted and supported under this section that enables clinicians, patients, consumers, and payers to make more informed health care decisions that improve quality and value.

The members of the Commission would consist of the Director of the Agency for Healthcare Research and Quality, the Chief Medical Officer of the Centers for Medicare and Medicaid Services, and 15 additional members who would represent broad constituencies of stakeholders, including clinicians, patients, researchers, third-party payers, and consumers of federal and state beneficiary programs. At least 9 of the 17 members would be practicing physicians, healthcare practitioners, consumers, or patients. The members of the Commission would represent a broad range of perspectives and collectively would have experience in epidemiology, health services research, bioethics, decision sciences, health disparities, and economics. To ensure a diverse representation of the healthcare community, at least one member would represent each of the following: (1) patients, (2) healthcare consumers, (3) practicing physicians, including surgeons, (4) other healthcare practitioners engaged in clinical care, (5) employers, (6) public payers, (7) insurance plans, and (8) clinical researchers who conduct research on behalf of pharmaceutical or device manufacturers. No more than 3 of the members of the Commission could be representatives of pharmaceutical or device manufacturers and these representatives could only be clinical researchers as described in (8).

The Secretary would appoint the members of the Commission; in considering candidates for appointment to the Commission, the Secretary could consult with the Government Accountability Office and the Institute of Medicine of the National Academy of Sciences. The Secretary would designate a member of the Commission, at the time of appointment, as Chairman and a member as Vice Chairman for that term of appointment, except that in the case of vacancy of the Chairmanship or Vice Chairmanship, the Secretary could designate another member for the remainder of that member's term. The Chairman would serve as an ex officio member of the National Advisory Council of the Agency for Healthcare Research and Quality. Of the members first appointed, 8 would be appointed for a term of 4 years, and 7 would be appointed for a term of three years. Subsequently, each member of the Commission would be appointed for a term of four years.

To enhance effectiveness and coordination, the Secretary would be encouraged, to the greatest extent possible, to seek coordination between the Commission and the National Advisory Council of the Agency for Healthcare Research and Quality.

The bill includes provisions to protect against potential conflicts of interest. In appointing the members of the Commission or a clinical perspective advisory panel, the Secretary or the Commission, respectively, would take into consideration any financial interest and develop a plan for managing any identified conflicts. When considering an appointment to the Commission or a clinical perspective advisory panel, the Secretary or the Commission would review the expertise of the individual and the financial disclosure report filed by the individual pursuant to the Ethics in Government Act of 1978 for each individual under consideration for the appointment, so as to reduce the likelihood that an appointed individual would later require any pertinent waivers.

Prior to a meeting of the Commission or a clinical perspective advisory panel, each member of the Commission or the clinical perspective advisory panel who is a full-time government employee or special government employee would disclose any relevant financial interests to the Secretary. A member of the Commission or a clinical perspective advisory panel could not participate with respect to a particular matter considered in a meeting of the Commission or the clinical perspective advisory panel if the member (or an immediate family member of the member) were to have a financial interest that could be affected by the advice given to the Secretary regarding the matter, excluding interests exempted in regulations issued by the Director of the Office of Government Ethics as too remote or inconsequential to affect the integrity of the services of the government officers or employees to which such regulations apply. The Secretary could grant a waiver if the Secretary were to determine it necessary to afford the Commission or a clinical perspective advisory panel the essential expertise of the member. The waiver would permit such a member to participate as a voting or non-voting member with respect to a particular matter under consideration in a Commission or a clinical perspective advisory panel meeting. The number of waivers granted to members of the Commission could not exceed one-half of the total number of members for the Commission. However, no voting member of any clinical perspective advisory panel would be in receipt of a waiver, and no more than two nonvoting members of any clinical perspective advisory panel would be serving under waiver. For purposes of determining conflict of interest under this section, the term "financial interest" would mean a financial interest under section 208(a) of title 18, United States Code.

While serving on the business of the Commission (including travel time), a member of the Commission would be entitled to compensation at the per diem equivalent of the rate provided for level IV of the Executive Schedule, and while serving away from home and the member's regular place of business, a member could be allowed travel expenses, as authorized by the Director of the Commission.

The Commission would transmit a copy of each report submitted to the Secretary and would make the reports available to the public.

The Commission could (1) appoint an executive director (subject to the approval of the Secretary) and other personnel as federal employees under section 2105 of title 5, United States Code as may be necessary to carry out its duties (without regard to the provisions of Title 5, United States Code, governing appointments in the competitive service); (2) seek assistance and support from appropriate federal departments and agencies as might be required in the performance of its duties; (3) enter into contracts or make other arrangements for the conduct of the work of the Commission, as may be necessary; (4) make advance payments, and other payments that relate to the work of the Commission; (5) provide transportation and subsistence for persons serving without compensation; and (6) prescribe such rules and regulations as it were to deem necessary with respect to the internal organization and operation of the Commission.

Any research conducted, supported, or synthesized by the Center would (1) be required to meet certain transparency, credibility and access conditions; (2) consider advice given by clinical perspective advisory panels; (3) consider stakeholder input; and (4) take into account potential differences across subgroups of populations. To ensure transparency, credibility, and access, the research would meet the following conditions: (1) the establishment of the agenda and the conduct of the research would be insulated from inappropriate political or stakeholder influence; (2) the methods of conducting the research would be scientifically based; (3) all aspects of the prioritization of research, conduct of the research, and development of conclusions based on the research would be transparent to all stakeholders; (4) the process and methods for conducting such research would be publicly documented and available to all stakeholders; and (5) throughout the process of the research, the Center would provide opportunities for all stakeholders involved to review and provide public comment on the methods and findings of such research.

The research would meet a national research priority as determined above and would consider advice given to the Center by the clinical perspective advisory panel for the national research priority.

The Commission would consult with patients, health care providers, health care consumer representatives, and other appropriate stakeholders with an interest in the research through a transparent process recommended by the Commission. Specifically, where deemed appropriate by the Commission, the consultation would include (1) recommending research priorities and questions, (2) recommending research methodologies, and (3) advising on and assisting with efforts to disseminate research findings. The Secretary would designate a patient ombudsman who would serve as an available point of contact for any patients with an interest in proposed comparative effectiveness studies by the Center and ensure that any comments from patients regarding proposed comparative effectiveness studies are reviewed by the Commission.

Research falling under the activities of this Center would (1) be designed, as appropriate, to take into account the potential for differences in the effectiveness of health care items and services used with various subpopulations such as racial and ethnic minorities, women, different age groups (including children, adolescents,

adults, and seniors), and individuals with different co-morbidities; and (2) seek, as feasible and appropriate, to include members of such subpopulations as subjects in the research.

The proposal would require public access to comparative effectiveness information. Not later than 90 days after receipt by the Center or Commission, as applicable, of a relevant report made by the Center, Commission, or clinical perspective advisory panel under this section, the appropriate information contained in the report would be posted on the official public Internet site of the Center and of the Commission, as applicable. For purposes of this section, a relevant report would be each of the following submitted by the Center or a grantee or contractor of the Center: (1) any interim progress report as deemed appropriate by the Secretary, (2) stakeholder comments, and (3) a final report.

To disseminate and assist in the incorporation of comparative effectiveness information, the Center would provide for the dissemination of appropriate findings produced by research supported, conducted, or synthesized under this section to health care providers, patients, vendors of health information technology focused on clinical decision support, appropriate professional associations, and federal and private health plans, and other relevant stakeholders. In disseminating such findings the Center would (1) convey findings of research so that they are comprehensible and useful to patients and providers in making health care decisions; (2) discuss findings and other considerations specific to certain sub-populations, risk factors, and co-morbidities as appropriate; (3) include considerations such as limitations of research and what further research may be needed, as appropriate; (4) not include any data that the dissemination of which would violate the privacy of research participants or violate any confidentiality agreements made with respect to the use of data under this section; and (5) assist the users of health information technology focused on clinical decision support to promote the timely incorporation of such findings into clinical practices and promote the ease of use of such incorporation.

The Center would develop protocols and strategies for the appropriate dissemination of research findings in order to ensure effective communication of the findings and the use and incorporation of the findings into relevant activities for the purpose of informing higher quality and better decisions regarding medical items and services. In developing and adopting the protocols and strategies, the Center would consult with stakeholders concerning the types of dissemination that would be most useful to the end users of information and could provide for the utilization of multiple formats for conveying findings to different audiences, including dissemination to individuals with limited English proficiency.

The provision would establish a number of reporting requirements:

• Beginning not later than one year after the date of the enactment, the Director of the Agency of Healthcare Research and Quality and the Commission would submit an annual report on the activities of the Center and the Commission and research conducted under this section to Congress. Each report would include a discussion of the Center's compliance with the requirements for inclusion of subpopulations in research, including any reasons for lack of compliance.

• Not later than December 31, 2011, the Secretary would submit to Congress an annual recommendation for a fair share per capita amount described below for purposes of funding the CERTF.

• Not later than December 31, 2013, the Secretary, in consultation with the Commission, would submit to Congress a report on all activities conducted or supported under this section as of such date. The report would include an evaluation of the overall costs of such activities and an analysis of the backlog of any research proposals approved by the Commission but not funded.

The proposal would establish the Health Care Comparative Effectiveness Research Trust Fund ("CERTF") under the Internal Revenue Code (the "Code") to carry out the proposal's provisions relating to comparative effectiveness research. For fiscal year 2010 and in each subsequent fiscal year, amounts in the CERTF under section 9511 of the Internal Revenue Code of 1986 would be available to the Secretary to carry out this section without the need for further appropriations and without fiscal year limitation.

Nothing in this section would be construed to permit the Commission or the Center to mandate coverage, reimbursement, or other policies for any public or private payer.

For information regarding the establishment and financing the Comparative Effectiveness Research Trust Fund, see section 1802.

The bill includes several limitations on the use of comparative effectiveness research. The proposal includes a rule of construction stating that nothing in the section would be construed to permit the Commission or the Center to mandate coverage, reimbursement or other policies for any public or private payer. A separate provision states that in no case could any research conducted, supported, or developed by the Center, the Commission, or the Federal Coordinating Council for Comparative Effectiveness Research be used by the federal government to deny or ration care. In addition, CMS could not use federally funded clinical comparative effectiveness research data to make coverage determinations for medical treatments, services, or items under the Medicare program on the basis of cost.

This section specifies that the work performed by the Commission or the Center should be performed in close collaboration with the specialty colleges and academies of medicine because these organizations have important expertise to be considered when formulating a research agenda. In addition, these same organizations are critical to the dissemination of new research.

Subtitle B—Nursing Home Transparency

PART 1—IMPROVING TRANSPARENCY OF INFORMATION ON SKILLED NURSING FACILITIES AND NURSING FACILITIES

Sec. 1411. Required disclosure of ownership and additional disclosable parties information

Current Law

In general, Medicare and Medicaid require that skilled nursing facilities (SNF) and nursing facilities (NFs) be administered in a manner that maintains residents' well-being and safety. SNFs and nursing facilities are also required to report certain changes in ownership or controlling interest; in those individuals who are offi-

cers, directors, agents or managing employees; in the corporation, association or other company responsible for facility management; or when a change occurs in the SNF or nursing facility administrator position. SNFs and nursing facilities also are required to disclose ownership and other information as a condition of participation, and of certification or re-certification. In general, administrators must meet standards established by the Secretary.

Under Title XI of the Social Security Act, Section 1124, a person is considered to have an ownership or controlling interest, directly or indirectly, when (1) they own 5% or more of an entity, or they hold a whole or part of any mortgage, deed of trust, note or other obligation secured by the entity (nursing facility) or any property or assets that equal 5% of the total property; (2) are an officer or director of the entity, if the entity is organized as a corporation; or (3) are a partner in the entity if it is organized as a partnership. To a limited extent as determined feasible by the Secretary, nursing facility entities also are required to report other ownership and control interests for any persons named as owners or having a control interest.

Proposed Law

In recent years it has become clear that, when nursing home quality problems arise, state and federal regulators are increasingly unable to effectively and quickly investigate complex webs of interlocking corporate relationships and identify and hold accountable nursing home owners and others who are responsible for these quality of care problems. Current disclosure and reporting rules for nursing homes are inadequate, failing to require that nursing homes divulge key ownership and non-ownership relationships with persons and entities that are in a position to control the resources and operations essential to good resident care are inadequate. The proposed provisions in Section 1411, which call for nursing homes to divulge those persons and entities that are in a position to make decisions about the operation, management and financing of services for resident care, will restore a measure of appropriate public accountability.

This provision would amend Section 1124 to require SNFs and nursing facilities to make available upon request by the Secretary, the Health and Human Services Office of the Inspector General (OIG), the state where the entity is located, and the state long-term care ombudsman, information on ownership (including direct and indirect ownership), information on additional disclosable parties and information describing the governing body and organizational structure of the facility. SNFs and nursing facilities would be required to update disclosure information whenever changes occur. Information would need to be made available to the Secretary, OIG, the state where the entity is located, the state long-term care ombudsman and members of the public upon request until such time as this information became available publicly in accordance with final regulations promulgated by the Secretary.

In addition, SNFs and nursing facilities would be required to post prominent notices in facility lobbies that ownership and additional disclosable party information are available upon request.

Facilities would be required to disclose the identity of and information on (1) each member of a facility's governing body including

their name, title, date of start, and period of service for each SNF or nursing facility; (2) each person or entity who is an officer, director, member, partner, trustee, or managing employee, including their name, title, and period of service; (3) each person or entity who is an additional disclosable party; and (4) the organizational structure and relationship of the organizational entities to each SNF or nursing facility and each other for each ownership and governing individual or entity.

To the extent practicable, the Secretary may allow SNFs and nursing facilities, in a manner specified by the Secretary, to submit information using existing reporting mechanisms on ownership interest, governance, and organizational structure if they already report such information to other oversight agencies, such as to the Internal Revenue Services (IRS) using Form 990, the Securities and Exchange Commission, the Secretary, or through information otherwise submitted to any other federal agency.

Ownership or controlling interest would include direct or indirect interests through any number of intermediate entities and would include owners of a whole or part interest in any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the entity or any of the property or assets, if the ownership interest is at least 5%.

Not later than two years after enactment, the Secretary would promulgate final regulations requiring SNFs and nursing facilities to report, in a standardized format, information about ownership, governing board, and organizational structure. The final regulations would require that as a condition of participation and payment, SNFs and nursing facilities certify that reported information is current and accurate. These regulations would take effect 90 days after the Secretary published the final regulations in the *Federal Register*.

The Secretary would provide technical assistance and guidance to states on how to adopt and implement the reporting requirements in the standardized format. This provision would not reduce, diminish, or alter any existing facility reporting requirements.

The following definitions would apply to this provision:

(A) "Additional disclosable party" would be any individual or entity who (i) exercises operational, financial, or managerial control over the facility or any part of the facility or provides policies or procedures for any facility operations or provides financial or cash management services to the facility; (ii) leases or subleases real property to the facility; or owns a whole or part interest of at least 5% of the total value of such real property; (iii) lends funds or provides a financial guarantee to the facility of at least $50,000; or (iv) provides management or administrative services, management or clinical consulting services, or accounting or financial services to the facility. Individuals such as janitors, landscapers, or security guards, or routine vendors who are independent third parties, and who do not or do not have the ability to directly or indirectly exercise operational or directional control over the facility are not intended to be considered additional disclosable parties under subparagraph (6)(A)(iv).

(B) The facility is defined as a "disclosing entity", which is a SNF operating under Medicare or a nursing facility operating under Medicaid.

(C) "Managing employees" include any employee, such as a general manager, business manager, administrator, director, or consultant, who directly or indirectly manages, advises, or supervises any element of a SNF or nursing facility's practices, finances, or operations.

(D) "Organizational structure" consists of the following: (a) the corporations, the officers, directors, and shareholders of corporations, who own at least 5% of the corporation; (b) the limited liability companies, the ownership interest of members and managers of limited liability companies (including the percentage owned by each member and manager); (c) the general partnerships, the general partners, the limited partnerships, the general and limited partners who own at least 10% of the partnership; (d) a trust, the trustees of the trust; (e) an individual, contact information for the individual; (f) and any other person or entity, as the Secretary determines appropriate.

Within one year of publication of the final regulations in the *Federal Register*, the Secretary shall make ownership disclosure and additional disclosable party information for SNF and nursing facilities available to the public as determined by the Secretary.

Sec. 1412. Accountability requirements

Current Law

There are no comparable requirements in current law for SNFs and nursing facilities to implement compliance and ethics training programs for their employees.

Proposed Law

For more than a decade the HHS Office of Inspector General and other federal agencies charged with responsibility for enforcement of federal law have emphasized the importance of compliance plans. Yet not all nursing homes have voluntarily implemented compliance and ethics programs. This section would require that nursing homes develop such programs.

In addition, this section proposes that nursing homes develop Quality Assurance and Performance Improvement (QAPI) programs, which are vital for health care providers of all types. QAPI programs are designed to make health care organizations recognize and establish comprehensive systems that aim to deliver patient-centered care encompassing all individuals in an organization, from board to bedside, in an environment that promotes and demonstrates measurable improved outcomes for patients and families.

Within two years of the effective date of this provision, the Secretary, in consultation with the HHS OIG, would promulgate regulations for effective compliance and ethics programs for operating organizations. These regulations may include a model compliance program, and would permit the design of the compliance and ethics programs to vary depending on an organization's size. Larger operating organizations would have more formal and rigorous programs with established written policies and procedures to guide employees. Regulations also would specifically address requirements for employees and managers of multi-nursing home chains.

Thirty-six months after enactment of this provision, SNFs and nursing facilities would be required to have complied with regula-

tions developed by the Secretary governing the operation of compliance and ethics programs. The compliance and ethics programs would need to be effective in preventing and detecting criminal, civil, and administrative violations and in promoting quality of care. Regulations may vary with the size of the organization, such that larger organizations have a more formal and rigorous program. Operating organizations (entities that operate SNFs and nursing facilities) would be required to comply with the compliance and ethics programs regulations, and corporate-level management of multi-unit nursing home chains would be specifically required to comply with the requirements of compliance and ethics programs.

Section 1635 of this Act also requires compliance program for Medicare and Medicaid providers. To prevent redundancy and to ensure that nursing homes and SNFs have effective compliance and ethics programs in place, the requirements of this section for nursing facilities and SNFs are intended to supersede the requirements in Section 1635.

Within three years after promulgation of final regulations, the Secretary would be required to evaluate the compliance and ethics programs and submit a report to Congress to determine if the compliance and ethics programs led to changes in deficiency citations, quality performance, or other patient care quality metrics. The Secretary's report to Congress would include recommendations to change the requirements of the compliance and ethics program, as the Secretary determined appropriate.

Compliance and ethics programs would need to be reasonably designed, implemented, and enforced to be generally effective in preventing and detecting civil, criminal, and administrative violations as well as in promoting quality of care, and would include the following required components:

(1) Compliance standards and procedures that would guide employees and other agents and would reduce criminal, civil, and administrative violations as defined under this Act;

(2) Responsibility by senior individuals within operating organizations for overseeing compliance with the standards and procedures the entity establishes for their compliance and ethics program. These individuals would have resources and authority to assure compliance;

(3) Diligence in ensuring that individuals who are at risk for engaging in criminal, civil, or administrative violations under this Act are not delegated responsibility for implementing or monitoring an organization's compliance and ethics program;

(4) Effective communication of standards and procedures to employees (and other agents), through training programs or explanatory publications that practically illustrate what is required;

(5) Assurance that the standards for their compliance and ethics programs are met by using procedures to detect criminal, civil, and administrative violations of this Act. Organizations can use procedures such as monitoring and auditing systems as well as installing a reporting system that enables employees (and other agents) to report violations by others without fear of retribution;

(6) Appropriate disciplinary mechanisms that are consistently followed to enforce the compliance and ethics program

standards. Operating organizations also must demonstrate that they have used, where appropriate, disciplinary measures for individuals failing to detect offenses;

(7) Appropriate mechanisms to respond to detected offenses and strategies to prevent future similar offenses, including repayment of any funds to which an organization was not entitled, and modification of compliance and ethics programs to detect criminal, civil, and administrative violations;

(8) Periodic reassessment of their compliance and ethics program standards to ensure that the programs continue to be effective as the organization and facilities change.

Before December 31, 2011, the Secretary would be required to establish and implement a quality assurance and performance improvement (QAPI) program. The QAPI program would include multi-unit chains. Under the QAPI program, the Secretary would establish facility standards and provide technical assistance to SNFs and nursing facilities on the development of best practices to meet the QAPI standards through regulation. Within one year after the Secretary promulgates such regulations, SNFs and nursing facilities would be required to submit plans to the Secretary describing how they will meet the QAPI standards and implement best practices.

The Comptroller General of the Government Accountability Office (GAO) would be required to conduct a study that examined the following: (1) the extent to which corporations that operate large numbers of SNFs and nursing facilities are undercapitalized, taking into account ownership type (including private equity and control interests) are undercapitalized; (2) the effects of undercapitalization on quality of care, including staffing and food costs; and (3) options to address undercapitalization issues, such as requirements for surety bonds, liability insurance, or minimum capitalization. Within 18 months after this provision became effective, GAO would submit a report to Congress.

Section 1413. Nursing home compare Medicare website

Current Law

There is no requirement in current law for Medicare's Nursing Home Compare website. The Nursing Home Compare website was developed by the Centers for Medicare and Medicaid Services (CMS) and launched in November 2002. The website was intended to bolster the agency's efforts to improve SNF and nursing facility quality of care and to make information on nursing home quality more accessible for long-term care consumers and their families. Since its launch, CMS has enhanced the website by adding or improving quality measures and website navigation. Medicare Nursing Home Compare includes national data on all nursing facilities that participate in Medicare and Medicaid. The data featured on Nursing Home Compare includes facility ratings, selected results from survey and certification inspections, and limited staffing information on SNFs and nursing facilities.

Proposed Law

The federal nursing home quality website, Nursing Home Compare, is visited annually by tens of thousands of individuals looking

for reliable, accurate information about a suitable facility for a loved one. While Nursing Home Compare is already a valuable resource, nursing home resident and their families would benefit from additional information

This section requires that the Secretary ensure that the Nursing Home Compare website (or a successor website) contain additional information, in searchable form and displayed in a manner that is prominent, easily accessible, and clearly understandable for consumers, for SNFs and nursing facilities. This information must include:

(1) Information on ownership and affiliated parties as would be required under Section 1411 , Required Disclosure of Ownership and Affiliated Parties Information, that identifies SNF and SNF facility chains' ownership, governing boards, and organizational structure;

(2) Information on CMS's Special Focus Facility facilities (or a successor program), including the names and locations of facilities that since the previous quarter that were: (a) newly enrolled in the program; (b) enrolled but failed to significantly improve; (c) enrolled and significantly improved; (d) graduated from the program; and (e) have closed voluntarily or been terminated by the Secretary;

(3) Staffing data for each facility, including resident census, hours of care provided per resident per day, staff turnover, and tenure. These data would need to be displayed in formats that are clearly understandable to consumers and would permit them to compare staffing differences between facilities. This staffing information also would need to assist consumers in comparing an individual facility's staffing with state and national facility averages by providing: (a) concise explanations of how to interpret data (i.e., plain English explanations of how to interpret data on nursing home staff hours per resident day), (b) differences between staffing categories and their associated training requirements, (c) the relationship between staff levels and quality of care, and (d) an explanation that residents with greater care needs can require greater staff levels or more staff training;

(4) Links to state websites where state survey and certification program information can be found, including Form 2567 state inspection reports (or successor forms) and facility correction plans or other facility responses, along with information to guide consumers in interpreting and understanding survey and certification reports;

(5) The standardized complaint form developed by the Secretary under Section 1415, which includes an explanation of how complaint forms are used and how to file a complaint with states' LTC ombudsman programs and survey and certification programs;

(6) Summary information on the number, type, severity, and outcome of substantiated complaints; and

(7) The number of adjudicated criminal violations by the nursing facility or crimes committed by nursing facility employees (a) that were committed inside a facility; (b) for crimes or violations committed outside a facility, the instances where these were elder abuse, neglect, exploitation, criminal sexual

abuse of an elder, or other violations that resulted in serious bodily injury; and (c) the number of civil monetary penalties levied against the facility, employees, contractors, and other agents.

The modifications of Nursing Home Compare described in this section would become effective within one year after enactment, except that the Secretary would ensure that Ownership and Affiliated Parties, and Accountability Information as described in Section 1411, would be included on the website within one year of the date when those requirements were implemented.

The Secretary is further directed to undertake, within one year after enactment, a process to review and modify the Nursing Home Compare website that would address the accuracy, clarity of presentation, timeliness, and comprehensiveness of the information reported on the website, and modify or revamp the website in accordance with the Secretary's findings. This website review process would include consultation with state LTC ombudsman programs, consumer advocacy groups, provider stakeholder groups, and representatives of programs or groups the Secretary determines appropriate.

To improve the public's access to timely information on state survey and certification inspections, states would be required to submit information, including any enforcement actions, to the Secretary not later than the date when the state nursing home surveyors sent that information to facilities. Corrections to prior information submitted to the state also would need to be submitted to the Secretary in a timely manner. The Secretary is directed to update the Nursing Home Compare website with the information from states' survey and certification inspections as expeditiously as practicable, but at least quarterly. This requirement would be required within one year after this provision became effective.

The Secretary is also directed to conduct a Special Focus Facility program for enforcement of requirements for SNFs and nursing facilities that the Secretary identified as having substantially failed to meet applicable requirements of this provision. Under the Special Focus Facility program, the Secretary would conduct a survey of each facility in the program at least every six months.

Within one year of the effective date of this provision, SNFs and nursing facilities would be required to make available for any individual's review reports on surveys, certifications, and complaint investigations for the past three years and to post notices in prominent and accessible facility areas that these reports are available for inspection. These reports would need to exclude information identifying complainants or residents.

The Secretary would be required to provide guidance to states on how to establish Internet links to Form 2567 state inspection reports (or successor forms), complaint investigation reports, and facilities' correction plans or other responses to Form 2567. This information would be available on the state website for SNFs and nursing facilities. These reports also would be required to exclude information that identifies complainants or residents. In addition, the Secretary shall, if possible, include such reports on Nursing Home Compare.

States would be required to maintain a consumer-oriented website that provided useful information on all SNF and nursing

facilities operating within that state. The information on each facility would include Form 2567 state inspection reports (or successor forms), complaint investigation reports, facilities' plans of correction, and other information as determined useful by the Secretary or the state for consumers to use in assessing the quality of LTC options and the quality of care in individual facilities.

Section 1414. Reporting of expenditures

Current Law

No comparable provisions are in current law that require SNFs or nursing facilities to report expenditures.

Proposed Law

Experts on nursing home quality have determined that the vast majority of nursing homes fail to provide adequate staffing to provide proper care for residents. This provision would make it possible for policymakers and other interested parties to accurately determine and analyze how much funding a facility or chain dedicates to staffing.

Within one year of the effective date of this provision, the Secretary would consult with private sector accountants with knowledge of SNF cost reports to re-design cost report forms to separately capture wages and benefit expenditures for direct care staff.

Beginning with cost reports submitted three years after the effective date of this provision, SNFs would need to separately report direct care staff wages and benefits including breaking out, at a minimum, data for registered nurses, licensed professional nurses, certified nurse assistants, and other medical and therapy staff.

Within 30 months (2½ years) of the effective date of this provision, the Secretary, in consultation with OIG, the Medicare Payment Advisory Commission (MedPAC), and other experts identified by the Secretary, would categorize SNF's newly collected annual expenditure data for each facility, regardless of payment source, into the following functional accounts: spending on direct care services, including nursing, therapy, and medical services; spending on indirect care, including housekeeping and dietary services; capital assets, including building and land costs; and administrative services costs. The Secretary would establish procedures to make the expenditure data submitted under this provision, readily available to interested parties upon request, subject to requirements established by the Secretary.

The Subcommittee on Health of the House Committee on Ways and Means heard testimony recommending the creation of cost centers as a way to improve nursing home financial accountability at a hearing held on November 15, 2007. This provision would make it possible for policymakers and other interested parties to accurately determine and analyze how much funding a facility or chain dedicates to one of the most important aspects of resident care—staffing. Medicare cost reports do not currently capture this information, with the result that facilities may, if they wish, easily save money by making decisions to cut staff. While research has established that staffing levels below a certain threshold are detrimental to good resident care, no consensus among policymakers has yet been achieved about the level of staffing that should be in place to

assure good or optimal care. This new source of data on what facilities spend on staffing, in conjunction with Section 1416, which improves data on staffing levels, will improve the quality and transparency of data on staffing levels and funding and ease analyses of the relationship between spending on staffing, staffing levels, and quality of care.

Section 1415. Standardized complaint form

Current Law

There are no provisions in current law requiring use of a standardized complaint form. Oversight of nursing homes is a shared federal-state responsibility. Based on statutory requirements, CMS defines standards that nursing homes must meet to participate in the Medicare and Medicaid programs and contracts with states to assess whether homes meet these standards through annual surveys and complaint investigations. A range of statutorily defined sanctions is available to CMS and the states to help ensure that homes maintain compliance with federal quality requirements. CMS also is responsible for monitoring the adequacy of state survey activities.

Every nursing home receiving Medicare or Medicaid payment must undergo a standard survey not less than once every 15 months, and the statewide average interval for these surveys must not exceed 12 months. During a standard survey, separate teams of surveyors conduct a comprehensive assessment of federal quality-of-care and fire safety requirements. In contrast, complaint investigations generally focus on a specific allegation regarding resident care or safety.

The quality-of-care component of a survey focuses on determining whether (1) the care and services provided meet the assessed needs of the residents and (2) the home is providing adequate quality care, including preventing avoidable pressure sores, weight loss, and accidents. Nursing homes that participate in Medicare and Medicaid are required to periodically assess residents' care needs in 17 areas, such as mood and behavior, physical functioning, and skin conditions, in order to develop an appropriate plan of care. Such resident assessment data are known as the minimum data set (MDS). To assess the care provided by SNF and nursing facilities, surveyors select a sample of residents and (1) review data derived from the residents' MDS assessments and medical records; (2) interview nursing home staff, residents, and family members; and (3) observe care provided to residents during the course of the survey. CMS establishes specific investigative protocols for state survey teams—generally consisting of RNs, social workers, dieticians, and other specialists—to use in conducting surveys. These procedural instructions are intended to make the on-site surveys thorough and consistent across states.

Complaint investigations provide an opportunity for state surveyors to intervene promptly if problems arise between standard surveys. Complaints may be filed against a home by a resident, the resident's family, or a nursing home employee either verbally, via a complaint hotline, or in writing. Surveyors generally follow state procedures when investigating complaints but must comply with certain federal guidelines and time frames. In cases involving resi-

dent abuse, such as pushing, slapping, beating, or otherwise assaulting a resident by individuals to whom their care has been entrusted, state survey agencies may notify state or local law enforcement agencies that can initiate criminal investigations. States must maintain a registry of qualified nurse aides, the primary caregivers in nursing homes, that includes any findings that an aide has been responsible for abuse, neglect, or theft of a resident's property. The inclusion of such a finding constitutes a ban on nursing home employment.

Proposed Law

Currently, there is inadequate documentation by the federal government and by states of the number and type of complaints that residents and families file, the processes used to examine these complaints, and how and if they are resolved. Section 1415 is designed to address these flaws by requiring states to establish more standardized, uniform processes and procedures for handling and addressing complaints, and in so doing, to improve resident care. This section also puts in place whistleblower protections for nursing home employees who bring a serious quality or safety issue to the attention of supervisors or owners.

The Secretary would be required to develop a standardized complaint form for SNF and nursing facility residents or their representatives to use in filing complaints on SNFs and nursing facilities to state survey and certification agencies and state LTC ombudsman programs. States would be required to make the new standardized complaint form available on request to SNF residents, people acting on behalf of residents, and employees or representatives of SNF and nursing facility employees.

States also would be required to establish a complaint resolution process that ensures that SNF and nursing facility residents, their representatives, or employees are not denied access to residents or retaliated against for complaining, in good faith, about quality of care or other issues in a facility, regardless of whether residents, their representatives or employees used the standardized form or some other method to submit their complaint. The state complaint resolution procedures would be required to include procedures to ensure accurate tracking of complaints, determine the likely severity of the complaint, investigate complaints, and ensure that the identity of complainants would be kept confidential and deadlines for responding to complaints and procedures that would enable a complainant to track the complaint and investigation.

The complaint resolution process would be required to include whistleblower protection prohibitions against retaliation to ensure that SNF and nursing facility employees would not be penalized, discriminated, or retaliated against because they or anyone they requested to act on their behalf, in good faith, complained about the quality of care, services provided, or other issues related to quality of care or service in a nursing facility. This retaliatory prohibition applies regardless of whether employees used the new standard or some other complaint method. This protection against retaliatory actions extends to any aspect of complainants' employment, including discharge, promotion, compensation, terms, conditions, or employment privileges, or termination of a contract for services. SNFs would not be permitted to file complaints or reports with state pro-

fessional disciplinary agencies against current or former employees because they (or their agents), acting in good faith, submitted complaints about quality of care or services in their employers' facility.

SNF and nursing facility employees who believed they were penalized, discriminated, or retaliated against, or lost service contracts because they submitted a quality of care complaint against a SNF, would be able to seek remedy in an appropriate U.S. district court. U.S. district courts would have jurisdiction to grant complete relief, regardless of citizenship or amount in question, but not limited to injunction, such as reinstatement, compensatory damages (reimbursement of lost wages, compensation, and benefits), costs of litigation (including attorney's and expert witnesses' fees), exemplary damages, and other relief deemed proper by the court.

SNF and nursing facility employees' rights under this provision would not be diminished by contract or other agreement and would not diminish greater protection through other federal or state laws, contracts, or agreements. Nothing in this provision would prevent a resident, an agent acting on their behalf, or an employee from submitting a complaint in any manner and not necessarily by using the standardized complaint form. SNFs and nursing facilities would be required to conspicuously post in an appropriate location a sign as specified by the Secretary that identifies employees' rights to bring complaints against the facility. Individuals would be considered to be acting in good faith when submitting complaints if they believe that (1) their complaint is true and (2) a violation has or may have occurred related to Medicare provisions of the Social Security Act. These amendments would apply one year after the effective date of this provision.

Section 1416. Ensuring staffing accountability

Current Law

No comparable provisions are in current law for SNF and nursing facilities to report staff levels that are derived from payroll data in a uniform format.

Proposed Law

Experts on nursing home quality have determined that the vast majority of nursing homes fail to provide adequate staffing to provide proper care for residents. This provision would improve and standardize the reporting of nursing home staffing levels. The additional reporting on staffing levels would help policymakers and families better assess the impact of staffing on quality of care, and determine which nursing homes are adequately staffed.

Within two years after the effective date of this provision, SNFs and nursing facilities would be required to electronically submit to the Secretary direct care staffing information, including agency and contract staff. In developing specifications and direct care staffing data requirements, the Secretary would consult with state long-term care ombudsman programs, consumer advocacy groups, provider stakeholder groups, employees and their representatives, and other parties deemed appropriate by the Secretary. The direct care staffing specifications would be based on payroll and other verifiable data provided by SNFs and nursing facilities to the Sec-

retary in a uniform format, and reporting on contract staff would be separate from information on employees. Specifications would include (1) work categories of certified employees, including registered nurses, licensed practical nurses, licensed vocational nurses, certified nursing assistants, therapists, or other medical personnel; (2) resident census data and information on resident case mix; (3) an established reporting schedule; and (4) employee tenure and turnover, as well as hours of care provided by each certified employee category, per resident per day.

PART 2—TARGETING ENFORCEMENT

Section 1421. Civil money penalties

Current Law

Under Medicaid law, states have authority either by regulation or law to impose money penalties of up to $10,000 for each day of noncompliance, deny payments, appoint temporary management to bring facilities into compliance, and close facilities if nursing facilities fail to meet state plan requirements or have deficiencies that jeopardize residents' health or safety. State expenses for enforcement may be funded under the proper and efficient state plan administration provision of the Medicaid Statute (Title XIX of the Social Security Act). States also have authority to establish reward programs for nursing facilities that deliver the highest quality care to medical assistance patients and fund these incentive rewards programs under Medicaid's proper and efficient administration provisions.

Proposed Law

Multiple reports issued by the Government Accountability Office have suggested that the penalties originally legislated as part of the 1987 Nursing Home Reform Act, and which took effect in 1994, may not be having a significant deterrent effect for several reasons.

The provisions in this section are designed to update and more effectively target civil money penalties (CMPs) authority by focusing higher penalties on serious quality of care and safety deficiencies that cause harm to residents, that put their health in immediate jeopardy, or that are life-threatening. Other modifications would allow facilities that self-report and promptly correct deficiencies to receive a 50% reduction in their CMP. Finally, the section aims to make more timely collection of CMPs by allowing the federal government and states to collect fines following an initial independent dispute resolution process and to escrow these funds, pending the results of any further appeals.

For SNFs and nursing facilities, the Secretary—and for nursing facilities, the states—would have the authority to impose per instance or per day civil money penalties for each instance or each day of noncompliance (as determined appropriate by the Secretary). The amounts of the per instance CMPs would be the following: (1) in the case where a deficiency is the direct proximate cause of a resident's death, the penalty would not exceed $100,000; (2) in each case where a facility is cited for a resident's actual harm or immediate jeopardy, an amount equal to or greater than $3,050, but not more than $25,000; and (3) in each case of any other deficiency, penalty amounts per deficiency would range from not less than

$250 to not more than $3,050. The amount of the applicable per day CMPs would be the following: (1) an amount equal to or greater than $3,050 up to $25,000 where facilities were cited for deficiencies that caused actual harm or immediate jeopardy to residents; and (2) an amount between $250 and $3,050 for each case of any other deficiency.

Subject to limitations where reductions are prohibited if SNFs and nursing facilities self-report and promptly correct deficiencies within 10 calendar days after imposition of a CMP, the Secretary—or the state if applicable—may reduce the amount of the imposed CMP by up to 50%. The Secretary—or the state if applicable—would be prohibited from reducing CMPs for SNFs where the Secretary had previously reduced a penalty for that facility in the last year, with respect to a repeat deficiency. The Secretary—or the state if applicable—would be prohibited from reducing CMPs for other deficiencies: (1) where the deficiency was found to result in a pattern of harm or widespread harm that immediately jeopardizes residents' safety or health; or (2) where a deficiency resulted in the death of a patient.

Aggregate CMP reductions would not be permitted to exceed 35% on the basis of self-reporting, on the basis of a waiver or an appeal, or on the basis of both a waiver and an appeal. In collecting CMPs, the Secretary—or the state if applicable—must provide for the facility to participate in an independent informal dispute resolution process that generates a written record prior to penalty collection, and cannot impose additional per-day penalties during the pendency of the dispute resolution process; may provide an escrow account for fees to be held beginning on the earlier of 90 days after fees are imposed or the date the informal resolution process was completed and may provide that penalty fees are held in escrow accounts until appeals are resolved.

To implement independent information dispute resolution (IIDR), the Secretary shall promulgate regulations pursuant to notice and comment rulemaking under the Administrative Procedures Act. Such regulations shall allow IIDR to be conducted by an independent state agency (including an umbrella agency, such as the Health and Human Services Commission), a Quality Improvement Organization, or the state survey agency, so long as the participants in IIDR are not involved in the initial decision to cite the deficiency and impose the remedy. Whoever is authorized to conduct IIDR must not have any conflicts of interest. The regulations may address the type of IIDR available to SNFs and NFs (desk review or in-person meeting) and the circumstances of each; may determine whether and when attorneys may represent the parties before IIDR; and may limit the duration of in-person meetings, depending on the scope and severity of deficiencies and other factors as determined by the Secretary.

As under current informal dispute resolution (IDR) processes, facilities may challenge only the factual basis of the deficiency. They may not challenge issues related to surveyors' compliance with the survey process or the scope and severity of the deficiencies. Also as under current IDR processes, states and the Secretary retain the right to reject the IIDR recommendations and to cite deficiencies and to impose remedies, as the states and the Secretary determine

appropriate. Finally, any person shall have the right to attend and participate in the conference.

In situations where appeals are resolved in favor of facilities, the Secretary—or the state if applicable—may provide, if escrow accounts are established, that penalty fees would be returned to facilities with interest; and may provide, when facility appeals are unsuccessful, that some portion of penalty amounts are used to support state LTC ombudsman activities and to protect residents, including residents who reside in facilities that voluntarily or involuntarily close or are decertified.

The activities funded with CMPs may include using the penalty funds to offset costs of relocating residents to home- and community-based settings and other facilities, as well as projects to support resident and family councils and other consumer quality of care involvement (including joint training of staff and surveyors, technical assistance for facilities under quality assurance programs, the appointment of temporary management, and other activities approved by the Secretary).

Provisions of the Social Security Act, Section 1128A (except subsections (a) and (b)) and provisions that require a hearing prior to imposing CMPs, also would apply to the CMPs described here.

The CMP amendments would apply one year after the effective date of the provision.

Section 1422. National independent monitor pilot program

Current Law

No comparable provisions are in current law for a national independent monitor program.

Proposed Law

Promising work pioneered by the HHS OIG in the context of agreements with nursing home chains that have chronic, severe quality and safety problems, and which agree to a system of close monitoring by independent contractors with expertise to undertake "root cause analyses" provide a model for CMS, as the principal regulatory agency, to develop a similar mechanism of oversight.

Within one year of the effective date of this provision, the Secretary in consultation with OIG would establish a pilot program to develop, test, and implement use of an independent monitor to oversee interstate and large intrastate SNF and nursing facility chains. The Secretary would select SNF and nursing facility chains to participate in a pilot independent monitor program from among those chains that apply to participate. The pilot independent monitor program would be conducted over two years. The pilot independent monitor program would commence within one year of the effective date of this provision.

The Secretary shall select chains to participate in the pilot program based on criteria selected by the Secretary, including chains with one or more facilities in CMS's Special Focus Facility program (or a successor program) or one or more facilities with a record of repeated serious safety and quality of care deficiencies.

An independent monitor that enters into a contract to participate in the pilot program would have the following responsibilities: conduct periodic reviews and root-cause deficiency analyses of chains

to assess their compliance with state and federal laws and regulations; sustained oversight of chains (whether public or private) to involve chain owners and principal partners in facilitating compliance with state and federal laws and regulations applicable to facilities; analyze management structure, expenditure distribution, and nurse staff levels of facilities of the chain compared to resident census, staff turnover rates, and tenure; report findings and recommendations with respect to reviews, analyses, and oversight to the chain and facilities in the chain, to the Secretary and to relevant states; and publish the results of these reviews, analyses, and oversight.

Within 10 days of a chain receiving a finding (of deficiency) from the independent monitor, the chain would be required to submit a report to the independent monitor (1) that outlines corrective actions the chain will take to address the independent monitor's recommendations or (2) indicates that the chain will not implement the recommendations and why it will not do so.

Within 10 days after receiving the chain's response-report, the independent monitor would be required to submit a report containing the monitor's final recommendations to: the chain, the chain's facilities, the Secretary, and the state or states where the facilities in question operate.

The chain would be responsible for a portion of the costs associated with the appointment of the pilot program independent monitors. The chain would pay their portion of the costs to the Secretary. The Secretary would determine the amount and procedures for collecting the independent pilot program costs. The Secretary would have authority to waive provisions of the Medicare and Medicaid statutes (Titles XVIII and XIX of the Social Security Act) if necessary to implement the independent monitor pilot program. Appropriations necessary to carry out the independent monitor pilot program would be authorized.

The OIG would evaluate the independent monitor program within six months of completion of the program. The OIG would submit a report to Congress on the independent monitor program that included recommendations for legislative and administrative action.

Section 1423. Notification of facility closure

Current Law

Medicare and Medicaid law identifies patients' rights and SNF and nursing home requirements in ensuring residents are aware of their rights. Residents have specific discharge and transfer rights, which include advance notification in cases where facilities close.

Proposed Law

When nursing homes close, residents and their families are left to quickly find an alternative setting for care, a task that can be challenging under a tight timeframe and if there is limited availability or variable quality in neighboring institutions. This provision ensures that residents and their families have proper advance notice of a closure, and that residents are relocated prior to closure.

SNF and nursing facility administrators would be required to issue written notification of intent to close to the Secretary, LTC Ombudsman programs in the state where facilities are located, fa-

cility residents, and facility residents' legal representatives or other responsible parties. SNF and nursing facility administrators would need to provide 60 days' notice of their pending closure or, if closed by the Secretary, within the time frame specified by the Secretary. SNF and nursing facility administrators would be required not to admit new patients on or after written notice of planned closure; and to include in the closure notices the plans to transfer and adequately relocate facility residents by a specified date prior to closure that has been approved by the state, and which also would include assurances that residents will be transferred to the most appropriate facilities or settings in terms of quality, services, and location as determined by residents' needs, best interests, and preferences.

The state would ensure that before SNFs and nursing facilities close, all residents would be relocated to alternative settings, such as home- and community-based settings or other facilities, taking into consideration the needs and best interests of each resident. The Secretary may determine the appropriate payment and whether and for how long to continue payments to closing facilities during the period after the notification of impending closure is submitted and the date when residents are transferred to other facilities or alternative settings. The notification of facility closure amendments would apply one year after the effective date of the provision.

PART 3—IMPROVING STAFF TRAINING

Section 1431. Dementia and abuse prevention training

Current Law

Under Medicare law, the Secretary establishes SNF requirements for nurse aide training and competency evaluation programs and requirements for states to follow in evaluating and re-evaluating these training programs. Similarly under Medicaid law, the Secretary establishes nursing facility requirements for nurse aide training and competency evaluation programs and requirements for states to follow in evaluating and re-evaluating these training programs.

Proposed Law

This provision would add dementia and abuse prevention training to staff training requirements for SNF and nursing facilities. The Secretary would revise initial nurse aide training, competency, and evaluation program requirements to include dementia management and patient abuse prevention training. If determined to be appropriate, the Secretary also may include dementia management training and patient abuse prevention in ongoing nurse aide training, competency, and evaluation program requirements. The dementia and abuse prevention training amendments would apply one year after the effective date of the provision.

It has been reported that the majority of older nursing home residents have some form of psychiatric illness, with dementia affecting 1 out of 5 residents. Timely recognition and intervention are key to the optimal care of older adults with dementia. Requiring appropriate training so that nursing home staff are best equipped to manage the care of these patients is important to ensuring good

quality of care. This provision will direct the Secretary to include dementia and abuse prevention training of nursing home staff.

Section 1432. Study and report on training required for certified nurse aides and supervisory staff

Current Law

Medicare and Medicaid law have provisions that govern training for nurse aides for both SNF and nursing facilities. These laws require the Secretary to establish requirements for nurse aide training and competency evaluation programs as well as parameters for states to use in monitoring these programs.

Proposed Law

Certified nurse aides and supervisory staff are typically the primary caregivers in a skilled nursing facility. It is important to know whether existing training requirements are sufficient to ensure appropriate care for the patient population in these facilities.

The Secretary would be required to conduct a study within two years of the effective date of this provision on the content of certified nurse aide and supervisory staff training in SNFs and nursing facilities. The report shall include the following: whether the 75 hours of initial nurse aide training required should be increased and if so, what the required number of initial training hours should be recommended (including dementia related training); and whether the 12 hours per year of ongoing nurse aide training should be increased and what content changes are recommended. In assessing the number of hours of initial nurse aide training required, the Secretary would consult with states that already have increased the number of hours of initial training above 75 hours. Within two years from the effective date of this provision, the Secretary would be required to submit a report to Congress on the certified nurse aide and supervisory training requirements. The report would include recommendations for legislative and administrative action.

Section 1433. Qualification of director of food services of a Medicaid nursing facility

Current Law

Medicaid law requires that participating nursing homes provide dietary services that assure that the meals meet the daily nutritional and special dietary needs of each resident. Federal regulation requires the facility to employ a qualified dietitian either full-time, part-time, or on a consultant basis. If a qualified dietitian is not employed full-time, the facility must designate a person to serve as the director of food service who receives frequently scheduled consultation from a qualified dietitian. A qualified dietitian is defined as one who is registered by the Commission on Dietetic Registration of the American Dietetic Association, or on the basis of education, training, or experience in identification of dietary needs, planning, and the implementation of dietary programs.

Proposed Law

The provision would require that the full-time director of food services of the facility, if not a qualified dietitian, be accredited as a Certified Dietary Manager meeting the requirements of the Certi-

fying Board for Dietary Managers, or as a Dietetic Technician, Registered meeting the requirements of the Commission on Dietetic Registration, or have equivalent military or academic qualifications, as specified by the Secretary of HHS. This provision would take effect on the date that is 180 days after enactment.

Subtitle C—Quality Measurements

Section 1441. Establishment of national priorities for quality improvement

Current Law

There are no provisions in current law that require the development of national priorities for performance improvement (directed either at the Secretary of Health and Human Services or the Agency for Healthcare Research and Quality).

Section 1890 of the Social Security Act, however, requires the Secretary to identify and have in effect a contract with a consensus-based entity, such as the National Quality Forum, to perform the following duties: (1) synthesize evidence and convene stakeholders to make recommendations, with respect to activities conducted under this Act, on an integrated national strategy and priorities for health care performance measurement in all applicable settings; (2) provide for the endorsement of standardized health care performance measures; (3) establish and implement a process to ensure that endorsed measures are updated or retired based on new evidence; (4) promote the development of electronic health records that facilitate the collection of performance measurement data; and (5) report annually to Congress.

The National Quality Forum has been awarded this contract and recently released its first report, *Improving Healthcare Performance: Setting Priorities and Enhancing Measurement Capacity,* in fulfillment of this statutory requirement.

Proposed Law

This provision would amend Title XI of the Social Security Act, as amended by section 1401(a), by adding a new Part E—Quality Improvement—Establishment of National Priorities for Performance Improvement. Specifically, it would add a new section 1191 to establish national priorities for performance improvement.

This section would require the Secretary to establish and periodically update (not less frequently than triennially) national priorities for performance improvement. Specifically, it would require the Secretary, when establishing and updating national priorities, to solicit and consider recommendations from multiple outside stakeholders.

This provision would require, with respect to the national priorities for performance improvement, the Secretary to give priority to areas in the delivery of health care services that (1) address a large burden of disease, as specified; (2) have the greatest potential to decrease morbidity and mortality in the United States, as specified; (3) have the greatest potential for improving the performance, affordability, and patient-centeredness of health care; (4) address health disparities across groups and areas; and (5) have the potential for rapid improvement due to existing evidence or standards of care.

For the purposes of this Section: (1) consensus-based entity would mean an entity with a contract with the Secretary under Section 1890 of the Social Security Act; and (2) quality measure would mean a national consensus standard for measuring the performance and improvement of population health, or of institutional providers of services, physicians, and other health care practitioners in the delivery of health care services.

This provision would require the Secretary to provide for the transfer, from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund, of $2 million for each of the fiscal years 2010 through 2014. It would also authorize the appropriation of $2 million for each of the fiscal years 2010 through 2014 from any funds in the Treasury not already appropriated.

It is the Committee's intent that the priorities established by the Secretary will have wide applicability and help direct health improvement activities across the nation's health care system.

Section 1442. Development of new quality measures; GAO evaluation of data collection process for quality measurement

Current Law

Section 1110(a)(1) of Title XI of the Social Security Act provides general authority to appropriate such sums as may be necessary for making grants to States and public and other organizations and agencies for research that will help improve the administration and effectiveness of the programs carried out under the Social Security Act, among other things.

The Agency for Healthcare Research and Quality (AHRQ) has significant existing statutory authorities with respect to the development of quality measures. Specifically, the Agency's mission, among other things, is to promote health care quality improvement by conducting and supporting research that develops and presents scientific evidence regarding all aspects of health care, including methods for measuring quality and strategies for improving quality (Section 901 of the PHSA).

Section 912 of the Public Health Service Act (PHSA) requires AHRQ to provide support for public and private efforts to improve health care quality, and that the role of the Agency shall specifically include the ongoing development, testing, and dissemination of quality measures, including measures of health and functional outcomes and the compilation and dissemination of health care quality measures developed in the private and public sector. To comply with this last requirement, the Agency has established the National Quality Measures Clearinghouse, an online resource that compiles and catalogues quality measures.

Finally, Section 917 of the PHSA requires AHRQ to coordinate all research, evaluations, and demonstrations related to health services research, quality measurement and quality improvement activities undertaken and supported by the Federal Government.

Proposed Law

This section would amend Part E of Title XI of the Social Security Act, as added by section 1441, by adding two new sections: sec-

tion 1192: development of new quality measures, and section 1193: GAO evaluation of data collection process for quality measurement.

Robust, accurate, and appropriate measures of health care quality are a critical component of improving the delivery system and health outcomes. It is difficult to develop and implement strategies to improve patient health without such measures, but in many cases measures do not exist or have yet to be fully developed. In other cases, measures do exist but need to be updated or modernized. Putting additional resources into quality measure development will speed the development of new measures and address shortcomings of existing measures.

Section 1192. This section would require the Secretary to enter into agreements with qualified entities to develop quality measures for the delivery of health care services in the United States. The Secretary would be authorized to carry out these agreements by contract, grant, or otherwise. In addition, this Section would require the Secretary to seek public input and take into consideration recommendations of the consensus-based entity with a contract with the Secretary under Section 1890(a) of the Social Security Act. The Secretary would be required, as specified, to determine areas in which quality measures for assessing health care services in the United States are needed.

Quality measures developed under these agreements would be required to be designed (1) to assess outcomes and functional status of patients; (2) to assess the continuity and coordination of care and care transitions, as specified; (3) to assess patient experience and patient engagement; (4) to assess the safety, effectiveness, and timeliness of care; (5) to assess health disparities as specified; (6) to assess the efficiency and resource use in the provision of care; (7) to the extent feasible, to be collected as part of health information technologies supporting better delivery of health care services; (8) to be available free of charge to users for the use of such measures; and (9) to assess delivery of health care service to individuals regardless of age.

This provision would also require the Secretary to make proposed quality measures available to the public; would authorize the Secretary to use amounts made available under this Section to fund the testing of proposed quality measures by qualified entities, as specified; and would authorize the Secretary to use amounts made available under this Section to fund the updating, by consensus-based entities, of quality measures that have been previously endorsed by such an entity as new evidence is developed (consistent with Section 1890(b)(3) of the Social Security Act).

Grants would be authorized to be made under this Section only if an application for the grant would be submitted to the Secretary as specified and the Secretary would be required to ensure, before entering into agreements with qualified entities, that the entity is a public, nonprofit or academic institution with technical expertise in the area of health quality measurement.

For purposes of carrying out this section, the Secretary would be required to provide for the transfer, from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund, of $25 million each year from fiscal years 2010 through 2014. In addition, this section would authorize the appro-

priation of $25 million for each of the fiscal years 2010 through 2014 from any funds in the Treasury not otherwise appropriated.

Section 1193. This Section would require the Comptroller General of the United States to conduct periodic evaluations of the implementation of the data collection processes for quality measures used by the Secretary.

It would require the Comptroller General to determine: (1) whether the system for the collection of data for quality measures provides for validation of data as relevant and scientifically credible; (2) whether data collection efforts under the system use the most efficient and cost-effective means in a manner that minimizes administrative burden on persons required to collect data and that adequately protects the privacy of patients' personal health information and provides data security; (3) whether standards under the system provide for an opportunity for physicians and other clinicians and institutional providers of services to review and correct findings; and (4) the extent to which quality measures are consistent with requirements for quality measures developed under this Act, as specified, or result in direct or indirect costs to users of such measures.

This section would require the Comptroller General to report to Congress and to the Secretary on the findings and conclusions of the results of each such evaluation.

Section 1443. Multi-stakeholder pre-rulemaking input into selection of quality measures

Current Law

None.

Proposed Law

The Medicare program is increasingly making use of health care quality measures in administration of its payment systems. As the program continues to evolve, the Committee expects this trend will continue and that a larger portion of provider payments will eventually become linked to performance on such measures. For instance, the Accountable Care Organization pilot program in section 1301 of this legislation will make extensive use of quality measures.

Given the greater reliance on quality measures within Medicare, the process for selecting such measures should be an open and collaborative one. This section provides the Medicare program with a process for engaging with a wide array of stakeholders and interested parties, including patient advocacy organizations, employers, private purchasers, and providers. Such engagement will help ensure that Medicare selects the most appropriate measures for each of its payment systems and promote consistent use of measures among other stakeholders.

This section would amend section 1808 of the Social Security Act by adding a new subsection (d): Multi-Stakeholder Pre-Rulemaking Input into Selection of Quality Measures.

The new subsection would require the Secretary, not later than December 1 before each year (beginning with 2011), to publish a list of measures being considered for selection for quality measurement by the Secretary in rulemaking with respect to payment sys-

tems under Title XVIII of the Social Security Act, as specified. This section would also require the consensus-based entity that has entered into a contract under section 1890 of the Social Security Act to convene multi-stakeholder groups to provide recommendations on the selection of individual or composite quality measures, for use in public reporting of performance information or in public health care programs. The section would also require the consensus-based entity, not later than February 1 of each year (beginning with 2011), to transmit to the Secretary the recommendations of these multi-stakeholder groups, as specified.

This section would require the consensus-based entity, in convening multi-stakeholder groups, to provide for an open and transparent process for the activities conducted pursuant to such convening. This process would have to ensure that the selection of representatives of multi-stakeholder groups includes provision for public nominations for, and the opportunity for public comment on, such selection. This section would require the respective proposed rule to contain a summary of the recommendations made by the multi-stakeholder groups under this section, as well as other comments received regarding the proposed measures, and the extent to which such proposed rule follows such recommendations and the rationale for not following such recommendations.

The provision would define the term "multi-stakeholder groups" to mean, with respect to a quality measure, a voluntary collaborative of organizations representing persons interested in or affected by the use of such quality measure, such as the following: (1) hospitals and other institutional providers; (2) physicians; (3) health care quality alliances; (4) nurses and other health care practitioners; (5) health plans; (6) patient advocates and consumer groups; (7) employers; (8) public and private purchasers of health care items and services; (9) labor organizations; (10) relevant departments or agencies of the United States; (11) biopharmaceutical companies and manufacturers of medical devices; (12) licensing, credentialing, and accrediting bodies.

For purposes of carrying out this section, the Secretary would be required to provide for the transfer, from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund under, of $1 million each year from fiscal years 2010 through 2014. In addition, this section would authorize the appropriation of $1 million for each of the fiscal years 2010 through 2014 from any funds in the Treasury not otherwise appropriated.

Section 1444. Application of quality measures

Current Law

Section 1886(b)(3)(B)(vii) of the Social Security Act requires hospitals to submit specified quality data to the Secretary in order to receive a full annual payment update. Section 1886(b)(3)(B)(viii)(V) provides that beginning with payments in fiscal year 2008, the Secretary shall add additional quality measures that reflect consensus among affected parties and, to the extent feasible and practicable, shall include measures set forth by one or more national consensus building entities.

Section 1833(t)(17)(A)(i) of the Social Security Act requires hospitals to submit data on outpatient quality measures to the Sec-

retary in order to receive a full outpatient department (OPD) fee schedule increase. In addition, section 1833(t)(17)(C)(i) requires the Secretary to develop measures that reflect consensus among affected parties, and to the extent feasible and practicable, to include measures set forth by one or more national consensus building entities.

Section 1848(k) of the Social Security Act requires the Secretary to implement a system for the reporting by eligible professionals of data on specified quality measures. Section 1848(k)(2)(C)(i) requires that for 2010 and subsequent years, the quality measures specified under this section will be such measures selected by the Secretary from measures that have been endorsed by the consensus-based entity with a contract under section 1890(a) of the Social Security Act. Section 1848(k)(2)(C)(ii) provides an exception in the case of a specified area or medical topic for which feasible and practical measures have not been endorsed, stipulating that such measures may be used as long as due consideration has been given to measures that have been endorsed or adopted by a consensus organization.

Section 1881(h)(1) of the Social Security Act requires renal dialysis facilities to meet (or exceed) a total performance score, based on quality measures as specified, in order to receive full payment for services furnished on or after January 1, 2012. In addition, section 1881(h)(2)(B) requires the Secretary to specify measures that have been endorsed by the consensus-based entity with a contract under section 1890(a), and authorizes the Secretary, where endorsed measures are not available, to use such measures provided that due consideration has been given to measures that have been endorsed or adopted by a consensus organization.

Section 1890 of the Social Security Act requires the Secretary to identify and have in effect a contract with a consensus-based entity, such as the National Quality Forum, to perform certain duties. Included in these, at section 1890(b)(2) of the Social Security Act, is a requirement that the consensus-based entity provide for the endorsement of standardized health care performance measures, as specified.

Proposed Law

To the extent feasible, the Medicare program should use measures of health quality that have been endorsed by a consensus-based organization, such as the National Quality Forum. The use of endorsed measures will help ensure that Medicare is utilizing the most appropriate and robust measures, while also using measures that have widespread support among various health care stakeholders.

Generally, this section places requirements on the Secretary when selecting quality measures for use in existing quality programs for inpatient, outpatient, physician and renal dialysis services. These requirements relate to the endorsement of quality measures. However, the Committee recognizes it is critical that the Medicare program maintain its independence and retain the flexibility to use non-endorsed measures when it deems necessary.

Specifically, this section would amend section 1886(b)(3)(B) of the Social Security Act to require the Secretary to select measures for purposes of reporting data for inpatient hospital services furnished

during fiscal year 2012 and each subsequent year, that have been endorsed by the consensus-based entity with a contract with the Secretary under section 1890 of the Social Security Act. If feasible and practical measures were not available, the Secretary would be authorized to select a non-endorsed measure, providing the Secretary gives due consideration to endorsed or adopted measures. The Secretary would be required to submit non-endorsed measures to the entity for consideration for endorsement, and if the entity were to not endorse the measure, and the Secretary were to continue to use the measure, the Secretary would be required to include the rationale for its continued use in rulemaking. This section would also amend section 1833(t)(17) of the Social Security Act to require that the provisions added to section 1886 (above) would also apply to quality measures for covered outpatient department services.

This section would also amend sections 1848(k)(2)(C)(ii) and 1881(h)(2)(B)(ii) of the Social Security Act, to require the Secretary to submit non-endorsed measures for physicians' services and renal dialysis services, respectively, to the consensus-based entity for consideration for endorsement. It would further require the Secretary, if the measure does not gain endorsement and if the Secretary continues to use the measure, to provide a rationale for continued use in rulemaking.

This section would, by amending section 1890(b)(2) of the Social Security Act, require the consensus-based entity with a contract with the Secretary in section 1890 to explain the reasons underlying non-endorsement of a given measure, and to provide suggestions about changes to such measure that might make such a measure potentially endorsable.

This section would apply to quality measures applied for payment years beginning with 2012 or fiscal year 2012, as the case may be.

Section 1445. Consensus-based entity funding

Current Law

Section 1890 of the Social Security Act requires the Secretary to identify and have in effect a contract with a consensus-based entity, such as the National Quality Forum, to perform the following duties: (1) synthesize evidence and convene stakeholders to make recommendations, with respect to activities conducted under this Act, on an integrated national strategy and priorities for health care performance measurement in all applicable settings; (2) provide for the endorsement of standardized health care performance measures; (3) establish and implement a process to ensure that endorsed measures are updated or retired based on new evidence; (4) promote the development of electronic health records that facilitate the collection of performance measurement data; and (5) report annually to Congress.

Section 1890(d) of the Social Security Act provides for $10 million to fund the activities of the consensus-based entity under contract in this section for each of fiscal years 2009 through 2012.

Proposed Law

This provision is needed to provide funding available under CMS's current contract with the National Quality Forum to cover additional expenses related to implementation of section 1441 of this legislation, regarding multi-stakeholder input on the selection of quality measures.

This section would amend section 1890(d) of the Social Security Act to provide for $10 million only for fiscal year 2009, and $12 million for each of the fiscal years 2010 through 2012.

Section 1446. Quality indicators for care of people with Alzheimer's disease

Current Law

No provision.

Proposed Law

This provision would required the Secretary of HHS, acting through the Agency for Healthcare Research and Quality (AHRQ), to develop either directly or with commissioned projects, a core set of quality indicators for the provision of medical services to people with Alzheimer's disease and other dementias and a plan for implementing the indicators to measure the quality of care provided for people with these conditions by physicians, hospitals, and other medical, residential, and home care agencies and providers.

The Secretary would be required to submit a report to the Committees on Energy and Commerce and Ways and Means of the United States House of Representatives and the Committees on Finance and Health, Education, and Pensions of the United States Senate setting forth the status of their efforts to implement the above mentioned requirements.

Section 1447. Study on five star quality rating system

Current Law

The Nursing Home Compare website was developed by the Centers for Medicare and Medicaid Services (CMS) and launched in November 2002. The website was intended to bolster the agency's efforts to improve SNF and nursing facility quality of care and to make information on nursing home quality more accessible for long-term care consumers and their families. Medicare Nursing Home Compare includes national data on all nursing facilities that participate in Medicare and Medicaid. The data in Medicare Nursing Home Compare include facility ratings, selected results from survey and certification inspections, and staffing information on all Medicare and Medicaid SNFs and nursing facilities. Since its launch, CMS has enhanced the website by adding or improving quality measures and website navigation.

The Nursing Home Compare website includes a quality rating system that gives each nursing home a rating of between 1 and 5 stars. Nursing homes with 5 stars are considered to have much above average quality; nursing homes with 4 stars are considered to be above average quality; nursing homes with 3 stars are considered to be average; nursing homes with 2 stars are considered to

be below average and nursing homes with 1 star are considered to be much below average.

Proposed Law

The Comptroller of the United States is required to conduct a study on the Five-Star Quality Rating System (or a successor program) established by CMS and to submit the results of this study, together with recommendations, not later than 1 year after the date of enactment to Congress and the Secretary of HHS.

The study would be required to do the following:

(1) Determine whether the composite star rating should be eliminated in favor of a multi-dimensional system under which a star rating is assigned to each individual domain;

(2) Determine whether an appeals process should be implemented for the Five Star Rating System to address situations in which questionable, inaccurate, or incomplete data has been identified;

(3) Evaluate the appropriateness of any weighting methodology used to adjust quality measures, including an assessment of whether such methodology is validated, whether it takes into account resident characteristics, the appropriateness of the weighting of individual quality measures, and whether the accuracy of information to consumers would be enhanced if the standard survey were weighted more heavily than the complaint survey;

(4) Assess the appropriateness of the case-mix adjustment methodology used to evaluate staffing levels, along with the appropriateness of the staffing levels established by CMS, to achieve a 5-star rating given the absence of any existing federal nursing home staffing guidelines or Medicare funding to support these staffing levels;

(5) If the Comptroller General determines that such target staffing levels are appropriate, evaluate, in consultation with the Secretary of Health and Human Services, the cost of modifying the Medicare Skilled Nursing Facility Resource Utilization Groups to reflect the costs to facilities of providing staffing at these target levels;

(6) Evaluate how best to represent resident/consumer satisfaction under the rating system, and review approaches to report other facility-specific characteristics to enable consumers to better identify facilities that will meet their individual needs;

(7) Evaluate the impact of the rating system on Medicare skilled nursing facilities and Medicaid nursing facilities, including a review of potential problems associated with inaccurate or incomplete data and other unanticipated consequences reported by facilities; and

(8) Assess whether the national program should be suspended and replaced with a pilot program testing potential nursing home quality rating systems in a limited number of States.

Subtitle D—Physician Payments Sunshine Provision

Section 1451. Reports on financial relationships between manufacturers and distributors of covered drugs, devices, biologics, or medical supplies under Medicare, Medicaid, or CHIP and physicians and other health care entities and between physicians and other health care entities

Current Law

Under section 1128B(b) of the Social Security Act, referred to as the federal anti-kickback statute, it is a felony for a person to knowingly and willfully offer, pay, solicit, or receive anything of value (i.e., "remuneration") in return for a referral or to induce generation of business reimbursable under a federal health care program. The statute prohibits the offer or payment of remuneration for patient referrals, as well as the offer or payment of anything of value in return for purchasing, leasing, ordering, or arranging for, or recommending the purchase, lease, or ordering of any item or service that is reimbursable by a federal health care program. Persons found guilty of violating the anti-kickback statute may be subject to a fine of up to $25,000, imprisonment of up to five years, and exclusion from participation in federal health care programs for up to one year. However, a number of statutory and regulatory "safe harbors" to the anti-kickback statute protect various business arrangements from prosecution. Safe harbors include certain types of investment interests, personal services and management contracts, referral services, space rental or equipment rental arrangements, warranties, discounts, and employment arrangements. In 2003, OIG issued "Compliance Program Guidance for Pharmaceutical Manufacturers" (68 *Federal Register* 23731), which stated that pharmaceutical companies and their employees and agents often engage in a number of arrangements that offer benefits to physicians or others in a position to make or influence prohibited referrals under the anti-kickback statute. Examples of remunerative arrangements between pharmaceutical manufacturers and parties in a position to influence referrals that were cited by OIG included entertainment, recreation, travel, meals, or other benefits in association with information or marketing presentations, as well as gifts, gratuities, and other business courtesies. OIG indicated these arrangements potentially implicate the anti-kickback statute if any one purpose of the arrangement is to generate business for the pharmaceutical company.

Under section 1877 of the Social Security Act, the federal prohibition on physician self-referrals, if a physician (or an immediate family member of a physician) has a "financial relationship" with an entity, the physician may not make a referral to the entity for the furnishing of designated health services (DHS) for which payment may be made under Medicare or Medicaid, and the entity may not present (or cause to be presented) a claim to the federal health care program or bill to any individual or entity for DHS furnished pursuant to a prohibited referral. "Financial relationship" is defined as either an ownership or investment interest or a compensation arrangement. An ownership or investment interest may be equity, debt, or other means; however, section 1877(c) specifies that an ownership interest does not include certain investment se-

curities which may be purchased on terms generally available to the public and meet additional requirements, or that are shares of certain regulated investment companies. A compensation arrangement means an arrangement involving remuneration between a physician or an immediate family member of such physician and an entity. Section 1877(f) requires an entity that provides covered services for which payment may be made under Medicare to report to the Secretary information on the entity's ownership, investment, and compensation arrangements, including the covered items and services provided by the entity, and the names and unique physician identification numbers of all physicians who have an ownership or investment interest in, or a compensation arrangement with the entity, or whose immediate relatives have such an ownership or investment interest or compensation relationship with the entity.

Multiple states and the District of Columbia have enacted legislation requiring pharmaceutical and other companies to disclose gifts and payments made to physicians and other entities. These state laws generally require annual disclosures to the states of such gifts and payments. Certain categories of gifts and payments are exempted from reporting requirements under most of the state laws. For example, state laws may exempt product samples intended for free distribution to patients and gifts worth less than a certain amount. While companies may make a voluntary disclosure of these gifts and other payments, there are currently no similar federal reporting requirements.

Proposed Law

The bill would add a new Section 1128H of the Social Security Act to create certain reporting requirements applicable to manufacturers or distributors of a drug, device, biological, or medical supply for which payment may be made available under Medicare, Medicaid, or the State Children's Health Insurance Program, as well as hospitals or other entities that bill Medicare.

Under the section, beginning in 2011, a manufacturer or distributor that provides a payment or other transfer of value to a covered recipient (e.g., a physician, a pharmacist, a hospital, a medical school, or a group purchasing organization) or a recipient's designee would be required to annually submit specified information to the Secretary regarding the recipients, any payments or other transfers of value, and information about a provided drug sample. Payments or transfers of value include, among other things, gifts, food, or entertainment, travel or trips, honoraria, research funding or grants, education or conference funding and consulting fees, profit distribution, stock or stock option grant, or any ownership or investment interest held by a physician in a manufacturer (subject to exclusion), but do not include payments or transfers of five dollars or less, a loan of a covered device for a short-term trial period for evaluation purposes, items or services provided under a contractual warranty where the terms are specified in a purchase or lease agreement, items given to a patient who is not acting in a professional capacity, in-kind items for the provision of charity care, a dividend or other profit distribution from or ownership or investment interest in a publicly traded security and mutual fund, compensation paid by a manufacturer or distributor to

an employee who works solely for a manufacturer or distributor, and any discount or cash rebate. The information submitted must include the aggregate amount of all payments or transfers of value from manufacturers to covered recipients, regardless of whether such payments or transfers were individually disclosed. If a manufacturer or distributor provides a payment to another entity or individual at the request of or designated on behalf of a covered recipient, the manufacturer or distributor must disclose the payment or transfer under the name of the covered recipient.

Section 1128H would allow manufacturers and distributors to delay submission of their reports to the Secretary of payments and transfers of value made to covered recipients pursuant to certain services furnished as part of a product development agreement, or in connection with a clinical investigation of a new drug, device, biological, or medical supply. The information subject to delayed reporting would be considered confidential and would not be subject to disclosure under the Freedom of Information Act or other similar federal, state, or local law until or after the date on which the information is made available to the public.

Manufacturers and distributors that fail to submit the required information in a timely manner in accordance with regulations would be subject to a civil monetary penalty of at least $1,000 but not more than $10,000 for each payment or transfer of value not reported, up to a maximum of $150,000 for each annual submission of information. Any manufacturer or distributor that knowingly fails to submit information would be subject to a civil monetary penalty of at least $10,000 but not more than $100,000 for each payment or transfer of value, and may not exceed $1 million or, if greater, 0.1% of the total annual revenue of the manufacturer or distributor.

Each hospital or other health care entity, excluding a Medicare Advantage organization, that bills the Secretary under Medicare Part A or Part B would have to report on the ownership shares (other than shares generally available to the public or shares of certain regulated investment companies as described in Section 1877(c) of the Social Security Act) of each physician and the physician's immediate family members. Hospitals and other entities that fail to submit the required information in a timely manner in accordance with regulations would be subject to a civil monetary penalty of at least $1,000 but not more than $10,000 for each ownership or investment interest not reported. Any hospital or other entity that knowingly fails to submit information would be subject to a civil monetary penalty of at least $10,000 but not more than $100,000 for each ownership or investment interest not reported. The total amount of civil monetary penalties imposed with respect to each annual submission of information may not exceed $1 million or, if greater, 0.1% of the total annual revenue of the entity. All funds collected by the Secretary under section 1128H from the imposition of civil monetary penalties would be used to carry out the requirements of the section.

The section would require the Secretary to establish procedures no later than September 30, 2011, and on June 30 each year after to ensure public availability of the submitted information through an Internet website that is searchable, has a clear and understandable format, and that meets various other requirements. Manufac-

turer and distributors, hospitals, and other entities that would be subject to reporting requirements under 1128H would be responsible for the accuracy of the information that is submitted to the Secretary and made available on the website. The Secretary would be required to establish procedures to ensure that a covered recipient has an opportunity to submit corrections to these entities the manufacturer with regard to information made public with respect to the covered recipient. Under such procedures, the corrections must be transmitted to the Secretary. Information relating to drug samples and national provider identification numbers would not be made available to the public by the Secretary, but may be made available outside of the Department of Health and Human Services for research or legitimate business purposes pursuant to data use agreements.

Under the section, if a state attorney general has provided notice to the Secretary of the intent to proceed on a specific case and the Secretary has had an opportunity to bring an action and has declined to do so, the attorney general of a state would be permitted to bring an action against a manufacturer or distributor in the state for a violation of the section.

Section 1128H would require the Secretary to submit a report to Congress no later than April 1 of each year, beginning in 2011, that includes information submitted in the preceding year by manufacturers and distributors and a description of any enforcement actions taken to carry out the section (including penalties imposed during the preceding year). The Secretary would also be required to submit to Congress a report on the results of the Disclosure of Physician Financial Relationships surveys required pursuant to section 5006 of the Deficit Reduction Act of 2005. This report would be submitted to Congress not later than 6 months after the date such surveys are collected and would be made publicly available on an Internet website of the Department of Health and Human Services. In addition, no later than April 1 of each year, beginning in 2011, the Secretary would be required to submit to states a report that includes information submitted by manufacturers and distributors in the preceding year, as well as other information.

Additionally, beginning on January 1, 2011, Section 1128H would preempt any law or regulation of a state or its political subdivision that requires a manufacturer or distributor to disclose or report information regarding a payment or other transfer of value to a covered recipient, in accordance with the section. However, the section would not preempt state laws or regulations under which (A) the disclosure or reporting of information is not of the type required to be disclosed or reported under Section 1128H, (B) the information reported is required to be disclosed or reported to a federal, state, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes, or (C) the state requires the discovery or admissibility of the information in a criminal, civil, or administrative proceeding.

Subtitle E—Public Reporting on Health Care-Associated Infections

Section 1461. Requirement for public reporting by hospitals and ambulatory surgical centers on health care-associated infections

Current Law

Current law does not, in general, require the reporting of health care-associated infections (HAIs), although such reporting is required in a number of states. Several provisions in current federal law have established programs that are somewhat related.

First, Section 5001(c) of the Deficit Reduction Act (P.L. 109–171) requires the Secretary, by regulation, to identify certain preventable conditions that are not present on admission, and that therefore are acquired in the health care facility. Medicare Part A reimbursement is not provided for the care of these secondary conditions. This provision is implemented in CMS's annual Inpatient Prospective Payment System (IPPS) rule for hospitals. At this time, listed conditions include some that are unrelated to infection (such as incompatible blood transfusions, and trauma resulting from falls in the facility), as well as specific types of catheter-associated and surgical site infections. The rules explain that some other infections (such as infection with methicillin-resistant *Staph. aureus*, or MRSA) are not included because, among other things, it can be hard to determine, in an individual patient, whether an infection is associated with health care or was acquired previously.

Also, two voluntary CMS reporting programs established under current law may capture information related to HAIs. The Physician Quality Reporting Initiative (PQRI), established under Section 101(b) of the Tax Relief and Healthcare Act of 2006 (P.L. 109–432), provides incentive payments to physicians who report certain quality measures, which include instances of catheter-associated or surgical site infection. Information from this program is not publicly reported. The Reporting Hospital Quality Data for Annual Payment Update (RHQDAPU) Program, originally established under section 501(b) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA, P.L. 108–173), requires participating hospitals to report quality data to CMS in order to receive a full annual payment update. Selected measures are publicly reported on the CMS Hospital Compare website. However, regarding infections, this program uses process measures (e.g., antibiotics were used properly in surgical patients) rather than outcome measures (e.g., a patient developed a surgical site infection).

The Health Information Technology for Economic and Clinical Health (HITECH) Act, which was incorporated into the American Recovery and Reinvestment Act of 2009 (P.L. 111–5), created a new Title XXX in the PHS Act to promote the widespread adoption of health information technology (HIT). Among its provisions, the HITECH Act established a process for the development of interoperability standards that support the nationwide electronic exchange of health information among doctors, hospitals, patients, health plans, the federal government, and other health care stakeholders.

Proposed Law

HAIs are a result of treatment in a healthcare service setting such as a hospital or an ambulatory surgery center, but secondary to the patient's original condition. Studies have shown that such infections have been increasing over the past few years due to factors such as increasing drug resistance of bacteria and improper infection control measures. Surveillance is critical as a public health measure so as to identify and respond to emerging threats, and over 20 states now have mandatory reporting for health facilities on health care-associated infections. These efforts have provided the infrastructure for effective interventions which can virtually eliminate certain types of health care-associated infections.

This section would establish a new SSA Section 1138A requiring the Secretary to provide, by regulation, that in order to participate in Medicare and Medicaid, hospitals and ambulatory surgical centers would have to report certain health care-associated infections that develop in the facility. The Secretary would specify the types of information that must be reported, and develop reporting protocols through the Centers for Disease Control and Prevention (CDC), assuring that such protocols are coordinated with systems established under the HITECH Act. The Secretary would be required: to establish procedures regarding the validity of reported data to assure appropriate comparisons between facilities; to promulgate, through the Director of CDC, regulations to carry out this section, within one year of enactment; and to post information from the system on the HHS website in a manner that permits comparisons by facility and by patient demographic characteristics.

This section would also require the Secretary annually to report to Congress on specified aspects of the program, and would provide that this section should not be construed as preempting or otherwise affecting state laws relating to the disclosure of information on HAIs or patient safety procedures for a hospital or ambulatory surgical center. It would also define an HAI and its relationship to the receipt of care, and would clarify that for the purposes of this section, hospitals include critical access hospitals.

This provision would provide that for hospitals and ambulatory surgical centers, reporting requirements would take effect when specified by the Secretary, but not later than 2 years after enactment. Within 18 months of enactment, the Comptroller General would be required to report to Congress regarding the reporting program, and the Secretary would be required to report to Congress regarding the appropriateness of expanding reporting requirements to include additional information, such as health care worker immunization rates.

TITLE V—MEDICARE GRADUATE MEDICAL EDUCATION

Sec. 1501. Distribution of unused residency positions

Current Law

With certain exceptions, the Balanced Budget Act of 1997 (BBA, P.L. 105–33) limited the number of allopathic and osteopathic residents for which Medicare would reimburse a teaching hospital at the level reported in its cost report ending on or before December 31, 1996. The limit does not include dental or podiatry residents.

The Medicare Prescription Drug, Improvement and Modernization Act of 2003 (P.L. 108–173, MMA) authorized the redistribution of up to 75% of each teaching hospital's unused resident positions to hospitals seeking to increase their medical residency training programs. Any adjustments made to teaching hospitals' resident limits would be permanent. Rural teaching hospitals with less than 250 beds were exempt from the redistribution of any of their unfilled positions. Under the redistribution program, teaching hospitals were allowed to request up to an additional 25 full time equivalent (FTE) positions for direct graduate medical education (DGME) and indirect medical education (IME) payments. Hospitals were required to demonstrate the likelihood that the redistributed positions would be filled within 3 cost reporting periods beginning July 1, 2005. MMA required that the unused slots be redistributed according to specific priorities: rural hospitals, urban hospitals located in areas with a population of one million or less, specialty training programs that are the only specialty program in a state, and all other hospitals. The redistribution was effective for portions of cost reporting periods starting July 1, 2005. The redistributed resident slots have different IME and DGME payment formulas from those used to reimburse hospitals' previous residents.

Proposed Law

The Secretary would reduce the otherwise applicable resident limit for a hospital that has residency positions that were unused. Unused positions would be established when a hospital's reference residence level is less than its otherwise applicable resident limit. The reduction would be effective for portions of cost reporting periods occurring on or after July 1, 2011. Hospitals that are members of the same affiliated group would be subject to redistribution. The Secretary would adjust the determination of available slots for affiliated hospitals depending upon the extent that these hospitals could demonstrate that they are filling any additional residents slots allocated to other hospitals through an affiliation agreement. 90% of unused slots would be redistributed to qualifying hospitals. The increase in resident training positions would be distributed to qualifying hospitals not later than July 1, 2011.

A hospital's reference residence level would be established as the highest resident level of any of the 3 most recent cost reporting periods (ending before the date of enactment). Hospital cost reports that had been settled or those that had been submitted, subject to audit, would be used to establish the residence level. Also, upon timely request, a hospital's reference resident level could be increased to reflect an expansion or planned expansion of an existing residency training program that is not reflected on the most recent settled or submitted cost report. The increase would occur after audit and would include the previous redistribution of unused resident positions that occurred under MMA. The Secretary would be authorized to determine an alternative resident reference level for hospitals that submit a timely request for an increase in their reference resident level due to a planned expansion before the start of the 2009–2010 academic year. A hospital's resident reference level would be increased to the extent that its level was increased because of the prior redistribution of resident slots.

The Secretary would be required to increase the otherwise applicable resident limit for each qualifying hospital that submits a timely application by such number for portions of cost reporting periods that occur on or after July 1, 2011. The aggregate number of increases in resident limits may not exceed the estimated aggregate reduction in resident limits. In no case would more than 20 FTE additional residents be made available to a qualifying hospital.

A hospital that qualifies for an increase in its otherwise applicable resident limit would be required to ensure that the number of primary care residents is maintained at its base level of primary care residents increased by the number of additional primary care residents provided to the hospital. The hospital would have to assign all additional resident positions for primary care residents. The hospital's residency programs in primary care would have to be fully accredited or, if not yet in operation as of the base year, the hospital would have to be actively applying for such accreditation for the program. A hospital's base level of primary care residents is the level of such residents in a base period determined without regard to whether such positions were in excess of the otherwise applicable resident limits. Hospitals receiving positions would be required to maintain records and periodically report on the number of primary care residents in its training programs. As a condition of continuing payment for a cost reporting period, the hospitals would be required to maintain the base level of positions at not less than the sum of the level of primary care resident positions before receiving additional positions plus the number of additional positions.

When determining which qualifying hospitals would receive an increase in their otherwise applicable resident limit, the Secretary would take into account the demonstrated likelihood that a hospital would fill the positions within the first 3 cost reporting periods beginning on or after July 1, 2011. Also, the Secretary would distribute the resident slots based on the following criteria: (1) the hospital had a reduction in the resident training positions under this section; (2) the hospital has a 3–year primary care residency training program, such as family practice and general internal medicine; (3) the hospital has formal arrangements, as determined by the Secretary, that place greater emphasis upon training in federally qualified health centers, rural health clinics, and other nonprovider settings and to hospitals that receive additional disproportionate share hospital payments and emphasize training in an outpatient department; (4) the hospital has resident training positions in excess of its otherwise applicable resident level as of July 1, 2009; (5) the hospital has formal arrangements that place greater emphasis on training in a health professional shortage area or health professional needs area; or (6) the hospital is in a state with a low resident-to-population ratio (including a greater preference for those states with lower resident-to-population ratios).

The per resident amounts (PRAs) for the resident positions distributed under this provision would equal the hospitals' PRAs for primary and nonprimary care positions for the purposes of calculating direct graduate medical payments. The indirect medical education adjustment for the resident positions distributed under this

provision would be computed in the same fashion as the hospital's existing resident positions.

Reasons for Change

The healthcare system is increasingly uncoordinated and complex, but a solid primary care workforce can help to support a well-coordinated and integrated delivery model. Despite clear advantages of a strong primary care workforce, the number of primary care slots and medical students choosing primary care as a specialty has decreased over the past decade. This is the case even though the total amount of the physician workforce has remained stable. Studies have recently shown that while 35% of the current physician workforce is in primary care, 21% to 24% of graduating medical students choose primary care medicine as a career specialty. According to the Council of Graduate Medical Education (COGME), since the Graduate Medical Education (GME) cap was put in place in 1996, primary care internal medicine positions in the annual student match have fallen 57%, primary care pediatric positions have fallen by 34%, and family medicine positions have fallen by 18%. Over the past ten years, nearly all of the graduate medical expansion in teaching hospitals has been in subspecialty medicine. Family practice residency programs and three-year training programs that emphasize a generalist training have decreased or have closed as well.

In its May 2009 report, COGME stated that graduate medical education should be realigned to meet society's evolving healthcare needs. COGME recommended an emphasis on training more primary care physicians, training residents capable of practicing in innovative delivery care models such as patient-centered medical homes and accountable care organizations, and increasing the accountability of graduate medical education's role in public health. Similarly, in its June 2009 report, MedPAC's recognized that residents will best learn the skills needed to provide high-quality, efficient care when medical education occurs in settings where such care is actually performed. MedPAC will explore policies in future work linking medical education incentives to delivery system reforms. This policy is intended to increase training of primary care physicians in a broader array of settings in order to meet the future healthcare needs of the American public.

The Committee notes that some policymakers point to earlier COGME reports to argue for the need for more Medicare-funded residency slots. However, COGME now recognizes that earlier calls for increased residency slots focused on the growth in medical schools, and failed to take into account the fact that GME positions already exceed allopathic medical school slots by 30%. For instance, in 2007–2008, the United States graduated about 17,500 allopathic students but had more than 25,000 first year residency positions. COGME points out that first-year residency positions grew eight percent from 2002 and 2007 and this expansion will accommodate increases in medical school production. The shortcoming is not in the number of medical residents being trained, but that nearly all of this expansion is in subspecialty training, resulting in a drop in primary care physicians.

The legislation increases primary care physicians by directing the Secretary to redistribute residency positions that have been un-

filled for the prior 3 cost reports and directs those slots for training of primary care physicians. Special preference will be given to programs that saw a reduction in their slots under this section, have formal arrangements to train residents in ambulatory settings or shortage areas, operate three-year primary care residency programs, currently operate residency programs over their cap, or are located in states with low resident-to-population ratios. Primary care physicians are trained in three-year general medicine, pediatrics or family practice residency programs. Within this universe of residency programs are a select number of programs that place emphasis on a generalist curriculum (such as family practice programs) and are referred to as "three-year primary care residency training programs," as compared to the "categorical" or basic programs where a resident will then go on to specialize. This provision directs the Secretary to give preference to these "three-year primary care" programs. The increase in resident training positions would be distributed to qualifying hospitals not later than July 1, 2011.

Effective Date

Cost reporting periods beginning on or after July 1, 2011.

Sec. 1502. Increasing training in nonprovider settings

Current Law

Medicare reimburses the direct costs of graduate medical education (DGME) for approved residency training programs without regard for the setting where the residents' activities relating to patient care are performed as long as the hospital incurs all, or substantially all, of the costs for the training program in that setting. Through regulation, CMS has defined all, or substantially all costs, as 90% of resident stipends and fringe benefits and costs associated with a supervising physician. As presently administered, however, a hospital cannot include the time spent by residents working at a non-hospital site if it incurs all, or substantially all, of the costs for only a portion of the residents in that program at the non-hospital site.

Section 1886(k) provides for payment to qualified nonhospital providers, such as FQHCs and rural health clinics, for their direct costs of medical educations if those costs are incurred in the operation of an approved medical residency training program.

Proposed Law

Effective for cost reporting periods beginning on or after July 1, 2009, all time spent by a resident would count towards the determination of an FTE resident with respect to Medicare's direct graduate education payment, without regard to the setting where the activities are performed, if the hospital incurs the costs of the stipends and the fringe benefits of the resident during the time the resident spends in that setting. Any hospital claiming payment for the time spent in a nonprovider setting would be required to maintain and make available necessary records regarding the amount of time and this amount in comparison to the amounts of time in a specified base year.

Effective for discharges on or after July 1, 2009, all the time spent by a resident inpatient care activities in a nonprovider setting would be counted towards the determination of an FTE resident with respect to Medicare's indirect medical education payment if the hospital incurs the costs of the stipends and fringe benefits of the resident during the time spent in that setting. The Office of the Inspector General (OIG) would be required to analyze the resident data to assess the extent to which there is an increase in time spent by medical residents training in nonprovider settings. No later than 4 years after the date of enactment, the OIG would submit a report to Congress on its analysis and assessment.

The Secretary would conduct a demonstration project where an approved teaching health center would be eligible for direct medical education payments for its own direct cost of graduate medical education activities for primary care residents as well as for the direct costs of such graduate medical education activities of its contracting hospital for such residents. Under the project, an approved teaching health center would contract with an accredited teaching hospital to carry out the inpatient responsibilities of the primary care residency program. The center would be responsible for payment of the hospital's costs of the salary and fringe benefits for residents. The hospital's full-time equivalent resident amount would not affect the contracting hospital's resident limit. The contracting hospital would not reduce the number of residents in its primary care residency training program. An approved teaching health center would be a nonprovider setting, such as a federally qualified health center or rural health clinic that develops and operates an accredited primary care residency program for which funding would be available if the hospital were to operate the program.

Reason for Change

MedPAC and COGME have recommended that physicians be trained at alternative care settings such as ambulatory settings. COGME called for a "broadening of the definition of the training venue" and emphasized preparing a physician workforce for outpatient care, where most of the health care takes place, and to consider placing physicians at community health centers, rural health clinics, and physician offices. Residents should also be exposed to patient care coordination in a variety of health care settings. Teaching hospitals face considerable financial incentives and regulatory barriers that discourage them from rotating residents to nonhospital settings.

The intent of this legislation is to decrease the regulatory barriers so that residents can increase their training in nonprovider care settings (settings outside of the acute care hospital). This policy modifies the rules that govern when hospitals can receive indirect medical education (IME) and direct graduate medical education (DGME) funding for residents who train in nonprovider settings so that any time spent by the resident in a nonprovider setting shall be counted for the purposes of calculating graduate medical education payments if the hospital incurs the costs of the residents' salaries and fringe benefits. A study by OIG shall assess the impact of this policy on increasing physician training in nonprovider settings.

The changes are effective for discharges on or after July 1, 2009, and the OIG is required to report to Congress within 4 years after the date of enactment.

A demonstration project is established to allow community health centers and other nonprovider entities to host an approved primary care residency program and receive DGME for itself and for the hospital that it will contract with to provide the inpatient training. This demonstration project will inform the Secretary and Congress on the feasibility of a nonprovider entity hosting a residency program in which it is the lead contracting entity with a hospital and inform possible alternative payment methodologies for nonhospital teaching sites. The Committee recognizes the importance of training in non-provider settings. Due to the fact that patients in the ambulatory setting are more likely to be healthier and younger than a hospital setting, any movement to train residents in the outpatient setting will direct Medicare dollars in ways that are not as focused on Medicare patients. In part, this is why the Committee believes it prudent to test multiple innovative strategies that will promote ambulatory training in order to inform future policy on the financing of graduate medical education. This demonstration project only addresses DGME payments and will promote training in ambulatory settings, consistent with COGME and MedPAC recommendations. It will also help ensure that primary care physicians are optimally prepared to deliver health services to Medicare and non-Medicare beneficiaries (and in particular pre-Medicare beneficiaries) to promote preventive care and reduce preventable hospitalizations.

Effective date

Cost reporting periods beginning on or after July 1, 2009.

Sec. 1503. Rules for counting resident time for didactic and scholarly activities and other activities

Current Law

Medicare pays teaching hospitals the costs of approved medical residency training programs through two mechanisms: an indirect medical education (IME) adjustment within the inpatient prospective payment system (IPPS) and direct graduate medical education (DGME) payments made outside of IPPS. Certain non-patient care activities that are part of an approved training program are not allowable for DGME or IME payment purposes. With respect to training that occurs in hospital settings, Medicare does not include the time that residents spend in non-patient care activities, including didactic activities, when calculating IME payments. With respect to training that occurs in nonhospital settings, Medicare would not count the time that residents spend in non-patient care activities, including didactic activities, when calculating DGME or IME payments.

Proposed Law

When calculating DGME payments, Medicare would count the time that residents in approved training programs spend in certain non-direct patient care activities in a nonhospital setting that is primarily engaged in furnishing patient care. The term "nonpro-

vider setting that is primarily engaged in furnishing patient care" would be a nonprovider setting in which the primary activity is the care and treatment of patients as defined by the Secretary. Reimbursable nonpatient care activities would include didactic conferences and seminars but would not include research that is not associated with the treatment or diagnosis of a particular patient. In addition, Medicare would count all the vacation, sick leave, and other approved leave spent by resident in an approved training program as long as the leave time does not extend the program's duration.

When calculating IME payments, Medicare would adopt the same rules about counting residents' leave time. Medicare would also include all the time spent by residents in approved training programs on certain nonpatient care activities (including didactic conferences and seminars, but not in certain research activities that are not associated with the treatment or diagnosis of a particular patient) if the hospital is an IPPS hospital, a hospital paid under the IPPS for Puerto Rico, is a hospital paid under a state specific hospital reimbursement system, or is a provider-based hospital outpatient department.

Except as otherwise provided, these provisions would be effective for cost reporting periods beginning on or after January 1, 1983. The provisions affecting DGME would apply to cost reporting periods on or after July 1, 2008. The provisions affecting IME would apply to cost reporting periods on or after October 1, 2001. This section would not affect the interpretation of the law in effect prior to that date. The provisions would not be implemented in a manner that would require reopening of any settled hospital cost reports where there is not a jurisdictionally proper appeal pending on IME and DGME payments as of the date of enactment.

Subsection (a)(1)(B) pertaining to direct graduate medical education is effective for cost reporting periods beginning on or after July 1, 2008. Subsection (b) pertaining to indirect medical education is effective for cost reporting periods beginning on or after October 1, 2001. All other provisions are effective for cost reporting periods beginning on or after January 1, 1983.

Reason for Change

While in residency training, physicians need to learn critical evidenced-based medicine and participate in scholarly activities related to the management of their patients. Time devoted during residency training in didactic and scholarly activities broadens residents' clinical knowledge base and improves their ability to deliver quality and efficient care. The policy modifies current rules to allow for inclusion of didactic and scholarly activities and other activities such as research related to the care of their patients in counting toward the determination of full-time equivalency for the purposes of calculating graduate medical education payments. This provision seeks to eliminate the financial disincentive for hospitals to facilitate residents' participation in these activities and training in ambulatory settings. The provisions affecting IME would apply to cost reporting periods on or after October 1, 2001, and the provisions affecting DGME would apply to cost reporting periods on or after July 1, 2008.

Sec. 1504. Preservation of resident cap positions from closed and acquired hospitals

Current Law

With certain exceptions, the Balanced Budget Act (BBA) of 1997 limited the number of allopathic and osteopathic residents for which Medicare would reimburse a teaching hospital at the level reported in its cost report ending on or before December 31, 1996. If a teaching hospital closes (defined as withdrawing participation in the Medicare program), CMS permits a temporary cap increase to other teaching hospitals to accommodate residents suddenly displaced from the closed hospital. Upon completion of their training, the residency slots cease to exist.

A hospital with a newly established residency program may receive an adjustment to its full-time equivalent (FTE) cap (which otherwise would be zero) if it establishes one or more new medical residency training programs, but only for new programs established within 3 academic years after residents begin training in the first new program. CMS recently put forth a final rule on July 31, 2009, that clarifies that a "newly established" residency program for Medicare GME purposes is not a program that existed previously at another hospital. In determining that a program is truly new, CMS will use certain "supporting factors," such as whether the program director, teaching staff, and residents are different. CMS will also consider whether the program relocated from a hospital that closed, and whether that program is part of any existing hospital's FTE cap determination. If the program did relocate from a closed hospital and that program is not part of any existing hospital's FTE cap determination, then even if there are significant similarities between the program in terms of the program director, teaching staff, or residents, CMS could consider the program that was transferred from the closed hospital to be new for Medicare DGME and IME, since there would be no danger that an FTE cap adjustment to reflect a new program would result in duplicative residency slots.

CMS also has established certain regulations governing Medicare's provider enrollment requirements that determine under which circumstances providers can bill the Medicare program including those involved in change of ownership (CHOW) transactions. Very generally, in order to acquire a teaching hospital's resident cap under a CHOW transaction, the acquiring entity must retain the original provider agreement of the provider it is acquiring. However, the acquiring entity would also assume all liabilities associated with that provider agreement.

Starting August 29, 2005 (the day after Hurricane Katrina), hospitals were permitted to form emergency affiliation agreements if located in federally declared disaster areas, starting the first day of a Section 1135 emergency period. Under 42 Code of Federal Regulations (CFR) 413.79, a home hospital located in such an area that experiences at least a 20% decline in inpatient occupancy can temporarily transfer its resident cap to a host hospital.

Proposed Law

The Secretary would promulgate regulations to establish a process where the FTE residency cap slots in a hospital with an ap-

proved medical residency program that closes on or after a date that is 2 years before the date of enactment could be used to increase the otherwise applicable residency limit for other hospitals in the State. The increase in residency programs would be distributed to one or more hospitals in the State in a manner specified by the Secretary. This process would be consistent with any recommendations submitted by the senior health official designated by the chief executive officer of the state in question, provided that the recommendations are not submitted later than 180 days after the date of a hospital closure. In cases where a hospital closed before date of enactment, the time limit would be 180 days from the date of enactment. The aggregate number of increased residency limits in the state would equal the number of FTE resident cap slots from the hospital(s) that closed. These provisions would not affect any temporary adjustment to a hospital's FTE resident cap established under 42 CFR 413.79 as in effect on the date of enactment.

Reason for Change

When hospitals close, the residency slots previously associated with those hospitals are no longer eligible for further Medicare reimbursement once the existing residents complete their training. This occurs regardless of any continued need for those residency slots to meet current or future workforce needs in the community or state. This provision allows for continued funding of the residency slots of closed hospitals at other hospitals within the state. Recommendations from the senior health official of the state will assist the Secretary in understanding the state's current and future workforce needs to inform her determination of which hospitals receive upward adjustments or new residency caps.

Sec. 1505. Improving accountability for approved medical residency training

Current Law

Medicare will reimburse teaching hospitals for the direct and indirect costs associated with an approved teaching program accredited by an independent entity, such as the Accreditation Council for Graduate Medical Education or the American Osteopathic Association. Medicare has never linked its payments to promoting or fostering any goals in medical education or accountability measures.

Proposed Law

Certain goals of medical residency training programs would be established. Specifically, resident training would be designed so that physicians would be able to: (1) work effectively in various health care delivery settings, such as nonprovider settings; (2) coordinate patient care within and across relevant settings; (3) understand the relevant cost and value of various diagnostic and treatment options; (4) work effectively in inter-professional and multi-disciplinary teams in provider and nonprovider settings; (5) identify systematic errors in health care delivery and implement solutions for such errors; and (6) be meaningful electronic health record users.

GAO would be required to evaluate the extent to which medical residency training programs are meeting the above workforce goals

in a range of residency programs, including primary care and other specialties; and have the appropriate faculty expertise to teach the topics required to achieve such goals. A report on the results of the study would be submitted to Congress no later than 18 months after the date of the enactment. The study would include recommendations with respect to the development of curriculum requirements and an assessment of the accreditation processes of the Accreditation Council for Graduate Medical Education (ACGME) and the American Osteopathic Association (AOA) and effectiveness of these processes in meeting the residency program goals established in this section.

Reason for Change

MedPAC recommends that the residency training experience should encourage physicians to increase care coordination and assume greater accountability for quality of care. Graduate medical education should train a future physician workforce exposed to innovative delivery models that would support more integration. A MedPAC-sponsored study conducted by RAND pointed out that the curricula of residency training programs fall short of recommendations by the Institute of Medicine and other experts on items such as formal training or experience in multidisciplinary teamwork, cost-awareness in clinical decision-making, comprehensive health information technology, and patient care in nonhospital settings. Residents should be trained in innovative delivery systems that will support coordinated care and enhance an integrated approach. The Accreditation Council for Graduate Medical Education has also included similar goals for residency programs to improve the training of residents. The COGME report calls for "making accountability for the public's health the driving force for graduate medical education." The report further states that the $10 billion spent annually on GME should have parameters on how our physician workforce should be trained and the type of training residents should receive. This policy is intended to highlight broad goals, consistent with MedPAC recommendations, for residency programs to improve their accountability. The Comptroller General will undertake a study to assess: (1) the extent to which residency programs are meeting these goals and (2) the accreditation processes of ACGME and AOA and effectiveness of these processes in promoting the workforce goals established in this section.

TITLE VI—PROGRAM INTEGRITY

Subtitle A—Increased Funding to Fight Fraud, Waste, and Abuse

Sec. 1601. Increased funding and flexibility to fight fraud and abuse

Current Law

The Health Care Fraud and Abuse Control (HCFAC) account funds activities to fight healthcare fraud. The HCFAC program along with the Medicare Integrity Program (MIP) were both established by the Health Insurance Portability and Accountability Act of 1996 (HIPAA, P.L. 104–191), which sought to increase and stabilize federal funding for healthcare anti-fraud activities. Specifically, HCFAC funds are directed to the enforcement and prosecu-

tion of healthcare fraud. MIP funding supports the program integrity activities undertaken by CMS contractors.

For HCFAC, HIPAA appropriated funds to the Department of Health and Human Services, the Department of Justice (DOJ), and the Federal Bureau of Investigation (FBI) for anti-fraud activities undertaken for fiscal years 1997 through 2003. Funds are appropriated to the Account from the Medicare Part A Trust Fund in amounts as the Secretary and the Attorney General certify are necessary to support audits, investigations, evaluations, and prosecutions related to healthcare fraud. For HHS and DOJ, the legislation authorized an amount, beginning at $104 million for FY1997, equal to the limit for the preceding year increased by 15%. Within this amount, the legislation authorized minimum and maximum appropriations for the HHS OIG. The maximum OIG appropriation increased from $70 million in FY1997 to $160 million in FY2003. For each fiscal year after 2003, the amount was capped at the 2003 level. In December 2006, Congress passed the Tax Relief and Health Care Act of 2006 (TRHCA, P.L. 109–432), which extended the mandatory annual appropriation for HCFAC to 2010. For fiscal years 2007 through 2010, the mandatory annual appropriation is the limit for the preceding year plus the percentage increase in the consumer price index for all urban consumers (CPI–U). For years after FY2010, the annual appropriation remains at the FY2010 level.

The MIP program authorizes the Secretary of HHS to enter into contracts with private organizations to conduct program integrity activities such as provider audits and medical review of claims. The largest share of the HIPAA appropriation was dedicated to the MIP program. Funding for MIP increased from $440 million in FY1997 to $720 million in FY2003. For fiscal years 2004 and 2005, the annual MIP appropriation remained at the FY2003 level. In 2005, Congress passed the Deficit Reduction Act (DRA, P.L. 109–171), which raised funding for the MIP program by $112 million for FY2006 to implement program integrity and oversight activities for the Medicare prescription drug benefit. This increased the annual MIP appropriation from $720 million to $832 million for FY2006 only. Congress did not increase funding for MIP in TRHCA. Therefore the mandatory annual appropriation for MIP remains at $720 million.

Proposed Law

The Congressional Budget Office has estimated that every dollar of increased funding for HCFAC results in a $1.75 return on investment. The provision would increase funding for HCFAC by $100 million annually beginning with FY2011, to allow for the implementation of new provisions in the legislation and providing new tools for CMS under current laws. Funding would be appropriated to HHS, DOJ, and MIP in the same manner as is currently appropriated in statute. Funding allocated to MIP would be authorized for HCFAC activities as well as MIP activities, ending the requirement that such funding be distributed solely to private organizations to conduct program integrity activities. Funding for both HCFAC and MIP would be available without further appropriation until expended.

Subtitle B—Enhanced Penalties for Fraud and Abuse

Sec. 1611. Enhanced penalties for false statements on provider or supplier enrollment applications

Current Law

Medicare statute provides the Secretary with general authority to prescribe regulations for the efficient administration of the Medicare program. Under this authority, the Center for Medicare and Medicaid Services (CMS) has implemented regulations requiring Medicare providers and suppliers to submit an application to enroll in the Medicare program and receive billing privileges. Providers and suppliers must resubmit and recertify the accuracy of their enrollment information every 5 years. Private contractors handle Medicare enrollment activities such as processing and reviewing applications. CMS may deny enrollment of a provider or supplier in Medicare or revoke a provider's billing privileges for the following reasons: non-compliance with enrollment requirements, exclusion from participation in federal health care programs, conviction of a felony, or the submission of false or misleading information on the enrollment application.

Medicaid statute delegates the administration of the Medicaid program to the states. There is considerable variation in how states administer their provider enrollment processes. State Medicaid agencies determine whether a provider or supplier is eligible to participate in the Medicaid program by providing for written agreements with providers and suppliers. Written agreements require that providers and suppliers maintain specific records, disclose certain ownership information, and grant access to federal and state auditors to books and records.

Section 1128A(a) of the Social Security Act (SSA) authorizes the imposition of Civil Monetary Penalties (CMPs) and assessments on a person, including an organization, agency, or other entity, who engages in various types of improper conduct with respect to federal health care programs. Under section 1128A(a)(1)(D) of the Act, a person who knowingly presents or causes to be presented a claim to federal or state agencies that the Secretary determines is for an item or service furnished during a period when the person was excluded from participation in the federal health care program under which the claim was made is subject to a civil monetary penalty of up to $10,000 for each item or service furnished, and an assessment of up to three times the amount claimed for each item or service.

Proposed Law

This provision would subject providers and suppliers applying to enroll or renewing enrollment in federal health care programs to CMPs for providing false information on an enrollment application. Medicaid managed care plans, MA plans, and PDP plans would also be subject to CMPs for providing false information on applications to participate in federal health care programs.

Specifically, the provision would provide that a person who knowingly makes or causes to be made any false statement, omission, or misrepresentation of a material fact on an application, agreement, bid, or contract to participate or enroll as a provider of serv-

ices or supplier under a federal health care program would be subject to a CMP of $50,000 for each violation. In addition to providers and suppliers, the provision would also apply to Medicaid managed care organizations, Medicare Advantage (MA) organizations and MA plans, Prescription Drug Plan (PDP) sponsors and plans, and providers and suppliers that participate in these Medicare or Medicaid plans. In addition, such a person may be subject to an assessment of not more than three times the amount claimed as the result of the false statement, omission, or misrepresentation.

The provision would also eliminate the requirement for a determination by the Secretary when a person knowingly presents or causes to be presented a claim for an item or service furnished during a period when the person was excluded under federal law from the federal health care program under which the claim was made.

Sec. 1612. Enhanced penalties for submission of false statements material to a false claim

Current Law

Section 1128A(a) of the Social Security Act authorizes the imposition of CMPs and assessments on a person, including an organization, agency, or other entity, who engages in various types of improper conduct with respect to federal health care programs. This penalty authority includes penalties against a person who knowingly presents or causes to be presented false or fraudulent claims. This section generally provides for CMPs of up to $10,000 for each item or service claimed, $15,000 or $50,000 under other circumstances, and an assessment of up to three times the amount claimed.

Proposed Law

The bill would create a new SSA section 1128A(a)(9) providing that persons who knowingly make, use, or cause to be made or used any false statement or record material to a false or fraudulent claim submitted for payment to a federal health care program would be subject to a civil monetary penalty of not more than $50,000 for each violation.

Sec. 1613. Enhanced penalties for delaying inspections

Current Law

The Secretary is required to provide for the annual auditing of the financial records of at least ⅓ of MA plans. Each contract with a MA plan is required to provide that the Secretary have the right to inspect or evaluate the quality, appropriateness and timeliness of services performed under the contract. Contracts must also provide the Secretary with right to audit any plan's books and records related to the plan's ability to bear risk or to the services performed, including determinations of amounts payable under the contract.

Proposed Law

The bill would create a new SSA section 1128A(a)(10) providing that persons who fail to grant timely access, upon reasonable request (as defined by the Secretary in regulations), to the Office of the Inspector General (OIG), for the purpose of audits, investiga-

tions, evaluations, or other statutory functions of the OIG, be subject to CMPs of $15,000 for each day of failure. The provision would also modify the contractual requirements for MA plans to allow the Secretary to conduct timely audits and inspections of MA plans. These provisions are designed to facilitate more timely and efficient audits, investigations, and evaluations by the OIG, and more rapid and enhanced audits of MA plans by the Secretary.

Sec. 1614. Enhanced hospice program safeguards

Current Law

Medicare statute mandates the establishment of minimum health and safety standards that must be met by providers participating in the Medicare and Medicaid programs (i.e. hospitals, hospices, nursing homes, and home health agencies). In order to receive payment, providers and suppliers must meet these health and safety standards, often referred to as Conditions of Participation (CoPs). Generally, state agencies, under contract with CMS, survey providers to determine compliance with CoPs. Alternatively, a provider can be deemed to meet these requirements if an approved national accreditation body has accredited it. If a provder has been found to be non-compliant with its CoPs, CMS has the authority to impose certain sanctions, including revoking the provider's participation agreement. States also have the authority to impose sanctions on Medicare and Medicaid participating facilities found to be non-compliant with CoPs.

Proposed Law

This provision would create new tools and penalties for the Secretary to use in improving quality of care in hospices. Under current law, the only options available to the Secretary are program exclusions for hospices. The provision would add a new SSA section 1819A that would require the Secretary to develop and implement intermediate sanctions to apply to hospices that, based on a determination by the Secretary, demonstrate a substandard quality of care and fail to meet such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals provided care and services by the agency or organization involved. The sanctions may include CMPs of up to $10,000 for each day of non-compliance or in the case of a per instance penalty not more than $25,000, a denial of all or part of future Medicare or Medicaid payments to which the hospice is entitled (which would terminate upon the Secretary's finding that the hospice program no longer demonstrated substandard quality and met other requirements as determined by the Secretary), requiring the appointment of managers to oversee the operation of the hospice program, correction plans, and staff training. The sanctions could be imposed in addition to those imposed under state or federal law and would not be construed as limiting other available remedies. The Secretary would have until January 1, 2012, to develop and implement the sanctions.

By July 1, 2011, the Secretary would be required to create the specific procedures and conditions under which the relevant sanctions would apply, including the amount of any fines and severity of the sanctions. The conditions would be required to minimize the

time between the identification of deficiencies and imposition of sanctions, and would provide for more severe fines for repeated deficiencies. The due process protections provided in the CMP law (SSA section 1128A), such as written notice and the right to a hearing, would apply in the same manner to the imposition of a CMP for hospices.

This provision would also require the Secretary to take immediate action to correct any identified deficiencies that immediately jeopardize the health and safety of patients being cared for in a hospice. The action would consist of either appointing managers to oversee the operations of the hospice or terminating the hospice's participation in federal health care programs. The Secretary would be authorized to impose additional remedies if necessary. If the Secretary determines that identified deficiencies do not immediately jeopardize the patients' health and safety, the Secretary, in lieu of terminating the provider's participation in the program, may impose other intermediate sanctions. If after a period of intermediate sanctions, the deficiencies have not been corrected, the Secretary would be required to terminate the provider's participation in federal health programs. The Secretary would also be authorized to impose CMPs on hospice providers for any former days of non-compliance with federal health and safety standards.

These provisions would also apply to hospice programs participating in Medicaid and CHIP.

Sec. 1615. Enhanced penalties for individuals excluded from program participation

Current Law

SSA section 1128A(a) authorizes the imposition of CMPs and assessments on a person, including an organization, agency, or other entity, who engages in various types of improper conduct with respect to federal health care programs, including the imposition of penalties against a person who knowingly presents or causes to be presented false or fraudulent claims. This section generally provides for CMPs of up to $10,000 for each item or service claimed, $15,000 or $50,000 under other circumstances, and an assessment of up to 3 times the amount claimed.

Proposed Law

This provision would create new penalties for individuals that are excluded from program participation but order or prescribe program items or services. The bill would create a new SSA section 1128A(a)(11) providing that a person who orders or prescribes an item or service, including without limitation home health care, diagnostic and clinical lab tests, prescription drugs, durable medical equipment, ambulance services, physical or occupational therapy, or any other item or service, during a period when the person has been excluded from participation in a federal health care program, and the person knows or should know that a claim for such item or service will be presented to such a program, be subject to a civil monetary penalty of up to $50,000 for each order or prescription. This amendment would apply to violations committed on or after January 1, 2010.

Sec. 1616. Enhanced penalties for provision of false Information by Medicare Advantage and part D plans

Current Law

MA plans enter into contracts with the Secretary to participate in the Medicare program. The Secretary has the authority to impose sanctions and CMPs on MA plans that violate the terms of the contract. Among the violations are failing to provide medically necessary care; imposing excess beneficiary premiums; expelling or refusing to re-enroll beneficiaries; discouraging or denying enrollment among eligible individuals expected to require future medical services; misrepresenting or falsifying information; failing to comply with balance billing requirements; interfering with a provider's advice to beneficiaries; and contracting with providers excluded from the Medicare program. For violations related to discouraging or denying enrollment or misrepresenting information provided to the Secretary, the Secretary can impose a maximum penalty of $100,000. For all other violations, the maximum penalty is $25,000. The Secretary has the authority to impose additional penalties for imposing excess beneficiary premiums and engaging in activities that discourage enrollment.

Proposed Law

This new provision is designed to increase penalties for the provision of false information by MA and Part D plans. Under the new provision, MA and part D plans that misrepresent or falsify information will be subject to penalties of up to three times the amount claimed by a plan or plan sponsor based on the misrepresentation or falsified information. The provision would apply to violations committed on or after January 1, 2010.

Sec. 1617. Enhanced penalties for Medicare Advantage and part D marketing violations

Current Law

MA plans enter into contracts with the Secretary to participate in the Medicare program. The Secretary has the authority to impose sanctions and CMPs on MA plans that violate the terms of the contract. Among the violations are failing to provide medically necessary care; imposing excess beneficiary premiums; expelling or refusing to re-enroll beneficiaries; discouraging or denying enrollment among eligible individuals expected to require future medical services; misrepresenting or falsifying information; failing to comply with balance billing requirements; interfering with a provider's advice to beneficiaries; and contracting with providers excluded from the Medicare program. For violations related to discouraging or denying enrollment or misrepresenting information provided to the Secretary, the Secretary can impose a maximum penalty of $100,000. For all other violations, the maximum penalty is $25,000. The Secretary has the authority to impose additional penalties for imposing excess beneficiary premiums and engaging in activities that discourage enrollment.

Proposed Law

This provision is designed to reduce marketing abuses by Medicare Advantage and Part D plans by increasing the number of violations subject to the imposition of sanctions and CMPs by the Secretary. Beginning January 1, 2010, plans that: (1) enroll individuals in a MA or Part D plan without their consent (except Part D dual eligibles), (2) transfer an individual from one plan to another for the purpose of earning a commission or without consent of the individual, (3) fail to comply with marketing requirements, including CMS guidance, or (4) employ or contract with an individual or entity that commits a violation would be subject to sanctions imposed by the Secretary. Sanctions would apply to any employee or agent of a MA or Part D plan, or any provider or supplier who contracts with a MA or Part D plan.

Sec. 1618. Enhanced penalties for obstruction of program audits

Current Law

The OIG has discretion to exclude an entity or individual from a federal health program for a conviction related to the obstruction of a health care fraud investigation.

Proposed Law

This provision is designed to strengthen the OIG's ability to conduct health care fraud investigations, by expanding the OIG's permissive exclusion authority to include a conviction related to the obstruction of an audit related to health care fraud as well as an investigation or audit related to the use of funds received from any health care program. The provision would apply to violations committed on or after January 1, 2010.

Sec. 1619. Exclusion of certain individuals and entities from participation in Medicare and State health care programs

Current Law

Section 1128 of the Social Security Act provides that the Secretary (and through delegation, OIG) has the authority to exclude individuals and entities from participation in federal health care programs under a variety of circumstances. Exclusion is mandatory for those convicted of certain criminal offenses, and generally the exclusion cannot be for a period of less than five years. OIG also has permissive authority to exclude an individual or entity from a federal health program, which includes the discretion to determine whether and for how long the exclusion will be imposed. A permissive exclusion may be imposed under numerous circumstances, including conviction of certain misdemeanors relating to fraud, theft, embezzlement, breach of fiduciary duty or other financial misconduct; a conviction based on an interference with or obstruction of an investigation into a criminal offense; and revocation or suspension of a health care practitioner's license for reasons bearing on the individual's or entity's professional competence, professional performance, or financial integrity.

Under 42 C.F.R. 1001.1901, unless and until an excluded individual or entity is reinstated into a federal health care program, no payment will be made by a program for any item or service fur-

nished by the individual or entity, or at the medical direction or on the prescription of a physician or other authorized individual who is excluded when the person furnishing such item or service knew or had reason to know of the exclusion.

Proposed Law

The bill would amend section 1128(c) to clarify the effect of an exclusion of an individual or entity on payment made under a federal health care program. The section would provide that payment cannot be made from any federal health care program with respect to an item or service furnished (1) by an excluded individual or entity, or (2) at the medical direction, or on the prescription of an authorized individual (e.g., a physician) when the person submitting a claim for the item or service knew or had reason to know of an individual's exclusion. Despite this prohibition, the bill would permit payment to be made for emergency items or services (not including items or services furnished in an emergency room of a hospital) that are furnished by these individuals and entities. For purposes of this section, as well as sections 1128A and 1128B (dealing with civil and criminal penalties in federal health care programs), an item or service would be considered furnished if the individual or entity directly or indirectly provided, ordered, manufactured, distributed, prescribed, or otherwise supplied the item or service regardless of how the item or service was paid for by a federal health care program or to whom such payment was made.

Section 1128(c) would also provide that if a person eligible for benefits under Medicare or Medicaid submits a claim for payment for items or services furnished by an excluded individual or entity, and the eligible person did not know or have reason to know that such individual or entity was excluded, then payment must be made for the items or services. In this case, the Secretary must notify the eligible person of the exclusion of the individual or entity, and payment must not be made for items or services furnished by an excluded individual or entity to an eligible person after a reasonable time after this notification.

The section would also provide that if a claim for payment for items or services furnished by an excluded individual or entity is submitted by an individual or entity other than a person eligible for benefits under Medicare or Medicaid or that excluded individual or entity itself, and the Secretary determines that the individual or entity that submitted the claim took reasonable steps to learn of the exclusion and reasonably relied upon inaccurate or misleading information from the relevant federal health care program or its contractor, the Secretary may waive repayment of the amount paid in violation of the exclusion to the individual or entity that submitted the claim. If a federal health care program contractor provided inaccurate or misleading information resulting in the waiver of an overpayment under this section, the Secretary must take appropriate action to recover the improperly paid amount from the contractor.

Subtitle C—Enhanced Program and Provider Protections

Sec. 1631. Enhanced CMS program protection authority

Current Law

CMS has implemented regulations requiring providers and suppliers to complete an application to enroll in the Medicare program and receive billing privileges. As part of the enrollment process, providers and suppliers are required to submit information necessary to verify identity and state licensure. CMS reserves the right to perform on-site inspections of a provider or supplier to verify compliance with standards. If enrollment requirements are not met, CMS may revoke Medicare billing privileges. Providers and suppliers must resubmit and recertify the accuracy of their enrollment information every 5 years. CMS may deny a provider's or supplier's enrollment in Medicare or revoke a provider's billing privileges for the following reasons: non-compliance with enrollment requirements, exclusion from participation in federal health care programs, conviction of a felony, or the submission of false or misleading information on the enrollment application.

CMS manual instructions require that Medicare contractors query the following databases prior to approving an application for enrollment in Medicare: Qualifier.net, the Medicare Exclusions Database (List of Excluded Individuals/Entities or LEIE), and the Government Services Administration (GSA) debarment list. All Medicare contractors are required to query these databases when enrolling providers in the program.

Medicaid beneficiaries may obtain services from any Medicaid participating provider recognized by the state. In addition, Medicaid beneficiaries enrolled in primary care case management system, a Medicaid managed care organization, or similar entities must not restrict the choice of a qualified provider of family planning services and supplies (with some other exceptions). States are not required to provide Medicaid coverage for such services when offered by persons or entities convicted of felonies.

Proposed Law

This provision is designed to give the Secretary new authority to protect the Medicare program from providers who may commit waste, fraud, and abuse. The provision would add a new section 1128G to the SSA that would authorize the Secretary, in cases where there is a significant risk of fraud, to subject providers and suppliers to enhanced screening, oversight, or a moratorium on enrollment. The provision would take effect on January 1, 2011. The Secretary would determine what constitutes a significant risk of fraud by reviewing complaints, reports, referrals from law enforcement or other sources, and the results from data analysis, trend information, or claims review. Risk could be determined with respect to a single category of providers or suppliers or a single category of providers or suppliers operating within a specific geographic area.

This provision would apply to providers or suppliers initially enrolling in Medicare, Medicaid, or CHIP as well as those renewing their enrollment. The Secretary would be authorized to require states to implement these program safeguards as a requirement in

their Medicaid or CHIP state plans. State CHIP plans would also be required to include their procedures for enforcing these requirements. Any actions taken or determinations made by the Secretary in imposing these requirements would not be subject to judicial review. Additionally, states would be allowed to conduct enhanced oversight activities beyond those required by the Secretary.

This provision would require the Secretary to establish procedures for screening and enhanced oversight. Screening procedures may include licensing board checks, reviews against the LEIE, background checks, and unannounced pre-enrollment or other site visits. During periods of enhanced oversight (between 30 days and one year) the Secretary would be authorized to take certain actions against providers, including required or unannounced site visits or inspections, prepayment review, enhanced review of claims, and other actions as specified by the Secretary. The Secretary would be allowed to extend these periods to more than one year if necessary.

In instances where the Secretary determinates that there is a risk of serious ongoing fraud, the Secretary would have the authority to impose a moratorium on enrolling providers within a category of providers and suppliers, including a category within a specific geographic area. Moratoriums could not be imposed if the Secretary makes a determination that the moratorium would adversely impact access to care. Medicaid providers would be prohibited from providing coverage for services delivered by providers under a moratorium.

Sec. 1632. Enhanced Medicare, Medicaid, and CHIP program disclosure requirements relating to previous affiliations

Current Law

In order to receive payment from Medicare, providers must enroll in the Medicare program. CMS regulations mandate that enrollment applications contain information necessary to uniquely identify the provider (i.e. proof of business name, social security number, or Tax ID number) and include documentation necessary to verify licensure or eligibility to furnish Medicare covered items or services. Persons who sign the enrollment applications are required to have an ownership or control interest in the provider or supplier. Upon initial enrollment in the program, the signature on the enrollment application must be that of an authorized official. A delegated official may sign renewal or updated applications. CMS has the authority to perform on-site inspections of a provider to verify enrollment information and determine compliance with Medicare enrollment requirements. CMS has established an Internet database called the Provider Enrollment, Chain and Ownership System (PECOS) for providers to submit enrollment information.

Medicaid statute delegates the administration of the Medicaid program to the states. There is considerable variation in how states' administer their provider enrollment processes. State Medicaid agencies determine whether a provider or supplier is eligible to participate in the Medicaid program by providing for written agreements with providers and suppliers. Written agreements require that providers and suppliers maintain specific records, disclose certain ownership information, and grant access to federal and state auditors to books and records.

Proposed Law

Providers or suppliers that have previous affiliations with entities that have had past problems with the Medicare or Medicaid program may themselves present increased waste, fraud, and abuse risks. This provision allows the Secretary to screen for and take these previous affiliations into account. Providers or suppliers submitting applications for enrollment or renewing enrollment in Medicare, Medicaid, or CHIP after January 1, 2011, would be required to disclose information related to any current or previous affiliation (within the last 10 years) with providers or suppliers that have uncollected debt, or with persons or entities that have been suspended or excluded, been placed on payment suspension, or had their billing privileges revoked. The Secretary would have the authority to apply program safeguards to providers and suppliers, such as enhanced screening of claims, required or unannounced site visits and inspections, additional reporting requirements, and surety bonds, if the Secretary determines that certain affiliations pose a risk of fraud, waste, and abuse. The provision would also provide the Secretary with the authority to deny enrollment in Medicare, Medicaid, or CHIP in instances when at least one affiliation or affiliations poses a serious risk of fraud, waste, or abuse.

Sec. 1633. Required inclusion of payment modifier for certain evaluation and management services

Current Law

Evaluation and management services include certain primary care services, hospital inpatient medical services, consultations, other visits, preventive medicine visits, psychiatric services, emergency care facility services, and critical care services.

Proposed Law

The provision would improve the ability of the Secretary to screen for waste, fraud, and abuse by requiring the Secretary to establish a payment modifier for evaluation and management services that result in the ordering of additional services (i.e. lab tests), prescription drugs, durable medical equipment, or other services determined by the Secretary to be at high risk of fraud, waste, and abuse. The Secretary would be authorized to require providers and suppliers to report the payment modifier on claims.

Sec. 1634. Evaluations and reports required under Medicare Integrity Program

Current Law

Medicare statute authorizes the establishment of the Medicare Integrity Program (MIP). MIP requires the Secretary to enter into contracts with private entities to conduct a variety of program integrity activities for the Medicare program including auditing providers, reviewing claims for medical necessity, and identifying and investigating alleged fraud. MIP was established along with the HCFAC program by HIPAA, which sought to increase and stabilize federal funding for health care anti-fraud activities.

The Medicaid Integrity Program is modeled after Medicare's MIP program. The Medicaid Integrity Program provides HHS with dedi-

cated resources to promote Medicaid integrity to contract with entities to reduce fraud, waste, and abuse and to add 100 full-time equivalent staff. Annual reports to Congress on program accomplishments and use of funds are required. In addition, the Secretary is required to develop comprehensive 5-year plans for the program.

Proposed Law

The new provision is designed to increase the accountability and effectiveness of MIP contractors. For the contract year beginning in 2011, this provision would require MIP contractors to assure the Secretary that they will conduct periodic evaluations of the effectiveness of their activities. Annual reports would be required to be submitted to the Secretary. A similar provision with respect to the Medicaid Integrity Program would be included in Section 1752 of this bill.

Sec. 1635. Require providers and suppliers to adopt programs to reduce waste, fraud, and abuse

Current Law

Since 1998, the OIG has been issuing a series of compliance guidance documents for providers participating in federal health care programs to assist in preventing fraud, waste, and abuse. The purpose of the documents is to encourage health care providers to adopt compliance programs and internal control measures to monitor their adherence to applicable rules, regulations, and requirements. The adoption of these programs is not mandatory. There is no current law explicitly directing health care providers to adopt compliance programs.

Proposed Law

This provision would require providers and suppliers to establish compliance programs to reduce fraud, waste, and abuse, supplementing the ability of the Secretary and law enforcement authorities to uncover program waste, fraud, and abuse. Providers and suppliers that do not meet requirements for establishing these programs would be subject to certain sanctions. The provision would also authorize the Secretary to conduct a pilot program, prior to mandating these requirements to all providers, to test the establishment of compliance programs for providers that the Secretary has determined to be a high risk for fraud, waste, and abuse.

The Secretary, in consultation with the OIG, would be required to establish the core requirements for provider compliance programs. Requirements may include written policies, procedures, and standards of conduct; a designated compliance officer and compliance committee; training and education on fraud, waste and abuse for employees and contractors; a confidential mechanism (i.e. hotline) for receiving compliance questions and reports; guidelines for enforcing standards; internal monitoring and auditing procedures applicable to providers and contractors; and procedures for (1) ensuring prompt responses to detected and potential offenses, (2) developing corrective action initiatives, and (3) returning all identified Medicare, Medicaid, and CHIP overpayments. The Secretary

would be required to develop a timeline for the establishment of these requirements and the date by which providers and suppliers would be required to have a compliance program in place.

The CMS Administrator would have the authority to assess whether or not a provider or supplier has met these requirements and impose a CMP of up to $50,000 for each violation. The Secretary would have the authority to impose other intermediate sanctions, such as corrective action plans and additional monitoring, on providers and suppliers for failing to meet these requirements. The provision would also give the Secretary the authority to disenroll a Medicare provider or supplier, or impose a CMP or intermediate sanction, on any provider or supplier who fails to establish a compliance program.

The provisions of this section would not apply to individual physicians or skilled nursing facilities, although nursing facilities would be required to develop compliance programs under Section 1412 of this Act.

Sec. 1636. Maximum period for submission of Medicare claims reduced to not more than 12 months

Current Law

Medicare statute requires that payments only be made, except in certain circumstances, to Medicare eligible providers and only if a written request for payment is filed within three calendar years after the year in which the services were provided. The Secretary is authorized to reduce this period to no less than one year if it deems it necessary for the efficient administration of the program.

As established by CMS regulations, in general, the time limit on submitting a claim for payment is the close of the calendar year after the year in which the services were furnished. For services furnished in the first nine months of the year, claims must be submitted on or before December 31 of the following year. For services furnished in the last three months of a calendar year, claims must be submitted to the contractor on or before December 31 of the second year following the year services were furnished.

Proposed Law

The provision is designed to reduce the ability of Medicare providers to game the system by testing payment systems to determine which payments are or are not approved, and tailor filings to prevent waste, fraud, and abuse from being identified. The provisions would reduce the time period for filing a written request for payment from three calendar years to one calendar year for services provided under Medicare Parts A and B. The Secretary would have the authority to specify exceptions to this one year period. The provision would eliminate the current statutory requirement that the Secretary must give Medicare Part A and B eligible providers at least one year to submit a claim for payment. The provision would also add a new requirement for MA and PDP plans. Contracts with MA organizations and PDP sponsors would be required to mandate that any provider under contract with, in partnership with, or affiliated with the MA organization or PDP sponsor ensure that a written request for payment be submitted no later than one calendar year after the date the services were fur-

nished. The Secretary would have the authority to specify exceptions to this one-year period.

The provision would apply to services furnished on or after January 1, 2011.

Sec. 1637. Physicians who order durable medical equipment or home health services required to be Medicare-enrolled physicians or eligible professions

Current Law

Medicare statute defines eligible professional as a physician, certain types of practitioners (i.e. physician assistant, nurse practitioner, clinical social worker, and others), a physical or occupational therapist, qualified speech language pathologist, or a qualified audiologist.

CMS has implemented regulations requiring Medicare providers and suppliers to submit an application to enroll in the Medicare program in order to receive billing privileges. Providers and suppliers must resubmit and recertify the accuracy of their enrollment information every 5 years. CMS may deny a provider or supplier's enrollment in Medicare or revoke a provider's billing privileges for the following reasons: non-compliance with enrollment requirements, exclusion from participation in federal health care programs, conviction of a felony, or the submission of false or misleading information on the enrollment application.

In order to receive payment from Medicare, physicians are required to certify that specified services (i.e. inpatient psychiatric services, post-hospital extended care services, and home health services) meet certain conditions. In the case of home health services, physicians are required to certify that such services were required because the individual was confined to his home and needs skilled nursing care or physical, speech, or occupational therapy; a plan for furnishing services to the individual has been established; and such services were provided under the care of a physician.

In the case of DME, the Secretary is authorized to require, for specified covered items, that payment be made for items and services only if a physician has communicated to the supplier a written order for the item.

Proposed Law

Beginning January 1, 2010, this provision would require physicians who order durable medical equipment or home health services to be a Medicare eligible professional or enrolled in the Medicare program. The Secretary would have the authority to extend these requirements to other Medicare items and services, including covered Part D drugs, based on a determination that such application would help to reduce the risk of fraud, waste, and abuse.

Sec. 1638. Requirement for physicians to provide documentation on referrals to programs at high risk of waste and abuse

Current Law

OIG has "permissive" authority to exclude an entity or an individual from a federal health program under numerous circumstances, including failing to supply documentation related to payment for items and services.

Proposed Law

This provision would assist investigations by improving the quality of documentation required by those who order or request payment for program areas that are at risk of waste, fraud, and abuse. Beginning January 1, 2010, the Secretary would have the authority to disenroll, for no more than one year, a Medicare enrolled physician or supplier that fails to maintain and provide access to written orders or requests for payment for DME, certification for home health services, or referrals for other items and services as specified by the Secretary, to the Secretary. Medicare providers would be required to maintain and provide access to documentation relating to written orders or requests for payment for DME, certifications for home health services, or referrals for items and services as specified by the Secretary, to the Secretary. The provision would also extend the OIG's permissive exclusion authority to include individuals or entities that order, refer, or certify the need for health care services that fail to provide adequate documentation to the Secretary to verify payment.

Sec. 1639. Face-to-face encounter with patient required before physicians may certify eligibility for home health services or durable medical equipment under Medicare

Current Law

Home health services are covered under Medicare Parts A and B. In order to receive payment from Medicare, physicians are required to certify and re-certify that specified services (i.e. inpatient psychiatric services, post-hospital extended care services, and home health services) meet certain conditions. In the case of home health services, physicians are required to certify that such services were required because the individual was confined to his home and needs skilled nursing care or physical, speech, or occupational therapy; a plan for furnishing services to the individual has been established; and such services were provided under the care of a physician.

In the case of DME, the Secretary is authorized to require, for specified covered items, that payment be made for items and services only if a physician has communicated to the supplier a written order for the item.

Proposed Law

This provision would require that after January 1, 2010, physicians have a face-to-face encounter (including through telehealth and other than with respect to encounters that are incident to services involved) with the individual prior to issuing a certification or re-certification for home health services or durable medical equipment as a condition for payment under Medicare Parts A and B. The provision would also apply to physicians making home health certifications in Medicaid and CHIP. Physicians must document that they had the face-to-face encounter with the individual during the 6-month period preceding the certification, or other reasonable timeframe as determined by the Secretary. This section is meant to be compatible with the National Coverage Provision, PHYS–004, subsection H, which states that in medically underserved areas, physicians may send physician extenders (physician assistants or

nurses) to see patients in their homes without personal or direct supervision by the physician, and the physician may then bill that service as a physician service.

The Secretary would be authorized to apply the face-to-face encounter requirement to other Medicare items and services based upon a finding that doing so would reduce the risk of waste, fraud, and abuse.

Sec. 1640. Extension of testimonial subpoena authority to program exclusion investigations

Current Law

Section 1128 of the SSA provides that the Secretary (and through delegation, OIG) has the authority to exclude individuals and entities from participation in federal health care programs under a variety of circumstances. Exclusion is mandatory for those convicted of certain criminal offenses, and generally the exclusion cannot be for a period of less than five years. OIG also has permissive authority under numerous circumstances to exclude an individual or entity from a federal health program, including the discretion to determine whether and for how long an exclusion will be imposed.

Proposed Law

The provision is designed to increase the ability of the Secretary to conduct program investigations, applying the subpoena provisions contained in section 205(d) and (e) of the SSA with respect to the Secretary's program exclusion authority. The Secretary would be able to issue subpoenas and require the attendance and testimony of witnesses and the production of any other evidence that relates to matters under investigation or in question by the Secretary. The Secretary would also have the ability to delegate this authority to the OIG and the Administrator of CMS for the purposes of a program exclusion investigation. Certain requirements regarding the serving of subpoenas and compensation for subpoenaed witnesses may apply. This section would also provide for judicial enforcement of subpoenas, including in cases where a person refuses to obey a properly served subpoena. This provision would apply to investigations beginning on or after January 1, 2010.

Sec. 1641. Required repayments of Medicare and Medicaid overpayments

Current Law

The Secretary is authorized to enter into contracts with private entities to conduct administrative functions, including audits of Medicare participating providers and suppliers to identify alleged overpayments. These entities are generally referred to as Medicare program integrity or MIP contractors.

Medicare statute specifies that identified overpayments to providers or suppliers that are not paid within 30 days of the date of the overpayment determination will accrue interest on the balance of the overpayment at the rate applicable to late payments established by the Secretary of the Treasury. The Secretary is required to enter into repayment plans with providers for which payment within 30 days would constitute a financial hardship. In the case

of a provider or supplier for which an overpayment has been identified seeks a reconsideration (the 2nd level of the Medicare appeals process), the Secretary is prohibited from recouping the overpayment until a decision on the reconsideration has been rendered.

Proposed Law

This provision would require the repayment of overpayments identified by Medicare and Medicaid participating providers, including private health plans. The term "overpayment" would be defined as any funds that a person receives or retains under Medicare or Medicaid of which they are not entitled. Person would be defined as any "person" including a provider of services, supplier, Medicaid managed care organization, MA organization, or PDP sponsor. Any person who knows of an overpayment would be required to report and return the overpayment, along with notification for the reason for the overpayment, to the Secretary, the state, an intermediary, a carrier, or a contractor. "Knows" under this provision means that a person with respect to information has actual knowledge of the information, acts in deliberate ignorance of the truth or falsity of the information, or acts in reckless disregard of the truth or falsity of the information. An overpayment is defined as funds that a person receives or retains under Medicare, Medicaid, or CHIP to which the person, after applicable reconciliation, is not entitled. The reference to applicable reconciliation in this definition refers to reconciliations procedures already be in place for the relevant programs and payments, and is not intended to create any new required reconciliation procedures or rights to reconciliation or appeal. Overpayments would be required to be reported and returned within 60 days of the date the person knows of the overpayment. Overpayments retained after the 60 days would create an obligation as defined in USC section 3729(b)(3) of title 31. If it is determined that the reason for the overpayment was related to fraud, repayment would not limit the provider or supplier's liability for additional administrative obligations such as interest, fines, specialties, or civil and criminal sanctions.

Sec. 1642. Expanded application of hardship waivers for OIG exclusions to beneficiaries of any Federal health care program

Current Law

Under SSA section 1128, the Secretary (and, through delegation, OIG) has the authority to exclude individuals and entities from participation in federal health care programs. Exclusions from federal health programs are mandatory under certain circumstances, and permissive in others (i.e., OIG has discretion in whether to exclude an entity or individual). For purposes of section 1128, the term "federal health care program" means (1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States government other than the health insurance program under chapter 89 of title 5, United States Code (governing health insurance for federal employees); or (2) any state health care program, as defined by the Social Security Act.

Subject to exceptions, in the case of a mandatory exclusion, the minimum period of exclusion cannot be less than five years. How-

ever, under SSA section 1128(c)(3)(B), upon the request of a federal health care program administrator who determines that the exclusion would impose a hardship on individuals entitled to benefits under Medicare Part A or enrolled under Medicare Part B (or both), the Secretary may waive the exclusion under certain circumstances with respect to that program, in the case of an individual or entity that is the sole community physician or sole source of essential specialized services in a community.

Proposed Law

This new provision would increase the ability of the Secretary to use discretion to protect beneficiaries in cases where providers are subject to program exclusion. Under SSA section 1128(c)(3)(B), the Secretary would, in accordance with the requirements of the section, be able to waive a mandatory exclusion period where a hardship is imposed on beneficiaries of other federal health care programs, in addition to Medicare Part A and Part B beneficiaries.

Sec. 1643. Access to certain information on renal dialysis facilities

Current Law

None.

Proposed Law

This provision is designed to allow additional oversight of financial relationships that may exist between medical directors and dialysis organizations, and the extent to which these may affect prescribing decisions. This provision would require End State Renal Disease Facilities to provide the Secretary with access to information relating to any ownership or compensation arrangement between the facility and the medical director of such facility or between the facility and any physician for the purposes of an audit or evaluation.

Sec. 1644. Billing Agents, Clearinghouses, or Other Alternate Payees Required to Register Under Medicare

Current Law

CMS has implemented regulations requiring Medicare providers and suppliers to submit an application to enroll in the Medicare program in order to receive billing privileges. Providers and suppliers must resubmit and recertify the accuracy of their enrollment information every 5 years. The enrollment application requires that providers and suppliers include the names, addresses, and tax ID numbers for billing agencies on their applications.

Proposed Law

This provision is designed to reduce waste, fraud, and abuse by providing for registration of financial intermediaries that handle payments for Medicare providers. Beginning January 1, 2012, this provision would require billing agencies, clearinghouses, or other payees that submit claims on behalf of a health care provider to register with the Secretary in a form and manner as determined by the Secretary. A similar provision is put in place with respect to the Medicaid program by section 1759 of this Act.

Sec. 1645. Conforming civil monetary penalties to False Claims Act amendments

Current Law

SSA section 1128A(a) authorizes the imposition of civil monetary penalties (CMPs) on any person, including an organization, agency, or other entity, who engages in various types of improper conduct with respect to federal health care programs. Under 1128A(a)(1), CMPs may be imposed on any person who knowingly presents or causes to be presented to certain government officers, employees, agents, or agencies certain false or fraudulent claims for items or services. As defined by section 1128A(i), an item or service includes any particular item, device, medical supply, or service purportedly provided to a patient and listed in an itemized claim for payment. A claim is defined by this section as an application for payments for items and services under a federal health care program.

Section 1128A generally provides for monetary penalties of up to $10,000 for each item or service claimed, and $15,000 or $50,000 under other circumstances, as well as additional assessments. Under Section 1128A(a)(4), certain persons excluded from participating in Medicare or a state health care program who retain a direct or indirect ownership or control interest in an entity that is participating in Medicare or a state health care program and know or should know of the action constituting the basis for the exclusion, or who are an officer or managing employee of such an entity, may be subject to civil penalties.

SSA section 1128A(c)(1) provides that the Secretary may initiate a proceeding to determine whether to impose a civil monetary penalty, assessment, or exclusion under the section only as authorized by the Attorney General pursuant to procedures agreed upon by them. The Secretary may not initiate an action with respect to any claim, request for payment, or other occurrence described in this section later than six years after the date the claim was presented, the request for payment was made, or the occurrence took place.

The federal False Claims Act (FCA), codified at 31 U.S.C. §§ 3729–3733, provides for judicial imposition of CMPs and damages for the knowing submission of false claims to the United States government. The recently enacted Fraud Enforcement and Recovery Act of 2009 (FERA), P.L. 111–21, made several amendments to the False Claims Act that, according to legislative history, were intended to clarify the meaning of several provisions of the FCA in light of judicial interpretations of the statute that were said to run contrary to congressional intent and limit the scope of the law. Among the changes made by FERA, the Act removed a requirement under 30 U.S.C. 3729(a)(1) that provided that in order for liability to attach, a false claim must be presented "to an officer or employee of the United States Government or a member of the Armed Forces of the United States." In addition, FERA expanded the definition of the term "claim" to include to include "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that . . . is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or

interest, and if the Government provided or has provided any portion of the money or property requested or demanded."

Proposed Law

This provision is designed to conform and ensure consistency between the OIGs CMP authority and the recently amended False Claims Act. Similar to FERA, the bill would amend section 1128A(a)(1) to remove the requirement for presentment of a claim to a government officer, employees, agents, or agencies in order to be liable for CMPs. The bill would also expand the reach of section 1128A(a)(4), under which a person excluded from participating in a federal health care program (in addition to Medicare or a state health care program) who retains ownership in an entity participating in the program, or is an officer or managing employee of such an entity, would be subject to CMPs. The bill would create a new section 1128A(a)(12), which would impose CMPs on a person who conspires to commit a violation of section 1128A. Persons violating section 1128A(a)(12) would be subject to a penalty of up to $50,000 for violations of the section and an additional assessment of no more than three times the total amount that would otherwise apply. In addition, a new section 1128A(a)(13) would provide that a person who knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to a federal health care program, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to a federal health care program can be subject to CMPs. Penalties under this section would be up to $50,000 for each false record or statement, concealment, avoidance, or decrease. Persons would also be subject to an assessment of no more than three times the total amount of the obligation under certain circumstances.

Under section 1128A(c)(1), the Secretary could initiate a proceeding to determine whether to impose a civil monetary penalty, assessment, or exclusion for an occurrence up to ten years, instead of six, after the occurrence took place.

The bill would also amend certain definitions in section 1128A(i). For example, under 1128(i)(2), the definition of a claim would be broadened to include any application, request, or demand, whether under contract, or otherwise, for money or property for items and services under a federal health care program, whether or not the United States or a State agency has title to the money or property, that is presented or caused to be presented to a government officer, employee, agent or agency. A claim under this section would also include applications, requests, or demands made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the federal health care program's behalf or to advance a federal health care program interest, and if the federal health care program (1) provides or has provided any portion of the money or property requested or demanded; or (2) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded. In addition, an "item or service" would include, without limitation, any medical, social, management, administrative, or other item or service used in connection with or directly or indirectly related to a federal health care program.

Subtitle D—Access to Information Needed to Prevent Fraud and Abuse

Sec. 1651. Access to information necessary to identify waste and abuse

Current Law

Statutory OIGs consolidate responsibility for audits and investigations within a federal agency. The Inspector General Act of 1978 and its amendments of 1988 granted inspectors general substantial independence and powers to carry out their mandate to combat waste, fraud, and abuse. In carrying out their functions, IGs have relatively unlimited authority, including subpoena power, to access all records and information of an agency.

Every contract with a PDP or MA–PD (Medicare Advantage Prescription Drug Plan) is required to provide the Secretary with the right to inspect and audit any books and records of the plan related to costs. Officers, employees, and HHS contractors may use information obtained or disclosed during an audit for the purposes of conducting the audit only.

Proposed Law

The provision would establish that the Attorney General has access to Medicare and Medicaid claims and payment data, facilitated by the HHS OIG and in consultation with CMS or the owner of any such data. Access would be required to be carried out for the purposes of law enforcement activity and in a manner consistent with any applicable disclosure, privacy, and security laws, including the HIPAA and Privacy Act of 1974, and subject to any statutory information systems security requirements in statute or mandated by the Secretary. Nothing in this section shall be construed as setting forth an exclusive avenue for obtaining data in civil and criminal fraud investigations. Nor does the section apply to state attorneys general.

Sec. 1652. Elimination of duplication between the Healthcare Integrity and Protection Data Bank and the National Practitioner Data Bank

Current Law

Medicare statute requires the Secretary to develop and maintain a national health care fraud and abuse data collection program for the reporting of adverse actions taken against health care providers or suppliers. The OIG issues regulations implementing the Health Care Integrity and Protection Data Bank (HIPDB). The statute requires the following types of health care related adverse actions to be reported: civil judgments, federal or state criminal convictions, actions taken by federal or state licensing agencies, and provider exclusions from Medicare and Medicaid. Only final adverse actions are reportable to the HIPDB. Administrative fines, citations, corrective action plans, and other personnel actions are not reportable except under certain circumstances. Settlements, in which a finding of liability has not been established, are also not reportable. Both federal and state government agencies as well as health plans are required to report to the HIPDB. Health plans that fail to report are subject to a civil monetary penalty of

$25,000. The Secretary is authorized to charge fees to access information in the database. However, fees cannot apply to requests from federal entities. HIPDB cannot duplicate the reporting requirements established for the National Practitioner Data Bank.

Title IV of the Health Care Quality Improvement Act of 1986, as amended, established the National Practitioner Data Bank (NPDB). The NPDB collects and releases data related to the professional competence of physicians, dentists, and certain healthcare practitioners. The types of information included in the NPDB are medical malpractice claims payments, certain adverse licensure actions, adverse clinical privileging actions, adverse professional society membership actions, and exclusions from Medicare and Medicaid. The statute defines the entities eligible to report and query the databank. Malpractice payers that fail to report are subject to a civil monetary penalty. Section 1921 of the Social Security Act expanded the scope of reporting requirements for the NPDB to encompass additional adverse licensure actions and actions taken by state licensing and certification agencies, peer review organizations, and private accreditation organizations. Section 1921 also required that actions taken against all health care practitioners be included in the databank. States are required to have a system for reporting adverse actions to the NPDB. The Health Resources and Services Administration (HRSA) within HHS oversees both databases.

Proposed Law

This provision is designed to establish a timeline for the process already underway of consolidation of existing waste, fraud, and abuse data sources, ensuring the efficient use of resources and greater access to data necessary for preserving program integrity. Upon enactment of this Act, this provision would require the Secretary to establish a process to terminate the HIPDB. The Secretary would be required to ensure that the information that was formerly collected in the HIPDB is transferred to the NPDB.

Requirements pertaining to the establishment of the HIPDB, such as rules for reporting information, the types of information that are reported, and rules for disclosure, would all apply to the NPDB upon termination of the HIPDB. The provision would eliminate the OIG's responsibility for reporting adverse actions to the database. After the Secretary certifies that the transition of information from the HIPDB to the NIPD is complete, any fees charged by the Secretary for access to the database would apply to federal agencies. The Department of Veterans Affairs (VA) would be exempted from these charges for one year. The transition would be funded from the fees collected to access the database and from additional amounts as necessary from the annual HCFAC appropriation available to the Secretary and the OIG. Funding would be available for one year after the enactment date of this legislation.

Sec. 1653. Compliance with HIPAA privacy and security standards

Current Law

The HIPAA Privacy and Security Rules were promulgated by HHS pursuant to sections 262(a) and 264 of the Health Insurance Portability and Accountability Act of 1996 (HIPAA) to establish na-

tional standards for the privacy and security of protected health information.

The HIPAA Privacy and Security Rules apply primarily to covered entities—health plans, health care clearinghouses, and health care providers who transmit financial and administrative transactions electronically. Failure to comply with these regulations may result in civil or criminal penalties for covered entities. The HITECH Act, enacted as part of the American Recovery and Reinvestment Act, extends civil and criminal liability to business associates of covered entities for violations that occur on or after February 17, 2010. Business associates are defined as persons who perform, or assist in the performance of a function or activity involving the use or disclosure of individually identifiable health information on behalf of a covered entity. Examples of business associates include persons who perform legal, actuarial, accounting, consulting, data aggregation, management, administrative, accreditation, or financial services to or for such covered entity where the provision of the service involves the disclosure of individually identifiable health information from such covered entity or arrangement, or from another business associate of such covered entity or arrangement, to the person.

The HIPAA Privacy Rule governs the disclosure of protected health information (PHI)—that is, individually identifiable health information "created or received by a [covered entity]" that "[r]elates to the . . . health or condition of an individual" or to the provision of or payment for health care. A covered entity is permitted to use or disclose PHI without patient authorization for treatment, payment, or health care operations. For other purposes, a covered entity may only use or disclose PHI with patient authorization subject to certain exceptions. Exceptions permit the use or disclosure of PHI without patient authorization or prior agreement for public health, judicial, law enforcement, and other narrow purposes. The HIPAA Privacy Rule also requires covered entities and business associates to provide an accounting of certain disclosures; to make reasonable efforts to disclose only the minimum information necessary; to safeguard PHI from inappropriate use or disclosure; and to provide a notice of their privacy practices. Individuals also have a right to review and obtain copies of their PHI and to request corrections.

The HIPAA Security Rule applies only to PHI in electronic form (EPHI), and requires a covered entity or business associate to maintain administrative, technical, and physical safeguards to ensure the confidentiality, integrity, and availability of all EPHI the covered entity creates, receives, maintains, or transmits.

The HITECH Act will also impose a breach notification requirement that is triggered when unsecured PHI or EPHI is compromised. This requirement is applicable to both covered entities and business associates and will become effective 30 days after HHS issues final regulations implementing this requirement.

The Privacy Act of 1974 generally prohibits disclosures of records contained in a system of records maintained by a federal agency without the written request or consent of the individual to whom the record pertains. A system of records is a group of records under the control of an agency from which information is retrieved by the name of the individual or by some identifier assigned to the indi-

vidual, such as a Social Security Number. The Privacy Act contains certain statutory exceptions, and a list of agency systems of records, including the routine uses of those records, is published in the *Federal Register*.

Proposed Law

The provision would mandate compliance with HIPAA privacy and security requirements and the Privacy Act of 1974 in carrying out the provisions of this subtitle.

TITLE VII—MEDICAID AND CHIP

Subtitle A—Medicaid and Health Reform

Sec. 1701. Eligibility for individuals with income below 133⅓ percent of the Federal poverty level

Current Law

Medicaid provides federal matching funds to states for the costs of covered health and long-term care services furnished to eligible low-income individuals. In order to qualify for and be entitled to these federal matching funds, states must cover certain groups, such as pregnant women and children under age 6 with family incomes at or below 133% of the federal poverty level (FPL). These are known as "mandatory" groups. In addition, states may extend Medicaid coverage to certain groups, such as pregnant women and children under 6 with family incomes above 133% of FPL. These are known as "optional" groups, and states are entitled to receive federal matching funds for the costs of covered services to these populations. In 2009, 133% of FPL is $14,404 per year for an individual and $29,326 for a family of four.

There is one group of low-income people for whom federal Medicaid law does not allow states to receive federal Medicaid matching funds, regardless of their degree of impoverishment. These are adults who are not elderly, not disabled, not pregnant, and not parents of dependent children; they are sometimes referred to as "childless adults." The only way in which states may receive federal Medicaid matching funds for the costs of providing health or long-term care services to these individuals is under a section 1115 demonstration waiver granted by the Secretary of HHS.

Proposed Law

The bill would add two new mandatory eligibility groups to Medicaid effective January 1, 2013. A new "non-traditional" group would consist of individuals under age 65 who do not meet existing categorical requirements for eligibility (e.g., childless adults) with family income up to 133⅓% of FPL. States would determine income using methodologies and procedures specified by the Secretary of HHS in consultation with the Health Choices Commissioner. The purpose of the consultation would be to align as closely as possible the income eligibility determinations for Medicaid with the income eligibility determinations for affordability credits in the Exchange. For the same reason, the non-traditional Medicaid eligibles would not be subject to an assets or resource test.

A new "traditional" group would consist of individuals under age 65 with family income up to 133⅓% of FPL who meet the existing

categorical requirements for eligibility (e.g., children, pregnant women, parents with dependent children, and individuals with disabilities) but do not meet income eligibility rules (standards, methodologies, and procedures) in effect in their state as of June 16, 2009. As in the case of non-traditional Medicaid eligibles, these traditional Medicaid eligibles would not be subject to an assets or resource test, even if the state applied such an eligibility requirement on or before June 16, 2009.

The federal Medicaid matching rate for the cost of covered services furnished to both the new non-traditional and traditional groups of Medicaid-eligible individuals would be 100% in 2013 and 2014, and 90% thereafter. This matching rate would apply to the cost of services for these new groups in every state, whether or not a state currently covers some or all of this population under a section 1115 waiver or only with state funds.

Section 205(d)(1) of the bill provides that children born in the United States who are not otherwise eligible for acceptable coverage at birth are deemed to have enrolled in Medicaid as a non-traditional Medicaid eligible for the first 60 days of life. (Acceptable coverage is defined in section 202(d)(2) of the bill.) The costs of care incurred by state Medicaid programs during this period would be matched by the federal government at a 100% rate in 2013 and 2014, then 90% thereafter. Section 205(d)(2) of the bill provides that if, at the end of the 60-day period, a newborn does not have acceptable coverage, the newborn will continue to be deemed a non-traditional Medicaid eligible until the child obtains other acceptable coverage or the child is determined to be eligible for Medicaid. This section provides that the cost of care during this continuation period would be matched by the federal government at a 100% rate in 2013 and 2014, then 90% thereafter.

The bill would prohibit a state from requiring non-traditional Medicaid eligibles to enroll in a Medicaid managed care organization (MCO) or primary care case management program (PCCM) until the state demonstrates, to the satisfaction of the Secretary, that the MCO or PCCM has the capacity to meet the health, mental health, and substance abuse needs of such individuals, whether through its provider network or through other arrangements. The purpose of this requirement is to avoid a repetition of the waste of federal Medicaid funds that has in the past occurred when Medicaid populations have been required to enroll in MCOs that do not have adequate capacity to furnish the services for which they are receiving capitation payments.

The effective date of this section would be the first day of fiscal year 2013; it would apply to all items and services furnished on or after that date.

Sec. 1702. Requirements and special rules for certain Medicaid eligible individuals

Current Law

There are no provisions in current Medicaid law relating to the Health Choices Administration or the Health Insurance Exchange established by the bill.

Proposed Law

The bill provides assistance to low-income individuals in affording health coverage through Medicaid or through affordability credits within the Health Insurance Exchange. In order to minimize procedural and bureaucratic barriers to such assistance, the bill requires coordination between the Health Choices Commissioner and the various state Medicaid programs. The purpose is to ensure a "single portal" to coverage—i.e., whether an individual initially seeks coverage through a Medicaid eligibility site or through the Exchange, the individual's application will be promptly processed and the individual will be enrolled in the coverage appropriate to his or her family income without the need to reapply at a different venue.

To this end, section 205(e)(3) of bill directs the Health Choices Commissioner, in consultation with the Secretary of HHS, to enter into a Medicaid memorandum of understanding (MOU) with each state Medicaid agency in order to coordinate enrollment in and implementation of Medicaid and the Exchange. This section of the bill imposes a reciprocal requirement on state Medicaid programs, as a condition of receiving federal matching funds, to enter into a Medicaid MOU with the Health Choices Commissioner to coordinate the implementation of Medicaid and the Exchange in order to ensure the enrollment of Medicaid-eligible individuals in acceptable coverage.

The MOU would implement a number of requirements designed to maximize participation in Medicaid by eligible individuals. First, state Medicaid programs would be required to accept without further determination the enrollment of non-traditional Medicaid eligible individuals who are determined eligible for Medicaid by the Exchange. Any redeterminations of eligibility by the state Medicaid agency would have to be consistent in periodicity with the periodicity for redeterminations of eligibility for affordability credits in the Exchange.

State Medicaid programs would also be required to accept without further determination the enrollment of an individual determined by the Commissioner to be a traditional Medicaid eligible individual. As in the case of non-traditional Medicaid eligibles, the state would conduct redeterminations of eligibility for these individuals consistent with the periodicity of the redeterminations of eligibility for affordability credits in the Exchange.

If the Commissioner determines that a state Medicaid agency has the capacity to make determinations of eligibility for affordability credits, then the MOU would provide for the state Medicaid agency to perform that function, and the Commissioner must reimburse the state Medicaid agency for the costs of conducting such determinations. Under this arrangement, the state Medicaid agency must make an eligibility determination for affordability credits for any Exchange-eligible individual who requests such a determination. If the state Medicaid agency determines that an Exchange-eligible individual is not eligible for affordability credits, the agency must forward the information on the basis of which such determination was made to the Commissioner. Errors by the state Medicaid agency in making eligibility determinations for affordability credits would not be included in the calculation of erroneous excess payments for purposes of Medicaid or CHIP.

The Committee expects that, consistent with the requirements described above, these Medicaid MOUs will be tailored to the operational circumstances of both the Medicaid program and the Exchange in each state. Neither the Commissioner nor the state Medicaid agencies have the authority to modify or vitiate any state Medicaid plan requirement under federal law in the MOU.

Section 205(d)(1) of the bill provides that children born in the United States who are not otherwise eligible for acceptable coverage at birth are deemed to have enrolled in Medicaid as a non-traditional Medicaid eligible for the first 60 days of life. Section 205(d)(2) of the bill provides that if, at the end of the 60–day period, a newborn does not have acceptable coverage, the newborn will continue to be deemed a non-traditional Medicaid eligible until the child obtains other acceptable coverage or the child is determined to be eligible for Medicaid. This section of the bill requires that the state Medicaid agency conduct a Medicaid eligibility determination for such newborns within the first 60 days after birth. In order to avoid any loss of coverage, it also deems newborns who are not otherwise covered under acceptable coverage at the end of the 60–day period to be eligible for Medicaid as a traditional Medicaid eligible (with federal matching rates appropriate to this eligibility group) until the child either obtains acceptable coverage or is otherwise determined eligible for Medicaid.

Sec. 1703. CHIP and Medicaid maintenance of eligibility

Current Law

State participation in the Medicaid program and in the Children's Health Insurance Program (CHIP) is voluntary. States that elect to participate in either program must meet certain federal statutory requirements in order to receive federal matching funds for the allowable costs they incur in purchasing covered items and services on behalf of program beneficiaries. All states currently participate in both programs. The Medicaid program is permanent. The CHIP program expires on September 30, 2013.

Within federal requirements, states have flexibility to determine which eligibility standards, methodologies, and procedures they use in administering their programs. The of the American Recovery and Reinvestment Act of 2009, P.L. 111–5, provides an increase in federal Medicaid matching rates for states during the period October 1, 2008, through December 31, 2010. Under the American Recovery and Reinvestment Act (ARRA) maintenance of eligibility requirement, a state is not eligible for the increased federal matching payment if its Medicaid eligibility standards, methodologies, or procedures are more restrictive than those in effect as of July 1, 2008. The Centers for Medicare & Medicaid Services has issued administrative guidance implementing this requirement (SMD #09–005, August 19, 2009).

Proposed Law

The bill would require states, as a condition of receiving federal Medicaid funds, to maintain eligibility standards, methodologies, or procedures under their CHIP programs (including those operating under section 1115 waivers) that are no more restrictive than those in effect as of June 16, 2009. This requirement would not prohibit

states with stand-alone CHIP programs from limiting the acceptance of applications or imposing numerical limitations or waiting lists in order to limit its CHIP spending in a fiscal year to amounts for which federal CHIP matching funds are available for that fiscal year.

The Committee expects that, in implementing this requirement, the Secretary will issue guidance parallel to that set forth in the August 19, 2009, guidance implementing the ARRA Medicaid maintenance of eligibility requirement. The purpose of this requirement is to ensure that low-income children and pregnant women who qualify for CHIP under current eligibility rules will continue to qualify for coverage until the Health Insurance Exchange is operational. The maintenance of eligibility requirement does not prohibit states from raising their CHIP eligibility standards or liberalizing their CHIP eligibility methodologies or procedures in order to cover more low-income children.

In order to ensure low-income children and pregnant women a seamless transition from coverage under CHIP to coverage in the Exchange, the CHIP maintenance of eligibility requirement would apply from the first quarter after enactment to the CHIP MOE termination date. This date is the later of January 1, 2013, the day on which the Exchange becomes operational, or the day after which both of the following determinations have been made; first, the Health Choices Commissioner has determined that the Exchange has the capacity to support CHIP enrollees who are eligible for the Exchange; and second, the Secretary of HHS has determined that comparable coverage is available through the Exchange and that procedures have been established for transferring CHIP enrollees into acceptable coverage without interruption of coverage and without interruption of a written plan of treatment. For this purpose, comparable coverage means that benefits standards in the Exchange are at least comparable to the benefits standards provided to children under an average state CHIP plan as in effect in 2011. A CHIP enrollee is a child or pregnant women who is eligible for CHIP coverage or would be eligible but for acceptable coverage (as defined in section 202(d)(2) of the bill).

The bill also includes a Medicaid maintenance-of-eligibility requirement. Under this requirement, a state is not eligible for federal Medicaid matching payments in any calendar quarter beginning after enactment if the state has in effect Medicaid eligibility standards, methodologies, or procedures under the state's Medicaid plan (or under any section 1115 Medicaid waiver) that are more restrictive than the eligibility standards, methodologies or procedures under the state's Medicaid plan (or waiver) as in effect on June 16, 2009. The Committee expects that, in implementing this requirement, the Secretary will follow the August 19, 2009, guidance implementing the ARRA Medicaid maintenance of eligibility requirement. This Medicaid MOE requirement does not prohibit states from changing their Medicaid eligibility standards or methodologies or procedures so as to make them less restrictive and thereby cover more low-income families and individuals. The bill requires the Secretary to extend any section 1115 Medicaid waiver, including the availability of federal Medicaid matching funds under such a waiver, for as long as necessary for a state to meet the maintenance of eligibility requirement.

The Secretary of HHS has granted a section 1115 waiver to the State of Vermont that limits coverage for certain individuals to payment of premium or cost-sharing subsidies for individual or group health insurance coverage only. The bill directs the Secretary to allow the State to amend the waiver to apply more restrictive standards, methodologies, or procedures to such individuals only and clarifies that such an amendment would not violate the maintenance of eligibility requirement.

Under section 242 of the bill, individuals who are not enrolled in an employer plan and are not eligible for Medicaid may qualify for affordability credits to assist in the purchase of health insurance coverage in the Exchange if their family income is below 400% of the federal poverty level (FPL). No assets or resource test will apply. In general, individuals and families with incomes at or below 133% of FPL will be eligible for Medicaid, and those with incomes above that level (but below 400% of FPL) who are not eligible for Medicaid under the MOE requirement will be eligible for affordability credits in the Exchange.

In order to align eligibility determinations for Medicaid with those for affordability credits so as to minimize administrative burden and cost, the bill prohibits state Medicaid programs from applying assets or resource tests in determining eligibility for certain populations effective on the day the Exchange becomes operational (January 1, 2013). This prohibition applies to both initial Medicaid eligibility determinations and redeterminations of new or existing eligibles.

The populations that would not be subject to assets or resource tests include the following mandatory populations: (1) individuals who are receiving benefits under Title IV–A (Temporary Assistance for Needy Families, TANF) or Title IV–E (Foster Care or Adoption Assistance); (2) pregnant women, infants, and children under age six with family income at or below 133% of FPL; (3) children ages 6 through 18 with family incomes at or below 100% FPL. They also include the following optional populations: (1) pregnant women, infants, and children with family income exceeding 133% FPL; (2) children ages 6 through 18 with family incomes above 100% FPL; (3) parents who would be eligible if their work-related child care costs were paid from their earnings; (4) optional targeted low-income children under CHIP; (5) independent foster care adolescents. Finally, these populations include parents and children in families who meet the eligibility standards under the AFDC programs that were in effect in their states on July 16, 1996, and those who qualify under less restrictive income and resource methodologies applied by their state. States could continue to apply assets or resources tests to individuals 65 and over and individuals with disabilities who may require long-term care services.

Section 121 of the bill requires that qualified health benefits plans operating in the Exchange must offer coverage that at least meets minimum benefits standards adopted by the Secretary of HHS. In order to align this minimum benefits standard with the floor on benefits in Medicaid, the bill modifies the current law state option under section 1937 of the Social Security Act relating to benchmark and benchmark-equivalent coverage. Effective January 1, 2013, benchmark or benchmark-equivalent coverage offered by a state Medicaid program would be required to meet at least the

minimum benefits and cost-sharing standards of a basic plan offered through the Exchange. The bill does not alter the current law limitations on the populations to which a state may offer benchmark or benchmark-equivalent coverage. Nor does it modify the current law requirement that, with respect to children under 21, benchmark or benchmark-equivalent coverage include Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services.

Sec. 1704. Reduction in Medicaid DSH.

Current Law

In reimbursing hospitals for covered services furnished to Medicaid patients, states must pay adjustments to hospitals serving a disproportionate share of low-income patients (DSH hospitals). States have flexibility in designating DSH hospitals, but must include at least all hospitals meeting either of two minimum criteria: (1) a Medicaid inpatient utilization rate in excess of one standard deviation above the mean rate for the state, or (2) a low-income patient utilization rate of 25%. State payments to DSH hospitals qualify for federal Medicaid matching funds at the state's regular federal matching rate. The amount of federal Medicaid matching funds for DSH payments available to each state in any fiscal year is capped; each state's allotment is specified in federal statute. Allotments of federal DSH matching funds to all states totaled $11.3 billion in FY 2009.

Proposed Law

The bill would require the Secretary of HHS to reduce federal Medicaid matching payments to states for Medicaid DSH by a total of $10 billion over three years: $1.5 billion in FY2017, $2.5 billion in FY2018, and $6.0 billion in FY2019. This reduction in federal payments would be carried out through a DSH Health Reform methodology issued by the Secretary. This methodology would impose the largest percentage reductions in federal DSH payments on states with the lowest percentages of uninsured individuals (determined on the basis of audited hospital cost reports) during the most recent year for which such data are available and on states that do not target their DSH payments on hospitals with high volumes of Medicaid inpatients and hospitals that have high amounts of uncompensated care (excluding bad debt).

To give the Congress an opportunity to review the Secretary's DSH Health Reform methodology prior to its implementation, the bill would require the Secretary to submit a report to Congress not later than January 1, 2016, nine months before the beginning of FY 2017. The report would specify the DSH Health Reform methodology. The bill would also require the Secretary to publish a notice in the *Federal Register* setting forth the state-specific DSH allotment (as determined by the DSH Health Reform methodology) for FY 2017 by January 1, 2016. Similar notices would be required by January 1, 2017 for the FY 2018 DSH allotments, and by January 1, 2018 for the FY 2019 DSH allotments. The timing of these reports is designed to give the Congress nine months to review the proposed allotments for a coming fiscal year and to take any needed corrective action before the reductions are implemented.

The Secretary's report would also discuss the extent to which there is a continued role for Medicaid DSH payments in light of the effectiveness of the health reforms carried out under the bill in reducing the number of uninsured individuals. The report would also include recommendations regarding (1) the appropriate targeting of Medicaid DSH payments within states and (2) the distribution of Medicaid DSH payments among states, taking into account the ratio of the amount of DSH funds allocated to a state to the number of uninsured individuals in such states. In preparing the report, the Secretary would be required to consult with community-based health care networks serving low-income beneficiaries. The Secretary would also be required to coordinate this report with the report on Medicare DSH required under section 1112 of the bill (described above).

Finally, the bill would clarify that a hospital may not be defined or deemed to be a Medicaid DSH hospital or an Essential Access Hospital, and may therefore not receive Medicaid DSH payments for which there is federal matching, unless the hospital meets the following requirements: first, the hospital must ensure that services in its facilities are provided to Medicaid beneficiaries without discrimination on the ground of race, color, national origin, creed, source of payment, status as a Medicaid beneficiary, or any other ground unrelated to such beneficiary's need for the services or the availability of the needed services in the hospital; and second, the hospital must make arrangements for, and accept, reimbursement for services provided to Medicaid beneficiaries. These requirements would apply with respect to Medicaid DSH payments made on or after July 1, 2010.

Sec. 1705. Expanded outstationing

Current Law

State Medicaid programs must provide for the receipt and initial processing of Medicaid eligibility applications for low-income pregnant women, infants, and children under age 19 at locations other than welfare offices. These outstation locations must include Medicaid disproportionate share (DSH) hospitals and federally-qualified health centers (FQHCs). State eligibility workers assigned to outstation locations perform initial processing of Medicaid applications including assisting applicants in completing the application, providing information and referrals, obtaining required documentation to complete processing of the application, ensuring that the information contained on the application form is complete, and conducting any necessary interviews. States must also use applications which are other than those used for aid under Temporary Assistance for Needy Families (TANF).

Proposed Law

There is evidence that the availability of outstation locations for submitting applications facilitates Medicaid enrollment by eligible individuals. In order to reduce the number of individuals who are eligible for Medicaid but not enrolled, the bill would require that state Medicaid programs provide for the receipt and initial processing of Medicaid eligibility applications at outstation locations by all applicants, not just low-income pregnant women, infants, or

children under age 19. This requirement would generally be effective July 1, 2010, whether or not final implementing regulations are issued.

Low-income individuals who are not eligible for Medicaid but are eligible for affordability credits in the Exchange may receive health services at Medicaid DSH hospitals, FQHCs, or other outstation locations. In order to facilitate receipt of affordability credits by these individuals, the bill would require state Medicaid programs to allow individuals to apply for affordability credits through these same outstation locations. The details of this outstation application process would be set forth in the Medicaid memorandum of understanding between each state Medicaid agency and the Commissioner of the Health Insurance Exchange under section 1702(a) of the bill.

Subtitle B—Prevention

Sec. 1711. Required coverage of preventive services

Current Law

States that elect to participate in Medicaid and receive federal matching funds must cover certain "mandatory" items and services. In addition, states may receive federal matching funds for the costs of covering certain "optional" items and services. In the case of eligible children under age 21, states must cover Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services, which include a range of preventive services for children. States may not impose copayments or other cost-sharing on preventive services provided to children under age 18 regardless of family income.

In the case of eligible adults, states may cover preventive services, and they may impose cost-sharing on such services for adults with incomes above 100% of the Federal Poverty Level. For adults with family income between 100 and 150% of FPL, cost-sharing cannot exceed 10% of the cost of the item or service. For adults with family income above 150% of FPL, cost-sharing cannot exceed 20% of the cost of the item or service. States may allow providers to withhold services from beneficiaries who do not pay their required cost-sharing amounts.

The U.S. Preventive Services Task Force (USPSTF) reviews the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services and issues recommendations to primary care clinicians for the provision of services in their practices. The recommendations are assigned one of five letter grades. Grade A means there is a high certainty that the net benefit is substantial. An example is screening all pregnant women for tobacco use and providing augmented pregnancy-tailored counseling to those who smoke. Grade B means there is high certainty that the net benefit is moderate or there is moderate certainty that the net benefit is moderate to substantial. An example is screening mammography, with or without clinical breast examination, every 1–2 years for women aged 40 and older. In both Grade A and Grade B recommendations, the USPSTF recommends that the clinician offer or provide the service.

Proposed Law

The bill would require state Medicaid programs to cover preventive services that are not otherwise covered through the EPSDT benefit for children under 21 and that the Secretary determines are (1) recommended with a grade of A or B by the Task Force on Clinical Preventive Services or are vaccines recommended by the Director of the Centers for Disease Control and Prevention, and (2) appropriate for Medicaid beneficiaries. The Task Force for Clinical Preventive Services is the statutory successor to the USPSTF established by section 2301(a) of the bill.

In order to promote the use of these evidence-based clinical services, the bill would prohibit state Medicaid programs from imposing any cost-sharing on a preventive service, regardless of the family income of the beneficiary. Both the requirement for the coverage of preventive services and the prohibition against the imposition of cost-sharing on such services would take effect July 1, 2010, except in cases where the Secretary determines that a state must enact legislation in order to amend its state Medicaid plan.

The bill makes two conforming amendments. It clarifies that vaccines covered under the Vaccines for Children (VFC) program are those recommended by the CDC Director, rather than an advisory committee to the Director. It also strikes the current law provision that terminates the VFC program in the event that federal law provides for immunization services for all children as part of a broad-based reform of the national health care system.

Sec. 1712. Tobacco cessation

Current Law

State Medicaid programs may cover prescription drugs. If a state Medicaid program elects to do so, as all currently do, the state must cover prescription drugs approved by the Food and Drug Administration (FDA). States may, however, exclude certain classes of FDA-approved drugs from coverage altogether. One of these excludable classes is agents when used to promote smoking cessation.

Proposed Law

The bill would remove agents approved by the FDA for purposes of promoting tobacco cessation from the list of excludable drugs. Thus, state Medicaid programs that cover prescription drugs would be required to cover these products, when they are used to promote tobacco cessation. This requirement would take effect with respect to drugs and services furnished January 1, 2010.

Sec. 1713. Optional coverage of nurse home visitation services

Current Law

Nurse home visitation programs involve registered nurses making home visits to low-income, first-time mothers, starting during pregnancy and continuing through the child's second birthday. The nurses work with the mothers on healthy behaviors to improve pregnancy outcomes, parenting skills to improve child health and development, and plans for the mother's life. Visits are initially weekly, then monthly. There is strong research evidence from rigorous random-assignment evaluations that these programs improve

the health of pregnant mothers, reduce emergency room visits, reduce rates of child abuse and neglect, and improve school achievement.

The Medicaid statute does not expressly recognize nurse home visitation programs as an optional service. It does, however, allow states to cover care coordination or case management services that include some of the elements of effective nurse home visitation programs. For example, states may cover case management services that are targeted to specific groups of beneficiaries, such as first-time pregnant mothers, and that assist Medicaid-eligible women gain access to needed medical, social, educational, and other services. Effective nurse home visitation programs involve more than case management, however.

Proposed Law

The bill would give states the option of covering nurse home visitation services at the state's regular matching rate beginning on January 1, 2010. The bill defines these services as home visits by trained nurses to families with first-time pregnant women or a child under age 2, either of whom is eligible for Medicaid.

The content and frequency of the home visitation services would be determined by the Secretary based upon evidence that the services are effective in one or more of the following areas: (1) improving maternal or child health and pregnancy outcomes or increasing birth intervals between pregnancies; (2) reducing the incidence of child abuse, neglect, and injury, improving family stability (including reduction in the incidence of intimate partner violence), or reducing maternal and child involvement in the criminal justice system; and (3) increasing economic self-sufficiency, employment advancement, school-readiness, and educational achievement, or reducing dependence on public assistance. The Secretary is not required to implement this provision by regulation, but may instead provide administrative guidance in the form of a letter to state Medicaid Directors.

The bill clarifies that this new state option does not alter any current authority in Medicaid or the Child Health Insurance Program (CHIP) that enables states to use federal matching funds, whether for services or administrative activities, to help cover the cost of nurse home visitation services for eligible women or children.

Sec. 1714. State eligibility option for family planning services

Current Law

States are required to extend Medicaid coverage to pregnant women with family incomes up to 133% of the federal poverty level ($14,400 for an individual in 2009). States have the option of covering pregnant women with incomes above 133% FPL. Coverage is limited to services related to pregnancy (including prenatal, delivery, postpartum, and family planning services) and to other conditions that may complicate pregnancy and extends for 60 days post-partum. In most states, after the 60-day post-partum period ends, the mother generally loses her Medicaid eligibility because the income eligibility levels for parents are lower than 133% of FPL (or higher in those states that have raised their eligibility levels).

Under section 1115 of the Social Security Act, the Secretary of HHS has the authority to grant waivers to states to enable them to use federal Medicaid funds for populations not otherwise eligible. As of 2009, the Secretary had granted section 1115 waivers under section 1115 to 27 states to enable them to extend coverage for family planning services and supplies to low-income women who are not pregnant and are not otherwise eligible for Medicaid. In some cases, the waivers cover women who would otherwise lose coverage post-partum, in other women who have not been previously eligible for Medicaid. Many of these waivers have been successful in reducing the incidence of unwanted births and improving the health of low-income women. The Congressional Budget Office has estimated that requiring states to cover family planning services for all women between the ages of 15 and 44 with family incomes up to 200% of FPL would save the federal government $160 million over 10 years.

Proposed Law

The bill would give states the option of extending coverage for family planning services and supplies to individuals who are not pregnant and whose income does not exceed an income eligibility level set by the state that is no higher than the highest income eligibility level in the state for pregnant women (either under the state's Medicaid or CHIP program). This would enable state Medicaid programs to cover family planning services and supplies for any individual who would be eligible for Medicaid coverage of pregnancy-related care. In determining income, the state could, at its option, consider only the income of the applicant or beneficiary and disregard the income of any family members. The state would not have authority to impose a resource or assets test or to prohibit participation of any otherwise eligible individual who has individual or group health insurance coverage that does not cover family planning services and supplies.

For purposes of this option, family planning services and supplies would include medical diagnosis and treatment services provided pursuant to a family planning services in a family planning setting (including, at state option, testing and treatment of sexually transmitted infections). As under current law, the federal matching rate for the costs of family planning services and supplies would be 90%. The federal matching rate for the cost of the medical diagnosis and treatment services provided pursuant to a family planning service would be the state's regular FMAP. The new option would be effective on enactment. The Secretary would not be required to issue regulations to implement the provision.

The bill does not require states to discontinue their current section 1115 family planning waivers, nor does it prohibit the Secretary from renewing existing waivers or granting new ones. The bill facilitates the conversion of existing waivers into a state plan amendment under this new option by allowing states to do so without modifying their existing eligibility policies. Specifically, the bill gives a state the ability to continue to use eligibility standards and processes, including application procedures and practices, that were operational under the state's waiver on or before January 1, 2007.

The bill would give states a related option of extending coverage for family planning services and supplies to presumptively eligible

individuals for a limited period of time during which the Medicaid application is being processed. The purpose of this option is to avoid any delay in the provision of services to women at risk of unwanted pregnancy. Under this option, the state may designate qualified entities, including family planning providers, to accept (and assist an individual in filing) applications for coverage, and to make a determination that an individual is presumptively eligible for Medicaid under the new family planning option. The presumptive eligibility period ends when the state Medicaid agency makes an eligibility determination with respect to the applicant or (in the case of an individual who does not file a timely application) the end of the month following the month in which the qualified entity made the determination of presumptive eligibility, whichever comes first.

The bill clarifies that, in the case of a state that elects the option to provide benchmark or benchmark-equivalent coverage under section 1937 of the Social Security Act, the coverage must include payment for family planning services and supplies for all Medicaid beneficiaries of child-bearing age who seek such services and supplies. This requirement applies to states that currently offer benchmark or benchmark-equivalent coverage under approved state plans as well as states that elect to do so in the future.

Subtitle C—Access

Sec. 1721. Payments to primary care practitioners

Current Law

State Medicaid programs are required to cover physicians' services, but they have flexibility in determining the amounts that physicians will be paid for those services either on a fee-for-service basis or in managed care organization networks. Current law requires that state Medicaid plans provide methods and procedures to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available promptly and at least to the extent that such care and services are available to the general population in the geographic area.

There is wide variation in Medicaid fee-for-service payment rates for physicians' services from state to state. In 2008, state payment rates for physicians' services averaged 72% of Medicare's payment rates. In the case of primary care services furnished by physicians, Medicaid payment rates averaged 66% of Medicare rates, with one state as low as 36% and one as high as 140%. These low Medicaid payment rates do not provide adequate incentives for physicians to participate in Medicaid, limiting access to physicians' services by Medicaid beneficiaries. In addition, low Medicaid payment rates discourage young physicians and other health professionals from entering careers in primary care, undermining efforts to address the shortage of primary care practitioners in many areas of the country.

Proposed Law

The bill would require state Medicaid programs to pay for primary care services furnished by physicians at a rate that is not less than (1) 80% of the payment rate under Medicare's physician fee

schedule for services furnished in 2010, (2) 90% of such rate for services furnished in 2011, and (3) 100% of such rate for services furnished in 2012 and subsequent years. States would continue to have the flexibility to pay for primary care services (or other physicians' services) at rates higher than Medicare.

The same minimum rate requirement would also apply to services furnished by other health care professionals that would be primary care services if furnished by a physician. In such cases, the Medicare rate would be the rate applicable to the health professional, not to the physician.

This minimum rate requirement would apply to payments for primary care services furnished by any participating physician or health professional, not just a primary care physician or professional such as a pediatrician or nurse practitioner. Thus, the requirement would apply to payments for primary care services furnished to a Medicaid beneficiary by a specialist or sub-specialist, but not to non-primary care services furnished by that specialist or sub-specialist.

Primary care services would be defined as evaluation and management services under section 1848(j)(5)(A)(i) of the Social Security Act (as added by section 1121(d) of the bill). These are services in the category designated Evaluation and Management in the Health Care Common Procedure Coding System as established and periodically modified by the Secretary of HHS.

This minimum rate requirement would apply whether a physician or health professional is furnishing services to Medicaid beneficiaries on a fee-for-service basis, as a primary care case manager, or as a member of the network of a Medicaid managed care organization (MCO). Medicaid MCOs would be required to pay physicians and other health professionals (whether in or out of network) for primary care services at rates no lower than the minimum rates specified above. In the case of MCOs that use compensation arrangements with network physicians and health professionals that are not based on fee-for-service, such as capitation or partial capitation, the compensation would have to be at least the same as the compensation the physician or health professional would receive were payment to be made on a fee-for-service basis.

This minimum rate requirement is effective for primary care services furnished on or after January 1, 2010. Initially, the federal government will finance all of the cost attributable to this new requirement. Specifically, for services furnished through December 31, 2014, the federal government will pay 100% of the increased cost. For services furnished after that date, the federal government will pay 90% of the increased cost.

The cost attributable to this requirement is the amount by which the minimum payment rate for a primary care service exceeds the payment rate applicable to the service for the physician or other health professional (as the case may be) under a state's Medicaid program as in effect on June 16, 2009.

The following hypothetical example illustrates this policy. Assume that the Medicare rate for a primary care office visit for an established patient in 2012 in the state (or locality) will be $70 and that the Medicaid payment in that state (or locality) in 2009 for that visit was two thirds of the $60 Medicare rate in 2009, or $40. Also assume that the state's regular federal matching rate is 50%

in both years. The minimum Medicaid rate the state is required to pay in 2012 is 100% of the Medicare rate. Thus, the physician would receive $70 for the office visit. Of this amount, the federal government would pay $50 (50% of $40, or $20, plus 100% of the $30 difference between the 2009 amount and the 2012 Medicare rate, or $30). The state would pay $20—the same amount it would have paid had its Medicaid rate remained unchanged at $40 per visit between 2009 and 2012.

If the state chose to pay the physician more for a service than the Medicare rate, the state's regular federal matching rate would apply to the costs attributable to amounts above the Medicare rate. In the above example, if the state's rate in 2012 for the primary care visit was $80, the state would pay half of the $10 increase above the Medicare rate of $70, and the federal government the other half. In total, the federal government would pay $55, and the state $25.

1722. Medical home pilot program

Current Law

There is no single definition of medical home. In the context of Medicaid, the term has been used to refer to a model of primary care in which teams of physicians and other health professionals provide comprehensive and coordinated patient-centered care for which they are adequately reimbursed. The concept of a medical home is not recognized in the Medicaid statute, and the federal government currently does not operate national or regional medical home demonstrations or pilots under Medicaid. The Medicaid Transformation Grants authorized by section 1903(z) of the Social Security Act for FY 2007 and FY 2008 were used by eight states to provide funding to develop information technology infrastructure for medical home programs. According to the National Academy of state Health Policy, as of June 2009, 31 states were operating medical home programs for one or more groups of Medicaid or CHIP beneficiaries, often with state funding only.

Proposed Law

The bill would require the Secretary of Health and Human Services to establish a 5-year medical home pilot program for the Medicaid program. This program would parallel (and be coordinated with) the Medicare medical home pilot authorized by section 1302 of the bill. The program would provide care for "high need" Medicaid beneficiaries (including medically fragile children and high-risk pregnant women). It would apply one or more of the models under the Medicare medical home pilot: the independent patient-centered medical home model described in section 1866F(c) of the Social Security Act and the community-based medical home model described in section 1866F(d)). The pilot could also include a test of other models the Secretary approves.

The bill authorizes higher federal matching rates for the administrative costs incurred by states in operating these pilots, such as the costs of community care workers. The higher rates could reach 90% for the first two years, then 75% of the last three. Total additional federal funding for these administrative expenditures could not exceed $1.235 billion over the five year period of the program.

States with pilot programs approved by the Secretary would be eligible to receive these higher administrative matching rates regardless of whether they were operating a medical home program prior to the establishment of this pilot program.

The bill authorizes the Secretary to waive the Medicaid statutory requirements of statewideness and comparability in order to facilitate these pilot programs. The bill does not authorize the Secretary to waive any other Medicaid statutory requirements, such as freedom of choice of provider.

In the case of a model involving medically fragile children, the bill would require the Secretary to ensure that the patient-centered medical home services received by each child provide for continuous involvement and education of the parent or caregiver and for assistance to the child in obtaining necessary transitional care if a child's enrollment ceases for any reason.

The bill directs the Secretary to conduct an evaluation of the pilot program using the criteria specified for purposes of the Medicare medical home pilot under section 1866F(e)(1) of the Social Security Act and to report the findings to Congress and the public.

Sec. 1723. Translation or interpretation services

Current Law

Section 201(b)(2)(A) of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA, P.L. 111–3) established a 75% federal matching rate for the cost to state Medicaid programs of providing language translation or interpretation services in connection with the enrollment and retention of, and use of services by, children of families for whom English is not the primary language.

Proposed Law

The bill would extend the 75% federal matching rate for the cost of providing language translation or interpretation services to all individuals for whom English is not the primary language. Allowable costs would include those found necessary by the Secretary for services to facilitate the enrollment and retention of individuals eligible for Medicaid as well as for services to promote access to covered health and long-term care services and to address language barriers to the appropriate delivery of those services. The provision would take effect January 1, 2010; the Secretary would not be required to issue implementing regulations.

Sec. 1724. Optional coverage for freestanding birth center services

Current Law

Medicaid pays for more than one in three births in the United States. One option other than a hospital birth or a homebirth is a freestanding birth center. State Medicaid programs have the option of covering clinic services furnished by or under the direction of a physician and receiving federal matching funds for those costs. However, there is no provision in the Medicaid statute that authorizes federal Medicaid matching funds for direct payments to freestanding birth centers not operated by a physician for providing services to eligible pregnant women.

Proposed Law

The bill would give state Medicaid programs the option of covering freestanding birth center services and other ambulatory services offered by a freestanding birth center that are otherwise covered under the state Medicaid plan at the state's regular federal matching rate. Freestanding birth center services are defined as services furnished to an individual at a freestanding birth center, including services furnished by a licensed birth attendant at the center. A freestanding birth center is defined as a health facility that is not a hospital and where childbirth is planned to occur away from the pregnant woman's residence. A licensed birth attendant is defined as an individual who is licensed or registered by the state to provide health care at childbirth and who provides such care which the individual is legally authorized to perform under state law (or state regulatory mechanism provided by state law), regardless of whether the individual is under the supervision of, or associated with, a physician or other health care provider. This provision would apply to items and services furnished on or after the date of enactment; the Secretary would not be required to issue regulations to implement this option.

Sec. 1725. Inclusion of public health clinics under the vaccines for children program

Current Law

Under the Vaccines for Children (VFC) program, Medicaid pays the costs of recommended vaccinations for certain low-income children. Children who are eligible for vaccines under the program—"federally vaccine-eligible children"—include children who receive vaccines purchased through the program and administered at a federally qualified health center (FQHC) or rural health clinic (RHC) and are not insured with respect to vaccines.

Proposed Law

The bill would expand the definition of federally-vaccine eligible children to include children who are not insured with respect to a recommended vaccine and are administered the vaccine at a public health clinic. The purpose of this change is to improve access by low-income children to recommended vaccines by expanding the locations at which recommended vaccines can be administered to include health clinics operated by state or local health departments or hospitals. The provision is effective on enactment; the Secretary would not be required to issue regulations in order to implement this change.

Sec. 1726. Requiring coverage of services of podiatrists

Current Law

State Medicaid programs are required to cover physicians' services furnished by a physician as the term "physician" defined in section 1861(r)(1) of the Social Security Act (i.e., a doctor of medicine or osteopathy). The Medicare definition of physician at section 1861(r)(3) includes a doctor of podiatric medicine, but this does not apply to the Medicaid coverage requirement. State Medicaid programs may, however, cover podiatry services at their option.

Proposed Law

The bill would require state Medicaid programs to cover physicians' services furnished by a doctor of podiatric medicine with respect to functions he or she is legally authorized to perform under state law. This requirement would apply to services furnished on or after January 1, 2010, unless the Secretary determines that state legislation (other than for appropriations) is needed in order for the state Medicaid plan to meet the additional requirements of this section. In this case the requirement would apply the first day of the first calendar quarter after the close of the first regular session of the state legislature after enactment.

Sec. 1726A. Requiring coverage of services of optometrists

Current Law

State Medicaid programs have the option of covering services furnished by optometrists within their scope of practice under state law. States may also cover eyeglasses prescribed by an optometrist.

Proposed Law

The bill would require state Medicaid programs to cover medical and other health services authorized by state law to be furnished by optometrists to the extent that the services may legally be furnished by an optometrist under state law. An optometrist is defined as a doctor of optometry. This requirement would apply to services furnished, or other actions required, on or after 90 days after enactment, unless the Secretary determines that state legislation (other than for appropriations) is needed in order for the State Medicaid plan to meet the additional requirements of this section. In this case the requirement would apply the first day of the first calendar quarter after the close of the first regular session of the state legislature after enactment.

Sec. 1727. Therapeutic foster care

Current Law

In general, therapeutic foster care programs place children and adolescents who have serious emotional and behavioral problems with specially trained foster families. Some State Medicaid programs have elected to cover therapeutic foster care under the optional rehabilitative services benefit.

In August 2007, the Centers for Medicare & Medicaid Services published a proposed rule amending the definition of rehabilitative services to exclude therapeutic foster care services furnished by foster care providers to children, except for medically necessary rehabilitation services that are clearly distinct from packaged therapeutic foster care services, 72 *Federal Register* at 45212 (August 13, 2007). The Congress imposed a series of moratoria on the implementation of this proposed rule through April 1, 2009. Section 5003(d)(3) of the American Recovery and Reinvestment Act of 2009 (P.L. 111–5) states a Sense of the Congress that the Secretary should not promulgate the August 13, 2007 proposed rule as a final rule.

Proposed Law

The bill would clarify that nothing in the federal Medicaid statute prevents or limits a state Medicaid program from covering therapeutic foster care for eligible children in out-of-home placements under the rehabilitative services option. Therapeutic foster care is defined as a foster care program that provides certain services to eligible children and to foster parents. For children, those services are: (1) structured daily activities that develop, improve, monitor, and reinforce age-appropriate social, communications, and behavioral skills; (2) crisis intervention and crisis support services; (3) medication monitoring; (4) counseling; and (5) case management services. For foster parents, those services are specialized training and consultation on the management of children with mental illnesses and related health and developmental problems.

Sec. 1728. Assuring adequate payment levels for services

Current Law

In general, state Medicaid programs have flexibility to determine the rates they pay to providers for furnishing covered services to eligible individuals. This flexibility is bounded by federal statutory requirements. One of these is sometimes referred to as the "equal access" requirement. Specifically, state Medicaid programs must provide methods and procedures relating to payment for care and services as may be necessary to assure that payments are sufficient to enlist enough providers so that care and services are promptly available to Medicaid beneficiaries at least to the extent that such care and services are available to the general population in the geographic area. The Committee heard testimony that beneficiary access to covered services has in some states been compromised by limited provider participation due to low Medicaid payment rates.

Proposed Law

The bill would establish a procedure for monitoring and enforcing compliance with this equal access requirement. Each state would be required to submit to CMS a state Medicaid plan amendment that specifies the payment rates the state intends to use to pay providers (including facilities and practitioners) and managed care organizations for the services it covers in the coming year, along with data that will enable the Secretary to evaluate the state's compliance with the equal access requirement. Such additional data would include how payments to Medicaid managed care organizations take into account payment rates to providers under the state Medicaid plan.

The state plan amendment would be due by April 1 prior to the year to which the payment rates apply. The Secretary would be required to review the state plan amendment within 90 days of submission and approve or disapprove it. If the Secretary disapproves the amendment, the state would be required to submit immediately a revised amendment that brings it into compliance with the requirement. The provision is effective on enactment; the first year to which this requirement applies would be 2011.

Sec. 1729. Preserving Medicaid coverage for youths upon release from public institutions

Current Law

In general, federal Medicaid matching funds are not available for services delivered to individuals who are otherwise eligible for Medicaid but who are living in a public institution—that is, an institution that is the responsibility of a governmental unit or over which a governmental unit exercises administrative control. This includes juvenile correctional or residential facilities operated by states or localities but not medical facilities that are not linked to a public institution. Federal law does not require states to terminate Medicaid eligibility when an individual becomes an inmate in a public institution, but research indicates that many states do so. In such cases, the individual must reapply for Medicaid upon release from the institution, a process that may take several months, during which time the individual typically does not have a source of payment for needed medical or behavioral treatment.

Proposed Law

The bill would impose three requirements on state Medicaid programs with respect to youths who are age 18 or younger and enrolled in Medicaid at the time of being incarcerated in a public institution and who are age 18 or younger and eligible for Medicaid at the time of being released from the institution. First, the state Medicaid program is prohibited from terminating the youth's Medicaid eligibility during the period of incarceration. Second, during the period the youth is incarcerated, the state must ensure that the youth receives Medicaid services for which federal matching funds are available (the state may not claim federal matching funds for care or services that are excluded from coverage). Third, on or before the date the youth is released, the state shall ensure that the youth is enrolled in Medicaid so that the youth can access Medicaid-covered services immediately upon leaving the institution. The youth would remain enrolled in Medicaid until the state determines that he or she is no longer eligible. The provision is effective on enactment.

Sec. 1730. Quality measures for maternity and adult health services under Medicaid and CHIP

Current Law

Section 401 of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA, P.L. 111–3) directs the Secretary of HHS to develop (1) an initial core set of health care quality child health quality measures for children enrolled in Medicaid or CHIP, (2) a standardized format for reporting information, and (3) procedures to encourage states to use the initial core measurement set to voluntarily report information on the quality of pediatric care in these two programs. There is no comparable requirement with respect to maternity care or services to adults purchased by Medicaid.

Section 1442 of the bill would add a new section 1192 to the Social Security Act that directs the Secretary of HHS to enter into

agreements with qualified entities to develop quality measures for the delivery of health care services in the U.S.

Section 1443 of the bill would add a new section 1808(d) to the Social Security Act that sets forth a process for multi-stakeholder pre-rulemaking input into the selection of quality measures.

Proposed Law

The bill would require the Secretary of HHS to develop and publish for comment no later than January 1, 2011, a proposed set of measures on the quality of maternity care provided under both Medicaid and CHIP. The bill would require that the final recommended set of maternity care quality measures be published no later than July 1, 2011. No later than January 1, 2012, the Secretary would be required to develop and publish a standardized reporting format for maternity care quality measures for use by state Medicaid and CHIP programs to collect data from participating managed care entities, providers, and practitioners, and to report such measures to the Secretary.

The bill would require the Secretary to develop quality measures that are not otherwise developed under the section 1192 program established by section 1442 of the bill for services purchased by state Medicaid programs for non-elderly adults (individuals between the ages of 21 and 64). The Secretary would be required to publish such quality measures through notice and comment rulemaking. The Secretary would also be required to develop and publish a standardized reporting format for these quality measures (and for those developed under section 1192) for services purchased by state Medicaid programs for non-elderly adults. The reporting format must enable state administering agencies to collect data from participating managed care entities, providers and practitioners, and to report such measures to the Secretary.

The bill sets forth certain requirements with respect to the development of these quality measures and reporting formats. The Secretary would be authorized (but not required) to enter into agreements (by contract, grant or otherwise) with public, non-profit or academic institutions with technical expertise in health quality measurement to assist in the development of these measures and reporting formats. The Secretary would be required to obtain the input of stakeholders with respect to such quality measures using a process similar to that described in new section 1808(d) of the Social Security Act as added by section 1143 of the bill. Finally, the bill directs the Secretary to coordinate the development of these maternity and adult care quality measures with the development of child health quality measures.

To enable the Secretary to carry out these requirements, the bill appropriates a total of $40 million for the five-year period beginning in FY 2010. These funds would remain available until expended.

The bill directs the Secretary to report annually to the Committee on Energy and Commerce and the Senate Finance Committee regarding (1) the availability of reliable data relating to quality of maternity care provided under the Medicaid and CHIP programs, (2) the availability of reliable data relating to quality of services provided under Medicaid and CHIP programs to adults ages 21 to 64, and (3) recommendations for improving the quality

of such care and services furnished under Medicaid and CHIP. The first report would be due January 1, 2013.

The bill provides that no quality measure developed, published or used as a basis of measurement or reporting under this section may be used to establish an irrefutable presumption regarding either the medical necessity of care or the maximum permissible coverage for an individual who is receives services under Medicaid or CHIP.

Sec. 1730A. Accountable care organization pilot program

Current Law

Section 1301 of the bill would establish an accountable care organization (ACO) pilot program to test different payment incentive models to reduce the growth of expenditures and improve health outcomes for Medicare beneficiaries. These models are intended to promote accountability for a patient population, to encourage investment in infrastructure and redesigned care processes, and to reward physicians for the provision of high quality services and for efficient service delivery. The models to be tested are the performance target model, the partial capitation model, and other payment models developed by the Secretary. There is no provision in current Medicaid law for an ACO pilot program.

Proposed Law

The bill would require the Secretary of HHS to establish a 5-year ACO pilot program under Medicaid that applies one or more of the payment incentive models tested under the Medicare ACO pilot program established under section 1301 of the bill. States could apply for approval of an ACO Medicaid pilot program. To facilitate these pilot programs, the Secretary would be authorized to waive Medicaid requirements relating to statewideness and to comparability requirements. (The Secretary would not have authority to waive other federal Medicaid requirements). The Secretary would also be authorized to increase the matching percentages for administrative costs incurred by a state in connection the an ACO pilot program from the regular 50% matching rate up to 90% for the first two years and up to 75% for the next three years.

The Secretary would be required to evaluate the impact of the Medicaid ACO pilot program on beneficiaries, providers, and the Medicaid program itself using the same criteria she uses to evaluate the Medicare ACO pilot program under section 1301 of the bill. The Secretary would be required to submit a report on her findings to the Congress within 60 days after completion of the evaluation and to make her findings available to the public.

Subtitle D—Coverage

Sec. 1731. Optional Medicaid coverage of low-income HIV-infected individuals

Current Law

With some exceptions, the federal Medicaid statute requires state Medicaid programs to cover certain persons with disabilities and certain persons age 65 and over who meet the income and resources criteria under the Supplemental Security Income (SSI) pro-

gram. In 2009, the income threshold for the SSI-related Medicaid eligibility group is $674 per month for an individual and $1,011 per month for a couple, and the resources threshold is $2,000 for an individual and $3,000 for a couple. States are also required to continue Medicaid coverage for certain working disabled individuals under age 65 who were eligible for SSI and but for their earnings would continue to be eligible for SSI. States have the option to allow applicants with higher amounts of countable income and assets qualify for Medicaid.

Low-income individuals with HIV infection do not meet the SSI standard for disability unless their HIV infection has progressed to full AIDS. However, individuals with HIV infection may be found to be presumptively disabled if they are able to document one or more of a specified listing of opportunistic infections, cancers, or conditions. Individuals who do not have one of the listed conditions will be unable to qualify for Medicaid unless they are able to qualify through another category—for example, they are a child under 19 or a parent with a dependent child or an individual 65 or over. If low-income people with HIV were eligible, Medicaid, which generally covers physician and diagnostic services and prescription drugs, could help them forestall the progressive collapse of their immune system, contracting these conditions, or progressing to full AIDS.

The federal government's share of the costs of most Medicaid services is determined by the federal medical assistance percentage (FMAP), which varies by state and ranges from at least 50% to no more than 83%. A state's share of program expenditures is equal to 100% minus its FMAP. States that elect to cover Medicaid services for uninsured women diagnosed with breast and/or cervical cancer receive an enhanced FMAP for the costs of such benefits in which a state's share of expenditures is 30% lower than under the regular FMAP (e.g., a state with a 50% regular FMAP would receive a 65% federal match).

For the 50 states and the District of Columbia there are no limits on federal matching payments for allowable costs incurred in operating their Medicaid programs. Medicaid programs in the five territories (American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, and the Virgin Islands) are subject to annual ceilings on federal Medicaid matching funds.

Proposed Law

The bill would allow states (including the territories) to extend Medicaid coverage to individuals who have HIV infection with income and resources levels that do not exceed the maximum income and resource levels allowed for the state's SSI-related Medicaid eligibility groups. These individuals would not have to establish presumptive disability or disability for SSI purposes. The federal government's share of expenditures for this new eligibility group would be determined by the enhanced FMAP applicable to the costs of treatment for uninsured women diagnosed with breast and/or cervical cancer. The expenditures incurred by the territories in covering this eligibility group would be matched at the enhanced FMAP without regard to their federal Medicaid spending ceilings.

The provision would apply to calendar quarters beginning on or after the date of enactment without regard to whether or not final

regulations to carry out such amendments have been promulgated by such date. Federal Medicaid matching funds would not be available for items or services furnished to such individuals on or after January 1, 2013, the date on which state Medicaid programs will be required to cover all individuals with incomes at or below 133% of the federal poverty level and the Health Insurance Exchange established by the bill would take effect. At that point, depending on their incomes, low-income individuals with HIV would be able to obtain coverage for physician and diagnostic services and prescription drugs either through Medicaid or through the Exchange (with financial assistance for the cost of premiums in the case of those with incomes below 400% of the federal poverty level).

Sec. 1732. Extending transitional Medicaid Assistance (TMA)

Current Law

States are required to continue Medicaid coverage for certain low-income families who would otherwise lose coverage because of increases in the numbers of hours worked or because of increases in earned income. The period of continuation extends up to 12 months so long as the family's gross monthly earnings (less child care costs) do not exceed 185% of the federal poverty level. The purpose of this transitional medical assistance (TMA) requirement is to promote the transition of low-income families from cash assistance to self-sufficiency by reducing the work disincentive that results from the loss of Medicaid coverage when the employer does not offer health insurance coverage, or offers coverage that the family cannot afford. This requirement expires on December 31, 2010.

Proposed Law

The bill extends the TMA requirement through December 31, 2012. Under this extension, families who would otherwise lose Medicaid coverage due to increased hours or work or earnings on or before that day will be entitled to up to one year of continuation Medicaid coverage. This will protect the work incentives resulting from the TMA requirement while the bill's coverage expansions are implemented. (On January 1, 2013, states will be required to offer Medicaid coverage to all working families with incomes at or below 133% of FPL, and the Health Insurance Exchange will offer coverage for working families with incomes above that level (along with assistance in purchasing coverage for those with incomes below 400% of FPL)).

Sec. 1733. Requirement of 12-month continuous coverage under certain CHIP programs

Current Law

Under the Children's Health Insurance Program (CHIP), states have three administrative options. They may enroll CHIP-eligible low-income children in their Medicaid programs, create a stand-alone CHIP program that is separate from Medicaid, or use a combination of both approaches.

Regardless of administrative structure, states are required to redetermine eligibility of children enrolled in CHIP at least every 12 months. Section 104 of the Children's Health Insurance Program

Reauthorization Act of 2009 (CHIPRA, P.L. 111–3) establishes a program of performance bonus payments to states that adopt 4 of a list of 7 enrollment and retention provisions. One such provision is continuous eligibility for a full 12 months for all children under both the state's Medicaid and CHIP programs. This allows a child, once determined eligible, to remain eligible for a full 12-month period, regardless of any intervening change in family income.

Proposed Law

The bill would require separate CHIP programs (including such programs in states that use a combination Medicaid and separate CHIP approach) to implement 12 months of continuous eligibility for eligible children with family incomes below 200% of the federal poverty line. This provision would apply to eligibility determinations and to redeterminations made on or after January 1, 2010, and would not require the issuance of a regulation by the Secretary in order to take effect.

Sec. 1734. Preventing the application under CHIP of coverage waiting periods for certain children

Current Law

State CHIP programs are required to have procedures to ensure that the coverage provided under the state CHIP program does not substitute for coverage under group health plans. One anti-substitution procedure that some state CHIP programs use is to impose a waiting period on an otherwise eligible child applying for CHIP coverage. The waiting period runs for a specified number of months after the loss of coverage under a group health plan. During this period, the child, although eligible for CHIP coverage, is uninsured.

Proposed Law

The bill would prohibit state CHIP programs from applying a waiting period to delay the enrollment of any of the following children: (1) infants and toddlers under two years of age; (2) children who have lost health insurance coverage under a group health plan or health insurance coverage offered through an employer due to (a) termination of employment, (b) a reduction in work hours, (c) elimination of an individual's retiree health benefits, or (d) termination of an individual's health insurance coverage offered through an employer; or (3) children in families that demonstrate that the cost of health insurance coverage (including the cost of premiums, co-payments, deductibles, and other cost sharing) exceeds 10% of the family's income. (Family income would be determined in the same manner as the state determines family income for purposes of eligibility determinations under its CHIP program). This prohibition would take effect 90 days after enactment. The Secretary would not be required to issue regulations to implement this prohibition.

Sec. 1735. Adult day health care services

Current Law

Adult day health care (ADHC) services are a type of long-term care service for elderly or disabled individuals who have chronic health conditions or cognitive impairments that require regular

monitoring or treatment. ADHC services provide nursing, physical and occupational and speech therapy, personal care, dietary and meal, activities, and transportation services designed to enable the frail elderly and individuals with disabilities to remain in the community and delay entry into a nursing facility.

State Medicaid programs may cover ADHC services under a section 1915(c) home- and community-based waiver for individuals who require the level of care available in a nursing facility. The Medicaid statute does not expressly recognize ADHC services as a service that states may cover at their option without obtaining a section 1915(c) waiver. However, prior to 1994, the federal government had approved state plan amendments authorizing 8 state Medicaid programs to cover ADHC services, in some cases under the statutory option to cover rehabilitative services.

In August 2007, the Centers for Medicare & Medicaid Services published a proposed rule amending the definition of the optional rehabilitative services benefit, 72 *Federal Register* at 45201 (Aug. 13, 2007). One effect of this proposed rule would have been to disallow federal Medicaid matching payments for coverage of ADHC services under the rehabilitative services option. Congress imposed a series of moratoria on the implementation of this proposed rule through April 1, 2009. Section 5003(d)(3) of the American Recovery and Reinvestment Act of 2009 (P.L. 111–5) states a "Sense of the Congress" that the Secretary should not promulgate the August 13, 2007, proposed rule as a final rule.

Proposed Law

The bill would prohibit the Secretary from withholding, suspending, disallowing, or otherwise denying federal Medicaid matching payments for the costs of adult day health care services, day activity and health services, or adult medical day care services, as defined under a state Medicaid plan approved during or before 1994, if these services are provided consistent with the definition in the approved state plan and the requirements of the plan. The bill would also prohibit the Secretary from withdrawing (by regulation or otherwise) federal approval of all or part of any such state Medicaid plan relating to the provision of ADHC services. This provision would apply to services provided on or after October 1, 2008.

Sec. 1736. Medicaid coverage for citizens of freely associated states

Current Law

The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA, P.L. 104–193) prohibits noncitizens who are not considered to be "qualified aliens" (e.g., legal permanent residents, asylees, refugees) from receiving Medicaid benefits (other than for treatment of an emergency medical condition). Citizens of the Freely Associated States (i.e., citizens of the Republic of the Marshall Islands (RMI), the Federated States of Micronesia (FSM), and the Republic of Palau) are not included in the PRWORA definition of "qualified alien" under PRWORA and are therefore barred from receiving non-emergency Medicaid.

PRWORA also bars "qualified aliens" arriving in the United States on or after August 22, 1996, from Medicaid coverage for the first five years after entry (other than for treatment of an emer-

gency medical condition). After an individual's 5-year waiting period has run, states have the option of extending Medicaid coverage to the individual if he or she is otherwise eligible. Section 214 of the Children's Health Insurance Reauthorization Act of 2009 (CHIPRA, P. L. 111–3) allows states to provide Medicaid and CHIP coverage to legal immigrant children and pregnant women notwithstanding this 5-year bar.

Proposed Law

The bill would nullify the PRWORA rules with respect to Medicaid coverage of individuals who lawfully reside in the United States (including territories and possessions of the United States) in accordance with the Compacts of Free Association between the Governments of the Federated States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau. These individuals would be defined as "qualified aliens" for purposes of receiving Medicaid benefits. They would not be subject to the 5-year bar, and states would not have discretion to deny Medicaid coverage on the grounds that these individuals are "qualified aliens." If these individuals otherwise meet the eligibility requirements for Medicaid in the state (or territory or possession) in which they reside, they would be entitled to Medicaid benefits.

Sec. 1737. Continuing requirement of Medicaid coverage of non-emergency transportation to medically necessary services

Current Law

Federal Medicaid regulations (42 CFR 431.53) require state Medicaid agencies to ensure necessary transportation for beneficiaries to and from providers, and to describe the methods that the agency will use to meet this requirement. The purpose of this requirement is to ensure access to covered services by low-income beneficiaries, including those in rural areas, who live far from their providers and have no personal means of transportation, as well by those beneficiaries with disabilities who require specialized transportation to access their treating providers.

In December 2007, the Centers for Medicare & Medicaid Services (CMS) issued a final rule (72 *Federal Register* 73635, Dec. 28, 2007) that, among other things, modified 42 CFR 431.53 to exclude from necessary transportation the transportation of school-age children between home and school. The Congress imposed a series of moratoria on the implementation of this rule through July 1, 2009. Just prior to this date, CMS rescinded the 2007 final rule on school-based administration and transportation (see 74 *Federal Register* 31183, June 30, 2009) and revised 42 CFR 431.53 to delete the exclusion for transportation of school-aged children between home and school.

Proposed Law

The bill would codify non-emergency transportation to medically necessary services, consistent with the requirement of 42 CFR 431.53 as in effect as of June 1, 2008, as a mandatory Medicaid benefit. (On June 1, 2008, the congressional moratorium on the December 2007 final rule was in effect, nullifying the changes that rule attempted to make in 42 CFR 431.53; thus the requirement

that is being codified is the one in place before the December 2007 rule was issued.). The provision would apply to non-emergency transportation to medically necessary services provided on or after enactment.

Sec. 1738. State option to disregard certain income in providing continued Medicaid Coverage for certain individuals with extremely high prescription costs

Current Law

State Medicaid programs have the option of extending coverage to "medically needy" individuals. These are aged or disabled individuals, or children and parents, whose countable assets are below the state's medically needy resource eligibility threshold and who incur high medical expenses which, when subtracted from their income, reduce that income to an amount below the State's medically needy income eligibility threshold.

There is no authority in current law for state Medicaid programs that do not cover the medically needy to offer coverage to individuals with rare diseases or conditions who incur extremely high prescription drug expenses due to the high cost of the orphan drugs (as designated under section 526 of the Food, Drug, and Cosmetic Act (21 U.S.C. 360bb)).

Proposed Law

The bill gives state Medicaid programs the option of covering certain individuals with extremely high prescription drug costs attributable to an orphan drug by disregarding a specified amount of family income when redetermining Medicaid eligibility. Individuals eligible under this option would have to (1) have extremely high prescription drug costs and (2) be determined otherwise eligible for Medicaid but for family income. A state electing this option would be required to impose nominal cost-sharing on the drugs purchased by the individual and could, at its option, impose additional cost-sharing up to a maximum level specified by the Secretary. The state would be required to consider an individual's reapplication for Medicaid under this option within 30 days of the filing of the application.

An individual would be considered to have extremely high prescription drug costs for a 12-month period if he or she: (1) is covered through an individual or group health insurance policy that has a maximum lifetime limit of at least $1 million, including prescription drug coverage; (2) has exhausted all available prescription drug coverage under the policy prior to the beginning of the 12-month period; (3) incurs (or is reasonably expected to incur) during the 12-month period costs for orphan drugs in excess of $200,000 (adjusted annually by the rate of medical inflation after 2010); and (4) has an annual family income at the beginning of the period of no more than 75% of the costs the individual incurs for orphan drugs in excess of $200,000, as adjusted.

The amount of family income that a state could disregard under this option could not exceed the greater of (1) $200,000 (adjusted annually by the rate of medical inflation after 2010) or (2) the cost of orphan drugs incurred (or reasonably expected to be incurred)

during the 12–month period. The provision would take effect on enactment.

Subtitle E—Financing

Sec. 1741. Payments to pharmacists

Current Law

Medicaid law requires the Secretary of HHS to establish upper limits on the amounts that state Medicaid programs may pay pharmacists for multiple source (generic) drugs and receive federal matching payments for the costs of such drugs. These are known as federal upper limits, or FULs, and they apply to aggregate state expenditures for each drug. Prior to January 1, 2007, the FUL limit was set at 150% of the lowest published price (i.e., wholesale acquisition cost, average wholesale price or direct price) for each dosage and strength of the generic drug products.

The Deficit Reduction Act of 2005 (DRA; P.L. 109–171) established a new limit for FULs, effective January 1, 2007, equal to 250% of the average manufacturer price (AMP) of the least costly therapeutic equivalent (excluding prompt-pay discounts to wholesalers). AMP is the average price paid to the manufacturer by wholesalers for drugs distributed to the retail pharmacy class of trade. Manufacturers, as a condition of Medicaid purchasing their products, must report AMP data to the Centers for Medicare & Medicaid Services (CMS).

Section 203 of Medicare Improvements for Patients and Providers Act of 2008 (MIPPA, P.L. 110–275) imposed a moratorium on the implementation of the DRA change in FUL limits until October 1, 2009. In the interim, FULs are set based on the pre-DRA methodology of 150% of the lowest published price.

Proposed Law

The bill would direct the Secretary to calculate FULs as 130% of the weighted average (determined on the basis of manufacturer utilization of multiple source drugs) of monthly average manufacturer prices (AMPs). FULs specified under this new formula would apply beginning January 1, 2011. The FULs specified under 42 CFR 447.332 as in effect on December 31, 2006, would continue to apply through December 31, 2010.

The bill revises the definition of AMP in the Medicaid statute, both for purposes of calculating FULs and for determining Medicaid rebate amounts. In determining the AMP, the Secretary would be required to exclude the following: (1) customary prompt-pay discounts extended to wholesalers; (2) *bona fide* service fees paid by manufacturers; (3) reimbursement by manufacturers for recalled, damaged, expired, or otherwise unsalable returned goods, including reimbursement for cost of the goods and reimbursement for the costs associated with return goods handling and processing, reverse logistics, and drug destruction; (4) sales directly to, or rebates, discounts, or other price concessions provided to, pharmacy benefit managers (PBMs), managed care organizations (MCOs), health maintenance organizations, insurers, mail-order pharmacies (such as those operated by PBMs) that are not open to all members of the public, or long-term care providers, so long as these discounts, rebates, and price concessions are not passed through to re-

tail pharmacies; (5) sales directly to, or rebates, discounts, or other price concessions provided to, hospitals, clinics, and physicians, unless the drug is an inhalation, infusion, or injectable drug, or the Secretary determines under HHS administrative procedures that it is necessary to include these sales, rebates, discounts, and price concessions in order to calculate an accurate AMP for the drug; and (6) rebates, discounts, and other price concessions required under subsections (f) and (g) of section 1860D–2(f) of the Social Security Act (as added by section 1181(b) of the bill). A determination by the Secretary that it is necessary to include certain sales or price concessions to hospitals, clinics, and physicians in order to obtain an accurate AMP for a drug would not be subject to judicial review.

The bill requires manufacturers that have entered into Medicaid drug rebate agreements with the Secretary to report within 30 days after the last day of each month of a rebate period, the manufacturer's total number of units used to calculate the monthly AMP for each covered drug. The bill clarifies that manufacturers are required to submit specified AMP pricing information to the Secretary within 30 days of the end of each month of a rebate period, rather than within 30 days of the end of a rebate period.

The bill authorizes the Secretary to promulgate in an expedited manner regulations setting forth the requirements for FULs and for the determination of AMPs. These regulations could be effective on an interim final basis pending opportunity for public comment.

The bill would eliminate the current law requirement that the Secretary post on a website accessible to the public, and update on a quarterly basis, the most recently reported AMPs for single source drugs and for multiple source drugs.

Sec. 1742. Prescription drug rebates

Current Law

Medicaid law requires prescription drug manufacturers that seek to sell any of their products to State Medicaid programs to enter into a rebate agreement with the Secretary of HHS. Under these agreements, manufacturers must provide state Medicaid programs with rebates for the drugs purchased for Medicaid beneficiaries on an outpatient basis, and state Medicaid programs must cover all drugs (except certain statutorily excluded drug classes) marketed by those manufacturers. The rebates are shared by the state and federal governments in proportion to their respective shares of Medicaid drug expenditures. Certain drugs are not subject to rebates, including drugs dispensed by Medicaid managed care organizations, drugs used on an inpatient basis, and drugs dispensed in physicians' or dentists' offices.

In the case of brand-name prescription drugs, a manufacturer's rebate obligation is the sum of two components—the basic rebate and an additional rebate. The basic rebate is the greater of (1) 15.1% of the average manufacturer price (AMP) or (2) the difference between AMP and the best price. The AMP is the average price that a manufacturer receives for sales in the United States to wholesalers for drugs distributed to the retail pharmacy class of trade. The "best price" is the lowest price available from the manufacturer to any wholesaler, retailer, provider, health maintenance organization, or nonprofit or governmental entity, subject to certain

exceptions. The additional rebate is the amount by which a drug's AMP exceeds the drug's base period AMP increased by the consumer price index.

Currently, modifications to existing drugs—new dosages or formulations, such as extended release versions, sometimes referred to as product line extensions—generally are considered new products for purposes of reporting AMPs to the Secretary. As a result, manufacturers can avoid incurring additional rebate obligations by making slight alterations to existing products. When new products are released, manufacturers can set their base period AMP to any price, so they are able to set new higher prices that will not incur Medicaid's additional rebates.

Proposed Law

The bill would increase the minimum rebate percentage for single source and innovator multiple source drugs from 15.1% to 22.1%. This increase would be effective for rebate periods beginning after December 31, 2009.

The bill would apply a rebate to new formulations of existing single source or innovator multiple source drugs. Under this provision, the rebate for a line extension of a single source or innovator multiple source prescription drug that is an oral solid dosage form would be the greater of (1) the rebate as calculated under current law (e.g., basic rebate plus additional rebate) or (2) a line extension rebate calculation. The line extension rebate amount would be product of: (1) the AMP for the line extension that is an oral solid dosage form; (2) the highest additional rebate (calculated as a percentage of AMP) for any strength of the original single source or innovator multiple source drug; and (3) the total number of units of each dosage form and strength of the line extension product paid for by the state Medicaid program during the rebate period (as reported by a state). For this purpose, the term "line extension" means an extended release formulation of the drug. This provision would be effective for new formulations dispensed to Medicaid beneficiaries after December 31, 2009, regardless of when the new formulations came to market.

Sec. 1743. Extension of prescription drug discounts to enrollees of Medicaid managed care organizations

Current Law

Medicaid law requires prescription drug manufacturers that seek to sell any of their products to state Medicaid programs to enter into a rebate agreement with the Secretary of HHS. Under these agreements, manufacturers must provide state Medicaid programs with rebates for the drugs purchased for Medicaid beneficiaries on an outpatient basis, and state Medicaid programs must cover all drugs (except certain statutorily excluded drug classes) marketed by those manufacturers. The rebates are shared by the state and federal governments in proportion to their respective shares of Medicaid drug expenditures.

Certain drugs are not subject to rebates, including drugs dispensed by Medicaid managed care organizations (MCOs) that contract on a risk basis with state Medicaid agencies when prescription drugs are included in the capitation agreement between the

state Medicaid agency and the MCO. In states that exclude or "carve out" prescription drug benefits from their contracts with MCOs, the prescriptions for the Medicaid MCO enrollees are purchased on a fee-for-service basis and the drugs are subject to rebates.

Proposed Law

The bill would eliminate the current exemption of drugs dispensed by Medicaid MCOs from the Medicaid rebate requirements. Manufacturers entering into Medicaid rebate agreements with the Secretary of HHS would be required to pay rebates on covered outpatient drugs dispensed to Medicaid beneficiaries enrolled in a Medicaid MCO if the organization is responsible for coverage of such drugs under its risk contract with the state Medicaid agency. As with other rebates, the manufacturers would pay the rebates owed to the state Medicaid agency, not to the MCO.

In order to implement this requirement, the bill would require that all risk contracts between a state Medicaid agency and a Medicaid MCO provide that the MCO report to the state agency the information the agency needs in order to submit its periodic report to the manufacturer regarding the covered outpatient drugs dispensed to Medicaid beneficiaries enrolled in the MCO for which the manufacturer owes rebates. The Secretary would specify the timeliness and frequency with which this information would have to be reported to state Medicaid agencies by Medicaid MCOs. The bill would require state Medicaid agencies to report to the Secretary, on a quarterly basis, the total dollar amount of rebates received from manufacturers for drugs provided to individuals enrolled in Medicaid MCOs for which the organization is responsible for coverage.

This provision would take effect on July 1, 2010, and would apply to drugs dispensed on or after that date without regard to whether or not final regulations to implement these changes have been issued.

Sec. 1744. Payments for graduate medical education

Current Law

Medicare and Medicaid, in paying for inpatient hospital services, have historically recognized two components of graduate medical education (GME) costs: (1) direct graduate medical education or DGME (e.g., resident salaries, teaching supervision), and (2) indirect graduate medical education, or IME (e.g., higher patient care costs because of additional tests ordered by residents). The Medicaid statute requires that states use a public process in determining payment rates for hospital services and publish their proposed and final rates and methodologies, but it does not specify payment for GME or IME costs.

In May 2007, the Centers for Medicare & Medicaid Services published a proposed rule to terminate federal Medicaid matching funds for the costs of GME, 72 *Federal Register* at 28930 (May 23, 2007). Congress imposed a series of moratoria on the implementation of this proposed rule through April 1, 2009. Section 5003(d)(2) of the American Recovery and Reinvestment Act of 2009 (P.L. 111–

5) states a "Sense of the Congress" that the Secretary should not promulgate the May 23, 2007, proposed rule as a final rule.

Section 2261 of the bill directs the Secretary of HHS to establish a permanent Advisory Committee on Health Workforce Evaluation and Assessment that is responsible for making recommendations to the Secretary for policies to improve the supply, diversity, and geographic distribution of the health workforce.

Section 1505 of the bill specifies goals for approved medical residency training programs for purposes of Medicare GME payments. The goals are to foster a physician workforce so that physicians are trained, among other things, to be able to work effectively in various health care delivery settings, coordinate patient care within and across settings, and be meaningful electronic health records users.

Proposed Law

The bill would give state Medicaid programs express statutory authority to make payments for the costs of graduate medical education, whether provided in or outside of a hospital, so long as certain requirements are met. In order to receive federal Medicaid matching funds for the costs of GME, state Medicaid programs would have to submit information to the Secretary annually on total payments for GME and how those payments are being used. In addition, state Medicaid GME payments would have to be consistent with program goals and requirements established by the Secretary by regulation, which would take into account the recommendations of the Advisory Committee on Health Workforce Evaluation and Assessment. The purpose of these requirements is to ensure that federal Medicaid matching funds for GME are effectively targeted to support national health workforce goals, such as increasing the supply of primary care practitioners.

The information that states would be required to submit to the Secretary includes: (1) the institutions and programs eligible for receiving the funding, (2) the manner in which such payments are calculated, (3) the types and fields of education being supported, (4) the workforce or other goals to which the funding is being applied, (5) state progress in meeting the goals established by the Secretary, and (6) any other information the Secretary determines will help inform the process of developing goals for approved medical residency training programs.

The bill establishes the following process for developing goals for approved medical residency programs. As described above, the Secretary would specify the information relating to GME that state Medicaid agencies must report as a condition of receiving federal Medicaid matching funds for the costs of GME. The Secretary would make the information submitted by the states available to the Advisory Committee on Health Workforce Evaluation and Assessment. Both the Secretary and the Advisory Committee would independently review this information, taking into account state and local workforce needs. The Advisory Committee would then make recommendations to the Secretary.

By no later than December 31, 2011, the Secretary would specify by rule program goals for the use of Medicaid GME funds, taking into account the recommendations of the Advisory Committee and the Medicare program goals for approved medical residency train-

ing programs specified by section 1505 of the bill. The rule would also specify requirements for the use of Medicaid GME funds consistent with these program goals. The Committee understands that as of 2005, 11 states linked Medicaid GME payments to state policy goals and 17 states extended Medicaid GME payments to training programs for health professions beyond medical students. The Committee expects that, in issuing the rule, the Secretary will consider available data regarding the success of state efforts to link Medicaid GME payment to workforce and other policy goals and consult available survey data regarding State Medicaid GME programs. The Secretary is authorized to issue this rule on an interim final basis pending revision after an opportunity for public comment.

The provision is effective on enactment and is not to be construed to affect GME payments made by a state Medicaid agency prior to enactment.

Sec. 1745. Report on Medicaid payments

Current Law

The Administrator of the Centers for Medicare & Medicaid Services (CMS) is responsible for implementing the duty of the Secretary of HHS to ensure that state Medicaid programs comply with federal Medicaid requirements, including those relating to the sufficiency of payments to physicians, hospitals, and other providers for furnishing covered services to program beneficiaries. The Medicaid statute does not require state Medicaid programs to report to CMS information regarding provider payment rates, methodologies, and justifications.

Proposed Law

The bill would require state Medicaid programs to submit to the CMS Administrator, on an annual basis, information on Medicaid payment rates to providers. The information would include, for each class of provider (e.g., hospitals, nursing facilities, pharmacies, physicians, etc.), final rates, the methodologies used to determine the final rates, and justifications for those rates. States would also have to provide an explanation of the process used to allow providers, beneficiaries and their representatives, and other concerned state residents an opportunity to comment on rates, methodologies, and justifications before the rates are made final. The Committee expects that the Administrator would review this information to determine whether states are in compliance with applicable federal requirements, including those relating to the sufficiency of provider payments.

Sec. 1746. Reviews of Medicaid

Current Law

Federal Medicaid matching payments to state Medicaid programs for the costs of covered services are determined by the federal medical assistance percentage (FMAP) formula set forth in the Medicaid statute. The federal government also provides matching funds for administrative costs incurred by state Medicaid agencies at specified rates. The Government Accountability Office (GAO) has

expertise in the FMAP formula and administration of the Medicaid program.

Proposed Law

The bill would direct the Comptroller General to conduct a study regarding federal payments to state Medicaid programs and submit a report to the appropriate committees on the effect of the following policy changes on the federal government, States, providers, and beneficiaries: (1) modifying the federal medical assistance percentage (FMAP) by removing the 50% floor, the 83% ceiling, or both; and (2) revising the current FMAP formula to better reflect state fiscal capacity and state effort to pay for health and long-term care services and to better adjust for national or regional economic downturns. The report would be due no later than February 15, 2011.

The bill would direct the Comptroller General to conduct a study of the administration of the Medicaid program by the Department of Health and Human Services, state Medicaid agencies, and local government agencies and to submit a report to the appropriate committees that would address the following issues: (1) the administrative functions, such as survey and certification and claims processing, on which federal Medicaid funds are expended and the amounts of such expenditures (whether spent directly or by contract) for each function; and (2) the extent to which federal funds for each administrative function are being used effectively and efficiently. The report would be due no later than February 15, 2011.

Sec. 1747. Extension of delay in managed care organization provider tax elimination

Current Law

The Medicaid statute allows states to use revenues from taxes on hospitals, nursing facilities, and other providers to fund the state share of Medicaid program costs if the tax meets certain requirements. Among the classes of providers that a state may tax subject to these requirements is managed care organizations (MCOs). Originally this class was limited to Medicaid managed care organizations with a risk contract with the state Medicaid agency. Section 6051 of the Deficit Reduction Act of 2005 (DRA, P.L. 109–171) broadened the definition of this class to encompass all managed care organizations. Under this revision, the revenues from an MCO tax may not be used to fund the state share of Medicaid costs unless the tax applies to all MCOs in the state, not just those contracting with the state Medicaid program.

The DRA change was effective February 8, 2006, except in states that, as of December 8, 2005, had enacted an MCO tax that used the more limited definition of the class of MCOs permissible under prior law (i.e., only those contracting with Medicaid). The purpose of this exception was to provide the excepted states with a grace period to revise their tax laws to bring them into conformity with the broader definition of the MCO class. This grace period ends on October 1, 2009.

Proposed Law

The bill would extend the grace period for states excepted from the DRA change in the definition of a permissible MCO class from October 1, 2009 to October 1, 2010. This change would be effective as if included in the enactment of section 6051 of P.L. 109–171.

Subtitle F—Waste, Fraud, and Abuse

Sec. 1751. Health care acquired conditions

Current Law

Subject to federal rules, states generally establish their own payment policies, rates, and reimbursement methodologies for Medicaid providers, including inpatient facilities such as hospitals, nursing facilities, and intermediate care facilities for the mentally retarded (ICF/MRs). Federal regulations require that Medicaid provider rates be sufficient to enlist enough providers so that covered services are promptly available at least to the extent that comparable care and services are available to the general population within that geographic area.

In Medicare, hospitals are reimbursed under a prospective payment system (PPS), where each admission is classified into a Medicare severity adjusted diagnosis-related group (MS–DRG) based on the patient's diagnosis and procedures performed. Each MS–DRG has a predetermined reimbursement amount. In general, a hospital is paid the same amount for an MS–DRG regardless of how long patients stay in the hospital or what is required to treat the patient. In some situations under Medicare's PPS, patients with certain complicating conditions could be reclassified into different MS–DRGs where the hospital would receive a higher payment.

To avoid additional hospital payments for complications that were acquired during patients' admission, the Deficit Reduction Act of 2005 (DRA, P.L. 109–171) required the Secretary to initiate a hospital-acquired condition (HAC) program for Medicare. In creating the HAC program, the Secretary was to select conditions that: (1) were high cost, high volume, or both; (2) were identified as complicating conditions or major complicating conditions; and (3) were reasonably preventable through the application of evidenced-based guidelines. Starting October 1, 2007 (FY2008), CMS required hospitals to report whether Medicare patients had certain conditions when they were admitted. Beginning October 1, 2008 (FY2009), if the HAC conditions identified by the Secretary were coded as present at admission, the conditions would not be considered to be acquired during the patient's hospital stay, and the case could receive additional MS–DRG payment. In addition to the HAC policy, in January 2009, CMS issued three national coverage determinations that precluded Medicare from paying any amount for certain serious preventable medical care errors. (These preventable errors are sometimes called "never events." Never events include surgery on the wrong body part or mismatched blood transfusions, which can cause serious injury or death to beneficiaries, and result in increased costs to the Medicare program to treat the consequences of the error.)

For Medicaid, CMS issued guidance to states in July 2008 to help states appropriately align Medicaid inpatient hospital pay-

ment policies with Medicare's HAC payment policies. In the guidance, CMS indicated that for patients eligible for both Medicare and Medicaid (dual eligibles), hospitals that were denied payment under Medicare might attempt to bill Medicaid for HACs as the secondary payer. CMS instructed state Medicaid agencies to deny payment when dual eligible beneficiaries acquired HACs during a hospitalization. CMS also encouraged Medicaid agencies to implement policies to deny payment when other Medicaid beneficiaries acquired HACs during a hospitalization. CMS directed states to several Medicaid authorities to deny payment appropriately for HACs, but unlike Medicare, DRA did not specifically apply the HAC initiative to Medicaid.

Proposed Law

This provision would require state Medicaid and CHIP programs to deny hospital payments for HACs as well as for certain serious preventable errors in medical care (never events) determined as non-covered by the Medicare program. In addition, states would have permission to identify other health-care acquired conditions for non-payment under Medicaid. This provision would be effective for hospital discharges that occurred on or after January 1, 2010.

Sec. 1752. Evaluations and reports required under Medicaid Integrity Program

Current Law

Under the Medicaid Integrity Program (MIP), the Secretary is required to contract with eligible entities to conduct program integrity activities such as auditing claims for payment and identifying overpayments. The MIP program is funded at $75 million per year.

Proposed Law

The bill would require eligible entities (MIP contractors) to conduct periodic evaluations of the effectiveness of their MIP contract activities and submit annual reports to CMS documenting these evaluations. This reporting requirement would be effective for contract years beginning in 2011.

Sec. 1753. Require providers and suppliers to adopt programs to reduce waste, fraud, and abuse

Current Law

Section 1635 of the bill would require providers and suppliers participating in Medicare (other than physicians and skilled nursing facilities) to establish a compliance program that contains core elements established by the Secretary of HHS. There is no comparable requirement in the Medicaid statute.

Proposed Law

The bill would require state Medicaid programs to require that any participating provider or supplier (other than a physician or nursing facility) to establish a compliance program that contains core elements established by the Secretary for purposes of the Medicare program under section 1635 of the bill. Those core elements could include (1) written policies, procedures, and standards of conduct; (2) a designated compliance officer and compliance com-

mittee; (3) effective fraud, waste, and abuse training and education for an entity's employees and contractors; (4) a mechanism, such as a hotline, to report waste, fraud, and abuse that is confidential or anonymous; (5) disciplinary guidelines to enforce standards; (6) internal monitoring and auditing procedures, including contractor monitoring and auditing; and (7) procedures for ensuring prompt responses when offenses are detected, which include development of corrective action initiatives, including response to potential offenses, and (8) returning all identified overpayments under Medicare, Medicaid and CHIP.

The bill authorizes the Secretary to conduct a pilot program on the application of this requirement with respect to a category of providers or services or suppliers (other than physicians or skilled nursing facilities) determined to be at high risk of waste, fraud, and abuse before requiring all providers or services and suppliers (other than physicians or skilled nursing facilities) to establish compliance programs. State Medicaid programs would be required to align the implementation of this requirement with the Secretary's implementation of the pilot program.

The provision would be effective on enactment.

Sec. 1754. Overpayments

Current Law

The Medicaid statute requires that when an overpayment made by a state Medicaid agency to a provider or contractor is discovered, the agency has 60 days to recover or attempt to recover the overpayment. At the end of the 60-day period, federal Medicaid matching payments to the state are reduced by the federal share of the overpayment, whether or not recovery has been made. The only exception is when the state is unable to recover because the overpayment (or a portion thereof) is a debt that has been discharged in bankruptcy or is otherwise uncollectable. The Committee heard testimony from state Medicaid administrators that this policy deters states from discovering overpayments due to fraud because the recovery of funds from fraudulent providers often takes considerably longer than 60 days, and during this extended period the federal government withdraws the federal funds involved from the state.

Proposed Law

In order to encourage state Medicaid agencies to identify overpayments due to fraud and seek recovery of the federal and state funds involved, the bill would create an exception to the 60-day recovery rule for such overpayments. In the case of overpayments due to fraud, the reduction in federal matching payments would not occur until a year after the discovery of the overpayment. This provision would apply to overpayments due to fraud discovered on or after enactment. The Secretary would not be required to issue regulations to implement this provision.

Sec. 1755. Managed care organizations

Current Law

The Medicaid statute requires that state Medicaid agencies that elect to enter into risk contracts with managed care organizations

(MCOs) to furnish services to program beneficiaries make capitation payments to those MCOs on an actuarially sound basis. The statute does not specify a minimum medical loss ratio, or share of total premium revenue spent on medical claims. The Congressional Budget estimates that in FY 2010 the federal government will spend $57.4 billion in matching funds for Medicaid managed care services.

Proposed Law

The bill would require that every risk contract between a state Medicaid agency and a Medicaid MCO have a medical loss ratio specified by the Secretary that is not less than 85%. The Secretary would specify the methodology to be used by State Medicaid agencies in determining whether a contracting MCO is in compliance with the medical loss ratio. The bill would apply a parallel requirement to State CHIP programs that contract with MCOs on a risk basis. Neither federal Medicaid or CHIP matching funds would be available for expenditures in connection with risk contracts or contracting MCOs that are not in compliance with this requirement. The purpose of this requirement is to ensure that the maximum amount of capitation revenues received by an MCO from Medicaid or CHIP programs are used to pay providers for furnishing covered services to enrolled beneficiaries rather than to pay for MCO administrative costs, marketing costs, taxes and other fees, or distributions to shareholders. This requirement would apply to contracts between state Medicaid or CHIP agencies and MCOs entered into or renewed on or after July 1, 2010. The Secretary is not required to issue a rule to implement this requirement.

The bill would require that each risk contract entered into between a state Medicaid agency and an MCO require that the MCO provide to the state Medicaid agency patient encounter data sufficient to identify the physician who delivers services to enrollees. To ensure comparability of patient encounter data among MCOs within a state and between MCOs in one state and those in another, the bill requires the Secretary to specify the frequency and level of detail of the patient encounter data to be supplied by each MCO. This provision would apply with respect to contract years beginning on or after January 1, 2010. The Secretary would not be required to implement this provision by regulation.

Sec. 1756. Termination of provider participation under Medicaid and CHIP if terminated under Medicare or other State plan or child health plan

Current Law

Subject to certain specified exceptions, the Secretary of HHS is required to exclude from participation in any federal health care program, including Medicare and Medicaid and CHIP, for a specified period of time individuals or entities that have been convicted of certain criminal offenses. The Secretary also has the authority to exclude for a specified period of time individuals or entities that have engaged in certain specified conduct. The Medicaid statute requires that state Medicaid agencies exclude an individual or entity from the Medicaid program, for the period specified by the Secretary, when the individual or entity is excluded by the Secretary.

Proposed Law

The bill would require state Medicaid programs to terminate the participation of any individual or entity in Medicaid if the individual or entity is terminated from participation in Medicare, any other state Medicaid program, or CHIP. Subject to certain specified exceptions, when Medicare provider reimbursement is precluded as a result of the termination of provider participation for reasons such as those listed above, this provision would require states to terminate federal financial participation for such providers under Medicaid and/or CHIP.

This provision would be effective for services provided on or after January 1, 2011, regardless of whether or not final regulations had been promulgated. If the Secretary determines that a state requires legislation (other than appropriations legislation) to amend its state Medicaid plan, then the state would not be considered to be out of compliance with this requirement until after the first day of the first calendar quarter after the close of the first regular state legislature session after enactment. In states with two-year legislative sessions, the Secretary would consider each year of the legislative session as a separate regular session of the state legislature.

Sec. 1757. Medicaid and CHIP exclusion from participation relating to certain ownership, control, and management affiliations

Current Law

Titles XI, XIX, and XXI of the Social Security Act specify the circumstances under which State Medicaid and Children's Health Insurance (CHIP) programs are required to exclude providers from participation.

Proposed Law

This bill would require state Medicaid and CHIP agencies to exclude any individual or entity from participation in Medicaid or CHIP for a period if the individual or entity owns, controls, or manages an entity that: (1) has overpayments under Medicaid or CHIP that have not been repaid and that the Secretary or state agency has determined to be delinquent during the period; (2) is suspended, excluded from participation under, or terminated from participation under Medicaid or CHIP during the period; or (3) is affiliated with an individual or entity that has been suspended, excluded, or terminated from participation in Medicaid or CHIP during the period.

This provision would be effective for services furnished under the Medicaid and CHIP programs on or after January 1, 2011, without regard to whether or not final regulations had been promulgated. If the Secretary determines that a state requires legislation (other than appropriations legislation) to amend its state Medicaid plan, then the state would not be considered to be out of compliance with this requirement until after the first day of the first calendar quarter after the close of the first regular state legislature session after enactment. In states with two-year legislative sessions, the Secretary would consider each year of the legislative session as a separate regular session of the state legislature.

Sec. 1758. Requirement to report expanded set of data elements under MMIS to detect fraud and abuse

Current Law

The Medicaid statute requires that state Medicaid programs, as a condition of receiving federal matching funds for automated data systems, operate a Medicaid Management Information System (MMIS) that meets certain specifications. For example, an MMIS system must provide for electronic transmission of claims data in a format specified by the Secretary of HHS.

Proposed Law

The bill would require state MMIS systems to transmit to the Secretary data elements determined by the Secretary to be necessary for the detection of waste, fraud, and abuse. This requirement would be effective with respect to state data submissions to the Secretary occurring on or after July 1, 2010.

Sec. 1759. Billing agents, clearinghouses, or other alternate payees required to register under Medicaid

Current Law

Section 1644 of the bill would require any agency, clearinghouse, or other alternate payee that submits claims to Medicare for reimbursement on behalf of a health care provider to register with the Secretary. There is no comparable requirement in Medicaid law.

Proposed Law

The bill would require state Medicaid agencies to require that any agent, clearinghouse, or other alternate payee that submits claims for Medicaid reimbursement on behalf of a health care provider register with the state Medicaid agency and with the Secretary in a form and manner that is consistent with the Medicare process for the enrollment of providers of services and supplies. Federal Medicaid matching funds would not be available to the state for any amounts paid to agents, clearinghouses, or other alternate payees that fail to register.

This provision would be effective for claims submitted on or after January 1, 2012, without regard to whether or not final regulations had been promulgated.

Sec. 1760. Denial of payments for litigation-related misconduct

Current Law

The federal government pays 50% of administrative costs incurred by states as are found necessary by the Secretary of HHS for the proper and efficient administration of the Medicaid program. Allowable administrative costs that qualify for federal matching include attorneys' fees and other litigation expenses incurred by states related to the Medicaid program.

Proposed Law

The bill would prohibit the payment of federal Medicaid matching funds for any amounts expended on litigation in which a court imposes sanctions on a state, its employees, or its counsel for litigation-related misconduct. For this purpose, litigation includes ad-

ministrative proceedings that are subject to laws and rules of procedure that authorize the imposition of sanctions for litigation misconduct. Examples of such litigation include state litigation with federal agencies, Medicaid contractors, health care providers, or Medicaid beneficiaries.

The bill would also prohibit the payment of federal Medicaid matching funds for any amounts to reimburse directly (or compensate through a capitation payment or otherwise) a managed care entity for payment of legal expenses associated with any action in which a court imposes sanctions on the managed care entity for litigation-related misconduct. For this purpose, litigation includes administrative proceedings that are subject to laws and rules of procedure that authorize the imposition of sanctions for litigation misconduct. Examples of such litigation include litigation with state or federal agencies, health care providers or Medicaid beneficiaries.

Federal Medicaid matching funds would continue to be available at a 50% rate for all other litigation costs as the Secretary finds necessary for the proper and efficient administration of the Medicaid program. The prohibition would apply to amounts expended for litigation expenses on or after January 1, 2010. The Secretary would not be required to issue regulations to implement this prohibition.

Sec. 1761. Mandatory State use of national correct coding initiative

Current Law

The Medicaid statute requires that state Medicaid programs, as a condition of receiving federal matching funds for automated data systems, operate a Medicaid Management Information System (MMIS) that meets certain specifications relating to the processing of provider claims for reimbursement.

The Centers for Medicare & Medicaid Services processes Medicare Part B claims, including claims for payments for physician, laboratory, and radiology services. In 1996, to help ensure correct payment of claims for reimbursement, CMS implemented the National Correct Coding Initiative (NCCI). Under NCCI, CMS contractors use automated pre-payment edits to review Medicare claims submitted by Part B providers to detect anomalies that indicate a claim has incorrect information and should not be paid as submitted.

Proposed Law

The bill would require that each state's MMIS system incorporate methodologies compatible with Medicare's National Correct Coding Initiative (or any successor initiative to promote correct coding and to control improper coding leading to inappropriate payment) and such other methodologies as the Secretary specifies. MMIS systems would have to meet this requirement effective for claims filed on or after October 1, 2010.

To enable state Medicaid programs to implement this requirement, the bill would require the Secretary, by September 1, 2010, to take the following actions: (1) identify NCCI methodologies (or methodologies of any successor initiative) that are compatible to claims filed under Medicaid; (2) identify those methodologies that

should be incorporated into claims filed under Medicaid with respect to items or services covered under Medicaid for which no national correct coding methodologies have been established with respect to Medicare; (3) notify states of the coding methodologies identified and how states should incorporate those methodologies into their Medicaid claims processing systems; and (4) submit a report to Congress that includes the notice given to states about the methodologies and an analysis that supports the identification of the methodologies to be applied to Medicaid claims.

The provision is effective on enactment. If the Secretary determines that a state requires legislation (other than appropriations legislation) to amend its state Medicaid plan, then the state would not be considered to be out of compliance with this requirement until after the first day of the first calendar quarter after the close of the first regular state legislature session after enactment. In states with two-year legislative sessions, the Secretary would consider each year of the legislative session as a separate regular session of the state legislature.

Subtitle G—Payments to the Territories

Sec. 1771. Payment to the territories

Current Law

The five U.S. territories—American Samoa, Guam, the Northern Mariana Islands, Puerto Rico, and the Virgin Islands—are eligible to participate in the Medicaid program but not on the same basis as the states (and the District of Columbia). The federal medical assistance percentage (FMAP) in the territories is set at 50%, rather than varying with per capita income between 50% and 83%, as in the case of the states. Total federal Medicaid matching payments in any fiscal year are subject to a statutory ceiling specific to each territory; in contrast, the federal government shares in the cost of all allowable Medicaid expenditures made by states without regard to a ceiling. In the case of American Samoa and Northern Marianas Islands, the Secretary has broad statutory authority to waive or modify almost all federal Medicaid requirements that apply to states participating in Medicaid.

Section 5001(d) of the American Recovery and Reinvestment Act of 2009 (ARRA, P.L. 111–5) allows each territory, for the period October 1, 2008, through December 31, 2010, a one-time choice between (1) an FMAP increase of 6.2 percentage points and a 15% increase in its statutory ceiling on federal Medicaid spending, or (2) its regular 50% FMAP and a 30% increase in its spending ceiling. All five territories have elected the 30% increase in their federal Medicaid spending ceiling.

Proposed Law

The bill would increase the FMAP for each of the territories from FY2011 through FY2019 to the highest FMAP in effect in that year for any state. For the first quarter of FY2011, this state FMAP would take into account the temporary FMAP increases under section 5001(a) and (b)(1) of ARRA. (The highest regular FMAP of any state in FY2009 was 75.8%).

The bill would increase the ceilings on federal Medicaid matching payments to each of the territories from FY2011 through FY2019 by the following amounts:

For Puerto Rico, for fiscal year 2011, $727.6 million; for fiscal year 2012, $775 million; for fiscal year 2013, $850 million; for fiscal year 2014, $925 million; for fiscal year 2015, $1 billion; for fiscal year 2016, $1.075 billion; for fiscal year 2017, $1.150 billion; for fiscal year 2018, $1.225 billion; and for fiscal year 2019, $1.396 billion.

For the Virgin Islands, for fiscal year 2011, $34 million; for fiscal year 2012, $37 million; for fiscal year 2013, $40 million; for fiscal year 2014, $43 million; for fiscal year 2015, $46 million; for fiscal year 2016, $49 million; for fiscal year 2017, $52 million; for fiscal year 2018, $55 million; and for fiscal year 2019, $58 million.

For Guam, for fiscal year 2011, $34 million; for fiscal year 2012, $37 million; for fiscal year 2013, $40 million; for fiscal year 2014, $43 million; for fiscal year 2015, $46 million; for fiscal year 2016, $49 million; for fiscal year 2017, $52 million; for fiscal year 2018, $55 million; and for fiscal year 2019, $58 million.

For the Northern Mariana Islands, for fiscal year 2011, $13.5 million; for fiscal year 2012, $14.5 million; for fiscal year 2013, $15.5 million; for fiscal year 2014, $16.5 million; for fiscal year 2015, $17.5 million; for fiscal year 2016, $18.5 million; for fiscal year 2017, $19.5 million; for fiscal year 2018, $21 million and for fiscal year 2019, $22 million.

For American Samoa, for fiscal year 2011, $22 million; for fiscal year 2012, $23.688 million; for fiscal year 2013, $24.688 million; for fiscal year 2014, $25.688 million; for fiscal year 2015, $26.688 million; for fiscal year 2016, $27.688 million; for fiscal year 2017, $28.688 million; for fiscal year 2018, $29.688 million; and for fiscal year 2019, $30.688 million.

The bill would expand the scope of the Secretary's current waiver authority with respect to American Samoa and the Northern Mariana Islands to include Puerto Rico, the Virgin Islands, and Guam. The bill would not alter the current law prohibition on waiving the FMAP, the federal spending ceilings, or the requirement that payment be made for Medicaid services described in section 1905(a) of the Social Security Act.

The bill directs the Secretary of HHS to submit a report to Congress that details a plan for the transition of each territory to full parity in Medicaid with the states in FY 2020. The transition plan must outline the actions that the Secretary and the governments of each territory must take by FY 2020 to ensure parity in financing. The report must include (1) a projection of the FMAP for each territory if the FMAP formula applicable to the states were applied to the territory; (2) recommendations as to whether the federal spending ceilings for each territory should be increased any time before fiscal year 2020 due to any factors that the Secretary deems relevant; (3) information about per capita income data that could be used to calculate FMAPs for each territory and on how such data might differ from the per capita income data used to promulgate FMAPs for the states; and (4) recommendations on how the FMAP would be calculated for the territories beginning in fiscal year 2020 to ensure parity with the states.

The Secretary's initial report would be due to Congress not later than October 1, 2013. The Secretary would be required to submit subsequent reports to Congress in 2015, 2017, and 2019 detailing the progress that the Secretary and the governments of each territory have made in fulfilling the actions outlined to achieve Medicaid parity in the Secretary's plan for transition to full parity in FY 2020.

The bill would require the Secretary provide technical assistance to the territories in upgrading their existing computer systems in order to anticipate meeting reporting requirements necessary to implement the transition plan prepared by the Secretary. The costs of this technical assistance would not be counted against the federal spending ceilings.

Subtitle H—Miscellaneous

Sec. 1781. Technical corrections

Section 1144 of the Social Security Act. Section 1144(c)(3) of the Social Security Act directs the Commissioner of Social Security to transmit applications for low-income subsidies under Medicare Part D to the appropriate State Medicaid agency in order to initiate an application for assistance under the Medicare Savings Program. The bill makes technical changes in the statutory text to correctly execute this policy. The provision is effective as if included in the enactment of section 113(b) of P.L. 110–275 (July 15, 2008).

Section 1935 of the Social Security Act. Section 1935(a)(4) of the Social Security Act requires state Medicaid agencies to accept data transmitted electronically by the Commissioner of Social Security regarding applications for low-income subsidies under Medicare Part D and to treat this data as an application for assistance under the Medicare Savings Program (MSP). The bill clarifies that the date of transmission by the Commissioner is the date of filing of the application for MSP for purposes of the state Medicaid agency's duty to process applications and to furnish medical assistance to eligible applicants with reasonable promptness. The provision is effective as if included in the enactment of section 113(b) of P.L. 110–275 (July 15, 2008).

Section 605 of CHIPRA. Section 605 of the Children's Health Insurance Program Reauthorization Act of 2009 (CHIPRA; P.L. 111–3) provides that nothing in CHIPRA allows federal payment for individuals who are not lawfully residing in the United States. The bill makes a technical change to an erroneous reference to "legal residents" in the statutory text to correctly execute this policy.

Section 1905 of the Social Security Act. Section 1905(a) of the Social Security Act defines the term "medical assistance." The term is expressly defined to refer to payment but has generally been understood to refer to both the funds provided to pay for care and services and to the care and services themselves. The Committee, which has legislative jurisdiction over Title XIX of the Social Security Act, has always understood the term to have this combined meaning. Four decades of regulations and guidance from the program's administering agency, the Department of Health and Human Services, have presumed such an understanding and the Congress has never given contrary indications.

Some recent court opinions have, however, questioned the longstanding practice of using the term "medical assistance" to refer to both the payment for services and the provision of the services themselves. These opinions have read the term to refer only to payment; this reading makes some aspects of the rest of Title XIX difficult and, in at least one case, absurd. If the term meant only payments, the statutory requirement that medical assistance be furnished with reasonable promptness "to all eligible individuals" in a system in which virtually no beneficiaries receive direct payments from the state or federal governments would be nearly incomprehensible.

Other courts have held the term to be payment as well as the actual provision of the care and services, as it has long been understood. The Circuit Courts are split on this issue and the Supreme Court has declined to review the question. To correct any misunderstandings as to the meaning of the term, and to avoid additional litigation, the bill would revise section 1905(a) to read, in relevant part: "The term 'medical assistance' means payment of part or all of the cost of the following care and services, or the care and services themselves, or both." This technical correction is made to conform this definition to the longstanding administrative use and understanding of the term. It is effective on enactment.

Section 1115 of the Social Security Act. Section 1115(a) of the Social Security Act authorizes the Secretary of HHS to waive compliance with the state Medicaid plan requirements under section 1902 of the Act if the Secretary finds the waiver necessary to enable a state to carry out a demonstration project that is likely to assist in promoting the objectives of Title XIX. The section also authorizes the Secretary to approve costs for such a demonstration project that would not otherwise be eligible for federal Medicaid matching payments under section 1903 of the Act. Section 1115(a) does not, however, provide statutory authority for either the states or the Secretary to use federal funds to provide health or long-term care services to low-income individuals independent of the usual requirements for the expenditure of funds under Title XIX of the Act.

The bill would clarify that if the Secretary approves a Medicaid demonstration project under section 1115(a), the demonstration project is to be treated as part of the state's Medicaid plan, subject to all of the usual state Medicaid plan requirements in section 1902(a) that have not been explicitly waived by the Secretary under the demonstration. All of the payments for care and services provided on behalf of any individuals affected by the demonstration project, including payments for "costs not otherwise matchable" under section 1115(a)(2), are medical assistance provided under the State Medicaid plan. The individuals affected by the demonstration project are individuals receiving medical assistance under the state Medicaid plan, and all provisions of Title XIX not expressly waived by the Secretary in approving the project remain fully applicable to all individuals eligible for or receiving benefits under the state Medicaid plan.

This clarification is effective on enactment.

Sec. 1782. Extension of QI program

Current Law

Medicaid pays Medicare Part B premiums for Medicare beneficiaries, referred to as "qualifying individuals" (QIs), with incomes between 120% and 135% of the federal poverty level and assets no greater than $4,000 for an individual and $6,000 for a couple. The federal government matches 100% of the cost of this premium assistance up to an allocation amount specific to each state for each fiscal year. To enable states to administer the program within a fixed allocation, the Medicaid statute sets forth procedures for selecting which eligible Medicare beneficiaries receive assistance with their premiums and specifies that this assistance is not an individual entitlement. The QI program ends in December 2010.

Proposed Law

The bill would extend the QI program through December 2012 and convert the program to an individual entitlement to assistance with the cost of Part B premiums. The state allocation limits, and the procedures for selecting among eligible Medicare beneficiaries within those limits, would be removed. The 100% FMAP would continue to apply to the costs of this assistance for QIs. The provision would take effect on January 1, 2011.

Sec. 1783. Outreach and enrollment of Medicaid and CHIP eligible individuals

Current Law

Section 201 of the Children's Health Insurance Program Reauthorization Act (CHIPRA, P.L. 111–3) provides $100 million over the period FY 2009 through FY 2010 for grants by the Secretary of HHS to states, localities, schools, nonprofit organizations, and other eligible entities to conduct outreach and enrollment efforts to increase the enrollment and participation of eligible children in Medicaid and CHIP. Ten percent of this amount is set aside for a national enrollment campaign to be developed by the Secretary in order to improve the enrollment of underserved child populations in Medicaid and CHIP. Section 212 of CHIPRA requires state CHIP programs to describe the procedures they use to reduce administrative barriers to the enrollment of eligible children and pregnant women in Medicaid and CHIP.

Proposed Law

The bill would require the Secretary of HHS to issue guidance regarding (1) standards and best practices for conducting outreach to inform eligible individuals about coverage under Medicaid or CHIP, (2) providing assistance to these individuals for enrollment in the appropriate program, and (3) establishing methods or procedures for eliminating application and enrollment barriers. The guidance relating to outreach and enrollment methods must address address how methods such as outstationing of eligibility workers, express lane eligibility, presumptive eligibility, continuous eligibility, and automatic renewal can be used to specifically target vulnerable and underserved populations: children, unaccompanied homeless youth, victims of abuse or trauma, individuals with men-

tal health or substance related disorders, and individuals with HIV/AIDS.

The bill would require that the Secretary issue this guidance not later than 12 months after enactment. Beginning two years after enactment, the Secretary would be required to review and report to Congress annually on progress in implementing targeted outreach, application and enrollment assistance, and administrative simplification methods for vulnerable and underserved populations.

Sec. 1784 Prohibitions on Federal Medicaid and CHIP payment for undocumented aliens

Current Law

The Medicaid statute prohibits federal payments to state Medicaid programs for Medicaid services furnished to unauthorized aliens (i.e., aliens not lawfully admitted for permanent residence or otherwise permanently residing in the U.S. under color of law). The statute makes an exception for services that are necessary to treat an emergency medical condition of an unauthorized alien who otherwise meets Medicaid eligibility requirements. The Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA, P.L. 104–193) prohibits noncitizens who are not considered to be "qualified aliens" (e.g., legal permanent residents, asylees, refugees) from receiving Medicaid or CHIP benefits (other than for treatment of an emergency medical condition).

Proposed Law

The bill provides that nothing in Title VII of Division B shall change current prohibitions against federal Medicaid and CHIP payments under titles XIX and XXI of the Social Security Act on behalf of individuals who are not lawfully present in the United States.

Sec. 1785. Demonstration project for stabilization of emergency medical conditions by non-publicly owned or operated institutions for mental diseases

Current Law

Medicaid does not reimburse for services provided to Medicaid beneficiaries receiving care in institutions for mental disease (IMD), except to those patients under age 21 receiving inpatient psychiatric care and individuals age 65 and over. The Medicaid statute defines an IMD as a hospital, nursing facility, or other institution of more than 16 beds that is primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases, including medical attention, nursing care and related services.

Proposed Law

The Secretary of HHS would be required to establish a three-year Medicaid demonstration project under which eligible states would reimburse IMDs that are not publicly owned or operated for services provided to Medicaid eligibles age 21 to 64 who are in need of medical assistance to stabilize an emergency medical condition. The Secretary would select among states applying to participate in the project so as to provide geographic diversity.

The bill appropriates $75 million in FY 2010 to carry out this demonstration project. These funds would remain available for obligation through December 31, 2012. Within this $75 million total, the Secretary would allocate funds among states selected to participate in the program. The Secretary would use these funds to pay, on a quarterly basis, the federal share of the cost of the project at the state's regular federal matching rate, up to the state's allocation. The Secretary could not make a matching payment to a state under this project after December 31, 2012.

For purposes of carrying out this demonstration project, the bill requires the Secretary to waive the limitation on payment for services to Medicaid beneficiaries residing in IMDs. The bill authorizes (but does not require) the Secretary to waive other requirements of Titles XI and XIX of the Social Security Act, including the requirements of statewideness and comparability, only to the extent necessary to carry out the demonstration project.

The Secretary would be required to establish a mechanism for instay review before the third day of inpatient stay to determine whether or not an individual with an emergency medical condition has been stabilized (i.e., the emergency medical condition no longer exists with respect to the individual and the individual is no longer dangerous to him or herself or others).

Up to $75 million would be appropriated for fiscal year 2010. Such funds would remain available for obligation for three years through December 31, 2012. The Secretary would be required to allocate funds, on a quarterly basis, based on their availability and the FMAP formula.

The bill would require the Secretary to submit annual reports to Congress on the progress of the demonstration project as well as a final report that includes an evaluation of the demonstration's impact on the functioning of the health and mental health service system and on Medicaid enrollees. The bill specifies certain evaluation measures, including whether the project produced a significant reduction in emergency room visits or the duration of emergency room stays by Medicaid beneficiaries. The Secretary would be required to include in the final report a recommendation regarding whether the demonstration project should be continued after December 31, 2012, and expanded on a national basis.

TITLE IX—MISCELLANEOUS PROVISIONS

Sec. 1901. Repeal of the trigger provision

Current Law

The Hospital Insurance (HI) and Supplementary Medical Insurance (SMI) trust funds are overseen by a board of trustees that reports annually to Congress. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. 108–173, MMA), Subtitle A of title VIII requires the trustees' report to include an expanded analysis of Medicare expenditures and revenues. Specifically, a determination must be made as to whether or not general revenue financing will exceed 45% of total Medicare outlays within the next seven years. General revenue financing is defined as total Medicare outlays minus dedicated financing sources (i.e., HI payroll taxes; income from taxation of Social Security benefits; state transfers for prescription drug benefits; premiums paid under Parts

A, B, and D; and any gifts received by the trust funds). MMA requires that if an excess general revenue funding determination is made for two successive years, the President must submit a legislative proposal to respond to the warning. Congress is required to consider the proposals on an expedited basis. However, passage of legislation within a specific time frame is not required.

Proposed Law

Because the 45% trigger is an arbitrary threshold with no connection to program efficiency or Medicare's long-term sustainability, it should not be given preference in setting the agenda for consideration of modifications to the program.

This provision repeals the 45% trigger.

Sec. 1902. Repeal of the comparative cost adjustment (CCA) program

Current Law

The MMA requires the Secretary to establish a program for the application of comparative cost adjustment (CCA) in CCA areas beginning in 2010. The six-year program will begin January 1, 2010, and end December 31, 2015. The program is designed to test direct competition among local Medicare Advantage (MA) plans, as well as competition between local MA plans and fee-for-service Medicare. This program will occur only in a limited number of statutorily qualifying areas in the country.

The benchmark for MA local plans in a CCA area will be calculated using a formula that weights (1) the projected (fee-for-service) FFS spending in an area (with certain adjustments for demographics and health status) and (2) a weighted average of plan bids.

For Medicare beneficiaries in traditional Medicare, Part B premiums in CCA areas will be adjusted either up or down, depending on whether the FFS amount is more or less than the CCA area benchmark. If the FFS amount is greater than the benchmark, beneficiaries in traditional Medicare FFS will pay a higher Part B premium than other FFS beneficiaries in non-CCA areas. If the FFS amount is less than the benchmark, the Part B premium for FFS beneficiaries will be reduced by 75% of the difference. These increases and decreases are subject to a 5% limit; that is, adjustments to Part B premiums in CCA areas cannot exceed 5% of the national part B premium. Beneficiaries in traditional Medicare FFS with incomes below 150% of poverty, who qualify for low-income subsidies under the Medicare prescription drug program, will not have their Part B premium increased.

Proposed Law

The CCA demonstration is projected by CBO to increase government spending because it incorporates inflated Medicare Advantage benchmarks. That runs counter to its goal of improving program efficiency. Accordingly, in order to minimize waste, the provision repeals the comparative cost adjustment program.

In addition, the provision addresses the problem of beneficiaries in fee-for-service Medicare facing changes in their Part B pre-

miums resulting from the bidding behaviors of private Medicare Advantage.

Sec. 1903. Extension of gainsharing demonstration

Current Law

Section 5007 of the Deficit Reduction Act of 2005 (P.L.109–171; DRA) authorizes a gainsharing demonstration to evaluate arrangements between hospitals and physicians designed to improve the quality and the efficiency of care provided to beneficiaries. In the absence of this DRA authority, gainsharing arrangements are restricted by the Civil Monetary Penalty law. CMS is operating two projects, each consisting of one hospital in New York and West Virginia. Although authorized to begin on January 1, 2007, the project began on October 1, 2008, and will end as mandated on December 31, 2009. The Secretary was required to submit a report on quality improvement and achieved savings as a result of the demonstration no later than December 1, 2008. The final report on these issues was due on May 1, 2010. The project was appropriated $6 million in FY2006 to be available for expenditure through FY2010.

Proposed Law

The authority to conduct the gainsharing demonstration would be extended until September 30, 2011. The due date of the quality improvement and achieved savings report would be extended from December 1, 2008, to March 31, 2011. The final report would be due March 31, 2013, instead of May 1, 2010. An additional $1.6 million would be appropriated in FY2010. All appropriations would be available for expenditure through FY2014.

Sec. 1904. Grants to States for quality home visitation programs for families with young children and families expecting children and families expecting children

and

Sec. 1905. Improved coordination and protection for dual eligibles

Current Law

There are no specific provisions in current law for coordination and protection of dual eligibles.

Proposed Law

The provision directs the Secretary to create an identifiable office or program within CMS to improve coordination between Medicare and Medicaid and to improve protections for dual eligibles. Dual eligibles would be defined as individuals eligible for both Medicare and Medicaid and would include those individuals who are eligible for benefits under the Medicare Savings Program (MSP). The CMS office or program would: (1) review Medicare (Parts A, B, and C) and Medicaid policies on enrollment, benefits, service delivery, payment, and grievance and appeals processes; (2) identify areas of Medicare and Medicaid policies where better coordination or protection could improve care and reduce costs for duals; and (3) issue guidance to states on how to improve coordination and protection for dual eligibles.

The elements of improved coordination and protection would include efforts (1) to simplify access by dual eligibles to benefits and services under Medicare and Medicaid; (2) to improve care continuity for dual eligibles and ensure safe and effective care transitions; (3) to harmonize regulatory conflicts between Medicare and Medicaid rules affecting dual eligibles; and (4) to improve Medicare and Medicaid's combined total cost and quality performance for dual eligibles.

The Secretary's responsibilities for implementing the CMS office or program for coordination and protection for dual eligibles would include: (1) examination of Medicare and Medicaid payment systems to develop strategies to foster more integrated and higher quality care; (2) development of methods to facilitate access for dual eligibles to post-acute and community-based services and to identify actions to improve coordination of community-based care; (3) a study of enrollment in MSP (for both Medicare and Medicaid) to identify methods to more efficiently and effectively reach and enroll dual eligibles; (4) an assessment of communication strategies aimed at dual eligibles, including the Medicare website, 1–800–MEDICARE, and the Medicare handbook; (5) research and evaluation of areas where service utilization, quality, and access to cost sharing protection could be improved and an assessment of factors relating to enrollee satisfaction with services and delivery; (6) collection and dissemination to the public of data and a database that describes eligibility, benefits, and cost-sharing assistance available to dual eligibles by state; (7) monitoring total combined Medicare and Medicaid program expenditures in serving dual eligibles and making recommendations to optimize total quality and cost performance across both programs; and (8) coordination of Medicare Advantage plan activities under Medicare and Medicaid.

Within one year after enactment of this provision and then every three years thereafter, the Secretary would be required to submit a report to Congress on the progress in improving coordination and protection for dual eligibles as described in this provision.

Sec. 1906. Standardized marketing requirements under the Medicare Advantage and Medicare prescription drug plans (PDP)

Current Law

Medicare Advantage (MA) organizations are required to submit marketing brochures and enrollment forms to CMS for review and approval at least 45 days before distribution. If using CMS model materials, the approval time is reduced from 45 to 10 days. As part of the review process, CMS must ensure that the information provided to beneficiaries is not inaccurate or misleading. MA organizations are also required to develop marketing materials that provide an adequate description of plan benefits, providers, and co-insurance; an explanation of the grievance and appeals process; notification of the open enrollment period; and a statement indicating that either the plan or CMS can terminate the contract, thereby resulting in the beneficiary's disenrollment from the plan.

CMS has also developed standards for regulating the marketing conduct of MA organizations. These standards include prohibitions against door-to-door soliciting, providing cash or other monetary rebates to induce enrollment, and conducting misleading or confusing

activities, such as claiming that the MA organization has been endorsed by CMS or Medicare. Further, providers cannot distribute information to beneficiaries comparing benefits across plans or allow beneficiaries to complete enrollment applications in provider offices.

Except in instances where the beneficiary initiates contact, plans will be prohibited from soliciting beneficiaries door-to-door or on the phone. Cross-selling of non-health products, providing meals to prospective enrollees, marketing or selling plans at educational events or in areas where health care is delivered (i.e., physician offices or pharmacies), and using sales agents that are not state licensed are also prohibited. The Medicare Improvement for Patients and Provides Act required that by November 15, 2008, the Secretary establish limitations on other plan marketing activities such as co-branding, the scope of marketing appointments with prospective enrollees, and agent compensation and training. MA plans will be required to provide states with information on (1) agent and broker terminations and (2) at state request, performance and licensing of agents, brokers, and any third party representing the plan. After January 1, 2010, MA plans will be required to include the plan type in all plan names.

Proposed Law

This provision would require the Secretary to request the National Association of Insurance Commissioners (NAIC) to develop standardized marketing requirements for MA and PDP plans and submit a report with the requirements to the Secretary no later than 9 months after the enactment date of this legislation. The requirements would be required to include the prohibitions on marketing activities already included in the statute and may prohibit a MA or PDP plan from completing any portion of an election form.

The standardized marketing requirements would also be required to include the following standards: (1) standards related to fair and appropriate commissions for MA and PDP plan agents and brokers, including a prohibition on extra bonuses or incentives; (2) standards for the disclosure of commissions; and (3) standards related to other forms of compensation. Standards would be required to ensure that the compensation paid to agents and brokers create incentives for enrolling beneficiaries in a plan that best meets their health care needs. Standards must also address the conduct of agents participating in on-site promotions at facilities that have a co-branding relationship with the MA or PDP plan. The NAIC would have the discretion to establish other standards related to unfair marketing and trade practices.

If the NAIC develops these standards and submits the required report to the Secretary, the Secretary would be required to promulgate regulations adopting the NAIC's requirements. If the NAIC does not develop or submit a report to the Secretary, the Secretary would still be required to promulgate regulations for standardized marketing requirements. These regulations would have to meet the same requirements mandated for the NAIC, and the Secretary would be authorized to establish other standards as appropriate. The regulations would take effect one year after enactment of this legislation beginning with the first open enrollment period. Both the NAIC and the Secretary would be required to consult with a

working group of representatives, selected in a manner that insures balanced representation, of MA or PDP plans, consumers groups, and other qualified individuals when developing the marketing standards.

With regards to enforcement, the provision would require that states report violations of these marketing requirements to CMS. The Secretary would then be required to submit an annual report to Congress on the enforcement of these requirements and any recommendations as appropriate. A list of alleged violations reported by a state, MA, or PDP plan and their disposition must be included in the report.

The Secretary would be prohibited from establishing other standards that would supersede state laws or regulations that enact these marketing requirements. Finally, this provision would preempt any provision in the Medicare statute or this legislation from: (1) prohibiting a state from conducting a market conduct examination, or (2) from imposing sanctions against MA or PDP plans or their agents and brokers for violations of these requirements. All MA and PDP plans would be required to comply with these requirements on the date these regulations were implemented.

Sec. 1907. NAIC recommendations on the establishment of standardized benefit packages for Medicare Advantage plan and Medicare prescription drug program plan

Current Law

No provision.

Proposed Law

This provision would require that the Secretary request that the NAIC establish a committee to study and make recommendations to the Secretary and Congress on the establishment and regulation of standardized benefit packages for MA and PDP plans.

Sec. 1908. Application of emergency services laws

Current Law

SSA section 1867 requires hospital emergency departments to examine and treat any individual who comes to the hospital with an emergency medical condition, and any woman who is in labor (the Emergency Medical Treatment and Active Labor Act—EMTALA). The section requires hospitals to offer treatment, within their capacity and with the individual's consent, to stabilize the emergency condition, or transfer the individual to another medical facility. The section specifies restrictions on transferring an individual to another medical facility. It also provides for civil penalties for hospitals that do not comply with the requirements of this section. This section may not be construed to preempt state or local law unless it conflicts directly with the specified requirements. In addition, the section prohibits discrimination and delay in examining or treating the individual with the emergency condition. It provides protections to whistleblowers who report violations of the requirements of this section.

Proposed Law

The provision states that this Act would not relieve health care providers of requirements to provide emergency services required by EMTALA or other relevant state or federal laws.

Sec. 1909. Nationwide program for national and State background checks on direct patient access employees of long-term care facilities and providers

Current Law

Section 307 of the Medicare Prescription Drug, Improvement, and Modernization Act (MMA) of 2003 (P.L. 108–173) established the framework for a program to evaluate national and state background checks on prospective employees who have direct access to patients of long-term care facilities or providers. According to CMS, the program's purpose was to identify efficient, effective, and economical procedures for conducting background checks. A pilot program was administered by CMS, in consultation with the Department of Justice (DoJ). The pilot program operated from January 2005 through September 2007 in seven States (Alaska, Idaho, Illinois, Michigan, Nevada, New Mexico, and Wisconsin) selected by CMS to participate in the Background Check Pilot Program.

Proposed Law

The provision would require the Secretary to establish a nationwide program for national and State background checks on direct patient access employees of certain long-term care (LTC) facilities or providers and provide federal matching funds to states to conduct these activities. Except for certain modifications described below, the Secretary would be required to carry out the nationwide program under similar terms and conditions as the Background Check Pilot program under MMA section 307, as specified. The Committee intends that the Secretary make relevant changes to the provisions based upon lessons learned from the MMA pilot program and that are reflected in the legislative language. Under the nationwide program, the Secretary would be required to enter into agreements with newly participating states, as specified, and certain previously participating states, as specified.

According to the procedures established under the pilot program, certain LTC providers would be required to obtain state and national criminal history and other background checks on their prospective employees through such means as the Secretary determines appropriate. To conduct these checks, states would utilize a search of state-based abuse and neglect registries and specified state and federal databases and records, including a fingerprint check. States would also be required to describe and test methods that reduce duplicative fingerprinting, including the development of a "rap back" capability, as specified. The Committee intends that the Secretary implement this provision in a fashion that does not result in application fees for potential long-term care workers.

States that enter into an agreement with the Secretary would be responsible for monitoring compliance with the requirements of the nationwide program and have specified procedures in place, including procedures to: (1) conduct screening and criminal history background checks; (2) monitor compliance by LTC facilities and pro-

viders; (3) provide for a provisional period of employment of a direct patient access employee, as specified; (4) provide procedures for an independent process by which a provisional employee or an employee may request an appeal, or dispute the accuracy of, the information obtained in a background check, as specified; (5) provide for the designation of a single state agency with specified responsibilities; (6) determine which individuals are direct patient access employees; (7) as appropriate, specify disqualifying offenses, including convictions for violent crimes; and (8) describe and test methods that reduce duplicative fingerprinting, as specified.

States would be required to guarantee (directly or through donations from public or private entities) a designated amount of nonfederal contributions to the program. The federal government would provide a match equal to three times the amount a state guarantees, except that federal funds would not exceed $3 million for newly participating states and $1.5 million for previously participating states.

The term "LTC facility or provider" would be defined to mean the following types of facilities or providers which receive payment for services under Medicare or Medicaid: skilled nursing facilities; nursing facilities; home health agencies; hospice providers; LTC hospitals; providers of personal care services; providers of adult day care; residential care providers that arrange for, or directly provide, LTC services, including certain assisted living facilities that provide a nursing home level of care established by the Secretary; intermediate care facilities for the mentally retarded (ICF/MRs); and other LTC facilities or providers of services under Medicare and/or Medicaid that the participating State determines appropriate. The term "direct patient access employee" would be defined to mean any individual who has access to a patient or resident of a LTC facility through employment or contract and who has duties that involve (or may involve) one-on-one contact with a patient or resident of a facility or provider, as determined by the state for purposes of the nationwide program. Such term does not include volunteers unless they have equivalent duties that involve (or may involve) one-on-one contact with a patient or resident of a LTC facility or provider.

The HHS Inspector General would be required to conduct an evaluation of the nationwide program and submit a report to Congress no later than 180 days after completion of the national program. The Secretary of the Treasury would be required to transfer to HHS an amount specified by the HHS Secretary as necessary (not to exceed $160 million) to carry out the nationwide program for fiscal years 2010 through 2012. Such amounts would be required to remain available until expended.

Sec. 1910. Establishment of Center for Medicare and Medicaid Payment Innovation (CMPI) within CMS

Current Law

Medicare undertakes research to study test new approaches to paying providers, delivering health care services, or providing benefits to Medicare beneficiaries. In accordance with Medicare's demonstration authority (Section 402 of the Social Security Amendments of 1967), demonstration projects are required to determine

whether or not changes in reimbursement would increase the efficiency and economy of health care services without adversely affecting quality. Demonstrations, which typically run from 1 to 5 years, are conducted in select geographic regions and with certain subgroups of beneficiaries. CMS requires that all demonstrations be evaluated. If successful, administrative or payment changes may be implemented nationwide across the Medicare program. For example, results from various demonstration studies helped facilitate the adoption of the inpatient prospective payment system (IPPS) and Medicare managed care. Although demonstrations may be initiated by both the agency and Congress, the number of congressionally mandated demonstrations has increased in recent years and the number of CMS-initiated pilots has declined.

Under the Medicaid program, the SSA authorizes several waiver and demonstration authorities to provide states with the flexibility to operate their programs outside of program rules. Medicaid waivers allow states to experiment with different approaches in the delivery of health care services or adapt their programs to the special needs of particular geographic areas or groups of Medicaid beneficiaries. The primary waiver authorities include: Section 1115 Research and Demonstration Projects, Section 1915(c) Home and Community-Based Services Waivers (HCBS), Section 1915(b) Managed Care/Freedom of Choice Waivers, and Section 1915(b)/(c) Waivers. States submit proposals outlining proposed waiver projects to CMS for approval before implementing these programs. In recent years, there has been increased interest among states in waiver programs as a means to restructure Medicaid coverage, control costs, and increase flexibility.

Both Medicare and Medicaid demonstrations are currently overseen by CMS's Office of Research and Development.

Proposed Law

This provision would add a new section (1115A) to the SSA to create a Center for Medicaid and Medicaid Payment Innovation (CMPI) within the Centers for Medicare and Medicaid Services (CMS) to test and evaluate Medicare and Medicaid payment models. Payment models would be selected according to their likelihood of improving patient care and reducing program costs.

The Director of the CMPI would report to the CMS Administrator. Demonstrations carried out under sections 1222 and 1236 of the AAHCA of 2009 would be conducted by the CMPI in accordance with the rules of this provision.

The Secretary would be required to give preference to testing models that address populations for which deficits in health care have resulted in poor clinical outcomes or avoidable expenditures. CMS staff would determine which payment models to test at the CMPI. If determined appropriate, the Secretary would be authorized to gather input from outside the Center when making decisions. The CMPI would also be required, through open door forums or other mechanisms, to consult with relevant federal agencies as well as experts in medicine and health care management in carrying out its functions. The Secretary would have the authority to waive Medicare statutory requirements and certain Medicaid rules governing provider payments and state plans, but only for purposes of testing of models under this section.

Models to be tested would be expected to reduce program costs in either or both programs and enhance the quality of care. Unlike current Medicare and Medicaid demonstration projects, payment models under the CMPI would not have to demonstrate budget neutrality as a condition of participation. However, the Secretary would be required to terminate or modify a model if the Chief Actuary of CMS certifies that the model does not meet one the of the three conditions: (1) improve the quality of care without increasing spending under Medicare or Medicaid, (2) reduce spending without decreasing the quality of care, or (3) improve the quality of care and reduce spending. Termination could occur at any time after the testing process has begun. The Secretary would be required to evaluate every payment model tested. Evaluations must include an analysis of the quality of care delivered under the model (using patient outcome measures) and changes in spending under Medicare and Medicaid. All evaluation results must be made public in a timely fashion.

The Secretary would be authorized to expand the duration and scope of a model, which could include nationwide implementation, if the Secretary determines that an expansion would improve quality without increasing spending under Medicare or Medicaid, reduce spending without decreasing quality, or improve quality and reduce spending. In the Medicaid program, implementation of payment models nationwide would be required unless a state demonstrates to the satisfaction of the Secretary that implementation would not be administratively feasible or appropriate to the state health care delivery system. The chief actuary of CMS would also have to certify that such an expansion would reduce net program spending or at least not increase program spending.

Judicial and administrative review of the selection, design, termination, modification, or expansion of payment models would be prohibited under this provision. This includes any judicial or administrative review of a determination made by either the Secretary or the Chief Actuary necessary for expansion. Additionally, United States Code regulations related to the Coordination of Federal Information (Chapter 35 of Title 44) would not apply to the testing, evaluation, or expansion of payment models.

The provision would provide funding in the amount of $350 million for FY2010 from the Medicare Part B Trust Fund for the design, implementation, and evaluation of payment models, as well as for additional benefits not otherwise covered under Title XI of the SSA. For fiscal years beyond 2010, the amount provided would be equal to the previous year's amount increased by the annual percentage increase in total Medicare expenditures for the previous fiscal year. The provision would also provide an additional $25 million, for each fiscal year for administrative costs related to the testing of payment models in the Medicaid program.

Beginning in 2012, and at least once every two years, the Secretary would be required to submit to Congress a report on the activities of the CMPI. Reports would be required to include descriptions of the payment models being tested, models chosen for expansion, results from evaluations, and recommendations for legislative action to facilitate the models' development and expansion.

DIVISION C—PUBLIC HEALTH AND WORKFORCE DEVELOPMENT EXPLANATION OF DIVISION C

The Committee has conducted multiple hearings and investigations about health insurance and how to get it to all Americans. But as valuable as it is, health insurance cannot do everything necessary to make our nation healthy. Even if other parts of this legislation make it possible for everyone to be insured, there will still be a major role for public health. Moreover, there will be an ongoing need for funding for these public health activities.

"Public health" includes many different things:

• It is working with *groups* and whole *communities* to improve health, often more effectively than could be done between a provider and a patient. Fluoridation of water for a town is, for instance, vastly better than simply filling every citizen's cavities. Exercise programs to prevent obesity are better than having to treat diabetes among people who become obese.

• It is tailoring health insurance and health care to *prevent* and *diagnose* disease early rather than simply treating it in its later stages. Immunizations are always better than outbreaks. Screening for hypertension is better than simply waiting for strokes.

• It is providing for *safety-net services* where the insurance market alone fails to do so. Community health centers, HIV-service providers, and family planning clinics provide care to people who might not otherwise be able to find a provider. Health professions education programs can add to the primary care workforce when the market might produce only specialists.

• And, least glamorous but crucial, it is the *infrastructure* of daily disease control and health promotion. Closing down unsanitary restaurants is better than treating food poisoning. Compiling and studying epidemic trends can prevent major waves of disease.

The case might be made be clearer by analogy: No community would be well-served if all its homeowners had fire insurance but there were no fire departments, firefighters, fire hydrants, smoke detectors, or indoor sprinklers. That very well-insured town would still burn to the ground. Insurance is necessary, but it is nowhere near sufficient.

The Committee intends to deal with both approaches, with insurance and with public health. This requires going beyond the investments in divisions A and B of the legislation to provide health insurance to enact these provisions of division C to make significant public health investments.

It would be insufficient simply to authorize future appropriations for these activities while providing mandatory spending for coverage initiatives. While the Committee on Appropriations has shown ongoing and great leadership in these public health programs, the budget allocations for that Committee are too tight to allow significant new initiatives of these sorts. Consequently the Committee on Energy and Committee, working closely with the Committee on Appropriations and the Committee on Budget, has endeavored to provide as firm a funding and organizational base for these services as possible—because they are essential in making insurance efficient and productive and in making the nation healthier.

This Division of the legislation and this accompanying report are laid out in five major parts:

- Title I: Community Health Centers
- Title II: Workforce
- Title III: Prevention and Wellness
- Title IV: Quality and Surveillance
- Title V: Other Public Health Initiatives

Each deals with an essential complement to health reform.

Community health centers are a known and valuable part of the primary care delivery system. As millions of people are newly insured and enter the health care system, CHCs will be a first point of call for many of them.

Moreover, as the system begins to provide basic care to the uninsured, it is generally agreed that we have insufficient numbers of health professionals—particularly primary care providers, nurses, and public health workers. The Workforce provisions are intended to help remedy this problem.

Everyone now seems to agree that the key to better investment and quality improvement in the American health care system lies in efforts to prevent disease and disability in the first place and to manage them if they occur. The Prevention and Wellness provisions outline an agenda of strategy, research, clinical prevention, community prevention that will move the nation to healthier lives.

The Quality and Surveillance sections establish a Center for Quality Improvement and an Assistant Secretary for Health Information. The former is to identify, develop, evaluate, and disseminate best practices in health care throughout the nation. The latter is to coordinate, develop, and disseminate the wealth of data that will become available as both new initiatives in health information technology and health reform come to be.

Other Public Health Initiatives contains a variety of activities, ranging from drug-pricing initiatives to school-based health clinics. Each of these deals with incremental improvements or corrections, and each plays a part in the overall goals of health reform.

Sec. 2001. Table of contents; references

Current Law

No comparable provisions.

Proposed Law

Following the table of contents for Division C, this provision states that all amendments made in such division are to the Public Health Service Act (PHSA).

Sec. 2002. Public Health Investment Fund

Current Law

No comparable provisions.

Proposed Law

This provision would establish a Public Health Investment Fund, into which the following amounts would be deposited from general revenues of the Treasury:

- $4.6 billion for FY2010
- $5.6 billion for FY2011

- $6.9 billion for FY2012
- $7.8 billion for FY2013
- $9.0 billion for FY2014

Amounts in the Fund would be authorized to be appropriated for carrying out various designated provisions in Division C, and would be in addition to any other amounts authorized to be appropriated for such purposes.

Amounts in the Fund could be authorized to be appropriated only if the following two conditions were met, regarding baseline funding: (1) appropriations for a given fiscal year are no less than the amounts appropriated in FY2008 for (i) the Agency for Healthcare Research and Quality (AHRQ); (ii) the National Center for Health Statistics; (iii) the National Health Service Corps (NHSC), including the scholarship and loan repayment programs; (iv) community health centers; and (v) various designated workforce programs under PHSA titles VII and VIII; and (2) the amount appropriated to the Prevention and Wellness Trust (as would be established in sec. 3111 of this legislation) for a given fiscal year is no less than the specified amount appropriated to the Prevention and Wellness Fund under the American Recovery and Reinvestment Act (P.L. 111–5) and allocated for evidence-based prevention and wellness programs (i.e., $650 million).

The Committee anticipates working with the Committee on Budget to draft language agreeable to both Committees to assure that amounts deposited in the Investment Fund by this legislation will be included in the budget score for such legislation, and that any amounts appropriated under this section in any future year, and associated outlays, would not count toward the allocations for the Committee on Appropriations under future budget resolutions.

TITLE I—COMMUNITY HEALTH CENTERS

Real health reform involves not only an expansion of health insurance coverage, but also access to high-quality care for patients and communities in need.

The community health centers (CHCs) program has long met this need. Currently, CHCs serve 19 million people in some 7,000 centers across the United States.

CHCs offer comprehensive primary and preventive care to all, regardless of ability to pay. Numerous studies have documented the quality of the care provided by the centers as well as their innovative service delivery mechanisms. As a result, CHCs are often credited with improving health outcomes as well as reducing, or in some cases even eliminating, health disparities.

The centers have also been demonstrated to produce significant healthcare cost savings. A 2009 study out of The George Washington University School of Public Health (*Using Primary Care to Bend the Curve: Estimating the Impact of a Health Center Expansion on Health Care Costs*) indicates that expenditures for health center users in 2006 were approximately 47.9% lower than for nonusers. This study also shows that a significant expansion in the number of patients served by health centers could yield a potential savings for the nation's health care system of $212 billion over 10 years, with $59 billion of that amount attributable to federal Medicaid savings.

Title I is intended to build on the extraordinary work of the CHC program and, in turn, to help lay the groundwork for many of the health reforms provided for in other divisions of this legislation.

Sec. 2101. Increased funding

Current Law

PHSA sec. 330 provides for the general authority for the federal community health centers program. Subsection (r) of that section authorizes appropriations for such program through FY2012.

Proposed Law

This provision would amend PHSA sec. 330(r) to reauthorize the community health centers program through FY2014, and to authorize to be appropriated such sums as may be necessary for FY2013 and FY2014.

The provision also would authorize to be appropriated from the Public Health Investment Fund (as would be established in sec. 2002 of the legislation) the following amounts:

- $1 billion for FY2010
- $1.5 billion for FY2011
- $2.5 billion for FY2012
- $3 billion for FY2013
- $4 billion for FY2014

These sums from the Fund are in addition to any other amounts authorized to be appropriated from general revenues for such purposes.

The Committee has taken this action to ensure immediate access to quality health care services to those most in need. It is estimated that with the increased funding provided through the legislation, the number of poor, low-income, and uninsured people served by these centers could double. Such access is critically important as the nation begins to implement the health insurance reform measures of the legislation (Divisions A and B), but that will not be in full effect until 2013.

TITLE II—WORKFORCE

Improvements in healthcare coverage do not automatically translate into access to healthcare services (especially primary care services), or produce a healthier nation. To achieve these twin goals, there must be a sufficient and quality health workforce in place. Experts agree: The United States does not meet this standard.

The American Association of Medical Colleges estimates that the nation now faces a shortage of some 11,000 primary care providers. The nursing problem is even greater: The U.S. Bureau of Labor reported in 2007 that the country's nursing shortage will grow to more than one million new and replacement nurses by the year 2016. And public health workers—whose numbers have never been at adequate levels—fare no better. The Association of Schools of Public Health estimates that more than 250,000 public health professionals will be needed by 2020. Expansions in health care coverage will undoubtedly strain this already stressed health workforce.

Better numbers alone, however, will not solve this problem completely. A sufficient and quality workforce must also be one that is

diversified and trained to meet the needs of the U.S. population in the 21st century.

The provisions of title II are designed to address these and other related health workforce issues. As well, they are expected to have both an immediate and long-term impact on enhancing the nation's health workforce—on the one hand, building capacity in anticipation of full implementation of the health reforms established in other divisions of the legislation and, in years ahead, sustaining that capacity such that the health care needs of all Americans can be met.

Subtitle A—Primary Care Workforce

PART 1—NATIONAL HEALTH SERVICE CORPS

Sec. 2201. National Health Service Corps

Current Law

PHSA sections 331, 338A, 338B, and 338I authorize various aspects of the National Health Service Corps (NHSC). The NHSC supports scholarship and loan repayment programs for medical school students, nurse practitioners, nurse midwives, physician assistants, dental school students, and allied health professionals who, in return, agree to a period of service as a primary care provider in a federally-designated health professional shortage area (HPSA). NHSC clinicians may fulfill their service commitments in health centers, rural health clinics, public or nonprofit medical facilities, federal or state correctional facilities, or within other community-based systems of care.

PHSA sec. 331(i) authorizes the Secretary to carry out demonstration projects through which waivers may be granted to individuals fulfilling service obligations under the NHSC Loan Repayment Program, allowing them to fulfill this obligation through work that is not full time. The sec. also provides the criteria to be met to qualify for such a waiver, including requirements that the Corps member agree: (1) to extend the service obligation in exchange for a waiver; and (2) that the part-time service provided by the Corps member not be less than 16 hours of clinical service per week.

PHSA sec. 337 establishes the National Advisory Council on the NHSC to advise the Secretary. Under PHSA sec. 337(b), members of the Council are appointed to non-renewable three-year terms.

PHSA sec. 338B authorizes the Secretary to make payments of up to $35,000 for the undergraduate and graduate loans of individuals in exchange for each year of obligated service.

PHSA sec. 338C provides authority for various administrative aspects related to periods of obligated service. Subsection (a) of that sec. requires individuals to meet their service obligation by providing clinical services in their medical specialty.

Proposed Law

This provision would amend PHSA sec. 331(i) to allow the Secretary to grant waivers permitting individuals to satisfy either part or all of their NHSC scholarship or loan repayment service obligation through clinical practice that is half time. To receive such a waiver, an individual must agree to double the period of obligated service that would otherwise be required (in the case of an NHSC

scholarship recipient), or accept 50% of the amount that would otherwise be provided for full-time service for a period of obligated service of two years (in the case of a NHSC loan repayment recipient). The provision would also make technical amendments throughout PHSA sec. 331(i) to conform to the new half-time option, and would define the terms "half-time" and "full-time."

The provision would amend PHSA sec. 337(b)(1) to delete language that prohibits the reappointment of members to the NHSC National Advisory Council.

The provision would amend PHSA sec. 338B(g)(2)(A) to increase the maximum annual loan repayment amount available to participating individuals, in exchange for each year of obligated service. The amount would be set at $50,000 per year through FY2011, which the Secretary would adjust for each subsequent fiscal year to reflect inflation. The Committee notes that the amount of the loan repayment benefit has not been adjusted since 1990. The increased amount provided under this provision—including the requirement for an annual inflation adjustment—is necessary to ensure that the NHSC is able to attract both a sufficient number and a highly qualified pool of participants.

The provision would also amend subsection (a) of PHSA sec. 338C to permit the Secretary to count teaching as clinical practice for up to 20% of a period of obligated service. The Committee intends that such teaching take place primarily in the ambulatory setting, where NHSC personnel are ideally located to train the next generation of primary care providers.

In making these improvements to the NHSC, the Committee also notes the important contribution the Corps continues to make in addressing the health care needs of those people living in underserved communities. Today, approximately 3,600 primary care providers are serving in the Corps, providing services to almost 3.8 million individuals.

But as this vulnerable population grows older, there is an increasing need and demand for services provided by geriatric health professionals as is the case throughout the nation's health care system. The Committee is supportive, then, of the recent decision by the Corps to include geriatric health professionals among those eligible for participation in either the scholarship or loan repayment program in all qualifying disciplines, including mental and behavioral health. Indeed, the Committee would encourage the Health Resources and Services Administration (HRSA) to take all appropriate steps to inform potential NHSC applicants about these new Corps opportunities.

Sec. 2202. Authorization of appropriations

Current Law

PHSA sec. 338(a) provides for an authorization of appropriations to carry out the NHSC program for each fiscal year through FY2012. PHSA sec. 338H(a) provides for an authorization of appropriations to support the NHSC scholarship and loan repayment programs for each fiscal year through FY2012.

Proposed Law

This provision would amend PHSA sec. 338 to authorize to be appropriated "such sums as may be necessary" for each of FY2010 through FY2014.

The provision would also amend PHSA sec. 338 to add a new subsection at the end to authorize to be appropriated the following sums from the Public Health Investment Fund (as would be established in sec. 2002 of the legislation):

- $63 million for FY2010
- $66 million for FY2011
- $70 million for FY2012
- $73 million for FY2013
- $77 million for FY2014.

These sums from the Fund are in addition to any other amounts authorized to be appropriated from general revenues for such purposes.

Funds made available through PHSA sec. 338 are intended for use in support of NHSC field placement activities, including travel and transportation costs of NHSC assignees and training and education.

In addition, this provision would amend PHSA sec. 338H to authorize to be appropriated "such sums as may be necessary" for the NHSC scholarship and loan repayment programs for each of FY2013 and FY2014.

The provision would also authorize the following sums to be appropriated from the Public Health Investment Fund (as would be established in sec. 2002 of this legislation):

- $254 million for FY2010
- $266 million for FY2011
- $278 million for FY2012
- $292 million for FY2013
- $306 million for FY2014

These sums from the Fund are in addition to any other amounts authorized to be appropriated from general revenues for such purposes. Funds made available through PHSA sec. 338H are intended for use for NHSC recruitment activities, including scholarship awards and loan repayment.

These increases in authorization levels are consistent with the action taken by the Congress under the American Recovery and Reinvestment Act of 2009 (P.L. 111–5). Under that law, HRSA was provided with sufficient resources to double the number of health professionals participating in the NHSC—to some 8,000 individuals—over the next two years, ensuring that HRSA's targeted field strength could be met. The funding increases provided under this provision will allow HRSA to sustain this doubling effort, an initiative that is especially important to ensure that there is an adequate supply of primary care professionals available to make access to health services a reality under the health insurance reform improvements made under other parts of this legislation (Divisions A and B).

PART 2—PROMOTION OF PRIMARY CARE AND DENTISTRY

Sec. 2211. Frontline health providers

Current Law

PHSA sections 331, 338A, 338B, and 338I authorize the NHSC. The NHSC supports scholarship and loan repayment programs for medical school students, nurse practitioners, nurse midwives, physician assistants, dental school students, and allied health professionals who, in return, agree to a period of service as a primary care provider in a federally designated health professional shortage area (HPSA).

PHSA sec. 332 authorizes HPSA designation by the Secretary and includes provisions related to the NHSC. Under this section, the Secretary may designate an area an HSPA on the basis of a: (1) rational delivery area for health services; (2) population group; or (3) type of health facility. All federally qualified health centers and all rural health clinics are deemed to be designated as HPSAs.

These efforts are focused exclusively on primary care providers—in the case of the Corps, only primary care providers can participate; in the case of HPSA designation, only the availability of primary care providers is measured. In each instance, the breadth and depth of the need for health services in an area is not necessarily captured. Indeed, there are many communities in which the need for medical specialists is even more significant than the call for primary care providers.

Proposed Law

This provision would amend PHSA title III (General Powers and Duties of Public Health Service) to add at the end a new subpart XI—"Health Professional Needs Areas"—and to establish in such subpart a new Frontline Health Provider Program. The new program would be modeled on the NHSC loan repayment program and is designed to complement that program. (The NHSC scholarship program intentionally was not replicated. This action was taken by the Committee to eliminate any potential competition for qualified applicants between the NHSC and the new Frontline Health Provider Program.)

The purpose of the program is twofold: (1) to create incentives to attract health care professionals to provide health services in areas which do not meet the threshold requirements of a HPSA (as specified in PHSA sec. 332), but which, nonetheless, are in great need of such services; and (2) to attract into service those health care professionals for whom scholarship and loan repayment programs have not previously been available. Among such providers are general surgeons and certain pediatric subspecialists such as pediatric rheumatologists whose services are now in great demand.

This provision would create new PHSA sections, including:

Sec. 340H. In General. In this section, the Secretary would be required to establish a Frontline Health Providers loan repayment program, to address unmet health care needs in health professional needs areas under sec. 340I (below).

The Secretary would be authorized to designate an area, a population or a facility as a "health professional needs area." To qualify as such, the following criteria would have to be met:

- In the case of an area, the area must be a rational area for the delivery of health services
- The area, population, or facility must have an insufficient capacity of health professionals, or high needs for health services, including services to address health disparities
- With respect to the delivery of primary health services, the area, population, or facility must not include a HPSA (as designated under PHSA sec. 332), except where the need for such services is not being met

In evaluating an area, population, or facility for potential HPSA designation, the Secretary would be guided by the criteria currently being used by HRSA for measuring "insufficient capacity" and "high needs." While some variation will be necessary, it is the intent of the Committee that these terms have consistent conceptual meaning across various HRSA-administered programs.

It is also the Committee's intent that HPSAs be made eligible for the placement of Frontline Health Providers. Today, there are many HPSAs whose health care needs are not fully met despite the availability of NHSC personnel in their area. And some HPSAs do not get NHSC placement at all. The Committee anticipates that this problem will continue even with the NHSC expansion authorized in this legislation. Thus, regardless of their NHSC status, HPSAs that can meet the test for unmet health care needs should be eligible to have NHSC personnel serve in their area.

Eligibility for participation would be based upon an individual's educational status or professional expertise. Thus, an individual must:

- Hold a degree from, or be enrolled as a full-time student in one of a number of specified health professions schools or training programs listed in PHSA sec. 799B; and
- Be a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, certified nurse midwife, clinical social worker, clinical psychologist, registered dietitian or nutritional professional, physical or occupational therapist, qualified speech-language pathologist, qualified audiologist, respiratory therapist, medical technologist, or radiologic technologist.

Individuals with a degree from a school of public health are explicitly excluded from participating in the new Frontline Health Providers Program. Sec. 2231 of this legislation establishes a new Public Health Service Corps under which financial assistance (through scholarship and loan repayment programs) is made available to both public health students and public health professionals. To avoid any duplication of effort such individuals are not eligible for the Frontline Health Providers Program.

For purposes of this section, the term "health disparities" would have the meaning given such term in PHSA sec. 3171 (as would be established in sec. 2301 of this legislation) and the term "primary health services" would have the meaning given that term in PHSA sec. 331(a)(3)(D).

Sec. 340I. Loan Repayments. In this sec. the Secretary would be required to enter into contracts for loan repayment with health professionals who agree:

- To serve as a full-time primary health services provider or as a full-time or part-time provider of other health services for a minimum of two years;
- To serve in a health professional needs area as designated under PHSA Sec. 340H (as would be established in this provision); and
- For individuals completing their health profession studies and who have accepted employment as a health services provider, to satisfactorily complete their education or training

For individuals who qualify for loan repayment, the Secretary would be required to pay, for each year of obligated service, an amount on the principal and interest of the individual's undergraduate or graduate educational loans (or both) that is not greater than 50% of the average award made under the NHSC loan repayment program in that year. Individuals could satisfy their service requirement through employment in a solo or group practice, a clinic, an accredited public or private nonprofit hospital, or any other health care entity, as deemed appropriate by the Secretary.

In keeping with the Committee's intention that HRSA look to the NHSC loan repayment program as the model in developing the new Frontline Health Providers Program, the provisions related to that program (PHSA sec. 338B) would be made applicable to the new program, except to extent they are inconsistent with the relevant provisions of this legislation. The Committee makes special note of one such difference. Under current NHSC law, the Secretary is not required to redirect any unobligated Corps funds to support other public health workforce activities; instead, they are automatically returned to the Treasury. To ensure that funds appropriated in any given year for public health workforce purposes are, in fact, used for those functions, the Secretary would be required to transfer any unobligated Frontline Health Providers loan repayment funds to the NHSC. The Corps, in turn, would be expected to use such funds ensure a sufficient number of Corps participants in the following fiscal year.

Sec. 340J. Reports. This section would require the Secretary to submit an annual report to Congress on the Frontline Health Providers Program.

Sec. 340K. Allocation. This section would require the Secretary to allocate each fiscal year, 90% of any obligated funds for loan repayments made to physicians and other health professionals who provide primary health services; the remaining 10% would be available for health professionals who provide other health services.

This allocation requirement is consistent with the Committee's focus on providing targeted support for programs designed to help address the nationwide shortage of primary health service providers. It recognizes, however, the lack of sufficient health care providers in other specialties or disciplines in some areas. Thus, the Committee expects the Secretary, in making her annual 10% distribution each year, to assess which health professionals are in the greatest demand, taking into account state and local health workforce needs.

Sec. 2212. Primary care student loan funds

Current Law

No comparable provisions.

Part A, Subpart II of Part A of PHSA title VII (Health Professions Education) establishes federally-supported student loan funds for specified health professions. PHSA sec. 735 establishes general provisions for these loans, which do not include provisions regarding personal or family financial information.

Proposed Law

This provision would amend PHSA sec. 735 by adding a new subsection (f). Under this subsection the Secretary would be authorized either to require (or to authorize a school or other entity to require) applicants for student loans to submit financial information for the purpose of determining the financial resources available to them to support their education as a primary care physician and, in turn, their eligibility for a student loan. In determining whether to require such information regarding an individual's family members, the Secretary would be required to take into account the extent to which the individual is financially independent from his or her family.

The provision would also require the Secretary to strike the second sentence of 42 CFR 57.206(b). This regulation, issued in 1979, establishes certain requirements and guidelines related to loan programs for all health profession students under PHSA title VII. Among these requirements is one that states the Secretary must take into account the financial resources of the "family members" of an applicant for a title VII student loan.

While this requirement may have been justified at some time, it has become apparent to the Committee that it is being misused in some instances, particularly with respect to medical students. With a significant percentage of such students spending time in the workforce before entering medical school—on their own—rising, the Committee believes it is appropriate to revisit this requirement. In so doing, the Committee has specifically eliminated the sentence in current regulations that requires a review of financial information of the family members of a student loan applicant. It is requiring instead that the Secretary issue new student loan regulations that are consistent with the provisions of this section. More specifically, the Committee is requiring that such regulations take into account the extent to which a loan applicant is financially independent of his or her family. If in fact an applicant is financially independent of her or his family, the submission of financial information of family members should not be required as part of the student loan application process; only the financial information of the individual applicant is relevant and should be considered.

Sec. 2213. Training in family medicine, general internal medicine, general pediatrics, geriatrics, and physician assistants

Current Law

Part C of PHSA title VII (Health Professions Education) establishes training programs in family medicine, general internal medicine, general pediatrics, physician assistants, general dentistry,

and pediatric dentistry that includes financial assistance for both trainees and physicians participating in such programs. Under subsections (a) through (d) of PHSA sec. 747, the Secretary may establish a program of grants and contracts for hospitals, medical and osteopathic schools, and other nonprofit entities for health professions training programs in family medicine, general internal medicine, or general pediatrics, and comparable programs in dentistry.

Subsection (e) of PHSA Sec. 747 authorizes appropriations for such program and requires the Secretary to use a specified allocation formula when making grants and contracts. The authorization of appropriations for the program expired at the end of FY2002.

Proposed Law

This provision would amend PHSA Sec. 747 to redesignate subsection (e) as subsection (f), and to strike subsections (a) through (d) and in essence, to replace them with following new section:

Sec. 747. Primary Care Training and Enhancement. This section is revised to require the Secretary to establish a program of grants and contracts for both primary care training programs and primary care capacity building activities at academic institutions.

With respect to primary care training programs, accredited schools of medicine or osteopathic medicine, accredited physician assistant training programs, accredited public or non-profit hospitals and public or private nonprofit entities (or a consortia of such programs or entities) would be eligible for awards to engage in a variety of specified activities in support of professional training in various specialties of primary care, including family medicine, general internal medicine, general pediatrics, or geriatrics as well as physician assistant education. Such activities include traineeships, fellowships and faculty development.

With respect to primary care capacity building activities, accredited schools of medicine or osteopathic medicine would be eligible for awards to support academic units or programs that improve clinical teaching in various specialties of primary care, including family medicine, general internal medicine, general pediatrics, or geriatrics.

For both the primary care training and capacity building awards, the Secretary would be required to give preference to applicants with a demonstrated record of one or more of the following activities:

- Training primary care providers
- Training individuals from underrepresented minority groups or disadvantaged backgrounds
- Training individuals who provide care in underserved areas or to populations experiencing health disparities including those eligible for Medicaid and the Children's Health Insurance Program
- Supporting teaching programs targeting vulnerable populations

In evaluating an applicant's record regarding the training of individuals who provide care to populations experiencing health disparities, this provision would require that the term "health disparities" have the meaning given that term in PHSA sec. 3171 (as would be established in sec. 2301 of this legislation). In evaluating an applicant's record regarding its teaching programs that target

vulnerable populations, the Committee intends to include among those groups, individuals who are homeless or living with HIV/AIDS as well as other high-risk people.

The Secretary would be required to submit an annual report to Congress on the program.

Sec. 2214. Training of medical residents in community-based settings

Current Law

No comparable provisions.

Proposed Law

The provision would redesignate PHSA sec. 748 as PHSA sec. 749A and insert the following new sec. after PHSA sec. 747:

Sec. 748. Training of Medical Residents in Community-Based Settings. This new sec. would require the Secretary to establish a program of grants and contracts for various activities related to the training of medical residents in community-based settings, including planning and developing new primary care residency training programs (new programs), and operating or participating in an established primary care residency training program (established programs). Entities eligible for support include those (1) designated as a recipient of Medicare graduate medical education (GME) payments under Sec. 1886(k) of the Social Security Act (e.g., non-hospital health providers such as clinics or community health centers); (2) designated as an approved teaching health center in the GME demonstration project required under Sec. 1502(d) of this legislation; or (3) which have applied for designation under the programs specified in (1) or (2) and have demonstrated appropriate involvement of an accredited teaching hospital to carry out the inpatient responsibilities associated with a primary care residency training program.

With respect to both new and established programs, the Secretary would be required to give preference to applicants that (1) support teaching programs that address the health care needs of vulnerable populations, or (2) are a federally qualified health center (as defined or a rural health clinic as those centers are defined respectively under SSA secs. 1861(aa)(4) and 1861(aa)(2). With respect to established programs, the Secretary would be further required to give preference to applicants with a demonstrated record in training health professionals who provide primary care; individuals who are from underrepresented minority groups or disadvantaged backgrounds; or individuals who practice in settings with the principal focus of serving underserved areas or populations experiencing health disparities.

In evaluating an applicant's record regarding its teaching programs that address the health care needs of vulnerable populations, the Committee intends to include among those groups individuals who are homeless or living with HIV/AIDS as well as other high-risk people. In evaluating an applicant's record regarding the training of individuals who practice in settings with the principal focus of serving populations experiencing health disparities, this provision would require that the term "health disparities" have the

meaning given that term in PHSA sec. 3171 (as would be established in sec. 2301 of this legislation).

Grant or contract award periods would vary, depending upon the type of grant or contact being sought. Grants or contracts for new programs could not exceed three years; grants or contracts for established programs could not exceed five years. Moreover, grants for new programs could not be renewed, although an entity receiving support for a new program would remain eligible for support as an established program provided that the two funding periods do not overlap. The Committee has taken this approach to help ensure the establishment and ongoing operation of as many community-based primary care residency programs as possible.

The Secretary would be required to submit an annual report on the programs carried out under this provision.

For purposes of this sec., the term "primary care resident" has the meaning given such term in SSA sec. 1886(h)(5)(H). The term "primary care residency training program" would mean an approved medical residency program training program described in SSA sec. 1886(h)(5)(A) for primary care residents that in case of new programs, is actively applying for accreditation by the appropriate accrediting body, or in the case of established programs, has been accredited by the appropriate accrediting body.

The Committee has established this program as part of its overall goal in title II to support professional education efforts designed to train those who provide primary care. Currently, the vast majority of GME training takes place in the hospital setting; only a tiny number of non-hospital providers have been designated as GME training facilities, despite widespread agreement that more such training should take place in the ambulatory setting—the practice setting for most clinical care. The Committee expects that with this program in place, additional GME training will take place in the outpatient setting, including the new demonstration project for teaching centers (as would be established in sec. 1502 of this legislation).

Sec. 2215. Training for general, pediatric, and public health dentists and dental hygienists

Current Law

Part C of PHSA title VII (Health Professions Education) establishes training programs in family medicine, general internal medicine, general pediatrics, physician assistants, general dentistry, and pediatric dentistry that includes financial assistance for both trainees and physicians participating in such programs. Under subsections (a) through (d) of PHSA sec. 747, the Secretary may establish a program of grants and contracts for hospitals, medical and osteopathic schools, and other nonprofit entities for health professions training programs in family medicine, general internal medicine, or general pediatrics, and comparable programs in dentistry.

Subsection (e) of PHSA sec. 747 authorizes appropriations for such program and requires the Secretary to use a specified allocation formula when making grants and contracts. The authorization of appropriations for the program expired at the end of FY2002.

PHSA sec. 791 sets forth criteria the Secretary is required to use in making grant or contract awards for programs authorized under

PHSA sec. 747 and sec. 750. Such criteria include giving preference to applicants that have a high or recently improved rate of placing program graduates in practice settings that provide care to medically underserved communities.

Proposed Law

This provision would amend part C of PHSA title VII (Health Professions Education) to add at the end a new PHSA sec. 749:

Sec. 749. Training for General, Pediatric, and Public Health Dentists and Dental Hygienists. This new sec. would require the Secretary to establish a program of grants and contracts to establish and maintain training programs for oral health professionals, including such individuals practicing in general dentistry, public health dentistry or dental hygiene. Entities eligible to participate in such a program include: (1) accredited schools of dentistry; (2) training programs in dental hygiene (located in either an accredited school of dentistry or an accredited institution of higher education; (3) public or private nonprofit entities; or (4) consortia of such entities. Such entities could receive support for various professional training-related activities, including scholarships, loan repayments, traineeships, fellowships, and faculty development.

With respect to loan repayments for full-time dental faculty, the Committee underscores the sec.'s focus on targeting such faculty who participate in programs of general, pediatric or public health dentistry. This view is consistent with the overall purpose of subtitle A to increase the number of primary care health professionals—including oral health professionals—across the country. In addition, in developing the loan repayment program under this sec., the Committee encourages the Secretary to be guided by the loan repayment process used in administering either the nurse faculty loan repayment program authorized in PHSA 846A or the loan repayment program for disadvantaged students authorized in PHSA sec. 738.

In awarding grants or contracts, the Secretary would be required to give preference to applicants with a demonstrated record of one or more of the following activities:

- Training oral health professionals who practice general, pediatric, or public health dentistry
- Training individuals from underrepresented minority groups or disadvantaged backgrounds
- Training individuals who practice in underserved areas or provide services to populations experiencing health disparities including those eligible for Medicaid and the Children's Health Insurance Program, or those with special health care needs
- Supporting teaching programs targeting vulnerable populations
- Providing instruction regarding the oral health status, dental health needs, and clinical oral disease management of children, especially underserved children

In evaluating an applicant's record regarding the training of individuals who provide services to populations experiencing health disparities, this provision would require that the term "health disparities" have the meaning given that term in PHSA sec. 3171 (as would be established in sec. 2301 of this legislation). In evaluating an applicant's record regarding its training programs that target

vulnerable populations, the Committee intends to include among those groups, individuals who are homeless or living with HIV/AIDS as well as other high-risk people.

The Secretary would be required to submit an annual report to Congress on the program.

Sec. 2216. Authorization of appropriations

Current Law

PHSA title VII (Health Professions Education) includes the authorization of appropriations for a number of training programs. Many of these authorizations have expired.

Proposed Law

This provision amends Part F of PHSA title VII (Health Professions Education) to add the following new sec. 799C:

Sec. 799C. Funding through Public Health Investment Fund. This new sec. would have the following sums authorized to be appropriated from the Public Health Investment Fund (as would be established in section 2002 of this legislation) for the purpose of carrying out various programs related to the promotion of primary care, including primary oral health care:

- $240 million for FY2010
- $253 million for FY2011
- $265 million for FY2012
- $278 million for FY2013
- $292 million for FY2014

These sums from the Fund are in addition to any other amounts authorized to be appropriated from general revenues for such purposes.

This section would also reauthorize PHSA section 747 through FY2014.

Sec. 2217. Study on effectiveness of scholarships and loan repayments

Current Law

No comparable provisions.

Proposed Law

This provision would require GAO to conduct a study on the effectiveness of both the National Health Service Corps and the Frontline Health Provider Program (as would be established in sec. 2211 of this legislation) in encouraging individuals to pursue and maintain careers in primary care and in encouraging them to practice in underserved areas. More specifically, the study would evaluate the scholarships and loan repayments attached to each of these programs to determine their appropriateness and adequacy in helping to achieve these twin goals.

Subtitle B—Nursing Workforce

Sec. 2221. Amendments to the Public Health Service Act

Current Law

PHSA title VIII (Nursing Workforce Development) contains several provisions on nurse workforce development, including programs to provide grants and loans to nursing students and schools of nursing.

PHSA sec. 811 authorizes the Secretary to provide grants to fund projects that support the enhancement of advanced nursing and practice, and traineeships for individuals in advanced nursing programs. PHSA sec. 811(f) places some limitations on the use of these grant funds for traineeships, restricting their use to certain education-related costs and living expenses, and limiting the amount of support for individuals in doctoral programs to no more than 10% of the total amount of obligated funds. Special consideration is provided under the sec. for entities that agree to train advanced education nurses who will practice in health professional shortage areas (HPSAs).

PHSA sec. 821 authorizes the Secretary to award grants to increase nursing education opportunities for individuals from disadvantaged backgrounds, including racial and ethnic minorities underrepresented in the nursing profession.

PHSA sec. 831 authorizes the Secretary to award grants to expand both nursing education and nurse practice arrangements and to develop nurse retention programs.

PHSA sec. 836 places limits on loans made by nursing schools authorized under PHSA sec. 835 (student loans). Such loans may not exceed $2,500 per year, with an exception for the final two academic years, during which they may not exceed $4,000 per year. Regardless of the time frame involved, no student may receive more than $13,000 in loans. The sec. also establishes a student loan repayment program for individuals who agree to serve as a nurse for at least two years at a qualified health care facility with a critical shortage of nurses.

PHSA sec. 846A authorizes the Secretary to establish agreements with nursing schools for the development and operation of nurse faculty loan programs. Subsection (c) of that sec. establishes requirements for such programs, including a limitation of $30,000 (plus an annual inflation adjustment) on the total amount of loans that a nursing school may make to a student through its loan program in any academic year.

PHSA sec. 845 requires the Secretary to establish the National Advisory Committee on Nursing Education and Practice.

PHSA sec. 855 requires the Secretary to award grants for training and education programs and initiatives in geriatric care. These programs and initiatives are to be coordinated with programs authorized under PHSA sec. 753 (geriatric education and training).

Part H of PHSA title VIII requires the Secretary to develop and issue public service announcements to advertise and promote the nursing professions. The Secretary is also authorized to fund state and local public service announcements for the same purpose.

Part F of PHSA title VIII provides for the authorization of appropriations for various nurse workforce programs through FY2002,

including Parts B, C and D (sections 811, 821, and 831 respectively) of the title.

The authorization of appropriations for six programs authorized under title VIII has expired, although the following programs have continued to be funded: advanced education nursing grants (PHSA sec. 811); nursing workforce diversity grants (PHSA sec. 821); nurse education, practice, and retention grants (PHSA sec. 831); National Nurse Services Corps (nurse educational loan repayment and scholarship programs) (PHSA sec. 846); nurse faculty loan program (PHSA sec. 846A); and comprehensive geriatric education (PHSA sec. 855).

Two PHSA title VIII programs have not received appropriations since they were first authorized: public service announcements (PHSA sections 851 and 852) and grants for health professions education for cultural competency (PHSA sec. 807). The nursing student loan program (PHSA sections 835–840), which provides loans to nursing students to pursue studies in all levels of nursing, has not received any funding support in recent years. However, nursing schools are able to utilize funds from other sources as well as loan repayments to operate loan funds from which they award student loans.

Proposed Law

This provision would amend PHSA title VIII regarding certain nursing grant and loan programs, and would authorize monies from the Public Health Investment Fund (established under sec. 2002 of this legislation) to support such programs for FY2010 through FY2014.

Congress first authorized comprehensive federal support for nursing workforce programs when it passed the Nurse Training Act of 1964 (P.L. 88–581). The initial programs were created in response to a 1963 Surgeon General's report that projected a nursing shortage within the decade. Subsequent legislation amended or reauthorized the title VIII programs to address evolving needs in nursing education and training. The programs were last reauthorized in 2002.

Thirty-five years after the passage of the 1964 Nurse Training Act, title VIII programs continue to be a primary source of federal funding for nursing education. Within the context of health reform, the Committee believes that it is time to renew the nation's commitment to these programs to ensure an adequate and well-qualified nurse workforce. Indeed, experts report that with an anticipated shortfall of at least 500,000 nurses by 2020, there is no time to lose.

Experts report that a major contributor to this projected shortage is the lack of faculty to train new recruits to the profession. According to the American Association of Colleges of Nursing (AACN), some 42,000 qualified applicants were turned away from nursing schools in 2006, to a significant extent as a result of insufficient faculty. Several causes are attributed to this capacity building problem, including the ability of nursing schools to attract and retain faculty. Replacing the aging nurse workforce—those out in the field—has become a great challenge as well. The need and demand for primary care nurses with advanced degrees has become espe-

cially acute in light of the current shortage of primary care providers.

The purpose, then, of this provision is to reauthorize various title VIII authorities and to provide improvements to those particular programs designed to help increase the nurse workforce. With such changes in place, the AACN estimates that 10,000 new nurses will be trained each year, and half of those would hold an advanced degree. More specifically, this provision would make the following changes:

• The provision would amend PHSA sec. 801 to allow "nurse-managed health centers" (NMHCs) (as defined in this provision) to be eligible for support under various programs authorized under title VIII. The Committee understands that under current practice, NMHCs are eligible for awards—and have received support—under title VIII. As such, the Committee simply intends for this provision to codify that practice to ensure that NMHCs are able to continue to participate in title VIII programs. This is especially important as part of the country's push to train more nurses. Administered by nurses with advanced degrees, NMHCs are important sites both for nursing education and for providing access to health services, particularly for vulnerable populations. In codifying NMHC eligibility for title VIII support, however, the Committee also intends for these centers to continue to operate in accordance with applicable state law requirements regarding the scope of practice under which an individual is legally authorized to perform services at an NMHC. Indeed, nothing in this provision is intended to have any impact or effect on such laws (or on any state regulatory mechanism authorized under state law).

• The provision would strike PHSA sec. 807, a grant program for cultural and linguistic competence training for nurses. As noted, this program has never been funded; the Committee does not anticipate a change in this funding status. Moreover, the Committee believes that cultural and linguistic competence training should be coordinated across the spectrum of health professionals rather than targeted on one or two types of providers. Thus, the Committee has chosen not to continue the program authorized under PHSA sec. 807 (as well as other similar programs), but rather to take a new approach, much broader approach in supporting diversity and cultural competency programs. (See sections 2243 and 2251 of this legislation).

• The provision would add a new PHSA sec. 809 to require the Secretary to submit annual reports to Congress on all of the loan and grant programs in title VIII that do not already require such a report (PHSA sections 811, 821, 836, 846A, and 861, as re-designated under this provision).

• The provision would amend PHSA sec. 811 (regarding the Advanced Education nursing grants) to strike the prohibition in paragraph (f), which currently restricts the percentage of traineeships that may be obligated to support individuals in doctoral programs to 10%. The provision would further amend PHSA sec. 811 to require the Secretary to give special consideration to applicants that either intend to expend their grant funds to train nurses with advanced degrees who will practice in HPSAs or to increase diversity among advanced education nurses.

• The provision would amend PHSA sec. 831 to revise one of the purposes of the nurse education, practice, and retention grants for practice priority areas to include the provision of coordinated care, quality care and other relevant skills and to replace the reference to managed care and quality improvement. The provision also strikes the outdated preference criterion for FY2003 through FY2005.

• The provision would amend PHSA sec. 836 to increase the total maximum amount of loans a student may receive on an annual basis from $2,500 to $3,300; to increase the annual such limit for a student's last two academic years from $4,000 to $5,200; and to increase the total amount of loans a student may receive over the course of his or her enrollment in a nursing program from $13,000 to $17,000. Effective FY2012, the provision also would instruct the Secretary to adjust these limits annually for inflation. In increasing these amounts, the Committee notes that no adjustment has been made since the program's inception in 2002.

• The provision would amend PHSA sec. 846(a) to allow individuals to be accepted into the loan repayment program if they agree to serve for not less than two years as a faculty member at an accredited school of nursing. This change is intended to complement other existing incentives designed to encourage nurses to become faculty. In addition, the revision is intended to expand the pool of nurses already serving as faculty who can qualify for loan repayment. Currently, the nurse faculty loan program is available only to nurses graduating from schools that operate loan funds. The provision would also amend PHSA sec. 846A(c) to raise the limit on the total amount of loan repayment any individual may receive for any academic year under the nurse faculty program from $30,000 to $35,000. Effective FY2012, the provision would require the Secretary to adjust these limits annually for inflation. In increasing these amounts, the Committee notes that no such adjustment has been made since the program's inception in 2002, heightening the financial barriers that make it more difficult to attract people into the profession.

• The provision would strike part H of title VIII (PHSA sections 851 and 852) to eliminate the authority to develop and issue public service announcements to promote careers in nursing. As noted above, Congress has never funded this activity; the Committee has no basis for believing that this will change. Moreover, data indicate that the current nursing shortage is not a result of a lack of interest in the field—some 42,000 qualified individuals were turned away from nursing schools in 2006 alone, according to the AACN. Instead, it is due in large measure to a lack of financial resources to support nurse education and training, including nurse faculty recruitment and retention. Thus, the Committee believes it is far more prudent to invest the limited dollars available in programs that support those activities rather than in advertising campaigns.

• The provision would authorize to be appropriated "such sums as may be necessary" for each fiscal year through FY2014 for part B (advanced education grants), part C (workforce diversity grants), and part D (nurse education, practice, and retention grants) of title VIII.

• The provision would also authorize the following sums to be appropriated from the Public Health Investment Fund (as would be

established in sec. 2002 of this legislation) for the purpose of carrying out various nurse workforce training programs:

- $115 million for FY2010
- $122 million for FY2011
- $127 million for FY2012
- $134 million for FY2013
- $140 million for FY2014

These sums from the Fund are in addition to any other amounts authorized to be appropriated from general revenues for such purposes.

In allocating funds to support nursing workforce programs, it is the intent of the Committee that priority be given to those programs and activities designed to (1) increase the number of nursing faculty; (2) address other factors impeding nursing education capacity; and (3) promote the training of advanced education nurses who deliver primary care.

- The provision would make technical and conforming changes to various programs in title VIII

Subtitle C—Public Health Workforce

For some time, experts have argued that the public health workforce is inadequate to meet the nation's public health needs. To help address this problem, Congress established five public health workforce training programs under PHSA title VII (Health Professions Education) as part of the Health Education Partnerships Act of 1998 (P.L. 105–392): general grant authority (PHSA sec. 7650; public health training centers (PHSA sec. 766); public health traineeships (PHSA sec. 767); preventive medicine; dental public health (PHSA sec. 768), and heath administration traineeships and special projects (PHSA sec. 769). Programs funded in sec. 765 have gone unfunded; programs authorized in PHSA sec. 769 have not been funded since FY2006.

Despite these efforts, the sufficiency and quality of the public health workforce remains of great concern. Today, the Association of Schools of Public Health estimates that within the next 10 years, the nation will experience a shortfall of more than 250,000 public health workers. Approximately one-quarter of the government's public health workforce will be eligible to retire by 2012, including nearly 50% of state employees who work in public health. And almost 20% of local public health employees will be qualified for retirement by 2010, according to the National Association of County and City Health Officials.

It is clear that state and local budget constraints are a major barrier to adequate staffing at public health agencies. Many prospective employees seek private sector employment because of the higher salaries and more generous benefits packages that are often available and that the public sector cannot match. Similarly, few state or local health departments have the resources to dedicate to recruiting, retaining, or training the professional workforce necessary to protect the public's health. This has become of increasing concern as the nation faces a number of emerging and ongoing public health challenges (e.g., salmonella outbreaks, H1N1 influenza, and the HIV/AIDS epidemic) that demand the use of trained experts. Indeed, according to CDC, the vast majority (80%) of the

public health workforce now lacks formal public health training for their specific job functions.

The provisions in subtitle C are intended to expand the efforts begun a decade ago. Their purpose is to improve the programs already on the books and to create a new program designed to encourage public health graduates to enter the public health workforce. Taken together, these initiatives, along with the funding made available for them, is expected to produce a larger and better trained workforce that can help meet the public health needs across the country.

Sec. 2231. Public Health Workforce Corps

Current Law

No comparable provisions.

Proposed Law

This provision would amend PHSA title III to add at the end a new subpart XII—"Public Health Workforce"—and to establish in that part a new Public Health Workforce Corps consisting of the following three new sections:

Sec. 340L. Public Health Workforce Corps. This sec. would require the establishment, within the U.S. Public Health Service, of a Public Health Workforce Corps (PHWC) to ensure an adequate national supply of public health professionals. The new program would be modeled on the National Health Service Corps (NHSC) that offers scholarships and loan repayments to attract health professionals to provide services in health professional shortage areas. Indeed, the sec. explicitly states that the PHSA sections regarding the general administrative aspects of the NHSC would apply to the PHWC unless they are inconsistent with such provisions.

The PHWC would be administered by HRSA, the agency which oversees virtually all of the federal health workforce training programs. The CDC would, however, have responsibility for developing a methodology for placing and assigning Corps participants in such organizations as state, local, and tribal health departments, and federally qualified health centers. The Committee has specifically tasked CDC with this duty because of both its expertise in public health and its ongoing, strong connection with health departments.

The Corps itself would consist of: (1) officers of the Regular and Reserve Corps of the U.S. Public Health Service Commissioned Corps; (2) civilian U.S. employees appointed by the Secretary; and (3) other individuals who are not employees of the United States. The Committee anticipates that students and graduates of accredited schools or programs of public health will comprise the majority of the Corps.

The Secretary would be required to submit an annual report to Congress on the PHWC.

Sec. 340M. Public Health Workforce Scholarship Program. This sec. would require the Secretary to establish a scholarship program for individuals who want to join PHWC. To be eligible for scholarship assistance, an applicant must:

Be accepted or enrolled full-time or part-time in an accredited graduate school or program of public health; or

Have public health expertise and be accepted or enrolled full-time or part-time in an accredited graduate school or program of nursing; health administration, management, or policy; preventive medicine; laboratory science; veterinary medicine; or dental medicine; or other accredited graduate school or program designated by the Secretary.

It is the Committee's intent that the Secretary have discretionary authority to extend scholarship assistance to individuals pursuing graduate degrees in public health disciplines at non-public health accredited schools or programs. For example, in the Committee's view, it may be appropriate for the Corps to provide support for individuals enrolled in an accredited school of education that offers a program of study in health communications or in a graduate school of arts and sciences that offers a course of study in biostatistics.

Scholarship awards could be made for up to four years. In return, scholarship recipients would be required to serve full-time as a public health professional for a period of one year for each academic year for which the recipient was provided scholarship support (with a maximum commitment of four years) or two years—whichever period is greater. Stipends would be provided on a monthly basis and would be required, effective FY2011, to be adjusted by the Secretary on an annual basis for inflation.

The Committee anticipates that many, or even most, scholarship recipients will fulfill their service obligation working at public health agencies such as state and local health departments or community health centers. While the Committee fully endorses the placement of Corps members at these sites, it understands that there may be other entities with a public health focus that may benefit from their service. Thus, the Committee expects CDC to take a broad view in developing an appropriate methodology for placing and assigning Corps participants so as to include those sites experiencing the most severe shortages of, and the most difficulty in recruiting, public health professionals.

As noted, it is the Committee's intent that the PHWC be administered in a manner similar to that followed with regard to the NHSC, except to the extent that the new subpart XII would require something different. The Committee underscores this intent with respect to the scholarship program that would be established in this section.

Sec. 340N. Public Health Workforce Loan Repayment Program. This sec. would require the Secretary to establish a loan repayment program for individuals who want to join PHWC. To be eligible for loan repayment assistance, an applicant must:

- Have a graduate degree from an accredited school or program of public health;
- Have demonstrated public health expertise and a graduate degree from an accredited school or program of nursing; health administration, management, or policy; preventive medicine; laboratory science; veterinary medicine; or dental medicine; or other accredited graduate school or program designated by the Secretary; or
- Be enrolled in the final year of study at an accredited school or program of public health or an accredited school or program of nursing; health administration, management, or

policy; preventive medicine; laboratory science; veterinary medicine; or dental medicine; or other accredited graduate school or program designated by the Secretary (with demonstrated expertise in public health).

It is the Committee's intent that the Secretary have discretionary authority to extend loan repayment assistance to individuals pursuing or holding graduate degrees in public health disciplines at non-public health accredited schools or programs. For example, in the Committee's view, it may be appropriate for the Corps to provide support for individuals enrolled in an accredited school of education that offers a program of study in health communications or in a graduate school of arts and sciences that offers a course of study in biostatistics.

In return for any assistance provided under this program, loan recipients would be required to serve for a minimum of two years as a public health professional in an appropriate setting. For each year of service provided, individuals could receive up to $35,000 in loan repayments, an amount that would be required, effective FY2012, to be adjusted by the Secretary on an annual basis for inflation.

The Committee anticipates that many or even most loan recipients will fulfill their service obligation working at public health agencies such as state and local health departments or community health centers. While the Committee fully endorses the placement of Corps members at these sites, it understands that there may be other entities with a public health focus that may benefit from their service. Thus, the Committee expects CDC to take a broad view in developing an appropriate methodology for placing and assigning Corps participants so as to include those sites experiencing the most severe shortages of, and the most difficulty in recruiting, public health professionals.

As noted, it is the Committee's intent that the PHWC be administered in a manner similar to that followed with regard to the NHSC except to the extent that the new subpart XII would require something different. The Committee underscores this intent with respect to the loan repayment program that would be established in this section.

Sec. 2232. Enhancing the public health workforce

Current Law

PHSA sec. 765 authorizes the Secretary to establish a program of grants and contracts to enhance the public health workforce, including efforts to increase the number of individuals in such workforce, to enhance the quality of such workforce, and to enhance the ability of such workforce to meet the nation's public health needs.

This program has not been funded.

Proposed Law

This provision would amend PHSA sec. 765, in essence, to replace it with the following new sec.:

Sec. 765. Enhancing the Public Health Workforce. This new sec. would require the Secretary to establish a program of grants and contracts to enhance the public health workforce. Entities eligible to participate in such programs include (1) various health profes-

sions schools; (2) state, local or tribal health departments; (3) public or private nonprofit organizations; and (4) consortia of these entities. Such entities could receive support for various public health professional training-related activities, including traineeships and fellowships.

In awarding grants or contracts, the Secretary would be required to give preference to applicants with a demonstrated record of one or more of the following activities:

- Training public health professionals who serve in underserved communities
- Training individuals from underrepresented minority groups or disadvantaged backgrounds
- Training individuals who practice in public health specialties experiencing a significant shortage of public health professionals
- Training public health professionals who serve in the federal government or state, local, or tribal governments

The Secretary would be required to submit an annual report to Congress on the program. In evaluating an applicant's record regarding the training of individuals who practice in public health specialties experiencing a significant shortage of public health professionals, the Committee expects the Secretary to take into account various public health workforce needs. For example, across the country, there is increasing demand for (and shortage of) public health professionals with expertise in nursing, epidemiology and health education, among others specialties. Entities providing training in these areas would be given preferential treatment in evaluating their application for support under this program. However, once these shortages are adequately addressed, this preferential treatment would no longer apply; the emphasis instead would be placed on those public health specialties then experiencing a shortage of public health professionals.

The Committee notes its interest in this program's focus on supporting training activities on mid-career public health professionals. As noted, some 80% of today's state and local public health workforce has not received formal training in their areas of responsibility. Many of them are at the mid-career level. This program would afford them the opportunity to build on the expertise they have developed through their work experience and in turn, to bring new public health knowledge back into the communities and organizations in which they serve.

The Committee further notes its intent that the Secretary administer this program in a manner that best integrates its activities with other existing public health workforce programs, including the public health training centers program (PHSA sec. 766) and the public health traineeships program (PHSA sec. 767). In so doing, however, it underscores the requirement that the HRSA Administrator consult with the CDC Director in establishing the PHSA sec. 765 public health workforce program.

Sec. 2233. Public health training centers

Current Law

PHSA sec. 766 authorizes the Secretary to establish a program of grants and contracts to support public health training centers.

Subsection (b)(1) of that section refers to "goals established by the Secretary for the year 2000." This clause refers to the decennial Healthy People goals developed and published by the Secretary.

Proposed Law

This provision would amend subsection (b)(1) of PHSA sec. 766 to strike the reference to the HHS Healthy People publication and to replace it with a reference to the HHS prevention and wellness goals that would be developed by the Secretary under PHSA sec. 3121 (as would be established in sec. 2301 of this legislation). PHSA sec. 3121 requires the Secretary to prepare such goals on a biennial basis, a timeframe much shorter than the 10-year span in between issuance of the HHS Healthy People reports. The change made in this provision would ensure that the required application standards for this program accurately reflect the status of the Department's work in the area of prevention and wellness.

This provision would require the Secretary to submit an annual report to Congress on this program.

In updating PHSA sec. 766, the Committee notes that the program authorized therein currently spans 45 states and the District of Columbia. While the Committee supports the program's continuation, it believes its work could be better integrated with the efforts undertaken through the program authorized in PHSA sec. 765. Thus, the Committee encourages the Secretary to bring these programs together as best as possible.

Sec. 2234. Preventive medicine and public health training grant program

Current Law

PHSA sec. 768 authorizes a program of grants and contracts to support preventive medicine residency and dental public health training. Eligible entities schools include schools of medicine, osteopathic medicine, public health, and dentistry.

Proposed Law

This provision would replace the existing language in PHSA sec. 768 with the following new provision.

Sec. 768. Preventive Medicine and Public Health Training Grant Program. This new provision would require the Secretary to establish a program of grants and contracts to provide training for graduate medical residents in preventive medicine. Entities eligible to participate in such program would include (1) accredited schools of public health, medicine, or osteopathic medicine; (2) accredited public or private hospitals; and (3) consortia of these entities. Such entities could receive support for various preventive medicine residency-related activities, including the operation of internship or residency programs in preventive medicine or public health; the defrayment of costs associated with required practical experiences; and faculty development.

In revising the authority for this program, the Committee notes the uniqueness of preventive medicine among the various medical specialties. It is perhaps the only specialty that combines knowledge and skills in clinical medicine with those in public health. A 2007 Institute of Medicine report (*Training Physicians for Public*

Health Careers) cited the importance of public health physicians in maintaining and improving the health of the public. It also emphasized the need to address the various barriers that make it difficult to practice as a public health physician, including inadequate support for graduate medical education.

Unlike other specialties, preventive medicine residents spend time training in community-based outpatient clinics and public health departments, both of which are ineligible for Medicare graduate medical education (GME) funding—by far and away, the main source of support for GME training. As a result, preventive medicine residency programs rely almost exclusively on HRSA funding and other sources to support the training of physicians specializing in this field, many of who go on to lead public health agencies. In the Committee's view, then, it is critically important that the preventive medicine and public health training program authorized under PHSA sec. 768 continue to receive adequate funding and other support.

In that spirit, the Committee further notes HRSA's recent decision to amend its own program guidance to clarify the program's eligibility standard of "preventive medicine" to include all three preventive medicine specialties—general preventive medicine and public health, occupational medicine, and aerospace medicine. The Committee strongly endorses the agency's action and in so doing, recognizes and supports the need for improved access to preventive medicine physicians in these three specialties, particularly in general preventive medicine and public health and occupational medicine.

Physicians who specialize in occupational medicine warrant special attention. Their efforts parallel those of general preventive medicine and public health clinicians within the general public health system—only their work takes place within in the workplace setting, rather than the traditional office or clinic site. There, they not only deal with illnesses and injuries that occur within the workplace population; they also focus on health promotion and wellness in helping to reduce the incidence rates of obesity, diabetes, heart disease, cancer, and other chronic diseases that this population may experience. These physicians are involved on all fronts—most especially in actively supporting and providing health promotion and wellness services. Thus, the Committee strongly supports HRSA's decision to amend its program guidance material to ensure that programs that train these preventive medicine specialists are eligible to participate in this program and receive appropriate emphasis. As HRSA moves forward with this new guidance, the Committee urges the agency to consult with the National Institute for Occupational Safety and Health.

Sec. 2235. Authorization of appropriations

Current Law

Subpart 2 (PHSA sections 765 through 770) of part E of PHSA title VII (Health Professions Education) authorizes various public health workforce programs, including general provisions (PHSA sec. 765); public health training centers (PHSA sec. 766); public health traineeships (PHSA sec. 767); preventive medicine and dental public health (PHSA sec. 768); and health administration

traineeships and special projects (PHSA sec. 769). The authorization of appropriations for subpart 2 (PHSA sec. 770) expired at the end of FY2002.

Proposed Law

This provision would authorize the following sums to be appropriated from the Public Health Investment Fund (as would be established in sec. 2002 of this legislation) for the purpose of carrying out various programs related to public health workforce training activities:

- $51 million for FY2010
- $54 million for FY2011
- $57 million for FY2012
- $59 million for FY2013
- $62 million for FY2014

These sums from the Fund are in addition to any other amounts authorized to be appropriated from general revenues for such purposes.

The provision would extend the authorization of appropriations for public health workforce programs through FY2014.

Subtitle D—Adapting Workforce to Evolving Health System Needs

Enhancing the nation's health workforce involves more than simply increasing the number of providers; it also entails the development of a more diverse, cultural competent workforce and the introduction of new and improved service delivery systems. Experts agree, for example, that it is important for the health workforce to reflect the nation's increasingly diverse population, especially since health professionals from diverse backgrounds are more likely to work in medically underserved communities. This point was made most recently in MedPAC's 2009 report to Congress (*Improving Incentives in the Medicare Program*) in which the advisory group discussed, among other indicators, the association between a racially and ethnically diverse health workforce and better access to, and quality of care for, disadvantaged populations.

Similarly, the complexity of modern medicine and the increase in chronic disease call for innovation in the ways health services are currently delivered. A number of expert panels (including MedPAC, the Institute of Medicine, and the Council of Graduate Medical Education (COGME)) have pushed for residency training to focus on increased care coordination, formal training or experience in multidisciplinary teamwork, and other such efforts indicative of an innovative approach to the delivery of health care. The Committee agrees with these recommendations and believes that incorporating them broadly in the training of the nation's health workforce is most appropriate.

Experts have also made a strong case for the creation of an independent advisory body to make recommendations regarding the composition of the health workforce. Indeed, in a report issued in 2007 (*Enhancing Flexibility in Graduate Medical Education*), COGME specifically supported the establishment of such a group whose mandate would also include a review of GME funding practices.

The purpose of subtitle D is to help address a number of these issues: diversity in the workforce; cultural and linguistic com-

petency; interdisciplinary care training; and workforce assessment and evaluation. Taken together, these efforts represent a coordinated approach to help ensure that the nation's 21st century health workforce needs—in their broadest sense—are met.

PART 1—HEALTH PROFESSIONS TRAINING FOR DIVERSITY

Sec. 2241. Scholarships for disadvantaged students, loan repayments and fellowships regarding faculty positions, and educational assistance in the health professions regarding individuals from disadvantaged backgrounds

Current Law

PHSA sec. 738(a) authorizes a program of loan repayments for individuals from disadvantaged backgrounds who (1) have a degree in medicine, osteopathic medicine, dentistry, nursing, public health or another specified health professions; or (2) are enrolled in an accredited program leading to one of these degrees and in the final year of study; and (3) agree to serve as a faculty member in a health professions school for at least two years. Individuals participating in the program may receive up to $20,000 of educational loan repayment for each year they serve as a faculty member.

Proposed Law

This provision would amend PHSA sec. 738(a) to increase the limit on the amount of loan repayment individuals may receive for each year they serve as a faculty member to $35,000. Effective FY2012, the Secretary would be required to adjust these limits annually for inflation. In increasing these amounts, the Committee notes that no adjustment has been made since the program's inception in 1991, heightening the financial barriers that make it more difficult to attract people from disadvantaged backgrounds into the teaching profession.

Sec. 2242. Nursing workforce diversity grants

Current Law

PHSA sec. 821 authorizes the Secretary to establish a program of grants and contracts to increase nursing education opportunities for individuals from disadvantaged backgrounds. Individuals participating in the program may receive various forms of support, including student scholarships or stipends. In carrying out this program, the Secretary would be required to take into account the recommendations of the first (1992), second (1993), and third (1997) Invitational Congresses for Minority Nurse Leaders to consult with specified nursing organizations.

Proposed Law

This provision would amend PHSA sec. 821(b) to delete the outdated reference to the three Invitational Congresses for Minority Nurse Leaders. The provision would also delete the requirement that the Secretary consult with specified nursing organizations and would instead provide her with the discretion to consult with such groups as she finds appropriate.

Sec. 2243. Coordination of diversity and cultural competency programs

Current Law

Part B (PHSA sections 736, 737, 738, and 739) of PHSA title VII (Health Professions Education) authorizes the Secretary to establish various programs of grants and contracts designed to help diversify the health professions, including scholarship and loan repayment programs, education assistance, and centers of excellence.

Part C (PHSA sec. 821) of PHSA title VIII (Nursing Workforce Development) authorizes the Secretary to establish a program of grants and contracts to increase nursing education opportunities for individuals from disadvantaged backgrounds, including racial and ethnic minorities underrepresented in the nursing profession.

Proposed Law

This provision would amend PHSA title VII to add the following new sec. after PHSA sec. 739:

Sec. 739A. Coordination of Diversity and Cultural Competency Programs. This new section would require the Secretary to coordinate the activities authorized under part B (PHSA sections 736, 737, 738, and 739) of PHSA title VII with those under part C (PHSA sec. 821) of PHSA title VIII to enhance their effectiveness and avoid any duplication of effort.

The Committee has taken this action in response to concerns that have been raised about HRSA's authority to coordinate the diversity and cultural competency programs separately authorized in PHSA titles VII and VIII. The Committee believes that HRSA does have such authority and that, indeed, it should coordinate programs and activities for which it has responsibility whenever appropriate and prudent to do so. With this new PHSA sec. 739A in place, the Committee believes that HRSA's ability to work in this fashion has been made clear.

The provision would also amend PHSA sec. 736 to require the Secretary to submit an annual report to Congress on the Centers for Excellence program.

PART 2—INTERDISCIPLINARY TRAINING PROGRAMS

Sec. 2251. Cultural and linguistic competency training for health care professionals

Current Law

Both PHSA sections 741 and 807 authorize the Secretary to establish a program of grants, contracts, and cooperative agreements to support research and demonstration projects on training health professionals in health disparities and the provision of culturally competent health care. Neither program has received funding since their inception in FY2001; the authority for appropriations under each sec. expired at the end of FY2004.

Proposed Law

This provision would amend PHSA sec. 741, in essence, to establish a new program of grants and contracts to develop and implement cultural and linguistic competency training models and programs for health professionals. Entities eligible for support would

include: (1) accredited health professions schools or programs; (2) academic health centers; (3) public or private nonprofit entities; or (4) consortia of these entities. In awarding grants or contracts, the Secretary would be required to give preference to applicants with a demonstrated record of one or more of the following activities:

- Addressing (or partnering with an entity with experience addressing) the cultural and linguistic competency needs of the population to be served
- Addressing health disparities
- Placing health professionals in regions experiencing significant changes in the cultural and linguistic demographics of populations (including communities along the United States-Mexico border)
- Carrying out cultural and linguistic training in more than one health profession discipline, specialty, or subspecialty

In evaluating an applicant's record regarding the training of individuals who provide services to populations experiencing health disparities, this provision would require that the term health disparities have the meaning given that term in PHSA sec. 3171 (as would be established in sec. 2301of this legislation).

The provision would also require the Secretary to consult with appropriate HHS agencies and offices in developing this new program. The Committee expects that among these agencies and offices, in addition to the Office of Minority Health, the Secretary would consult with the NIH's National Center on Minority Health and Disparities.

The provision would require the Secretary to submit an annual report to Congress on the program.

In restructuring PHSA sec. 741, the Committee has chosen to consolidate both this sec. and PHSA sec. 807 into a single authority. The language of both sections is identical, with the only difference between them being their location in the PHSA—PHSA sec. 741 is authorized in title VII (Health Professions Education) and PHSA sec. 807 is authorized in title VIII (Nursing Workforce Development). The provision basically eliminates this duplication of effort and establishes a new program designed to better reflect the priorities for cultural and linguistic competency training necessary to help develop and maintain a 21st century U.S. health workforce.

Towards that end, the Committee emphasizes its intent that the new PHSA sec. 741 program include grants and contracts for the training of any health professional that is a part of the U.S. health workforce (as that term is defined in sec. 2261 of this legislation)—not just those who have traditionally been supported through the title VII and title VIII programs. In addition, the Committee notes its interest in having this program support continuing education efforts whose purpose is to provide appropriate cultural and linguistic competency training to those who are already in the health workforce.

Sec. 2252. Innovations in interdisciplinary care training

Current Law

Part D (PHSA sections 750–758) of PHSA title VII (Health Professions Education) is comprised of several authorities to support

various programs to provide interdisciplinary and community-based education and training.

Proposed Law

This provision would add the following new sec. at the end of part D of PHSA title VII:

Sec. 759. Innovations in Interdisciplinary Care Training. This new sec. would require the Secretary to establish a program of grants and contracts to develop and implement training programs for health professionals whose focus is the promotion of health care delivery through interdisciplinary and team-based models as well as through the coordination of health care services across various delivery settings, including health care institutions, the community, and the patient's home. Entities eligible for support would include: (1) accredited health professions schools or programs; (2) academic health centers; (3) public or private nonprofit entities (including an area health education center or geriatric education center); or (4) consortia of these entities. In awarding grants or contracts, the Secretary would be required to give preference to applicants with a demonstrated record of one or more of the following activities:

- Training health professionals who serve in underserved communities
- Broad, interdisciplinary, team-based collaboration
- Addressing health disparities

In evaluating an applicant's record regarding its interdisciplinary, team-based collaborations, this sec. would define the term interdisciplinary to mean collaboration across health professions and specialties that include public health, nursing, allied health, and appropriate medical specialties. The Committee has chosen to define this term to underscore its purpose in establishing this program—to train health professionals in delivering their services as part of a team effort, integrating the whole of patients' physical, mental, and even oral health needs.

In evaluating an applicant's record regarding its efforts in addressing health disparities, this sec. would require that the term "health disparities" have the meaning given that term in PHSA sec. 3171 (as would be established in sec. 2301 of this legislation).

The Secretary would be required to submit an annual report to Congress on the program.

The establishment of this new program is complementary to the Committee's actions in other parts of this legislation regarding collaborative approaches to patient care. Sections 1301, 1302, and 1722, for example, provide for innovative payment systems under Medicare and Medicaid that are designed to reward more collaborative efforts in providing patient care, including the medical home and accountable care organizations. Taken together, the Committee believes that these initiatives can result in an increased number of health professionals providing better-coordinated care to their patients.

Toward that end, the Committee emphasizes its intent that this program include grants and contracts for the training of any health professional that is a part of the U.S. health workforce (as that term is defined in sec. 2261 of this legislation)—not just those who have traditionally been supported through the title VII and title

VIII programs. In addition, the Committee notes its interest in having this program support continuing education efforts whose purpose is to provide training in interdisciplinary and team-based health service delivery to those who are already in the health workforce.

PART 3—ADVISORY COMMITTEE ON HEALTH WORKFORCE EVALUATION AND ASSESSMENT

Sec. 2261. Health workforce evaluation and assessment

Current Law

Subpart 1 (PHSA sections 761, 762, and 763) of part E of PHSA title VII (Health Professions Education) authorizes activities related to the health workforce, including a program of grants and contracts for the analysis of information on the health workforce; an Advisory Council on Graduate Medical Education; and an annual evaluation of the number of pediatric rheumatologists.

Additional health-related advisory committees are authorized in PHSA sec. 337 (National Advisory Council for the National Health Service Corps); PHSA sec. 748 (Advisory Committee on Training in Primary Care and Dentistry); PHSA sec. 756 (Advisory Committee on Interdisciplinary, Community-Based Linkages; and PHSA sec. 845 (National Advisory Council on Nurse Education and Practice).

Proposed Law

This provision would add the following new sec. at the end of subpart 1 of part E of PHSA title VII:

Sec. 764. Health Workforce Evaluation and Assessment. This new sec. would require the Secretary to establish a new and permanent Advisory Committee on Health Workforce Evaluation and Assessment. The purpose of the Advisory Committee would be to provide for the continuous and independent review, assessment, and update of information on the U.S. health workforce as well as for recommendations on how best to ensure that such workforce is—and remains—sufficient and of high quality. More specifically, the Committee expects the scope of the Advisory Committee's work to include periodic assessments and recommendations regarding:

- The effect of federal policies on ensuring a sufficient and high quality health workforce, including the Medicare and Medicaid graduate medical education programs and HRSA workforce programs
- Factors in the health care environment that may influence the decision making of health professionals in choosing which discipline, specialty, and subspecialty they wish to pursue and, as appropriate, in rebuffing a discipline, specialty, and subspecialty they may wish to practice
- Incentives to encourage health professionals to become primary care providers
- Foreign-trained health professionals and international medical graduates
- The feasibility of an all-payer graduate medical education system

The Secretary would be required to provide ongoing support for the Advisory Committee, including support for the Committee's administrative, research, dissemination, and technical operations.

In carrying out its work, the Advisory Committee would first be required to develop classifications, methodologies, and procedures to be used for health workforce data collection purposes, particularly in counting the nation's health workforce. The term "health workforce" would be defined to include all health care providers with direct patient care and support responsibilities, including physicians, nurses, physician assistants, pharmacists, and specified professionals in oral health, allied health, mental and behavioral health, and public health (including veterinarians engaged in public health practice). The Committee has chosen to define this term very broadly so as to include within the Advisory Committee's charge, the broad spectrum of health professions that make up the country's health workforce.

Membership on the Advisory Committee would include a diverse group of individuals with expertise in numerous health workforce-related areas such as health finance and health workforce education and training, and with experience working with various populations, including populations who are underrepresented in the health professions. Such membership may not, however, include a majority of individuals who are directly involved in health professions education or practice. The Committee underscores the diversity of backgrounds that is required in assembling and maintaining the Advisory Committee's membership. The Committee believes such diversity is necessary to ensure that the questions of health workforce adequacy and quality are addressed from varying perspectives and take into account the needs of specific groups or populations, not just those of the nation as a whole.

The activities of the Advisory Committee would be carried out in accordance with the Federal Advisory Committee Act (FACA) (5 U.S.C. App.), except with regard to sec. 14 of that Act, to the extent that its provisions do not conflict with this section. The Committee has included this requirement to ensure the work of the Advisory Committee is conducted in an open and transparent manner. The Committee believes this is especially important as the nation transitions through the health insurance and finance reforms established in other divisions of this legislation (divisions A and B).

The Secretary would also be required to submit an annual report to Congress on the activities of the Advisory Committee.

In establishing this new Advisory Committee, the Committee notes, appreciates, and is encouraged by HRSA's recent efforts to coordinate the activities of other advisory committees assembled to examine health workforce issues related to their specific areas of interest. These committees play an important role in making programmatic recommendations and assessing the needs of the specific health professions they represent. For example, the Council on Graduate Medical Education makes recommendations pertaining only to the physician workforce; the National Advisory Council on Nurse Education and Practice looks at only nurse workforce issues. They do not, however, consider broader questions, such as the overall need for primary care—irrespective of the classification of provider. It would be the specific task of the Advisory Committee established in this section to take on that kind of evaluation.

The Committee strongly believes the work of these specialty committees should continue and that HRSA, too, should continue to promote coordination among their activities whenever and wher-

ever appropriate and effective. But the Committee also believes—along with numerous health workforce experts—that these initiatives are no substitute for an independent body charged with the responsibility to perform regular and periodic assessments of the nation's health workforce and to make recommendations to Congress on policies for ensuring that this workforce—in all its many facets—is both sufficient in number and of high quality. Thus, the Committee has not only established the Advisory Committee on a permanent and ongoing basis; it also intends that its work extend beyond those workforce programs authorized under the PHSA titles III (General Powers and Duties of Public Health Service), VII (Health Professions Education), and VIII (Nursing Workforce Development) to include health workforce-related programs under Medicare, Medicaid, the VA, and the Department of Defense.

PART 4—HEALTH WORKFORCE ASSESSMENT

Sec. 2271. Health workforce assessment

Current Law

PHSA section 761 authorizes the Secretary to establish a program of grants and contracts to support the development and provision of information and analysis related to the health workforce, including the nurse workforce. Subsection (c) of PHSA sec. 761 requires the Secretary to reserve no less than $600,000 of funds appropriated for this program for conducting health professions research and for carrying out data collection and analysis in accordance with PHSA sec. 792 (Health Professions Data). Subsection (a) of that section requires the Secretary to establish a program to collect, compile, and analyze data on health professions personnel. The authorization of appropriations under PHSA sec. 761 expired at the end of FY2002, although the program continued to receive funding through FY2005.

Proposed Law

This provision would amend subsections (a) and (b) of PHSA sec. 761 to strike these subsections and to replace them with new requirements designed to implement the health workforce data collection classifications, methodologies, and procedures developed by the Advisory Committee on Health Workforce Evaluation and Assessment (as would be established in sec. 2261 of this legislation). Using these standards, the Secretary would be required to collect data on the nation's health workforce supply, diversity, and geographic distribution. In addition, the Secretary would be required to collect such data on individuals participating in the programs that would be authorized in subtitles A (Primary Care Workforce); B (Nursing Workforce); and C (Public Health Workforce); and part 1 of subtitle D (Health Professions Training for Diversity), all of title II of division C of this legislation.

Pending the completion of the development of the Advisory Committee's data collection standards, the Secretary (in consultation with the Advisory Committee) would be authorized to make a judgment about the classifications, methodologies, and procedures to be used in carrying out the data collection activities required under this provision. This authority would expire at the time the Secretary adopts the Advisory Committee's recommendations regard-

ing such standards. The Committee has granted the Secretary this time-limited authority in order to avoid any delay in the implementation of this provision's data collection requirements. The Committee believes that it is imperative that these efforts more forward as quickly as possible and that the timeline for action by the Advisory Committee should not impede her progress in collecting all relevant data.

The Secretary would be authorized to award grants or contracts to carry out the data collection activities required under this provision. Entities eligible to participate in this effort include (1) accredited health professions schools or programs; (2) academic health centers; (3) state, local or tribal governments; (4) public or private entities; or (5) consortia of these entities.

In carrying out these data collection requirements, the Secretary would be required to collaborate with federal departments and agencies, health professions organizations, and professional medical societies. Because neither HHS nor the federal government as a whole either collects or maintains all of the information relevant to the nation's health workforce supply, diversity or geographic distribution, the Committee believes it is necessary for the Secretary to work with groups outside the government in obtaining this information.

The Secretary would also be required to submit an annual report to Congress on various requirements of this provision.

The Committee understands that the Secretary is already engaged in some health workforce collection activities. But they have not been nearly as targeted as those required in this provision. Nor have they received adequate resources to develop the kind of projections contemplated by the Committee.

In establishing these new data collection requirements, the Committee is responding to these concerns as well as recommendations made by the GAO (*Health Professions Education Programs: Action Still Needed to Measure Impact* (Feb. 2006) (GAO–06–55)) and numerous experts about the importance of collecting, analyzing, and reporting information on the supply, demand, and diversity of the nation's health workforce. The Committee believes such information is important for the purpose of evaluating the government's own efforts in addressing the nation's health workforce needs. But it also believes that this information will become even more critical to both HHS and the Congress as the health reforms established in other divisions of this legislation (divisions A and B) are implemented.

PART 5—AUTHORIZATION OF APPROPRIATIONS

Sec. 2281. Authorization of appropriations

Current Law

The authorizations of appropriations for the following programs expired at the end of FY2002: centers of excellence (PHSA sec. 736); programs authorized for appropriations under PHSA sec. 740 (including scholarships for disadvantaged students (PHSA sec. 737); loans repayments for faculty (PHSA sec. 738); educational assistance in the health professions regarding individuals from disadvantaged backgrounds (PHSA sec. 739); and health workforce information and analysis (PHSA sec. 761)). However, with the excep-

tion of the activities authorized under PHSA sec. 761 (which has never been funded), each of these programs has continued to receive annual appropriations.

The authorization of appropriations for the education and health disparities and cultural competency program (PHSA sec. 741) expired at the end of FY2004.

Proposed Law

This provision would authorize the following sums to be appropriated from the Public Health Investment Fund (as would be established in sec. 2002 of this legislation) for the purpose of carrying out various programs related to health workforce diversity and assessment and evaluation activities:

Health Professions Training for Diversity (PHSA sections 736 through 739A)—

- $90 million for FY2010
- $97 million for FY2011
- $100 million for FY2012
- $104 million for FY2013
- $110 million for FY2014

Interdisciplinary Training Programs; Advisory Committee on Health Workforce Evaluation and Assessment; and Health Workforce Assessment (PHSA sections 741, 759, 761, and 764)—

- $87 million for FY2010
- $97 million for FY2011
- $103 million for FY2012
- $105 million for FY2013
- $113 million for FY2014

These sums from the Fund are in addition to any other amounts authorized to be appropriated from general revenues for such purposes.

The provision would also authorize to be appropriated "such sums as may be necessary" for each fiscal year through FY2014 for the education and health disparities and cultural competency program authorized under PHSA sec. 741. In addition, the provision would extend existing authorizations of appropriations through FY2014 for centers of excellence (PHSA sec. 736); programs authorized for appropriations under PHSA sec. 740 (including scholarships for disadvantaged students (PHSA sec. 737); loan repayments for faculty (PHSA sec. 738); educational assistance for individuals from disadvantaged backgrounds (PHSA sec. 739); and health workforce information and analysis (PHSA sec. 761)).

These workforce diversity programs are widely regarded as being highly successful in bringing individuals from disadvantaged backgrounds (especially those from racial and ethnic minorities) into the health professions and, in turn, helping to diversity the health workforce. It is the Committee's view that these programs should continue to receive appropriate funding support through FY2014.

TITLE III—PREVENTION AND WELLNESS

The evidence is clear: An individual's health status is determined not only by the availability and quality of clinical care he or she receives, but also by various social, economic, and behavioral factors. Thus, improving America's health requires ensuring both access to quality medical services when citizens are in need of care,

and the presence of a strong public health system designed to keep people well in the first place and their communities safe all the time. Divisions A and B of this legislation are intended to help achieve the first goal; title III of division C targets the second.

There are many ways in which this latter objective can be met. Promoting the use of evidence-based analyses of preventive services can help arm health care providers and communities alike with the tools necessary to detect public health problems early on or to prevent them altogether. Improvements in state and local public health infrastructure (such as public health departments and laboratories) can, for example, assist community-wide efforts in addressing the nation's obesity epidemic or stopping outbreaks of food-borne disease. And bolstering resources across the board at the federal, state, and local level can enhance government's capacity to put programs that work into place.

But unlike medical services and biomedical research, the federal government has not made sustained and sizeable investments in public health. Indeed, support for public health activities account for less than 3% of all federal spending on health care.

Title III establishes new public health initiatives and provides fixed public health funding to support them. When taken together and fully implemented, the result is expected to be an enormous impact on improving the nation's health.

Sec. 2301. Prevention and wellness

Current Law

No comparable provisions.

Although the PHSA as well as other federal laws such as Medicare and Medicaid authorize numerous programs and activities related to prevention and wellness, there is no statute (or sec. of a statute) that provides for a comprehensive, national approach for these efforts. In particular, there is no comparable provision that provides for dedicated, mandatory spending to support them.

Proposed Law

Subsection (a) of this provision would establish a new PHSA entitled "Prevention and Wellness" consisting of the following seven subtitles:

TITLE XXXI—PREVENTION AND WELLNESS

"Subtitle A—Prevention and Wellness Trust

"Sec. 3111. Prevention and Wellness Trust"

Current Law

No comparable provisions.

Proposed Law

This sec. would establish a Prevention and Wellness Trust. The following amounts would be authorized to be appropriated to the Trust:

- For each fiscal year, any amount appropriated to the Prevention and Wellness Fund under the American Recovery and Reinvestment Act (P.L. 111–5)

- From the Public Health Investment Fund (as would be established in sec. 2002 of this legislation)
  - $2.4 billion for FY2010
  - $2.845 billion for FY2011
  - $3.1 billion for FY2012
  - $3.455 billion for FY2013
  - $3.6 billion for FY2014

These sums from the Fund are in addition to any other amounts authorized to be appropriated from general revenues for such purposes.

The sec. would also specify the amounts authorized to be appropriated from the Trust for each of FY2010 through FY2014 for carrying out the activities of each of subtitle C (Prevention Task Forces); subtitle D (Prevention and Wellness Research); subtitle E (Delivery of Community Preventive and Wellness Services); and subtitle F (Core Public Health Infrastructure).

The Committee has established this special funding source in recognition of the need for dedicated sources to support prevention and wellness activities. Currently, approximately 78% of all health care spending in the United States is attributable to chronic illness, while only 3% of such spending goes to preventive services and health promotion. Funds made available through the Prevention and Wellness Trust will help address this disparity. The Committee expects that, in turn, Americans can become healthier and over time, the burden of chronic disease can be reduced.

"Subtitle B—National Prevention and Wellness Strategy

"Sec. 3121. National Prevention and Wellness Strategy"

Current Law

No comparable provisions.

Under the general authorities of PHSA title XVII, the Surgeon General of the U.S. Public Health Service has developed the Healthy People Program that is responsible for setting the nation's health prevention strategy and goals. The Secretary issues the decennial *Healthy People* report through this program. The report includes broad population-based health goals that are targeted to be met on a national basis, within the decade covered by the report.

Proposed Law

The Secretary would be required to develop (and periodically update) a national strategy to improve the nation's health through evidence-based clinical and community-based prevention and wellness activities (including core public health infrastructure improvements). In essence, this strategy would provide a national blueprint for action in making the United States a healthier nation. Such strategy would include specific national prevention and wellness goals, objectives, and priorities as well as a detailed plan for meeting each of them. Throughout the strategy, special attention is required to be given to health disparities in prevention and wellness.

In developing this strategy, the Committee intends that special attention also be given in developing prevention and wellness goals, objectives, and priorities related to the prevention of chronic disease. Currently, some nearly one in two American adults suffers

from one or more chronic diseases, incurring approximately $1.5 trillion in costs each year, or some 75% of the nation's annual health care spending. In the Committee's view, it is imperative that the national strategy takes on this issue directly.

In addition, the Committee notes the importance of the strategy's addressing the issue of payment or reimbursement for prevention services. Without sufficient payment mechanisms in place (or other appropriate incentives or rewards), the Committee is concerned that neither health care professionals nor communities will be able to adequately provide those prevention services and interventions that have been demonstrated to be effective.

"Subtitle C—Prevention Task Forces

"Sec. 3131. Task Force on Clinical Preventive Services"

Current Law

PHSA sec. 915(a) establishes the authority for the U.S. Preventive Services Task Force (USPSTF), administered by the Agency for Healthcare Research and Quality (AHRQ). The sec. charges the USPSTF to conduct evidence-based systemic reviews of data and literature to determine what clinical preventive services—preventive services delivered to one patient at a time by traditional health care providers in clinical settings—are scientifically proven to be effective, and based upon such reviews, to develop recommendations for the health care community. It also requires AHRQ to provide administrative, research, and technical support to the USPSTF, and exempts the Task Force from requirements of the Federal Advisory Committee Act (FACA) (5 U.S.C. App.).

The U.S. Public Health Service first convened the USPSTF in 1984. Since that time, the Task Force has produced 74 reviews and 120 age and gender-specific recommendations.

Proposed Law

The Secretary would be required to establish a permanent Task Force on Clinical Preventive Services (Clinical Preventive Task Force) that would continue the work of the USPSTF. The charge to the Clinical Preventive Task Force would remain just as it is today—to study and make evidenced-based recommendations on the effectiveness of clinical preventive services. Administrative responsibility for the Clinical Preventive Task Force would also remain where it is today—AHRQ.

The Committee underscores its overall objective to maintain for the Clinical Preventive Task Force, the well-earned credibility, independence, and scientific integrity of its predecessor organization, the USPSTF. In revising the authority for this preventive services task force, the Committee simply intends to statutorily improve some of the current practices and procedures and to augment available resources. Indeed, as the USPSTF transitions to the Task Force on Clinical Preventive Services, the Committee does not anticipate any significant changes in operations.

As noted, while the core mission of the Clinical Preventive Task Force would not change, the provision would make some structural and funding modifications designed to ensure that the group can carry out its work most effectively and efficiently. Such modifications include increasing the size of the membership of the Task

Force; establishing criteria for such membership; and providing for an authorization of appropriations.

In addition to mandating its principal duties to identify, review, and make recommendations on clinical preventive services, the sec. would also require the Clinical Preventive Task Force to take on new responsibilities, all of which are directly related to its basic assignment. More specifically, in performing its work, the Clinical Preventive Task Force would be required to: (1) consider health disparities in making its recommendations: (2) consult with the Task Force on Community Preventive Services (as would be established in sec. 3132 of PHSA title XXXI of this legislation); (3) make recommendations regarding clinical preventive services research and evaluation; (4) as appropriate, consult with the clinical preventive stakeholders board that would be established as part of the operation of the Clinical Preventive Task Force; and (5) as appropriate, consider the national strategy on prevention and wellness (as would be developed in sec. 3121 of PHSA title XXXI of this legislation).

In requiring that the Clinical Preventive Task Force consider health disparities in making its recommendations, the Committee underscores its intent that the Task Force act not only with regard to national recommendations, but also as appropriate, with respect to specific populations and even sub-populations. For example, should the Task Force make general recommendations regarding screening for lipid disorders among persons at risk for coronary heart disease (CHD), the Committee would expect it to include recommendations that may be different for African Americans than for other U.S. populations because this group has a higher prevalence of diabetes, hypertension, and obesity, conditions that increase the risk for CHD.

The activities of the Clinical Preventive Task Force would be carried out in accordance with the FACA (5 U.S.C. App.), except with regard to sec. 14 of that Act, to the extent that its provisions do not conflict with the provisions of this section. The Committee has included this requirement to ensure the work of the Task Force is conducted in an open and transparent manner, while preserving its function and status as an expert panel that advises not only federal officials but also the broader health and health care communities. The Committee believes this is especially important because of the new and important role of the Task Force's work in implementing some of the reforms in the health care system provided for in this legislation, including the elimination of all cost-sharing requirements for clinical preventive services covered in the essential benefits package (as would be established in sec. 122 of this legislation) and provided under Medicare and Medicaid (as would be established respectively in sec. 1305 and sec. 1711 of this legislation). Such services would include those that receive either an "A" or "B" rating by the Clinical Preventive Task Force (or its predecessor organization, the USPSTF).

The Secretary would be required to submit an annual report to Congress on the work of the Clinical Preventive Task Force.

PHSA sec. 3111 (as would be established in PHSA title XXXI of this legislation) would authorize an annual appropriation of $30 million from the Prevention and Wellness Trust for each of FY2010 through FY2014 to support the work of both the Clinical Preven-

tive Task Force and the Task Force on Community Preventive Services (as would be established in sec. 3132 of PHSA title XXXI of this legislation). These sums from the Fund are in addition to any other amounts authorized to be appropriated from general revenues for such purposes.

"Sec. 3132. Task Force on Community Preventive Services"

Current Law

No comparable provisions.

The Task Force on Community Preventive Services (TFCPS) is not explicitly authorized in statute; rather, it functions under the general authorities of the Secretary found in PHSA title III (General Powers and Duties of Public Health Service).

The TFCPS is a non-governmental panel of public health and prevention experts that is administered and supported by the CDC. Much like the U.S. Preventive Services Task Force, it is charged with conducting evidence-based systematic reviews of data and literature and based upon such reviews, making recommendations regarding preventive services. Its focus, however, is on population-based or community interventions, rather than clinical preventive services. Such interventions are designed to be provided to groups of people—rather than to an individual as is the case with clinical preventive services—by a range of providers in a variety of settings. Their purpose is to facilitate and reinforce, from a public health perspective, what is taught or learned in the health provider's office or other traditional clinical setting.

The TFCPS was first convened in 1996. Since that time, the Task Force has produced recommendations on some 200 community preventive services or interventions. Among these are worksite wellness programs to promote physical activity among employees; school-based sealant programs to reduce the risk of dental caries; and tobacco cessation activities.

Proposed Law

The Secretary would be required to establish a permanent Task Force on Community Preventive Services (Community Preventive Task Force) that would continue the work of the TFCPS. The charge to the Community Preventive Task Force would remain just as it is today—to study and make evidenced-based recommendations on the effectiveness of community preventive services or interventions. Administrative responsibility for the Community Preventive Task Force would also remain where it is today—CDC.

The Committee underscores its overall objective to maintain for the Community Preventive Task Force, the well-earned credibility, independence, and scientific integrity of its predecessor organization, the TFCPS. In establishing an explicit authority for the Task Force on Community Preventive Services, the Committee simply intends to make the TFCPS permanent and in so doing, to statutorily improve some of its current practices and procedures and to augment available resources. Indeed, as the TFCPS transitions to a group with permanent authority, the Committee does not anticipate any significant changes in operations.

As noted, while the core mission of the Community Preventive Task Force would not change, the provision would make some

structural and funding modifications designed to ensure that the group can carry out its work most effectively and efficiently. Such modifications include increasing the size of the membership of the Task Force; establishing criteria for such membership; and providing for an authorization of appropriations.

In addition to mandating its principal duties to identify, review, and make recommendations on community preventive services or interventions, the provision would also require the Community Preventive Task Force to take on new responsibilities, all of which are directly related to its basic assignment. More specifically, in performing its work, the Community Preventive Task Force would be required to: (1) as appropriate, consider health disparities in making its recommendations; (2) consult with the Task Force on Clinical Preventive Services (as would be established in sec. 3131 of PHSA title XXXI of this legislation); (3) make recommendations regarding community preventive services research and evaluation; (4) as appropriate, consult with the community preventive stakeholders board that would be established as part of the operation of the Community Preventive Task Force; and (5) as appropriate, consider the national strategy on prevention and wellness (as would be developed in sec. 3121 of PHSA title XXXI of this legislation).

In requiring that the Community Preventive Task Force consider health disparities in making its recommendations, the Committee underscores its intent that the Task Force act not only with regard to national recommendations, but also, as appropriate, with respect to specific populations and even sub-populations. For example, client reminders and small media campaigns promoting breast cancer screening among African-American women might put greater emphasis on educating these women about the importance of early diagnosis since African Americans have higher breast cancer mortality rates due, in large part, to late diagnosis.

The activities of the Community Preventive Task Force would be carried out in accordance with FACA (5 U.S.C. App.), except with regard to sec. 14 of that Act, to the extent that its provisions do not conflict with the provisions of this section. The Committee has included this requirement to ensure that the work of the Community Preventive Task Force is conducted in an open and transparent manner, while preserving its function and status as an expert panel that advises not only federal officials but also the broader health and health care communities. The Committee believes this is especially important because of the new and important role of the Task Force's work in implementing the community prevention and wellness services grant community (as would be established in sec. 3151 of PHSA title XXXI of this legislation).

The Secretary would be required to submit an annual report to Congress on the work of the Community Preventive Task Force.

PHSA sec. 3111 (as would be established in PHSA title XXXI in this legislation) would authorize to be appropriated $30 million from the Prevention and Wellness Trust for each of FY2010 through FY2014 to support the work of both the Community Preventive Task Force and the Task Force on Clinical Preventive Services (as would be established in section 3131 of PHSA title XXXI in this legislation). These sums from the Fund are in addition to any other amounts authorized to be appropriated from general revenues for such purposes.

"Subtitle D—Prevention and Wellness Research

"Sec. 3141. Prevention and wellness research activity coordination"

Current Law

No comparable provisions.

Proposed Law

The Directors of the CDC and NIH and the heads of other HHS agencies would be required, in conducting or supporting research on prevention and wellness, to take into consideration the national strategy on prevention and wellness (as would be developed in section 3121 of PHSA title XXXI of this legislation) and the recommendations of both the Task Force on Clinical Preventive Services (as would be established in section 3131 of PHSA title XXXI of this legislation) and the Task Force on Community Preventive Services (as would be established in section 3132 of PHSA title XXXI of this legislation). The Committee has taken this action to ensure that research efforts called for to help address the priorities and needs identified in this strategy and by these task forces are not only funded, but also coordinated—especially by the federal government's two principal prevention and wellness research agencies: CDC and NIH. With limited dollars available for such research, the Committee believes it is imperative that these agencies work together in formulating an appropriate and robust prevention and wellness research agenda.

"Sec. 3142. Community prevention and wellness research grants"

Current Law

No comparable provisions.

Proposed Law

The Secretary would be required to establish a program to conduct or support research in priority areas identified in the national strategy on prevention and wellness (as would be developed in section 3121 of PHSA title XXXI of this legislation) or by the Task Force on Community Preventive Services (as would be established in section 3132 of PHSA title XXXI of this legislation). Entities eligible to participate in such program include: (1) state, local, or tribal departments of health; (2) public and nonprofit private entities; and (3) consortia of these entities. The Secretary would be required to submit an annual report to Congress on the research supported through this program.

PHSA section 3111 (as would be established in PHSA title XXXI of this legislation) would authorize the following sums to be appropriated from the Prevention and Wellness Trust for the purpose of carrying out prevention and wellness research:

- $100 million for FY2010
- $150 million for FY2011
- $200 million for FY2012
- $250 million for FY2013
- $300,000,000 for FY2014

These sums from the Fund are in addition to any other amounts authorized to be appropriated from general revenues for such purposes.

The Committee has established this program to ensure that community prevention and wellness research needs and priorities identified through various mechanisms provided under PHSA title XXXI (as would be established in this legislation) are addressed. But beyond those immediate and ongoing concerns, the Committee believes that it is necessary to create a dedicated prevention and wellness research program to underscore the importance of this research. Community-based research (including community-based participatory research) is the primary means by which innovative prevention and wellness programs become effective public health interventions. Yet it is often under-funded or even neglected altogether because of the long-standing emphasis on and support for traditional clinical or medical research models. With a separate pool funds made available through this new and targeted research authority, the Committee would expect a significant increase in community prevention and wellness research and in turn, the development and implementation of additional evidence-based community public health interventions.

"Subtitle E—Delivery of Community Prevention and Wellness Services

"Sec. 3151. Community prevention and wellness services grants"

Current Law

No comparable provisions.

PHSA title III (General Powers and Duties of Public Health Service) provides CDC with various authorities to support numerous prevention and wellness activities, including those targeted at chronic diseases. Part A of PHSA title XIX (Block Grants) requires the Secretary to provide formula-based grants to states through the Preventive Health and Health Services Block Grant Program to address state-identified prevention priorities. The authorization of appropriations for that program expired at the end of FY1998, although the program has continued to receive annual appropriations.

Proposed Law

The Secretary would be required to establish a program of grants to plan or implement programs that deliver evidence-based community prevention and wellness services and interventions in priority areas that have been identified by the Secretary in the national strategy on prevention and wellness (as would be developed in section 3121 of PHSA title XXXI of this legislation). Entities eligible to participate in such a program include: (1) state, local, or tribal departments of health; (2) public or private entities; (3) consortia of these entities; or (4) community partnerships representing health empowerment zones (as that term would be defined in this sec.).

In awarding grants or contracts, the Secretary would be required to give preference to applicants that:

- Will address one or more goals or objectives identified by the Secretary in the national strategy on prevention and wellness
- Will address significant health disparities
- Will address unmet community prevention and wellness needs

• Have a demonstrated record of effectiveness in communities comparable to those that are the subject of the grant application
• Will make a significant contribution to the evidence base for community prevention and wellness services
• Demonstrate that the prevention and wellness activities to be funded will be sustainable
• Demonstrate coordination or collaboration across governmental and nongovernmental partners

The program would be structured to allow great latitude in the types of services or interventions that could be supported—so long as such services and interventions: (1) have been determined to be a priority in the national prevention and wellness strategy or by the Community Preventive Task Force; and (2) are evidenced-based. Indeed, effective FY2013, grants could only be awarded to support services and interventions recommended by the Community Preventive Task Force or deemed to be effective, based on a review of comparable rigor (as determined by the CDC Director). Thus, the Committee intends that a broad spectrum of evidence-based prevention and wellness services and interventions may be supported through this program, including those related to physical, mental, oral and other appropriate areas of health. Examples of the many types of activities that could be funded include workplace obesity reduction programs; programs to improve and expand access to mental health services for at-risk youth and their families; the promotion of healthy, nutritious, and sustainable food in schools and other appropriate institutions; and community-based health screenings and education. The Committee further intends that funding be available not only to support programs targeted on a single community preventive service or intervention, (*e.g.,* workplace obesity reduction programs), but also those that may be designed to include multiple, but related such services or interventions (*e.g.,* workplace obesity reduction programs, community exercise programs, and nutrition education) or to address more than one prevention and wellness priority (*e.g.,* diabetes and heart disease).

Although the Committee intends for the program to be able to support a broad array of community prevention and wellness services or interventions, grant awards may not be used to build or acquire real property, for construction, or to provide services that would otherwise be paid (or expected to be paid) by a private insurance plan or a public health benefits program such as Medicaid.

The Secretary would also be required to award at least 50% of available funds to projects whose primary purpose is to achieve a measurable reduction in one or more "health disparities" (as that term would be defined in section 3171 of PHSA title XXXI of this legislation). Accordingly, community prevention and wellness programs or projects could be designed to address health disparities by race, ethnicity, or geographic setting (such as rural or urban setting), or disparities experienced by other populations or subpopulations as determined appropriate by the Secretary.

The Secretary would be required to submit an annual report to Congress on the programs, projects, and other activities supported through this program.

PHSA section 3111 (as would be established in this legislation) would authorize the following sums to be appropriated from the

Prevention and Wellness Trust for the purpose of supporting community prevention and wellness services grants:

- $1.065 billion for FY2010
- $1.26 billion for FY2011
- $1.365 billion for FY2012
- $1.570 billion for FY2013
- $1.6 billion for FY2014

These sums from the Fund are in addition to any other amounts authorized to be appropriated from general revenues for such purposes.

It is Committee's expectation that the implementation of this new program will help to minimize the duplication of existing CDC prevention activities and maximize the delivery of services that promote national prevention and wellness goals and objectives. Consistent with these aims, the Committee intends for CDC to determine how to best integrate or coordinate this program with its current prevention and wellness efforts, including the Racial and Ethnic Approaches to Community Health (REACH) Program and the Healthy Communities Program.

"Subtitle F—Core Public Health Infrastructure

"Sec. 3161. Core public health Infrastructure for State, local, and tribal health departments

Current Law

No comparable provisions.

PHSA section 319C authorizes both state formula grants and competitive grants to expand the core public health infrastructure for terrorism and disaster preparedness. Many other PHSA authorities, including several found in PHSA title III (General Powers and Duties of Public Health Service) are available to support state and local public health capacity. However, these authorities are usually targeted for specific purposes rather than for public health infrastructure as more broadly defined.

Proposed Law

The Secretary would be required to establish a program of grants to provide support for "core public health infrastructure" needs (as that term would be defined in section 3171 of PHSA title XXXI of this legislation) to state, local, and tribal health departments. Two types of awards would be made available: (1) mandatory awards (formula-based) for each state health department; and (2) competitive awards for which state, local, and tribal health departments would be eligible. In awarding competitive grants to state, local, or tribal health departments, the Secretary would be required to give preference to applicants demonstrating core public health infrastructure needs that may be identified as part of the voluntary accreditation process for public health departments (and laboratories) that would be established in subsection (g) of this section.

Of the total amount of funds made available each year, the Secretary would be required to award at least 50% to state health departments and at least 30% to state, local, or tribal health departments; the remaining 20% would be distributed at the discretion of the Secretary. All departments—regardless of the type of grant

awarded—would be mandated to meet maintenance of effort requirements as a condition for participating in the program.

Health departments could receive support to address various core public health infrastructure needs, including those identified in the voluntary accreditation process for public health departments. That process would be required to be developed and implemented by the Secretary. Its purpose is to advance the quality and performance of these government agencies.

It is the Committee's understanding that significant progress has already been made in designing such a process. In 2006 and in response to the recommendations in a 2003 Institute of Medicine report (*The Future of the Public's Health*), several public health experts and leading public health organizations, including the American Public Health Association (APHA), the Association of State and Territorial Health Officials (ASTHO), the National Association of County and City Health Officials (NACCHO), and the National Association of Local Boards of Health (NALBOH) convened and launched a public health accreditation initiative, *Exploring Accreditation Project.* That work led to the 2007 incorporation of the Public Health Accreditation Board (PHAB), a nonprofit private entity whose mission is to develop a national voluntary accreditation program for public health departments.

PHAB is now entering its beta stage of pilot testing accreditation standards that address public health administrative capacity as well as governance issues in addition to the 10 public health services identified by CDC as essential (*e.g.,* diagnosing and investigating health outbreaks and other health hazards). PHAB is on track to accredit its first public health department in 2011. In preparation for the implementation of the accreditation process, in 2008, NACCHO (with the support of the CDC and The Robert Wood Johnson Foundation) selected 66 local health departments to conduct self assessments and quality improvement activities. In the Committee's view, this is clear indication that many public health departments expect to take part in the accreditation process once it is in full force.

The Committee is very much encouraged by the PHAB activities and the overall progress being made and does not wish to see these efforts interrupted or slowed down as a result of the enactment of this section. It has, therefore, provided authority to the Secretary to enter into a cooperative agreement with a private, nonprofit entity to carry out her responsibility to develop and implement a voluntary accreditation process for public health departments. It is the Committee's expectation that the Secretary will determine how best to integrate or coordinate these activities with existing accreditation activities and outreach efforts at CDC, including those within its Office of Public Health Practice and National Center for Health Marketing.

The Secretary would be required to submit an annual report to Congress on the activities supported through this program.

PHSA section 3111 (as would be established in PHSA title XXXI of this legislation) would authorize the following sums to be appropriated from the Prevention and Wellness Trust for the purpose of supporting core public health infrastructure grants to state, local, and tribal health department:

- $800 million for FY2010

- $1 billion for FY2011
- $1.1 billion for FY2012
- $1.2 billion for FY2013
- $1.265 billion for FY2014

These sums from the Fund are in addition to any other amounts authorized to be appropriated from general revenues for such purposes.

Although the Committee has required that all state health departments receive funding under this program, it emphasizes its expectation that large local health departments will also receive appropriate support. Indeed, the Committee strongly believes that funding be made available for competitive grants for local and tribal health departments and that in awarding such grants, the Secretary take into account the needs of health departments of varying sizes and scope of responsibilities.

Sec. 3162. Core public health infrastructure and activities for CDC

Current Law

No comparable provisions.

Proposed Law

The Secretary would be required to expand and improve the core public health infrastructure and activities of the CDC to address unmet and emerging public health needs. The Secretary would be required to submit an annual report to Congress on the activities supported through this program.

PHSA section 3111 (as would be established in PHSA title XXXI of this legislation) would authorize to be appropriated $350 million for each of FY2010 through FY2014 from the Prevention and Wellness Trust for the purpose of expanding and improving core public health infrastructure and activities at CDC. These sums from the Fund are in addition to any other amounts authorized to be appropriated from general revenues for such purposes.

As the country's central public health authority, CDC has enormous responsibilities. Its mission—to serve as the national focus for developing and applying disease prevention and control, environmental health, and health promotion and health education activities designed to improve the health of the people of the United States—is very broad. And its portfolio of activities is extensive (and growing), ranging from confronting the HIV/AIDS epidemic and outbreaks of *E. coli* to fighting obesity; from monitoring lead poisoning to addressing emergency preparedness (including bioterrorism) and pandemic flu; and from supporting state and local health departments to providing assistance to the global health community. And the CDC is seen as the world leader in promoting and protecting the public's health.

As it carries out its work, however, the agency often finds itself without the flexibility necessary to respond to unmet and emerging public health needs. Sometimes this is a result of restrictions placed on the agency by legislative authority; in other cases it is because of a lack of resources. The purpose of this provision is to provide CDC with additional funding so it can be prepared to address these needs in a timely fashion.

The Committee recognizes the importance of supporting basic public health infrastructure activities as part of this effort. Thus, for example, funds from this new authority could be used to enhance real-time surveillance capacity for emerging or critical public health issues (such as food safety); to upgrade public health surveillance systems so that they are well integrated and promote rapid information sharing among public health agencies; or to improve CDC capacity for the development of laboratory methods, tests, and protocols that can be used in state, local, territorial, and tribal health department and clinical settings.

Support might also go to increase CDC's capacity for rigorous evaluation of public health interventions, and to improve the speed at which public health research gets translated into the field. The Committee believes this evaluation function will be crucial not only for reviewing existing programs, but also the new programs established in PHSA title XXXI of this legislation. Indeed, in the Committee's view, systematic evaluation and continuous application of new evidence will help ensure maximum health impact from these new investments.

"Subtitle G—General Provisions

"Sec. 3171. Definitions"

Current Law

The term "public health infrastructure" is not defined in the U.S. Code. Nor is the term "health disparities", although there are related terms that are defined, including "minority health conditions" and "health disparity populations" (defined in PHSA section 485E, establishing the National Center on Minority Health and Health Disparities at NIH). Other PHSA sections, such as PHSA section 903 (establishing AHRQ), cross reference these sections.

Proposed Law

The following terms, among others, would be defined for purposes of carrying out relevant sections of title III of division C of this legislation: "core public health infrastructure"; "health disparities"; and "tribal".

The Committee underscores its intent to include within the meaning of the term "health disparities" differences among populations and subpopulations not only in the presence of disease, but also in health outcomes and access to health care. In the Committee's view, it is critically important to view health disparities from this broader perspective so as to capture the full extent to which certain populations and subpopulations experience such disparities.

The Committee notes that under section 2402 of subtitle D of division C of this legislation (related to the Assistant Secretary for Health Information), the new Assistant Secretary for Health Information would be required to develop standards for the collection of data that is expected to assist in the measurement of health disparities. It is the Committee's intent that these data, in turn, be used to help inform the meaning of the term health disparities under this section.

Sec. 2301(b). Transition provisions applicable to task forces

Current Law

PHSA section 915(a) establishes the authority for the U.S. Preventive Services Task Force (USPSTF), administered by the Agency for Healthcare Research and Quality (AHRQ). The section charges the USPSTF to conduct evidence-based systemic reviews of data and literature to determine what clinical preventive services—preventive services delivered to one patient at a time by traditional health care providers in clinical settings—are scientifically proven to be effective and based upon such reviews, to develop recommendations for the health care community. It also requires AHRQ to provide administrative, research, and technical support to the USPSTF, and exempts the Task Force from requirements of FACA (5 U.S.C. App.).

The Task Force on Community Preventive Services (TFCPS) is not explicitly authorized in statute; rather, it functions under the general authorities of the Secretary found in PHSA title III (General Powers and Duties of Public Health Service).

The TFCPS is a non-governmental panel of public health and prevention experts that is administered and supported by the CDC. Much like the U.S. Preventive Services Task Force, it is charged with conducting evidence-based systematic reviews of data and literature and based upon such reviews, making recommendations regarding preventive services. Its focus, however, is on population-based or community interventions, rather than clinical preventive services. Such interventions are designed for groups of people from a range of providers in a variety of settings, rather than individuals, as is the case with clinical preventive services. Their purpose is to facilitate and reinforce, from a public health perspective, what is taught or learned in the health provider's office or other traditional clinical setting.

Proposed Law

This provision would establish rules for transitioning the operations of the existing USPSTF and TFCPS to respectively, the Task Force on Clinical Preventive Services (as would be established in section 3131 of PHSA title XXXI of this legislation) and the Task Force on Community Preventive Services (as would be established in section 3132 of PHSA title XXXI of this legislation). More specifically, the provision would:

- Require the transfer of all functions, personnel, assets, and liabilities of the USPSTF and TFCPS to their respective new task force
- Require all recommendations of the USPSTF and TFCPS in existence before the enactment of this legislation to be considered recommendations of their respective new task force
- Authorize the Secretary to select members of the USPSTF and TFCPS to serve as members of their respective new task force
- Discount any prior service on the USPSTF or TFCPS by any member of either respective new task force in calculating his or her total years of service for purposes of meeting term limit requirements

In establishing these transition rules, the Committee underscores its intent in creating the new Task Force on Clinical Preventive

Services and the Task Force on Community Preventive Services and made clear in its comments in sections 3131 and 3132 (as would be established in PHSA title XXXI of this legislation): To continue and maintain the work of the USPSTF and TFCPS, and to provide for improvements in some of their current practices and procedures. In the Committee's view, the changes or adjustments in operations that are required in those sections are not significant and should be easily implemented. These transition rules should further allow for a seamless transition from one entity to the other, limiting the disruption in work that might otherwise occur.

Sec. 2301(c). Period before completion of national strategy

Current Law

No comparable provisions.

Proposed Law

This provision would authorize the Secretary, pending completion of the national prevention and wellness strategy (as would be required in sec. 3121 of PHSA title XXXI of this legislation) to make a judgment about how the strategy would address an issue (and rely on that judgment) in carrying out any provision of subtitles C, D, E or F of such title as it may relate to such national strategy.

In establishing this transition rule, the Committee emphasizes its intent that the activities required under subtitles C, D, E, or F of PHSA title XXXI move forward even as the national prevention and wellness strategy (as would be required in section 3121 of PHSA title XXXI of this legislation) is being developed. To ensure that work is begun and that progress is being made, the Committee has provided temporary authority to the Secretary to make her best judgment about the potential impact of the national strategy in carrying out the programs and activities established under these subtitles. This authority would expire at the time the national prevention and wellness strategy is completed and released.

Sec. 2301(d). Conforming amendments

Proposed Law

This provision would make appropriate and conforming amendments to the Indian Health Care Improvement Act, the Social Security Act (with regard to Medicare, Medicaid, and SCHIP), and the Public Health Service Act.

TITLE IV—QUALITY AND SURVEILLANCE

The United States spends more on health care than any other country in the world; yet its health care system ranks number 37 out of 191 countries measured by the World Health Organization. Other titles within this division as well as other divisions of this legislation are primarily intended to change that statistic. Title IV is intended to focus on two areas through which the nation's progress in meeting this goal can be met: health care quality and public health surveillance.

Tens of thousands of Americans die each year from poor quality care. A 1999 Institute of Medicine report (*To Err is Human: Building a Safer Health System*) estimated that between 44,000 and

98,000 Americans die each year due to preventable medical errors. Some 10 years later, the number of such deaths remains alarmingly high.

Medical errors are not the only source for poor quality of care. According to CDC, almost 100,000 Americans die annually because of health care-associated infections alone (Klevens *et al, Estimating Health Care-Associated Infections and Deaths in U.S. Hospitals,* 2002; Public Health Reports, March–April 2007). CDC also estimates that the direct medical costs to hospitals of treating such infections ranges from $28 to $45 billion annually (*Direct Medical Costs of Healthcare-Associated Infections in U.S. Hospitals and the Benefits of Prevention,* March 2009).

These statistics and other important health and health care information come about through the use of various data collection and surveillance tools. When working well and in concert with each other, these activities combine to create a common metric for understanding the public's health as well as the country's health care delivery system. Today's patchwork of programs at the national level has made it difficult to achieve this end.

The health and health care of the nation cannot be truly improved—even with the health reforms established in other divisions of this legislation in place—without also constructing better pathways to enhanced quality and better surveillance mechanisms. Indeed, efforts to expand access and to control costs can only be meaningful if accompanied by improvements in the actual care being provided and in the tools being used to measure success.

Sec. 2401. Implementation of best practices in the delivery of health care

Current Law

PHSA title IX (Agency for Healthcare Research and Quality) (AHRQ) specifically provides AHRQ with broad research authority regarding the development, presentation, publication and dissemination of evidence-based information on all aspects of health care, including best practices. Such activities are authorized more generally under section 301 of PHSA title III (General Powers and Duties of Public Health Service).

Since its creation in 1989 as the Agency for Health Care Policy and Research (renamed the Agency for Healthcare Research and Quality in 1999), AHRQ has been the lead government agency in conducting and otherwise supporting evidence-based research on health care quality, safety, efficiency, and effectiveness of health care for all Americans.

Despite important successes by the agency, clinical practice continues to lag behind the best science available. Researchers estimate that it may take as long as 17 years for scientific research to be adopted widely into patient care. These delays in the implementation of best practices are rooted in the large volume of new studies and journal articles released every day, generated in part by work supported with billions of dollars in federal investments for the National Institutes of Health (NIH). It is critical to be able to access the research produced at NIH to create a scientific foundation for medical care. Such efforts are significantly hampered, however, by the resources available to AHRQ—with the agency re-

ceiving only two cents on every dollar allocated to NIH, its ability to assist in the dissemination and adoption of this important new science is limited and the 17-year lag in the adoption of best practices looks to continue.

A recent example dramatically makes this point. A large body of research has long demonstrated the success of various interventions in reducing the health care-associated infections, central-line associated bloodstream infections. Yet, such infections continue to kill about 30,000 Americans each year. An AHRQ-funded study, *An Intervention to Decrease Catheter-Related Bloodstream Infections in the ICU (New England Journal of Medicine,* December 2006), demonstrated that the use of a simple checklist of the most important interventions could virtually eliminate these deadly infections. These stunning results led to a February 2009 promulgation from AHRQ to institute this best practice in institutions in 10 states, with a goal of reducing central-line associated bloodstream infections by 80%. A number of additional states expressed interest in participating in this effort but were forced to look for private funding because of a lack of resources at AHRQ.

Proposed Law

This provision would amend PHSA title IX to add a new part D—"Implementation of Best Practices in the Delivery of Health Care"—and to establish in that part a new Center for Quality Improvement within AHRQ. The purpose of the Center is to identify, develop, evaluate, and implement best practices in health care delivery, i.e., those health care practices that result in the delivery of consistently high quality, efficient health services and that in turn significantly improve the quality of patient care. The Director of AHRQ would head this Center.

The Director would be required to prioritize those areas (such as heart disease) for the identification, development, evaluation, and implementation of best practices in health care delivery. In so doing, the Director would be required to take into account the priorities established under SSA section 1191 (as would be established in section 1441 of this legislation) as well as the key health indicators that would be identified by the Assistant Secretary for Health Information (as would be established in section 2402 of this legislation).

With regard to each priority targeted for action, the Secretary would be further required to: (1) identify existing best practices; (2) develop new best practices; (3) evaluate all best practices; and (4) implement all appropriate best practices (through arrangements with Quality Improvement Organizations (QIAs) (authorized under SSA section 1153) and other entities. The Secretary would be specifically prohibited, however, from developing quality-adjusted life year measures or other methodologies that could be used to deny health care benefits on the basis of a beneficiary's age, life expectancy, disability, or expected quality of life. The Committee has taken this action to ensure that the Center does not target its efforts too narrowly and instead keep the Center focused on developing and disseminating information about the best science that can have impact on the greatest number of Americans. Nonetheless, this restriction should not preclude AHRQ from developing best practices that may affect one population or sub-population

more directly than another (or others) when the evidence suggests that such an approach is justified.

The Director would be required to carry out these activities through a program of grants and contracts. Only nonprofit entities would be eligible for support under this program, including QIAs. Because of their extensive experience and expertise in working with best practices, it is the Committee's expectation that such groups will be common recipients of awards made under this program. In some areas, however, the Committee would also expect that other organizations would play a central role in the dissemination of a particular best practice.

The Director would be required to provide for the public dissemination of information regarding the Center's various efforts. This is to ensure that the public has easy access to the Center's work and recommendations. The Director would also be required to submit an annual report to Congress (and the Secretary) on the activities carried out under this provision. Such report would be required to include summary data on patient outcomes before, during, and after the implementation of best practices that are the focus of the Center as well as recommendations on the adaptability of such best practices for use by health providers.

Pending the Director's designation of an initial set of priority areas for the identification, development, evaluation, and implementation of best practices, the Director would be directed to prioritize the following five topics: (1) reducing health care-associated infections; (2) increasing hospital and outpatient perioperative patient safety; (3) improving care in hospital emergency rooms; (4) improving the provision of obstetrical and neonatal care; and (5) improving the provision of preventive and developmental child health services. This authority would expire at the time the Director establishes her own set of priorities for action by the Center.

The Committee has selected these areas for focus because of the potential for relatively quick, important, and widespread improvements in quality of care that is expected to result from this work. In each of these areas, the Committee understands some success has already been demonstrated; with this push it would anticipate seeing much more and much sooner than might otherwise take place.

The Director would also be required to submit an initial report to Congress on the impact of the nurse-to-patient ratio on the quality of care and patient outcomes.

The Committee has chosen to establish a new Center for Quality Improvement to provide a targeted focus on issues of quality improvement as well as additional resources to help ensure success of AHRQ in this field. The need for such improvement is undisputed. Tens of thousands of Americans die each year due to preventable conditions, including medical errors and health care-associated infections. Indeed, CDC reports that such infections alone account for 1.7 million infections and almost 100,000 deaths each year. The Committee believes such results are unacceptable and can be prevented. In its view, the new Center for Quality Improvement can play a critical role in helping to address this ongoing problem, most especially through its work on best practices.

Sec. 2402. Assistant Secretary for Health Information

Current Law

HHS supports and conducts a number of programs and activities related to the collecting and dissemination of health statistics and other health information. These efforts are primarily directed by CDC's National Center for Health Statistics (NCHS) and AHRQ.

PHSA section 306 establishes the authority for NCHS to conduct and support various statistical and epidemiological activities related to health and health care in the United States. Among these is the collection of statistics on illness and disability (including their economic impact); environmental, social, and other health hazards; determinants of health; health resources; health care utilization, including associated costs and financing; and family formation, growth, and dissolution.

Several authorities under PHSA title IX (AHRQ) also provide for the collection and dissemination of health and healthcare-related data and information. Among other such activities, AHRQ is responsible for preparing annual reports on disparities in health care delivery and national trends in the quality of U.S. health care.

In addition to these efforts, under the general authorities of PHSA title XVII (Health Information and Health Promotion), HHS supports the Healthy People Program through which the decennial Healthy People report is issued. This report provides a national assessment of the health of the nation based upon a series of health indicators such as tobacco use and obesity.

There is no authority under which the Secretary is required to share health data, analyses, and other information among the various HHS agencies. Such sharing is facilitated, however, through the Office of Management and Budget's (OMB) Directive 15 (Standards for the Classification of Federal Data on Race and Ethnicity), which outlines standards for the collection of race and ethnicity data on federally-sponsored surveys, administrative forms, and other records (e.g., school applications). OMB Directive 15 does not mandate the collection of such data; instead it sets the requirements that must be met when such data are collected. In general, these requirements do not apply to state and local public health departments or to Medicaid.

Proposed Law

This provision would amend PHSA title XVII (Health Information and Health Promotion) to re-designate PHSA sections 1709 and 1710 and to insert a new PHSA section 1709—"Assistant Secretary for Health Information." The new PHSA section 1709 would establish within HHS the new position of Assistant Secretary for Health Information who would be appointed by the Secretary.

The Assistant Secretary would be charged with the following responsibilities with respect to information regarding the nation's health and health care:

- Ensure the collection, collation, reporting, and publishing of information on key health indicators (as identified and periodically updated by the Assistant Secretary)
- Develop standards for the collection of data, including standards for the collection of data on race, ethnicity, primary language, sex, and other relevant population categories

• Provide support to federal departments and agencies whose programs have a significant impact upon health for the collection and collation of such information

• Ensure the sharing of such information among HHS agencies

• Facilitate the sharing of such information by and among federal departments and agencies whose programs have a significant impact upon health

• Identify gaps in such information and the appropriate agency or entity to address such gaps

• Award grants or contracts for the collection and collation of such information

The Assistant Secretary would also be required to facilitate public accessibility of datasets (such as de-identified Medicare datasets) related to health and health care. Such accessibility must be in keeping, however, with all privacy, proprietary, and other appropriate safeguards.

In addition to these duties, the Assistant Secretary would be mandated to facilitate and coordinate the identification and monitoring of "health disparities" (as that term would be defined in section 3171, as would be established in section 2301 of this legislation) by HHS agencies in order to inform their program and policy activities designed to reduce such disparities.

The Assistant Secretary's reporting and publishing functions regarding information on the key health indicators he or she identifies would be guided by OMB regulations, rules, processes, and procedures governing the review, release, and dissemination of Principal Federal Economic Indicators made available by the Bureau of Labor Statistics (OMB Statistical Policy Directive No. 3: Compilation, Release, and Evaluation of Principal Federal Economic Indicators (72 *Federal Register* 42266, August 1, 2007); and OMB Statistical Policy Directive No. 4: Release and Dissemination of Statistical Products Produced by Federal Statistical Agencies (73 *Federal Register* 12622, March 7, 2008). Indeed, these OMB policy directives would specifically be required to be applied to any OMB regulations, rules, processes, and procedures governing the review, release, and dissemination of information on these key health indicators in the same manner as they are used in the review, release, and dissemination of key economic indicators.

The Committee has mandated the application of these OMB policy directives with regard to the reporting and publishing of information on key health indicators to ensure its timely release, reliability, and scientific integrity. The Committee understands that such directives have worked very well in helping to provide information relatively quickly and on a regular basis to both government officials and the public on key economic indicators that inform the country's fiscal policies. In the Committee's view, information on the nation's key health indicators should receive this very same treatment.

In developing standards for the collection of data on race, ethnicity, and primary language, as well as a set of other appropriate population and subpopulation categories (such as sexual orientation and gender identity, socioeconomic status, and disability), it is the Committee's expectation that the Assistant Secretary will work to establish standards that that can be used and applied consistently among the Department's various data collection efforts as

well as those of other federal departments and agencies. In so doing, however, the Committee intends for the Assistant Secretary to take into account the health and health care context in which these data will be used.

In doing all this, the Assistant Secretary would be authorized to obtain information from any federal department or agency that is necessary to enable the Assistant Secretary to perform his or her functions. The Committee has provided this authority to the Assistant Secretary in response to concerns that have been raised about the ability of HHS to secure data and other relevant information from various government agencies (e.g., Centers on Medicare and Medicaid Services and the Social Security Administration) that would be useful in measuring and reporting on the nation's health and health care. The Committee understands, for example, that it has been difficult to bring various HHS agencies together to share data related to ethnicity. It is the Committee's expectation that with this authority in place, this problem can be alleviated and hopefully, avoided altogether.

The Assistant Secretary would be required to submit an annual report to the Secretary and the Congress on his or her work. Such report would be required to include information on national, regional, or state changes in health and health care (as measured by the key health indicators she or he has identified); gaps in data collection on the nation's health and health care (and recommendations for addressing such gaps); and health disparities analyses.

The Committee has established this new position to provide a central and unified source for data and other information regarding the health and health care of the nation. Currently, no single office within HHS is charged with the responsibility of collecting, collating, reporting, and publishing such information. Nor is there any statutory mechanism in place that gives the Secretary the authority to require HHS agencies engaged in these activities to share their results with each other, allowing for a more complete and up-to-date national health and health care assessment.

The Committee believes that this new administrative structure is necessary to reduce the duplication and otherwise enhance and strengthen the Department's ongoing health information activities. This will be especially important as the health reforms spelled out in other provisions of this legislation (see Divisions A and B) are implemented and subsequently evaluated, in terms of helping to improve the nation's health and health care.

Sec. 2403. Authorization of appropriations

This provision would authorize to be appropriated $300 million for each of FY2010 through FY2014 from the Public Health Investment Fund (as would be established in section 2002 of this legislation) for the purpose of supporting various health quality and surveillance activities.

These sums from the Fund are in addition to any other amounts authorized to be appropriated from general revenues for such purposes.

TITLE V—OTHER PROVISIONS

Subtitle A—Drug Discount for Rural and Other Hospitals

Sec. 2501. Expanded participation in 340B program

Current Law

PHSA section 340B requires pharmaceutical drug manufacturers that participate in the Medicaid drug rebate program to enter into pharmaceutical pricing agreements with the Secretary (340B Program). Under these agreements, manufacturers provide discounts on covered outpatient drugs purchased by certain groups of providers known as "covered entities," including community health centers, state-operated AIDS drug assistance programs, and hospitals with high Medicare disproportionate share adjustments. The discounts are calculated to ensure that covered entities can purchase covered outpatient drugs at the same price that Medicaid pays net of the rebates it receives from manufacturers. Approximately 13,000 covered entities and 800 pharmaceutical manufacturers currently participate in the 340B Program, which is administered by HRSA.

Proposed Law

This provision would amend PHSA Section 340B to add the following categories to the list of covered entities that would be entitled to discounted drug prices under the 340B Program:

- Certain children's hospitals excluded from the Medicare prospective payment system
- Medicare critical access hospitals
- Entities receiving funds for the provision of services under the Maternal and Child Health Services Block Grant Program (SSA title V)
- Entities receiving funds for the provision of services under the Comprehensive Community Mental Health Services Block Grant Program (subpart I of part B of PHSA title XIX (Block Grants))
- Entities receiving funds for the provision of treatment services under the Substance Abuse Prevention and Treatment Block Grant Program (subpart II of part B of PHSA title XIX (Block Grants))
- Medicare-dependent small rural hospitals
- Medicare sole community hospitals
- Medicare rural referral centers

The provision would apply to covered outpatient drugs dispensed by these covered entities on or after July 1, 2010, without regard to whether implementing regulations have been issued.

Hospitals participating in the 340B Program, including those added as covered entities under this provision, would generally be prohibited from obtaining covered outpatient drugs through a group purchasing organization (GPO) or other group purchasing arrangement. The Secretary would be required to establish reasonable exceptions to this prohibition in the following cases:

- For outpatient drugs that are unavailable under the 340B Program due to a supply shortage, manufacturer noncompliance, or other circumstances beyond the hospital's control
- To facilitate generic substitution when generic drugs are available at lower prices

• To reduce the administrative burdens in managing inventories of drugs purchased under the 340B Program and uncovered drugs (unless a duplicate discount or drug diversion problem would be created)

The Committee emphasizes that these exceptions are not intended to create an opportunity for group purchasing organizations to purchase drugs through the 340B Program at the program's prices. Instead, prices paid by GPOs for outpatient covered drugs are to be based on the ability of the GPOs to negotiate with drug manufactures on behalf of the purchasers they represent, not on the statutory discounts that the 340B program provides.

Sec. 2502. Extension of discounts to inpatient drugs

Current Law

PHSA Section 340B requires pharmaceutical drug manufacturers that participate in the Medicaid drug rebate program to enter into pharmaceutical pricing agreements with the Secretary (340B Program). Such agreements cover outpatient drugs and do not extend to drugs provided on an inpatient basis.

Proposed Law

This provision would expand discounts available to hospitals participating in the 340B Program to include drugs provided on an inpatient basis. The provision would apply to inpatient drugs dispensed by these hospitals on or after July 1, 2010, without regard to whether implementing regulations have been issued.

The availability of 340B Program discounts for inpatient drugs is expected to reduce the costs that participating hospitals incur in furnishing services to their patients. To ensure that the Medicaid program gets the full benefit of those savings when it purchases inpatient services from hospitals participating in the 340B Program, the provision would establish a Medicaid credit process. Under this process, hospitals participating in the 340B Program would be required to issue credits to state Medicaid programs based on the estimated annual costs to the hospital of brand-name and generic drugs provided to Medicaid beneficiaries for inpatient use.

More specifically, a hospital participating in the 340B Program would be required to issue credits to each state Medicaid program from which it has received revenue (either directly on a fee-for-service basis or from a Medicaid managed care organization) during the most recent Medicare cost reporting period. The credit amounts would be calculated by the state Medicaid agency based on information supplied by the hospital within 30 days of the filing of its Medicare cost report. (Hospitals would be required to submit the dosage, form, strength, package size, date of purchase, and the number of units for each inpatient drug purchased during the cost reporting period.) The credit payments would be due to the state Medicaid program within 60 days after the hospital has been notified by the state of the amounts owed. To ensure the federal government's participation in these savings, amounts of credits received by the state Medicaid program would be treated as a reduction in the state's Medicaid expenditures that are subject to federal matching.

Two types of credits would be available for: (1) the estimated annual costs of single source and innovator multiple source drugs provided by the hospital to Medicaid beneficiaries during that cost reporting period; and (2) non-innovator multiple source drugs.

The credit amount for single source and innovator multiple source inpatient prescription drugs would be the product of: (1) the annual value of such drugs based on the drug's average manufacturer price (AMP); (2) the estimated percentage of the hospital's inpatient drugs purchases attributable to use by Medicaid beneficiaries on an inpatient basis; and (3) the minimum Medicaid rebate percentage (currently 15.1%). (Section 1742 of the legislation would increase this minimum rebate percentage to 22.1%.)

The credit amount for non-innovator multiple source drugs would be the product of: (1) the annual value of those drugs purchased based on each drug's AMP; (2) the estimated percentage of the hospital's purchases of the drug attributable to inpatient use by Medicaid beneficiaries; and (3) the applicable Medicaid rebate percentage for non-innovator single source drugs (currently 11%).

A hospital participating in the 340B Program would not be required to pay Medicaid credits for any cost reporting period if it could demonstrate to the state Medicaid agency that it would lose Medicaid reimbursement as a result of extending discounts to inpatient drugs and the amount of reimbursement it would lose would exceed the amount of the credit otherwise owed by the hospital.

For purposes of calculating credit amounts, the provision would define AMP to have the same meaning as that term is used under current Medicaid law, except if an inpatient drug is not distributed to the retail pharmacy class of trade. In that case, AMP would be defined as the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the acute care class of trade, after deducting customary prompt pay discounts. (Section 1741 of the legislation would change the definition of AMP under Medicaid law.)

The provision would not prohibit hospitals participating in the 340B Program for the purchase of inpatient drugs from also using GPOs for the purchase of inpatient drugs. The Committee emphasizes that the absence of a prohibition on GPO participation is not intended to create an opportunity for GPOs through the 340B Program to purchase drugs at the program's statutory prices. Instead, prices paid by GPOs for inpatient drugs are to be based on the ability of the GPOs to negotiate with drug manufactures on behalf of the purchasers they represent, not on the statutory discounts that the 340B Program provides.

Sec. 2503. Effective date

Current Law

No comparable provisions.

Proposed Law

This provision would establish an effective date for subtitle II (regarding the program under PHSA section 340B) of July 1, 2010, making the provisions of such subtitle applicable to drugs dispensed on or after that date.

It is the intent of the Committee that the provisions of subtitle II be used to determine if prescription drug manufacturers meet Medicaid and PHSA section 340B requirements.

Subtitle B—Programs

PART 1—GRANTS FOR CLINICS AND CENTERS

Sec. 2511. School-based health clinics

Current Law

No comparable provisions.

The PHSA does not explicitly authorize a program of support for school-based health clinics (SBHCs). Support is provided, however, through the PHSA section 330, the authority for community health centers (CHCs).

The 2008 reauthorization of the CHC program (P.L. 110–355) included a provision requiring GAO to conduct a study on the economic costs and benefits of SBHCs as well as their impact on student health. The results of that study are not yet available.

Proposed Law

This provision would amend part Q of PHSA title III (General Powers and Duties of Public Health Service) to add a new PHSA section 399Z–1 to require the Secretary to establish a program of grants to support school-based health clinics. The provision mandates that no funds made available through such program may be used to provide abortions.

PHSA section 399Z–1 would authorize $50 million to be appropriated for FY2010 and "such sums as may be necessary" for each of FY2011 through FY2014. The Secretary would be required to begin awarding grants under this program not later than July 1, 2010, whether or not the final regulations that pertain to the program have been issued.

Sec. 2512. Nurse-managed health centers

Current Law

No comparable provisions.

Proposed Law

This provision would amend title III (Powers and Duties of Public Health Service) to establish at the end a new "Part S—"Nurse-Managed Health Centers" that includes a new PHSA section 399GG to establish a nurse-managed health center program.

In establishing this program, the Committee has used the community health centers program as a model. It expects, therefore, that the Secretary will look to the CHC program for guidance in implementing the nurse-managed health centers program. In so doing, the Committee underscores its intent to preserve applicable state law with regard to the scope of practice under which an individual has the legal authority to provide services at or through a nurse-managed health center. Indeed, the Committee intends that nothing in this provision be construed to change or otherwise impact such state laws.

Sec. 2513. Federally qualified behavioral health centers

Current Law

Subpart I (PHSA sections 1911 through 1920) of part B of PHSA title XIX (Block Grants) requires the Secretary to provide grants to states (formula-based) to support community mental health services. The authorization for appropriations for this subpart expired at the end of FY2003.

Proposed Law

This provision would amend PHSA section 1913 to establish criteria for the certification of federally qualified behavioral health centers and to otherwise recognize the role of such centers as a safety net provider for individuals with behavioral, mental health, and substance abuse disorders.

The Committee has taken this step in an effort to establish a foundation for strengthening the nation's health care delivery system to better meet the needs of underserved individuals with mental health and substance abuse problems. It is anticipated that such improvements will be especially important as the health reforms required under this legislation (see divisions A and B) are put into place.

PART 2—OTHER GRANT PROGRAMS

Sec. 2521. Comprehensive programs to provide education to nurses and create a pipeline to nursing

Current Law

PHSA section 831 requires the Secretary to establish a program of grants and contracts to support nurse education, practice, and retention activities. The authorization of appropriations for this program expired at the end of FY2007.

Proposed Law

This provision would require the Secretary of Labor to establish a program of grants to provide education to nurses and to create a pipeline to nursing for ancillary health care workers who wish to advance their careers.

The provision would authorize "such sums as may be necessary" to support this program.

Sec. 2522. Mental and behavioral health training

Current Law

Part E (sections 761 through 770) of PHSA title VII (Health Professions Education) provides support for various programs and activities related to the health professions and public health workforce. A number of authorizations of appropriations are included within part E, all of which have expired.

Proposed Law

This provision would amend part E of PHSA title VII to add a new subpart 3—"Mental and Behavioral Health Training" that includes a new PHSA section 775. Under PHSA section 775, the Secretary would be required to establish a program of grants and con-

tracts to support an interdisciplinary mental and behavioral health training program.

In establishing this new program, the Committee intends to formally authorize and allow for the expansion of the scope of the Graduate Psychology Education program to involve all mental and behavioral health professionals, including those specializing in substance abuse counseling and addiction medicine. This program, in existence since 2004 and administered by HRSA, trains psychologists in behavioral and mental health to work with individuals and families in medically underserved areas.

PHSA section 775 would authorize $60 million to be appropriated for each of FY2010 through FY2014.

Sec. 2523. Programs to increase awareness of advance care planning issues

Current Law

Section 4751(d) of the 1990 Omnibus Budget Reconciliation Act (P.L. 101–508) required the Secretary to develop and implement a national public education campaign to inform individuals about their option to execute an advance directive as well as their rights to participate in, and direct decisions related to, their health care. The Secretary was also required to develop or approve national information materials and to assist states in developing state specific documents regarding such information that healthcare providers would be required to distribute. In addition, the Secretary is required to mail to Social Security recipients, and to include a page in the Medicare Handbook, information about advance directives and patients rights.

Section 6 of the Assisted Suicide Funding Restriction Act of 1997 (P.L. 105–12) prohibits appropriations from being used to provide, procure, furnish, or fund any item, good, benefit, activity, or service, furnished or performed for the purpose of causing, or assisting in causing, the suicide, euthanasia, or mercy killing of any individual.

Proposed Law

This provision would amend PHSA title III (General Powers and Duties of the Public Health Service) to add at the end a new part T—"Programs to Increase Awareness of Advance Care Planning Issues"—that would include a new PHSA section 399HH. Under PHSA section 399HH, the Secretary would be required to establish a program of grants and contracts to conduct a national education campaign to increase awareness and educate the public about end of life issues, including: (1) the importance of planning for care near the end of life; (2) the need for readily available legal documents (such as an advance directive, living will, durable power of attorney, or physician's orders for life-sustaining treatment) that express an individual's wishes regarding such care; and (3) the availability of hospice and palliative care. The Secretary would also be required to establish a national, toll-free information telephone line and clearinghouse for the public and health professionals to access information about advance directives and other end-of-life-related decisions.

The Secretary would be prohibited from awarding a grant to any entity that promotes suicide, assisted suicide, or the active hastening of death. Such prohibition would not apply, however, to entities that provide palliative or hospice care.

With respect to the national education campaign, PHSA section 399HH would authorize to be appropriated $10 million for FY2010.

With respect to the information telephone line and clearinghouse, PHSA section 399HH would authorize to be appropriated $5 million for FY2010 and each subsequent fiscal year.

Sec. 2524. Reauthorization of telehealth and telemedicine grant programs

Current Law

PHSA section 330I provides for a program of grants to support telehealth networks and telehealth resource centers. The authorization of appropriations for this program expired at the end of FY2006, although the program has continued to receive annual appropriations.

PHSA section 330L authorizes the Secretary to establish a program of grants to provide incentives to coordinate telemedicine licensure activities among the states. The authorization of appropriations for this program expired at the end of FY2006, although the program has continued to receive annual appropriations.

Proposed Law

This provision would amend PHSA section 330I to reauthorize both telehealth networks and telehealth resource centers programs and revise the requirements for funding priorities within each of them.

With respect to each of the programs authorized under PHSA section 330I, the provision would authorize $10 million for FY2010 and "such sums as may be necessary" for each of FY2011 through FY2014.

With respect to the program authorized under PHSA section 330L, the provision would also authorize $10 million for FY2010 and "such sums as may be necessary" for each of FY2011 through FY2014.

The Committee has reauthorized these programs because of the continuing and ongoing problem of access to health care for individuals living in rural areas. By facilitating the use of health-related telecommunications technologies through technical assistance and other means, these programs play a critical role in ensuring such access.

Sec. 2525. No child left unimmunized against influenza: demonstration program using elementary and secondary schools as influenza vaccination centers

Current Law

No comparable provisions.

Various PHSA authorities support federal immunization efforts that target children. PHSA section 317 authorizes a program of grants to states and local governments for the provision of childhood vaccines; PHSA section 319(A) requires the Secretary to develop a voluntary tracking system for use during major outbreaks

of infectious disease (such as an influenza epidemic); and PHSA title XXI (Vaccines) requires the Secretary to establish a National Vaccine Program, responsible for developing and recommending national immunization policy.

The Medicaid program (SSA title XIX) also provides coverage for childhood immunizations.

PHSA title XXII—and more broadly, the Health Insurance Portability and Accountability Act of 1996 (HIPPA) (P.L. 104–191)—provides for the privacy of certain records containing health-related information. Section 444 of the General Education Provisions Act (commonly referred to as the Family Educational Rights and Privacy Act of 1974 (FERPA)) (P.L. 93–380) establishes requirements regarding the use and disclosure of information contained in student education files.

Proposed Law

This provision would require the Secretary to establish a program of demonstration projects designed to study the feasibility of using elementary and secondary schools as influenza vaccination centers. Such program would be required to adhere to the privacy, confidentiality, and requirements included in both HIPPA and FERPA.

The provision would authorize to be appropriated "such sums as may be necessary" to carry out the program.

Sec. 2526. Extension of Wisewoman Program

Current Law

PHSA section 1509 authorizes the Secretary to establish a program of grants for up to three state-based demonstration projects to provide preventive health (and appropriate follow-up) services to women in addition to the breast and cervical cancer screening services that are provided through the breast and cervical cancer program authorized in PHSA section 1501. Known as the "Well-Integrated Screening and Evaluation for Women Across the Nation" or WISEWOMAN program, the program has been expanded under the authority of PHSA title III (General Powers and Duties of Public Health Service) to include 19 states and two tribal organizations. The authorization of appropriations for the WISEWOMAN program expired at the end FY2003.

Proposed Law

This provision would amend PHSA section 1509 to remove the three-state limitation on state participation in the WISEWOMAN program.

The provision would authorize appropriations of $70 million for FY2010; $73.5 million for FY2011; $77 million for FY2012; $81 million for FY2013; and $85 million for FY2014.

Sec. 2527. Healthy teen initiative to prevent teen pregnancy

Current Law

SSA section 510(b)(2) requires the Secretary to establish a grant program (formula-based) for states to support abstinence-only-until-marriage programs. State programs must adhere to a strict eight-point definition of "abstinence education" and are not per-

mitted to provide instruction regarding condoms or other prevention methods other than to offer information on contraception failure rates. The authorization of appropriations (mandatory spending of $50 million for each fiscal year) for this program expired at the end of FY2003, although the program has continued to receive annual funding. In addition to this effort, since FY2001 funding has been given to support grants to community-based organizations to also provide abstinence-only-until marriage education in accordance with the eight-point plan required under the section 510(b)(2) program.

Various PHSA authorities support federal programs and other activities related to teen pregnancy.

PHSA title XX (Adolescent Family Life Demonstration Projects) authorizes the Secretary to establish a program of grants to support teen pregnancy care and prevention initiatives. With respect to teen pregnancy prevention initiatives, grantees are required to adhere to the eight-point "abstinence education" requirements of the abstinence education program authorized under SSA sec. 510(b)(2). The authorization of appropriations for this program expired at the end of FY1985, although the program has continued to receive annual funding.

PHSA title X (Population Research and Voluntary Family Planning Programs) authorizes the Secretary to establish a program of grants and contracts to provide comprehensive voluntary family planning and related preventive health services, including such services for adolescents. The authorization of appropriations for this program expired at the end of FY1985, although it has continued to receive annual funding.

In addition, PHSA sections 318 and 318A authorize the Secretary to establish programs of grants and contracts to support various activities related to diagnosis, treatment, and control of sexually transmitted infections. The authorization of appropriations for the program authorized in PHSA section 318A expired at the end of FY1998.

Proposed Law

The provision would amend part B of PHSA title III (General Powers and Duties of Public Health Service) by adding the following new section:

Sec. 317U. Healthy Teen Initiative to Prevent Teen Pregnancy. The Secretary would be required to establish a program of grants for states to provide "evidence-based" (as that term is defined in this section) education programs to reduce teen pregnancy or sexually transmitted infections. In designing such programs, states would be required to choose an evidence-based education program among those listed on a registry. The Secretary would be required to develop (and periodically update) this registry that would include evidence-based, medically and scientifically accurate, and age-appropriate programs. The Committee has explicitly required that this registry be made available publicly—not only in keeping with good government rules of transparency, but also in the belief that the information it contains can serve as a valuable resource for policymakers and program experts both within and outside the program.

In carrying out their programs, states would be allowed to work with public or private nonprofit organizations, including schools and community-based and faith-based organizations.

Funds would be available for distribution to states based upon the product of: (1) the amount of funds appropriated to carry out this program each fiscal year; and (2) the percentage of low-income children determined for a state under the abstinence education program authorized in SSA section 502. In order to receive any funds, however, states would be required to make their own contribution—in cash or in kind—to support program activities.

States would also be required to arrange for an independent evaluation of their healthy teen initiatives and, in turn, to submit a report to the Secretary on such evaluation.

PHSA section 317U would authorize to be appropriated $50 million for each of FY2010 through FY2014.

In establishing this new initiative, the Committee notes the different approach it has taken to the teen pregnancy issue as compared to that which underlies the federal government's most visible teen pregnancy efforts in recent years. Unlike both the state-based and community-based programs that have mandated the use of a very rigid eight-point curriculum, this initiative would not establish ideological requirements for participation. Indeed, the Committee, in effect, specifically rejected this philosophy in defeating an amendment to reauthorize the section 510(b)(2) program. Instead, the new healthy teen initiative would evaluate state programs based upon their effectiveness, accuracy, and age-appropriateness in reducing the risks of teen pregnancy and sexually transmitted infections. It is the Committee's expectation that an emphasis on the benefits of abstinence and delaying sexual activity will be a primary component of these programs.

In establishing this program as well, the Committee underscores its intent to preserve applicable state law with regard to parental involvement and decision-making in children's education. Thus, the Committee has made clear that nothing in this section may be construed to change or otherwise impact such state laws.

Sec. 2528. National training initiative on autism supplemental grants and technical assistance

Current Law

Part R (sections 399AA through 399EE) of PHSA title III (General Powers and Duties of Public Health Service) establishes authorities for several programs related to autism spectrum disorder (ASD) and other developmental disabilities. The authorizations of appropriations for these various programs each expire at the end of FY2011.

Proposed Law

This provision would amend part R of PHSA title III to create two subparts. Subpart 1—"Surveillance and Research Program; Education, Early Detection, and Intervention; and Reporting"—would include PHSA sections 399A through 399EE, as they are in current law. Subpart 2—"National Training Initiative"—would include a new PHSA section 399FF.

Under PHSA section 399FF, the Secretary would be required to award supplemental grants to University Centers of Excellence in Developmental Disabilities (authorized by the Developmental Disabilities Assistance and Bill of Rights Act of 2000, P.L. 106–402) to support training programs in ASD and related developmental disabilities. The Secretary would also be required to award additional grants to such centers to enhance the number of training facilities serving minority institutions with a primary focus on ASD and related developmental disabilities.

With respect to the supplemental training grants, PHSA section 399FF would authorize to be appropriated $17 million for FY2011 and "such sums as may be necessary" for FY2012 through FY2015.

With respect to the additional grants targeted on facilities serving minority institutions, PHSA section 399FF would authorize to be appropriated $2 million for each of FY2011 through FY2015.

Sec. 2529. Implementation of medication management services in treatment of chronic diseases

Current Law

No applicable provisions.

Although there is no statute that explicitly authorizes a program to provide medication therapy management services (MTM) for the treatment for chronic diseases, both Medicare and Medicaid include provisions related to such services. Regulations (42 CFR part 423, subpart D) issued under the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (P.L. 108–173) established requirements for MTM programs. Section 6081 of the Deficit Reduction Act (P.L. 109–171) establishes a program of grants for state Medicaid programs to improve effectiveness in providing medical assistance under Medicaid, including the implementation of a medication risk management program.

Proposed Law

This provision would require the Secretary to establish a program of grants to implement MTM services provided by licensed pharmacists as part of a collaborative approach to the treatment of chronic diseases.

Sec. 2530. Postpartum depression

Current Law

No comparable provisions.

PHSA section 508 requires the Director of the Center for Substance Abuse and Treatment of the National Institutes of Health (authorized under PHSA section 507) to establish a program of grants, contracts, and cooperative agreements to provide residential substance abuse treatment for pregnant and postpartum women.

Proposed Law

This provision would encourage the Secretary to expand and intensify activities on postpartum conditions, including research, epidemiological studies, the development of improved screening and diagnostic techniques, and information and education programs. In

addition, it would require the Secretary to conduct a study on the benefits of screening for postpartum conditions.

The provision would also express the sense of Congress that the Director of the National Institute of Mental Health may conduct a nationally representative longitudinal study on the relative mental health consequences for women of resolving a pregnancy (intended and unintended) in various ways.

The provision would authorize to be appropriated "such sums as may be necessary" for each of FY2010 through FY2012 to carry out these activities (in addition to any other amounts authorized to be appropriated for such activities).

Sec. 2531. Grants to promote positive health behaviors and outcomes

Current Law

No comparable provisions.

Although there is no statute that explicitly authorizes a program to provide training for community health workers, such training is among the activities authorized for funding under PHSA section 752 (Health Education and Training Centers).

Proposed Law

This provision would amend part P of PHSA title III (General Powers and Duties of Public Health Service) to add at the end a new section PHSA section 399V to require the Secretary to establish a program of grants to train community health workers. Such workers would promote positive health behaviors among populations in medically underserved areas.

PHSA section 399V would authorize to be appropriated $30 million for each of FY2010 through FY2014.

PART 3—EMERGENCY CARE-RELATED PROGRAMS

Sec. 2541. Trauma care centers

Current Law

Part D (sections 1241 through 1245) of PHSA title XII (Trauma Care) requires the Secretary to establish a program of grants to support the operating costs of trauma centers that have incurred substantial uncompensated costs in providing care in geographic areas with a significant incidence of violence arising from the illicit trafficking of drugs. The authorization of appropriations for the program expired at the end of FY1994.

Proposed Law

This provision would amend PHSA sections 1241 through 1245, in essence to establish a new program of grants to provide: (1) operating support for existing trauma centers; and (2) start up support for new trauma centers in urban areas with a substantial degree of trauma resulting from violent crime.

PHSA section 1245 would authorize to be appropriated $100 million for FY2010 and "such sums as may be necessary" for FY2011 through FY2014 to carry out the program.

Sec. 2542. Emergency care coordination

Current Law

Subtitle B of PHSA title XXVIII (National Preparedness for Bioterrorism and Other Public Health Emergencies) establishes the HHS Office of the Assistant Secretary for Preparedness and Response (ASPR). The Office is responsible for carrying out a number of duties with respect to bioterrorism and other public health emergencies, including the coordination of the Department's various medical incident response assets and activities.

The Emergency Care Coordination Center is located within ASPR. The Secretary established the Center in January 2009; it has no authority in statute.

Proposed Law

This provision would amend subtitle B of PHSA title XXVIII to add a new section 2816 to require the Secretary to establish an Emergency Care Coordination Center within ASPR. All functions, personnel, assets, and liabilities of, and administrative actions applicable to, the Emergency Care Coordination Center that was established in January 2009 would be transferred to the Emergency Care Coordination Center that would be established under this section.

PHSA section 2816 would authorize to be appropriated such sums as may be necessary for each of FY2010 through FY2014 to carry out the various activities of the Center.

Sec. 2543. Pilot programs to improve emergency medical care

Current Law

No comparable provisions.

Part B of PHSA title III (General Powers and Duties of Public Health Service) establishes authorities for various programs and other activities designed to encourage, foster, or otherwise promote cooperation between the federal government and among the states.

Proposed Law

This provision would amend part B of PHSA title III to add a new PHSA section 315 to require the Secretary to establish a program of demonstration projects on regionalized communication systems for emergency care response.

PHSA section 315 would authorize to be appropriated $12 million in each of FY2010 through FY2015 to support the demonstration projects.

Sec. 2544. Assisting veterans with military emergency medical training to become State-licensed or certified emergency medical technicians (EMTs)

Current Law

No comparable provisions.

Proposed Law

This provision would amend part B of PHSA title III (General Powers and Duties of Public Health Service) to add a new PHSA section 315A to require the Secretary to establish a program of

grants to states to assist veterans with military emergency training to become state-licensed or certified medical technicians.

PHSA section 315A would authorize to be appropriated "such sums as may be necessary" in each of FY2010 through FY2015 to support the program.

The provision would also require the Comptroller General of the Government Accountability Office to conduct a study on the barriers experienced by veterans with military emergency training in becoming licensed or certified civilian health professionals.

Sec. 2545. Dental emergency responders: public health and medical response

Current Law

PHSA section 2802 requires the Secretary to prepare on a quadrennial basis, the National Health Security Strategy. Such strategy is to include a national plan for public health emergency preparedness that, among other things, addresses the preparedness of various medical providers for public health emergencies.

PHSA section 319F(a)(5)(B) requires the Secretary to develop curricula and training programs for health professionals to respond to public health emergencies.

Proposed Law

This provision would amend PHSA section 2802 to clarify that dental health facilities are to be included among the medical providers whose preparedness for public health emergencies is to be addressed in the National Health Security Strategy required under such section.

The provision would also amend PHSA section 319F(a)(5)(B) to clarify that emergency curricula and training programs could be carried out at federal dental health facilities.

Sec. 2546. Dental emergency responders: homeland security

Current Law

Section 2 of the Homeland Security Act of 2002 (P.L. 107–296) provides a definition of the term "emergency response provider" for purposes of carrying out the various activities authorized under such Act. Section 516 of this Act establishes within the Department of Homeland Security the position of Chief Medical Officer whose responsibilities include serving as the Department's primary point of contact with the medical community.

Section 653 of the Post-Katrina Emergency Management Reform Act of 2006 (P.L. 109–295) requires operational plans for a coordinated federal response to natural and man-made disasters and terrorism to include the preparedness and deployment of public health and medical resources.

Proposed Law

This provision would amend section 2 of the Homeland Security Act of 2002 to clarify that the definition of the term "emergency response provider" includes emergency dental personnel, agencies, and authorities. In addition, it would amend section 516 of that Act, clarifying that the Department of Homeland Security's Chief

Medical Officer serves as the Department's primary point of contact with the dental as well as the medical community.

The provision also would amend section 653 of the Post-Katrina Emergency Management Reform Act of 2006 to clarify that operational plans for a coordinated federal response to natural and man-made disasters and terrorism include the preparedness and deployment of dental as well as public health and medical resources.

PART 4—PAIN CARE AND MANAGEMENT PROGRAMS

Sec. 2551. Institute of Medicine Conference on Pain

Current Law

No comparable provisions.

Proposed Law

This provision would require the Secretary to seek to enter into an agreement with the Institute of Medicine of the National Academies to convene a Conference on Pain.

To support the conference the provision would authorize to be appropriated $500,000 for each of FY2010 and FY2011.

Sec. 2552. Pain research at National Institutes of Health

Current Law

No comparable provisions.

Although there is no statute that explicitly authorizes a program to support research on pain, under the authority of both PHSA title III (General Powers and Duties of Public Health Service) and PHSA title IV (National Research Institutes), NIH has established the Pain Consortium. The purpose of such Consortium is to enhance pain research and promote collaboration among researchers across various NIH institutes and centers that support programs and activities designed to address pain.

PHSA section 403 requires the NIH Director to prepare a biennial report that includes, among other things, a summary of the research activities carried out by the various NIH institutes and centers, organized by category; the chronic disease category includes pain and palliative care.

Proposed Law

This provision would amend part B of PHSA title IV to add a new PHSA section 409J to encourage the NIH Director to continue and expand, through the Pain Consortium, a program of basic and clinical research on pain, including research on the treatment of pain.

Sec. 2553. Public awareness campaign on pain management

Current Law

No comparable provisions.

Proposed Law

This provision would amend part B of PHSA title II (Administration and Miscellaneous Provisions) to add a new PHSA section 249

to require the Secretary to establish and implement a national education outreach and awareness campaign on pain management.

PHSA section 249 would authorize to be appropriated $2 million for FY2010 and $4 million for each of FY2011 and FY2012 to carry out the campaign.

Subtitle C—Food and Drug Administration

PART 1—IN GENERAL

Sec. 2561. National medical device registry

Current Law

Several provisions of current law are intended to facilitate surveillance of the safety of devices after they are marketed. In particular, sec. 519(a) of the Federal Food, Drug and Cosmetic Act (FFDCA) authorizes FDA to require manufacturers of marketed devices to submit reports of adverse events and device malfunctions to FDA. This information can be used as a signal of potential safety problems. The usefulness of the information is limited by two factors: (1) the reporting of adverse events by physicians to manufacturers is voluntary, so the true number of adverse events is not usually known; and (2) when FDA receives adverse event reports, it does not know the total number of such devices in use, and so cannot reliably assess the likely incidence of a given adverse event in the total patient population.

The FDA Amendments Act of 2007 (P.L. 110–85) added a new FFDCA sec. 519(f), which requires the Secretary to promulgate regulations establishing a unique device identification system for medical devices, requiring the label of devices to bear a unique device identifier (UDI). When fully implemented, a UDI system can be a useful tool for tracking device risks and patient outcomes, particularly when used in conjunction with electronic health records. FDA has not yet issued regulations to implement FFDCA section 519(f).

The Office of the National Coordinator for Health Information Technology is the principal federal entity charged with coordination of nationwide efforts to implement and use the most advanced health information technology and the electronic exchange of health information. The position of National Coordinator was created in 2004, through Executive Order 13335, and legislatively mandated in the Health Information Technology for Economic and Clinical Health Act of 2009, which was incorporated in the American Recovery and Reinvestment Act of 2009 (P.L. 111–5).

Proposed Law

This provision would amend the FFDCA to add a new paragraph (g) to sec. 519 to require the Secretary, in consultation with certain agency heads, to establish a public national medical device registry. The purpose of the registry would be to provide more rapid, reliable information about risks and performance of devices once they are out on the market. The registry would also allow researchers to track many more patients than in clinical trials, with much more complex medical conditions, allowing them to understand how to optimize the use of devices in "real-life" patients, and to help locate patients when serious device risks emerge.

Manufacturers would be required to register each covered device at the time of sale and provide the device's UDI, if available, or other identifying information. The Secretary would be required to establish and validate a procedure to link specified medical device data from manufacturers with patient safety and outcomes data from disparate sources (such as relevant Medicare data). When linked to patient safety and outcome data from external databases, the registry would facilitate analysis of postmarket safety and effectiveness data on certain implantable, life-sustaining, and other types of medical devices. The Secretary would conduct analyses of the linked data and provide public access to the data and analysis collected or developed through the registry in a manner and form that protects patient privacy and proprietary information, and is comprehensive, useful, and not misleading to patients, physicians, and scientists.

To avoid overlap and duplication, the Secretary would also be required to integrate the registry activities with certain other postmarket risk and safety activities authorized under the FFDCA, such as the Sentinel Initiative. To ensure that implementation of the registry does not slow FDA's work on a unique device identification system, the provision includes a requirement that FDA issue a proposed regulation on UDIs within six months of enactment.

In addition, acting through the Office of the National Coordinator for Health Information Technology, the Secretary would be required to adopt standards, implementation specifications, and certification criteria for the electronic exchange and use in certified electronic health records of a unique device identifier.

Sec. 2562. Nutrition labeling of standard menu items at chain restaurants and of articles of food sold at vending machines

Current Law

Section 403(q) of the Federal Food, Drug and Cosmetic Act (FFDCA) requires that food offered for sale must adhere to the FFDCA's nutrition labeling requirements. Among other things, a food's label must include: (1) the serving size; (2) the total number of calories per serving; (3) the total fat, saturated fat, cholesterol, sodium, carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein per serving; and (4) any vitamin, mineral, or other nutrient required to be placed on the label by the Secretary.

Under FFDCA section 403(q)(5)(A), certain food is exempt from those requirements, including: (1) food that is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments; and (2) food which is processed and prepared primarily in a retail establishment, which is ready for human consumption, which is of the type described in (1), and which is offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment.

FFDCA section 403A prohibits states and localities from establishing their own nutrition labeling that is not identical to the FFDCA's nutrition labeling requirements. This prohibition against

states and localities establishing nutrition-labeling requirements does not apply to food that is exempt from FFDCA's labeling requirements, such as food served in restaurants. States and localities may petition the Secretary of HHS for an exemption from the preemption clause in FFDCA sec. 403A.

Proposed Law

This provision would modify the nutrition labeling exemption in FFDCA section 403(q)(5)(A) for food served in certain restaurants, similar retail food establishments, and vending machines to require that certain information be provided to consumers about caloric and other nutritional content. The purpose of the requirements is to give consumers important health information, and allow them to exercise choice and responsibility about what they and their children eat.

For food served in restaurants and similar retail food establishments, the labeling requirements would apply to standard menu items offered for sale in a restaurant or similar retail food establishment that is part of a chain with 20 or more locations and offering for sale substantially the same menu items. Such establishments would be required, for each standard menu item, to disclose, in a clear and conspicuous manner on the menu, and on a menu board (including a drive-through menu board), adjacent to the name of the item the number of calories contained in the item and a statement concerning suggested daily caloric intake. Such establishments would also be required to make available, on request, written information regarding, for each standard menu item: (1) the total number of calories derived from any source; (2) the total number of calories derived from the total fat; and (3) the amount of total fat, saturated fat, cholesterol, sodium, total carbohydrates, complex carbohydrates, sugars, dietary fiber, and total protein.

A restaurant or similar retail food establishment offering food for sale at a salad bar, buffet line, cafeteria line, or similar self-service facility, and for self-service beverages or food that is on display and that is visible to customers, would be required to place adjacent to each food offered a sign that lists calories per displayed food item or per serving.

These requirements would not apply to certain food items, including those items that are not listed on a menu or menu board (such as condiments and other items for general use), or temporary menu items.

The Secretary would be required to establish standards for determining and disclosing the nutrient content for standard menu items that come in different flavors, varieties, or combinations, but which are listed as a single menu item, such as soft drinks, pizza, or children's combination meals.

If the Secretary determines that a nutrient (other than a nutrient whose disclosure is already required, such as saturated fat) should be disclosed to assist consumers in maintaining healthy dietary practices, the Secretary would be permitted to require disclosure of such nutrient in written form, available on the premises.

If a food sold from a vending machine operated by a person who owns or operates 20 or more vending machines does not permit a prospective purchaser to examine nutrition information at the point of purchase, the vending machine operator would be required to

provide in close proximity to each food item, a clear and conspicuous statement of the number of calories in the food.

Failure to comply with the new requirements would render a food misbranded under FFDCA sec. 403, and therefore unlawfully in commerce.

A restaurant, similar retail food establishment or vending machine operator not subject to the requirements of this provision could elect to be subject to such requirements by voluntarily registering, biannually, its name and address.

In promulgating regulations to implement this provision the Secretary would be required to: (1) consider, among other things, standardization of recipes and methods of preparation, reasonable variation in serving size and formulation of menu items, and space on menus and menu boards; and (2) specify the format and manner of the nutrient disclosure requirements.

This provision would also amend FFDCA section 403A to preempt states and their political subdivisions from establishing or continuing in effect any requirement for nutrition labeling of a food that is specifically covered by this provision if the requirement that is not identical to the requirements of this provision would expressly exempt from its preemptive effect state and local regulations governing food that is not covered by this provision, i.e., food that is offered for sale in a restaurant or similar retail food establishment that is not part of a chain with 20 or more locations and offering for sale substantially the same menu items, unless the restaurant or similar retail food establishment elected to comply with the requirements for restaurants that are part of a chain of 20 or more locations by registering biannually under the voluntary registration provisions of the provision. The provision also includes a rule of construction further limiting the preemptive effect of the amendment to 403A, by disclaiming preemption of: (1) any state or local law that is not expressly preempted by 403A, and (2) any requirements related to safety warnings.

Sec. 2563. Protecting consumer access to generic drugs

Current Law

Under section 505(j) of the Federal Food, Drug and Cosmetic Act (FFDCA), generic drug companies commonly file an abbreviated new drug application (ANDA) in order to receive approval to sell a generic version of a brand name drug. The filing of an ANDA may trigger patent infringement litigation between the brand name drug manufacturer and the ANDA applicant. The FFDCA encourages the early resolution of patent litigation to permit consumers access to low-cost generic drugs as early as possible, by allowing patent litigation to begin during the period that the ANDA is under review by the FDA, and by providing incentives to generic companies to challenge patents on brand name drugs. Current law does not restrict the ability of these parties to resolve their patent disputes through settlement. The Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (MMA) (P.L. 108–173) required that certain settlements be filed with the Department of Justice and the Federal Trade Commission (FTC).

The FTC has documented a growing number of settlements in which the brand name manufacturer grants the generic an "exclu-

sion payment" in return for a delay in the market entry of the generic. Rather than giving consumers the savings they would gain from competition, this practice allows the brand name and generic drug companies to share in the monopoly profits that are preserved by a delay in competition. Because monopoly drug prices are so high, both parties can make more money from such a settlement than they could by competing in the open market. The cost of such settlements is borne by individual and institutional consumers, who must pay monopoly prices during the period that generic competition is delayed.

The FTC has determined that settlements that include exclusion payments are anti-competitive. Two courts of appeal, however, have ruled that these settlements do not violate the anti-trust laws.

Proposed Law

This provision would amend FFDCA section 505 to make unlawful any agreement resolving or settling a patent infringement claim in which an ANDA applicant receives anything of value; and the ANDA applicant agrees to limit or forgo research, development, manufacturing, marketing, or sales, for any period of time, of the drug that is the subject of the ANDA and the patent. Agreements under which the ANDA applicant receives no more than the right to sell the drug that is the subject of the ANDA and the patent, along with the waiver of past damages for patent infringement, would remain permissible.

The provision would authorize the FTC to enforce these provisions under section 5 of the FTC Act. The provision would allow the FTC to exempt, by rule, certain agreements from the provision's requirements if the FTC finds that such agreements are "in furtherance of market competition and for the benefit of consumers." The provision states that such rules can include interpretive rules and general statements of policy.

This provision also would expand the types of settlements required to be filed under the MMA to include any patent litigation settlement covered by this provision. The chief executive officer or company official responsible for negotiating the agreement would also be required to certify, under penalty of perjury, that the filing constitutes the complete, final, and exclusive agreement between the parties, including any ancillary agreements and oral agreements.

The provision would require GAO to conduct a series of studies regarding the pharmaceutical patent litigation settlements and the impact of this provision on the timing of market entry of generic drugs, and whether the provision has benefited or harmed consumers.

PART 2—BIOSIMILARS

Sec. 2565. Licensure pathway for biosimilar biological products

Current Law

No comparable provisions.

The Drug Price Competition and Patent Term Restoration Act of 1984 (P.L. 98–417)—often referred to as the Hatch-Waxman Act—provides authority to the FDA to approve generic chemical drugs.

Proposed Law

The provision would amend PHSA section 351 to require the Secretary to approve applications for biological products that have been shown to be biosimilar or interchangeable to an already licensed biological product (the reference product).

The provision would require an applicant for a biosimilar or interchangeable product to submit an application containing data derived from analytical, animal, and clinical studies demonstrating biosimilarity or interchangeability. The provision would, however, provide discretion to the Secretary to determine that any of the data elements (such as clinical studies) are unnecessary in an application.

The Secretary would be required to approve an application for a biosimilar product if, among other things, the application demonstrates that it is highly similar to the reference product, notwithstanding minor differences in clinically inactive components, and that there is no clinically meaningful difference from the reference product.

The Secretary would be required to approve an application for an interchangeable product if the biological product is biosimilar to the reference product; can be expected to produce the same clinical result in any given patient; and if administered more than once to an individual, the risk of switching between the reference product and the biological product (in terms of safety or diminished efficacy) is not greater than using only the reference product. The term "interchangeable" would be defined to mean that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

If the biological product is, bears, or contains a select agent, toxin, or schedule I or II controlled substance, the application or supplement would not be approved unless the Secretary determines, after consultation with appropriate agencies, that there is no increased risk to the security or health of the public from licensing such product.

The provision would allow for a period of exclusive marketing for the biological product that is the first to be established as interchangeable with the reference product for any approved condition of use. The Secretary would be prohibited from approving another interchangeable version of the reference drug during the exclusivity period. Biosimilar versions of the reference drug that were not approved as interchangeable could, however, be approved and marketed during the exclusivity period.

The provision would provide a 12–year exclusive marketing period (from the date on which the reference product was first approved) for the reference product and would provide an additional six months of exclusivity if pediatric studies show health benefits in that population. To help ensure that companies could not obtain additional 12–year exclusivity periods for changes in already-approved biologics that do not provide significant clinical benefits to patients, the provision includes a number of minor changes in an approved product that are not eligible for 12 years of exclusivity:

- Any change that can be accomplished through filing of a supplemental application rather than a new application
- New indications

• Changes in dosage form, strength, or route of administration
• Modifications in molecular structure that are not shown to improve the safety or effectiveness of the original product

The Secretary would be permitted, but not required, to publish proposed guidance for public comment prior to publication of final guidance on general or specific matters related to the licensure of biosimilar or interchangeable biological products. If guidance is to be developed, a process would have to be established to allow for public input regarding priorities for issuing guidance. The issuance or non-issuance of guidance would not preclude the review of, or action on, an application.

The provision would also require the Secretary to ensure that the labeling and packaging of each biological product bears a unique name that distinguishes it from the reference product and any other biological products that are evaluated against the reference product.

The provision would set forth a process governing patent infringement claims against an applicant or prospective applicant for a biological product license. It would also establish new processes for identifying patents that might be disputed between the reference product company and the company submitting a biosimilar application as well as a multistep patent resolution process.

The provision stipulates that all biological product applications would have to be submitted under the requirements of PHSA section 351. For the small number of biological products that have been approved under FFDCA section 505, the approved application would be deemed to be a license for the biological product under PHSA sec. 351 as of 10 years after the date of the enactment of this legislation.

The Committee notes that the approval process set forth in this sec. is intended to be analogous to the authority FDA has for approving generic chemical drugs under the Drug Price Competition and Patent Term Restoration Act of 1984 (P.L. 98–417), often called the Hatch-Waxman Act.

Sec. 2566. Fees relating to biosimilar biological products.

Current Law

No comparable provisions.

Proposed Law

The provision would amend Federal Food, Drug and Cosmetic Act section 735(1) to allow for the collection of user fees for the approval of biosimilar or interchangeable biological products.

Subtitle D—Community Living Assistance Services and Supports

Sec. 2571. Establishment of national voluntary insurance program for purchasing community living assistance services and supports

Current Law

No comparable provisions.

Proposed Law

This provision would amend the PHSA to establish a new title XXXII—"Community Living Assistance Services and Supports"

(CLASS)—that includes several new sections. The plan would take effect on the effective date of a statute establishing a voluntary deduction under the Internal Revenue Code of 1986 to support such plan.

Sec. 3201. In general. This section requires the Secretary to establish a national voluntary insurance program—to be known as the CLASS Independence Benefit Plan—for the purchase of community living services and supports. Supported through an innovative financing mechanism, the plan would be designed to:

- Provide individuals with functional limitations with tools to allow them to maintain their personal and financial independence and to live in their homes and community
- Establish an infrastructure to help address the nation's community living assistance services and supports needs
- Alleviate burdens on family caregivers who provide care to family members with functional limitations
- Address institutional bias by providing a financing mechanism that supports personal choice and independence to live at home and in the community

Sec. 3202. Development and Management of the Program. This section requires the Secretary to develop and administer the CLASS Plan in an actuarially sound manner such that the plan will remain solvent, and with respect to the federal budget, deficit neutral. This would include, as appropriate, the Secretary's making adjustments to the premiums collected in and/or the benefits paid out under the plan.

In addition, the Secretary would be required to:

- Set criteria for CLASS Plan participation that do not restrict eligibility based on underwriting
- Establish criteria for eligibility for benefits
- Establish benefit levels
- Establish mechanisms for collecting and distributing payments
- Provide mechanisms to assist beneficiaries in the use of benefits
- Promulgate regulations necessary to implement the CLASS Plan program

Sec. 3203. Report. This section would require the Secretary to submit an annual report to the Congress on the CLASS Plan.

The Committee has taken this action in response to the nation's growing and ongoing long-term care challenges. Today, 10 million Americans are in need of long-term care services and support, including 4 million people under the age of 65. As the population continues to age, these numbers will more than double.

Currently, seniors and people with disabilities have great difficulty in accessing affordable and quality insurance that provides coverage for services and supports offered in a community setting. While Medicaid remains the main option for long-term care and supports, the program's menu of services is restricted and it is only available to those who have become impoverished. Similarly, private long-term care insurance remains out of reach for most people because of its high costs and limited protections.

The purpose of the CLASS Plan is to provide a voluntary and affordable alternative to these increasingly unworkable options. It is the Committee's belief that with this plan in place, seniors and those with disabilities will have much improved access to the serv-

ices and supports they need to continue living independently and productively.

Subtitle E—Miscellaneous

Sec. 2581. States failing to adhere to certain employment obligations

Current Law

No comparable provisions.

PHSA title XXII (Requirements for Certain Group Health Plans for Certain State and Local Employees) includes provisions requiring public employers to provide continuation of insurance coverage (popularly known as "COBRA Continuation"). Such title conditions a state's eligibility for PHSA funds on its agreement to be subject to the requirements of COBRA continuation with respect to its employees.

Proposed Law

This provision is modeled on PHSA title XXII. The provision would condition a state's eligibility for funds under the PHSA on a state's agreement to be subject in its capacity as an employer to each employer obligation under division A of this legislation and to assure that all political subdivisions in the state, and agencies and instrumentalities thereof, will also be subject to such employer obligations.

The Committee recognizes the national goal of increasing the number of individuals who have quality affordable health insurance is an integral and fundamental part of assuring the general welfare of the nation. Consistent with this goal is encouraging the participation of state and local governments, as employers in the shared responsibility of health care reform for their millions of workers. The Committee also recognizes the particular importance of ensuring that civil servants who are in contact with the public or perform important governmental functions have access to health care coverage in order to reduce the spread of contagious or infectious diseases (both within a state and across state line—germs being notoriously peripatetic and involved in interstate operations, whether we like it or not). The Committee also believes that it is of national significance to reduce absenteeism due to illness and disease among civil servants who are vital to performing needed governmental functions that are key to community well-being and public safety of the state itself and possibly the nation. At a time when the adequacy and reliability of the infrastructure of transportation, security, information, and research all depend on attention being paid by local, state, and federal authorities, one jurisdiction's absent workers can become another jurisdiction's bridge collapse or power blackout.

The intent of this provision is to encourage state and all political subdivisions in the state, and agencies and instrumentalities thereof, to agree, in their capacity as employers to comply with each of specific responsibilities applicable to other similarly situated employers under division A of this legislation. Inducing public sector employers to comply with the requirements applicable to other employers will help achieve the important public interest objective of

ensuring that the 19 million public employees, like other Americans, receive health care coverage.

The provision provides states with clearly stated conditions for eligibility for federal grants under the PHSA. Public employers must simply comply with the same conditions under the Act as private employers.

In conditioning eligibility for federal monies under the PHSA upon compliance with the employer related responsibilities in division A, the Committee is advancing common and interconnected goals. Both the employer responsibilities and the programs of the PHSA promote the protection and advancement of the nation's physical and mental health. Compliance with the employer conditions of this legislation and spending of PHSA funds both serve to increase quality and years of healthy life by preventing and reducing disease and disorders, eliminating health disparities, and improving systems for personal and public health.

Sec. 2582. Study, report, and termination of duplicative grant programs

Current Law

No comparable provisions.

Proposed Law

This provision would require the Secretary to conduct a study to determine if any grant program established in division C of this legislation (or any change made under such Division) is duplicative of one or more other federal grant programs under the authority of the Secretary in existence on the date of the enactment of this legislation. In addition, the Secretary would be required to submit to Congress and to make available to the public, a report that contains the results of the study. Based upon such results, the provision would also require the Secretary to terminate, to the maximum extent appropriate, any federal grant program she may find to be duplicative of any grant program established in division C of this legislation (or any change made under such division).

Sec. 2583. Health centers under Public Health Service Act; liability protections for volunteer practitioners

Current Law

PHSA sec. 224 gives employees of the Public Health Service (PHS) protection from medical malpractice claims resulting from the services provided as part of their public health service employment or contract. It both requires the Attorney General to defend PHS employees in cases involving claims of medical malpractice and empowers him to settle such lawsuits.

For purposes of providing this protection, PHSA section 224 deems any officer, governing board member, employee, or licensed or certified health professional under contract with a community health center (CHC) (authorized under PHSA section 330) to be a PHS employee. Volunteer health professionals are not afforded any protection against malpractice claims that may arise from the services they provide at a CHC.

Proposed Law

This provision would amend PHSA section 224 to revise the list of individuals associated with a CHC who are deemed to be PHS employees for purposes of carrying out such section, to include "volunteer practitioners". Such individuals are defined to include licensed physicians, clinical psychologists, or other licensed or certified health care professionals who provide uncompensated services at CHC sites.

The provision would establish an effective date for including CHC volunteer practitioners among those entitled to the medical malpractice protection provided under PHSA section 224: the first fiscal year for which a congressional appropriations act provides that funds are available to cover such individuals.

Sec. 2584. Report to Congress on the current state of parasitic diseases that have been overlooked among the poorest Americans

Current Law

No comparable provisions.

Proposed Law

This provision would require the Secretary to conduct a study on the epidemiology of, impact of, and appropriate funding required to address neglected diseases of poverty, including Chagas Disease, cysticercosis, toxocariasis, toxoplasmosis, trichomoniasis, and the soil-transmitted helminthes, and others.

Sec. 2585. Study of impact of optometrists on access to health care and on availability of support under Federal health programs for optometry

Current Law

No comparable provisions.

Proposed Law

This provision would require the Secretary to conduct a study on optometrists and optometry, including the role of optometrists in the health workforce.

ADDITIONAL COMMITTEE ACTION RELATING TO H.R. 3200

At the conclusion of the Committee's markup of H.R. 3200 on July 31, 2009, a number of majority and minority amendments had been filed with the Committee clerk but not yet considered by the Committee. At that time, the Chairman and Ranking Member reached an agreement to have a supplemental Committee meeting to consider certain amendments.

After H.R. 3200 was ordered reported, amended, on July 31, 2009, pursuant to this agreement, the Committee met on September 23, 2009, to consider a motion to instruct the Chairman to transmit to the Committee on Rules additional recommended amendments to H.R. 3200 for consideration. The Committee approved this motion by a roll call vote of 28–22.

Following is a description of the amendments included in this motion:

An amendment by Rep. Baldwin of Wisconsin—To provide for technical assistance to states to improve coordination between Medicare and Medicaid for those dually-eligible, and new quality measures for reporting relating to care for dual eligibles.

An amendment by Reps. Barton of Texas, Green of Texas, and Burgess of Texas—To require insurers to provide requested out-of-pocket cost information to enrollees prior to receiving services. In addition, requires states, as a condition of receiving federal Medicaid funding, to enact laws requiring hospitals to publically disclose: (1) charges for the most common services, (2) the Medicaid and Medicare reimbursement amounts for these services; and (3) the charity care policy for the hospital, including any formula used to calculate financial aid for low-income individuals.

An amendment by Rep. Butterfield of North Carolina—To require a report by the Secretary of Health and Human Services on the need and cost of providing oral health care as part of the essential benefits package.

An amendment by Rep. Buyer of Indiana—To ensure that the veterans healthcare program can seek reimbursement from the public health insurance plans for non-duty related injuries like they can from private plans.

An amendment by Rep. Castor of Florida—To provide grants for employer wellness programs.

An amendment by Rep. Christensen of the Virgin Islands—To require that the Health Benefits Advisory Committee include "an expert in child and adolescent health".

An amendment by Reps. DeGette of Colorado, Sarbanes of Maryland, and McNerney of California—To require that the Health Benefits Advisory Committee include "experts in oral health care".

An amendment by Rep. Green of Texas—To provide for a special enrollment period for chronic-care special needs plans targeted at end-stage renal disease.

An amendment by Rep. Green of Texas—To authorize the Secretary of Health and Human Services to award grants to certain communities to help develop integrated health care delivery systems.

An amendment by Rep. Hill of Indiana—To make minor and technical changes to the Physician Payments Sunshine provisions reported by the Committee.

An amendment by Rep. Markey of Massachusetts—To authorize the Commissioner to use data on enrollee demographics, inpatient and outpatient diagnoses, and other such information as the Secretary of Health and Human Services may determine is necessary, in creating risk adjustment mechanisms for the Exchange.

An amendment by Rep. Murphy of Connecticut—To require the Secretary of Health and Human Services to attempt to attract 10 percent of all eligible providers to act as bundling test sites under acute care bundling pilot program.

An amendment by Rep. Murphy of Connecticut—To establish an Office on Women's Health within the Office of the Secretary of Health and Human Services and within the director's office of each of the following agencies: Agency for Health Research and Quality (AHRQ), Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), Health Resources and Services

Administration (HRSA), and Substance Abuse and Mental Health Services Administration (SAMHSA).

An amendment by Rep. Pallone of New Jersey—To authorize the Secretary of Health and Human Services to establish pilot programs to reduce infant mortality. (001)

An amendment by Rep. Pallone of New Jersey—To modify the standards for qualified health benefit plans, including the public option, to provide for rules regarding Indian enrollees and Indian health care providers.

An amendment by Rep. Ross of Arkansas—To preserve State insurance laws prohibiting discrimination among providers by insurance companies.

An amendment by Rep. Rush of Illinois—To authorize the Secretary of Health and Human Services and the Secretary of Education to award grants to public secondary schools to establish health science training programs to prepare students for careers in health sciences.

An amendment by Rep. Rush of Illinois—To authorize the Secretary of Health and Human Services to award grants to community-based collaborative care networks that assist low-income patient populations in accessing health care services and in participating in case management.

An amendment by Reps. Sarbanes of Maryland and Dingell of Michigan—To designate school-based health clinics funded under the new grant program in section 2511 of the Committee-reported bill as federally-qualified health centers for purposes of Medicaid.

An amendment by Rep. Sarbanes of Maryland—To provide that Medicare Advantage plans serving continuing care retirement communities with a contract in effect on January 1, 2009, may continue operations with a waiver of geographic integrity rules.

An amendment by Rep. Stupak—To clarify that manufacturers need not pay rebates to Medicaid on the drugs purchased by Medicaid managed care organizations (MCOs) if the MCOs have received discounts on the drugs through the 340B program.

An amendment by Rep. Sutton of Ohio—To clarify the means by which individuals can submit information to the Qualified Health Benefits Plan Ombudsman, including mail, telephone, electronically, and in person.

An amendment by Rep. Waxman of California—To provide program integrity in the 340B program through procedures for improving compliance by covered entities and manufacturers with program requirements.

An amendment by Rep. Welch of Vermont—To clarify the scope of preemption of state law by the provisions of the Physician Payment Sunshine Act (Section 1451) relating to the disclosure of payments to physicians.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

The bill was referred to this committee for consideration of such provisions of the bill as fall within the jurisdiction of this committee pursuant to clause 2 of rule XII of the Rules of the House of Representatives. In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter

is printed in italic, existing law in which no change is proposed is shown in roman):

PUBLIC HEALTH SERVICE ACT

TITLE II—ADMINISTRATION AND MISCELLANEOUS PROVISIONS

PART A—ADMINISTRATION

* * * * * * *

DEFENSE OF CERTAIN MALPRACTICE AND NEGLIGENCE SUITS

SEC. 224. (a) * * *

* * * * * * *

(g)(1)(A) For purposes of this section and subject to the approval by the Secretary of an application under subparagraph (D), an entity described in paragraph (4), and any officer, governing board member, [or employee] *employee, or (subject to subsection (k)(4)) volunteer practitioner* of such an entity, and any contractor of such an entity who is a physician or other licensed or certified health care practitioner (subject to paragraph (5)), shall be deemed to be an employee of the Public Health Service for a calendar year that begins during a fiscal year for which a transfer was made under subsection (k)(3) (subject to paragraph (3)). The remedy against the United States for an entity described in paragraph (4) and any officer, governing board member, [employee, or contractor] *employee, volunteer practitioner, or contractor* (subject to paragraph (5) *and subsection (k)(4)*) of such an entity who is deemed to be an employee of the Public Health Service pursuant to this paragraph shall be exclusive of any other civil action or proceeding to the same extent as the remedy against the United States is exclusive pursuant to subsection (a).

(B) The deeming of any entity or officer, governing board member, [employee, or contractor] *employee, volunteer practitioner, or contractor* of the entity to be an employee of the Public Health Service for purposes of this section shall apply with respect to services provided—

(i) * * *

* * * * * * *

(C) Subparagraph (B)(ii) applies to services provided to individuals who are not patients of an entity if the Secretary determines, after reviewing an application submitted under subparagraph (D), that the provision of the services to such individuals—

(i) * * *

* * * * * * *

(iii) are otherwise required under an employment contract (or similar arrangement) between the entity and an officer, governing board member, [employee, or contractor] *employee, volunteer practitioner, or contractor* of the entity.

(D) The Secretary may not under subparagraph (A) deem an entity or an officer, governing board member, [employee, or contractor] *employee, volunteer practitioner, or contractor* of the entity to be an employee of the Public Health Service for purposes of this

section, and may not apply such deeming to services described in subparagraph (B)(ii), unless the entity has submitted an application for such deeming to the Secretary in such form and such manner as the Secretary shall prescribe. The application shall contain detailed information, along with supporting documentation, to verify that the entity, and the officer, governing board member, [employee, or contractor] *employee, volunteer practitioner, or contractor* of the entity, as the case may be, meets the requirements of subparagraphs (B) and (C) of this paragraph and that the entity meets the requirements of paragraphs (1) through (4) of subsection (h).

(E) The Secretary shall make a determination of whether an entity or an officer, governing board member, [employee, or contractor] *employee, volunteer practitioner, or contractor* of the entity is deemed to be an employee of the Public Health Service for purposes of this section within 30 days after the receipt of an application under subparagraph (D). The determination of the Secretary that an entity or an officer, governing board member, [employee, or contractor] *employee, volunteer practitioner, or contractor* of the entity is deemed to be an employee of the Public Health Service for purposes of this section shall apply for the period specified by the Secretary under subparagraph (A).

(F) Once the Secretary makes a determination that an entity or an officer, governing board member, [employee, or contractor] *employee, volunteer practitioner, or contractor* of an entity is deemed to be an employee of the Public Health Service for purposes of this section, the determination shall be final and binding upon the Secretary and the Attorney General and other parties to any civil action or proceeding. Except as provided in subsection (i), the Secretary and the Attorney General may not determine that the provision of services which are the subject of such a determination are not covered under this section.

* * * * * * *

(H) In the case of an entity described in paragraph (4) for which an application under subparagraph (D) is in effect, the entity may, through notifying the Secretary in writing, elect to terminate the applicability of this subsection to the entity. With respect to such election by the entity:

(i) * * *

(ii) Upon taking effect, the election terminates the applicability of this subsection to the entity and each officer, governing board member, [employee, and contractor] *employee, volunteer practitioner, and contractor* of the entity.

* * * * * * *

(iv) If after making the election the entity submits an application under subparagraph (D), the election does not preclude the Secretary from approving the application (and thereby restoring the applicability of this subsection to the entity and each officer, governing board member, [employee, and contractor] *employee, volunteer practitioner, and contractor* of the entity, subject to the provisions of this subsection and the subsequent provisions of this section.

* * * * * * *

(h) The Secretary may not approve an application under subsection (g)(1)(D) unless the Secretary determines that the entity—

(1) * * *

* * * * * * *

(3) has no history of claims having been filed against the United States as a result of the application of this section to the entity or its officers, [employees, or contractors] *employees, volunteer practitioners, or contractors* as provided for under this section, or, if such a history exists, has fully cooperated with the Attorney General in defending against any such claims and either has taken, or will take, any necessary corrective steps to assure against such claims in the future; and

* * * * * * *

(i)(1) Notwithstanding subsection (g)(1), the Attorney General, in consultation with the Secretary, may on the record determine, after notice and opportunity for a full and fair hearing, that an individual physician or other licensed or certified health care practitioner who is an officer, [employee, or contractor] *employee, volunteer practitioner, or contractor* of an entity described in subsection (g)(4) shall not be deemed to be an employee of the Public Health Service for purposes of this section, if treating such individual as such an employee would expose the Government to an unreasonably high degree of risk of loss because such individual—

(A) * * *

* * * * * * *

(j) In the case of a health care provider who is an officer, [employee, or contractor] *employee, volunteer practitioner, or contractor* of an entity described in subsection (g)(4), section 335(e) shall apply with respect to the provider to the same extent and in the same manner as such section applies to any member of the National Health Service Corps.

(k)(1)(A) For each fiscal year, the Attorney General, in consultation with the Secretary, shall estimate by the beginning of the year the amount of all claims which are expected to arise under this section (together with related fees and expenses of witnesses) for which payment is expected to be made in accordance with section 1346 and chapter 171 of title 28, United States Code, from the acts or omissions, during the calendar year that begins during that fiscal year, of entities described in subsection (g)(4) and of officers, [employees, or contractors] *employees, volunteer practitioners, or contractors* (subject to subsection (g)(5)) of such entities.

(B) The estimate under subparagraph (A) shall take into account—

(i) the value and frequency of all claims for damage for personal injury, including death, resulting from the performance of medical, surgical, dental, or related functions by entities described in subsection (g)(4) or by officers, [employees, or contractors] *employees, volunteer practitioners, or contractors* (subject to subsection (g)(5)) of such entities who are deemed to be employees of the Public Health Service under subsection (g)(1) that, during the preceding 5-year period, are filed under this section or, with respect to years occurring before this sub-

section takes effect, are filed against persons other than the United States,

* * * * * * *

(3) In order for payments to be made for judgments against the United States (together with related fees and expenses of witnesses) pursuant to this section arising from the acts or omissions of entities described in subsection (g)(4) and of officers, [employees, or contractors] *employees, volunteer practitioners, or contractors* (subject to subsection (g)(5)) of such entities, the total amount contained within the fund established by the Secretary under paragraph (2) for a fiscal year shall be transferred not later than the December 31 that occurs during the fiscal year to the appropriate accounts in the Treasury.

(4)(A) Subsections (g) through (m) apply with respect to volunteer practitioners beginning with the first fiscal year for which an appropriations Act provides that amounts in the fund under paragraph (2) are available with respect to such practitioners.

(B) For purposes of subsections (g) through (m), the term "volunteer practitioner" means a practitioner who, with respect to an entity described in subsection (g)(4), meets the following conditions:

(i) The practitioner is a licensed physician, a licensed clinical psychologist, or other licensed or certified health care practitioner.

(ii) At the request of such entity, the practitioner provides services to patients of the entity, at a site at which the entity operates or at a site designated by the entity. The weekly number of hours of services provided to the patients by the practitioner is not a factor with respect to meeting conditions under this subparagraph.

(iii) The practitioner does not for the provision of such services receive any compensation from such patients, from the entity, or from third-party payors (including reimbursement under any insurance policy or health plan, or under any Federal or State health benefits program).

(l)(1) If a civil action or proceeding is filed in a State court against any entity described in subsection (g)(4) or any officer, governing board member, [employee, or any contractor] *employee, volunteer practitioner, or contractor* of such an entity for damages described in subsection (a), the Attorney General, within 15 days after being notified of such filing, shall make an appearance in such court and advise such court as to whether the Secretary has determined under subsections (g) and (h), that such entity, officer, governing board member, [employee, or contractor] *employee, volunteer practitioner, or contractor* of the entity is deemed to be an employee of the Public Health Service for purposes of this section with respect to the actions or omissions that are the subject of such civil action or proceeding. Such advice shall be deemed to satisfy the provisions of subsection (c) that the Attorney General certify that an entity, officer, governing board member, [employee, or contractor] *employee, volunteer practitioner, or contractor* of the entity was acting within the scope of their employment or responsibility.

(2) If the Attorney General fails to appear in State court within the time period prescribed under paragraph (1), upon petition of any entity or officer, governing board member, [employee, or contractor] *employee, volunteer practitioner, or contractor* of the entity

named, the civil action or proceeding shall be removed to the appropriate United States district court. The civil action or proceeding shall be stayed in such court until such court conducts a hearing, and makes a determination, as to the appropriate forum or procedure for the assertion of the claim for damages described in subsection (a) and issues an order consistent with such determination.

(m)(1) An entity or officer, governing board member, [employee, or contractor] *employee, volunteer practitioner, or contractor* of an entity described in subsection (g)(1) shall, for purposes of this section, be deemed to be an employee of the Public Health Service with respect to services provided to individuals who are enrollees of a managed care plan if the entity contracts with such managed care plan for the provision of services.

(2) Each managed care plan which enters into a contract with an entity described in subsection (g)(4) shall deem the entity and any officer, governing board member, [employee, or contractor] *employee, volunteer practitioner, or contractor* of the entity as meeting whatever malpractice coverage requirements such plan may require of contracting providers for a calendar year if such entity or officer, governing board member, [employee, or contractor] *employee, volunteer practitioner, or contractor* of the entity has been deemed to be an employee of the Public Health Service for purposes of this section for such calendar year. Any plan which is found by the Secretary on the record, after notice and an opportunity for a full and fair hearing, to have violated this subsection shall upon such finding cease, for a period to be determined by the Secretary, to receive and to be eligible to receive any Federal funds under titles XVIII or XIX of the Social Security Act.

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PART B—MISCELLANEOUS PROVISIONS

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SEC. 249. NATIONAL EDUCATION OUTREACH AND AWARENESS CAMPAIGN ON PAIN MANAGEMENT.

(a) ESTABLISHMENT.—Not later than June 30, 2010, the Secretary shall establish and implement a national pain care education outreach and awareness campaign described in subsection (b).

(b) REQUIREMENTS.—The Secretary shall design the public awareness campaign under this section to educate consumers, patients, their families, and other caregivers with respect to—

(1) the incidence and importance of pain as a national public health problem;

(2) the adverse physical, psychological, emotional, societal, and financial consequences that can result if pain is not appropriately assessed, diagnosed, treated, or managed;

(3) the availability, benefits, and risks of all pain treatment and management options;

(4) having pain promptly assessed, appropriately diagnosed, treated, and managed, and regularly reassessed with treatment adjusted as needed;

(5) the role of credentialed pain management specialists and subspecialists, and of comprehensive interdisciplinary centers of treatment expertise;

(6) the availability in the public, nonprofit, and private sectors of pain management-related information, services, and resources for consumers, employers, third-party payors, patients, their families, and caregivers, including information on—

(A) appropriate assessment, diagnosis, treatment, and management options for all types of pain and pain-related symptoms; and

(B) conditions for which no treatment options are yet recognized; and

(7) other issues the Secretary deems appropriate.

(c) CONSULTATION.—In designing and implementing the public awareness campaign required by this section, the Secretary shall consult with organizations representing patients in pain and other consumers, employers, physicians including physicians specializing in pain care, other pain management professionals, medical device manufacturers, and pharmaceutical companies.

(d) COORDINATION.—

(1) LEAD OFFICIAL.—The Secretary shall designate one official in the Department of Health and Human Services to oversee the campaign established under this section.

(2) AGENCY COORDINATION.—The Secretary shall ensure the involvement in the public awareness campaign under this section of the Surgeon General of the Public Health Service, the Director of the Centers for Disease Control and Prevention, and such other representatives of offices and agencies of the Department of Health and Human Services as the Secretary determines appropriate.

(e) UNDERSERVED AREAS AND POPULATIONS.—In designing the public awareness campaign under this section, the Secretary shall—

(1) take into account the special needs of geographic areas and racial, ethnic, gender, age, and other demographic groups that are currently underserved; and

(2) provide resources that will reduce disparities in access to appropriate diagnosis, assessment, and treatment.

(f) GRANTS AND CONTRACTS.—The Secretary may make awards of grants, cooperative agreements, and contracts to public agencies and private nonprofit organizations to assist with the development and implementation of the public awareness campaign under this section.

(g) EVALUATION AND REPORT.—Not later than the end of fiscal year 2012, the Secretary shall prepare and submit to the Congress a report evaluating the effectiveness of the public awareness campaign under this section in educating the general public with respect to the matters described in subsection (b).

(h) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this section, there are authorized to be appropriated $2,000,000 for fiscal year 2010 and $4,000,000 for each of fiscal years 2011 and 2012.

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TITLE III—GENERAL POWERS AND DUTIES OF PUBLIC HEALTH SERVICE

PART A—RESEARCH AND INVESTIGATION

* * * * * * *

GENERAL AUTHORITY RESPECTING RESEARCH, EVALUATIONS, AND DEMONSTRATIONS IN HEALTH STATISTICS, HEALTH SERVICES, AND HEALTH CARE TECHNOLOGY ASSESSMENT

SEC. 304. (a) * * *

* * * * * * *

(c)(1) The Secretary*, acting through the Assistant Secretary for Health Information,* shall coordinate all health services research, evaluations, and demonstrations, all health statistical and epidemiological activities, and all research, evaluations, and demonstrations respecting the assessment of health care technology undertaken and supported through units of the Department of Health and Human Services. To the maximum extent feasible such coordination shall be carried out through the Agency for Health Care Policy and Research and the National Center for Health Statistics.

(2) The Secretary*, acting through the Assistant Secretary for Health Information,* shall coordinate the health services research, evaluations, and demonstrations, the health statistical and (where appropriate) epidemiological activities, and the research, evaluations, and demonstrations respecting the assessment of health care technology authorized by this Act through the Agency for Health Care Policy and Research and the National Center for Health Statistics.

NATIONAL CENTER FOR HEALTH STATISTICS

SEC. 306. (a) * * *

* * * * * * *

(j) In carrying out the requirements of section 304(c) and paragraph (1) of subsection (e) of this section, the Secretary*, acting through the Assistant Secretary for Health Information,* shall coordinate health statistical and epidemiological activities of the Department of Health and Human Services by—

(1) * * *

* * * * * * *

PART B—FEDERAL-STATE COOPERATION

* * * * * * *

SEC. 315. REGIONALIZED COMMUNICATION SYSTEMS FOR EMERGENCY CARE RESPONSE.

(a) IN GENERAL.—The Secretary, acting through the Assistant Secretary for Preparedness and Response, shall award not fewer than 4 multiyear contracts or competitive grants to eligible entities to support demonstration programs that design, implement, and evaluate innovative models of regionalized, comprehensive, and accountable emergency care systems.

(b) ELIGIBLE ENTITY; REGION.—

(1) ELIGIBLE ENTITY.—In this section, the term "eligible entity" means a State or a partnership of 1 or more States and 1 or more local governments.

(2) REGION.—In this section, the term "region" means an area within a State, an area that lies within multiple States, or a similar area (such as a multicounty area), as determined by the Secretary.

(c) DEMONSTRATION PROGRAM.—The Secretary shall award a contract or grant under subsection (a) to an eligible entity that proposes a demonstration program to design, implement, and evaluate an emergency medical system that—

(1) coordinates with public safety services, public health services, emergency medical services, medical facilities, and other entities within a region;

(2) coordinates an approach to emergency medical system access throughout the region, including 9-1-1 public safety answering points and emergency medical dispatch;

(3) includes a mechanism, such as a regional medical direction or transport communications system, that operates throughout the region to ensure that the correct patient is taken to the medically appropriate facility (whether an initial facility or a higher level facility) in a timely fashion;

(4) allows for the tracking of prehospital and hospital resources, including inpatient bed capacity, emergency department capacity, on-call specialist coverage, ambulance diversion status, and the coordination of such tracking with regional communications and hospital destination decisions; and

(5) includes a consistent regionwide prehospital, hospital, and interfacility data management system that—

(A) complies with the National EMS Information System, the National Trauma Data Bank, and others;

(B) reports data to appropriate Federal and State databanks and registries; and

(C) contains information sufficient to evaluate key elements of prehospital care, hospital destination decisions, including initial hospital and interfacility decisions, and relevant outcomes of hospital care.

(d) APPLICATION.—

(1) IN GENERAL.—An eligible entity that seeks a contract or grant described in subsection (a) shall submit to the Secretary an application at such time and in such manner as the Secretary may require.

(2) APPLICATION INFORMATION.—Each application shall include—

(A) an assurance from the eligible entity that the proposed system—

(i) has been coordinated with the applicable State office of emergency medical services (or equivalent State office);

(ii) is compatible with the applicable State emergency medical services system;

(iii) includes consistent indirect and direct medical oversight of prehospital, hospital, and interfacility transport throughout the region;

(iv) coordinates prehospital treatment and triage, hospital destination, and interfacility transport throughout the region;

(v) includes a categorization or designation system for special medical facilities throughout the region that is—

(I) consistent with State laws and regulations; and

(II) integrated with the protocols for transport and destination throughout the region; and

(vi) includes a regional medical direction system, a patient tracking system, and a resource allocation system that—

(I) support day-to-day emergency care system operation;

(II) can manage surge capacity during a major event or disaster; and

(III) are integrated with other components of the national and State emergency preparedness system;

(B) an agreement to make available non-Federal contributions in accordance with subsection (e); and

(C) such other information as the Secretary may require.

(e) MATCHING FUNDS.—

(1) IN GENERAL.—With respect to the costs of the activities to be carried out each year with a contract or grant under subsection (a), a condition for the receipt of the contract or grant is that the eligible entity involved agrees to make available (directly or through donations from public or private entities) non-Federal contributions toward such costs in an amount that is not less than 25 percent of such costs.

(2) DETERMINATION OF AMOUNT CONTRIBUTED.—Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including plant, equipment, or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such non-Federal contributions.

(f) PRIORITY.—The Secretary shall give priority for the award of the contracts or grants described in subsection (a) to any eligible entity that serves a medically underserved population (as defined in section 330(b)(3)).

(g) REPORT.—Not later than 90 days after the completion of a demonstration program under subsection (a), the recipient of such contract or grant described in such subsection shall submit to the Secretary a report containing the results of an evaluation of the program, including an identification of—

(1) the impact of the regional, accountable emergency care system on patient outcomes for various critical care categories, such as trauma, stroke, cardiac emergencies, and pediatric emergencies;

(2) the system characteristics that contribute to the effectiveness and efficiency of the program (or lack thereof);

(3) methods of assuring the long-term financial sustainability of the emergency care system;

(4) the State and local legislation necessary to implement and to maintain the system; and

(5) the barriers to developing regionalized, accountable emergency care systems, as well as the methods to overcome such barriers.

(h) EVALUATION.—The Secretary, acting through the Assistant Secretary for Preparedness and Response, shall enter into a contract with an academic institution or other entity to conduct an independent evaluation of the demonstration programs funded under subsection (a), including an evaluation of—

(1) the performance of the eligible entities receiving the funds; and

(2) the impact of the demonstration programs.

(i) DISSEMINATION OF FINDINGS.—The Secretary shall, as appropriate, disseminate to the public and to the appropriate committees of the Congress, the information contained in a report made under subsection (h).

(j) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—There is authorized to be appropriated to carry out this section $12,000,000 for each of fiscal years 2010 through 2015.

(2) RESERVATION.—Of the amount appropriated to carry out this section for a fiscal year, the Secretary shall reserve 3 percent of such amount to carry out subsection (h) (relating to an independent evaluation).

SEC. 315A. ASSISTING VETERANS WITH MILITARY EMERGENCY MEDICAL TRAINING TO BECOME STATE-LICENSED OR CERTIFIED EMERGENCY MEDICAL TECHNICIANS (EMTS).

(a) PROGRAM.—The Secretary shall establish a program consisting of awarding grants to States to assist veterans who received and completed military emergency medical training while serving in the Armed Forces of the United States to become, upon their discharge or release from active duty service, State-licensed or certified emergency medical technicians.

(b) USE OF FUNDS.—Amounts received as a grant under this section may be used to assist veterans described in subsection (a) to become State-licensed or certified emergency medical technicians as follows:

(1) Providing training.

(2) Providing reimbursement for costs associated with—

(A) training; or

(B) applying for licensure or certification.

(3) Expediting the licensing or certification process.

(c) ELIGIBILITY.—To be eligible for a grant under this section, a State shall demonstrate to the Secretary's satisfaction that the State has a shortage of emergency medical technicians.

(d) REPORT.—The Secretary shall submit to the Congress an annual report on the program under this section.

(e) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated such sums as may be necessary for fiscal years 2010 through 2014.

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PREVENTIVE HEALTH MEASURES WITH RESPECT TO PROSTATE CANCER

SEC. 317D. (a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, may make grants to States and local health departments for the purpose of enabling such States and departments to carry out programs that may include the following:

(1) * * *

* * * * * * *

(7) Upon a determination by the Secretary, who shall take into consideration recommendations by the [United States Preventive Services Task Force] *Task Force on Clinical Preventive Services* and shall seek input, where appropriate, from professional societies and other private and public entities, that there is sufficient consensus on the effectiveness of prostate cancer screening—

(A) * * *

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SEC. 317U. HEALTHY TEEN INITIATIVE TO PREVENT TEEN PREGNANCY.

(a) PROGRAM.—To the extent and in the amount of appropriations made in advance in appropriations Acts, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a program consisting of making grants, in amounts determined under subsection (c), to each State that submits an application in accordance with subsection (d) for an evidence-based education program described in subsection (b).

(b) USE OF FUNDS.—Amounts received by a State under this section shall be used to conduct or support evidence-based education programs (directly or through grants or contracts to public or private nonprofit entities, including schools and community-based and faith-based organizations) to reduce teen pregnancy or sexually transmitted diseases.

(c) DISTRIBUTION OF FUNDS.—The Director shall, for fiscal year 2010 and each subsequent fiscal year, make a grant to each State described in subsection (a) in an amount equal to the product of—

(1) the amount appropriated to carry out this section for the fiscal year; and

(2) the percentage determined for the State under section 502(c)(1)(B)(ii) of the Social Security Act.

(d) APPLICATION.—To seek a grant under this section, a State shall submit an application at such time, in such manner, and containing such information and assurance of compliance with this section as the Secretary may require. At a minimum, an application shall to the satisfaction of the Secretary—

(1) describe how the State's proposal will address the needs of at-risk teens in the State;

(2) identify the evidence-based education program or programs selected from the registry developed under subsection (g) that will be used to address risks in priority populations;

(3) describe how the program or programs will be implemented and any adaptations to the evidence-based model that will be made;

(4) list any private and public entities with whom the State proposes to work, including schools and community-based and faith-based organizations, and demonstrate their capacity to implement the proposed program or programs; and

(5) identify an independent entity that will evaluate the impact of the program or programs.

(e) EVALUATION.—

(1) REQUIREMENT.—As a condition on receipt of a grant under this section, a State shall agree—

(A) to arrange for an independent evaluation of the impact of the programs to be conducted or supported through the grant; and

(B) submit reports to the Secretary on such programs and the results of evaluation of such programs.

(2) FUNDING LIMITATION.—Of the amounts made available to a State through a grant under this section for any fiscal year, not more than 10 percent may be used for such evaluation.

(f) RULE OF CONSTRUCTION.—This section shall not be construed to preempt or limit any State law regarding parental involvement and decisionmaking in children's education.

(g) REGISTRY OF ELIGIBLE PROGRAMS.—The Secretary shall develop not later than 180 days after the date of the enactment of the America's Affordable Health Choices Act of 2009, and periodically update thereafter, a publicly available registry of programs described in subsection (b) that, as determined by the Secretary—

(1) meet the definition of the term "evidence-based" in subsection (i);

(2) are medically and scientifically accurate; and

(3) provide age-appropriate information.

(h) MATCHING FUNDS.—The Secretary may award a grant to a State under this section for a fiscal year only if the State agrees to provide, from non-Federal sources, an amount equal to $1 (in cash or in kind) for each $4 provided through the grant to carry out the activities supported by the grant.

(i) DEFINITION.—In this section, the term "evidence-based" means based on a model that has been found, in methodologically sound research—

(1) to delay initiation of sex;

(2) to decrease number of partners;

(3) to reduce teen pregnancy;

(4) to reduce sexually transmitted infection rates; or

(5) to improve rates of contraceptive use.

(j) APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $50,000,000 for each of the fiscal years 2010 through 2014.

* * * * * * *

SEC. 319F. PUBLIC HEALTH COUNTERMEASURES TO A BIOTERRORIST ATTACK.

(a) ALL-HAZARDS PUBLIC HEALTH AND MEDICAL RESPONSE CURRICULA AND TRAINING.—

(1) * * *

* * * * * * *

(5) DISSEMINATION AND TRAINING.—

(A) * * *

(B) CERTAIN ENTITIES.—The education and training activities described in subparagraph (A) may be carried out by Federal [public health or medical] *public health, medical, or dental* entities, appropriate educational entities, professional organizations and societies, private accrediting organizations, and other nonprofit institutions or entities meeting criteria established by the Secretary.

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PART D—PRIMARY HEALTH CARE

Subpart I—Health Centers

SEC. 330. HEALTH CENTERS.

(a) * * *

* * * * * * *

(r) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—For the purpose of carrying out this section, in addition to the amounts authorized to be appropriated under subsection (d), there are authorized to be appropriated—

(A) * * *

* * * * * * *

(D) $2,940,000,000 for fiscal year 2011; [and]

(E) $3,337,000,000 for fiscal year 2012[.]*; and*

(F) such sums as may be necessary for each of fiscal years 2013 and 2014.

* * * * * * *

(s) ADDITIONAL FUNDING.—For the purpose of carrying out this section, in addition to any other amounts authorized to be appropriated for such purpose, there are authorized to be appropriated, out of any monies in the Public Health Investment Fund, the following:

(1) For fiscal year 2010, $1,000,000,000.

(2) For fiscal year 2011, $1,500,000,000.

(3) For fiscal year 2012, $2,500,000,000.

(4) For fiscal year 2013, $3,000,000,000.

(5) For fiscal year 2014, $4,000,000,000.

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SEC. 330I. TELEHEALTH NETWORK AND TELEHEALTH RESOURCE CENTERS GRANT PROGRAMS.

(a) DEFINITIONS.—In this section:

(1) * * *

* * * * * * *

[(3) FRONTIER COMMUNITY.—The term "frontier community" shall have the meaning given the term in regulations issued under subsection (r).]

(3) HEALTH DISPARITIES.—The term "health disparities" has the meaning given such term in section 3171.

* * * * * * *

(d) GRANTS.—

(1) TELEHEALTH NETWORK GRANTS.—The Director may, in carrying out the telehealth network grant program referred to in subsection (b), award grants to eligible entities for projects to demonstrate how telehealth technologies can be used through telehealth networks in rural areas, frontier communities, and medically underserved areas, and for medically underserved populations, to—

(A) * * *

(B) improve and expand the training of health care providers; [and]

(C) expand and improve the quality of health information available to health care providers, and patients and their families, for decisionmaking[.]*; and*

(D) reduce health disparities.

* * * * * * *

(f) ELIGIBLE ENTITIES.—

(1) TELEHEALTH NETWORK GRANTS.—

(A) * * *

(B) TELEHEALTH NETWORKS.—

(i) * * *

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(iii) COMPOSITION OF NETWORK.—The telehealth network shall include at least 2 of the following entities (at least 1 of which shall be a community-based health care provider):

(I) * * *

* * * * * * *

(VII) Long-term care providers*, including skilled nursing facilities*.

* * * * * * *

(IX) Providers of outpatient mental health services and entities operating outpatient mental health facilities*, including county mental health and public mental health facilities*.

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(XIII) Renal dialysis facilities.

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[(i) PREFERENCES.—

[(1) TELEHEALTH NETWORKS.—In awarding grants under subsection (d)(1) for projects involving telehealth networks, the Secretary shall give preference to an eligible entity that meets at least 1 of the following requirements:

[(A) ORGANIZATION.—The eligible entity is a rural community-based organization or another community-based organization.

[(B) SERVICES.—The eligible entity proposes to use Federal funds made available through such a grant to develop plans for, or to establish, telehealth networks that provide mental health, public health, long-term care, home care, preventive, or case management services.

[(C) COORDINATION.—The eligible entity demonstrates how the project to be carried out under the grant will be

coordinated with other relevant federally funded projects in the areas, communities, and populations to be served through the grant.

[(D) NETWORK.—The eligible entity demonstrates that the project involves a telehealth network that includes an entity that—

[(i) provides clinical health care services, or educational services for health care providers and for patients or their families; and

[(ii) is—

[(I) a public library;

[(II) an institution of higher education; or

[(III) a local government entity.

[(E) CONNECTIVITY.—The eligible entity proposes a project that promotes local connectivity within areas, communities, or populations to be served through the project.

[(F) INTEGRATION.—The eligible entity demonstrates that health care information has been integrated into the project.

[(2) TELEHEALTH RESOURCE CENTERS.—In awarding grants under subsection (d)(2) for projects involving telehealth resource centers, the Secretary shall give preference to an eligible entity that meets at least 1 of the following requirements:

[(A) PROVISION OF SERVICES.—The eligible entity has a record of success in the provision of telehealth services to medically underserved areas or medically underserved populations.

[(B) COLLABORATION AND SHARING OF EXPERTISE.—The eligible entity has a demonstrated record of collaborating and sharing expertise with providers of telehealth services at the national, regional, State, and local levels.

[(C) BROAD RANGE OF TELEHEALTH SERVICES.—The eligible entity has a record of providing a broad range of telehealth services, which may include—

[(i) a variety of clinical specialty services;

[(ii) patient or family education;

[(iii) health care professional education; and

[(iv) rural residency support programs.]

(i) PREFERENCES.—

(1) TELEHEALTH NETWORKS.—In awarding grants under subsection (d)(1) for projects involving telehealth networks, the Secretary shall give preference to eligible entities meeting the following:

(A) NETWORK.—The eligible entity is a health care provider in, or proposing to form, a health care network that furnishes services in a medically underserved area or a health professional shortage area.

(B) BROAD GEOGRAPHIC COVERAGE.—The eligible entity demonstrates broad geographic coverage in the rural or medically underserved areas of the State or States in which the entity is located.

(C) HEALTH DISPARITIES.—The eligible entity demonstrates how the project to be funded through the grant will address health disparities.

(D) LINKAGES.—The eligible entity agrees to use the grant to establish or develop plans for telehealth systems that will link rural hospitals and rural health care providers to other hospitals, health care providers, and patients.

(E) EFFICIENCY.—The eligible entity agrees to use the grant to promote greater efficiency in the use of health care resources.

(F) VIABILITY.—The eligible entity demonstrates the long-term viability of projects through—

(i) availability of non-Federal funding sources; or

(ii) institutional and community support for the telehealth network.

(G) SERVICES.—The eligible entity provides a plan for coordinating system use by eligible entities and prioritizes use of grant funds for health care services over nonclinical uses.

(2) TELEHEALTH RESOURCE CENTERS.—In awarding grants under subsection (d)(2) for projects involving telehealth resource centers, the Secretary shall give preference to eligible entities meeting the following:

(A) PROVISION OF A BROAD RANGE OF SERVICES.—The eligible entity has a record of success in the provision of a broad range of telehealth services to medically underserved areas or populations.

(B) PROVISION OF TELEHEALTH TECHNICAL ASSISTANCE.—The eligible entity has a record of success in the provision of technical assistance to providers serving medically underserved communities or populations in the establishment and implementation of telehealth services.

(C) COLLABORATION AND SHARING OF EXPERTISE.—The eligible entity has a demonstrated record of collaborating and sharing expertise with providers of telehealth services at the national, regional, State, and local levels.

(j) DISTRIBUTION OF FUNDS.—

(1) * * *

(2) TELEHEALTH NETWORKS.—In awarding grants under subsection (d)(1) for a fiscal year, the Director shall ensure that—

(A) * * *

(B) the total amount of funds awarded for such projects for that fiscal year shall be not less than the total amount of funds awarded for ❚such projects for fiscal year 2001 under section 330A (as in effect on the day before the date of enactment of the Health Care Safety Net Amendments of 2002).❚ *such project for fiscal year 2009.*

(k) USE OF FUNDS.—

(1) TELEHEALTH NETWORK PROGRAM.—The recipient of a grant under subsection (d)(1) may use funds received through such grant for salaries, equipment, and operating or other costs, including the cost of—

(A) * * *

* * * * * * *

(E)(i) providing for [transmission of medical data] *transmission and electronic archival of medical data*, and maintenance of equipment; and

* * * * * * *

[(F) developing projects to use telehealth technology to facilitate collaboration between health care providers;]

(F) developing projects to use telehealth technology—

(i) to facilitate collaboration between health care providers;

(ii) to promote telenursing services; or

(iii) to promote patient understanding and adherence to national guidelines for chronic disease and self-management of such conditions;

* * * * * * *

(q) REPORT.—[Not later than September 30, 2005] *Not later than 1 year after the date of the enactment of the America's Affordable Health Choices Act of 2009, and annually thereafter*, the Secretary shall prepare and submit to the appropriate committees of Congress a report on the progress and accomplishments of the grant programs described in subsection (b).

[(r) REGULATIONS.—The Secretary shall issue regulations specifying, for purposes of this section, a definition of the term "frontier area". The definition shall be based on factors that include population density, travel distance in miles to the nearest medical facility, travel time in minutes to the nearest medical facility, and such other factors as the Secretary determines to be appropriate. The Secretary shall develop the definition in consultation with the Director of the Bureau of the Census and the Administrator of the Economic Research Service of the Department of Agriculture.]

[(s)] *(r)* AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section—

(1) for grants under subsection (d)(1), $40,000,000 for fiscal year 2002, [and] such sums as may be necessary for each of fiscal years 2003 through 2006*, $10,000,000 for fiscal year 2010, and such sums as may be necessary for each of fiscal years 2011 through 2014*; and

(2) for grants under subsection (d)(2), $20,000,000 for fiscal year 2002, [and] such sums as may be necessary for each of fiscal years 2003 through 2006*, $10,000,000 for fiscal year 2010, and such sums as may be necessary for each of fiscal years 2011 through 2014*.

* * * * * * *

SEC. 330L. TELEMEDICINE; INCENTIVE GRANTS REGARDING COORDINATION AMONG STATES.

(a) * * *

(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out subsection (a), there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2002 through 2006*, $10,000,000 for fiscal year 2010, and such sums as may be necessary for each of fiscal years 2011 through 2014*.

Subpart II—National Health Service Corps Program

NATIONAL HEALTH SERVICE CORPS

SEC. 331. (a) * * *

* * * * * * *

(i)(1) [In carrying out subpart III, the Secretary may, in accordance with this subsection, carry out demonstration projects in which individuals who have entered into a contract for obligated service under the Loan Repayment Program receive waivers under which the individuals are authorized to satisfy the requirement of obligated service through providing clinical service that is not full-time.] *In carrying out subpart III, the Secretary may, in accordance with this subsection, issue waivers to individuals who have entered into a contract for obligated service under the Scholarship Program or the Loan Repayment Program under which the individuals are authorized to satisfy the requirement of obligated service through providing clinical practice that is half-time.*

(2) A waiver described in paragraph (1) may be provided by the Secretary only if—

(A) the entity for which the service is to be performed—

(i) * * *

(ii) has requested in writing assignment of a health professional who would serve [less than full time] *half time*;

(B) the Secretary has determined that assignment of a health professional who would serve [less than full time] *half time* would be appropriate for the area where the entity is located;

(C) a Corps member who is required to perform obligated service has agreed in writing to be assigned for [less than full-time service] *half-time service* to an entity described in subparagraph (A);

[(D) the entity and the Corps member agree in writing that the less than full-time service provided by the Corps member will not be less than 16 hours of clinical service per week;

[(E) the Corps member agrees in writing that the period of obligated service pursuant to section 338B will be extended so that the aggregate amount of less than full-time service performed will equal the amount of service that would be performed through full-time service under section 338C; and]

(D) the entity and the Corps member agree in writing that the Corps member will perform half-time clinical practice;

(E) the Corps member agrees in writing to fulfill all of the service obligations under section 338C through half-time clinical practice and either—

(i) double the period of obligated service that would otherwise be required; or

(ii) in the case of contracts entered into under section 338B, accept a minimum service obligation of 2 years with an award amount equal to 50 percent of the amount that would otherwise be payable for full-time service; and

(F) the Corps member agrees in writing that if the Corps member begins providing [less than full-time service] *half-time service* but fails to begin or complete the period of obligated service, the method stated in 338E(c) for determining the

damages for breach of the individual's written contract will be used after converting periods of obligated service or of service performed into their full-time equivalents.

(3) [In evaluating a demonstration project described in paragraph (1)] *In evaluating waivers issued under paragraph (1)*, the Secretary shall examine the effect of multidisciplinary teams.

(j) For the purposes of this subpart and subpart III:

(1) * * *

* * * * * * *

(5) The terms "full time" and "full-time" mean a minimum of 40 hours per week in a clinical practice, for a minimum of 45 weeks per year.

(6) The terms "half time" and "half-time" mean a minimum of 20 hours per week (not to exceed 39 hours per week) in a clinical practice, for a minimum of 45 weeks per year.

* * * * * * *

NATIONAL ADVISORY COUNCIL

SEC. 337. (a) * * *

(b)(1) Members of the Council shall be appointed for a term of three years, except that any member appointed to fill a vacancy occurring prior to the expiration of the term for which the member's predecessor was appointed shall be appointed for the remainder of such term. No member shall be removed, except for cause. [Members may not be reappointed to the Council.]

* * * * * * *

AUTHORIZATION OF APPROPRIATION

SEC. 338. (a) For the purpose of carrying out this subpart, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2008 through [2012] *2014*.

* * * * * * *

(c) For the purpose of carrying out this subpart, in addition to any other amounts authorized to be appropriated for such purpose, there are authorized to be appropriated, out of any monies in the Public Health Investment Fund, the following:

(1) $63,000,000 for fiscal year 2010.

(2) $66,000,000 for fiscal year 2011.

(3) $70,000,000 for fiscal year 2012.

(4) $73,000,000 for fiscal year 2013.

(5) $77,000,000 for fiscal year 2014.

Subpart III—Scholarship Program and Loan Repayment Program

SEC. 338B. NATIONAL HEALTH SERVICE CORPS LOAN REPAYMENT PROGRAM.

(a) * * *

* * * * * * *

(g) PAYMENTS.—

(1) * * *

(2) PAYMENTS FOR YEARS SERVED.—

(A) IN GENERAL.—For each year of obligated service that an individual contracts to serve under subsection (f) the Secretary may pay up to [$35,000] *$50,000, plus, beginning with fiscal year 2012, an amount determined by the Secretary on an annual basis to reflect inflation,* on behalf of the individual for loans described in paragraph (1). In making a determination of the amount to pay for a year of such service by an individual, the Secretary shall consider the extent to which each such determination—

(i) * * *

* * * * * * *

OBLIGATED SERVICE

SEC. 338C. (a) Except as provided in section 338D, each individual who has entered into a written contract with the Secretary under section 338A or 338B shall provide service in the full-time clinical practice of such individual's profession as a member of the Corps for the period of obligated service provided in such contract. *The Secretary may treat teaching as clinical practice for up to 20 percent of such period of obligated service.*

* * * * * * *

SEC. 338H. AUTHORIZATION OF APPROPRIATIONS.

(a) AUTHORIZATION OF APPROPRIATIONS.—For the purposes of carrying out this subpart, there are authorized to be appropriated—

(1) * * *

* * * * * * *

(4) for fiscal year 2011, $170,296,310; [and]

(5) for fiscal year 2012, $185,622,980[.]*; and*

(6) for fiscal years 2013 and 2014, such sums as may be necessary.

* * * * * * *

SEC. 338H–1. ADDITIONAL FUNDING.

For the purpose of carrying out this subpart, in addition to any other amounts authorized to be appropriated for such purpose, there are authorized to be appropriated, out of any monies in the Public Health Investment Fund, the following:

(1) $254,000,000 for fiscal year 2010.

(2) $266,000,000 for fiscal year 2011.

(3) $278,000,000 for fiscal year 2012.

(4) $292,000,000 for fiscal year 2013.

(5) $306,000,000 for fiscal year 2014.

* * * * * * *

Subpart VII—Drug Pricing Agreements

LIMITATION ON PRICES OF DRUGS PURCHASED BY COVERED ENTITIES

SEC. 340B. (a) REQUIREMENTS FOR AGREEMENT WITH SECRETARY.—

(1) * * *

* * * * * * *

(4) COVERED ENTITY DEFINED.—In this section, the term "covered entity" means an entity that meets the requirements described in paragraph (5) and is one of the following:

(A) * * *

* * * * * * *

(L) A subsection (d) hospital (as defined in section 1886(d)(1)(B) of the Social Security Act) that—

(i) is owned or operated by a unit of State or local government, is a public or private non-profit corporation which is formally granted governmental powers by a unit of State or local government, or is a private non-profit hospital which has a contract with a State or local government to provide health care services to low income individuals who are not entitled to benefits under title XVIII of the Social Security Act or eligible for assistance under the State plan under this title; *and*

(ii) for the most recent cost reporting period that ended before the calendar quarter involved, had a disproportionate share adjustment percentage (as determined under section 1886(d)(5)(F) of the Social Security Act) greater than 11.75 percent or was described in section 1886(d)(5)(F)(i)(II) of such Act**[**; and**]**.

[(iii) does not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement.**]**

(M) A children's hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act which would meet the requirements of subparagraph (L), including the disproportionate share adjustment percentage requirement under subparagraph (L)(ii), if the hospital were a subsection (d) hospital as defined in section 1886(d)(1)(B) of the Social Security Act.

(N) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act).

(O) An entity receiving funds under title V of the Social Security Act (relating to maternal and child health) for the provision of health services.

(P) An entity receiving funds under subpart I of part B of title XIX of the Public Health Service Act (relating to comprehensive mental health services) for the provision of community mental health services.

(Q) An entity receiving funds under subpart II of such part B (relating to the prevention and treatment of substance abuse) for the provision of treatment services for substance abuse.

(R) An entity that is a Medicare-dependent, small rural hospital (as defined in section 1886(d)(5)(G)(iv) of the Social Security Act).

(S) An entity that is a sole community hospital (as defined in section 1886(d)(5)(D)(iii) of the Social Security Act).

(T) An entity that is classified as a rural referral center under section 1886(d)(5)(C) of the Social Security Act.

(5) REQUIREMENTS FOR COVERED ENTITIES.—

(A) * * *

(B) PROHIBITING RESALE OF DRUGS.—With respect to any covered [outpatient] drug that is subject to an agreement under this subsection, a covered entity shall not resell or otherwise transfer the drug to a person who is not a patient of the entity.

(C) PROHIBITING USE OF GROUP PURCHASING ARRANGEMENTS.—

(i) A hospital described in subparagraph (L), (M), (N), (R), (S), or (T) of paragraph (4) shall not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement, except as permitted or provided pursuant to clause (ii).

(ii) The Secretary shall establish reasonable exceptions to the requirement of clause (i)—

(I) with respect to a covered outpatient drug that is unavailable to be purchased through the program under this section due to a drug shortage problem, manufacturer noncompliance, or any other reason beyond the hospital's control;

(II) to facilitate generic substitution when a generic covered outpatient drug is available at a lower price; and

(III) to reduce in other ways the administrative burdens of managing both inventories of drugs obtained under this section and not under this section, if such exception does not create a duplicate discount problem in violation of subparagraph (A) or a diversion problem in violation of subparagraph (B).

[(C)] *(D)* AUDITING.—A covered entity shall permit the Secretary and the manufacturer of a covered outpatient drug that is subject to an agreement under this subsection with the entity (acting in accordance with procedures established by the Secretary relating to the number, duration, and scope of audits) to audit at the Secretary's or the manufacturer's expense the records of the entity that directly pertain to the entity's compliance with the requirements described in subparagraphs (A) or (B) with respect to drugs of the manufacturer.

[(D)] *(E)* ADDITIONAL SANCTION FOR NONCOMPLIANCE.—If the Secretary finds, after notice and hearing, that a covered entity is in violation of a requirement described in subparagraphs (A) or (B), the covered entity shall be liable to the manufacturer of the covered [outpatient] drug that is the subject of the violation in an amount equal to the reduction in the price of the drug (as described in subparagraph (A)) provided under the agreement between the entity and the manufacturer under this paragraph.

* * * * * * *

(7) CERTIFICATION OF CERTAIN COVERED ENTITIES.—

(A) * * *

(B) INCLUSION OF PURCHASE INFORMATION.—The process developed under subparagraph (A) shall include a require-

ment that an entity applying for certification under this paragraph submit information to the Secretary concerning the amount such entity expended for covered [outpatient] drugs in the preceding year so as to assist the Secretary in evaluating the validity of the entity's subsequent purchases of covered [outpatient] drugs at discounted prices.

(C) CRITERIA.—The Secretary shall make available to all manufacturers of covered [outpatient] drugs a description of the criteria for certification under this paragraph.

* * * * * * *

(9) NOTICE TO MANUFACTURERS.—The Secretary shall notify manufacturers of covered [outpatient] drugs and single State agencies under section 1902(a)(5) of the Social Security Act of the identities of covered entities under this paragraph, and of entities that no longer meet the requirements of paragraph (5) or that are no longer certified pursuant to paragraph (7).

* * * * * * *

(b) OTHER DEFINITIONS.—[In this section, the terms] *In this section:*

(1) IN GENERAL.—The terms "average manufacturer price", "covered outpatient drug", and "manufacturer" have the meaning given such terms in section 1927(k) of the Social Security Act.

(2) COVERED DRUG.—The term "covered drug"—

(A) means a covered outpatient drug (as defined in section 1927(k)(2) of the Social Security Act); and

(B) includes, notwithstanding the section 1927(k)(3)(A) of such Act, a drug used in connection with an inpatient or outpatient service provided by a hospital described in subparagraph (L), (M), (N), (R), (S), or (T) of subsection (a)(4) that is enrolled to participate in the drug discount program under this section.

[(c) REFERENCES TO SOCIAL SECURITY ACT.—Any reference in this section to a provision of the Social Security Act shall be deemed to be a reference to the provision as in effect on the date of the enactment of this section.]

(c) MEDICAID CREDITS ON INPATIENT DRUGS.—

(1) IN GENERAL.—For the cost reporting period covered by the most recently filed Medicare cost report under title XVIII of the Social Security Act , a hospital described in subparagraph (L), (M), (N), (R), (S), or (T) of subsection (a)(4) and enrolled to participate in the drug discount program under this section shall provide to each State under its plan under title XIX of such Act—

(A) a credit on the estimated annual costs to such hospital of single source and innovator multiple source drugs provided to Medicaid beneficiaries for inpatient use; and

(B) a credit on the estimated annual costs to such hospital of noninnovator multiple source drugs provided to Medicaid beneficiaries for inpatient use.

(2) AMOUNT OF CREDITS.—

(A) SINGLE SOURCE AND INNOVATOR MULTIPLE SOURCE DRUGS.—For purposes of paragraph (1)(A)—

(i) the credit under such paragraph shall be equal to the product of—

(I) the annual value of single source and innovator multiple source drugs purchased under this section by the hospital based on the drugs' average manufacturer price;

(II) the estimated percentage of the hospital's drug purchases attributable to Medicaid beneficiaries for inpatient use; and

(III) the minimum rebate percentage described in section 1927(c)(1)(B) of the Social Security Act;

(ii) the reference in clause (i)(I) to the annual value of single source and innovator multiple source drugs purchased under this section by the hospital based on the drugs' average manufacturer price shall be equal to the sum of—

(I) the annual quantity of each single source and innovator multiple source drug purchased during the cost reporting period, multiplied by

(II) the average manufacturer price for that drug;

(iii) the reference in clause (i)(II) to the estimated percentage of the hospital's drug purchases attributable to Medicaid beneficiaries for inpatient use shall be equal to—

(I) the Medicaid inpatient drug charges as reported on the hospital's most recently filed Medicare cost report, divided by

(II) total drug charges reported on the cost report; and

(iv) the terms "single source drug" and "innovator multiple source drug" have the meanings given such terms in section 1927(k)(7) of the Social Security Act.

(B) NONINNOVATOR MULTIPLE SOURCE DRUGS.—For purposes of paragraph (1)(B)—

(i) the credit under such paragraph shall be equal to the product of—

(I) the annual value of noninnovator multiple source drugs purchased under this section by the hospital based on the drugs' average manufacturer price;

(II) the estimated percentage of the hospital's drug purchases attributable to Medicaid beneficiaries for inpatient use; and

(III) the applicable percentage as defined in section 1927(c)(3)(B) of the Social Security Act;

(ii) the reference in clause (i)(I) to the annual value of noninnovator multiple source drugs purchased under this section by the hospital based on the drugs' average manufacturer price shall be equal to the sum of—

(I) the annual quantity of each noninnovator multiple source drug purchased during the cost reporting period, multiplied by

(II) the average manufacturer price for that drug;

(iii) the reference in clause (i)(II) to the estimated percentage of the hospital's drug purchases attributable to Medicaid beneficiaries for inpatient use shall be equal to—

(I) the Medicaid inpatient drug charges as reported on the hospital's most recently filed Medicare cost report, divided by

(II) total drug charges reported on the cost report; and

(iv) the term "noninnovator multiple source drug" has the meaning given such term in section 1927(k)(7) of the Social Security Act.

(3) CALCULATION OF CREDITS.—

(A) IN GENERAL.—Each State calculates credits under paragraph (1) and informs hospitals of amount under section 1927(a)(5)(D) of the Social Security Act.

(B) HOSPITAL PROVISION OF INFORMATION.—Not later than 30 days after the date of the filing of the hospital's most recently filed Medicare cost report, the hospital shall provide the State with the information described in paragraphs (2)(A)(ii) and (2)(B)(ii). With respect to each drug purchased during the cost reporting period, the hospital shall provide the dosage form, strength, package size, date of purchase, and the number of units purchased.

(4) PAYMENT DEADLINE.—The credits provided by a hospital under paragraph (1) shall be paid within 60 days after receiving the information specified in paragraph (3)(A).

(5) OPT OUT.—A hospital shall not be required to provide the Medicaid credit required under paragraph (1) if it can demonstrate to the State that it will lose reimbursement under the State plan resulting from the extension of discounts to inpatient drugs under subsection (b)(2) and that the loss of reimbursement will exceed the amount of the credit otherwise owed by the hospital.

(6) OFFSET AGAINST MEDICAL ASSISTANCE.—Amounts received by a State under this subsection in any quarter shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1903(a)(1) of the Social Security Act.

* * * * * * *

Subpart XI—Health Professional Needs Areas

SEC. 340H. IN GENERAL.

(a) PROGRAM.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall establish a program, to be known as the Frontline Health Providers Loan Repayment Program, to address unmet health care needs in health professional needs areas through loan repayments under section 340I.

(b) DESIGNATION OF HEALTH PROFESSIONAL NEEDS AREAS.—

(1) IN GENERAL.—In this subpart, the term "health professional needs area" means an area, population, or facility that is designated by the Secretary in accordance with paragraph (2).

(2) DESIGNATION.—To be designated by the Secretary as a health professional needs area under this subpart:

(A) In the case of an area, the area must be a rational area for the delivery of health services.

(B) The area, population, or facility must have, in one or more health disciplines, specialties, or subspecialties for the population served, as determined by the Secretary—

(i) insufficient capacity of health professionals; or

(ii) high needs for health services, including services to address health disparities.

(C) With respect to the delivery of primary health services, the area, population, or facility must not include a health professional shortage area (as designated under section 332), except that the area, population, or facility may include such a health professional shortage area in which there is an unmet need for such services.

(c) ELIGIBILITY.—To be eligible to participate in the Program, an individual shall—

(1) hold a degree in a course of study or program (approved by the Secretary) from a school defined in section 799B(1)(A) (other than a school of public health);

(2) hold a degree in a course of study or program (approved by the Secretary) from a school or program defined in subparagraph (C), (D), or (E)(4) of section 799B(1), as designated by the Secretary;

(3) be enrolled as a full-time student—

(A) in a school or program defined in subparagraph (C), (D), or (E)(4) of section 799B(1), as designated by the Secretary, or a school described in paragraph (1); and

(B) in the final year of a course of study or program, offered by such school or program and approved by the Secretary, leading to a degree in a discipline referred to in subparagraph (A) (other than a graduate degree in public health), (C), (D), or (E)(4) of section 799B(1);

(4) be a practitioner described in section 1842(b)(18)(C) or 1848(k)(3)(B)(iii) or (iv) of the Social Security Act; or

(5) be a practitioner in the field of respiratory therapy, medical technology, or radiologic technology.

(d) DEFINITIONS.—In this subpart:

(1) The term "health disparities" has the meaning given to the term in section 3171.

(2) The term "primary health services" has the meaning given to such term in section 331(a)(3)(D).

SEC. 340I. LOAN REPAYMENTS.

(a) LOAN REPAYMENTS.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall enter into contracts with individuals under which—

(1) the individual agrees—

(A) to serve as a full-time primary health services provider or as a full-time or part-time provider of other health

services for a period of time equal to 2 years or such longer period as the individual may agree to;

(B) to serve in a health professional needs area in a health discipline, specialty, or a subspecialty for which the area, population, or facility is designated as a health professional needs area under section 340H; and

(C) in the case of an individual described in section 340H(c)(3) who is in the final year of study and who has accepted employment as a primary health services provider or provider of other health services in accordance with subparagraphs (A) and (B), to complete the education or training and maintain an acceptable level of academic standing (as determined by the educational institution offering the course of study or training); and

(2) the Secretary agrees to pay, for each year of such service, an amount on the principal and interest of the undergraduate or graduate educational loans (or both) of the individual that is not more than 50 percent of the average award made under the National Health Service Corps Loan Repayment Program under subpart III in that year.

(b) PRACTICE SETTING.—A contract entered into under this section shall allow the individual receiving the loan repayment to satisfy the service requirement described in subsection (a)(1) through employment in a solo or group practice, a clinic, an accredited public or private nonprofit hospital, or any other health care entity, as deemed appropriate by the Secretary.

(c) APPLICATION OF CERTAIN PROVISIONS.—The provisions of subpart III of part D shall, except as inconsistent with this section, apply to the loan repayment program under this subpart in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program established under section 338B.

(d) INSUFFICIENT NUMBER OF APPLICANTS.—If there are an insufficient number of applicants for loan repayments under this section to obligate all appropriated funds, the Secretary shall transfer the unobligated funds to the National Health Service Corps for the purpose of recruiting applicants and entering into contracts with individuals so as to ensure a sufficient number of participants in the National Health Service Corps for the following year.

SEC. 340J. REPORT.

The Secretary shall submit to the Congress an annual report on the program carried out under this subpart.

SEC. 340K. ALLOCATION.

Of the amount of funds obligated under this subpart each fiscal year for loan repayments—

(1) 90 percent shall be for physicians and other health professionals providing primary health services; and

(2) 10 percent shall be for health professionals not described in paragraph (1).

Subpart XII—Public Health Workforce

SEC. 340L. PUBLIC HEALTH WORKFORCE CORPS.

(a) ESTABLISHMENT.—There is established, within the Service, the Public Health Workforce Corps (in this subpart referred to as the "Corps"), for the purpose of ensuring an adequate supply of public health professionals throughout the Nation. The Corps shall consist of—

(1) such officers of the Regular and Reserve Corps of the Service as the Secretary may designate;

(2) such civilian employees of the United States as the Secretary may appoint; and

(3) such other individuals who are not employees of the United States.

(b) ADMINISTRATION.—Except as provided in subsection (c), the Secretary shall carry out this subpart acting through the Administrator of the Health Resources and Services Administration.

(c) PLACEMENT AND ASSIGNMENT.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall develop a methodology for placing and assigning Corps participants as public health professionals. Such methodology may allow for placing and assigning such participants in State, local, and tribal health departments and Federally qualified health centers (as defined in section 1861(aa)(4) of the Social Security Act).

(d) APPLICATION OF CERTAIN PROVISIONS.—The provisions of subpart II shall, except as inconsistent with this subpart, apply to the Public Health Workforce Corps in the same manner and to the same extent as such provisions apply to the National Health Service Corps established under section 331.

(e) REPORT.—The Secretary shall submit to the Congress an annual report on the programs carried out under this subpart.

SEC. 340M. PUBLIC HEALTH WORKFORCE SCHOLARSHIP PROGRAM.

(a) ESTABLISHMENT.—The Secretary shall establish the Public Health Workforce Scholarship Program (referred to in this section as the "Program") for the purpose described in section 340L(a).

(b) ELIGIBILITY.—To be eligible to participate in the Program, an individual shall—

(1)(A) be accepted for enrollment, or be enrolled, as a full-time or part-time student in a course of study or program (approved by the Secretary) at an accredited graduate school or program of public health; or

(B) have demonstrated expertise in public health and be accepted for enrollment, or be enrolled, as a full-time or part-time student in a course of study or program (approved by the Secretary) at—

(i) an accredited graduate school or program of nursing; health administration, management, or policy; preventive medicine; laboratory science; veterinary medicine; or dental medicine; or

(ii) another accredited graduate school or program, as deemed appropriate by Secretary;

(2) be eligible for, or hold, an appointment as a commissioned officer in the Regular or Reserve Corps of the Service or be eligible for selection for civilian service in the Corps; and

(3) sign and submit to the Secretary a written contract (described in subsection (c)) to serve full-time as a public health professional, upon the completion of the course of study or program involved, for the period of obligated service described in subsection (c)(2)(E).

(c) CONTRACT.—The written contract between the Secretary and an individual under subsection (b)(3) shall contain—

(1) an agreement on the part of the Secretary that the Secretary will—

(A) provide the individual with a scholarship for a period of years (not to exceed 4 academic years) during which the individual shall pursue an approved course of study or program to prepare the individual to serve in the public health workforce; and

(B) accept (subject to the availability of appropriated funds) the individual into the Corps;

(2) an agreement on the part of the individual that the individual will—

(A) accept provision of such scholarship to the individual;

(B) maintain full-time or part-time enrollment in the approved course of study or program described in subsection (b)(1) until the individual completes that course of study or program;

(C) while enrolled in the approved course of study or program, maintain an acceptable level of academic standing (as determined by the educational institution offering such course of study or program);

(D) if applicable, complete a residency or internship; and

(E) serve full-time as a public health professional for a period of time equal to the greater of—

(i) 1 year for each academic year for which the individual was provided a scholarship under the Program; or

(ii) 2 years; and

(3) an agreement by both parties as to the nature and extent of the scholarship assistance, which may include—

(A) payment of reasonable educational expenses of the individual, including tuition, fees, books, equipment, and laboratory expenses; and

(B) payment of a stipend of not more than $1,269 (plus, beginning with fiscal year 2011, an amount determined by the Secretary on an annual basis to reflect inflation) per month for each month of the academic year involved, with the dollar amount of such a stipend determined by the Secretary taking into consideration whether the individual is enrolled full-time or part-time.

(d) APPLICATION OF CERTAIN PROVISIONS.—The provisions of subpart III shall, except as inconsistent with this subpart, apply to the scholarship program under this section in the same manner and to the same extent as such provisions apply to the National Health Service Corps Scholarship Program established under section 338A.

SEC. 340N. PUBLIC HEALTH WORKFORCE LOAN REPAYMENT PROGRAM.

(a) ESTABLISHMENT.—The Secretary shall establish the Public Health Workforce Loan Repayment Program (referred to in this section as the "Program") for the purpose described in section 340L(a).

(b) ELIGIBILITY.—To be eligible to participate in the Program, an individual shall—

(1)(A) have a graduate degree from an accredited school or program of public health;

(B) have demonstrated expertise in public health and have a graduate degree in a course of study or program (approved by the Secretary) from—

(i) an accredited school or program of nursing; health administration, management, or policy; preventive medicine; laboratory science; veterinary medicine; or dental medicine; or

(ii) another accredited school or program approved by the Secretary; or

(C) be enrolled as a full-time or part-time student in the final year of a course of study or program (approved by the Secretary) offered by a school or program described in subparagraph (A) or (B), leading to a graduate degree;

(2) be eligible for, or hold, an appointment as a commissioned officer in the Regular or Reserve Corps of the Service or be eligible for selection for civilian service in the Corps;

(3) if applicable, complete a residency or internship; and

(4) sign and submit to the Secretary a written contract (described in subsection (c)) to serve full-time as a public health professional for the period of obligated service described in subsection (c)(2).

(c) CONTRACT.—The written contract between the Secretary and an individual under subsection (b)(4) shall contain—

(1) an agreement by the Secretary to repay on behalf of the individual loans incurred by the individual in the pursuit of the relevant public health workforce educational degree in accordance with the terms of the contract;

(2) an agreement by the individual to serve full-time as a public health professional for a period of time equal to 2 years or such longer period as the individual may agree to; and

(3) in the case of an individual described in subsection (b)(1)(C) who is in the final year of study and who has accepted employment as a public health professional, in accordance with section 340L(c), an agreement on the part of the individual to complete the education or training, maintain an acceptable level of academic standing (as determined by the educational institution offering the course of study or training), and serve the period of obligated service described in paragraph (2).

(d) PAYMENTS.—

(1) IN GENERAL.—A loan repayment provided for an individual under a written contract under the Program shall consist of payment, in accordance with paragraph (2), on behalf of the individual of the principal, interest, and related expenses on government and commercial loans received by the individual regarding the undergraduate or graduate education of the individual (or both), which loans were made for reasonable edu-

cational expenses, including tuition, fees, books, equipment, and laboratory expenses, incurred by the individual.

(2) PAYMENTS FOR YEARS SERVED.—

(A) IN GENERAL.—For each year of obligated service that an individual contracts to serve under subsection (c), the Secretary may pay up to $35,000 (plus, beginning with fiscal year 2012, an amount determined by the Secretary on an annual basis to reflect inflation) on behalf of the individual for loans described in paragraph (1).

(B) REPAYMENT SCHEDULE.—Any arrangement made by the Secretary for the making of loan repayments in accordance with this subsection shall provide that any repayments for a year of obligated service shall be made no later than the end of the fiscal year in which the individual completes such year of service.

(e) APPLICATION OF CERTAIN PROVISIONS.—The provisions of subpart III shall, except as inconsistent with this subpart, apply to the loan repayment program under this section in the same manner and to the same extent as such provisions apply to the National Health Service Corps Loan Repayment Program established under section 338B.

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PART F—LICENSING—BIOLOGICAL PRODUCTS AND CLINICAL LABORATORIES

Subpart 1—Biological Products

REGULATION OF BIOLOGICAL PRODUCTS

SEC. 351. (a)(1) No person shall introduce or deliver for introduction into interstate commerce any biological product unless—

(A) a biologics license *under this subsection or subsection (k)* is in effect for the biological product; and

* * * * * * *

(i) ❚In this section, the term "biological product" means❚ *In this section:*

(1) The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, *protein (except any chemically synthesized polypeptide),* or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

(2) The term "biosimilar" or "biosimilarity", in reference to a biological product that is the subject of an application under subsection (k), means—

(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and

(B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

(3) The term "interchangeable" or "interchangeability", in reference to a biological product that is shown to meet the stand-

ards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

(4) The term "reference product" means the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k).

* * * * * * *

(k) LICENSURE OF BIOLOGICAL PRODUCTS AS BIOSIMILAR OR INTERCHANGEABLE.—

(1) IN GENERAL.—Any person may submit an application for licensure of a biological product under this subsection.

(2) CONTENT.—

(A) IN GENERAL.—

(i) REQUIRED INFORMATION.—An application submitted under this subsection shall include information demonstrating that—

(I) the biological product is biosimilar to a reference product based upon data derived from—

(aa) analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;

(bb) animal studies (including the assessment of toxicity); and

(cc) a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and potency in 1 or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product;

(II) the biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product;

(III) the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product;

(IV) the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product; and

(V) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

(ii) DETERMINATION BY SECRETARY.—The Secretary may determine, in the Secretary's discretion, that an

element described in clause (i)(I) is unnecessary in an application submitted under this subsection.

(iii) ADDITIONAL INFORMATION.—An application submitted under this subsection—

(I) shall include publicly available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent; and

(II) may include any additional information in support of the application, including publicly available information with respect to the reference product or another biological product.

(B) INTERCHANGEABILITY.—An application (or a supplement to an application) submitted under this subsection may include information demonstrating that the biological product meets the standards described in paragraph (4).

(3) EVALUATION BY SECRETARY.—Upon review of an application (or a supplement to an application) submitted under this subsection, the Secretary shall license the biological product under this subsection if—

(A) the Secretary determines that the information submitted in the application (or the supplement) is sufficient to show that the biological product—

(i) is biosimilar to the reference product; or

(ii) meets the standards described in paragraph (4), and therefore is interchangeable with the reference product; and

(B) the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

(4) SAFETY STANDARDS FOR DETERMINING INTERCHANGEABILITY.—Upon review of an application submitted under this subsection or any supplement to such application, the Secretary shall determine the biological product to be interchangeable with the reference product if the Secretary determines that the information submitted in the application (or a supplement to such application) is sufficient to show that—

(A) the biological product—

(i) is biosimilar to the reference product; and

(ii) can be expected to produce the same clinical result as the reference product in any given patient; and

(B) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

(5) GENERAL RULES.—

(A) ONE REFERENCE PRODUCT PER APPLICATION.—A biological product, in an application submitted under this subsection, may not be evaluated against more than 1 reference product.

(B) REVIEW.—An application submitted under this subsection shall be reviewed by the division within the Food and Drug Administration that is responsible for the review

and approval of the application under which the reference product is licensed.

(C) RISK EVALUATION AND MITIGATION STRATEGIES.—The authority of the Secretary with respect to risk evaluation and mitigation strategies under the Federal Food, Drug, and Cosmetic Act shall apply to biological products licensed under this subsection in the same manner as such authority applies to biological products licensed under subsection (a).

(D) RESTRICTIONS ON BIOLOGICAL PRODUCTS CONTAINING DANGEROUS INGREDIENTS.—If information in an application submitted under this subsection, in a supplement to such an application, or otherwise available to the Secretary shows that a biological product—

(i) is, bears, or contains a select agent or toxin listed in section 73.3 or 73.4 of title 42, section 121.3 or 121.4 of title 9, or section 331.3 of title 7, Code of Federal Regulations (or any successor regulations); or

(ii) is, bears, or contains a controlled substance in schedule I or II of section 202 of the Controlled Substances Act, as listed in part 1308 of title 21, Code of Federal Regulations (or any successor regulations);

the Secretary shall not license the biological product under this subsection unless the Secretary determines, after consultation with appropriate national security and drug enforcement agencies, that there would be no increased risk to the security or health of the public from licensing such biological product under this subsection.

(6) EXCLUSIVITY FOR FIRST INTERCHANGEABLE BIOLOGICAL PRODUCT.—Upon review of an application submitted under this subsection relying on the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, the Secretary shall not make a determination under paragraph (4) that the second or subsequent biological product is interchangeable for any condition of use until the earlier of—

(A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;

(B) 18 months after—

(i) a final court decision on all patents in suit in an action instituted under subsection (l)(5) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(ii) the dismissal with or without prejudice of an action instituted under subsection (l)(5) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

(C)(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (l)(5) and such litigation is still ongoing within such 42-month period; or

(ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued under subsection (l)(5).

For purposes of this paragraph, the term "final court decision" means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken.

(7) EXCLUSIVITY FOR REFERENCE PRODUCT.—

(A) EFFECTIVE DATE OF BIOSIMILAR APPLICATION APPROVAL.—Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).

(B) FILING PERIOD.—An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a).

(C) FIRST LICENSURE.—Subparagraphs (A) and (B) shall not apply to a license for or approval of—

(i) a supplement for the biological product that is the reference product; or

(ii) a subsequent application filed by the same sponsor or manufacturer of the biological product that is the reference product (or a licensor, predecessor in interest, or other related entity) for—

(I) a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

(II) a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

(8) PEDIATRIC STUDIES.—

(A) EXCLUSIVITY.—If, before or after licensure of the reference product under subsection (a) of this section, the Secretary determines that information relating to the use of such product in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the applicant or holder of the approved application agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act the period referred to in paragraph (7)(A) of this subsection is deemed to be 12 years and 6 months rather than 12 years.

(B) EXCEPTION.—The Secretary shall not extend the period referred to in subparagraph (A) of this paragraph if the determination under section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act is made later than 9 months prior to the expiration of such period.

(C) APPLICATION OF CERTAIN PROVISIONS.—The provisions of subsections (a), (d), (e), (f), (h), (j), (k), and (l) of section 505A of the Federal Food, Drug, and Cosmetic Act shall apply with respect to the extension of a period under subparagraph (A) of this paragraph to the same extent and in the same manner as such provisions apply with respect to the extension of a period under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act.

(9) GUIDANCE DOCUMENTS.—

(A) IN GENERAL.—The Secretary may, after opportunity for public comment, issue guidance in accordance, except as provided in subparagraph (B)(i), with section 701(h) of the Federal Food, Drug, and Cosmetic Act with respect to the licensure of a biological product under this subsection. Any such guidance may be general or specific.

(B) PUBLIC COMMENT.—

(i) IN GENERAL.—The Secretary shall provide the public an opportunity to comment on any proposed guidance issued under subparagraph (A) before issuing final guidance.

(ii) INPUT REGARDING MOST VALUABLE GUIDANCE.—The Secretary shall establish a process through which the public may provide the Secretary with input regarding priorities for issuing guidance.

(C) NO REQUIREMENT FOR APPLICATION CONSIDERATION.—The issuance (or non-issuance) of guidance under subparagraph (A) shall not preclude the review of, or action on, an application submitted under this subsection.

(D) REQUIREMENT FOR PRODUCT CLASS-SPECIFIC GUIDANCE.—If the Secretary issues product class-specific guidance under subparagraph (A), such guidance shall include a description of—

(i) the criteria that the Secretary will use to determine whether a biological product is highly similar to a reference product in such product class; and

(ii) the criteria, if available, that the Secretary will use to determine whether a biological product meets the standards described in paragraph (4).

(E) CERTAIN PRODUCT CLASSES.—

(i) GUIDANCE.—The Secretary may indicate in a guidance document that the science and experience, as of the date of such guidance, with respect to a product or product class (not including any recombinant protein) does not allow approval of an application for a license as provided under this subsection for such product or product class.

(ii) MODIFICATION OR REVERSAL.—The Secretary may issue a subsequent guidance document under subparagraph (A) to modify or reverse a guidance document under clause (i).

(iii) NO EFFECT ON ABILITY TO DENY LICENSE.—Clause (i) shall not be construed to require the Secretary to approve a product with respect to which the Secretary has not indicated in a guidance document

that the science and experience, as described in clause (i), does not allow approval of such an application.

(10) NAMING.—The Secretary shall ensure that the labeling and packaging of each biological product licensed under this subsection bears a name that uniquely identifies the biological product and distinguishes it from the reference product and any other biological products licensed under this subsection following evaluation against such reference product.

(l) PATENT NOTICES; RELATIONSHIP TO FINAL APPROVAL.—

(1) DEFINITIONS.—For the purposes of this subsection, the term—

(A) "biosimilar product" means the biological product that is the subject of the application under subsection (k);

(B) "relevant patent" means a patent that—

(i) expires after the date specified in subsection (k)(7)(A) that applies to the reference product; and

(ii) could reasonably be asserted against the applicant due to the unauthorized making, use, sale, or offer for sale within the United States, or the importation into the United States of the biosimilar product, or materials used in the manufacture of the biosimilar product, or due to a use of the biosimilar product in a method of treatment that is indicated in the application;

(C) "reference product sponsor" means the holder of an approved application or license for the reference product; and

(D) "interested third party" means a person other than the reference product sponsor that owns a relevant patent, or has the right to commence or participate in an action for infringement of a relevant patent.

(2) HANDLING OF CONFIDENTIAL INFORMATION.—Any entity receiving confidential information pursuant to this subsection shall designate one or more individuals to receive such information. Each individual so designated shall execute an agreement in accordance with regulations promulgated by the Secretary. The regulations shall require each such individual to take reasonable steps to maintain the confidentiality of information received pursuant to this subsection and use the information solely for purposes authorized by this subsection. The obligations imposed on an individual who has received confidential information pursuant to this subsection shall continue until the individual returns or destroys the confidential information, a court imposes a protective order that governs the use or handling of the confidential information, or the party providing the confidential information agrees to other terms or conditions regarding the handling or use of the confidential information.

(3) PUBLIC NOTICE BY SECRETARY.—Within 30 days of acceptance by the Secretary of an application filed under subsection (k), the Secretary shall publish a notice identifying—

(A) the reference product identified in the application; and

(B) the name and address of an agent designated by the applicant to receive notices pursuant to paragraph (4)(B).

(4) EXCHANGES CONCERNING PATENTS.—

(A) EXCHANGES WITH REFERENCE PRODUCT SPONSOR.—

(i) Within 30 days of the date of acceptance of the application by the Secretary, the applicant shall provide the reference product sponsor with a copy of the application and information concerning the biosimilar product and its production. This information shall include a detailed description of the biosimilar product, its method of manufacture, and the materials used in the manufacture of the product.

(ii) Within 60 days of the date of receipt of the information required to be provided under clause (i), the reference product sponsor shall provide to the applicant a list of relevant patents owned by the reference product sponsor, or in respect of which the reference product sponsor has the right to commence an action of infringement or otherwise has an interest in the patent as such patent concerns the biosimilar product.

(iii) If the reference product sponsor is issued or acquires an interest in a relevant patent after the date on which the reference product sponsor provides the list required by clause (ii) to the applicant, the reference product sponsor shall identify that patent to the applicant within 30 days of the date of issue of the patent, or the date of acquisition of the interest in the patent, as applicable.

(B) EXCHANGES WITH INTERESTED THIRD PARTIES.—

(i) At any time after the date on which the Secretary publishes a notice for an application under paragraph (3), any interested third party may provide notice to the designated agent of the applicant that the interested third party owns or has rights under 1 or more patents that may be relevant patents. The notice shall identify at least 1 patent and shall designate an individual who has executed an agreement in accordance with paragraph (2) to receive confidential information from the applicant.

(ii) Within 30 days of the date of receiving notice pursuant to clause (i), the applicant shall send to the individual designated by the interested third party the information specified in subparagraph (A)(i), unless the applicant and interested third party otherwise agree.

(iii) Within 90 days of the date of receiving information pursuant to clause (ii), the interested third party shall provide to the applicant a list of relevant patents which the interested third party owns, or in respect of which the interested third party has the right to commence or participate in an action for infringement.

(iv) If the interested third party is issued or acquires an interest in a relevant patent after the date on which the interested third party provides the list required by clause (iii), the interested third party shall identify that patent within 30 days of the date of issue of the patent, or the date of acquisition of the interest in the patent, as applicable.

(C) IDENTIFICATION OF BASIS FOR INFRINGEMENT.—For any patent identified under clause (ii) or (iii) of subparagraph (A) or under clause (iii) or (iv) of subparagraph (B), the reference product sponsor or the interested third party, as applicable—

(i) shall explain in writing why the sponsor or the interested third party believes the relevant patent would be infringed by the making, use, sale, or offer for sale within the United States, or importation into the United States, of the biosimilar product or by a use of the biosimilar product in treatment that is indicated in the application;

(ii) may specify whether the relevant patent is available for licensing; and

(iii) shall specify the number and date of expiration of the relevant patent.

(D) CERTIFICATION BY APPLICANT CONCERNING IDENTIFIED RELEVANT PATENTS.—Not later than 45 days after the date on which a patent is identified under clause (ii) or (iii) of subparagraph (A) or under clause (iii) or (iv) of subparagraph (B), the applicant shall send a written statement regarding each identified patent to the party that identified the patent. Such statement shall either—

(i) state that the applicant will not commence marketing of the biosimilar product and has requested the Secretary to not grant final approval of the application before the date of expiration of the noticed patent; or

(ii) provide a detailed written explanation setting forth the reasons why the applicant believes—

(I) the making, use, sale, or offer for sale within the United States, or the importation into the United States, of the biosimilar product, or the use of the biosimilar product in a treatment indicated in the application, would not infringe the patent; or

(II) the patent is invalid or unenforceable.

(5) ACTION FOR INFRINGEMENT INVOLVING REFERENCE PRODUCT SPONSOR.—If an action for infringement concerning a relevant patent identified by the reference product sponsor under clause (ii) or (iii) of paragraph (4)(A), or by an interested third party under clause (iii) or (iv) of paragraph (4)(B), is brought within 60 days of the date of receipt of a statement under paragraph (4)(D)(ii), and the court in which such action has been commenced determines the patent is infringed prior to the date applicable under subsection (k)(7)(A) or (k)(8), the Secretary shall make approval of the application effective on the day after the date of expiration of the patent that has been found to be infringed. If more than one such patent is found to be infringed by the court, the approval of the application shall be made effective on the day after the date that the last such patent expires.

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PART P—ADDITIONAL PROGRAMS

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SEC. 399V. GRANTS TO PROMOTE POSITIVE HEALTH BEHAVIORS AND OUTCOMES.

(a) GRANTS AUTHORIZED.—The Secretary, in collaboration with the Director of the Centers for Disease Control and Prevention and other Federal officials determined appropriate by the Secretary, is authorized to award grants to eligible entities to promote positive health behaviors for populations in medically underserved communities through the use of community health workers.

(b) USE OF FUNDS.—Grants awarded under subsection (a) shall be used to support community health workers—

(1) to educate, guide, and provide outreach in a community setting regarding health problems prevalent in medically underserved communities, especially racial and ethnic minority populations;

(2) to educate, guide, and provide experiential learning opportunities that target behavioral risk factors including—

(A) poor nutrition;

(B) physical inactivity;

(C) being overweight or obese;

(D) tobacco use;

(E) alcohol and substance use;

(F) injury and violence;

(G) risky sexual behavior;

(H) untreated mental health problems;

(I) untreated dental and oral health problems; and

(J) understanding informed consent;

(3) to educate and provide guidance regarding effective strategies to promote positive health behaviors within the family;

(4) to educate and provide outreach regarding enrollment in health insurance including the State Children's Health Insurance Program under title XXI of the Social Security Act, Medicare under title XVIII of such Act, and Medicaid under title XIX of such Act;

(5) to educate and refer underserved populations to appropriate health care agencies and community-based programs and organizations in order to increase access to quality health care services, including preventive health services, and to eliminate duplicative care; or

(6) to educate, guide, and provide home visitation services regarding maternal health and prenatal care.

(c) APPLICATION.—

(1) IN GENERAL.—Each eligible entity that desires to receive a grant under subsection (a) shall submit an application to the Secretary, at such time, in such manner, and accompanied by such information as the Secretary may require.

(2) CONTENTS.—Each application submitted pursuant to paragraph (1) shall—

(A) describe the activities for which assistance is sought under this section;

(B) contain an assurance that, with respect to each community health worker program receiving funds under the grant, such program will provide training and supervision

to community health workers to enable such workers to provide authorized program services;

(C) contain an assurance that the applicant will evaluate the effectiveness of community health worker programs receiving funds under the grant;

(D) contain an assurance that each community health worker program receiving funds under the grant will provide services in the cultural context most appropriate for the individuals served by the program;

(E) contain a plan to document and disseminate project descriptions and results to other States and organizations as identified by the Secretary; and

(F) describe plans to enhance the capacity of individuals to utilize health services and health-related social services under Federal, State, and local programs by—

(i) assisting individuals in establishing eligibility under the programs and in receiving the services or other benefits of the programs; and

(ii) providing other services as the Secretary determines to be appropriate, that may include transportation and translation services.

(d) PRIORITY.—In awarding grants under subsection (a), the Secretary shall give priority to applicants that—

(1) propose to target geographic areas—

(A) with a high percentage of residents who are eligible for health insurance but are uninsured or underinsured;

(B) with a high percentage of residents who suffer from chronic diseases including pulmonary conditions, hypertension, heart disease, mental disorders, diabetes, and asthma; and

(C) with a high infant mortality rate;

(2) have experience in providing health or health-related social services to individuals who are underserved with respect to such services; and

(3) have documented community activity and experience with community health workers.

(e) COLLABORATION WITH ACADEMIC INSTITUTIONS.—The Secretary shall encourage community health worker programs receiving funds under this section to collaborate with academic institutions, especially those that graduate a disproportionate number of health and health care students from underrepresented racial and ethnic minority backgrounds. Nothing in this section shall be construed to require such collaboration.

(f) EVIDENCE-BASED INTERVENTIONS.—The Secretary shall encourage community health worker programs receiving funding under this section to implement an outcome-based payment system that rewards community health workers for connecting underserved populations with the most appropriate services at the most appropriate time. Nothing in this section shall be construed to require such payment.

(g) QUALITY ASSURANCE AND COST EFFECTIVENESS.—The Secretary shall establish guidelines for assuring the quality of the training and supervision of community health workers under the programs funded under this section and for assuring the cost-effectiveness of such programs.

(h) MONITORING.—The Secretary shall monitor community health worker programs identified in approved applications under this section and shall determine whether such programs are in compliance with the guidelines established under subsection (g).

(i) TECHNICAL ASSISTANCE.—The Secretary may provide technical assistance to community health worker programs identified in approved applications under this section with respect to planning, developing, and operating programs under the grant.

(j) REPORT TO CONGRESS.—

(1) IN GENERAL.—Not later than 4 years after the date on which the Secretary first awards grants under subsection (a), the Secretary shall submit to Congress a report regarding the grant project.

(2) CONTENTS.—The report required under paragraph (1) shall include the following:

(A) A description of the programs for which grant funds were used.

(B) The number of individuals served under such programs.

(C) An evaluation of—

(i) the effectiveness of such programs;

(ii) the cost of such programs; and

(iii) the impact of the programs on the health outcomes of the community residents.

(D) Recommendations for sustaining the community health worker programs developed or assisted under this section.

(E) Recommendations regarding training to enhance career opportunities for community health workers.

(k) DEFINITIONS.—In this section:

(1) COMMUNITY HEALTH WORKER.—The term "community health worker" means an individual who promotes health or nutrition within the community in which the individual resides—

(A) by serving as a liaison between communities and health care agencies;

(B) by providing guidance and social assistance to community residents;

(C) by enhancing community residents' ability to effectively communicate with health care providers;

(D) by providing culturally and linguistically appropriate health or nutrition education;

(E) by advocating for individual and community health, including oral and mental, or nutrition needs; and

(F) by providing referral and followup services or otherwise coordinating care.

(2) COMMUNITY SETTING.—The term "community setting" means a home or a community organization located in the neighborhood in which a participant resides.

(3) MEDICALLY UNDERSERVED COMMUNITY.—The term "medically underserved community" means a community identified by a State, United States territory or possession, or federally recognized Indian tribe—

(A) that has a substantial number of individuals who are members of a medically underserved population, as defined by section 330(b)(3); and

(B) a significant portion of which is a health professional shortage area as designated under section 332.

(4) SUPPORT.—The term "support" means the provision of training, supervision, and materials needed to effectively deliver the services described in subsection (b), reimbursement for services, and other benefits.

(5) ELIGIBLE ENTITY.—The term "eligible entity" means a public or nonprofit private entity (including a State or public subdivision of a State, a public health department, or a federally qualified health center), or a consortium of any of such entities, located in the United States or territory thereof.

(l) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $30,000,000 for each of fiscal years 2010, 2011, 2012, 2013, and 2014.

PART Q—PROGRAMS TO IMPROVE THE HEALTH OF CHILDREN

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SEC. 399Z–1. SCHOOL-BASED HEALTH CLINICS.

(a) PROGRAM.—The Secretary shall establish a school-based health clinic program consisting of awarding grants to eligible entities to support the operation of school-based health clinics (referred to in this section as "SBHCs").

(b) ELIGIBILITY.—To be eligible for a grant under this section, an entity shall—

(1) be an SBHC (as defined in subsection (l)(4)); and

(2) submit an application at such time, in such manner, and containing such information as the Secretary may require, including at a minimum—

(A) evidence that the applicant meets all criteria necessary to be designated as an SBHC;

(B) evidence of local need for the services to be provided by the SBHC;

(C) an assurance that—

(i) SBHC services will be provided in accordance with Federal, State, and local laws;

(ii) the SBHC has established and maintains collaborative relationships with other health care providers in the catchment area of the SBHC;

(iii) the SBHC will provide onsite access during the academic day when school is in session and has an established network of support and access to services with backup health providers when the school or SBHC is closed;

(iv) the SBHC will be integrated into the school environment and will coordinate health services with appropriate school personnel and other community providers co-located at the school; and

(v) the SBHC sponsoring facility assumes all responsibility for the SBHC administration, operations, and oversight; and

(D) such other information as the Secretary may require.

(c) USE OF FUNDS.—Funds awarded under a grant under this section—

(1) may be used for—

(A) providing training related to the provision of comprehensive primary health services and additional health services;

(B) the management and operation of SBHC programs;

(C) the payment of salaries for health professionals and other appropriate SBHC personnel; and

(2) may not be used to provide abortions.

(d) CONSIDERATION OF NEED.—In determining the amount of a grant under this section, the Secretary shall take into consideration—

(1) the financial need of the SBHC;

(2) State, local, or other sources of funding provided to the SBHC; and

(3) other factors as determined appropriate by the Secretary.

(e) PREFERENCES.—In awarding grants under this section, the Secretary shall give preference to SBHCs that have a demonstrated record of service to the following:

(1) A high percentage of medically underserved children and adolescents.

(2) Communities or populations in which children and adolescents have difficulty accessing health and mental health services.

(3) Communities with high percentages of children and adolescents who are uninsured, underinsured, or eligible for medical assistance under Federal or State health benefits programs (including titles XIX and XXI of the Social Security Act).

(f) MATCHING REQUIREMENT.—The Secretary may award a grant to an SBHC under this section only if the SBHC agrees to provide, from non-Federal sources, an amount equal to 20 percent of the amount of the grant (which may be provided in cash or in kind) to carry out the activities supported by the grant.

(g) SUPPLEMENT, NOT SUPPLANT.—The Secretary may award a grant to an SBHC under this section only if the SBHC demonstrates to the satisfaction of the Secretary that funds received through the grant will be expended only to supplement, and not supplant, non-Federal and Federal funds otherwise available to the SBHC for operation of the SBHC (including each activity described in paragraph (1) or (2) of subsection (c)).

(h) PAYOR OF LAST RESORT.—The Secretary may award a grant to an SBHC under this section only if the SBHC demonstrates to the satisfaction of the Secretary that funds received through the grant will not be expended for any activity to the extent that payment has been made, or can reasonably be expected to be made—

(1) under any insurance policy;

(2) under any Federal or State health benefits program (including titles XIX and XXI of the Social Security Act); or

(3) by an entity which provides health services on a prepaid basis.

(i) REGULATIONS REGARDING REIMBURSEMENT FOR HEALTH SERVICES.—The Secretary shall issue regulations regarding the reimbursement for health services provided by SBHCs to individuals eligible to receive such services through the program under this section, including reimbursement under any insurance policy or any Federal or State health benefits program (including titles XIX and XXI of the Social Security Act).

(j) TECHNICAL ASSISTANCE.—The Secretary shall provide (either directly or by grant or contract) technical and other assistance to SBHCs to assist such SBHCs to meet the requirements of this section. Such assistance may include fiscal and program management assistance, training in fiscal and program management, operational and administrative support, and the provision of information to the SBHCs of the variety of resources available under this title and how those resources can be best used to meet the health needs of the communities served by the SBHCs.

(k) EVALUATION; REPORT.—The Secretary shall—

(1) develop and implement a plan for evaluating SBHCs and monitoring quality performances under the awards made under this section; and

(2) submit to the Congress on an annual basis a report on the program under this section.

(l) DEFINITIONS.—In this section:

(1) COMPREHENSIVE PRIMARY HEALTH SERVICES.—The term "comprehensive primary health services" means the core services offered by SBHCs, which shall include the following:

(A) PHYSICAL.—Comprehensive health assessments, diagnosis, and treatment of minor, acute, and chronic medical conditions and referrals to, and followup for, specialty care.

(B) MENTAL HEALTH.—Mental health assessments, crisis intervention, counseling, treatment, and referral to a continuum of services including emergency psychiatric care, community support programs, inpatient care, and outpatient programs.

(C) OPTIONAL SERVICES.—Additional services, which may include oral health, social, and age-appropriate health education services, including nutritional counseling.

(2) MEDICALLY UNDERSERVED CHILDREN AND ADOLESCENTS.—The term "medically underserved children and adolescents" means a population of children and adolescents who are residents of an area designated by the Secretary as an area with a shortage of personal health services and health infrastructure for such children and adolescents.

(3) SCHOOL-BASED HEALTH CLINIC.—The term "school-based health clinic" means a health clinic that—

(A) is located in, or is adjacent to, a school facility of a local educational agency;

(B) is organized through school, community, and health provider relationships;

(C) is administered by a sponsoring facility;

(D) provides, at a minimum, comprehensive primary health services during school hours to children and adolescents by health professionals in accordance with State and local laws and regulations, established standards, and community practice; and

(E) does not perform abortion services.

(4) SPONSORING FACILITY.—The term "sponsoring facility" is—

(A) a hospital;

(B) a public health department;

(C) a community health center;

(D) a nonprofit health care agency;

(E) a local educational agency; or

(F) a program administered by the Indian Health Service or the Bureau of Indian Affairs or operated by an Indian tribe or a tribal organization under the Indian Self-Determination and Education Assistance Act, a Native Hawaiian entity, or an urban Indian program under title V of the Indian Health Care Improvement Act.

(m) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this section, there are authorized to be appropriated $50,000,000 for fiscal year 2010 and such sums as may be necessary for each of the fiscal years 2011 through 2014.

PART R—PROGRAMS RELATING TO AUTISM

Subpart 1—Surveillance and Research Program; Education, Early Detection, and Intervention; and Reporting

SEC. 399AA. DEVELOPMENTAL DISABILITIES SURVEILLANCE AND RESEARCH PROGRAM.

(a) * * *

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(d) DEFINITIONS.—In this [part] *subpart*:

(1) * * *

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Subpart 2—National Training Initiative

SEC. 399FF. NATIONAL TRAINING INITIATIVE.

(a) NATIONAL TRAINING INITIATIVE SUPPLEMENTAL GRANTS AND TECHNICAL ASSISTANCE.—

(1) SUPPLEMENTAL GRANTS.—

(A) IN GENERAL.—The Secretary shall award, in consultation with the Interagency Autism Coordinating Committee, multiyear national training initiative supplemental grants to University Centers for Excellence in Developmental Disabilities authorized by the Developmental Disabilities Assistance and Bill of Rights Act of 2000, public or private nonprofit entities, and other comparable interdisciplinary service, training, and academic entities to provide interdisciplinary training, continuing education initiatives, technical assistance, dissemination, and services to address the unmet needs of children and adults with autism spectrum disorders and related developmental disabilities, and their families.

(B) REQUIREMENTS.—A University Center for Excellence in Developmental Disabilities that desires to receive a grant under this paragraph shall submit to the Secretary an application containing such agreements and information as the Secretary may require, including agreements that the training program shall—

(i) provide trainees with an appropriate balance of interdisciplinary academic and community-based experiences;

(ii) have a demonstrated capacity to provide training and technical assistance in evidence-based practices to evaluate, and provide effective interventions, treatment, services, and supports to children and adults with autism and related developmental disabilities, and their families;

(iii) have a demonstrated capacity to include persons with autism spectrum disorders, parents, and family members as part of the training program to ensure that a person and family-centered approach is used;

(iv) provide to the Secretary, in the manner prescribed by the Secretary, data regarding the number of persons who have benefitted and outcomes of the provision of training and technical assistance;

(v) demonstrate a capacity to share and disseminate materials and practices that are developed and evaluated to be effective in the provision of training and technical assistance;

(vi) provide assurances that training, technical assistance, dissemination, and services performed under grants made pursuant to this paragraph shall be consistent with the goals of the Developmental Disabilities Act of 1984, the Americans with Disabilities Act of 1990, the Individuals with Disabilities Education Act, and the No Child Left Behind Act of 2001 and conducted in coordination with other relevant State agencies, other institutions of higher education, and service providers; and

(vii) have a demonstrated capacity to provide training, technical assistance, supports, and services under this section statewide.

(C) ACTIVITIES.—A University Center for Excellence in Developmental Disabilities, or other eligible entity that receives a grant under this paragraph shall expand and develop interdisciplinary training and continuing education initiatives for parents, health, allied health, vocational, educational, and other professionals and develop model services and supports that demonstrate evidence-based practices, by engaging in the following activities:

(i) Training health, allied health, vocational, and educational professionals to identify, evaluate the needs, and develop treatments, interventions, services, and supports for children and adults with, autism spectrum disorder and related developmental disabilities.

(ii) Developing systems and products that allow for the interventions, services and supports to be evaluated for fidelity of implementation.

(iii) Working to expand the availability of evidence-based, lifelong interventions, educational, employment, and transition services, and community supports.

(iv) Providing statewide technical assistance in collaboration with relevant State agencies, other institutions of higher education, autism spectrum disorder advocacy groups, and community-based service providers.

(v) Working to develop comprehensive systems of supports and services for individuals with autism and related developmental disabilities and their families, including seamless transitions between educational and health systems across the lifespan.

(vi) Promoting training, technical assistance, dissemination, supports, and services.

(vii) Developing mechanisms to provide training and technical assistance, including for-credit courses, intensive summer institutes, continuing education programs, distance based programs, and Web-based information dissemination strategies.

(viii) Promoting activities that support community-based family and individual services and enable individuals with autism and related developmental disabilities to fully participate in society and achieve good quality of life outcomes.

(ix) Collecting data on the outcomes of training and technical assistance programs to meet statewide needs for the expansion of services to children and adults with autism spectrum disorders and related developmental disabilities.

(2) TECHNICAL ASSISTANCE.—The Secretary shall reserve 2 percent of the appropriated funds to make a grant to a national organization with demonstrated capacity for proving training and technical assistance to University Centers for Excellence in Developmental Disabilities to—

(A) assist in national dissemination of specific information, including evidence-based best practices, from interdisciplinary training programs, and when appropriate, other entities whose findings would inform the work performed by entities awarded grants;

(B) compile and disseminate strategies and materials that prove to be effective in the provision of training and technical assistance so that the entire network can benefit from the models, materials, and practices developed in individual centers;

(C) assist in the coordination of activities of grantees under this section;

(D) develop a Web portal that will provide linkages to each of the individual training initiatives and provide access to training modules, promising training, and technical assistance practices and other materials developed by grantees;

(E) serve as a research-based resource for Federal and State policymakers on information concerning the provision of training and technical assistance for the assessment, and provision of supports and services for children and adults with autism spectrum disorders and related developmental disabilities;

(F) convene experts from multiple interdisciplinary training programs, individuals with autism spectrum disorders, and their families to discuss and make recommendations with regard to training issues related to the assessment, and treatment, interventions, supports, and services for children and adults with autism spectrum disorders and related developmental disorders; and

(G) undertake any other functions that the Secretary determines to be appropriate.

(3) AUTHORIZATION OF APPROPRIATIONS.—

(A) IN GENERAL.—Subject to subparagraph (B), there is authorized to be appropriated to carry out this subsection $17,000,000 for fiscal year 2011 to be equally divided among existing University Centers for Excellence in Developmental Disabilities and such sums for fiscal years 2012 through 2015 in the case of University Centers for Excellence in Developmental Disabilities located in American Samoa or the Commonwealth of the Northern Mariana Islands, supplemental grants of not less than $100,000.

(B) APPROPRIATIONS LESS THAN $17,000,000.—With respect to any fiscal year in which the amount appropriated under subsection (A) to carry out this section is less than $17,000,000, the Secretary shall make competitive grants from such amount to individual University Centers for Excellence in Developmental Disabilities but would not be less than $250,000 per individual grant, in the case of University Centers for Excellence for Developmental Disabilities located in American Samoa or the Commonwealth of the Northern Mariana Islands, supplemental grants of not less than $100,000.

(C) RESERVATION.—Not more than 2 percent of the amount appropriated under subparagraphs (A) or (B) shall be reserved to carry out paragraph (2).

(b) EXPANSION OF THE NUMBER OF UNIVERSITY CENTERS FOR EXCELLENCE IN DEVELOPMENTAL DISABILITIES RESEARCH, EDUCATION, AND SERVICES.—

(1) PURPOSE.—The Secretary shall award up to four additional grants for the University Centers for Excellence in Developmental Disabilities for the purpose of expanding the capacity of existing national network and enhance the number of training facilities serving minority institutions with a primary focus on autism spectrum disorder and related developmental disabilities. Such centers shall—

(A) train health, allied health, and educational professionals to identify, diagnose, treat, and provide services for individuals with autism spectrum disorders;

(B) provide services, including early identification, diagnosis, and intervention for individuals with autism spectrum disorders; and

(C) provide other training and technical assistance, as necessary.

(2) PRIORITY.—The Secretary shall give priority to establishing such centers in—

(A) minority-serving institutions that have demonstrated capacity to meet the requirements to qualify as a University Center for Excellence in Developmental Disabilities and provide services to individuals with autism spectrum disorders; or

(B) States with underserved populations.

(3) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection $2,000,000 for each of the fiscal years 2011 through 2015.

PART S—NURSE-MANAGED HEALTH CENTERS

SEC. 399GG. NURSE-MANAGED HEALTH CENTERS.

(a) PROGRAM.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall establish a nurse-managed health center program consisting of awarding grants to entities under subsection (b).

(b) GRANT.—The Secretary shall award grants to entities—

(1) to plan and develop a nurse-managed health center; or

(2) to operate a nurse-managed health center.

(c) USE OF FUNDS.—Amounts received as a grant under subsection (b) may be used for activities including the following:

(1) Purchasing or leasing equipment.

(2) Training and technical assistance related to the provision of comprehensive primary care services and wellness services.

(3) Other activities for planning, developing, or operating, as applicable, a nurse-managed health center.

(d) ASSURANCES APPLICABLE TO BOTH PLANNING AND OPERATION GRANTS.—

(1) IN GENERAL.—The Secretary may award a grant under this section to an entity only if the entity demonstrates to the Secretary's satisfaction that—

(A) nurses, in addition to managing the center, will be adequately represented as providers at the center; and

(B) not later than 90 days after receiving the grant, the entity will establish a community advisory committee composed of individuals, a majority of whom are being served by the center, to provide input into the nurse-managed health center's operations.

(2) MATCHING REQUIREMENT.—The Secretary may award a grant under this section to an entity only if the entity agrees to provide, from non-Federal sources, an amount equal to 20 percent of the amount of the grant (which may be provided in cash or in kind) to carry out the activities supported by the grant.

(3) PAYOR OF LAST RESORT.—The Secretary may award a grant under this section to an entity only if the entity demonstrates to the satisfaction of the Secretary that funds received through the grant will not be expended for any activity to the extent that payment has been made, or can reasonably be expected to be made—

(A) under any insurance policy;

(B) under any Federal or State health benefits program (including titles XIX and XXI of the Social Security Act); or

(C) by an entity which provides health services on a prepaid basis.

(4) MAINTENANCE OF EFFORT.—The Secretary may award a grant under this section to an entity only if the entity demonstrates to the satisfaction of the Secretary that—

(A) funds received through the grant will be expended only to supplement, and not supplant, non-Federal and Federal funds otherwise available to the entity for the activities to be funded through the grant; and

(B) with respect to such activities, the entity will maintain expenditures of non-Federal amounts for such activities at a level not less than the lesser of such expenditures maintained by the entity for the fiscal year preceding the fiscal year for which the entity receives the grant.

(e) ADDITIONAL ASSURANCE FOR PLANNING GRANTS.—The Secretary may award a grant under subsection (b)(1) to an entity only if the entity agrees—

(1) to assess the needs of the medically underserved populations proposed to be served by the nurse-managed health center; and

(2) to design services and operations of the nurse-managed health center for such populations based on such assessment.

(f) ADDITIONAL ASSURANCES FOR OPERATION GRANTS.—The Secretary may award a grant under subsection (b)(2) to an entity only if the entity assures that the nurse-managed health center will provide—

(1) comprehensive primary care services, wellness services, and other health care services deemed appropriate by the Secretary;

(2) care without respect to insurance status or income of the patient; and

(3) direct access to client-centered services offered by advanced practice nurses, other nurses, physicians, physician assistants, or other qualified health professionals.

(g) TECHNICAL ASSISTANCE.—The Secretary shall provide (either directly or by grant or contract) technical and other assistance to nurse-managed health centers to assist such centers in meeting the requirements of this section. Such assistance may include fiscal and program management assistance, training in fiscal and program management, operational and administrative support, and the provision of information to nurse-managed health centers regarding the various resources available under this section and how those resources can best be used to meet the health needs of the communities served by nurse-managed health centers.

(h) REPORT.—The Secretary shall submit to the Congress an annual report on the program under this section.

(i) DEFINITIONS.—

(1) COMPREHENSIVE PRIMARY CARE SERVICES.—The term "comprehensive primary care services" has the meaning given to the term "required primary health services" in section 330(b)(1).

(2) MEDICALLY UNDERSERVED POPULATION.—The term "medically underserved population" has the meaning given to such term in section 330(b)(3).

(3) NURSE-MANAGED HEALTH CENTER.—The term "nurse-managed health center" has the meaning given to such term in section 801.

(4) WELLNESS SERVICES.—The term "wellness services" means any health-related service or intervention, not including primary care, which is designed to reduce identifiable health risks and increase healthy behaviors intended to prevent the onset of disease or lessen the impact of existing chronic conditions by teaching more effective management techniques that focus on individual self-care and patient-driven decisionmaking.

PART T—PROGRAMS TO INCREASE AWARENESS OF ADVANCE CARE PLANNING ISSUES

SEC. 399HH. ADVANCE CARE PLANNING EDUCATION CAMPAIGNS AND INFORMATION PHONE LINE AND CLEARINGHOUSE.

(a) ADVANCE CARE PLANNING EDUCATION CAMPAIGN.—The Secretary shall, directly or through grants awarded under subsection (c), conduct a national public education campaign—

(1) to raise public awareness of the importance of planning for care near the end of life;

(2) to improve the public's understanding of the various situations in which individuals may find themselves if they become unable to express their health care wishes;

(3) to explain the need for readily available legal documents that express an individual's wishes through—

(A) advance directives (including living wills, comfort care orders, and durable powers of attorney for health care); and

(B) other planning tools, such as a physician's orders for life-sustaining treatment (POLST); and

(4) to educate the public about the availability of hospice care and palliative care.

(b) INFORMATION PHONE LINE AND CLEARINGHOUSE.—The Secretary, directly or through grants awarded under subsection (c), shall provide for the establishment of a national, toll-free, information telephone line and a clearinghouse that the public and health professionals may access to find out about State-specific and other information regarding advance directive and end-of-life decisions.

(c) GRANTS.—

(1) IN GENERAL.—The Secretary shall use funds appropriated under subsection (d) for the purpose of awarding grants to public or nonprofit private entities (including States or political subdivisions of a State), or a consortium of any of such entities, for the purpose of conducting education campaigns under subsection (a).

(2) LIMITATION ON ELIGIBILITY.—Any grant awarded under this Act shall not go to any governmental or nongovernmental organization that promotes suicide, assisted suicide, or the active hastening of death. Nothing in the previous clause shall be construed to prohibit palliative or hospice care.

(3) PERIOD.—Any grant awarded under paragraph (1) shall be for a period of 3 years.

(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated—

(1) for purposes of carrying out subsection (b), $5,000,000 for fiscal year 2010 and each subsequent year; and

(2) for purposes of making grants under subsection (c), $10,000,000 for fiscal year 2010, to remain available until expended.

TITLE IV—NATIONAL RESEARCH INSTITUTES

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PART B—GENERAL PROVISIONS RESPECTING NATIONAL RESEARCH INSTITUTES

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SEC. 409J. PAIN RESEARCH.

(a) RESEARCH INITIATIVES.—

(1) IN GENERAL.—The Director of NIH is encouraged to continue and expand, through the Pain Consortium, an aggressive program of basic and clinical research on the causes of and potential treatments for pain.

(2) ANNUAL RECOMMENDATIONS.—Not less than annually, the Pain Consortium, in consultation with the Division of Program Coordination, Planning, and Strategic Initiatives, shall develop and submit to the Director of NIH recommendations on appropriate pain research initiatives that could be undertaken with funds reserved under section 402A(c)(1) for the Common Fund or otherwise available for such initiatives.

(3) DEFINITION.—In this subsection, the term "Pain Consortium" means the Pain Consortium of the National Institutes of Health or a similar trans-National Institutes of Health coordinating entity designated by the Secretary for purposes of this subsection.

(b) INTERAGENCY PAIN RESEARCH COORDINATING COMMITTEE.—

(1) ESTABLISHMENT.—The Secretary shall establish not later than 1 year after the date of the enactment of this section and as necessary maintain a committee, to be known as the Interagency Pain Research Coordinating Committee (in this section referred to as the "Committee"), to coordinate all efforts within the Department of Health and Human Services and other Federal agencies that relate to pain research.

(2) MEMBERSHIP.—

(A) IN GENERAL.—The Committee shall be composed of the following voting members:

(i) Not more than 7 voting Federal representatives as follows:

(I) The Director of the Centers for Disease Control and Prevention.

(II) The Director of the National Institutes of Health and the directors of such national research institutes and national centers as the Secretary determines appropriate.

(III) The heads of such other agencies of the Department of Health and Human Services as the Secretary determines appropriate.

(IV) Representatives of other Federal agencies that conduct or support pain care research and treatment, including the Department of Defense and the Department of Veterans Affairs.

(ii) 12 additional voting members appointed under subparagraph (B).

(B) ADDITIONAL MEMBERS.—The Committee shall include additional voting members appointed by the Secretary as follows:

(i) 6 members shall be appointed from among scientists, physicians, and other health professionals, who—

(I) are not officers or employees of the United States;

(II) represent multiple disciplines, including clinical, basic, and public health sciences;

(III) represent different geographical regions of the United States; and

(IV) are from practice settings, academia, manufacturers, or other research settings; and

(ii) 6 members shall be appointed from members of the general public, who are representatives of leading research, advocacy, and service organizations for individuals with pain-related conditions.

(C) NONVOTING MEMBERS.—The Committee shall include such nonvoting members as the Secretary determines to be appropriate.

(3) CHAIRPERSON.—The voting members of the Committee shall select a chairperson from among such members. The selection of a chairperson shall be subject to the approval of the Director of NIH.

(4) MEETINGS.—The Committee shall meet at the call of the chairperson of the Committee or upon the request of the Director of NIH, but in no case less often than once each year.

(5) DUTIES.—The Committee shall—

(A) develop a summary of advances in pain care research supported or conducted by the Federal agencies relevant to the diagnosis, prevention, and treatment of pain and diseases and disorders associated with pain;

(B) identify critical gaps in basic and clinical research on the symptoms and causes of pain;

(C) make recommendations to ensure that the activities of the National Institutes of Health and other Federal agencies, including the Department of Defense and the Department of Veteran Affairs, are free of unnecessary duplication of effort;

(D) make recommendations on how best to disseminate information on pain care; and

(E) make recommendations on how to expand partnerships between public entities, including Federal agencies, and private entities to expand collaborative, cross-cutting research.

(6) REVIEW.—The Secretary shall review the necessity of the Committee at least once every 2 years.

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TITLE V—SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION

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PART B—CENTERS AND PROGRAMS

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Subpart 3—Center for Mental Health Services

CENTER FOR MENTAL HEALTH SERVICES

SEC. 520. (a) * * *

(b) DUTIES.—The Director of the Center shall—

(1) * * *

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(13) monitor and enforce obligations incurred by [community mental health centers] *federally qualified behavioral health centers* pursuant to the Community Mental Health Centers Act (as in effect prior to the repeal of such Act on August 13, 1981, by section 902(e)(2)(B) of Public Law 97–35 (95 Stat. 560));

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SEC. 520F. GRANTS FOR EMERGENCY MENTAL HEALTH CENTERS.

(a) * * *

(b) HEALTH CENTER.—In this section, the term "health center" has the meaning given such term in section 330, and includes community health centers and [community mental health centers] *federally qualified behavioral health centers*.

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TITLE VII—HEALTH PROFESSIONS EDUCATION

PART A—STUDENT LOANS

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Subpart II—Federally-Supported Student Loan Funds

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SEC. 735. GENERAL PROVISIONS.

(a) * * *

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(f) DETERMINATION OF FINANCIAL NEED.—The Secretary—

(1) may require, or authorize a school or other entity to require, the submission of financial information to determine the financial resources available to any individual seeking assistance under this subpart; and

(2) shall take into account the extent to which such individual is financially independent in determining whether to require or authorize the submission of such information regarding such individual's family members.

[(f)] *(g)* FUNDING FOR CERTAIN MEDICAL SCHOOLS.—

(1) * * *

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PART B—HEALTH PROFESSIONS TRAINING FOR DIVERSITY

SEC. 736. CENTERS OF EXCELLENCE.

(a) * * *

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(h) REPORT.—The Secretary shall submit to the Congress an annual report on the activities carried out under this section.

[(h)] *(i)* FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of making grants under subsection (a), there are authorized to be appropriated $26,000,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through [2002] *2014*.

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SEC. 738. LOAN REPAYMENTS AND FELLOWSHIPS REGARDING FACULTY POSITIONS.

(a) LOAN REPAYMENTS.—

(1) ESTABLISHMENT OF PROGRAM.—The Secretary shall establish a program of entering into contracts with individuals described in paragraph (2) under which the individuals agree to serve as members of the faculties of schools described in paragraph (3) in consideration of the Federal Government agreeing to pay, for each year of such service, [not more than $20,000 of the principal and interest of the educational loans of such individuals.] *not more than $35,000 (plus, beginning with fiscal year 2012, an amount determined by the Secretary on an annual basis to reflect inflation) of the principal and interest of the educational loans of such individuals.*

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SEC. 739A. COORDINATION OF DIVERSITY AND CULTURAL COMPETENCY PROGRAMS.

The Secretary shall, to the extent practicable, coordinate the activities carried out under this part and section 821 in order to enhance the effectiveness of such activities and avoid duplication of effort.

SEC. 740. AUTHORIZATION OF APPROPRIATION.

(a) SCHOLARSHIPS.—There are authorized to be appropriated to carry out section 737, $37,000,000 for fiscal year 1998, and such

sums as may be necessary for each of the fiscal years 1999 through [2002] *2014*. Of the amount appropriated in any fiscal year, the Secretary shall ensure that not less than 16 percent shall be distributed to schools of nursing.

(b) LOAN REPAYMENTS AND FELLOWSHIPS.—For the purpose of carrying out section 738, there is authorized to be appropriated $1,100,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through [2002] *2014*.

(c) EDUCATIONAL ASSISTANCE IN HEALTH PROFESSIONS REGARDING INDIVIDUALS FOR DISADVANTAGED BACKGROUNDS.—For the purpose of grants and contracts under section 739(a)(1), there is authorized to be appropriated $29,400,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through [2002] *2014*. The Secretary may use not to exceed 20 percent of the amount appropriated for a fiscal year under this subsection to provide scholarships under section 739(a)(2)(F).

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SEC. 741. [GRANTS FOR HEALTH PROFESSIONS EDUCATION] *CULTURAL AND LINGUISTIC COMPETENCY TRAINING FOR HEALTH PROFESSIONALS*.

[(a) GRANTS FOR HEALTH PROFESSIONS EDUCATION IN HEALTH DISPARITIES AND CULTURAL COMPETENCY.—

[(1) IN GENERAL.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, may make awards of grants, contracts, or cooperative agreements to public and nonprofit private entities (including tribal entities) for the purpose of carrying out research and demonstration projects (including research and demonstration projects for continuing health professions education) for training and education of health professionals for the reduction of disparities in health care outcomes and the provision of culturally competent health care.

[(2) ELIGIBLE ENTITIES.—Unless specifically required otherwise in this title, the Secretary shall accept applications for grants or contracts under this section from health professions schools, academic health centers, State or local governments, or other appropriate public or private nonprofit entities (or consortia of entities, including entities promoting multidisciplinary approaches) for funding and participation in health professions training activities. The Secretary may accept applications from for-profit private entities as determined appropriate by the Secretary.]

(a) PROGRAM.—The Secretary shall establish a cultural and linguistic competency training program for health professionals, including nurse professionals, consisting of awarding grants and contracts under subsection (b).

(b) CULTURAL AND LINGUISTIC COMPETENCY TRAINING.—The Secretary shall award grants and contracts to eligible entities—

(1) to test, develop, and evaluate models of cultural and linguistic competency training (including continuing education) for health professionals; and

(2) to implement cultural and linguistic competency training programs for health professionals developed under paragraph (1) or otherwise.

(c) ELIGIBILITY.—To be eligible for a grant or contract under subsection (b), an entity shall be—

(1) an accredited health professions school or program;

(2) an academic health center;

(3) a public or private nonprofit entity; or

(4) a consortium of 2 or more entities described in paragraphs (1) through (3).

(d) PREFERENCE.—In awarding grants and contracts under this section, the Secretary shall give preference to entities that have a demonstrated record of the following:

(1) Addressing, or partnering with an entity with experience addressing, the cultural and linguistic competency needs of the population to be served through the grant or contract.

(2) Addressing health disparities.

(3) Placing health professionals in regions experiencing significant changes in the cultural and linguistic demographics of populations, including communities along the United States-Mexico border.

(4) Carrying out activities described in subsection (b) with respect to more than one health profession discipline, specialty, or subspecialty.

(e) CONSULTATION.—The Secretary shall carry out this section in consultation with the heads of appropriate health agencies and offices in the Department of Health and Human Services, including the Office of Minority Health.

(f) DEFINITION.—In this section, the term "health disparities" has the meaning given to the term in section 3171.

(g) REPORT.—The Secretary shall submit to the Congress an annual report on the program carried out under this section.

[(b)**]** *(h)* AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out subsection (a), $3,500,000 for fiscal year 2001, $7,000,000 for fiscal year 2002, $7,000,000 for fiscal year 2003, **[**and**]** $3,500,000 for fiscal year 2004*, and such sums as may be necessary for subsequent fiscal years through the end of fiscal year 2014*.

PART C—TRAINING IN FAMILY MEDICINE, GENERAL INTERNAL MEDICINE, GENERAL PEDIATRICS, PHYSICIAN ASSISTANTS, GENERAL DENTISTRY, AND PEDIATRIC DENTISTRY

SEC. 747. [FAMILY MEDICINE, GENERAL INTERNAL MEDICINE, GENERAL PEDIATRICS, GENERAL DENTISTRY, PEDIATRIC DENTISTRY, AND PHYSICIAN ASSISTANTS.] *PRIMARY CARE TRAINING AND ENHANCEMENT.*

[(a) TRAINING GENERALLY.—The Secretary may make grants to, or enter into contracts with, any public or nonprofit private hospital, school of medicine or osteopathic medicine, or to or with a public or private nonprofit entity (which the Secretary has determined is capable of carrying out such grant or contract)—

[(1) to plan, develop, and operate, or participate in, an approved professional training program (including an approved residency or internship program) in the field of family medicine, internal medicine, or pediatrics for medical (M.D. and

D.O.) students, interns (including interns in internships in osteopathic medicine), residents, or practicing physicians that emphasizes training for the practice of family medicine, general internal medicine, or general pediatrics (as defined by the Secretary);

[(2) to provide financial assistance (in the form of traineeships and fellowships) to medical (M.D. and D.O.) students, interns (including interns in internships in osteopathic medicine), residents, practicing physicians, or other medical personnel, who are in need thereof, who are participants in any such program, and who plan to specialize or work in the practice of family medicine, general internal medicine, or general pediatrics;

[(3) to plan, develop, and operate a program for the training of physicians who plan to teach in family medicine (including geriatrics), general internal medicine or general pediatrics training programs;

[(4) to provide financial assistance (in the form of traineeships and fellowships) to physicians who are participants in any such program and who plan to teach in a family medicine (including geriatrics), general internal medicine or general pediatrics training program;

[(5) to meet the costs of projects to plan, develop, and operate or maintain programs for the training of physician assistants (as defined in section 799B), and for the training of individuals who will teach in programs to provide such training; and

[(6) to meet the costs of planning, developing, or operating programs, and to provide financial assistance to residents in such programs, of general dentistry or pediatric dentistry.

For purposes of paragraph (6), entities eligible for such grants or contracts shall include entities that have programs in dental schools, approved residency programs in the general or pediatric practice of dentistry, approved advanced education programs in the general or pediatric practice of dentistry, or approved residency programs in pediatric dentistry.

[(b) ACADEMIC ADMINISTRATIVE UNITS.—

[(1) IN GENERAL.—The Secretary may make grants to or enter into contracts with schools of medicine or osteopathic medicine to meet the costs of projects to establish, maintain, or improve academic administrative units (which may be departments, divisions, or other units) to provide clinical instruction in family medicine, general internal medicine, or general pediatrics.

[(2) PREFERENCE IN MAKING AWARDS.—In making awards of grants and contracts under paragraph (1), the Secretary shall give preference to any qualified applicant for such an award that agrees to expend the award for the purpose of—

[(A) establishing an academic administrative unit for programs in family medicine, general internal medicine, or general pediatrics;

[(B) substantially expanding the programs of such a unit; or

[(3) PRIORITY IN MAKING AWARDS.—In making awards of grants and contracts under paragraph (1), the Secretary shall

give priority to any qualified applicant for such an award that proposes a collaborative project between departments of primary care.

[(c) PRIORITY.—

[(1) IN GENERAL.—With respect to programs for the training of interns or residents, the Secretary shall give priority in awarding grants under this section to qualified applicants that have a record of training the greatest percentage of providers, or that have demonstrated significant improvements in the percentage of providers, which enter and remain in primary care practice or general or pediatric dentistry.

[(2) DISADVANTAGED INDIVIDUALS.—With respect to programs for the training of interns, residents, or physician assistants, the Secretary shall give priority in awarding grants under this section to qualified applicants that have a record of training individuals who are from disadvantaged backgrounds (including racial and ethnic minorities underrepresented among primary care practice or general or pediatric dentistry).

[(3) SPECIAL CONSIDERATION.—In awarding grants under this section the Secretary shall give special consideration to projects which prepare practitioners to care for underserved populations and other high risk groups such as the elderly, individuals with HIV-AIDS, substance abusers, homeless, and victims of domestic violence.

[(d) DURATION OF AWARD.—The period during which payments are made to an entity from an award of a grant or contract under subsection (a) may not exceed 5 years. The provision of such payments shall be subject to annual approval by the Secretary of the payments and subject to the availability of appropriations for the fiscal year involved to make the payments.]

(a) PROGRAM.—The Secretary shall establish a primary care training and capacity building program consisting of awarding grants and contracts under subsections (b) and (c).

(b) SUPPORT AND DEVELOPMENT OF PRIMARY CARE TRAINING PROGRAMS.—

(1) IN GENERAL.—The Secretary shall make grants to, or enter into contracts with, eligible entities—

(A) to plan, develop, operate, or participate in an accredited professional training program, including an accredited residency or internship program, in the field of family medicine, general internal medicine, general pediatrics, or geriatrics for medical students, interns, residents, or practicing physicians;

(B) to provide financial assistance in the form of traineeships and fellowships to medical students, interns, residents, or practicing physicians, who are participants in any such program, and who plan to specialize or work in family medicine, general internal medicine, general pediatrics, or geriatrics;

(C) to plan, develop, operate, or participate in an accredited program for the training of physicians who plan to teach in family medicine, general internal medicine, general pediatrics, or geriatrics training programs including in community-based settings;

(D) to provide financial assistance in the form of traineeships and fellowships to practicing physicians who are participants in any such programs and who plan to teach in a family medicine, general internal medicine, general pediatrics, or geriatrics training program; and

(E) to plan, develop, operate, or participate in an accredited program for physician assistant education, and for the training of individuals who plan to teach in programs to provide such training.

(2) ELIGIBILITY.—To be eligible for a grant or contract under paragraph (1), an entity shall be—

(A) an accredited school of medicine or osteopathic medicine, public or nonprofit private hospital, or physician assistant training program;

(B) a public or private nonprofit entity; or

(C) a consortium of 2 or more entities described in subparagraphs (A) and (B).

(c) CAPACITY BUILDING IN PRIMARY CARE.—

(1) IN GENERAL.—The Secretary shall make grants to or enter into contracts with eligible entities to establish, maintain, or improve—

(A) academic administrative units (including departments, divisions, or other appropriate units) in the specialties of family medicine, general internal medicine, general pediatrics, or geriatrics; or

(B) programs that improve clinical teaching in such specialties.

(2) ELIGIBILITY.—To be eligible for a grant or contract under paragraph (1), an entity shall be an accredited school of medicine or osteopathic medicine.

(d) PREFERENCE.—In awarding grants or contracts under this section, the Secretary shall give preference to entities that have a demonstrated record of the following:

(1) Training the greatest percentage, or significantly improving the percentage, of health professionals who provide primary care.

(2) Training individuals who are from underrepresented minority groups or disadvantaged backgrounds.

(3) A high rate of placing graduates in practice settings having the principal focus of serving in underserved areas or populations experiencing health disparities (including serving patients eligible for medical assistance under title XIX of the Social Security Act or for child health assistance under title XXI of such Act or those with special health care needs).

(4) Supporting teaching programs that address the health care needs of vulnerable populations.

(e) REPORT.—The Secretary shall submit to the Congress an annual report on the program carried out under this section.

(f) DEFINITION.—In this section, the term "health disparities" has the meaning given the term in section 3171.

[(e)**]** *(g)* FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated

$78,300,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through [2002] *2014*.

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SEC. 748. TRAINING OF MEDICAL RESIDENTS IN COMMUNITY-BASED SETTINGS.

(a) PROGRAM.—The Secretary shall establish a program for the training of medical residents in community-based settings consisting of awarding grants and contracts under this section.

(b) DEVELOPMENT AND OPERATION OF COMMUNITY-BASED PROGRAMS.—The Secretary shall make grants to, or enter into contracts with, eligible entities—

(1) to plan and develop a new primary care residency training program, which may include—

(A) planning and developing curricula;

(B) recruiting and training residents and faculty; and

(C) other activities designated to result in accreditation of such a program; or

(2) to operate or participate in an established primary care residency training program, which may include—

(A) planning and developing curricula;

(B) recruitment and training of residents; and

(C) retention of faculty.

(c) ELIGIBLE ENTITY.—To be eligible to receive a grant or contract under subsection (b), an entity shall—

(1) be designated as a recipient of payment for the direct costs of medical education under section 1886(k) of the Social Security Act;

(2) be designated as an approved teaching health center under section 1502(d) of the America's Affordable Health Choices Act of 2009 and continuing to participate in the demonstration project under such section; or

(3) be an applicant for designation described in paragraph (1) or (2) and have demonstrated to the Secretary appropriate involvement of an accredited teaching hospital to carry out the inpatient responsibilities associated with a primary care residency training program.

(d) PREFERENCES.—In awarding grants and contracts under paragraph (1) or (2) of subsection (b), the Secretary shall give preference to entities that—

(1) support teaching programs that address the health care needs of vulnerable populations; or

(2) are a Federally qualified health center (as defined in section 1861(aa)(4) of the Social Security Act) or a rural health clinic (as defined in section 1861(aa)(2) of such Act).

(e) ADDITIONAL PREFERENCES FOR ESTABLISHED PROGRAMS.—In awarding grants and contracts under subsection (b)(2), the Secretary shall give preference to entities that have a demonstrated record of training—

(1) a high or significantly improved percentage of health professionals who provide primary care;

(2) individuals who are from underrepresented minority groups or disadvantaged backgrounds; or

(3) individuals who practice in settings having the principal focus of serving underserved areas or populations experiencing

health disparities (including serving patients eligible for medical assistance under title XIX of the Social Security Act or for child health assistance under title XXI of such Act or those with special health care needs).

(f) PERIOD OF AWARDS.—

(1) IN GENERAL.—The period of a grant or contract under this section—

(A) shall not exceed 3 years for awards under subsection (b)(1); and

(B) shall not exceed 5 years for awards under subsection (b)(2).

(2) SPECIAL RULES.—

(A) An award of a grant or contract under subsection (b)(1) shall not be renewed.

(B) The period of a grant or contract awarded to an entity under subsection (b)(2) shall not overlap with the period of any grant or contact awarded to the same entity under subsection (b)(1).

(g) REPORT.—The Secretary shall submit to the Congress an annual report on the program carried out under this section.

(h) DEFINITIONS.—In this section:

(1) HEALTH DISPARITIES.—The term "health disparities" has the meaning given the term in section 3171.

(2) PRIMARY CARE RESIDENT.—The term "primary care resident" has the meaning given the term in section 1886(h)(5)(H) of the Social Security Act.

(3) PRIMARY CARE RESIDENCY TRAINING PROGRAM.—The term "primary care residency training program" means an approved medical residency training program described in section 1886(h)(5)(A) of the Social Security Act for primary care residents that is—

(A) in the case of entities seeking awards under subsection (b)(1), actively applying to be accredited by the Accreditation Council for Graduate Medical Education or the American Osteopathic Association; or

(B) in the case of entities seeking awards under subsection (b)(2), so accredited.

SEC. 749. TRAINING FOR GENERAL, PEDIATRIC, AND PUBLIC HEALTH DENTISTS AND DENTAL HYGIENISTS.

(a) PROGRAM.—The Secretary shall establish a training program for oral professionals consisting of awarding grants and contracts under this section.

(b) SUPPORT AND DEVELOPMENT OF DENTAL TRAINING PROGRAMS.—The Secretary shall make grants to, or enter into contracts with, eligible entities—

(1) to plan, develop, operate, or participate in an accredited professional training program for oral health professionals;

(2) to provide financial assistance to oral health professionals who are in need thereof, who are participants in any such program, and who plan to work in general, pediatric, or public health dentistry, or dental hygiene;

(3) to plan, develop, operate, or participate in a program for the training of oral health professionals who plan to teach in general, pediatric, or public health dentistry, or dental hygiene;

(4) to provide financial assistance in the form of traineeships and fellowships to oral health professionals who plan to teach in general, pediatric, or public health dentistry or dental hygiene;

(5) to establish, maintain, or improve—

(A) academic administrative units (including departments, divisions, or other appropriate units) in the specialties of general, pediatric, or public health dentistry; or

(B) programs that improve clinical teaching in such specialties;

(6) to plan, develop, operate, or participate in predoctoral and postdoctoral training in general, pediatric, or public health dentistry programs;

(7) to plan, develop, operate, or participate in a loan repayment program for full-time faculty in a program of general, pediatric, or public health dentistry; and

(8) to provide technical assistance to pediatric dental training programs in developing and implementing instruction regarding the oral health status, dental care needs, and risk-based clinical disease management of all pediatric populations with an emphasis on underserved children.

(c) ELIGIBILITY.—To be eligible for a grant or contract under subsection (a), an entity shall be—

(1) an accredited school of dentistry, training program in dental hygiene, or public or nonprofit private hospital;

(2) a training program in dental hygiene at an accredited institution of higher education;

(3) a public or private nonprofit entity; or

(4) a consortium of—

(A) 1 or more of the entities described in paragraphs (1) through (3); and

(B) an accredited school of public health.

(d) PREFERENCE.—In awarding grants or contracts under this section, the Secretary shall give preference to entities that have a demonstrated record of the following:

(1) Training the greatest percentage, or significantly improving the percentage, of oral health professionals who practice general, pediatric, or public health dentistry.

(2) Training individuals who are from underrepresented minority groups or disadvantaged backgrounds.

(3) A high rate of placing graduates in practice settings having the principal focus of serving in underserved areas or populations experiencing health disparities (including serving patients eligible for medical assistance under title XIX of the Social Security Act or for child health assistance under title XXI of such Act or those with special health care needs).

(4) Supporting teaching programs that address the dental needs of vulnerable populations.

(5) Providing instruction regarding the oral health status, dental care needs, and risk-based clinical disease management of all pediatric populations with an emphasis on underserved children.

(e) REPORT.—The Secretary shall submit to the Congress an annual report on the program carried out under this section.

(f) DEFINITIONS.—In this section:

(1) The term "health disparities" has the meaning given the term in section 3171.

(2) The term "oral health professional" means an individual training or practicing—

(A) in general dentistry, pediatric dentistry, public health dentistry, or dental hygiene; or

(B) another oral health specialty, as deemed appropriate by the Secretary.

SEC. [748] *749A.* ADVISORY COMMITTEE ON TRAINING IN PRIMARY CARE MEDICINE AND DENTISTRY.

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PART D—INTERDISCIPLINARY, COMMUNITY-BASED LINKAGES

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SEC. 759. INNOVATIONS IN INTERDISCIPLINARY CARE TRAINING.

(a) PROGRAM.—The Secretary shall establish an innovations in interdisciplinary care training program consisting of awarding grants and contracts under subsection (b).

(b) TRAINING PROGRAMS.—The Secretary shall award grants to, or enter into contracts with, eligible entities—

(1) to test, develop, and evaluate health professional training programs (including continuing education) designed to promote—

(A) the delivery of health services through interdisciplinary and team-based models, which may include patient-centered medical home models, medication therapy management models, and models integrating physical, mental, or oral health services; and

(B) coordination of the delivery of health care within and across settings, including health care institutions, community-based settings, and the patient's home; and

(2) to implement such training programs developed under paragraph (1) or otherwise.

(c) ELIGIBILITY.—To be eligible for a grant or contract under subsection (b), an entity shall be—

(1) an accredited health professions school or program;

(2) an academic health center;

(3) a public or private nonprofit entity (including an area health education center or a geriatric education center); or

(4) a consortium of 2 or more entities described in paragraphs (1) through (3).

(d) PREFERENCES.—In awarding grants and contracts under this section, the Secretary shall give preference to entities that have a demonstrated record of the following:

(1) Training the greatest percentage, or significantly increasing the percentage, of health professionals who serve in underserved communities.

(2) Broad interdisciplinary team-based collaborations.

(3) Addressing health disparities.

(e) REPORT.—The Secretary shall submit to the Congress an annual report on the program carried out under this section.

(f) DEFINITIONS.—In this section:

(1) The term "health disparities" has the meaning given the term in section 3171.

(2) The term "interdisciplinary" means collaboration across health professions and specialties, which may include public health, nursing, allied health, and appropriate medical specialties.

PART E—HEALTH PROFESSIONS AND PUBLIC HEALTH WORKFORCE

Subpart 1—Health Professions Workforce Information and Analysis

SEC. 761. HEALTH PROFESSIONS WORKFORCE INFORMATION AND ANALYSIS.

[(a) PURPOSE.—It is the purpose of this section to—

[(1) provide for the development of information describing the health professions workforce and the analysis of workforce related issues; and

[(2) provide necessary information for decision-making regarding future directions in health professions and nursing programs in response to societal and professional needs.

[(b) GRANTS OR CONTRACTS.—The Secretary may award grants or contracts to State or local governments, health professions schools, schools of nursing, academic health centers, community-based health facilities, and other appropriate public or private non-profit entities to provide for—

[(1) targeted information collection and analysis activities related to the purposes described in subsection (a);

[(2) research on high priority workforce questions;

[(3) the development of a non-Federal analytic and research infrastructure related to the purposes described in subsection (a); and

[(4) the conduct of program evaluation and assessment.]

(a) IN GENERAL.—The Secretary shall, based upon the classifications and standardized methodologies and procedures developed by the Advisory Committee on Health Workforce Evaluation and Assessment under section 764(b)—

(1) collect data on the health workforce (as defined in section 764(i)), disaggregated by field, discipline, and specialty, with respect to—

(A) the supply (including retention) of health professionals relative to the demand for such professionals;

(B) the diversity of health professionals (including with respect to race, ethnic background, and gender); and

(C) the geographic distribution of health professionals; and

(2) collect such data on individuals participating in the programs authorized by subtitles A, B, and C and part 1 of subtitle D of title II of division C of the America's Affordable Health Choices Act of 2009.

(b) GRANTS AND CONTRACTS FOR HEALTH WORKFORCE ANALYSIS.—

(1) IN GENERAL.—The Secretary may award grants or contracts to eligible entities to carry out subsection (a).

(2) ELIGIBILITY.—To be eligible for a grant or contract under this subsection, an entity shall be—

(A) an accredited health professions school or program;

(B) an academic health center;

(C) a State, local, or tribal government;

(D) a public or private entity; or

(E) a consortium of 2 or more entities described in subparagraphs (A) through (D).

(c) COLLABORATION AND DATA SHARING.—The Secretary shall collaborate with Federal departments and agencies, health professions organizations (including health professions education organizations), and professional medical societies for the purpose of carrying out subsection (a).

(d) REPORT.—The Secretary shall submit to the Congress an annual report on the data collected under subsection (a).

[(c)**]** *(e)* AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—There are authorized to be appropriated to carry out this section, $750,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through **[**2002**]** *2014*.

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SEC. 764. HEALTH WORKFORCE EVALUATION AND ASSESSMENT.

(a) ADVISORY COMMITTEE.—The Secretary, acting through the Assistant Secretary for Health, shall establish a permanent advisory committee to be known as the Advisory Committee on Health Workforce Evaluation and Assessment (referred to in this section as the "Advisory Committee").

(b) RESPONSIBILITIES.—The Advisory Committee shall—

(1) not later than 1 year after the date of the establishment of the Advisory Committee, submit recommendations to the Secretary on—

(A) classifications of the health workforce to ensure consistency of data collection on the health workforce; and

(B) based on such classifications, standardized methodologies and procedures to enumerate the health workforce;

(2) not later than 2 years after the date of the establishment of the Advisory Committee, submit recommendations to the Secretary on—

(A) the supply, diversity, and geographic distribution of the health workforce;

(B) the retention of the health workforce to ensure quality and adequacy of such workforce; and

(C) policies to carry out the recommendations made pursuant to subparagraphs (A) and (B); and

(3) not later than 4 years after the date of the establishment of the Advisory Committee, and every 2 years thereafter, submit updated recommendations to the Secretary under paragraphs (1) and (2).

(c) ROLE OF AGENCY.—The Secretary shall provide ongoing administrative, research, and technical support for the operations of

the Advisory Committee, including coordinating and supporting the dissemination of the recommendations of the Advisory Committee.

(d) MEMBERSHIP.—

(1) NUMBER; APPOINTMENT.—The Secretary shall appoint 15 members to serve on the Advisory Committee.

(2) TERMS.—

(A) IN GENERAL.—The Secretary shall appoint members of the Advisory Committee for a term of 3 years and may reappoint such members, but the Secretary may not appoint any member to serve more than a total of 6 years.

(B) STAGGERED TERMS.—Notwithstanding subparagraph (A), of the members first appointed to the Advisory Committee under paragraph (1)—

(i) 5 shall be appointed for a term of 1 year;

(ii) 5 shall be appointed for a term of 2 years; and

(iii) 5 shall be appointed for a term of 3 years.

(3) QUALIFICATIONS.—Members of the Advisory Committee shall be appointed from among individuals who possess expertise in at least one of the following areas:

(A) Conducting and interpreting health workforce market analysis, including health care labor workforce analysis.

(B) Conducting and interpreting health finance and economics research.

(C) Delivering and administering health care services.

(D) Delivering and administering health workforce education and training.

(4) REPRESENTATION.—In appointing members of the Advisory Committee, the Secretary shall—

(A) include no less than one representative of each of—

(i) health professionals within the health workforce;

(ii) health care patients and consumers;

(iii) employers;

(iv) labor unions; and

(v) third-party health payors; and

(B) ensure that—

(i) all areas of expertise described in paragraph (3) are represented;

(ii) the members of the Advisory Committee include members who, collectively, have significant experience working with—

(I) populations in urban and federally designated rural and nonmetropolitan areas; and

(II) populations who are underrepresented in the health professions, including underrepresented minority groups; and

(iii) individuals who are directly involved in health professions education or practice do not constitute a majority of the members of the Advisory Committee.

(5) DISCLOSURE AND CONFLICTS OF INTEREST.—Members of the Advisory Committee shall not be considered employees of the Federal Government by reason of service on the Advisory Committee, except members of the Advisory Committee shall be considered to be special Government employees within the meaning of section 107 of the Ethics in Government Act of 1978 (5 U.S.C. App.) and section 208 of title 18, United States Code,

for the purposes of disclosure and management of conflicts of interest under those sections.

(6) NO PAY; RECEIPT OF TRAVEL EXPENSES.—Members of the Advisory Committee shall not receive any pay for service on the Committee, but may receive travel expenses, including a per diem, in accordance with applicable provisions of subchapter I of chapter 57 of title 5, United States Code.

(e) CONSULTATION.—In carrying out this section, the Secretary shall consult with the Secretary of Education and the Secretary of Labor.

(f) COLLABORATION.—The Advisory Committee shall collaborate with the advisory bodies at the Health Resources and Services Administration, the National Advisory Council (as authorized in section 337), the Advisory Committee on Training in Primary Care Medicine and Dentistry (as authorized in section 749A), the Advisory Committee on Interdisciplinary, Community-Based Linkages (as authorized in section 756), the Advisory Council on Graduate Medical Education (as authorized in section 762), and the National Advisory Council on Nurse Education and Practice (as authorized in section 851).

(g) FACA.—The Federal Advisory Committee Act (5 U.S.C. App.) except for section 14 of such Act shall apply to the Advisory Committee under this section only to the extent that the provisions of such Act do not conflict with the requirements of this section.

(h) REPORT.—The Secretary shall submit to the Congress an annual report on the activities of the Advisory Committee.

(i) DEFINITION.—In this section, the term "health workforce" includes all health care providers with direct patient care and support responsibilities, including physicians, nurses, physician assistants, pharmacists, oral health professionals (as defined in section 749(f)), allied health professionals, mental and behavioral health professionals, and public health professionals (including veterinarians engaged in public health practice).

Subpart 2—Public Health Workforce

[SEC. 765. GENERAL PROVISIONS.

[(a) IN GENERAL.—The Secretary may award grants or contracts to eligible entities to increase the number of individuals in the public health workforce, to enhance the quality of such workforce, and to enhance the ability of the workforce to meet national, State, and local health care needs.

[(b) ELIGIBILITY.—To be eligible to receive a grant or contract under subsection (a) an entity shall—

[(1) be—

[(A) a health professions school, including an accredited school or program of public health, health administration, preventive medicine, or dental public health or a school providing health management programs;

[(B) an academic health center;

[(C) a State or local government; or

[(D) any other appropriate public or private nonprofit entity; and

[(2) prepare and submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

[(c) PREFERENCE.—In awarding grants or contracts under this section the Secretary may grant a preference to entities—

[(1) serving individuals who are from disadvantaged backgrounds (including underrepresented racial and ethnic minorities); and

[(2) graduating large proportions of individuals who serve in underserved communities.

[(d) ACTIVITIES.—Amounts provided under a grant or contract awarded under this section may be used for—

[(1) the costs of planning, developing, or operating demonstration training programs;

[(2) faculty development;

[(3) trainee support;

[(4) technical assistance;

[(5) to meet the costs of projects—

[(A) to plan and develop new residency training programs and to maintain or improve existing residency training programs in preventive medicine and dental public health, that have available full-time faculty members with training and experience in the fields of preventive medicine and dental public health; and

[(B) to provide financial assistance to residency trainees enrolled in such programs;

[(6) the retraining of existing public health workers as well as for increasing the supply of new practitioners to address priority public health, preventive medicine, public health dentistry, and health administration needs;

[(7) preparing public health professionals for employment at the State and community levels; or

[(8) other activities that may produce outcomes that are consistent with the purposes of this section.

[(e) TRAINEESHIPS.—

[(1) IN GENERAL.—With respect to amounts used under this section for the training of health professionals, such training programs shall be designed to—

[(A) make public health education more accessible to the public and private health workforce;

[(B) increase the relevance of public health academic preparation to public health practice in the future;

[(C) provide education or training for students from traditional on-campus programs in practice-based sites; or

[(D) develop educational methods and distance-based approaches or technology that address adult learning requirements and increase knowledge and skills related to community-based cultural diversity in public health education.

[(2) SEVERE SHORTAGE DISCIPLINES.—Amounts provided under grants or contracts under this section may be used for the operation of programs designed to award traineeships to students in accredited schools of public health who enter educational programs in fields where there is a severe shortage of public health professionals, including epidemiology, biostatis-

tics, environmental health, toxicology, public health nursing, nutrition, preventive medicine, maternal and child health, and behavioral and mental health professions.]

SEC. 765. ENHANCING THE PUBLIC HEALTH WORKFORCE.

(a) PROGRAM.—The Secretary, acting through the Administrator of the Health Resources and Services Administration and in consultation with the Director of the Centers for Disease Control and Prevention, shall establish a public health workforce training and enhancement program consisting of awarding grants and contracts under subsection (b).

(b) GRANTS AND CONTRACTS.—The Secretary shall award grants and contracts to eligible entities—

(1) to plan, develop, operate, or participate in, an accredited professional training program in the field of public health (including such a program in nursing; health administration, management, or policy; preventive medicine; laboratory science; veterinary medicine; or dental medicine) for members of the public health workforce including mid-career professionals;

(2) to provide financial assistance in the form of traineeships and fellowships to students who are participants in any such program and who plan to specialize or work in the field of public health;

(3) to plan, develop, operate, or participate in a program for the training of public health professionals who plan to teach in any program described in paragraph (1); and

(4) to provide financial assistance in the form of traineeships and fellowships to public health professionals who are participants in any program described in paragraph (1) and who plan to teach in the field of public health, including nursing; health administration, management, or policy; preventive medicine; laboratory science; veterinary medicine; or dental medicine.

(c) ELIGIBILITY.—To be eligible for a grant or contract under subsection (a), an entity shall be—

(1) an accredited health professions school, including an accredited school or program of public health; nursing; health administration, management, or policy; preventive medicine; laboratory science; veterinary medicine; or dental medicine;

(2) a State, local, or tribal health department;

(3) a public or private nonprofit entity; or

(4) a consortium of 2 or more entities described in paragraphs (1) through (3).

(d) PREFERENCE.—In awarding grants or contracts under this section, the Secretary shall give preference to entities that have a demonstrated record of the following:

(1) Training the greatest percentage, or significantly improving the percentage, of public health professionals who serve in underserved communities.

(2) Training individuals who are from underrepresented minority groups or disadvantaged backgrounds.

(3) Training individuals in public health specialties experiencing a significant shortage of public health professionals (as determined by the Secretary).

(4) Training the greatest percentage, or significantly improving the percentage, of public health professionals serving in the Federal Government or a State, local, or tribal government.

(e) REPORT.—The Secretary shall submit to the Congress an annual report on the program carried out under this section.

SEC. 766. PUBLIC HEALTH TRAINING CENTERS.

(a) * * *

(b) ELIGIBLE ENTITIES.—

(1) IN GENERAL.—A public health training center shall be an accredited school of public health, or another public or nonprofit private institution accredited for the provision of graduate or specialized training in public health, that plans, develops, operates, and evaluates projects that are [in furtherance of the goals established by the Secretary for the year 2000] *in furtherance of the goals established by the Secretary in the national prevention and wellness strategy under section 3121* in the areas of preventive medicine, health promotion and disease prevention, or improving access to and quality of health services in medically underserved communities.

* * * * * * *

(d) REPORT.—The Secretary shall submit to the Congress an annual report on the program carried out under this section.

* * * * * * *

[SEC. 768. PREVENTIVE MEDICINE; DENTAL PUBLIC HEALTH.

[(a) IN GENERAL.—The Secretary may make grants to and enter into contracts with schools of medicine, osteopathic medicine, public health, and dentistry to meet the costs of projects—

[(1) to plan and develop new residency training programs and to maintain or improve existing residency training programs in preventive medicine and dental public health; and

[(2) to provide financial assistance to residency trainees enrolled in such programs.

[(b) ADMINISTRATION.—

[(1) AMOUNT.—The amount of any grant under subsection (a) shall be determined by the Secretary.

[(2) ELIGIBILITY.—To be eligible for a grant under subsection (a), the applicant must demonstrate to the Secretary that it has or will have available full-time faculty members with training and experience in the fields of preventive medicine or dental public health and support from other faculty members trained in public health and other relevant specialties and disciplines.

[(3) OTHER FUNDS.—Schools of medicine, osteopathic medicine, dentistry, and public health may use funds committed by State, local, or county public health officers as matching amounts for Federal grant funds for residency training programs in preventive medicine.]

SEC. 768. PREVENTIVE MEDICINE AND PUBLIC HEALTH TRAINING GRANT PROGRAM.

(a) GRANTS.—The Secretary, acting through the Administrator of the Health Resources and Services Administration and in consultation with the Director of the Centers for Disease Control and Prevention, shall award grants to, or enter into contracts with, eligible entities to provide training to graduate medical residents in preventive medicine specialties.

(b) ELIGIBILITY.—To be eligible for a grant or contract under subsection (a), an entity shall be—

(1) an accredited school of public health or school of medicine or osteopathic medicine;

(2) an accredited public or private hospital;

(3) a State, local, or tribal health department; or

(4) a consortium of 2 or more entities described in paragraphs (1) through (3).

(c) USE OF FUNDS.—Amounts received under a grant or contract under this section shall be used to—

(1) plan, develop (including the development of curricula), operate, or participate in an accredited residency or internship program in preventive medicine or public health;

(2) defray the costs of practicum experiences, as required in such a program; and

(3) establish, maintain, or improve—

(A) academic administrative units (including departments, divisions, or other appropriate units) in preventive medicine and public health; or

(B) programs that improve clinical teaching in preventive medicine and public health.

(d) REPORT.—The Secretary shall submit to the Congress an annual report on the program carried out under this section.

* * * * * * *

SEC. 770. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—For the purpose of carrying out this subpart, there is authorized to be appropriated $9,100,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through [2002] *2014*.

* * * * * * *

Subpart 3—Mental and Behavioral Health Training

SEC. 775. MENTAL AND BEHAVIORAL HEALTH TRAINING PROGRAM.

(a) PROGRAM.—The Secretary shall establish an interdisciplinary mental and behavioral health training program consisting of awarding grants and contracts under subsection (b).

(b) SUPPORT AND DEVELOPMENT OF MENTAL AND BEHAVIORAL HEALTH TRAINING PROGRAMS.—The Secretary shall make grants to, or enter into contracts with, eligible entities—

(1) to plan, develop, operate, or participate in an accredited professional training program for mental and behavioral health professionals to promote—

(A) interdisciplinary training; and

(B) coordination of the delivery of health care within and across settings, including health care institutions, community-based settings, and the patient's home;

(2) to provide financial assistance to mental and behavioral health professionals, who are participants in any such program, and who plan to work in the field of mental and behavioral health;

(3) to plan, develop, operate, or participate in an accredited program for the training of mental and behavioral health professionals who plan to teach in the field of mental and behavioral health; and

(4) to provide financial assistance in the form of traineeships and fellowships to mental and behavioral health professionals who are participants in any such program and who plan to teach in the field of mental and behavioral health.

(c) ELIGIBILITY.—To be eligible for a grant or contract under subsection (b), an entity shall be—

(1) an accredited health professions school, including an accredited school or program of psychology, psychiatry, social work, marriage and family therapy, professional mental health and substance abuse counseling, or addiction medicine;

(2) an accredited public or nonprofit private hospital;

(3) a public or private nonprofit entity; or

(4) a consortium of 2 or more entities described in paragraphs (1) through (3).

(d) PREFERENCE.—In awarding grants or contracts under this section, the Secretary shall give preference to entities that have a demonstrated record of the following:

(1) Training the greatest percentage, or significantly improving the percentage, of health professionals who serve in underserved communities.

(2) Supporting teaching programs that address the health care needs of vulnerable populations.

(3) Training individuals who are from underrepresented minority groups or disadvantaged backgrounds.

(4) Training individuals who serve geriatric populations with an emphasis on underserved elderly.

(5) Training individuals who serve pediatric populations with an emphasis on underserved children.

(e) REPORT.—The Secretary shall submit to the Congress an annual report on the program under this section.

(f) DEFINITION.—In this section:

(1) The term "health disparities" has the meaning given the term in section 3171.

(2) The term "mental and behavioral health professional" means an individual training or practicing—

(A) in psychology; general, geriatric, child or adolescent psychiatry; social work; marriage and family therapy; professional mental health and substance abuse counseling; or addiction medicine; or

(B) another mental and behavioral health specialty, as deemed appropriate by the Secretary.

(3) The term "interdisciplinary" means collaboration across health professions, specialties, and subspecialties, which may include public health, nursing, allied health, and appropriate medical specialties.

(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there is authorized to be appropriated $60,000,000 for each of fiscal years 2010 through 2014. Of the amounts appropriated to carry out this section for a fiscal year, not less than 15 percent shall be used for training programs in psychology.

PART F—GENERAL PROVISIONS

SEC. 791. PREFERENCES AND REQUIRED INFORMATION IN CERTAIN PROGRAMS.

(a) PREFERENCES IN MAKING AWARDS.—

(1) IN GENERAL.—Subject to paragraph (2), in making awards of grants or contracts under any of sections [747 and 750] *747, 749, and 750*, the Secretary shall give preference to any qualified applicant that—

(A) * * *

* * * * * * *

SEC. 799C. FUNDING THROUGH PUBLIC HEALTH INVESTMENT FUND.

(a) PROMOTION OF PRIMARY CARE AND DENTISTRY.—For the purpose of carrying out subpart XI of part D of title III and sections 747, 748, and 749, in addition to any other amounts authorized to be appropriated for such purpose, there are authorized to be appropriated, out of any monies in the Public Health Investment Fund, the following:

(1) $240,000,000 for fiscal year 2010.
(2) $253,000,000 for fiscal year 2011.
(3) $265,000,000 for fiscal year 2012.
(4) $278,000,000 for fiscal year 2013.
(5) $292,000,000 for fiscal year 2014.

(b) PUBLIC HEALTH WORKFORCE.—For the purpose of carrying out subpart XII of part D of title III and sections 765, 766, and 768, in addition to any other amounts authorized to be appropriated for such purpose, there are authorized to be appropriated, out of any monies in the Public Health Investment Fund, the following:

(1) $51,000,000 for fiscal year 2010.
(2) $54,000,000 for fiscal year 2011.
(3) $57,000,000 for fiscal year 2012.
(4) $59,000,000 for fiscal year 2013.
(5) $62,000,000 for fiscal year 2014.

(c) HEALTH PROFESSIONS TRAINING FOR DIVERSITY.—For the purpose of carrying out sections 736, 737, 738, 739, and 739A, in addition to any other amounts authorized to be appropriated for such purpose, there are authorized to be appropriated, out of any monies in the Public Health Investment Fund, the following:

(1) $90,000,000 for fiscal year 2010.
(2) $97,000,000 for fiscal year 2011.
(3) $100,000,000 for fiscal year 2012.
(4) $104,000,000 for fiscal year 2013.
(5) $110,000,000 for fiscal year 2014.

(d) INTERDISCIPLINARY TRAINING PROGRAMS, ADVISORY COMMITTEE ON HEALTH WORKFORCE EVALUATION AND ASSESSMENT, AND HEALTH WORKFORCE ASSESSMENT.—For the purpose of carrying out sections 741, 759, 761, and 764, in addition to any other amounts authorized to be appropriated for such purpose, there are authorized to be appropriated, out of any monies in the Public Health Investment Fund, the following:

(1) $87,000,000 for fiscal year 2010.
(2) $97,000,000 for fiscal year 2011.
(3) $103,000,000 for fiscal year 2012.
(4) $105,000,000 for fiscal year 2013.

(5) $113,000,000 for fiscal year 2014.

(e) QUALITY AND SURVEILLANCE.—For the purpose of carrying out part D of title IX and section 1709, in addition to any other amounts authorized to be appropriated for such purpose, there are authorized to be appropriated, out of any monies in the Public Health Investment Fund, $300,000,000 for each of fiscal years 2010 through 2014.

TITLE VIII—NURSING WORKFORCE DEVELOPMENT

PART A—GENERAL PROVISIONS

SEC. 801. DEFINITIONS.

As used in this title:

(1) ELIGIBLE ENTITIES.—The term "eligible entities" means schools of nursing, nursing centers, *nurse-managed health centers,* academic health centers, State or local governments, and other public or private nonprofit entities determined appropriate by the Secretary that submit to the Secretary an application in accordance with section 802.

* * * * * * *

(16) NURSE-MANAGED HEALTH CENTER.—The term "nurse-managed health center" means a nurse-practice arrangement, managed by advanced practice nurses, that provides primary care or wellness services to underserved or vulnerable populations and is associated with an accredited school of nursing, Federally qualified health center, or independent nonprofit health or social services agency.

* * * * * * *

[SEC. 807. GRANTS FOR HEALTH PROFESSIONS EDUCATION.

[(a) GRANTS FOR HEALTH PROFESSIONS EDUCATION IN HEALTH DISPARITIES AND CULTURAL COMPETENCY.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, may make awards of grants, contracts, or cooperative agreements to eligible entities for the purpose of carrying out research and demonstration projects (including research and demonstration projects for continuing health professions education) for training and education for the reduction of disparities in health care outcomes and the provision of culturally competent health care. Grants under this section shall be the same as provided in section 741.

[(b) AUTHORIZATION OF APPROPRIATIONS.—There are to be appropriated to carry out subsection (a) such sums as may be necessary for each of the fiscal years 2001 through 2004.]

* * * * * * *

SEC. 809. REPORTS.

The Secretary shall submit to the Congress a separate annual report on the activities carried out under each of sections 811, 821, 836, 846A, and 861.

PROHIBITION AGAINST DISCRIMINATION BY SCHOOLS ON THE BASIS OF SEX

SEC. 810. The Secretary may not make a grant, loan guarantee, or interest subsidy payment under this title to, or for the benefit of, any school of nursing unless the application for the grant, loan guarantee, or interest subsidy payment contains assurances satisfactory to the Secretary that the school will not discriminate on the basis of sex in the admission of individuals to its training programs. The Secretary may not enter into a contract under this title with any school unless the school furnishes assurances satisfactory to the Secretary that it will not discriminate on the basis of sex in the admission of individuals to its training programs.

PART B—NURSE PRACTITIONERS, NURSE MIDWIVES, NURSE ANESTHETISTS, AND OTHER ADVANCED EDUCATION NURSES

SEC. 811. ADVANCED EDUCATION NURSING GRANTS.

(a) * * *

* * * * * * *

(f) TRAINEESHIPS.—

(1) * * *

[(2) DOCTORAL PROGRAMS.—The Secretary may not obligate more than 10 percent of the traineeships under subsection (a) for individuals in doctorate degree programs.]

[(3)] *(2)* SPECIAL CONSIDERATION.—In making awards of grants and contracts under subsection (a)(2), the Secretary shall give special consideration to an eligible entity [that agrees to expend the award to train advanced education nurses who will practice in health professional shortage areas designated under section 332.] *that agrees to expend the award—*

(A) to train advanced education nurses who will practice in health professional shortage areas designated under section 332; or

(B) to increase diversity among advanced education nurses.

PART C—INCREASING NURSING WORKFORCE DIVERSITY

SEC. 821. WORKFORCE DIVERSITY GRANTS.

(a) * * *

(b) [GUIDANCE] *CONSULTATION*.—In carrying out subsection (a), the Secretary [shall take into consideration the recommendations of the First, Second and Third Invitational Congresses for Minority Nurse Leaders on "Caring for the Emerging Majority," in 1992, 1993 and 1997, and consult with nursing associations] *shall, as appropriate, consult with nursing associations* including the American Nurses Association, the National League for Nursing, the American Association of Colleges of Nursing, the National Black Nurses Association, the National Association of Hispanic Nurses, the Association of Asian American and Pacific Islander Nurses, the Native

American Indian and Alaskan Nurses Association, and the National Council of State Boards of Nursing.

* * * * * * *

PART D—STRENGTHENING CAPACITY FOR BASIC NURSE EDUCATION AND PRACTICE

SEC. 831. NURSE EDUCATION, PRACTICE, AND RETENTION GRANTS.

(a) * * *

(b) PRACTICE PRIORITY AREAS.—The Secretary may award grants to or enter into contracts with eligible entities for—

(1) * * *

* * * * * * *

[(3) providing managed care, quality improvement, and other skills needed to practice in existing and emerging organized health care systems; or]

(3) providing coordinated care, quality care, and other skills needed to practice nursing; or

* * * * * * *

[(e) PREFERENCE.—For purposes of any amount of funds appropriated to carry out this section for fiscal year 2003, 2004, or 2005 that is in excess of the amount of funds appropriated to carry out this section for fiscal year 2002, the Secretary shall give preference to awarding grants or entering into contracts under subsections (a)(2) and (c).]

[(f)] *(e)* REPORT.—The Secretary shall submit to the Congress before the end of each fiscal year a report on the grants awarded and the contracts entered into under this section. Each such report shall identify the overall number of such grants and contracts and provide an explanation of why each such grant or contract will meet the priority need of the nursing workforce.

[(g)] *(f)* ELIGIBLE ENTITY.—For purposes of this section, the term "eligible entity" includes a school of nursing, a health care facility, or a partnership of such a school and facility.

[(h)] *(g)* AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2003 through [2007] *2014*.

PART E—STUDENT LOANS

LOAN AGREEMENTS

SEC. 835. (a) The Secretary is authorized to enter into an agreement for the establishment and operation of a student loan fund in accordance with [this subpart] *this part* with any public or nonprofit private school of nursing which is located in a State.

(b) Each agreement entered into under this section shall—

(1) * * *

(2) provide for deposit in the fund, except as provided in section [841] *871*, of (A) the Federal capital contributions paid from allotments under section 838 to the school by the Secretary, (B) an additional amount from other sources equal to not less than one-ninth of such Federal capital contributions, (C) collections of principal and interest on loans made from the

fund, (D) collections pursuant to section 836(f), and (E) any other earnings of the fund;

(3) provide that the fund, except as provided in section [841] *871*, shall be used only for loans to students of the school in accordance with the agreement and for costs of collection of such loans and interest thereon;

* * * * * * *

(c)(1) Any standard established by the Secretary by regulation for the collection by schools of nursing of loans made pursuant to loan agreements under [this subpart] *this part* shall provide that the failure of any such school to collect such loans shall be measured in accordance with this subsection. With respect to the student loan fund established pursuant to such agreements, this subsection may not be construed to require such schools to reimburse such loan fund for loans that became uncollectable prior to 1983.

(2) The measurement of a school's failure to collect loans made under [this subpart] *this part* shall be the ratio (stated as a percentage) that the defaulted principal amount outstanding of such school bears to the matured loans of such school.

(3) For purposes of this subsection—

(A) the term "default" means the failure of a borrower of a loan made under [this subpart] *this part* to—

(i) * * *

* * * * * * *

except that a loan made under [this subpart] *this part* shall not be considered to be in default if the loan is discharged in bankruptcy or if the school reasonably concludes from written contacts with the borrower that the borrower intends to repay the loan;

* * * * * * *

(D) the term "matured loans" means the total principal amount of all loans made by a school of nursing under [this subpart] *this part* minus the total principal amount of loans made by such school to students who are—

(i) * * *

* * * * * * *

LOAN PROVISIONS

SEC. 836. (a) The total of the loans for any academic year (or its equivalent, as determined under regulations of the Secretary) made by schools of nursing from loan funds established pursuant to agreements under [this subpart] *this part* may not exceed [$2,500] *$3,300* in the case of any student, except that for the final two academic years of the program involved, such total may not exceed [$4,000] *$5,200*. The aggregate of the loans for all years from such funds may not exceed [$13,000] *$17,000* in the case of any student. In the granting of such loans, a school shall give preference to licensed practical nurses, to persons with exceptional financial need, and to persons who enter as first-year students after enactment of this title. *Beginning with fiscal year 2012, the dollar amounts specified in this subsection shall be adjusted by an amount determined by the Secretary on an annual basis to reflect inflation.*

(b) Loans from any such student loan fund by any school shall be made on such terms and conditions as the school may determine; subject, however, to such conditions, limitations, and requirements as the Secretary may prescribe (by regulation or in the agreement with the school) with a view to preventing impairment of the capital of such fund to the maximum extent practicable in the light of the objective of enabling the student to complete his course of study; and except that—

(1) * * *

* * * * * * *

(7) no note or other evidence of any such loan may be transferred or assigned by the school making the loan except that, if the borrower transfers to another school participating in the program under [this subpart] *this part*, such note or other evidence of a loan may be transferred to such other school; and

* * * * * * *

(d) Any loan for any year by a school from a student loan fund established pursuant to an agreement under [this subpart] *this part* shall be made in such installments as may be provided in regulations of the Secretary or such agreement and, upon notice to the Secretary by the school that any recipient of a loan is failing to maintain satisfactory standing, any or all further installments of his loans shall be withheld, as may be appropriate.

(e) An agreement under [this subpart] *this part* with any school shall include provisions designed to make loans from the student loan fund established thereunder reasonably available (to the extent of the available funds in such fund) to all eligible students in the school in need thereof.

(f) Subject to regulations of the Secretary and in accordance with this section, a school shall assess a charge with respect to a loan from the loan fund established pursuant to an agreement under [this subpart] *this part* for failure of the borrower to pay all or any part of an installment when it is due and, in the case of a borrower who is entitled to deferment of the loan under subsection (b)(2) or cancellation of part or all of the loan under subsection (b)(3), for any failure to file timely and satisfactory evidence of such entitlement. No such charge may be made if the payment of such installment or the filing of such evidence is made within 60 days after the date on which such installment or filing is due. The amount of any such charge may not exceed an amount equal to 6 percent of the amount of such installment. The school may elect to add the amount of any such charge to the principal amount of the loan as of the first day after the day on which such installment or evidence was due, or to make the amount of the charge payable to the school not later than the due date of the next installment after receipt by the borrower of notice of the assessment of the charge.

(g) A school may provide in accordance with regulations of the Secretary, that during the repayment period of a loan from a loan fund established pursuant to an agreement under [this subpart] *this part* payments of principal and interest by the borrower with respect to all the outstanding loans made to him from loan funds so established shall be at a rate equal to not less than $40 per month.

(h) Notwithstanding the amendment made by section 6(b) of the Nurse Training Act of 1971 to this section—

(A) any person who obtained one or more loans from a loan fund established under [this subpart] *this part*, who before the date of the enactment of the Nurse Training Act of 1971 became eligible for cancellation of all or part of such loans (including accrued interest) under this section (as in effect on the day before such date), and who on such date was not engaged in a service for which loan cancellation was authorized under this section (as so in effect), may at any time elect to receive such cancellation in accordance with this subsection (as so in effect); and

(B) in the case of any person who obtained one or more loans from a loan fund established under [this subpart] *this part* and who on such date was engaged in a service for which cancellation of all or part of such loans (including accrued interest) was authorized under this section (as so in effect), this section (as so in effect) shall continue to apply to such person for purposes of providing such loan cancellation until he terminates such service.

[Nothing in this subsection shall be construed to prevent any person from entering into an agreement for loan cancellation under subsection (h) (as amended by section 6(b)(2) of the Nurse Training Act of 1971).]

* * * * * * *

(j) The Secretary is authorized to attempt to collect any loan which was made under [this subpart] *this part*, which is in default, and which was referred to the Secretary by a school of nursing with which the Secretary has an agreement under [this subpart] *this part*, on behalf of that school under such terms and conditions as the Secretary may prescribe (including reimbursement from the school's student loan fund for expenses the Secretary may reasonably incur in attempting collection), but only if the school has complied with such requirements as the Secretary may specify by regulation with respect to the collection of loans under [this subpart] *this part*. A loan so referred shall be treated as a debt subject to section 5514 of title 5, United States Code. Amounts collected shall be deposited in the school's student loan fund. Whenever the Secretary desires the institution of a civil action regarding any such loan, the Secretary shall refer the matter to the Attorney General for appropriate action.

[(l)] *(k)* ELIMINATION OF STATUTE OF LIMITATION FOR LOAN COLLECTIONS.—

(1) * * *

(2) PROHIBITION.—Notwithstanding any other provision of Federal or State law, no limitation shall terminate the period within which suit may be filed, a judgment may be enforced, or an offset, garnishment, or other action may be initiated or taken by a school of nursing that has an agreement with the Secretary pursuant to section 835 that is seeking the repayment of the amount due from a borrower on a loan made under [this subpart] *this part* after the default of the borrower on such loan.

ALLOTMENTS AND PAYMENTS OF FEDERAL CAPITAL CONTRIBUTIONS

SEC. 838. (a)(1) * * *

* * * * * * *

(3) Funds which, pursuant to section 839(c) or pursuant to a loan agreement under section 835, are returned to the Secretary in any fiscal year, shall be available for allotment until expended. Funds described in the preceding sentence shall be allotted among schools of nursing in such manner as the Secretary determines will best carry out [this subpart] *this part*.

* * * * * * *

(c) The Federal capital contributions to a loan fund of a school under [this subpart] *this part* shall be paid to it from time to time in such installments as the Secretary determines will not result in unnecessary accumulations in the loan fund at such school.

DISTRIBUTION OF ASSETS FROM LOAN FUNDS

SEC. [839.

[(a)] *839. (a)* If a school terminates a loan fund established under an agreement pursuant to section 835(b), or if the Secretary for good cause terminates the agreement with the school, there shall be a capital distribution as follows:

(1) * * *

* * * * * * *

ADMINISTRATIVE PROVISIONS

SEC. 840. The Secretary may agree to modifications of agreements made under [this subpart] *this part*, and may compromise, waive, or release any right, title, claim, or demand of the United States arising or acquired under [this subpart] *this part*.

* * * * * * *

PROCEDURES FOR APPEAL OF TERMINATIONS

SEC. 842. In any case in which the Secretary intends to terminate an agreement with a school of nursing under [this subpart] *this part*, the Secretary shall provide the school with a written notice specifying such intention and stating that the school may request a formal hearing with respect to such termination. If the school requests such a hearing within 30 days after the receipt of such notice, the Secretary shall provide such school with a hearing conducted by an administrative law judge.

* * * * * * *

LOAN REPAYMENT AND SCHOLARSHIP PROGRAMS

SEC. 846. (a) IN GENERAL.—In the case of any individual—

(1) * * *

* * * * * * *

[(3) who enters into an agreement with the Secretary to serve as nurse for a period of not less than two years at a health care facility with a critical shortage of nurses;]

(3) who enters into an agreement with the Secretary to serve for a period of not less than 2 years—

(A) as a nurse at a health care facility with a critical shortage of nurses; or

(B) as a faculty member at an accredited school of nursing;

* * * * * * *

(g) BREACH OF AGREEMENT.—

(1) IN GENERAL.—In the case of any program under this section under which an individual makes an agreement [to provide health services] *to provide health services or serve as a faculty member* for a period of time in accordance with such program in consideration of receiving an award of Federal funds regarding education as a nurse (including an award for the repayment of loans), the following applies if the agreement provides that this subsection is applicable:

(A) * * *

(B) The individual is liable to the Federal Government for the amount of such award (including amounts provided for expenses related to such attendance), and for interest on such amount at the maximum legal prevailing rate, if the individual fails [to provide health services] *to provide health services or serve as a faculty member* in accordance with the program under this section for the period of time applicable under the program.

* * * * * * *

(i) FUNDING.—

(1) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of payments under agreements entered into under subsection (a) or (d), there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2003 through [2007] *2014*.

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NURSE FACULTY LOAN PROGRAM

SEC. 846A. (a) * * *

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(c) LOAN PROVISIONS.—Loans from any student loan fund established by a school pursuant to an agreement under subsection (a) shall be made to an individual on such terms and conditions as the school may determine, except that—

(1) * * *

(2) in the case of any individual, the total of the loans for any academic year made by schools of nursing from loan funds established pursuant to agreements under subsection (a) may not exceed [$30,000, plus any amount determined by the Secretary on an annual basis to reflect inflation;] *$35,000, plus, beginning with fiscal year 2012, an amount determined by the Secretary on an annual basis to reflect inflation;*

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(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2003 through [2007] *2014*.

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PART [G] *F*—NATIONAL ADVISORY COUNCIL ON NURSE EDUCATION AND PRACTICE

SEC. [845.] *851.* NATIONAL ADVISORY COUNCIL ON NURSE EDUCATION AND PRACTICE.

(a) * * *

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[PART H—PUBLIC SERVICE ANNOUNCEMENTS

[SEC. 851. PUBLIC SERVICE ANNOUNCEMENTS.

[(a) IN GENERAL.—The Secretary shall develop and issue public service announcements that advertise and promote the nursing profession, highlight the advantages and rewards of nursing, and encourage individuals to enter the nursing profession.

[(b) METHOD.—The public service announcements described in subsection (a) shall be broadcast through appropriate media outlets, including television or radio, in a manner intended to reach as wide and diverse an audience as possible.

[(c) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2003 through 2007.

[SEC. 852. STATE AND LOCAL PUBLIC SERVICE ANNOUNCEMENTS.

[(a) IN GENERAL.—The Secretary may award grants to eligible entities to support State and local advertising campaigns through appropriate media outlets to promote the nursing profession, highlight the advantages and rewards of nursing, and encourage individuals from disadvantaged backgrounds to enter the nursing profession.

[(b) USE OF FUNDS.—An eligible entity that receives a grant under subsection (a) shall use funds received through such grant to acquire local television and radio time, place advertisements in local newspapers, or post information on billboards or on the Internet in a manner intended to reach as wide and diverse an audience as possible, in order to—

[(1) advertise and promote the nursing profession;

[(2) promote nursing education programs;

[(3) inform the public of financial assistance regarding such education programs;

[(4) highlight individuals in the community who are practicing nursing in order to recruit new nurses; or

[(5) provide any other information to recruit individuals for the nursing profession.

[(c) LIMITATION.—An eligible entity that receives a grant under subsection (a) shall not use funds received through such grant to advertise particular employment opportunities.

[(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2003 through 2007.]

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PART [I] *G*—COMPREHENSIVE GERIATRIC EDUCATION

SEC. [855] *861*. COMPREHENSIVE GERIATRIC EDUCATION.

(a) * * *

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(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2003 through [2007] *2014*.

[PART F] *PART H*—FUNDING

[SEC. 841. FUNDING.

[(a) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out parts B, C, and D (subject to section 845(g)), there are authorized to be appropriated $65,000,000 for fiscal year 1998, and such sums as may be necessary for each of the fiscal years 1999 through 2002.

[(b) ALLOCATIONS FOR FISCAL YEARS 1998 THROUGH 2002.—

[(1) NURSE PRACTITIONERS; NURSE MIDWIVES.—

[(A) FISCAL YEAR 1998.—Of the amount appropriated under subsection (a) for fiscal year 1998, the Secretary shall reserve not less than $17,564,000 for making awards of grants and contracts under section 822 as such section was in effect for fiscal year 1998.

[(B) FISCAL YEARS 1999 THROUGH 2002.—Of the amount appropriated under subsection (a) for fiscal year 1999 or any of the fiscal years 2000 through 2002, the Secretary, subject to subsection (d), shall reserve for the fiscal year involved, for making awards of grants and contracts under part B with respect to nurse practitioners and nurse midwives, not less than the percentage constituted by the ratio of the amount appropriated under section 822 as such section was in effect for fiscal year 1998 to the total of the amounts appropriated under this title for such fiscal year. For purposes of the preceding sentence, the Secretary, in determining the amount that has been reserved for the fiscal year involved, shall include any amounts appropriated under subsection (a) for the fiscal year that are obligated by the Secretary to continue in effect grants or contracts under section 822 as such section was in effect for fiscal year 1998.

[(2) NURSE ANESTHETISTS.—

[(A) FISCAL YEAR 1998.—Of the amount appropriated under subsection (a) for fiscal year 1998, the Secretary shall reserve not less than $2,761,000 for making awards of grants and contracts under section 831 as such section was in effect for fiscal year 1998.

[(B) FISCAL YEARS 1999 THROUGH 2002.—Of the amount appropriated under subsection (a) for fiscal year 1999 or any of the fiscal years 2000 through 2002, the Secretary, subject to subsection (d), shall reserve for the fiscal year involved, for making awards of grants and contracts under part B with respect to nurse anesthetists, not less than the percentage constituted by the ratio of the amount appropriated under section 831 as such section was in effect for fiscal year 1998 to the total of the amounts appropriated under this title for such fiscal year. For purposes of the preceding sentence, the Secretary, in determining the amount that has been reserved for the fiscal year involved, shall include any amounts appropriated under subsection (a) for the fiscal year that are obligated by the Secretary to continue in effect grants or contracts under section 831 as such section was in effect for fiscal year 1998.

[(c) ALLOCATIONS AFTER FISCAL YEAR 2002.—

[(1) IN GENERAL.—For fiscal year 2003 and subsequent fiscal years, amounts appropriated under subsection (a) for the fiscal year involved shall be allocated by the Secretary among parts B, C, and D (and programs within such parts) according to a methodology that is developed in accordance with paragraph (2). The Secretary shall enter into a contract with a public or private entity for the purpose of developing the methodology. The contract shall require that the development of the methodology be completed not later than February 1, 2002.

[(2) USE OF CERTAIN FACTORS.—The contract under paragraph (1) shall provide that the methodology under such paragraph will be developed in accordance with the following:

[(A) The methodology will take into account the need for and the distribution of health services among medically underserved populations, as determined according to the factors that apply under section 330(b)(3).

[(B) The methodology will take into account the need for and the distribution of health services in health professional shortage areas, as determined according to the factors that apply under section 332(b).

[(C) The methodology will take into account the need for and the distribution of mental health services among medically underserved populations and in health professional shortage areas.

[(D) The methodology will be developed in consultation with individuals in the field of nursing, including registered nurses, nurse practitioners, nurse midwives, nurse anesthetists, clinical nurse specialists, nursing educators and educational institutions, nurse executives, pediatric nurse associates and practitioners, and women's health, obstetric, and neonatal nurses.

[(E) The methodology will take into account the following factors with respect to the States:

[(i) A provider population ratio equivalent to a managed care formula of 1/1,500 for primary care services.

[(ii) The use of whole rather than fractional counts in determining the number of health care providers.

[(iii) The counting of only employed health care providers in determining the number of health care providers.

[(iv) The number of families whose income is less than 200 percent of the official poverty line (as established by the Director of the Office of Management and Budget and revised by the Secretary in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981).

[(v) The rate of infant mortality and the rate of low-birthweight births.

[(vi) The percentage of the general population constituted by individuals who are members of racial or ethnic minority groups, stated both by minority group and in the aggregate.

[(vii) The percentage of the general population constituted by individuals who are of Hispanic ethnicity.

[(viii) The number of individuals residing in health professional shortage areas, and the number of individuals who are members of medically underserved populations.

[(ix) The percentage of the general population constituted by elderly individuals.

[(x) The extent to which the populations served have a choice of providers.

[(xi) The impact of care on hospitalizations and emergency room use.

[(xii) The number of individuals who lack proficiency in speaking the English language.

[(xiii) Such additional factors as the Secretary determines to be appropriate.

[(3) REPORT TO CONGRESS.—Not later than 30 days after the completion of the development of the methodology required in paragraph (1), the Secretary shall submit to the Committee on Commerce of the House of Representatives, and to the Committee on Labor and Human Resources of the Senate, a report describing the methodology and explaining the effects of the methodology on the allocation among parts B, C, and D (and programs within such parts) of amounts appropriated under subsection (a) for the first fiscal year for which the methodology will be in effect. Such explanation shall include a comparison of the allocation for such fiscal year with the allocation made under this section for the preceding fiscal year.

[(d) USE OF METHODOLOGY BEFORE FISCAL YEAR 2003.—With respect to the fiscal years 1999 through 2002, if the report required in subsection (c)(3) is submitted in accordance with such subsection not later than 90 days before the beginning of such a fiscal year, the Secretary may for such year implement the methodology described in the report (rather than implementing the methodology in fiscal year 2003), in which case subsection (b) ceases to be in effect. The authority under the preceding sentence is subject to the condition that the fiscal year for which the methodology is implemented be the same fiscal year identified in such report as the fiscal year for which the methodology will first be in effect.

[(e) AUTHORITY FOR USE OF ADDITIONAL FACTORS IN METHODOLOGY.—

[(1) IN GENERAL.—The Secretary shall make the determinations specified in paragraph (2). For any fiscal year beginning after the first fiscal year for which the methodology under subsection (c)(1) is in effect, the Secretary may alter the methodology by including the information from such determinations as factors in the methodology.

[(2) RELEVANT DETERMINATIONS.—The determinations referred to in paragraph (1) are as follows:

[(A) The need for and the distribution of health services among populations for which it is difficult to determine the number of individuals who are in the population, such as homeless individuals; migratory and seasonal agricultural workers and their families; individuals infected with the human immunodeficiency virus, and individuals who abuse drugs.

[(B) In the case of a population for which the determinations under subparagraph (A) are made, the extent to which the population includes individuals who are members of racial or ethnic minority groups and a specification of the skills needed to provide health services to such individuals in the language and the educational and cultural context that is most appropriate to the individuals.

[(C) Data, obtained from the Director of the Centers for Disease Control and Prevention, on rates of morbidity and mortality among various populations (including data on the rates of maternal and infant mortality and data on the rates of low-birthweight births of living infants).

[(D) Data from the Health Plan Employer Data and Information Set, as appropriate.]

SEC. 871. FUNDING.

For the purpose of carrying out parts B, C, and D (subject to section 845(g)), there are authorized to be appropriated such sums as may be necessary for each fiscal year through fiscal year 2014.

SEC. 872. FUNDING THROUGH PUBLIC HEALTH INVESTMENT FUND.

For the purpose of carrying out this title, in addition to any other amounts authorized to be appropriated for such purpose, there are authorized to be appropriated, out of any monies in the Public Health Investment Fund, the following:

(1) $115,000,000 for fiscal year 2010.
(2) $122,000,000 for fiscal year 2011.
(3) $127,000,000 for fiscal year 2012.
(4) $134,000,000 for fiscal year 2013.
(5) $140,000,000 for fiscal year 2014.

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TITLE IX—AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

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PART B—HEALTH CARE IMPROVEMENT RESEARCH

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SEC. 915. RESEARCH SUPPORTING PRIMARY CARE AND ACCESS IN UNDERSERVED AREAS.

[(a) PREVENTIVE SERVICES TASK FORCE.—

[(1) ESTABLISHMENT AND PURPOSE.—The Director may periodically convene a Preventive Services Task Force to be composed of individuals with appropriate expertise. Such a task force shall review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the health care community, and updating previous clinical preventive recommendations.

[(2) ROLE OF AGENCY.—The Agency shall provide ongoing administrative, research, and technical support for the operations of the Preventive Services Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force.

[(3) OPERATION.—In carrying out its responsibilities under paragraph (1), the Task Force is not subject to the provisions of Appendix 2 of title 5, United States Code.]

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PART D—IMPLEMENTATION OF BEST PRACTICES IN THE DELIVERY OF HEALTH CARE

SEC. 931. CENTER FOR QUALITY IMPROVEMENT.

(a) IN GENERAL.—There is established the Center for Quality Improvement (referred to in this part as the "Center"), to be headed by the Director.

(b) PRIORITIZATION.—

(1) IN GENERAL.—The Director shall prioritize areas for the identification, development, evaluation, and implementation of best practices (including innovative methodologies and strategies) for quality improvement activities in the delivery of health care services (in this section referred to as "best practices").

(2) CONSIDERATIONS.—In prioritizing areas under paragraph (1), the Director shall consider—

(A) the priorities established under section 1191 of the Social Security Act; and

(B) the key health indicators identified by the Assistant Secretary for Health Information under section 1709.

(3) LIMITATIONS.—In conducting its duties under this subsection, the Center for Quality Improvement shall not develop quality-adjusted life year measures or any other methodologies that can be used to deny benefits to a beneficiary against the beneficiary's wishes on the basis of the beneficiary's age, life expectancy, present or predicted disability, or expected quality of life.

(c) OTHER RESPONSIBILITIES.—The Director, acting directly or by awarding a grant or contract to an eligible entity, shall—

(1) identify existing best practices under subsection (e);

(2) develop new best practices under subsection (f);

(3) evaluate best practices under subsection (g);

(4) implement best practices under subsection (h);

(5) ensure that best practices are identified, developed, evaluated, and implemented under this section consistent with standards adopted by the Secretary under section 3004 for health information technology used in the collection and reporting of quality information (including for purposes of the demonstration of meaningful use of certified electronic health record (EHR) technology by physicians and hospitals under the Medicare program (under sections 1848(o)(2) and 1886(n)(3), respectively, of the Social Security Act)); and

(6) provide for dissemination of information and reporting under subsections (i) and (j).

(d) ELIGIBILITY.—To be eligible for a grant or contract under subsection (c), an entity shall—

(1) be a nonprofit entity;

(2) agree to work with a variety of institutional health care providers, physicians, nurses, and other health care practitioners; and

(3) if the entity is not the organization holding a contract under section 1153 of the Social Security Act for the area to be served, agree to cooperate with and avoid duplication of the activities of such organization.

(e) IDENTIFYING EXISTING BEST PRACTICES.—The Secretary shall identify best practices that are—

(1) currently utilized by health care providers (including hospitals, physician and other clinician practices, community cooperatives, and other health care entities) that deliver consistently high-quality, efficient health care services; and

(2) easily adapted for use by other health care providers and for use across a variety of health care settings.

(f) DEVELOPING NEW BEST PRACTICES.—The Secretary shall develop best practices that are—

(1) based on a review of existing scientific evidence;

(2) sufficiently detailed for implementation and incorporation into the workflow of health care providers; and

(3) designed to be easily adapted for use by health care providers across a variety of health care settings.

(g) EVALUATION OF BEST PRACTICES.—The Director shall evaluate best practices identified or developed under this section. Such evaluation—

(1) shall include determinations of which best practices—

(A) most reliably and effectively achieve significant progress in improving the quality of patient care; and

(B) are easily adapted for use by health care providers across a variety of health care settings;

(2) shall include regular review, updating, and improvement of such best practices; and

(3) may include in-depth case studies or empirical assessments of health care providers (including hospitals, physician and other clinician practices, community cooperatives, and other health care entities) and simulations of such best practices for determinations under paragraph (1).

(h) IMPLEMENTATION OF BEST PRACTICES.—

(1) IN GENERAL.—The Director shall enter into arrangements with entities in a State or region to implement best practices identified or developed under this section. Such implementation—

(A) may include forming collaborative multi-institutional teams; and

(B) shall include an evaluation of the best practices being implemented, including the measurement of patient outcomes before, during, and after implementation of such best practices.

(2) PREFERENCES.—In carrying out this subsection, the Director shall give priority to health care providers implementing best practices that—

(A) have the greatest impact on patient outcomes and satisfaction;

(B) are the most easily adapted for use by health care providers across a variety of health care settings;

(C) promote coordination of health care practitioners across the continuum of care; and

(D) engage patients and their families in improving patient care and outcomes.

(i) PUBLIC DISSEMINATION OF INFORMATION.—The Director shall provide for the public dissemination of information with respect to best practices and activities under this section. Such information shall be made available in appropriate formats and languages to reflect the varying needs of consumers and diverse levels of health literacy.

(j) REPORT.—

(1) IN GENERAL.—The Director shall submit an annual report to the Congress and the Secretary on activities under this section.

(2) CONTENT.—Each report under paragraph (1) shall include—

(A) information on activities conducted pursuant to grants and contracts awarded;

(B) summary data on patient outcomes before, during, and after implementation of best practices; and

(C) recommendations on the adaptability of best practices for use by health providers.

PART [D] *E*—GENERAL PROVISIONS

SEC. [931.] *941.* ADVISORY COUNCIL FOR HEALTHCARE RESEARCH AND QUALITY.

(a) * * *

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SEC. [932.] *942.* PEER REVIEW WITH RESPECT TO GRANTS AND CONTRACTS.

(a) * * *

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SEC. [933.] *943.* CERTAIN PROVISIONS WITH RESPECT TO DEVELOPMENT, COLLECTION, AND DISSEMINATION OF DATA.

(a) * * *

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SEC. [934.] *944.* DISSEMINATION OF INFORMATION.

(a) * * *

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SEC. [935.] *945.* ADDITIONAL PROVISIONS WITH RESPECT TO GRANTS AND CONTRACTS.

(a) * * *

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SEC. [936.] *946.* CERTAIN ADMINISTRATIVE AUTHORITIES.

(a) * * *

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SEC. [937.] *947.* FUNDING.

(a) * * *

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SEC. [938.] *948.* DEFINITIONS.

In this title:

(1) ADVISORY COUNCIL.—The term "Advisory Council" means the National Advisory Council on Healthcare Research and Quality established under section [931] *941*.

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TITLE XII—TRAUMA CARE

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PART D—TRAUMA CENTERS OPERATING IN AREAS SEVERELY AFFECTED BY DRUG-RELATED VIOLENCE

[SEC. 1241. GRANTS FOR CERTAIN TRAUMA CENTERS.

[(a) IN GENERAL.—The Secretary may make grants for the purpose of providing for the operating expenses of trauma centers that have incurred substantial uncompensated costs in providing trauma care in geographic areas with a significant incidence of violence arising directly or indirectly from illicit trafficking in drugs. Grants under this subsection may be made only to such trauma centers.

[(b) MINIMUM QUALIFICATIONS OF CENTERS.—

[(1) SIGNIFICANT INCIDENCE OF TREATING CERTAIN PATIENTS.—

[(A) The Secretary may not make a grant under subsection (a) to a trauma center unless the population of patients that has been served by the center for the period specified in subparagraph (B) includes a significant number of patients who were treated for—

[(i) trauma resulting from the penetration of the skin by knives, bullets, or any other implement that can be used as a weapon; or

[(ii) trauma that the center reasonably believes results from violence arising directly or indirectly from illicit trafficking in drugs.

[(B) The period specified in this subparagraph is the 2-year period preceding the fiscal year for which the trauma center involved is applying to receive a grant under subsection (a).

[(2) PARTICIPATION IN TRAUMA CARE SYSTEM OPERATING UNDER CERTAIN PROFESSIONAL GUIDELINES.—The Secretary may not make a grant under subsection (a) unless the trauma center involved is a participant in a system that—

[(A) provides comprehensive medical care to victims of trauma in the geographic area in which the trauma center is located;

[(B) is established by the State or political subdivision in which such center is located; and

[(C)(i) has adopted guidelines for the designation of trauma centers, and for triage, transfer, and transportation policies, equivalent to (or more protective than) the applicable guidelines developed by the American College of Surgeons or utilized in the model plan established under section 1213(c); or

[(ii) agrees that such guidelines will be adopted by the system not later than 6 months after the date on which the trauma center submits to the Secretary the application for the grant.

[(3) SUBMISSION AND APPROVAL OF LONG-TERM PLAN.—The Secretary may not make a grant under subsection (a) unless the trauma center involved—

[(A) submits to the Secretary a plan satisfactory to the Secretary that—

[(i) is developed on the assumption that the center will continue to incur substantial uncompensated costs in providing trauma care; and

[(ii) provides for the long-term continued operation of the center with an acceptable standard of medical care, notwithstanding such uncompensated costs; and

[(B) agrees to implement the plan according to a schedule approved by the Secretary.

[SEC. 1242. PREFERENCES IN MAKING GRANTS.

[(a) IN GENERAL.—In making grants under section 1241(a), the Secretary shall give preference to any application—

[(1) made by a trauma center that, for the purpose specified in such section, will receive financial assistance from the State or political subdivision involved for each fiscal year during which payments are made to the center from the grant, which financial assistance is exclusive of any assistance provided by the State or political subdivision as a non-Federal contribution under any Federal program requiring such a contribution; or

[(2) made by a trauma center that, with respect to the system described in section 1241(b)(2) in which the center is a participant—

[(A) is providing trauma care in a geographic area in which the availability of trauma care has significantly decreased as a result of a trauma center in the area permanently ceasing participation in such system as of a date occurring during the 2-year period specified in section 1241(b)(1)(B); or

[(B) will, in providing trauma care during the 1-year period beginning on the date on which the application for the grant is submitted, incur uncompensated costs in an amount rendering the center unable to continue participation in such system, resulting in a significant decrease in the availability of trauma care in the geographic area.

[(b) FURTHER PREFERENCE FOR CERTAIN APPLICATIONS.—With respect to applications for grants under section 1241 that are receiving preference for purposes of subsection (a), the Secretary shall give further preference to any such application made by a trauma center for which a disproportionate percentage of the uncompensated costs of the center result from the provision of trauma care to individuals who neither are citizens nor aliens lawfully admitted to the United States for permanent residence.

[SEC. 1243. CERTAIN AGREEMENTS.

[(a) COMMITMENT REGARDING CONTINUED PARTICIPATION IN TRAUMA CARE SYSTEM.—The Secretary may not make a grant under subsection (a) of section 1241 unless the trauma center involved agrees that—

[(1) the center will continue participation in the system described in subsection (b) of such section throughout the 3-year period beginning on the date that the center first receives payments under the grant; and

[(2) if the agreement made pursuant to paragraph (1) is violated by the center, the center will be liable to the United States for an amount equal to the sum of—

[(A) the amount of assistance provided to the center under subsection (a) of such section; and

[(B) an amount representing interest on the amount specified in subparagraph (A).

[(b) MAINTENANCE OF FINANCIAL SUPPORT.—With respect to activities for which a grant under section 1241 is authorized to be expended, the Secretary may not make such a grant unless the trauma center involved agrees that, during the period in which the center is receiving payments under the grant, the center will maintain expenditures for such activities at a level that is not less than the level maintained by the center during the fiscal year preceding the first fiscal year for which the center receives such payments.

[(c) TRAUMA CARE REGISTRY.—The Secretary may not make a grant under section 1241(a) unless the trauma center involved agrees that—

[(1) the center will operate a registry of trauma cases in accordance with the applicable guidelines described in section 1241(b)(2)(C), and will begin operation of the registry not later than 6 months after the date on which the center submits to the Secretary the application for the grant; and

[(2) in carrying out paragraph (1), the center will maintain information on the number of trauma cases treated by the cen-

ter and, for each such case, the extent to which the center incurs uncompensated costs in providing trauma care.

[SEC. 1244. GENERAL PROVISIONS.

[(a) APPLICATION.—The Secretary may not make a grant under section 1241(a) unless an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this part.

[(b) LIMITATION ON DURATION OF SUPPORT.—The period during which a trauma center receives payments under section 1241(a) may not exceed 3 fiscal years, except that the Secretary may waive such requirement for the center and authorize the center to receive such payments for 1 additional fiscal year.

[(c) LIMITATION ON AMOUNT OF GRANT.—A grant under section 1241 may not be made in an amount exceeding $2,000,000.

[SEC. 1245. AUTHORIZATION OF APPROPRIATIONS.

[For the purpose of carrying out this part, there are authorized to be appropriated $100,000,000 for fiscal year 1993, and such sums as may be necessary for fiscal year 1994. Such authorization of appropriations is in addition to any other authorization of appropriations or amounts that are available for such purpose.]

SEC. 1241. GRANTS FOR CERTAIN TRAUMA CENTERS.

(a) IN GENERAL.—The Secretary shall establish a trauma center program consisting of awarding grants under section (b).

(b) GRANTS.—The Secretary shall award grants as follows:

(1) EXISTING CENTERS.—Grants to public, private nonprofit, Indian Health Service, Indian tribal, and urban Indian trauma centers—

(A) to further the core missions of such centers; or

(B) to provide emergency relief to ensure the continued and future availability of trauma services by trauma centers—

(i) at risk of closing or operating in an area where a closing has occurred within their primary service area; or

(ii) in need of financial assistance following a natural disaster or other catastrophic event, such as a terrorist attack.

(2) NEW CENTERS.—Grants to local governments and public or private nonprofit entities to establish new trauma centers in urban areas with a substantial degree of trauma resulting from violent crimes.

(c) MINIMUM QUALIFICATIONS OF TRAUMA CENTERS.—

(1) PARTICIPATION IN TRAUMA CARE SYSTEM OPERATING UNDER CERTAIN PROFESSIONAL GUIDELINES.—

(A) LIMITATION.—Subject to subparagraph (B), the Secretary may not award a grant to an existing trauma center under this section unless the center is a participant in a trauma care system that substantially complies with section 1213.

(B) EXEMPTION.—Subparagraph (A) shall not apply to trauma centers that are located in States with no existing trauma care system.

(2) DESIGNATION.—The Secretary may not award a grant under this section to an existing trauma center unless the center is—

(A) verified as a trauma center by the American College of Surgeons; or

(B) designated as a trauma center by the applicable State health or emergency medical services authority.

SEC. 1242. CONSIDERATIONS IN MAKING GRANTS.

(a) CORE MISSION AWARDS.—

(1) IN GENERAL.—In awarding grants under section 1241(b)(1)(A), the Secretary shall—

(A) reserve a minimum of 25 percent of the amount allocated for such grants for level III and level IV trauma centers in rural or underserved areas;

(B) reserve a minimum of 25 percent of the amount allocated for such grants for level I and level II trauma centers in urban areas; and

(C) give preference to any application made by a trauma center—

(i) in a geographic area where growth in demand for trauma services exceeds capacity;

(ii) that demonstrates the financial support of the State or political subdivision involved;

(iii) that has at least 1 graduate medical education fellowship in trauma or trauma-related specialties, including neurological surgery, surgical critical care, vascular surgery, and spinal cord injury, for which demand is exceeding supply; or

(iv) that demonstrates a substantial commitment to serving vulnerable populations.

(2) FINANCIAL SUPPORT.—For purposes of paragraph (1)(C)(ii), financial support may be demonstrated by State or political subdivision funding for the trauma center's capital or operating expenses (including through State trauma regional advisory coordination activities, Medicaid funding designated for trauma services, or other governmental funding). State funding derived from Federal support shall not constitute State or local financial support for purposes of preferential treatment under this subsection.

(3) USE OF FUNDS.—The recipient of a grant under section 1241(b)(1)(A) shall carry out, consistent with furthering the core missions of the center, one or more of the following activities:

(A) Providing 24-hour-a-day, 7-day-a-week trauma care availability.

(B) Reducing overcrowding related to throughput of trauma patients.

(C) Enhancing trauma surge capacity.

(D) Ensuring physician and essential personnel availability.

(E) Trauma education and outreach.

(F) Coordination with local and regional trauma care systems.

(G) Such other activities as the Secretary may deem appropriate.

(b) EMERGENCY AWARDS; NEW CENTERS.—In awarding grants under paragraphs (1)(B) and (2) of section 1241(b), the Secretary shall—

(1) give preference to any application submitted by an applicant that demonstrates the financial support (in accordance with subsection (a)(2)) of the State or political subdivision involved for the activities to be funded through the grant for each fiscal year during which payments are made to the center under the grant; and

(2) give preference to any application submitted for a trauma center that—

(A) is providing or will provide trauma care in a geographic area in which the availability of trauma care has either significantly decreased as a result of a trauma center in the area permanently ceasing participation in a system described in section 1241(c)(1) as of a date occurring during the 2-year period preceding the fiscal year for which the trauma center is applying to receive a grant, or in geographic areas where growth in demand for trauma services exceeds capacity;

(B) will, in providing trauma care during the 1-year period beginning on the date on which the application for the grant is submitted, incur substantial uncompensated care costs in an amount that renders the center unable to continue participation in such system and results in a significant decrease in the availability of trauma care in the geographic area;

(C) operates or will operate in rural areas where trauma care availability will significantly decrease if the center is forced to close or downgrade service and substantial costs are contributing to a likelihood of such closure or downgradation;

(D) is in a geographic location substantially affected by a natural disaster or other catastrophic event such as a terrorist attack; or

(E) will establish a new trauma service in an urban area with a substantial degree of trauma resulting from violent crimes.

(c) DESIGNATIONS OF LEVELS OF TRAUMA CENTERS IN CERTAIN STATES.—In the case of a State which has not designated 4 levels of trauma centers, any reference in this section to—

(1) a level I or level II trauma center is deemed to be a reference to a trauma center within the highest 2 levels of trauma centers designated under State guidelines; and

(2) a level III or IV trauma center is deemed to be a reference to a trauma center not within such highest 2 levels.

SEC. 1243. CERTAIN AGREEMENTS.

(a) COMMITMENT REGARDING CONTINUED PARTICIPATION IN TRAUMA CARE SYSTEM.—The Secretary may not award a grant to an applicant under section 1241(b) unless the applicant agrees that—

(1) the trauma center involved will continue participation, or in the case of a new center will participate, in the system described in section 1241(c)(1), except as provided in section 1241(c)(1)(B), throughout the grant period beginning on the

date that the center first receives payments under the grant; and

(2) if the agreement made pursuant to paragraph (1) is violated by the center, the center will be liable to the United States for an amount equal to the sum of—

(A) the amount of assistance provided to the center under section 1241; and

(B) an amount representing interest on the amount specified in subparagraph (A).

(b) MAINTENANCE OF FINANCIAL SUPPORT.—With respect to activities for which funds awarded through a grant under section 1241 are authorized to be expended, the Secretary may not award such a grant unless the applicant agrees that, during the period in which the trauma center involved is receiving payments under the grant, the center will maintain access to trauma services at levels not less than the levels for the prior year, taking into account—

(1) reasonable volume fluctuation that is not caused by intentional trauma boundary reduction;

(2) downgrading of the level of services; and

(3) whether such center diverts its incoming patients away from such center 5 percent or more of the time during which the center is in operation over the course of the year.

(c) TRAUMA CARE REGISTRY.—The Secretary may not award a grant to a trauma center under section 1241(b)(1) unless the center agrees that—

(1) not later than 6 months after the date on which the center submits a grant application to the Secretary, the center will establish and operate a registry of trauma cases in accordance with guidelines developed by the American College of Surgeons; and

(2) in carrying out paragraph (1), the center will maintain information on the number of trauma cases treated by the center and, for each such case, the extent to which the center incurs uncompensated costs in providing trauma care.

SEC. 1244. GENERAL PROVISIONS.

(a) LIMITATION ON DURATION OF SUPPORT.—The period during which a trauma center receives payments under a grant under section 1241(b)(1) shall be for 3 fiscal years, except that the Secretary may waive such requirement for the center and authorize the center to receive such payments for 1 additional fiscal year.

(b) ELIGIBILITY.—The acquisition of, or eligibility for, a grant under section 1241(b) shall not preclude a trauma center's eligibility for another grant described in such section.

(c) FUNDING DISTRIBUTION.—Of the total amount appropriated for a fiscal year under section 1245—

(1) 90 percent shall be used for grants under paragraph (1)(A) of section 1241(b); and

(2) 10 percent shall be used for grants under paragraphs (1)(B) and (2) of section 1241(b).

(d) REPORT.—Beginning 2 years after the date of the enactment of the America's Affordable Health Choices Act of 2009, and every 2 years thereafter, the Secretary shall biennially—

(1) report to Congress on the status of the grants made pursuant to section 1241;

(2) evaluate and report to Congress on the overall financial stability of trauma centers in the United States;

(3) report on the populations using trauma care centers and include aggregate patient data on income, race, ethnicity, and geography; and

(4) evaluate the effectiveness and efficiency of trauma care center activities using standard public health measures and evaluation methodologies.

SEC. 1245. AUTHORIZATION OF APPROPRIATIONS.

(a) IN GENERAL.—For the purpose of carrying out this part, there are authorized to be appropriated $100,000,000 for fiscal year 2010, and such sums as may be necessary for each of fiscal years 2011 through 2015. Such authorization of appropriations is in addition to any other authorization of appropriations or amounts that are available for such purpose.

(b) REALLOCATION.—The Secretary shall reallocate for grants under section 1241(b)(1)(A) any funds appropriated for grants under paragraph (1)(B) or (2) of section 1241(b), but not obligated due to insufficient applications eligible for funding.

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TITLE XV—PREVENTIVE HEALTH MEASURES WITH RESPECT TO BREAST AND CERVICAL CANCERS

* * * * * * *

SEC. 1509. SUPPLEMENTAL GRANTS FOR ADDITIONAL PREVENTIVE HEALTH SERVICES.

(a) [DEMONSTRATION PROJECTS] *IN GENERAL.*—In the case of States receiving grants under section 1501, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, [may make grants to not more than 3 such States to carry out demonstration projects for the purpose] *may make grants to such States for the purpose* of—

(1) * * *

* * * * * * *

(d) FUNDING.—

(1) IN GENERAL.—Subject to paragraph (2), for the purpose of carrying out this section, [there are authorized to be appropriated $3,000,000 for fiscal year 1994, and such sums as may be necessary for each of the fiscal years 1995 through 2003.] *there are authorized to be appropriated $70,000,000 for fiscal year 2010, $73,500,000 for fiscal year 2011, $77,000,000 for fiscal year 2012, $81,000,000 for fiscal year 2013, and $85,000,000 for fiscal year 2014.*

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TITLE XVII—HEALTH INFORMATION AND HEALTH PROMOTION

* * * * * * *

SEC. 1709. ASSISTANT SECRETARY FOR HEALTH INFORMATION.

(a) IN GENERAL.—There is established within the Department an Assistant Secretary for Health Information (in this section referred to as the "Assistant Secretary"), to be appointed by the Secretary.

(b) RESPONSIBILITIES.—The Assistant Secretary shall—

(1) ensure the collection, collation, reporting, and publishing of information (including full and complete statistics) on key health indicators regarding the Nation's health and the performance of the Nation's health care;

(2) facilitate and coordinate the collection, collation, reporting, and publishing of information regarding the Nation's health and the performance of the Nation's health care (other than information described in paragraph (1));

(3)(A) develop standards for the collection of data regarding the Nation's health and the performance of the Nation's health care; and

(B) in carrying out subparagraph (A)—

(i) ensure appropriate specificity and standardization for data collection at the national, regional, State, and local levels;

(ii) include standards, as appropriate, for the collection of accurate data on health and health care by race, ethnicity, primary language, sex, sexual orientation, gender identity, disability, socioeconomic status, rural, urban, or other geographic setting, and any other population or subpopulation determined appropriate by the Secretary;

(iii) ensure, with respect to data on race and ethnicity, consistency with the 1997 Office of Management and Budget Standards for Maintaining, Collecting and Presenting Federal Data on Race and Ethnicity (or any successor standards); and

(iv) in consultation with the Director of the Office of Minority Health, and the Director of the Office of Civil Rights, of the Department, develop standards for the collection of data on health and health care with respect to primary language;

(4) provide support to Federal departments and agencies whose programs have a significant impact upon health (as determined by the Secretary) for the collection and collation of information described in paragraphs (1) and (2);

(5) ensure the sharing of information described in paragraphs (1) and (2) among the agencies of the Department;

(6) facilitate the sharing of information described in paragraphs (1) and (2) by Federal departments and agencies whose programs have a significant impact upon health (as determined by the Secretary);

(7) identify gaps in information described in paragraphs (1) and (2) and the appropriate agency or entity to address such gaps;

(8) facilitate and coordinate identification and monitoring by the agencies of the Department of health disparities to inform program and policy efforts to reduce such disparities, including facilitating and funding analyses conducted in cooperation with the Social Security Administration, the Bureau of the Census, and other appropriate agencies and entities;

(9) consistent with privacy, proprietary, and other appropriate safeguards, facilitate public accessibility of datasets (such as de-identified Medicare datasets or publicly available data on key health indicators) by means of the Internet; and

(10) award grants or contracts for the collection and collation of information described in paragraphs (1) and (2) (including through statewide surveys that provide standardized information).

(c) KEY HEALTH INDICATORS.—

(1) IN GENERAL.—In carrying out subsection (b)(1), the Assistant Secretary shall—

(A) identify, and reassess at least once every 3 years, key health indicators described in such subsection;

(B) publish statistics on such key health indicators for the public—

(i) not less than annually; and

(ii) on a supplemental basis whenever warranted by—

(I) the rate of change for a key health indicator; or

(II) the need to inform policy regarding the Nation's health and the performance of the Nation's health care; and

(C) ensure consistency with the national strategy developed by the Secretary under section 3121 and consideration of the indicators specified in the reports under sections 308, 903(a)(6), and 913(b)(2).

(2) RELEASE OF KEY HEALTH INDICATORS.—The regulations, rules, processes, and procedures of the Office of Management and Budget governing the review, release, and dissemination of key health indicators shall be the same as the regulations, rules, processes, and procedures of the Office of Management and Budget governing the review, release, and dissemination of Principal Federal Economic Indicators (or equivalent statistical data) by the Bureau of Labor Statistics.

(d) COORDINATION.—In carrying out this section, the Assistant Secretary shall coordinate with—

(1) public and private entities that collect and disseminate information on health and health care, including foundations; and

(2) the head of the Office of the National Coordinator for Health Information Technology to ensure optimal use of health information technology.

(e) REQUEST FOR INFORMATION FROM OTHER DEPARTMENTS AND AGENCIES.—Consistent with applicable law, the Assistant Secretary may secure directly from any Federal department or agency information necessary to enable the Assistant Secretary to carry out this section.

(f) REPORT.—

(1) SUBMISSION.—The Assistant Secretary shall submit to the Secretary and the Congress an annual report containing—

(A) a description of national, regional, or State changes in health or health care, as reflected by the key health indicators identified under subsection (c)(1);

(B) a description of gaps in the collection, collation, reporting, and publishing of information regarding the Nation's health and the performance of the Nation's health care;

(C) recommendations for addressing such gaps and identification of the appropriate agency within the Department or other entity to address such gaps;

(D) a description of analyses of health disparities, including the results of completed analyses, the status of ongoing longitudinal studies, and proposed or planned research; and

(E) a plan for actions to be taken by the Assistant Secretary to address gaps described in subparagraph (B).

(2) CONSIDERATION.—In preparing a report under paragraph (1), the Assistant Secretary shall take into consideration the findings and conclusions in the reports under sections 308, 903(a)(6), and 913(b)(2).

(g) PROPRIETARY AND PRIVACY PROTECTIONS.—Nothing in this section shall be construed to affect applicable proprietary or privacy protections.

(h) CONSULTATION.—In carrying out this section, the Assistant Secretary shall consult with—

(1) the heads of appropriate health agencies and offices in the Department, including the Office of the Surgeon General of the Public Health Service, the Office of Minority Health, and the Office on Women's Health; and

(2) as appropriate, the heads of other Federal departments and agencies whose programs have a significant impact upon health (as determined by the Secretary).

(i) DEFINITION.—In this section:

(1) The terms "agency" and "agencies" include an epidemiology center established under section 214 of the Indian Health Care Improvement Act.

(2) The term "Department" means the Department of Health and Human Services.

(3) The term "health disparities" has the meaning given to such term in section 3171.

BIENNIAL REPORT REGARDING NUTRITION AND HEALTH

SEC. **[**1709.**]** *1710.* (a) * * *

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EDUCATION REGARDING DES

SEC. **[**1710.**]** *1711.* (a) * * *

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TITLE XIX—BLOCK GRANTS

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PART B—BLOCK GRANTS REGARDING MENTAL HEALTH AND SUBSTANCE ABUSE

Subpart I—Block Grants for [Community Mental Health Services] *Behavioral Mental Health Services*

SEC. 1912. STATE PLAN FOR COMPREHENSIVE [COMMUNITY MENTAL HEALTH SERVICES] *BEHAVIORAL MENTAL HEALTH SERVICES* FOR CERTAIN INDIVIDUALS.

(a) IN GENERAL.—The Secretary may make a grant under section 1911 only if—

(1) the State involved submits to the Secretary a plan for providing comprehensive [community mental health services] *behavioral mental health services* to adults with a serious mental illness and to children with a serious emotional disturbance;

* * * * * * *

(b) CRITERIA FOR PLAN.—With respect to the provision of comprehensive [community mental health services] *behavioral mental health services* to individuals who are either adults with a serious mental illness or children with a serious emotional disturbance, the criteria referred to in subsection (a) regarding a plan are as follows:

(1) * * *

* * * * * * *

(3) CHILDREN'S SERVICES.—In the case of children with serious emotional disturbance, the plan—

(A) * * *

(B) provides that the grant under section 1911 for the fiscal year involved will not be expended to provide any service under such system other than comprehensive [community mental health services] *behavioral mental health services*; and

* * * * * * *

SEC. 1913. CERTAIN AGREEMENTS.

(a) ALLOCATION FOR SYSTEMS OF INTEGRATED SERVICES FOR CHILDREN.—

(1) * * *

(2) WAIVER.—

(A) Upon the request of a State, the Secretary may provide to the State a waiver of all or part of the requirement established in paragraph (1) if the Secretary determines that the State is providing an adequate level of comprehensive [community mental health services] *behavioral health services* for children with a serious emotional distrubance, as indicated by a comparison of the number of such children for which such services are sought with the availability in the State of the services.

* * * * * * *

(b) PROVIDERS OF SERVICES.—A funding agreement for a grant under section 1911 for a State is that, with respect to the plan submitted under section 1912(a) for the fiscal year involved—

[(1) services under the plan will be provided only through appropriate, qualified community programs (which may include community mental health centers, child mental-health programs, psychosocial rehabilitation programs, mental health peer-support programs, and mental-health primary consumer-directed programs); and]

(1) services under the plan will be provided only through appropriate, qualified community programs (which may include federally qualified behavioral health centers, child mental health programs, psychosocial rehabilitation programs, mental health peer-support programs, and mental health primary consumer-directed programs); and

(2) services under the plan will be provided through [community mental health centers] *federally qualified behavioral health centers* only if the centers meet the criteria specified in subsection (c).

[(c) CRITERIA FOR MENTAL HEALTH CENTERS.—The criteria referred to in subsection (b)(2) regarding community mental health centers are as follows:

[(1) With respect to mental health services, the centers provide services as follows:

[(A) Services principally to individuals residing in a defined geographic area (hereafter in this subsection referred to as a "service area").

[(B) Outpatient services, including specialized outpatient services for children, the elderly, individuals with a serious mental illness, and residents of the service areas of the centers who have been discharged from inpatient treatment at a mental health facility.

[(C) 24-hour-a-day emergency care services.

[(D) Day treatment or other partial hospitalization services, or psychosocial rehabilitation services.

[(E) Screening for patients being considered for admission to State mental health facilities to determine the appropriateness of such admission.

[(2) The mental health services of the centers are provided, within the limits of the capacities of the centers, to any individual residing or employed in the service area of the center regardless of ability to pay for such services.

[(3) The mental health services of the centers are available and accessible promptly, as appropriate and in a manner which preserves human dignity and assures continuity and high quality care.]

(c) CRITERIA FOR FEDERALLY QUALIFIED BEHAVIORAL HEALTH CENTERS.—

(1) IN GENERAL.—The Administrator shall certify, and recertify at least every 5 years, federally qualified behavioral health centers as meeting the criteria specified in this subsection.

(2) REGULATIONS.—Not later than 18 months after the date of the enactment of the America's Affordable Health Choices Act of 2009, the Administrator shall issue final regulations for certifying centers under paragraph (1).

(3) CRITERIA.—The criteria referred to in subsection (b)(2) are that the center performs each of the following:

(A) Provide services in locations that ensure services will be available and accessible promptly and in a manner which preserves human dignity and assures continuity of care.

(B) Provide services in a mode of service delivery appropriate for the target population.

(C) Provide individuals with a choice of service options where there is more than one efficacious treatment.

(D) Employ a core staff of clinical staff that is multidisciplinary and culturally and linguistically competent.

(E) Provide services, within the limits of the capacities of the center, to any individual residing or employed in the service area of the center.

(F) Provide, directly or through contract, to the extent covered for adults in the State Medicaid plan and for children in accordance with section 1905(r) of the Social Security Act regarding early and periodic screening, diagnosis, and treatment, each of the following services:

(i) Screening, assessment, and diagnosis, including risk assessment.

(ii) Person-centered treatment planning or similar processes, including risk assessment and crisis planning.

(iii) Outpatient clinic mental health services, including screening, assessment, diagnosis, psychotherapy, substance abuse counseling, medication management, and integrated treatment for mental illness and substance abuse which shall be evidence-based (including cognitive behavioral therapy, dialectical behavioral therapy, motivational interviewing, and other such therapies which are evidence-based).

(iv) Outpatient clinic primary care services, including screening and monitoring of key health indicators and health risk (including screening for diabetes, hypertension, and cardiovascular disease and monitoring of weight, height, body mass index (BMI), blood pressure, blood glucose or HbA1C, and lipid profile).

(v) Crisis mental health services, including 24-hour mobile crisis teams, emergency crisis intervention services, and crisis stabilization.

(vi) Targeted case management (services to assist individuals gaining access to needed medical, social, educational, and other services and applying for income security and other benefits to which they may be entitled).

(vii) Psychiatric rehabilitation services including skills training, assertive community treatment, family psychoeducation, disability self-management, supported employment, supported housing services, therapeutic foster care services, multisystemic therapy, and such other evidence-based practices as the Secretary may require.

(viii) Peer support and counselor services and family supports.

(G) Maintain linkages, and where possible enter into formal contracts with, inpatient psychiatric facilities and substance abuse detoxification and residential programs.

(H) Make available to individuals served by the center, directly, through contract, or through linkages with other programs, each of the following:

(i) Adult and youth peer support and counselor services.

(ii) Family support services for families of children with serious mental disorders.

(iii) Other community or regional services, supports, and providers, including schools, child welfare agencies, juvenile and criminal justice agencies and facilities, housing agencies and programs, employers, and other social services.

(iv) Onsite or offsite access to primary care services.

(v) Enabling services, including outreach, transportation, and translation.

(vi) Health and wellness services, including services for tobacco cessation.

SEC. 1915. ADDITIONAL PROVISIONS.

(a) * * *

(b) MAINTENANCE OF EFFORT REGARDING STATE EXPENDITURES FOR MENTAL HEALTH.—

(1) IN GENERAL.—A funding agreement for a grant under section 1911 is that the State involved will maintain State expenditures for [community mental health services] *behavioral mental health services* at a level that is not less than the average level of such expenditures maintained by the State for the 2-year period preceding the fiscal year for which the State is applying for the grant.

* * * * * * *

SEC. 1918. DETERMINATION OF AMOUNT OF ALLOTMENT.

(a) STATES.—

(1) * * *

* * * * * * *

(8) DETERMINATION OF CERTAIN FACTOR.—

(A) The factor determined under this paragraph for the State involved is a factor whose purpose is to adjust the amount determined under clause (i) of paragraph (4)(A), and the amounts determined under each of subparagraphs (B)(i) and (D)(ii)(I) of paragraph (6), to reflect the differences that exist between the State and other States in the costs of providing comprehensive [community mental health services] *behavioral mental health services* to adults with a serious mental illness and to children with a serious emotional disturbance.

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TITLE XXVII—REQUIREMENTS RELATING TO HEALTH INSURANCE COVERAGE

PART A—GROUP MARKET REFORMS

Subpart 1—Portability, Access, and Renewability Requirements

SEC. 2701. INCREASED PORTABILITY THROUGH LIMITATION ON PREEXISTING CONDITION EXCLUSIONS.

(a) LIMITATION ON PREEXISTING CONDITION EXCLUSION PERIOD; CREDITING FOR PERIODS OF PREVIOUS COVERAGE.—Subject to subsection (d), a group health plan, and a health insurance issuer offering group health insurance coverage, may, with respect to a participant or beneficiary, impose a preexisting condition exclusion only if—

(1) such exclusion relates to a condition (whether physical or mental), regardless of the cause of the condition, for which medical advice, diagnosis, care, or treatment was recommended or received within the **[**6-month period**]** *30-day period* ending on the enrollment date;

(2) such exclusion extends for a period of not more than **[**12 months**]** *3 months* (or **[**18 months**]** *9 months* in the case of a late enrollee) after the enrollment date; and

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Subpart 2—Other Requirements

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SEC. 2708. STANDARDS RELATING TO BENEFITS FOR MINOR CHILD'S CONGENITAL OR DEVELOPMENTAL DEFORMITY OR DISORDER.

(a) REQUIREMENTS FOR TREATMENT FOR CHILDREN WITH DEFORMITIES.—

(1) IN GENERAL.—A group health plan, and a health insurance issuer offering group health insurance coverage, that provides coverage for surgical benefits shall provide coverage for outpatient and inpatient diagnosis and treatment of a minor child's congenital or developmental deformity, disease, or injury. A minor child shall include any individual who 21 years of age or younger.

(2) REQUIREMENTS.—Any coverage provided under paragraph (1) shall be subject to pre-authorization or pre-certification as required by the plan or issuer, and such coverage shall include any surgical treatment which, in the opinion of the treating physician, is medically necessary to approximate a normal appearance.

(3) TREATMENT DEFINED.—

(A) IN GENERAL.—In this section, the term "treatment" includes reconstructive surgical procedures (procedures that are generally performed to improve function, but may also be performed to approximate a normal appearance) that are performed on abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease, including—

(i) procedures that do not materially affect the function of the body part being treated; and

(ii) procedures for secondary conditions and follow-up treatment.

(B) EXCEPTION.—Such term does not include cosmetic surgery performed to reshape normal structures of the body to improve appearance or self-esteem.

(b) NOTICE.—A group health plan under this part shall comply with the notice requirement under section 714(b) of the Employee Retirement Income Security Act of 1974 with respect to the requirements of this section as if such section applied to such plan.

Subpart 3—Provisions Applicable Only to Health Insurance Issuers

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SEC. 2714. ENSURING VALUE AND LOWER PREMIUMS.

(a) IN GENERAL.—Each health insurance issuer that offers health insurance coverage in the small or large group market shall provide that for any plan year in which the coverage has a medical loss ratio below a level specified by the Secretary, the issuer shall provide in a manner specified by the Secretary for rebates to enrollees of payment sufficient to meet such loss ratio. Such methodology shall be set at the highest level medical loss ratio possible that is designed to ensure adequate participation by issuers, competition in the health insurance market, and value for consumers so that their premiums are used for services.

(b) UNIFORM DEFINITIONS.—The Secretary shall establish a uniform definition of medical loss ratio and methodology for determining how to calculate the medical loss ratio. Such methodology shall be designed to take into account the special circumstances of smaller plans, different types of plans, and newer plans.

Subpart 4—Exclusion of Plans; Enforcement; Preemption

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SEC. 2723. PREEMPTION; STATE FLEXIBILITY; CONSTRUCTION.

(a) * * *

* * * * * * *

(c) RULES OF CONSTRUCTION.—Nothing in this part (other than [section 2704] *sections 2704 and 2708*) shall be construed as requiring a group health plan or health insurance coverage to provide specific benefits under the terms of such plan or coverage.

* * * * * * *

PART B—INDIVIDUAL MARKET RULES

Subpart 1—Portability, Access, and Renewability Requirements

SEC. 2741. GUARANTEED AVAILABILITY OF INDIVIDUAL HEALTH INSURANCE COVERAGE TO CERTAIN INDIVIDUALS WITH PRIOR GROUP COVERAGE.

(a) * * *

(b) ELIGIBLE INDIVIDUAL DEFINED.—In this part, the term "eligible individual" means an individual—

(1) * * *

(2) who is not eligible for coverage under (A) a group health plan, (B) part A or part B of title XVIII of the Social Security Act, or (C) a State plan under title XIX of such Act (or any suc-

cessor program), and does not have other health insurance coverage; *and*

(3) with respect to whom the most recent coverage within the coverage period described in paragraph (1)(A) was not terminated based on a factor described in paragraph (1) or (2) of section 2712(b) (relating to nonpayment of premiums or fraud)**[**;**]**.

[(4) if the individual had been offered the option of continuation coverage under a COBRA continuation provision or under a similar State program, who elected such coverage; and

[(5) who, if the individual elected such continuation coverage, has exhausted such continuation coverage under such provision or program.**]**

* * * * * * *

[(e)**]** *(f)* MARKET REQUIREMENTS.—

(1) * * *

* * * * * * *

[(f)**]** *(g)* CONSTRUCTION.—Nothing in this section shall be construed—

(1) * * *

* * * * * * *

(h) APPLICATION OF GROUP HEALTH INSURANCE LIMITATIONS ON IMPOSITION OF PREEXISTING CONDITION EXCLUSIONS.—

(1) IN GENERAL.—Subject to paragraph (2), a health insurance issuer that provides individual health insurance coverage may not impose a preexisting condition exclusion (as defined in subsection (b)(1)(A) of section 2701) with respect to such coverage except to the extent that such exclusion could be imposed consistent with such section if such coverage were group health insurance coverage.

(2) LIMITATION.—In the case of an individual who—

(A) is enrolled in individual health insurance coverage;

(B) during the period of such enrollment has a condition for which no medical advice, diagnosis, care, or treatment had been recommended or received as of the enrollment date; and

(C) seeks to enroll under other individual health insurance coverage which provides benefits different from those provided under the coverage referred to in subparagraph (A) with respect to such condition,

the issuer of the individual health insurance coverage described in subparagraph (C) may impose a preexisting condition exclusion with respect to such condition and any benefits in addition to those provided under the coverage referred to in subparagraph (A), but such exclusion may not extend for a period of more than 3 months.

SEC. 2742. GUARANTEED RENEWABILITY *AND CONTINUATION IN FORCE, INCLUDING PROHIBITION OF RESCISSION,* OF INDIVIDUAL HEALTH INSURANCE COVERAGE.

(a) IN GENERAL.—Except as provided in this section, a health insurance issuer that provides individual health insurance coverage to an individual shall renew or continue in force*, including without rescission,* such coverage at the option of the individual.

* * * * * * *

(f) RESCISSION.—A health insurance issuer may rescind health insurance coverage only upon clear and convincing evidence of fraud described in subsection (b)(2). The Secretary, no later than July 1, 2010, shall issue guidance implementing this requirement, including procedures for independent, external third party review.

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SEC. 2744. STATE FLEXIBILITY IN INDIVIDUAL MARKET REFORMS.

(a) WAIVER OF REQUIREMENTS WHERE IMPLEMENTATION OF ACCEPTABLE ALTERNATIVE MECHANISM.—

(1) IN GENERAL.—The requirements of section 2741 *(other than subsection (h))* shall not apply with respect to health insurance coverage offered in the individual market in the State so long as a State is found to be implementing, in accordance with this section and consistent with section 2762(b), an alternative mechanism (in this section referred to as an "acceptable alternative mechanism")—

(A) * * *

* * * * * * *

SEC. 2746. OPPORTUNITY FOR INDEPENDENT, EXTERNAL THIRD PARTY REVIEW IN CASES OF RESCISSION.

(a) NOTICE AND REVIEW RIGHT.—If a health insurance issuer determines to rescind health insurance coverage for an individual in the individual market, before such rescission may take effect the issuer shall provide the individual with notice of such proposed rescission and an opportunity for a review of such determination by an independent, external third party under procedures specified by the Secretary under section 2742(f).

(b) INDEPENDENT DETERMINATION.—If the individual requests such review by an independent, external third party of a rescission of health insurance coverage, the coverage shall remain in effect until such third party determines that the coverage may be rescinded under the guidance issued by the Secretary under section 2742(f).

Subpart 2—Other Requirements

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SEC. 2754. ENSURING VALUE AND LOWER PREMIUMS.

The provisions of section 2714 shall apply to health insurance coverage offered in the individual market in the same manner as such provisions apply to health insurance coverage offered in the small or large group market.

SEC. 2755. STANDARDS RELATING TO BENEFITS FOR MINOR CHILD'S CONGENITAL OR DEVELOPMENTAL DEFORMITY OR DISORDER.

(a) REQUIREMENTS FOR RECONSTRUCTIVE SURGERY.—

(1) IN GENERAL.—A health insurance issuer offering health insurance coverage in the individual market that provides coverage for surgical benefits shall provide coverage for outpatient and inpatient diagnosis and treatment of a minor child's congenital or developmental deformity, disease, or injury. A minor child shall include any individual through 21 years of age.

(2) REQUIREMENTS.—Any coverage provided under paragraph (1) shall be subject to pre-authorization or pre-certification as

required by the insurance issuer offering such coverage, and such coverage shall include any surgical treatment which, in the opinion of the treating physician, is medically necessary to approximate a normal appearance.

(3) TREATMENT DEFINED.—

(A) IN GENERAL.—In this section, the term "treatment" includes reconstructive surgical procedures (procedures that are generally performed to improve function, but may also be performed to approximate a normal appearance) that are performed on abnormal structures of the body caused by congenital defects, developmental abnormalities, trauma, infection, tumors, or disease, including—

(i) procedures that do not materially affect the function of the body part being treated; and

(ii) procedures for secondary conditions and follow-up treatment.

(B) EXCEPTION.—Such term does not include cosmetic surgery performed to reshape normal structures of the body to improve appearance or self-esteem.

(b) NOTICE.—A health insurance issuer under this part shall comply with the notice requirement under section 714(b) of the Employee Retirement Income Security Act of 1974 with respect to the requirements referred to in subsection (a) as if such section applied to such issuer and such issuer were a group health plan.

Subpart 3—General Provisions

* * * * * * *

SEC. 2762. PREEMPTION.

(a) * * *

(b) RULES OF CONSTRUCTION.—(1) * * *

(2) Nothing in this part (other than [section 2751] *sections 2751 and 2754*) shall be construed as requiring health insurance coverage offered in the individual market to provide specific benefits under the terms of such coverage.

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PART C—DEFINITIONS; MISCELLANEOUS PROVISIONS

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SEC. 2793. NATIONAL HEALTH COVERAGE PARTICIPATION REQUIREMENTS.

(a) ELECTION OF EMPLOYER TO BE SUBJECT TO NATIONAL HEALTH COVERAGE PARTICIPATION REQUIREMENTS.—

(1) IN GENERAL.—An employer may make an election with the Secretary to be subject to the health coverage participation requirements.

(2) TIME AND MANNER.—An election under paragraph (1) may be made at such time and in such form and manner as the Secretary may prescribe.

(b) TREATMENT OF COVERAGE RESULTING FROM ELECTION.—

(1) IN GENERAL.—If an employer makes an election to the Secretary under subsection (a)—

(A) such election shall be treated as the establishment and maintenance of a group health plan for purposes of

this title, subject to section 151 of the America's Affordable Health Choices Act of 2009, and

(B) the health coverage participation requirements shall be deemed to be included as terms and conditions of such plan.

(2) PERIODIC INVESTIGATIONS TO DETERMINE COMPLIANCE WITH HEALTH COVERAGE PARTICIPATION REQUIREMENTS.—The Secretary shall regularly audit a representative sampling of employers and conduct investigations and other activities with respect to such sampling of employers so as to discover noncompliance with the health coverage participation requirements in connection with such employers (during any period with respect to which an election under subsection (a) is in effect). The Secretary shall communicate findings of noncompliance made by the Secretary under this subsection to the Secretary of the Treasury and the Health Choices Commissioner. The Secretary shall take such timely enforcement action as appropriate to achieve compliance.

(c) HEALTH COVERAGE PARTICIPATION REQUIREMENTS.—For purposes of this section, the term "health coverage participation requirements" means the requirements of part 1 of subtitle B of title III of division A of the America's Affordable Health Choices Act of 2009 (as in effect on the date of the enactment of this section).

(d) SEPARATE ELECTIONS.—Under regulations prescribed by the Secretary, separate elections may be made under subsection (a) with respect to full-time employees and employees who are not full-time employees.

(e) TERMINATION OF ELECTION IN CASES OF SUBSTANTIAL NONCOMPLIANCE.—The Secretary may terminate the election of any employer under subsection (a) if the Secretary (in coordination with the Health Choices Commissioner) determines that such employer is in substantial noncompliance with the health coverage participation requirements and shall refer any such determination to the Secretary of the Treasury as appropriate.

(f) ENFORCEMENT OF HEALTH COVERAGE PARTICIPATION REQUIREMENTS.—

(1) CIVIL PENALTIES.—In the case of any employer who fails (during any period with respect to which the election under subsection (a) is in effect) to satisfy the health coverage participation requirements with respect to any employee, the Secretary may assess a civil penalty against the employer of $100 for each day in the period beginning on the date such failure first occurs and ending on the date such failure is corrected.

(2) LIMITATIONS ON AMOUNT OF PENALTY.—

(A) PENALTY NOT TO APPLY WHERE FAILURE NOT DISCOVERED EXERCISING REASONABLE DILIGENCE.—No penalty shall be assessed under paragraph (1) with respect to any failure during any period for which it is established to the satisfaction of the Secretary that the employer did not know, or exercising reasonable diligence would not have known, that such failure existed.

(B) PENALTY NOT TO APPLY TO FAILURES CORRECTED WITHIN 30 DAYS.—No penalty shall be assessed under paragraph (1) with respect to any failure if—

(i) such failure was due to reasonable cause and not to willful neglect, and

(ii) such failure is corrected during the 30-day period beginning on the 1st date that the employer knew, or exercising reasonable diligence would have known, that such failure existed.

(C) OVERALL LIMITATION FOR UNINTENTIONAL FAILURES.—In the case of failures which are due to reasonable cause and not to willful neglect, the penalty assessed under paragraph (1) for failures during any 1-year period shall not exceed the amount equal to the lesser of—

(i) 10 percent of the aggregate amount paid or incurred by the employer (or predecessor employer) during the preceding taxable year for group health plans, or

(ii) $500,000.

(3) ADVANCE NOTIFICATION OF FAILURE PRIOR TO ASSESSMENT.—Before a reasonable time prior to the assessment of any penalty under paragraph (1) with respect to any failure by an employer, the Secretary shall inform the employer in writing of such failure and shall provide the employer information regarding efforts and procedures which may be undertaken by the employer to correct such failure.

(4) ACTIONS TO ENFORCE ASSESSMENTS.—The Secretary may bring a civil action in any District Court of the United States to collect any civil penalty under this subsection.

(5) COORDINATION WITH EXCISE TAX.—Under regulations prescribed in accordance with section 324 of the America's Affordable Health Choices Act of 2009, the Secretary and the Secretary of the Treasury shall coordinate the assessment of penalties under paragraph (1) in connection with failures to satisfy health coverage participation requirements with the imposition of excise taxes on such failures under section 4980H(b) of the Internal Revenue Code of 1986 so as to avoid duplication of penalties with respect to such failures.

(6) DEPOSIT OF PENALTY COLLECTED.—Any amount of penalty collected under this subsection shall be deposited as miscellaneous receipts in the Treasury of the United States.

(g) REGULATIONS.—The Secretary may promulgate such regulations as may be necessary or appropriate to carry out the provisions of this section, in accordance with section 324(a) of the America's Affordable Health Choices Act of 2009. The Secretary may promulgate any interim final rules as the Secretary determines are appropriate to carry out this section.

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TITLE XXVIII—NATIONAL ALL-HAZARDS PREPAREDNESS FOR PUBLIC HEALTH EMERGENCIES

Subtitle A—National All-Hazards Preparedness and Response Planning, Coordinating, and Reporting

* * * * * * *

SEC. 2802. NATIONAL HEALTH SECURITY STRATEGY.

(a) * * *

(b) PREPAREDNESS GOALS.—The National Health Security Strategy shall include provisions in furtherance of the following:

(1) * * *

* * * * * * *

(3) MEDICAL.—Increasing the preparedness, response capabilities, and surge capacity of hospitals, other health care facilities (including *dental and* mental health facilities), and trauma care and emergency medical service systems, with respect to public health emergencies, which shall include developing plans for the following:

(A) * * *

* * * * * * *

(D) Effective utilization of any available public and private mobile medical *and dental* assets and integration of other Federal assets.

* * * * * * *

Subtitle B—All-Hazards Emergency Preparedness and Response

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SEC. 2816. EMERGENCY CARE COORDINATION.

(a) EMERGENCY CARE COORDINATION CENTER.—

(1) ESTABLISHMENT.—The Secretary shall establish, within the Office of the Assistant Secretary for Preparedness and Response, an Emergency Care Coordination Center (in this section referred to as the "Center"), to be headed by a director.

(2) DUTIES.—The Secretary, acting through the Director of the Center, in coordination with the Federal Interagency Committee on Emergency Medical Services, shall—

(A) promote and fund research in emergency medicine and trauma health care;

(B) promote regional partnerships and more effective emergency medical systems in order to enhance appropriate triage, distribution, and care of routine community patients; and

(C) promote local, regional, and State emergency medical systems' preparedness for and response to public health events.

(b) COUNCIL OF EMERGENCY CARE.—

(1) ESTABLISHMENT.—The Secretary, acting through the Director of the Center, shall establish a Council of Emergency Care to provide advice and recommendations to the Director on carrying out this section.

(2) COMPOSITION.—The Council shall be comprised of employees of the departments and agencies of the Federal Government who are experts in emergency care and management.

(c) REPORT.—

(1) SUBMISSION.—Not later than 12 months after the date of the enactment of the America's Affordable Health Choices Act of 2009, the Secretary shall submit to the Congress an annual report on the activities carried out under this section.

(2) CONSIDERATIONS.—In preparing a report under paragraph (1), the Secretary shall consider factors including—

(A) emergency department crowding and boarding; and

(B) delays in care following presentation.

(d) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated such sums as may be necessary for fiscal years 2010 through 2014.

* * * * * * *

TITLE XXXI—PREVENTION AND WELLNESS

Subtitle A—Prevention and Wellness Trust

SEC. 3111. PREVENTION AND WELLNESS TRUST.

(a) DEPOSITS INTO TRUST.—There is established a Prevention and Wellness Trust. There are authorized to be appropriated to the Trust—

(1) amounts described in section 2002(b)(2)(A)(ii) of the America's Affordable Health Choices Act of 2009 for each fiscal year; and

(2) in addition, out of any monies in the Public Health Investment Fund—

(A) for fiscal year 2010, $2,400,000,000;

(B) for fiscal year 2011, $2,845,000,000;

(C) for fiscal year 2012, $3,100,000,000;

(D) for fiscal year 2013, $3,455,000,000; and

(E) for fiscal year 2014, $3,600,000,000.

(b) AVAILABILITY OF FUNDS.—Amounts in the Prevention and Wellness Trust shall be available, as provided in advance in appropriation Acts, for carrying out this title.

(c) ALLOCATION.—Of the amounts authorized to be appropriated in subsection (a)(2), there are authorized to be appropriated—

(1) for carrying out subtitle C (Prevention Task Forces), $30,000,000 for each of fiscal years 2010 through 2014;

(2) for carrying out subtitle D (Prevention and Wellness Research)—

(A) for fiscal year 2010, $100,000,000;
(B) for fiscal year 2011, $150,000,000;
(C) for fiscal year 2012, $200,000,000;
(D) for fiscal year 2013, $250,000,000; and
(E) for fiscal year 2014, $300,000,000;

(3) for carrying out subtitle E (Delivery of Community Preventive and Wellness Services)—
(A) for fiscal year 2010, $1,065,000,000;
(B) for fiscal year 2011, $1,260,000,000;
(C) for fiscal year 2012, $1,365,000,000;
(D) for fiscal year 2013, $1,570,000,000; and
(E) for fiscal year 2014, $1,600,000,000;

(4) for carrying out section 3161 (Core Public Health Infrastructure for State, Local, and Tribal Health Departments)—
(A) for fiscal year 2010, $800,000,000;
(B) for fiscal year 2011, $1,000,000,000;
(C) for fiscal year 2012, $1,100,000,000;
(D) for fiscal year 2013, $1,200,000,000; and
(E) for fiscal year 2014, $1,265,000,000; and

(5) for carrying out section 3162 (Core Public Health Infrastructure and Activities for CDC), $350,000,000 for each of fiscal years 2010 through 2014.

Subtitle B—National Prevention and Wellness Strategy

SEC. 3121. NATIONAL PREVENTION AND WELLNESS STRATEGY.

(a) IN GENERAL.—The Secretary shall submit to the Congress within one year after the date of the enactment of this section, and at least every 2 years thereafter, a national strategy that is designed to improve the Nation's health through evidence-based clinical and community prevention and wellness activities (in this section referred to as "prevention and wellness activities"), including core public health infrastructure improvement activities.

(b) CONTENTS.—The strategy under subsection (a) shall include each of the following:

(1) Identification of specific national goals and objectives in prevention and wellness activities that take into account appropriate public health measures and standards, including departmental measures and standards (including Healthy People and National Public Health Performance Standards).

(2) Establishment of national priorities for prevention and wellness, taking into account unmet prevention and wellness needs.

(3) Establishment of national priorities for research on prevention and wellness, taking into account unanswered research questions on prevention and wellness.

(4) Identification of health disparities in prevention and wellness.

(5) Review of prevention payment incentives, the prevention workforce, and prevention delivery system capacity.

(6) A plan for addressing and implementing paragraphs (1) through (5).

(c) CONSULTATION.—In developing or revising the strategy under subsection (a), the Secretary shall consult with the following:

(1) The heads of appropriate health agencies and offices in the Department, including the Office of the Surgeon General of the Public Health Service, the Office of Minority Health, the Office on Women's Health, and the Substance Abuse and Mental Health Services Administration.

(2) As appropriate, the heads of other Federal departments and agencies whose programs have a significant impact upon health (as determined by the Secretary).

(3) As appropriate, nonprofit and for-profit entities.

(4) The Association of State and Territorial Health Officials and the National Association of County and City Health Officials.

(5) The Task Force on Community Preventive Services and the Task Force on Clinical Preventive Services.

Subtitle C—Prevention Task Forces

SEC. 3131. TASK FORCE ON CLINICAL PREVENTIVE SERVICES.

(a) IN GENERAL.—The Secretary, acting through the Director of the Agency for Healthcare Research and Quality, shall establish a permanent task force to be known as the Task Force on Clinical Preventive Services (in this section referred to as the "Task Force").

(b) RESPONSIBILITIES.—The Task Force shall—

(1) identify clinical preventive services for review;

(2) review the scientific evidence related to the benefits, effectiveness, appropriateness, and costs of clinical preventive services identified under paragraph (1) for the purpose of developing, updating, publishing, and disseminating evidence-based recommendations on the use of such services;

(3) as appropriate, take into account health disparities in developing, updating, publishing, and disseminating evidence-based recommendations on the use of such services;

(4) identify gaps in clinical preventive services research and evaluation and recommend priority areas for such research and evaluation;

(5) as appropriate, consult with the clinical prevention stakeholders board in accordance with subsection (f);

(6) consult with the Task Force on Community Preventive Services established under section 3132; and

(7) as appropriate, in carrying out this section, consider the national strategy under section 3121.

(c) ROLE OF AGENCY.—The Secretary shall provide ongoing administrative, research, and technical support for the operations of the Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force.

(d) MEMBERSHIP.—

(1) NUMBER; APPOINTMENT.—The Task Force shall be composed of 30 members, appointed by the Secretary.

(2) TERMS.—

(A) IN GENERAL.—The Secretary shall appoint members of the Task Force for a term of 6 years and may reappoint

such members, but the Secretary may not appoint any member to serve more than a total of 12 years.

(B) STAGGERED TERMS.—Notwithstanding subparagraph (A), of the members first appointed to serve on the Task Force after the enactment of this title—

(i) 10 shall be appointed for a term of 2 years;

(ii) 10 shall be appointed for a term of 4 years; and

(iii) 10 shall be appointed for a term of 6 years.

(3) QUALIFICATIONS.—Members of the Task Force shall be appointed from among individuals who possess expertise in at least one of the following areas:

(A) Health promotion and disease prevention.

(B) Evaluation of research and systematic evidence reviews.

(C) Application of systematic evidence reviews to clinical decisionmaking or health policy.

(D) Clinical primary care in child and adolescent health.

(E) Clinical primary care in adult health, including women's health.

(F) Clinical primary care in geriatrics.

(G) Clinical counseling and behavioral services for primary care patients.

(4) REPRESENTATION.—In appointing members of the Task Force, the Secretary shall ensure that—

(A) all areas of expertise described in paragraph (3) are represented; and

(B) the members of the Task Force include individuals with expertise in health disparities.

(e) SUBGROUPS.—As appropriate to maximize efficiency, the Task Force may delegate authority for conducting reviews and making recommendations to subgroups consisting of Task Force members, subject to final approval by the Task Force.

(f) CLINICAL PREVENTION STAKEHOLDERS BOARD.—

(1) IN GENERAL.—The Task Force shall convene a clinical prevention stakeholders board composed of representatives of appropriate public and private entities with an interest in clinical preventive services to advise the Task Force on developing, updating, publishing, and disseminating evidence-based recommendations on the use of clinical preventive services.

(2) MEMBERSHIP.—The members of the clinical prevention stakeholders board shall include representatives of the following:

(A) Health care consumers and patient groups.

(B) Providers of clinical preventive services, including community-based providers.

(C) Federal departments and agencies, including—

(i) appropriate health agencies and offices in the Department, including the Office of the Surgeon General of the Public Health Service, the Office of Minority Health, the National Center on Minority Health and Health Disparities, and the Office on Women's Health; and

(ii) as appropriate, other Federal departments and agencies whose programs have a significant impact upon health (as determined by the Secretary).

(D) Private health care payors.

(3) RESPONSIBILITIES.—In accordance with subsection (b)(5), the clinical prevention stakeholders board shall—

(A) recommend clinical preventive services for review by the Task Force;

(B) suggest scientific evidence for consideration by the Task Force related to reviews undertaken by the Task Force;

(C) provide feedback regarding draft recommendations by the Task Force; and

(D) assist with efforts regarding dissemination of recommendations by the Director of the Agency for Healthcare Research and Quality.

(g) DISCLOSURE AND CONFLICTS OF INTEREST.—Members of the Task Force or the clinical prevention stakeholders board shall not be considered employees of the Federal Government by reason of service on the Task Force or the clinical prevention stakeholders board, except members of the Task Force or the clinical prevention stakeholders board shall be considered to be special Government employees within the meaning of section 107 of the Ethics in Government Act of 1978 (5 U.S.C. App.) and section 208 of title 18, United States Code, for the purposes of disclosure and management of conflicts of interest under those sections.

(h) NO PAY; RECEIPT OF TRAVEL EXPENSES.—Members of the Task Force or the clinical prevention stakeholders board shall not receive any pay for service on the Task Force, but may receive travel expenses, including a per diem, in accordance with applicable provisions of subchapter I of chapter 57 of title 5, United States Code.

(i) APPLICATION OF FACA.—The Federal Advisory Committee Act (5 U.S.C. App.) except for section 14 of such Act shall apply to the Task Force to the extent that the provisions of such Act do not conflict with the provisions of this title.

(j) REPORT.—The Secretary shall submit to the Congress an annual report on the Task Force, including with respect to gaps identified and recommendations made under subsection (b)(4).

(k) DEFINITION.—In this section, the term "health disparities" has the meaning given the term in section 3171.

SEC. 3132. TASK FORCE ON COMMUNITY PREVENTIVE SERVICES.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a permanent task force to be known as the Task Force on Community Preventive Services (in this section referred to as the "Task Force").

(b) RESPONSIBILITIES.—The Task Force shall—

(1) identify community preventive services for review;

(2) review the scientific evidence related to the benefits, effectiveness, appropriateness, and costs of community preventive services identified under paragraph (1) for the purpose of developing, updating, publishing, and disseminating evidence-based recommendations on the use of such services;

(3) as appropriate, take into account health disparities in developing, updating, publishing, and disseminating evidence-based recommendations on the use of such services;

(4) identify gaps in community preventive services research and evaluation and recommend priority areas for such research and evaluation;

(5) as appropriate, consult with the community prevention stakeholders board in accordance with subsection (f);

(6) consult with the Task Force on Clinical Preventive Services established under section 3131; and

(7) as appropriate, in carrying out this section, consider the national strategy under section 3121.

(c) ROLE OF AGENCY.—The Secretary shall provide ongoing administrative, research, and technical support for the operations of the Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force.

(d) MEMBERSHIP.—

(1) NUMBER; APPOINTMENT.—The Task Force shall be composed of 30 members, appointed by the Secretary.

(2) TERMS.—

(A) IN GENERAL.—The Secretary shall appoint members of the Task Force for a term of 6 years and may reappoint such members, but the Secretary may not appoint any member to serve more than a total of 12 years.

(B) STAGGERED TERMS.—Notwithstanding subparagraph (A), of the members first appointed to serve on the Task Force after the enactment of this section—

(i) 10 shall be appointed for a term of 2 years;

(ii) 10 shall be appointed for a term of 4 years; and

(iii) 10 shall be appointed for a term of 6 years.

(3) QUALIFICATIONS.—Members of the Task Force shall be appointed from among individuals who possess expertise in at least one of the following areas:

(A) Public health.

(B) Evaluation of research and systematic evidence reviews.

(C) Disciplines relevant to community preventive services, including health promotion; disease prevention; chronic disease; worksite health; qualitative and quantitative analysis; and health economics, policy, law, and statistics.

(4) REPRESENTATION.—In appointing members of the Task Force, the Secretary—

(A) shall ensure that all areas of expertise described in paragraph (3) are represented;

(B) shall ensure that such members include sufficient representatives of each of—

(i) State health officers;

(ii) local health officers;

(iii) health care practitioners; and

(iv) public health practitioners; and

(C) shall appoint individuals who have expertise in health disparities.

(e) SUBGROUPS.—As appropriate to maximize efficiency, the Task Force may delegate authority for conducting reviews and making recommendations to subgroups consisting of Task Force members, subject to final approval by the Task Force.

(f) COMMUNITY PREVENTION STAKEHOLDERS BOARD.—

(1) IN GENERAL.—The Task Force shall convene a community prevention stakeholders board composed of representatives of appropriate public and private entities with an interest in community preventive services to advise the Task Force on devel-

oping, updating, publishing, and disseminating evidence-based recommendations on the use of community preventive services.

(2) MEMBERSHIP.—The members of the community prevention stakeholders board shall include representatives of the following:

(A) Health care consumers and patient groups.

(B) Providers of community preventive services, including community-based providers.

(C) Federal departments and agencies, including—

(i) appropriate health agencies and offices in the Department, including the Office of the Surgeon General of the Public Health Service, the Office of Minority Health, the National Center on Minority Health and Health Disparities, and the Office on Women's Health; and

(ii) as appropriate, other Federal departments and agencies whose programs have a significant impact upon health (as determined by the Secretary).

(D) Private health care payors.

(3) RESPONSIBILITIES.—In accordance with subsection (b)(5), the community prevention stakeholders board shall—

(A) recommend community preventive services for review by the Task Force;

(B) suggest scientific evidence for consideration by the Task Force related to reviews undertaken by the Task Force;

(C) provide feedback regarding draft recommendations by the Task Force; and

(D) assist with efforts regarding dissemination of recommendations by the Director of the Centers for Disease Control and Prevention.

(g) DISCLOSURE AND CONFLICTS OF INTEREST.—Members of the Task Force or the community prevention stakeholders board shall not be considered employees of the Federal Government by reason of service on the Task Force or the community prevention stakeholders board, except members of the Task Force or the community prevention stakeholders board shall be considered to be special Government employees within the meaning of section 107 of the Ethics in Government Act of 1978 (5 U.S.C. App.) and section 208 of title 18, United States Code, for the purposes of disclosure and management of conflicts of interest under those sections.

(h) NO PAY; RECEIPT OF TRAVEL EXPENSES.—Members of the Task Force or the community prevention stakeholders board shall not receive any pay for service on the Task Force, but may receive travel expenses, including a per diem, in accordance with applicable provisions of subchapter I of chapter 57 of title 5, United States Code.

(i) APPLICATION OF FACA.—The Federal Advisory Committee Act (5 U.S.C. App.) except for section 14 of such Act shall apply to the Task Force to the extent that the provisions of such Act do not conflict with the provisions of this title.

(j) REPORT.—The Secretary shall submit to the Congress an annual report on the Task Force, including with respect to gaps identified and recommendations made under subsection (b)(4).

(k) DEFINITION.—In this section, the term "health disparities" has the meaning given the term in section 3171.

Subtitle D—Prevention and Wellness Research

SEC. 3141. PREVENTION AND WELLNESS RESEARCH ACTIVITY COORDINATION.

In conducting or supporting research on prevention and wellness, the Director of the Centers for Disease Control and Prevention, the Director of the National Institutes of Health, and the heads of other agencies within the Department of Health and Human Services conducting or supporting such research, shall take into consideration the national strategy under section 3121 and the recommendations of the Task Force on Clinical Preventive Services under section 3131 and the Task Force on Community Preventive Services under section 3132.

SEC. 3142. COMMUNITY PREVENTION AND WELLNESS RESEARCH GRANTS.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall conduct, or award grants to eligible entities to conduct, research in priority areas identified by the Secretary in the national strategy under section 3121 or by the Task Force on Community Preventive Services as required by section 3132.

(b) ELIGIBILITY.—To be eligible for a grant under this section, an entity shall be—

(1) a State, local, or tribal department of health;

(2) a public or private nonprofit entity; or

(3) a consortium of 2 or more entities described in paragraphs (1) and (2).

(c) REPORT.—The Secretary shall submit to the Congress an annual report on the program of research under this section.

Subtitle E—Delivery of Community Prevention and Wellness Services

SEC. 3151. COMMUNITY PREVENTION AND WELLNESS SERVICES GRANTS.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a program for the delivery of community prevention and wellness services consisting of awarding grants to eligible entities—

(1) to provide evidence-based, community prevention and wellness services in priority areas identified by the Secretary in the national strategy under section 3121; or

(2) to plan such services.

(b) ELIGIBILITY.—

(1) DEFINITION.—To be eligible for a grant under this section, an entity shall be—

(A) a State, local, or tribal department of health;

(B) a public or private entity; or

(C) a consortium of—

(i) 2 or more entities described in subparagraph (A) or (B); and

(ii) a community partnership representing a Health Empowerment Zone.

(2) HEALTH EMPOWERMENT ZONE.—In this subsection, the term "Health Empowerment Zone" means an area—

(A) in which multiple community prevention and wellness services are implemented in order to address one or more health disparities, including those identified by the Secretary in the national strategy under section 3121; and

(B) which is represented by a community partnership that demonstrates community support and coordination with State, local, or tribal health departments and includes—

(i) a broad cross section of stakeholders;

(ii) residents of the community; and

(iii) representatives of entities that have a history of working within and serving the community.

(c) PREFERENCES.—In awarding grants under this section, the Secretary shall give preference to entities that—

(1) will address one or more goals or objectives identified by the Secretary in the national strategy under section 3121;

(2) will address significant health disparities, including those identified by the Secretary in the national strategy under section 3121;

(3) will address unmet community prevention and wellness needs and avoids duplication of effort;

(4) have been demonstrated to be effective in communities comparable to the proposed target community;

(5) will contribute to the evidence base for community prevention and wellness services;

(6) demonstrate that the community prevention and wellness services to be funded will be sustainable; and

(7) demonstrate coordination or collaboration across governmental and nongovernmental partners.

(d) HEALTH DISPARITIES.—Of the funds awarded under this section for a fiscal year, the Secretary shall award not less than 50 percent for planning or implementing community prevention and wellness services whose primary purpose is to achieve a measurable reduction in one or more health disparities, including those identified by the Secretary in the national strategy under section 3121.

(e) EMPHASIS ON RECOMMENDED SERVICES.—For fiscal year 2013 and subsequent fiscal years, the Secretary shall award grants under this section only for planning or implementing services recommended by the Task Force on Community Preventive Services under section 3122 or deemed effective based on a review of comparable rigor (as determined by the Director of the Centers for Disease Control and Prevention).

(f) PROHIBITED USES OF FUNDS.—An entity that receives a grant under this section may not use funds provided through the grant—

(1) to build or acquire real property or for construction; or

(2) for services or planning to the extent that payment has been made, or can reasonably be expected to be made—

(A) under any insurance policy;

(B) under any Federal or State health benefits program (including titles XIX and XXI of the Social Security Act); or

(C) by an entity which provides health services on a prepaid basis.

(g) REPORT.—The Secretary shall submit to the Congress an annual report on the program of grants awarded under this section.

(h) DEFINITIONS.—In this section, the term "evidence-based" means that methodologically sound research has demonstrated a beneficial health effect, in the judgment of the Director of the Centers for Disease Control and Prevention.

Subtitle F—Core Public Health Infrastructure

SEC. 3161. CORE PUBLIC HEALTH INFRASTRUCTURE FOR STATE, LOCAL, AND TRIBAL HEALTH DEPARTMENTS.

(a) PROGRAM.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention shall establish a core public health infrastructure program consisting of awarding grants under subsection (b).

(b) GRANTS.—

(1) AWARD.—For the purpose of addressing core public health infrastructure needs, the Secretary—

(A) shall award a grant to each State health department; and

(B) may award grants on a competitive basis to State, local, or tribal health departments.

(2) ALLOCATION.—Of the total amount of funds awarded as grants under this subsection for a fiscal year—

(A) not less than 50 percent shall be for grants to State health departments under paragraph (1)(A); and

(B) not less than 30 percent shall be for grants to State, local, or tribal health departments under paragraph (1)(B).

(c) USE OF FUNDS.—The Secretary may award a grant to an entity under subsection (b)(1) only if the entity agrees to use the grant to address core public health infrastructure needs, including those identified in the accreditation process under subsection (g).

(d) FORMULA GRANTS TO STATE HEALTH DEPARTMENTS.—In making grants under subsection (b)(1)(A), the Secretary shall award funds to each State health department in accordance with—

(1) a formula based on population size; burden of preventable disease and disability; and core public health infrastructure gaps, including those identified in the accreditation process under subsection (g); and

(2) application requirements established by the Secretary, including a requirement that the State submit a plan that demonstrates to the satisfaction of the Secretary that the State's health department will—

(A) address its highest priority core public health infrastructure needs; and

(B) as appropriate, allocate funds to local health departments within the State.

(e) COMPETITIVE GRANTS TO STATE, LOCAL, AND TRIBAL HEALTH DEPARTMENTS.—In making grants under subsection (b)(1)(B), the Secretary shall give priority to applicants demonstrating core public health infrastructure needs identified in the accreditation process under subsection (g).

(f) MAINTENANCE OF EFFORT.—The Secretary may award a grant to an entity under subsection (b) only if the entity demonstrates to the satisfaction of the Secretary that—

(1) funds received through the grant will be expended only to supplement, and not supplant, non-Federal and Federal funds otherwise available to the entity for the purpose of addressing core public health infrastructure needs; and

(2) with respect to activities for which the grant is awarded, the entity will maintain expenditures of non-Federal amounts for such activities at a level not less than the level of such expenditures maintained by the entity for the fiscal year preceding the fiscal year for which the entity receives the grant.

(g) ESTABLISHMENT OF A PUBLIC HEALTH ACCREDITATION PROGRAM.—

(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall—

(A) develop, and periodically review and update, standards for voluntary accreditation of State, local, or tribal health departments and public health laboratories for the purpose of advancing the quality and performance of such departments and laboratories; and

(B) implement a program to accredit such health departments and laboratories in accordance with such standards.

(2) COOPERATIVE AGREEMENT.—The Secretary may enter into a cooperative agreement with a private nonprofit entity to carry out paragraph (1).

(h) REPORT.—The Secretary shall submit to the Congress an annual report on progress being made to accredit entities under subsection (g), including—

(1) a strategy, including goals and objectives, for accrediting entities under subsection (g) and achieving the purpose described in subsection (g)(1); and

(2) identification of gaps in research related to core public health infrastructure and recommendations of priority areas for such research.

SEC. 3162. CORE PUBLIC HEALTH INFRASTRUCTURE AND ACTIVITIES FOR CDC.

(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall expand and improve the core public health infrastructure and activities of the Centers for Disease Control and Prevention to address unmet and emerging public health needs.

(b) REPORT.—The Secretary shall submit to the Congress an annual report on the activities funded through this section.

Subtitle G—General Provisions

SEC. 3171. DEFINITIONS.

In this title:

(1) The term "core public health infrastructure" includes workforce capacity and competency; laboratory systems; health information, health information systems, and health information analysis; communications; financing; other relevant components of organizational capacity; and other related activities.

(2) The terms "Department" and "departmental" refer to the Department of Health and Human Services.

(3) The term "health disparities" includes health and health care disparities and means population-specific differences in the presence of disease, health outcomes, or access to health care. For purposes of the preceding sentence, a population may be delineated by race, ethnicity, geographic setting, and other populations or subpopulations determined by the Secretary to experience significant gaps in disease, health outcomes, or access to health care.

(4) The term "tribal" refers to an Indian tribe, a Tribal organization, or an Urban Indian organization, as such terms are defined in section 4 of the Indian Health Care Improvement Act.

TITLE XXXII—COMMUNITY LIVING ASSISTANCE SERVICES AND SUPPORTS

SEC. 3201. IN GENERAL.

The Secretary shall establish a national voluntary insurance program to be known as the CLASS Independence Benefit Plan for purchasing community living assistance services and supports. Such program shall—

(1) provide individuals who have functional limitations with tools that will allow them—

(A) to maintain their personal and financial independence; and

(B) to live in the community through a new financing strategy for community living assistance services and supports;

(2) establish an infrastructure that will help address the Nation's community living assistance services and supports needs;

(3) alleviate burdens on family caregivers; and

(4) address institutional bias by providing a financing mechanism that supports personal choice and independence to live in the community.

SEC. 3202. DEVELOPMENT AND MANAGEMENT OF PROGRAM.

The Secretary shall develop the CLASS Independence Benefit Plan in an actuarially sound manner and—

(1) set criteria for participation in the CLASS Independence Benefit Plan that do not restrict eligibility based on underwriting;

(2) establish criteria for eligibility for benefits;

(3) establish benefit levels;

(4) establish mechanisms for collecting and distributing payments;

(5) provide mechanisms to assist beneficiaries in the use of benefits;

(6) promulgate such regulations as are necessary to carry out the CLASS program in accordance with this title; and

(7) take any other action appropriate to develop, manage, and maintain the CLASS Independence Benefit Plan, including making adjustments to benefits paid out and premiums collected in order to—

(A) maintain program solvency; and

(B) ensure the program remains deficit neutral.

SEC. 3203. REPORT.

The Secretary shall submit to the Congress an annual report on the program under this title.

* * * * * * *

SECTION 104 OF THE HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT OF 1996

SEC. 104. ASSURING COORDINATION.

The Secretary of the Treasury, the Secretary of Health and Human Services, and the Secretary of Labor shall ensure, through the execution of an interagency memorandum of understanding among such Secretaries, that—

(1) regulations, rulings, and interpretations issued by such Secretaries relating to the same matter over which two or more such Secretaries have responsibility under **[**this subtitle (and the amendments made by this subtitle and section 401)**]** *the provisions of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, the provisions of parts A and C of title XXVII of the Public Health Service Act, and chapter 100 of the Internal Revenue Code of 1986* are administered so as to have the same effect at all times; and

* * * * * * *

SOCIAL SECURITY ACT

* * * * * * *

TITLE II—FEDERAL OLD-AGE, SURVIVORS, AND DISABILITY INSURANCE BENEFITS

* * * * * * *

SPECIAL PROVISIONS RELATING TO COVERAGE UNDER MEDICARE PROGRAM FOR END STAGE RENAL DISEASE

SEC. 226A. (a) * * *

(b) Subject to subsection (c), entitlement of an individual to benefits under part A and eligibility to enroll under part B of title XVIII by reasons of this section on the basis of end stage renal disease—

(1) * * *

(2) shall end, in the case of an individual who receives a kidney transplant *(except for coverage of immunosuppressive drugs under section 1861(s)(2)(J))*, with the thirty-sixth month after the month in which such individual receives such transplant or, in the case of an individual who has not received a kidney

transplant and no longer requires a regular course of dialysis, with the twelfth month after the month in which such course of dialysis is terminated.

* * * * * * *

[(c)] *(d)* For purposes of this section, each person whose monthly insurance benefit for any month is terminated or is otherwise not payable solely by reason of paragraph (1) or (7) of section 225(c) shall be treated as entitled to such benefit for such month.

* * * * * * *

TITLE IV—GRANTS TO STATES FOR AID AND SERVICES TO NEEDY FAMILIES WITH CHILDREN AND FOR CHILD-WELFARE SERVICES

* * * * * * *

PART B—CHILD AND FAMILY SERVICES

* * * * * * *

Subpart 3—Support for Quality Home Visitation Programs

SEC. 440. HOME VISITATION PROGRAMS FOR FAMILIES WITH YOUNG CHILDREN AND FAMILIES EXPECTING CHILDREN.

(a) PURPOSE.—The purpose of this section is to improve the well-being, health, and development of children by enabling the establishment and expansion of high quality programs providing voluntary home visitation for families with young children and families expecting children.

(b) GRANT APPLICATION.—A State that desires to receive a grant under this section shall submit to the Secretary for approval, at such time and in such manner as the Secretary may require, an application for the grant that includes the following:

(1) DESCRIPTION OF HOME VISITATION PROGRAMS.—A description of the high quality programs of home visitation for families with young children and families expecting children that will be supported by a grant made to the State under this section, the outcomes the programs are intended to achieve, and the evidence supporting the effectiveness of the programs.

(2) RESULTS OF NEEDS ASSESSMENT.—The results of a statewide needs assessment that describes—

(A) the number, quality, and capacity of home visitation programs for families with young children and families expecting children in the State;

(B) the number and types of families who are receiving services under the programs;

(C) the sources and amount of funding provided to the programs;

(D) the gaps in home visitation in the State, including identification of communities that are in high need of the services; and

(E) training and technical assistance activities designed to achieve or support the goals of the programs.

(3) ASSURANCES.—Assurances from the State that—

(A) in supporting home visitation programs using funds provided under this section, the State shall identify and prioritize serving communities that are in high need of such services, especially communities with a high proportion of low-income families or a high incidence of child maltreatment;

(B) the State will reserve 5 percent of the grant funds for training and technical assistance to the home visitation programs using such funds;

(C) in supporting home visitation programs using funds provided under this section, the State will promote coordination and collaboration with other home visitation programs (including programs funded under title XIX) and with other child and family services, health services, income supports, and other related assistance;

(D) home visitation programs supported using such funds will, when appropriate, provide referrals to other programs serving children and families; and

(E) the State will comply with subsection (i), and cooperate with any evaluation conducted under subsection (j).

(4) OTHER INFORMATION.—Such other information as the Secretary may require.

(c) ALLOTMENTS.—

(1) INDIAN TRIBES.—From the amount reserved under subsection (l)(2) for a fiscal year, the Secretary shall allot to each Indian tribe that meets the requirement of subsection (d), if applicable, for the fiscal year the amount that bears the same ratio to the amount so reserved as the number of children in the Indian tribe whose families have income that does not exceed 200 percent of the poverty line bears to the total number of children in such Indian tribes whose families have income that does not exceed 200 percent of the poverty line.

(2) STATES AND TERRITORIES.—From the amount appropriated under subsection (m) for a fiscal year that remains after making the reservations required by subsection (l), the Secretary shall allot to each State that is not an Indian tribe and that meets the requirement of subsection (d), if applicable, for the fiscal year the amount that bears the same ratio to the remainder of the amount so appropriated as the number of children in the State whose families have income that does not exceed 200 percent of the poverty line bears to the total number of children in such States whose families have income that does not exceed 200 percent of the poverty line.

(3) REALLOTMENTS.—The amount of any allotment to a State under a paragraph of this subsection for any fiscal year that the State certifies to the Secretary will not be expended by the State pursuant to this section shall be available for reallotment using the allotment methodology specified in that paragraph.

Any amount so reallotted to a State is deemed part of the allotment of the State under this subsection.

(d) MAINTENANCE OF EFFORT.—Beginning with fiscal year 2011, a State meets the requirement of this subsection for a fiscal year if the Secretary finds that the aggregate expenditures by the State from State and local sources for programs of home visitation for families with young children and families expecting children for the then preceding fiscal year was not less than 100 percent of such aggregate expenditures for the then 2nd preceding fiscal year.

(e) PAYMENT OF GRANT.—

(1) IN GENERAL.—The Secretary shall make a grant to each State that meets the requirements of subsections (b) and (d), if applicable, for a fiscal year for which funds are appropriated under subsection (m), in an amount equal to the reimbursable percentage of the eligible expenditures of the State for the fiscal year, but not more than the amount allotted to the State under subsection (c) for the fiscal year.

(2) REIMBURSABLE PERCENTAGE DEFINED.—In paragraph (1), the term "reimbursable percentage" means, with respect to a fiscal year—

(A) 85 percent, in the case of fiscal year 2010;

(B) 80 percent, in the case of fiscal year 2011; or

(C) 75 percent, in the case of fiscal year 2012 and any succeeding fiscal year.

(f) ELIGIBLE EXPENDITURES.—

(1) IN GENERAL.—In this section, the term "eligible expenditures"—

(A) means expenditures to provide voluntary home visitation for as many families with young children (under the age of school entry) and families expecting children as practicable, through the implementation or expansion of high quality home visitation programs that—

(i) adhere to clear evidence-based models of home visitation that have demonstrated positive effects on important program-determined child and parenting outcomes, such as reducing abuse and neglect and improving child health and development;

(ii) employ well-trained and competent staff, maintain high quality supervision, provide for ongoing training and professional development, and show strong organizational capacity to implement such a program;

(iii) establish appropriate linkages and referrals to other community resources and supports;

(iv) monitor fidelity of program implementation to ensure that services are delivered according to the specified model; and

(v) provide parents with—

(I) knowledge of age-appropriate child development in cognitive, language, social, emotional, and motor domains (including knowledge of second language acquisition, in the case of English language learners);

(II) knowledge of realistic expectations of age-appropriate child behaviors;

(III) knowledge of health and wellness issues for children and parents;

(IV) modeling, consulting, and coaching on parenting practices;

(V) skills to interact with their child to enhance age-appropriate development;

(VI) skills to recognize and seek help for issues related to health, developmental delays, and social, emotional, and behavioral skills; and

(VII) activities designed to help parents become full partners in the education of their children;

(B) includes expenditures for training, technical assistance, and evaluations related to the programs; and

(C) does not include any expenditure with respect to which a State has submitted a claim for payment under any other provision of Federal law.

(2) PRIORITY FUNDING FOR PROGRAMS WITH STRONGEST EVIDENCE.—

(A) IN GENERAL.—The expenditures, described in paragraph (1), of a State for a fiscal year that are attributable to the cost of programs that do not adhere to a model of home visitation with the strongest evidence of effectiveness shall not be considered eligible expenditures for the fiscal year to the extent that the total of the expenditures exceeds the applicable percentage for the fiscal year of the allotment of the State under subsection (c) for the fiscal year.

(B) APPLICABLE PERCENTAGE DEFINED.—In subparagraph (A), the term "applicable percentage" means, with respect to a fiscal year—

(i) 60 percent for fiscal year 2010;

(ii) 55 percent for fiscal year 2011;

(iii) 50 percent for fiscal year 2012;

(iv) 45 percent for fiscal year 2013; or

(v) 40 percent for fiscal year 2014.

(g) NO USE OF OTHER FEDERAL FUNDS FOR STATE MATCH.—A State to which a grant is made under this section may not expend any Federal funds to meet the State share of the cost of an eligible expenditure for which the State receives a payment under this section.

(h) WAIVER AUTHORITY.—

(1) IN GENERAL.—The Secretary may waive or modify the application of any provision of this section, other than subsection (b) or (f), to an Indian tribe if the failure to do so would impose an undue burden on the Indian tribe.

(2) SPECIAL RULE.—An Indian tribe is deemed to meet the requirement of subsection (d) for purposes of subsections (c) and (e) if—

(A) the Secretary waives the requirement; or

(B) the Secretary modifies the requirement, and the Indian tribe meets the modified requirement.

(i) STATE REPORTS.—Each State to which a grant is made under this section shall submit to the Secretary an annual report on the progress made by the State in addressing the purposes of this section. Each such report shall include a description of—

(1) the services delivered by the programs that received funds from the grant;

(2) the characteristics of each such program, including information on the service model used by the program and the performance of the program;

(3) the characteristics of the providers of services through the program, including staff qualifications, work experience, and demographic characteristics;

(4) the characteristics of the recipients of services provided through the program, including the number of the recipients, the demographic characteristics of the recipients, and family retention;

(5) the annual cost of implementing the program, including the cost per family served under the program;

(6) the outcomes experienced by recipients of services through the program;

(7) the training and technical assistance provided to aid implementation of the program, and how the training and technical assistance contributed to the outcomes achieved through the program;

(8) the indicators and methods used to monitor whether the program is being implemented as designed; and

(9) other information as determined necessary by the Secretary.

(j) EVALUATION.—

(1) IN GENERAL.—The Secretary shall, by grant or contract, provide for the conduct of an independent evaluation of the effectiveness of home visitation programs receiving funds provided under this section, which shall examine the following:

(A) The effect of home visitation programs on child and parent outcomes, including child maltreatment, child health and development, school readiness, and links to community services.

(B) The effectiveness of home visitation programs on different populations, including the extent to which the ability of programs to improve outcomes varies across programs and populations.

(2) REPORTS TO THE CONGRESS.—

(A) INTERIM REPORT.—Within 3 years after the date of the enactment of this section, the Secretary shall submit to the Congress an interim report on the evaluation conducted pursuant to paragraph (1).

(B) FINAL REPORT.—Within 5 years after the date of the enactment of this section, the Secretary shall submit to the Congress a final report on the evaluation conducted pursuant to paragraph (1).

(k) ANNUAL REPORTS TO THE CONGRESS.—The Secretary shall submit annually to the Congress a report on the activities carried out using funds made available under this section, which shall include a description of the following:

(1) The high need communities targeted by States for programs carried out under this section.

(2) The service delivery models used in the programs receiving funds provided under this section.

(3) The characteristics of the programs, including—

(A) the qualifications and demographic characteristics of program staff; and

(B) recipient characteristics including the number of families served, the demographic characteristics of the families served, and family retention and duration of services.

(4) The outcomes reported by the programs.

(5) The research-based instruction, materials, and activities being used in the activities funded under the grant.

(6) The training and technical activities, including on-going professional development, provided to the programs.

(7) The annual costs of implementing the programs, including the cost per family served under the programs.

(8) The indicators and methods used by States to monitor whether the programs are being been implemented as designed.

(l) RESERVATIONS OF FUNDS.—From the amounts appropriated for a fiscal year under subsection (m), the Secretary shall reserve—

(1) an amount equal to 5 percent of the amounts to pay the cost of the evaluation provided for in subsection (j), and the provision to States of training and technical assistance, including the dissemination of best practices in early childhood home visitation; and

(2) after making the reservation required by paragraph (1), an amount equal to 3 percent of the amount so appropriated, to pay for grants to Indian tribes under this section.

(m) APPROPRIATIONS.—Out of any money in the Treasury of the United States not otherwise appropriated, there is appropriated to the Secretary to carry out this section—

(1) $50,000,000 for fiscal year 2010;

(2) $100,000,000 for fiscal year 2011;

(3) $150,000,000 for fiscal year 2012;

(4) $200,000,000 for fiscal year 2013; and

(5) $250,000,000 for fiscal year 2014.

(n) INDIAN TRIBES TREATED AS STATES.—In this section, paragraphs (4), (5), and (6) of section 431(a) shall apply.

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TITLE XI—GENERAL PROVISIONS, PEER REVIEW, AND ADMINISTRATIVE SIMPLIFICATION

PART A—GENERAL PROVISIONS

* * * * * * *

SEC. 1108. ADDITIONAL GRANTS TO PUERTO RICO, THE VIRGIN ISLANDS, GUAM, AND AMERICAN SAMOA; LIMITATION ON TOTAL PAYMENTS.

(a) * * *

* * * * * * *

(f) Subject to [subsection (g)] *subsections (g) and (h)* and section 1935(e)(1)(B), the total amount certified by the Secretary under title XIX with respect to a fiscal year for payment to—

(1) * * *

* * * * * * *

(g) MEDICAID PAYMENTS TO TERRITORIES FOR FISCAL YEAR 1998 AND THEREAFTER.—

(1) FISCAL YEAR 1998.—[With respect to] *Subject to subsection (h), with respect to* fiscal year 1998, the amounts otherwise determined for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa under subsection (f) for such fiscal year shall be increased by the following amounts:

(A) * * *

* * * * * * *

(5) DISREGARDING MEDICAL ASSISTANCE FOR OPTIONAL LOW-INCOME HIV-INFECTED INDIVIDUALS.—The limitations under subsection (f) and the previous provisions of this subsection shall not apply to amounts expended for medical assistance for individuals described in section 1902(ii) who are only eligible for such assistance on the basis of section 1902(a)(10)(A)(ii)(XXI).

(h) ADDITIONAL INCREASE FOR FISCAL YEARS 2011 THROUGH 2019.—With respect to fiscal years 2011 through 2019, the amounts otherwise determined under subsections (f) and (g) for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands and American Samoa shall be increased by the following amounts:

(1) For Puerto Rico, for fiscal year 2011, $727,600,000; for fiscal year 2012, $775,000,000; for fiscal year 2013, $850,000,000; for fiscal year 2014, $925,000,000; for fiscal year 2015, $1,000,000,000; for fiscal year 2016, $1,075,000,000; for fiscal year 2017, $1,150,000,000; for fiscal year 2018, $1,225,000,000; and for fiscal year 2019, $1,396,400,000.

(2) For the Virgin Islands, for fiscal year 2011, $34,000,000; for fiscal year 2012, $37,000,000; for fiscal year 2013, $40,000,000; for fiscal year 2014, $43,000,000; for fiscal year 2015, $46,000,000; for fiscal year 2016, $49,000,000; for fiscal year 2017, $52,000,000; for fiscal year 2018, $55,000,000; and for fiscal year 2019, $58,000,000.

(3) For Guam, for fiscal year 2011, $34,000,000; for fiscal year 2012, $37,000,000; for fiscal year 2013, $40,000,000; for fiscal year 2014, $43,000,000; for fiscal year 2015, $46,000,000; for fiscal year 2016, $49,000,000; for fiscal year 2017, $52,000,000; for fiscal year 2018, $55,000,000; and for fiscal year 2019, $58,000,000.

(4) For the Northern Mariana Islands, for fiscal year 2011, $13,500,000; fiscal year 2012, $14,500,000; for fiscal year 2013, $15,500,000; for fiscal year 2014, $16,500,000; for fiscal year 2015, $17,500,000; for fiscal year 2016, $18,500,000; for fiscal year 2017, $19,500,000; for fiscal year 2018, $21,000,000; and for fiscal year 2019, $22,000,000.

(5) For American Samoa, fiscal year 2011, $22,000,000; fiscal year 2012, $23,687,500; for fiscal year 2013, $24,687,500; for fiscal year 2014, $25,687,500; for fiscal year 2015, $26,687,500; for fiscal year 2016, $27,687,500; for fiscal year 2017, $28,687,500; for fiscal year 2018, $29,687,500; and for fiscal year 2019, $30,687,500.

* * * * * * *

DEMONSTRATION PROJECTS

SEC. 1115. (a) In the case of any experimental, pilot, or demonstration project which, in the judgment of the Secretary, is likely to assist in promoting the objectives of title I, X, XIV, XVI, or XIX, or part A or D of title IV, in a State or States—

(1) * * *

* * * * * * *

In addition, not to exceed $4,000,000 of the aggregate amount appropriated for payments to States under such titles for any fiscal year beginning after June 30, 1967, shall be available, under such terms and conditions as the Secretary may establish, for payments to States to cover so much of the cost of such projects as is not covered by payments under such titles and is not included as part of the cost of projects for purposes of section 1110. *If an experimental, pilot, or demonstration project that relates to title XIX is approved pursuant to any part of this subsection, such project shall be treated as part of the State plan, all medical assistance provided on behalf of any individuals affected by such project shall be medical assistance provided under the State plan, and all provisions of this Act not explicitly waived in approving such project shall remain fully applicable to all individuals receiving benefits under the State plan.*

* * * * * * *

CENTER FOR MEDICARE AND MEDICAID PAYMENT INNOVATION

SEC. 1115A. (a) CENTER FOR MEDICARE AND MEDICAID PAYMENT INNOVATION ESTABLISHED.—

(1) IN GENERAL.—There is created within the Centers for Medicare & Medicaid Services a Center for Medicare and Medicaid Payment Innovation (in this section referred to as the "CMPI") to carry out the duties described in paragraph (4).

(2) DIRECTOR.—The CMPI shall be headed by a Director who shall report directly to the Administrator of the Centers for Medicare & Medicaid Services.

(3) DEADLINE.—The Secretary shall ensure that the CMPI is carrying out the duties described in paragraph (4) by not later than January 1, 2011.

(4) DUTIES.—The duties described in this paragraph are the following:

(A) To carry out the duties described in this section.

(B) Such other duties as the Secretary may specify.

(5) CONSULTATION.—In carrying out the duties under paragraph (4), the CMPI shall consult representatives of relevant Federal agencies and outside clinical and analytical experts with expertise in medicine and health care management. The CMPI shall use open door forums or other mechanisms to seek input from interested parties.

(b) TESTING OF MODELS (PHASE I).—

(1) IN GENERAL.—The CMPI shall test payment models in accordance with selection criteria under paragraph (2) to determine the effect of applying such models under title XVIII, title XIX, or both titles on program expenditures under such titles and the quality of care received by individuals receiving benefits under such titles.

(2) SELECTION OF MODELS TO BE TESTED.—

(A) IN GENERAL.—The Secretary shall give preference to testing models for which, as determined by the professional staff at the Centers for Medicare & Medicaid Services and using such input from outside the Centers as the Secretary determines appropriate, there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expenditures. The Secretary shall focus on models expected to reduce program costs under title XVIII, title XIX, or both titles while preserving or enhancing the quality of care received by individuals receiving benefits under such titles.

(B) APPLICATION TO OTHER DEMONSTRATIONS.—The Secretary shall operate the demonstration programs under sections 1222 and 1236 of the America's Affordable Health Choices Act of 2009 through the CMPI in accordance with the rules applicable under this section, including those relating to evaluations, terminations, and expansions.

(3) BUDGET NEUTRALITY.—

(A) INITIAL PERIOD.—The Secretary shall not require as a condition for testing a model under paragraph (1) that the design of the model ensure that the model is budget neutral initially with respect to expenditures under titles XVIII and XIX.

(B) TERMINATION.—The Secretary shall terminate or modify the design and implementation of a model unless the Secretary determines (and the Chief Actuary of the Centers for Medicare & Medicaid Services, with respect to spending under such titles, certifies), after testing has begun, that the model is expected to—

(i) improve the quality of patient care (as determined by the Administrator of the Centers for Medicare & Medicaid Services) without increasing spending under such titles;

(ii) reduce spending under such titles without reducing the quality of patient care; or

(iii) do both.

Such termination may occur at any time after such testing has begun and before completion of the testing.

(4) EVALUATION.—The Secretary shall conduct an evaluation of each model tested under this subsection. Such evaluation shall include an analysis of—

(A) the quality of patient care furnished under the model, including through the use of patient-level outcomes measures; and

(B) the changes in spending under titles XVIII and XIX by reason of the model.

The Secretary shall make the results of each evaluation under this paragraph available to the public in a timely fashion.

(c) EXPANSION OF MODELS (PHASE II).—The Secretary may expand the duration and the scope of a model that is being tested under subsection (b) (including implementation on a nationwide basis), to the extent determined appropriate by the Secretary, if—

(1) the Secretary determines that such expansion is expected—

(A) to improve the quality of patient care without increasing spending under titles XVIII and XIX;

(B) to reduce spending under such titles without reducing the quality of patient care; or

(C) to do both; and

(2) the Chief Actuary of the Centers for Medicare & Medicaid Services certifies that such expansion would reduce (or not result in any increase in) net program spending under such titles.

(d) IMPLEMENTATION.—

(1) WAIVER AUTHORITY.—The Secretary may waive such requirements of title XVIII and of sections 1902(a)(1), 1902(a)(13), and 1903(m)(2)(A)(iii) as may be necessary solely for purposes of carrying out this section with respect to testing models described in subsection (b).

(2) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of—

(A) the selection of models for testing or expansion under this section;

(B) the elements, parameters, scope, and duration of such models for testing or dissemination;

(C) the termination or modification of the design and implementation of a model under subsection (b)(3)(B); and

(D) determinations about expansion of the duration and scope of a model under subsection (c) including the determination that a model is not expected to meet criteria described in paragraphs (1) or (2) of such subsection.

(3) ADMINISTRATION.—Chapter 35 of title 44, United States Code shall not apply to this section and testing and evaluation of models or expansion of such models under this section.

(4) FUNDING FOR TESTING ITEMS AND SERVICES AND ADMINISTRATIVE COSTS.—There shall be available from the Federal Supplementary Medical Insurance Trust Fund for payments for designing, conducting, and evaluating payment models, as well as for additional benefits for items and services under models tested under subsection (b) not otherwise covered under this title and the evaluation of such models, $350,000,000 for fiscal year 2010 and, for a subsequent fiscal year, the amount determined under this sentence for the preceding fiscal year increased by the annual percentage rate of increase in total expenditures under this title for the previous fiscal year. There are also appropriated, from any amounts in the Treasury not otherwise appropriated, $25,000,000 for each fiscal year (beginning with fiscal year 2010) for administrative costs of administering this section with respect to the Medicaid program under title XIX of the Social Security Act.

(e) REPORT TO CONGRESS.—Beginning in 2012, and not less than once every other year thereafter, the Secretary shall submit to Congress a report on activities under this section. Each such report shall describe the payment models tested under subsection (b), any models chosen for expansion under subsection (c), and the results from evaluations under subsection (b)(4). In addition, each such report shall provide such recommendations as the Secretary believes

are appropriate for legislative action to facilitate the development and expansion of successful payment models.

* * * * * * *

DISCLOSURE OF OWNERSHIP AND RELATED INFORMATION

SEC. 1124. (a) * * *

* * * * * * *

(c) REQUIRED DISCLOSURE OF OWNERSHIP AND ADDITIONAL DISCLOSABLE PARTIES INFORMATION.—

(1) DISCLOSURE.—A facility (as defined in paragraph (7)(B)) shall have the information described in paragraph (3) available—

(A) during the period beginning on the date of the enactment of this subsection and ending on the date such information is made available to the public under section 1411(b) of the America's Affordable Health Choices Act of 2009, for submission to the Secretary, the Inspector General of the Department of Health and Human Services, the State in which the facility is located, and the State long-term care ombudsman in the case where the Secretary, the Inspector General, the State, or the State long-term care ombudsman requests such information; and

(B) beginning on the effective date of the final regulations promulgated under paragraph (4)(A), for reporting such information in accordance with such final regulations.

Nothing in subparagraph (A) shall be construed as authorizing a facility to dispose of or delete information described in such subparagraph after the effective date of the final regulations promulgated under paragraph (4)(A).

(2) PUBLIC AVAILABILITY OF INFORMATION.—During the period described in paragraph (1)(A), a facility shall—

(A) make the information described in paragraph (3) available to the public upon request and update such information as may be necessary to reflect changes in such information; and

(B) post a notice of the availability of such information in the lobby of the facility in a prominent manner.

(3) INFORMATION DESCRIBED.—

(A) IN GENERAL.—The following information is described in this paragraph:

(i) The information described in subsections (a) and (b), subject to subparagraph (C).

(ii) The identity of and information on—

(I) each member of the governing body of the facility, including the name, title, and period of service of each such member;

(II) each person or entity who is an officer, director, member, partner, trustee, or managing employee of the facility, including the name, title, and date of start of service of each such person or entity; and

(III) each person or entity who is an additional disclosable party of the facility.

(iii) The organizational structure of each person and entity described in subclauses (II) and (III) of clause (ii) and a description of the relationship of each such person or entity to the facility and to one another.

(B) SPECIAL RULE WHERE INFORMATION IS ALREADY REPORTED OR SUBMITTED.—To the extent that information reported by a facility to the Internal Revenue Service on Form 990, information submitted by a facility to the Securities and Exchange Commission, or information otherwise submitted to the Secretary or any other Federal agency contains the information described in clauses (i), (ii), or (iii) of subparagraph (A), the Secretary may allow, to the extent practicable, such Form or such information to meet the requirements of paragraph (1) and to be submitted in a manner specified by the Secretary.

(C) SPECIAL RULE.—In applying subparagraph (A)(i)—

(i) with respect to subsections (a) and (b), "ownership or control interest" shall include direct or indirect interests, including such interests in intermediate entities; and

(ii) subsection (a)(3)(A)(ii) shall include the owner of a whole or part interest in any mortgage, deed of trust, note, or other obligation secured, in whole or in part, by the entity or any of the property or assets thereof, if the interest is equal to or exceeds 5 percent of the total property or assets of the entirety.

(4) REPORTING.—

(A) IN GENERAL.—Not later than the date that is 2 years after the date of the enactment of this subsection, the Secretary shall promulgate regulations requiring, effective on the date that is 90 days after the date on which such final regulations are published in the Federal Register, a facility to report the information described in paragraph (3) to the Secretary in a standardized format, and such other regulations as are necessary to carry out this subsection. Such final regulations shall ensure that the facility certifies, as a condition of participation and payment under the program under title XVIII or XIX, that the information reported by the facility in accordance with such final regulations is accurate and current.

(B) GUIDANCE.—The Secretary shall provide guidance and technical assistance to States on how to adopt the standardized format under subparagraph (A).

(5) NO EFFECT ON EXISTING REPORTING REQUIREMENTS.—Nothing in this subsection shall reduce, diminish, or alter any reporting requirement for a facility that is in effect as of the date of the enactment of this subsection.

(6) DEFINITIONS.—In this subsection:

(A) ADDITIONAL DISCLOSABLE PARTY.—The term "additional disclosable party" means, with respect to a facility, any person or entity who—

(i) exercises operational, financial, or managerial control over the facility or a part thereof, or provides policies or procedures for any of the operations of the

facility, or provides financial or cash management services to the facility;

(ii) leases or subleases real property to the facility, or owns a whole or part interest equal to or exceeding 5 percent of the total value of such real property;

(iii) lends funds or provides a financial guarantee to the facility in an amount which is equal to or exceeds $50,000; or

(iv) provides management or administrative services, clinical consulting services, or accounting or financial services to the facility.

(B) FACILITY.—The term "facility" means a disclosing entity which is—

(i) a skilled nursing facility (as defined in section 1819(a)); or

(ii) a nursing facility (as defined in section 1919(a)).

(C) MANAGING EMPLOYEE.—The term "managing employee" means, with respect to a facility, an individual (including a general manager, business manager, administrator, director, or consultant) who directly or indirectly manages, advises, or supervises any element of the practices, finances, or operations of the facility.

(D) ORGANIZATIONAL STRUCTURE.—The term "organizational structure" means, in the case of—

(i) a corporation, the officers, directors, and shareholders of the corporation who have an ownership interest in the corporation which is equal to or exceeds 5 percent;

(ii) a limited liability company, the members and managers of the limited liability company (including, as applicable, what percentage each member and manager has of the ownership interest in the limited liability company);

(iii) a general partnership, the partners of the general partnership;

(iv) a limited partnership, the general partners and any limited partners of the limited partnership who have an ownership interest in the limited partnership which is equal to or exceeds 10 percent;

(v) a trust, the trustees of the trust;

(vi) an individual, contact information for the individual; and

(vii) any other person or entity, such information as the Secretary determines appropriate.

* * * * * * *

EXCLUSION OF CERTAIN INDIVIDUALS AND ENTITIES FROM PARTICIPATION IN MEDICARE AND STATE HEALTH CARE PROGRAMS

SEC. 1128. (a) * * *

(b) PERMISSIVE EXCLUSION.—The Secretary may exclude the following individuals and entities from participation in any Federal health care program (as defined in section 1128B(f)):

(1) * * *

(2) CONVICTION RELATING TO OBSTRUCTION OF AN INVESTIGATION *OR AUDIT*.—Any individual or entity that has been convicted, under Federal or State law, in connection with the interference with or obstruction of any [investigation into any criminal offense described in paragraph (1) or in subsection (a).] *investigation or audit related to—*

(A) any offense described in paragraph (1) or in subsection (a); or

(B) the use of funds received, directly or indirectly, from any Federal health care program (as defined in section 1128B(f)).

* * * * * * *

(11) FAILURE TO SUPPLY PAYMENT INFORMATION.—Any individual or entity furnishing*, ordering, referring for furnishing, or certifying the need for* items or services for which payment may be made under title XVIII or a State health care program that fails to provide such information as the Secretary or the appropriate State agency finds necessary to determine whether such payments are or were due and the amounts thereof, or has refused to permit such examination of its records by or on behalf of the Secretary or that agency as may be necessary to verify such information.

* * * * * * *

(c) NOTICE, EFFECTIVE DATE, [AND PERIOD] *PERIOD, AND EFFECT* OF EXCLUSION.—(1) * * *

* * * * * * *

(3)(A) * * *

(B) Subject to subparagraph (G), in the case of an exclusion under subsection (a), the minimum period of exclusion shall be not less than five years, except that, upon the request of the administrator of a Federal health care program (as defined in section 1128B(f)) who determines that the exclusion would impose a hardship on [individuals entitled to benefits under part A of title XVIII or enrolled under part B of such title, or both] *beneficiaries (as defined in section 1128A(i)(5)) of that program*, the Secretary may, after consulting with the Inspector General of the Department of Health and Human Services, waive the exclusion under subsection (a)(1), (a)(3), or (a)(4) with respect to that program in the case of an individual or entity that is the sole community physician or sole source of essential specialized services in a community. The Secretary's decision whether to waive the exclusion shall not be reviewable.

* * * * * * *

(4)(A) For purposes of this Act, subject to subparagraph (C), the effect of exclusion is that no payment may be made by any Federal health care program (as defined in section 1128B(f)) with respect to any item or service furnished—

(i) by an excluded individual or entity; or

(ii) at the medical direction or on the prescription of a physician or other authorized individual when the person submitting a claim for such item or service knew or had reason to know of the exclusion of such individual.

(B) For purposes of this section and sections 1128A and 1128B, subject to subparagraph (C), an item or service has been furnished by an individual or entity if the individual or entity directly or indirectly provided, ordered, manufactured, distributed, prescribed, or otherwise supplied the item or service regardless of how the item or service was paid for by a Federal health care program or to whom such payment was made.

(C)(i) Payment may be made under a Federal health care program for emergency items or services (not including items or services furnished in an emergency room of a hospital) furnished by an excluded individual or entity, or at the medical direction or on the prescription of an excluded physician or other authorized individual during the period of such individual's exclusion.

(ii) In the case that an individual eligible for benefits under title XVIII or XIX submits a claim for payment for items or services furnished by an excluded individual or entity, and such individual eligible for such benefits did not know or have reason to know that such excluded individual or entity was so excluded, then, notwithstanding such exclusion, payment shall be made for such items or services. In such case the Secretary shall notify such individual eligible for such benefits of the exclusion of the individual or entity furnishing the items or services. Payment shall not be made for items or services furnished by an excluded individual or entity to an individual eligible for such benefits after a reasonable time (as determined by the Secretary in regulations) after the Secretary has notified the individual eligible for such benefits of the exclusion of the individual or entity furnishing the items or services.

(iii) In the case that a claim for payment for items or services furnished by an excluded individual or entity is submitted by an individual or entity other than an individual eligible for benefits under title XVIII or XIX or the excluded individual or entity, and the Secretary determines that the individual or entity that submitted the claim took reasonable steps to learn of the exclusion and reasonably relied upon inaccurate or misleading information from the relevant Federal health care program or its contractor, the Secretary may waive repayment of the amount paid in violation of the exclusion to the individual or entity that submitted the claim for the items or services furnished by the excluded individual or entity. If a Federal health care program contractor provided inaccurate or misleading information that resulted in the waiver of an overpayment under this clause, the Secretary shall take appropriate action to recover the improperly paid amount from the contractor.

* * * * * * *

(f) NOTICE, HEARING, AND JUDICIAL REVIEW.—(1) * * *

* * * * * * *

(4) The provisions of subsections (d) and (e) of section 205 shall apply with respect to this section to the same extent as they are applicable with respect to title II. The Secretary may delegate the authority granted by section 205(d) (as made applicable to this section) to the Inspector General of the Department of Health and Human Services or the Administrator of the Centers for Medicare & Medicaid Services for purposes of any investigation under this section.

* * * * * * *

CIVIL MONETARY PENALTIES

SEC. 1128A. (a) Any person (including an organization, agency, or other entity, but excluding a beneficiary, as defined in subsection (i)(5)) that—

(1) knowingly presents or causes to be presented [to an officer, employee, or agent of the United States, or of any department or agency thereof, or of any State agency (as defined in subsection (i)(1))], a claim (as defined in subsection (i)(2)) that the Secretary determines—

(A) * * *

* * * * * * *

(D) is for a medical or other item or service furnished during a period in which the person was excluded [from the program under which the claim was made pursuant to a determination by the Secretary under this section or under section 1128, 1156, 1160(b) (as in effect on September 2, 1982), 1862(d) (as in effect on the date of the enactment of the Medicare and Medicaid Patient and Program Protection Act of 1987), or 1866(b) or as a result of the application of the provisions of section 1842(j)(2), or] *under Federal law from the Federal health care program under which the claim was made, or*

* * * * * * *

(4) in the case of a person who is not an organization, agency, or other entity, is excluded from [participating in a program under title XVIII or a State health care program] *participating in a Federal health care program (as defined in section 1128B(f))* in accordance with this subsection or under section 1128 and who, at the time of a violation of this subsection—

(A) retains a direct or indirect ownership or control interest in an entity that is participating in a program under [title XVIII or a State health care program] *a Federal health care program (as defined in section 1128B(f))*, and who knows or should know of the action constituting the basis for the exclusion; or

* * * * * * *

(6) arranges or contracts (by employment or otherwise) with an individual or entity that the person knows or should know is excluded from participation in a Federal health care program (as defined in section 1128B(f)), for the provision of items or services for which payment may be made under such a program; [or]

(7) commits an act described in paragraph (1) or (2) of section 1128B(b);

(8) knowingly makes or causes to be made any false statement, omission, or misrepresentation of a material fact in any application, agreement, bid, or contract to participate or enroll as a provider of services or supplier under a Federal health care program, including managed care organizations under title XIX, Medicare Advantage organizations under part C of title XVIII, prescription drug plan sponsors under part D of title XVIII, and entities that apply to participate as providers of

services or suppliers in such managed care organizations and such plans;

(9) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a Federal health care program;

(10) fails to grant timely access, upon reasonable request (as defined by the Secretary in regulations), to the Inspector General of the Department of Health and Human Services, for the purpose of audits, investigations, evaluations, or other statutory functions of the Inspector General of the Department of Health and Human Services;

(11) orders or prescribes an item or service, including without limitation home health care, diagnostic and clinical lab tests, prescription drugs, durable medical equipment, ambulance services, physical or occupational therapy, or any other item or service, during a period when the person has been excluded from participation in a Federal health care program, and the person knows or should know that a claim for such item or service will be presented to such a program;

(12) conspires to commit a violation of this section; or

(13) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to a Federal health care program, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to a Federal health care program;

shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than $10,000 for each item or service (or, in cases under paragraph (3), $15,000 for each individual with respect to whom false or misleading information was given; in cases under paragraph (4), $10,000 for each day the prohibited relationship occurs; **[**or in cases under paragraph (7), $50,000 for each such act)**]** *in cases under paragraph (7), $50,000 for each such act, in cases under paragraph (8), $50,000 for each false statement, omission, or misrepresentation of a material fact, in cases under paragraph (9), $50,000 for each false record or statement, in cases under paragraph (10), $15,000 for each day of the failure described in such paragraph, in cases under paragraph (11), $50,000 for each order or prescription for an item or service by an excluded individual, in cases under paragraph (12), $50,000 for any violation described in this section committed in furtherance of the conspiracy involved; or in cases under paragraph (13), $50,000 for each false record or statement, or concealment, avoidance, or decrease)*. In addition, such a person shall be subject to an assessment of not more than 3 times the amount claimed for each such item or service in lieu of damages sustained by the United States or a State agency because of such claim (or, in cases under paragraph (7), damages of not more than 3 times the total amount of remuneration offered, paid, solicited, or received, without regard to whether a portion of such remuneration was offered, paid, solicited, or received **[**for a lawful purpose)**]** *for a lawful purpose, in cases under paragraph (8), an assessment of not more than 3 times the amount claimed as the result of the false statement, omission, or misrepresentation of material fact claimed by a provider of serv-*

ices or supplier whose application to participate contained such false statement or misrepresentation, in cases under paragraph (12), an assessment of not more than 3 times the total amount that would otherwise apply for any violation described in this section committed in furtherance of the conspiracy involved, or in cases under paragraph (13), an assessment of not more than 3 times the total amount of the obligation to which the false record or statment was material or that was avoided or decreased). In addition the Secretary may make a determination in the same proceeding to exclude the person from participation in the Federal health care programs (as defined in section 1128B(f)(1)) and to direct the appropriate State agency to exclude the person from participation in any State health care program.

* * * * * * *

(c)(1) The Secretary may initiate a proceeding to determine whether to impose a civil money penalty, assessment, or exclusion under subsection (a) or (b) only as authorized by the Attorney General pursuant to procedures agreed upon by them. The Secretary may not initiate an action under this section with respect to any claim, request for payment, or other occurrence described in this section later than ⟦six years⟧ *10 years* after the date the claim was presented, the request for payment was made, or the occurrence took place. The Secretary may initiate an action under this section by serving notice of the action in any manner authorized by Rule 4 of the Federal Rules of Civil Procedure.

* * * * * * *

(i) For the purposes of this section:

(1) * * *

⟦(2) The term "claim" means an application for payments for items and services under a Federal health care program (as defined in section 1128B(f)).

⟦(3) The term "item or service" includes (A) any particular item, device, medical supply, or service claimed to have been provided to a patient and listed in an itemized claim for payment, and (B) in the case of a claim based on costs, any entry in the cost report, books of account or other documents supporting such claim.⟧

(2) The term "claim" means any application, request, or demand, whether under contract, or otherwise, for money or property for items and services under a Federal health care program (as defined in section 1128B(f)), whether or not the United States or a State agency has title to the money or property, that—

(A) is presented or caused to be presented to an officer, employee, or agent of the United States, or of any department or agency thereof, or of any State agency (as defined in subsection (i)(1)); or

(B) is made to a contractor, grantee, or other recipient if the money or property is to be spent or used on the Federal health care program's behalf or to advance a Federal health care program interest, and if the Federal health care program—

(i) provides or has provided any portion of the money or property requested or demanded; or

(ii) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

(3) The term "item or service" means, without limitation, any medical, social, management, administrative, or other item or service used in connection with or directly or indirectly related to a Federal health care program.

* * * * * * *

(6) The term "remuneration" includes the waiver of coinsurance and deductible amounts (or any part thereof), and transfers of items or services for free or for other than fair market value. The term "remuneration" does not include—

(A) * * *

* * * * * * *

(C) differentials in coinsurance and deductible amounts as part of a benefit plan design as long as the differentials have been disclosed in writing to all beneficiaries, third party payers, and providers, to whom claims are presented and as long as the differentials meet the standards as defined in regulations promulgated by the Secretary not later than 180 days after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996; **[**or**]**

* * * * * * *

(D) incentives given to individuals to promote the delivery of preventive care as determined by the Secretary in regulations so promulgated**[**.**]***; or*

[(D)**]** *(E)* a reduction in the copayment amount for covered OPD services under section 1833(t)(5)(B).

[(7) The term "should know" means that a person, with respect to information—

[(A) acts in deliberate ignorance of the truth or falsity of the information; or

[(B) acts in reckless disregard of the truth or falsity of the information,

and no proof of specific intent to defraud is required.**]**

(7) The terms "knowing", "knowingly", and "should know" mean that a person, with respect to information—

(A) has actual knowledge of the information;

(B) acts in deliberate ignorance of the truth or falsity of the information; or

(C) acts in reckless disregard of the truth or falsity of the information;

and require no proof of specific intent to defraud.

(8) The term "obligation" means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, from a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment.

(9) The term "material" means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

* * * * * * *

FRAUD AND ABUSE CONTROL PROGRAM

SEC. 1128C. (a) ESTABLISHMENT OF PROGRAM.—

(1) IN GENERAL.—Not later than January 1, 1997, the Secretary, acting through the Office of the Inspector General of the Department of Health and Human Services, and the Attorney General shall establish a program—

(A) * * *

* * * * * * *

(C) to facilitate the enforcement of the provisions of sections 1128, 1128A, and 1128B and other statutes applicable to health care fraud and abuse, *and*

(D) to provide for the modification and establishment of safe harbors and to issue advisory opinions and special fraud alerts pursuant to section 1128D**[**, and**]**.

[(E) to provide for the reporting and disclosure of certain final adverse actions against health care providers, suppliers, or practitioners pursuant to the data collection system established under section 1128E.**]**

* * * * * * *

HEALTH CARE FRAUD AND ABUSE DATA COLLECTION PROGRAM

SEC. 1128E. (a) GENERAL PURPOSE.—**[**Not later than**]** *Subject to subsection (h), not later than* January 1, 1997, the Secretary shall establish a national health care fraud and abuse data collection program for the reporting of final adverse actions (not including settlements in which no findings of liability have been made) against health care providers, suppliers, or practitioners as required by subsection (b), with access as set forth in subsection (c), and shall maintain a database of the information collected under this section.

* * * * * * *

(d) ACCESS TO REPORTED INFORMATION.—

(1) * * *

(2) FEES FOR DISCLOSURE.—The Secretary may establish or approve reasonable fees for the disclosure of information in such database **[**(other than with respect to requests by Federal agencies)**]**. The amount of such a fee shall be sufficient to recover the full costs of operating the database. Such fees shall be available to the Secretary or, in the Secretary's discretion to the agency designated under this section to cover such costs.

* * * * * * *

(h) SUNSET OF THE HEALTHCARE INTEGRITY AND PROTECTION DATA BANK; TRANSITION PROCESS.—Effective upon the enactment of this subsection, the Secretary shall implement a process to eliminate duplication between the Healthcare Integrity and Protection Data Bank (in this subsection referred to as the "HIPDB" established pursuant to subsection (a) and the National Practitioner Data Bank (in this subsection referred to as the "NPDB") as implemented under the Health Care Quality Improvement Act of 1986 and section 1921 of this Act, including systems testing necessary to ensure that information formerly collected in the HIPDB will be accessible through the NPDB, and other activities necessary to eliminate duplication

between the two data banks. Upon the completion of such process, notwithstanding any other provision of law, the Secretary shall cease the operation of the HIPDB and shall collect information required to be reported under the preceding provisions of this section in the NPDB. Except as otherwise provided in this subsection, the provisions of subsections (a) through (g) shall continue to apply with respect to the reporting of (or failure to report), access to, and other treatment of the information specified in this section.

* * * * * * *

SEC. 1128G. ENHANCED PROGRAM AND PROVIDER PROTECTIONS IN THE MEDICARE, MEDICAID, AND CHIP PROGRAMS.

(a) CERTAIN AUTHORIZED SCREENING, ENHANCED OVERSIGHT PERIODS, AND ENROLLMENT MORATORIA.—

(1) IN GENERAL.—For periods beginning after January 1, 2011, in the case that the Secretary determines there is a significant risk of fraudulent activity (as determined by the Secretary based on relevant complaints, reports, referrals by law enforcement or other sources, data analysis, trending information, or claims submissions by providers of services and suppliers) with respect to a category of provider of services or supplier of items or services, including a category within a geographic area, under title XVIII, XIX, or XXI, the Secretary may impose any of the following requirements with respect to a provider of services or a supplier (whether such provider or supplier is initially enrolling in the program or is renewing such enrollment):

(A) Screening under paragraph (2).

(B) Enhanced oversight periods under paragraph (3).

(C) Enrollment moratoria under paragraph (4).

In applying this subsection for purposes of title XIX and XXI the Secretary may require a State to carry out the provisions of this subsection as a requirement of the State plan under title XIX or the child health plan under title XXI. Actions taken and determinations made under this subsection shall not be subject to review by a judicial tribunal.

(2) SCREENING.—For purposes of paragraph (1), the Secretary shall establish procedures under which screening is conducted with respect to providers of services and suppliers described in such paragraph. Such screening may include—

(A) licensing board checks;

(B) screening against the list of individuals and entities excluded from the program under title XVIII, XIX, or XXI;

(C) the excluded provider list system;

(D) background checks; and

(E) unannounced pre-enrollment or other site visits.

(3) ENHANCED OVERSIGHT PERIOD.—For purposes of paragraph (1), the Secretary shall establish procedures to provide for a period of not less than 30 days and not more than 365 days during which providers of services and suppliers described in such paragraph, as the Secretary determines appropriate, would be subject to enhanced oversight, such as required or unannounced (or required and unannounced) site visits or inspections, prepayment review, enhanced review of claims, and such other actions as specified by the Secretary, under the programs

under titles XVIII, XIX, and XXI. Under such procedures, the Secretary may extend such period for more than 365 days if the Secretary determines that after the initial period such additional period of oversight is necessary.

(4) MORATORIUM ON ENROLLMENT OF PROVIDERS AND SUPPLIERS.—For purposes of paragraph (1), the Secretary, based upon a finding of a risk of serious ongoing fraud within a program under title XVIII, XIX, or XXI, may impose a moratorium on the enrollment of providers of services and suppliers within a category of providers of services and suppliers (including a category within a specific geographic area) under such title. Such a moratorium may only be imposed if the Secretary makes a determination that the moratorium would not adversely impact access of individuals to care under such program.

(5) CLARIFICATION.—Nothing in this subsection shall be interpreted to preclude or limit the ability of a State to engage in provider screening or enhanced provider oversight activities beyond those required by the Secretary.

(b) ENHANCED PROGRAM DISCLOSURE REQUIREMENTS.—

(1) DISCLOSURE.—A provider of services or supplier who submits on or after July 1, 2011, an application for enrollment and renewing enrollment in a program under title XVIII, XIX, or XXI shall disclose (in a form and manner determined by the Secretary) any current affiliation or affiliation within the previous 10-year period with a provider of services or supplier that has uncollected debt or with a person or entity that has been suspended or excluded under such program, subject to a payment suspension, or has had its billing privileges revoked.

(2) ENHANCED SAFEGUARDS.—If the Secretary determines that such previous affiliation of such provider or supplier poses a risk of fraud, waste, or abuse, the Secretary may apply such enhanced safeguards as the Secretary determines necessary to reduce such risk associated with such provider or supplier enrolling or participating in the program under title XVIII, XIX, or XXI. Such safeguards may include enhanced oversight, such as enhanced screening of claims, required or unannounced (or required and unannounced) site visits or inspections, additional information reporting requirements, and conditioning such enrollment on the provision of a surety bond.

(3) AUTHORITY TO DENY PARTICIPATION.—If the Secretary determines that there has been at least one such affiliation and that such affiliation or affiliations, as applicable, of such provider or supplier poses a serious risk of fraud, waste, or abuse, the Secretary may deny the application of such provider or supplier.

(c) REPORTS ON AND REPAYMENT OF OVERPAYMENTS IDENTIFIED THROUGH INTERNAL AUDITS AND REVIEWS.—

(1) REPORTING AND RETURNING OVERPAYMENTS.—If a person knows of an overpayment, the person must—

(A) report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address, and

(B) notify the Secretary, the State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.

(2) TIMING.—An overpayment must be reported and returned under paragraph (1)(A) by not later than the date that is 60 days after the date the person knows of the overpayment. Any known overpayment retained later than the applicable date specified in this paragraph creates an obligation as defined in section 3729(b)(3) of title 31 of the United States Code.

(3) CLARIFICATION.—Repayment of any overpayments (or refunding by withholding of future payments) by a provider of services or supplier does not otherwise limit the provider or supplier's potential liability for administrative obligations such as applicable interests, fines, and specialties or civil or criminal sanctions involving the same claim if it is determined later that the reason for the overpayment was related to fraud by the provider or supplier or the employees or agents of such provider or supplier.

(4) DEFINITIONS.—In this subsection:

(A) KNOWS.—The term "knows" has the meaning given the terms "knowing" and "knowingly" in section 3729(b) of title 31 of the United States Code.

(B) OVERPAYMENT.—The term "overpayment" means any finally determined funds that a person receives or retains under title XVIII, XIX, or XXI to which the person, after applicable reconciliation, is not entitled under such title.

(C) PERSON.—The term "person" means a provider of services, supplier, Medicaid managed care organization (as defined in section 1903(m)(1)(A)), Medicare Advantage organization (as defined in section 1859(a)(1)), or PDP sponsor (as defined in section 1860D–41(a)(13)), but excluding a beneficiary.

(d) ACCESS TO INFORMATION NECESSARY TO IDENTIFY FRAUD, WASTE, AND ABUSE.—For purposes of law enforcement activity, and to the extent consistent with applicable disclosure, privacy, and security laws, including the Health Insurance Portability and Accountability Act of 1996 and the Privacy Act of 1974, and subject to any information systems security requirements enacted by law or otherwise required by the Secretary, the Attorney General shall have access, facilitation by the Inspector General of the Department of Health and Human Services, to claims and payment data relating to titles XVIII and XIX, in consultation with the Centers for Medicare & Medicaid Services or the owner of such data.

SEC. 1128H. FINANCIAL REPORTS ON PHYSICIANS' FINANCIAL RELATIONSHIPS WITH MANUFACTURERS AND DISTRIBUTORS OF COVERED DRUGS, DEVICES, BIOLOGICALS, OR MEDICAL SUPPLIES UNDER MEDICARE, MEDICAID, OR CHIP AND WITH ENTITIES THAT BILL FOR SERVICES UNDER MEDICARE.

(a) REPORTING OF PAYMENTS OR OTHER TRANSFERS OF VALUE.—

(1) IN GENERAL.—Except as provided in this subsection, not later than March 31, 2011 and annually thereafter, each applicable manufacturer or distributor that provides a payment or other transfer of value to a covered recipient, or to an entity or individual at the request of or designated on behalf of a covered recipient, shall submit to the Secretary, in such electronic form as the Secretary shall require, the following information with respect to the preceding calendar year:

(A) With respect to the covered recipient, the recipient's name, business address, physician specialty, and national provider identifier.

(B) With respect to the payment or other transfer of value, other than a drug sample—

(i) its value and date;

(ii) the name of the related drug, device, or supply, if available; and

(iii) a description of its form, indicated (as appropriate for all that apply) as—

(I) cash or a cash equivalent;

(II) in-kind items or services;

(III) stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment; or

(IV) any other form (as defined by the Secretary).

(C) With respect to a drug sample, the name, number, date, and dosage units of the sample.

(2) AGGREGATE REPORTING.—Information submitted by an applicable manufacturer or distributor under paragraph (1) shall include the aggregate amount of all payments or other transfers of value provided by the manufacturer or distributor to covered recipients (and to entities or individuals at the request of or designated on behalf of a covered recipient) during the year involved, including all payments and transfers of value regardless of whether such payments or transfer of value were individually disclosed.

(3) SPECIAL RULE FOR CERTAIN PAYMENTS OR OTHER TRANSFERS OF VALUE.—In the case where an applicable manufacturer or distributor provides a payment or other transfer of value to an entity or individual at the request of or designated on behalf of a covered recipient, the manufacturer or distributor shall disclose that payment or other transfer of value under the name of the covered recipient.

(4) DELAYED REPORTING FOR PAYMENTS MADE PURSUANT TO PRODUCT DEVELOPMENT AGREEMENTS.—In the case of a payment or other transfer of value made to a covered recipient by an applicable manufacturer or distributor pursuant to a product development agreement for services furnished in connection with the development of a new drug, device, biological, or medical supply, the applicable manufacturer or distributor may report the value and recipient of such payment or other transfer of value in the first reporting period under this subsection in the next reporting deadline after the earlier of the following:

(A) The date of the approval or clearance of the covered drug, device, biological, or medical supply by the Food and Drug Administration.

(B) Two calendar years after the date such payment or other transfer of value was made.

(5) DELAYED REPORTING FOR PAYMENTS MADE PURSUANT TO CLINICAL INVESTIGATIONS.—In the case of a payment or other transfer of value made to a covered recipient by an applicable manufacturer or distributor in connection with a clinical investigation regarding a new drug, device, biological, or medical supply, the applicable manufacturer or distributor may report

as required under this section in the next reporting period under this subsection after the earlier of the following:

(A) The date that the clinical investigation is registered on the website maintained by the National Institutes of Health pursuant to section 671 of the Food and Drug Administration Amendments Act of 2007.

(B) Two calendar years after the date such payment or other transfer of value was made.

(6) CONFIDENTIALITY.—Information described in paragraph (4) or (5) shall be considered confidential and shall not be subject to disclosure under section 552 of title 5, United States Code, or any other similar Federal, State, or local law, until or after the date on which the information is made available to the public under such paragraph.

(b) REPORTING OF OWNERSHIP INTEREST BY PHYSICIANS IN HOSPITALS AND OTHER ENTITIES THAT BILL MEDICARE.—Not later than March 31 of each year (beginning with 2011), each hospital or other health care entity (not including a Medicare Advantage organization) that bills the Secretary under part A or part B of title XVIII for services shall report on the ownership shares (other than ownership shares described in section 1877(c)) of each physician who, directly or indirectly, owns an interest in the entity. In this subsection, the term "physician" includes a physician's immediate family members (as defined for purposes of section 1877(a)).

(c) PUBLIC AVAILABILITY.—

(1) IN GENERAL.—The Secretary shall establish procedures to ensure that, not later than September 30, 2011, and on June 30 of each year beginning thereafter, the information submitted under subsections (a) and (b), other than information regard drug samples, with respect to the preceding calendar year is made available through an Internet website that—

(A) is searchable and is in a format that is clear and understandable;

(B) contains information that is presented by the name of the applicable manufacturer or distributor, the name of the covered recipient, the business address of the covered recipient, the specialty (if applicable) of the covered recipient, the value of the payment or other transfer of value, the date on which the payment or other transfer of value was provided to the covered recipient, the form of the payment or other transfer of value, indicated (as appropriate) under subsection (a)(1)(B)(ii), the nature of the payment or other transfer of value, indicated (as appropriate) under subsection (a)(1)(B)(iii), and the name of the covered drug, device, biological, or medical supply, as applicable;

(C) contains information that is able to be easily aggregated and downloaded;

(D) contains a description of any enforcement actions taken to carry out this section, including any penalties imposed under subsection (d), during the preceding year;

(E) contains background information on industry-physician relationships;

(F) in the case of information submitted with respect to a payment or other transfer of value described in subsection (a)(5), lists such information separately from the other in-

formation submitted under subsection (a) and designates such separately listed information as funding for clinical research;

(G) contains any other information the Secretary determines would be helpful to the average consumer; and

(H) provides the covered recipient an opportunity to submit corrections to the information made available to the public with respect to the covered recipient.

(2) ACCURACY OF REPORTING.—The accuracy of the information that is submitted under subsections (a) and (b) and made available under paragraph (1) shall be the responsibility of the applicable manufacturer or distributor of a covered drug, device, biological, or medical supply reporting under subsection (a) or hospital or other health care entity reporting physician ownership under subsection (b). The Secretary shall establish procedures to ensure that the covered recipient is provided with an opportunity to submit corrections to the manufacturer, distributor, hospital, or other entity reporting under subsection (a) or (b) with regard to information made public with respect to the covered recipient and, under such procedures, the corrections shall be transmitted to the Secretary.

(3) SPECIAL RULE FOR DRUG SAMPLES.—Information relating to drug samples provided under subsection (a) shall not be made available to the public by the Secretary but may be made available outside the Department of Health and Human Services by the Secretary for research or legitimate business purposes pursuant to data use agreements.

(4) SPECIAL RULE FOR NATIONAL PROVIDER IDENTIFIERS.—Information relating to national provider identifiers provided under subsection (a) shall not be made available to the public by the Secretary but may be made available outside the Department of Health and Human Services by the Secretary for research or legitimate business purposes pursuant to data use agreements.

(d) PENALTIES FOR NONCOMPLIANCE.—

(1) FAILURE TO REPORT.—

(A) IN GENERAL.—Subject to subparagraph (B), except as provided in paragraph (2), any applicable manufacturer or distributor that fails to submit information required under subsection (a) in a timely manner in accordance with regulations promulgated to carry out such subsection, and any hospital or other entity that fails to submit information required under subsection (b) in a timely manner in accordance with regulations promulgated to carry out such subsection shall be subject to a civil money penalty of not less than $1,000, but not more than $10,000, for each payment or other transfer of value or ownership or investment interest not reported as required under such subsection. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.

(B) LIMITATION.—The total amount of civil money penalties imposed under subparagraph (A) with respect to each annual submission of information under subsection (a) by

an applicable manufacturer or distributor or other entity shall not exceed $150,000.

(2) KNOWING FAILURE TO REPORT.—

(A) IN GENERAL.—Subject to subparagraph (B), any applicable manufacturer or distributor that knowingly fails to submit information required under subsection (a) in a timely manner in accordance with regulations promulgated to carry out such subsection and any hospital or other entity that fails to submit information required under subsection (b) in a timely manner in accordance with regulations promulgated to carry out such subsection, shall be subject to a civil money penalty of not less than $10,000, but not more than $100,000, for each payment or other transfer of value or ownership or investment interest not reported as required under such subsection. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.

(B) LIMITATION.—The total amount of civil money penalties imposed under subparagraph (A) with respect to each annual submission of information under subsection (a) or (b) by an applicable manufacturer, distributor, or entity shall not exceed $1,000,000, or, if greater, 0.1 percentage of the total annual revenues of the manufacturer, distributor, or entity.

(3) USE OF FUNDS.—Funds collected by the Secretary as a result of the imposition of a civil money penalty under this subsection shall be used to carry out this section.

(4) ENFORCEMENT THROUGH STATE ATTORNEYS GENERAL.—The attorney general of a State, after providing notice to the Secretary of an intent to proceed under this paragraph in a specific case and providing the Secretary with an opportunity to bring an action under this subsection and the Secretary declining such opportunity, may proceed under this subsection against a manufacturer or distributor in the State.

(e) ANNUAL REPORT TO CONGRESS.—Not later than April 1 of each year beginning with 2011, the Secretary shall submit to Congress a report that includes the following:

(1) The information submitted under this section during the preceding year, aggregated for each applicable manufacturer or distributor of a covered drug, device, biological, or medical supply that submitted such information during such year.

(2) A description of any enforcement actions taken to carry out this section, including any penalties imposed under subsection (d), during the preceding year.

(f) DEFINITIONS.—In this section:

(1) APPLICABLE MANUFACTURER; APPLICABLE DISTRIBUTOR.—The term "applicable manufacturer" means a manufacturer of a covered drug, device, biological, or medical supply, and the term "applicable distributor" means a distributor of a covered drug, device, or medical supply.

(2) CLINICAL INVESTIGATION.—The term "clinical investigation" means any experiment involving one or more human subjects, or materials derived from human subjects, in which a drug or device is administered, dispensed, or used.

(3) COVERED DRUG, DEVICE, BIOLOGICAL, OR MEDICAL SUPPLY.—The term "covered" means, with respect to a drug, device, biological, or medical supply, such a drug, device, biological, or medical supply for which payment is available under title XVIII or a State plan under title XIX or XXI (or a waiver of such a plan).

(4) COVERED RECIPIENT.—The term "covered recipient" means the following:

(A) A physician.

(B) A physician group practice.

(C) Any other prescriber of a covered drug, device, biological, or medical supply.

(D) A pharmacy or pharmacist.

(E) A health insurance issuer, group health plan, or other entity offering a health benefits plan, including any employee of such an issuer, plan, or entity.

(F) A pharmacy benefit manager, including any employee of such a manager.

(G) A hospital.

(H) A medical school.

(I) A sponsor of a continuing medical education program.

(J) A patient advocacy or disease specific group.

(K) A organization of health care professionals.

(L) A biomedical researcher.

(M) A group purchasing organization.

(5) DISTRIBUTOR OF A COVERED DRUG, DEVICE, OR MEDICAL SUPPLY.—The term "distributor of a covered drug, device, or medical supply" means any entity which is engaged in the marketing or distribution of a covered drug, device, or medical supply (or any subsidiary of or entity affiliated with such entity), but does not include a wholesale pharmaceutical distributor.

(6) EMPLOYEE.—The term "employee" has the meaning given such term in section 1877(h)(2).

(7) KNOWINGLY.—The term "knowingly" has the meaning given such term in section 3729(b) of title 31, United States Code.

(8) MANUFACTURER OF A COVERED DRUG, DEVICE, BIOLOGICAL, OR MEDICAL SUPPLY.—The term "manufacturer of a covered drug, device, biological, or medical supply" means any entity which is engaged in the production, preparation, propagation, compounding, conversion, processing, marketing, or distribution of a covered drug, device, biological, or medical supply (or any subsidiary of or entity affiliated with such entity).

(9) PAYMENT OR OTHER TRANSFER OF VALUE.—

(A) IN GENERAL.—The term "payment or other transfer of value" means a transfer of anything of value for or of any of the following:

(i) Gift, food, or entertainment.

(ii) Travel or trip.

(iii) Honoraria.

(iv) Research funding or grant.

(v) Education or conference funding.

(vi) Consulting fees.

(vii) Ownership or investment interest and royalties or license fee.

(B) INCLUSIONS.—Subject to subparagraph (C), the term "payment or other transfer of value" includes any compensation, gift, honorarium, speaking fee, consulting fee, travel, services, dividend, profit distribution, stock or stock option grant, or any ownership or investment interest held by a physician in a manufacturer (excluding a dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security or mutual fund (as described in section 1877(c))).

(C) EXCLUSIONS.—The term "payment or other transfer of value" does not include the following:

(i) Any payment or other transfer of value provided by an applicable manufacturer or distributor to a covered recipient where the amount transferred to, requested by, or designated on behalf of the covered recipient does not exceed $5.

(ii) The loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient.

(iii) Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.

(iv) A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient.

(v) In-kind items used for the provision of charity care.

(vi) A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund (as described in section 1877(c)).

(vii) Compensation paid by a manufacturer or distributor of a covered drug, device, biological, or medical supply to a covered recipient who is directly employed by and works solely for such manufacturer or distributor.

(viii) Any discount or cash rebate.

(10) PHYSICIAN.—The term "physician" has the meaning given that term in section 1861(r). For purposes of this section, such term does not include a physician who is an employee of the applicable manufacturer that is required to submit information under subsection (a).

(g) ANNUAL REPORTS TO STATES.—Not later than April 1 of each year beginning with 2011, the Secretary shall submit to States a report that includes a summary of the information submitted under subsections (a) and (d) during the preceding year with respect to covered recipients or other hospitals and entities in the State.

(h) RELATION TO STATE LAWS.—

(1) IN GENERAL.—Effective on January 1, 2011, subject to paragraph (2), the provisions of this section shall preempt any law or regulation of a State or of a political subdivision of a State that requires an applicable manufacturer and applicable distributor (as such terms are defined in subsection (f)) to dis-

close or report, in any format, the type of information (described in subsection (a)) regarding a payment or other transfer of value provided by the manufacturer to a covered recipient (as so defined).

(2) NO PREEMPTION OF ADDITIONAL REQUIREMENTS.—Paragraph (1) shall not preempt any law or regulation of a State or of a political subdivision of a State that requires any of the following:

(A) The disclosure or reporting of information not of the type required to be disclosed or reported under this section.

(B) The disclosure or reporting, in any format, of the type of information required to be disclosed or reported under this section to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes.

(C) The discovery or admissibility of information described in this section in a criminal, civil, or administrative proceeding.

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SEC. 1138A. REQUIREMENT FOR PUBLIC REPORTING BY HOSPITALS AND AMBULATORY SURGICAL CENTERS ON HEALTH CARE-ASSOCIATED INFECTIONS.

(a) REPORTING REQUIREMENT.—

(1) IN GENERAL.—The Secretary shall provide that a hospital (as defined in subsection (g)) or ambulatory surgical center meeting the requirements of titles XVIII or XIX may participate in the programs established under such titles (pursuant to the applicable provisions of law, including sections 1866(a)(1) and 1832(a)(1)(F)(i)) only if, in accordance with this section, the hospital or center reports such information on health care-associated infections that develop in the hospital or center (and such demographic information associated with such infections) as the Secretary specifies.

(2) REPORTING PROTOCOLS.— Such information shall be reported in accordance with reporting protocols established by the Secretary through the Director of the Centers for Disease Control and Prevention (in this section referred to as the "CDC") and to the National Healthcare Safety Network of the CDC or under such another reporting system of such Centers as determined appropriate by the Secretary in consultation with such Director.

(3) COORDINATION WITH HIT.—The Secretary, through the Director of the CDC and the Office of the National Coordinator for Health Information Technology, shall ensure that the transmission of information under this subsection is coordinated with systems established under the HITECH Act, where appropriate.

(4) PROCEDURES TO ENSURE THE VALIDITY OF INFORMATION.—The Secretary shall establish procedures regarding the validity of the information submitted under this subsection in order to ensure that such information is appropriately compared across hospitals and centers. Such procedures shall address failures to report as well as errors in reporting.

(5) IMPLEMENTATION.—Not later than 1 year after the date of enactment of this section, the Secretary, through the Director of CDC, shall promulgate regulations to carry out this section.

(b) PUBLIC POSTING OF INFORMATION.—The Secretary shall promptly post, on the official public Internet site of the Department of Health and Human Services, the information reported under subsection (a). Such information shall be set forth in a manner that allows for the comparison of information on health care-associated infections—

(1) among hospitals and ambulatory surgical centers; and

(2) by demographic information.

(c) ANNUAL REPORT TO CONGRESS.—On an annual basis the Secretary shall submit to the Congress a report that summarizes each of the following:

(1) The number and types of health care-associated infections reported under subsection (a) in hospitals and ambulatory surgical centers during such year.

(2) Factors that contribute to the occurrence of such infections, including health care worker immunization rates.

(3) Based on the most recent information available to the Secretary on the composition of the professional staff of hospitals and ambulatory surgical centers, the number of certified infection control professionals on the staff of hospitals and ambulatory surgical centers.

(4) The total increases or decreases in health care costs that resulted from increases or decreases in the rates of occurrence of each such type of infection during such year.

(5) Recommendations, in coordination with the Center for Quality Improvement established under section 931 of the Public Health Service Act, for best practices to eliminate the rates of occurrence of each such type of infection in hospitals and ambulatory surgical centers.

(d) NON-PREEMPTION OF STATE LAWS.—Nothing in this section shall be construed as preempting or otherwise affecting any provision of State law relating to the disclosure of information on health care-associated infections or patient safety procedures for a hospital or ambulatory surgical center.

(e) HEALTH CARE-ASSOCIATED INFECTION.—For purposes of this section:

(1) IN GENERAL.—The term "health care-associated infection" means an infection that develops in a patient who has received care in any institutional setting where health care is delivered and is related to receiving health care.

(2) RELATED TO RECEIVING HEALTH CARE.—The term "related to receiving health care", with respect to an infection, means that the infection was not incubating or present at the time health care was provided.

(f) APPLICATION TO CRITICAL ACCESS HOSPITALS.—For purposes of this section, the term "hospital" includes a critical access hospital, as defined in section 1861(mm)(1).

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SEC. 1139B. QUALITY MEASURES FOR MATERNITY AND ADULT HEALTH SERVICES UNDER MEDICAID AND CHIP.

(a) MATERNITY CARE QUALITY MEASURES UNDER MEDICAID AND CHIP.—

(1) DEVELOPMENT OF MEASURES.—No later than January 1, 2011, the Secretary shall develop and publish for comment a proposed set of measures that accurately describe the quality of maternity care provided under State plans under titles XIX and XXI. The Secretary shall publish a final recommended set of such measures no later than July 1, 2011.

(2) STANDARDIZED REPORTING FORMAT.—No later than January 1, 2012, the Secretary shall develop and publish a standardized reporting format for maternity care quality measures for use by State programs under titles XIX and XXI to collect data from managed care entities and providers and practitioners that participate in such programs and to report maternity care quality measures to the Secretary.

(b) OTHER ADULT HEALTH QUALITY MEASURES UNDER MEDICAID.—

(1) DEVELOPMENT OF MEASURES.—The Secretary shall develop quality measures that are not otherwise developed under section 1192 for services received under State plans under title XIX by individuals who are 21 years of age or older but have not attained age 65. The Secretary shall publish such quality measures through notice and comment rulemaking.

(2) STANDARDIZED REPORTING FORMAT.—The Secretary shall develop and publish a standardized reporting format for quality measures developed under paragraph (1) and section 1192 for services furnished under State plans under title XIX to individuals who are 21 years of age or older but have not attained age 65 for use under such plans and State plans under title XXI. The format shall enable State agencies administering such plans to collect data from managed care entities and providers and practitioners that participate in such plans and to report quality measures to the Secretary.

(c) DEVELOPMENT PROCESS.—With respect to the development of quality measures under subsections (a) and (b)—

(1) USE OF QUALIFIED ENTITIES.—The Secretary may enter into agreements with public, nonprofit, or academic institutions with technical expertise in the area of health quality measurement to assist in such development. The Secretary may carry out these agreements by contract, grant, or otherwise.

(2) MULTI-STAKEHOLDER PRE-RULEMAKING INPUT.—The Secretary shall obtain the input of stakeholders with respect to such quality measures using a process similar to that described in section 1808(d).

(3) COORDINATION.—The Secretary shall coordinate the development of such measures under such subsections and with the development of child health quality measures under section 1139A.

(d) ANNUAL REPORT TO CONGRESS.—No later than January 1, 2013, and annually thereafter, the Secretary shall report to the Committee on Energy and Commerce of the House of Representatives the Committee on Finance of the Senate regarding—

(1) the availability of reliable data relating to the quality of maternity care furnished under State plans under titles XIX and XXI;

(2) the availability of reliable data relating to the quality of services furnished under State plans under title XIX to adults who are 21 years of age or older but have not attained age 65; and

(3) recommendations for improving the quality of such care and services furnished under such State plans.

(e) RULE OF CONSTRUCTION.—Notwithstanding any other provision in this section, no quality measure developed, published, or used as a basis of measurement or reporting under this section may be used to establish an irrefutable presumption regarding either the medical necessity of care or the maximum permissible coverage for any individual who receives medical assistance under title XIX or child health assistance under title XXI.

(f) APPROPRIATION.—For purposes of carrying out this section, in addition to funds otherwise available, out of any funds in the Treasury not otherwise appropriated, there are appropriated $40,000,000 for the 5-fiscal-year period beginning with fiscal year 2010. Funds appropriated under this subsection shall remain available until expended.

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OUTREACH EFFORTS TO INCREASE AWARENESS OF THE AVAILABILITY OF MEDICARE COST-SHARING AND SUBSIDIES FOR LOW-INCOME INDIVIDUALS UNDER TITLE XVIII

SEC. 1144. (a) * * *

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(c) ASSISTANCE WITH MEDICARE SAVINGS PROGRAM AND LOW-INCOME SUBSIDY PROGRAM APPLICATIONS.—

(1) * * *

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(3) TRANSMITTAL OF DATA TO STATES.—Beginning on January 1, 2010, with the consent of an individual completing an application for benefits described in paragraph (1)(B), the Commissioner shall electronically transmit to the appropriate State Medicaid agency data from such application, as determined by the Commissioner, which [transmittal] shall initiate an application of the individual for benefits under the Medicare Savings Program with the State Medicaid agency *as specified in section 1935(a)(4)*. In order to ensure that such data transmittal provides effective assistance for purposes of State adjudication of applications for benefits under the Medicare Savings Program, the Commissioner shall consult with the Secretary, after the Secretary has consulted with the States, regarding the content, form, frequency, and manner in which data (on a uniform basis for all States) shall be transmitted under this subparagraph.

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IMPROVED COORDINATION AND PROTECTION FOR DUAL ELIGIBLES

SEC. 1150A. (a) IN GENERAL.—The Secretary shall provide, through an identifiable office or program within the Centers for Medicare & Medicaid Services, for a focused effort to provide for improved coordination between Medicare and Medicaid and protection in the case of dual eligibles (as defined in subsection (e)). The office or program shall—

(1) review Medicare and Medicaid policies related to enrollment, benefits, service delivery, payment, and grievance and appeals processes under parts A and B of title XVIII, under the Medicare Advantage program under part C of such title, and under title XIX;

(2) identify areas of such policies where better coordination and protection could improve care and costs; and

(3) issue guidance to States regarding improving such coordination and protection.

(b) ELEMENTS.—The improved coordination and protection under this section shall include efforts—

(1) to simplify access of dual eligibles to benefits and services under Medicare and Medicaid;

(2) to improve care continuity for dual eligibles and ensure safe and effective care transitions;

(3) to harmonize regulatory conflicts between Medicare and Medicaid rules with regard to dual eligibles; and

(4) to improve total cost and quality performance under Medicare and Medicaid for dual eligibles.

(c) RESPONSIBILITIES.—In carrying out this section, the Secretary shall provide for the following:

(1) An examination of Medicare and Medicaid payment systems to develop strategies to foster more integrated and higher quality care.

(2) Development of methods to facilitate access to post-acute and community-based services and to identify actions that could lead to better coordination of community-based care.

(3) A study of enrollment of dual eligibles in the Medicare Savings Program (as defined in section 1144(c)(7)), under Medicaid, and in the low-income subsidy program under section 1860D–14 to identify methods to more efficiently and effectively reach and enroll dual eligibles.

(4) An assessment of communication strategies for dual eligibles to determine whether additional informational materials or outreach is needed, including an assessment of the Medicare website, 1-800-MEDICARE, and the Medicare handbook.

(5) Research and evaluation of areas where service utilization, quality, and access to cost sharing protection could be improved and an assessment of factors related to enrollee satisfaction with services and care delivery.

(6) Collection (and making available to the public) of data and a database that describe the eligibility, benefit and cost-sharing assistance available to dual eligibles by State.

(7) Monitoring total combined Medicare and Medicaid program costs in serving dual eligibles and making recommendations for optimizing total quality and cost performance across both programs.

(8) Coordination of activities relating to Medicare Advantage plans under 1859(b)(6)(B)(ii) and Medicaid.

(d) PERIODIC REPORTS.—Not later than 1 year after the date of the enactment of this section and every 3 years thereafter the Secretary shall submit to Congress a report on progress in activities conducted under this section.

(e) DEFINITIONS.—In this section:

(1) DUAL ELIGIBLE.—The term "dual eligible" means an individual who is dually eligible for benefits under title XVIII, and medical assistance under title XIX, including such individuals who are eligible for benefits under the Medicare Savings Program (as defined in section 1144(c)(7)).

(2) MEDICARE; MEDICAID.—The terms "Medicare" and "Medicaid" mean the programs under titles XVIII and XIX, respectively.

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PART C—ADMINISTRATIVE SIMPLIFICATION

DEFINITIONS

SEC. 1171. For purposes of this part:

(1) * * *

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(7) STANDARD.—The term "standard", when used [with reference to a data element of health information or a transaction referred to in section 1173(a)(1), means any such data element or transaction that meets each of the standards and implementation specifications adopted or established by the Secretary with respect to the data element or transaction under sections 1172 through 1174.] *with reference to a transaction or data element of health information in section 1173 means implementation specifications, certification criteria, operating rules, messaging formats, codes, and code sets adopted or established by the Secretary for the electronic exchange and use of information.*

* * * * * * *

(9) OPERATING RULES.—The term "operating rules" means business rules for using and processing transactions. Operating rules should address the following:

(A) Requirements for data content using available and established national standards.

(B) Infrastructure requirements that establish best practices for streamlining data flow to yield timely execution of transactions.

(C) Policies defining the transaction related rights and responsibilities for entities that are transmitting or receiving data.

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SEC. 1173A. STANDARDIZE ELECTRONIC ADMINISTRATIVE TRANSACTIONS.

(a) STANDARDS FOR FINANCIAL AND ADMINISTRATIVE TRANSACTIONS.—

(1) IN GENERAL.—The Secretary shall adopt and regularly update standards consistent with the goals described in paragraph (2).

(2) GOALS FOR FINANCIAL AND ADMINISTRATIVE TRANSACTIONS.—The goals for standards under paragraph (1) are that such standards shall—

(A) be unique with no conflicting or redundant standards;

(B) be authoritative, permitting no additions or constraints for electronic transactions, including companion guides;

(C) be comprehensive, efficient and robust, requiring minimal augmentation by paper transactions or clarification by further communications;

(D) enable the real-time (or near real-time) determination of an individual's financial responsibility at the point of service and, to the extent possible, prior to service, including whether the individual is eligible for a specific service with a specific physician at a specific facility, which may include utilization of a machine-readable health plan beneficiary identification card;

(E) enable, where feasible, near real-time adjudication of claims;

(F) provide for timely acknowledgment, response, and status reporting applicable to any electronic transaction deemed appropriate by the Secretary;

(G) describe all data elements (such as reason and remark codes) in unambiguous terms, not permit optional fields, require that data elements be either required or conditioned upon set values in other fields, and prohibit additional conditions; and

(H) harmonize all common data elements across administrative and clinical transaction standards.

(3) TIME FOR ADOPTION.—Not later than 2 years after the date of implementation of the X12 Version 5010 transaction standards implemented under this part, the Secretary shall adopt standards under this section.

(4) REQUIREMENTS FOR SPECIFIC STANDARDS.—The standards under this section shall be developed, adopted, and enforced so as to—

(A) clarify, refine, complete, and expand, as needed, the standards required under section 1173;

(B) require paper versions of standardized transactions to comply with the same standards as to data content such that a fully compliant, equivalent electronic transaction can be populated from the data from a paper version;

(C) enable electronic funds transfers, in order to allow automated reconciliation with the related health care payment and remittance advice;

(D) require timely and transparent claim and denial management processes, including tracking, adjudication, and appeal processing;

(E) require the use of a standard electronic transaction with which health care providers may quickly and effi-

ciently enroll with a health plan to conduct the other electronic transactions provided for in this part; and

(F) provide for other requirements relating to administrative simplification as identified by the Secretary, in consultation with stakeholders.

(5) BUILDING ON EXISTING STANDARDS.—In developing the standards under this section, the Secretary shall build upon existing and planned standards.

(6) IMPLEMENTATION AND ENFORCEMENT.—Not later than 6 months after the date of the enactment of this section, the Secretary shall submit to the appropriate committees of Congress a plan for the implementation and enforcement, by not later than 5 years after such date of enactment, of the standards under this section. Such plan shall include—

(A) a process and timeframe with milestones for developing the complete set of standards;

(B) an expedited upgrade program for continually developing and approving additions and modifications to the standards as often as annually to improve their quality and extend their functionality to meet evolving requirements in health care;

(C) programs to provide incentives for, and ease the burden of, implementation for certain health care providers, with special consideration given to such providers serving rural or underserved areas and ensure coordination with standards, implementation specifications, and certification criteria being adopted under the HITECH Act;

(D) programs to provide incentives for, and ease the burden of, health care providers who volunteer to participate in the process of setting standards for electronic transactions;

(E) an estimate of total funds needed to ensure timely completion of the implementation plan; and

(F) an enforcement process that includes timely investigation of complaints, random audits to ensure compliance, civil monetary and programmatic penalties for non-compliance consistent with existing laws and regulations, and a fair and reasonable appeals process building off of enforcement provisions under this part.

(b) LIMITATIONS ON USE OF DATA.—Nothing in this section shall be construed to permit the use of information collected under this section in a manner that would adversely affect any individual.

(c) PROTECTION OF DATA.—The Secretary shall ensure (through the promulgation of regulations or otherwise) that all data collected pursuant to subsection (a) are—

(1) used and disclosed in a manner that meets the HIPAA privacy and security law (as defined in section 3009(a)(2) of the Public Health Service Act), including any privacy or security standard adopted under section 3004 of such Act; and

(2) protected from all inappropriate internal use by any entity that collects, stores, or receives the data, including use of such data in determinations of eligibility (or continued eligibility) in health plans, and from other inappropriate uses, as defined by the Secretary.

SEC. 1173B. OPERATING RULES.

(a) IN GENERAL.—The Secretary shall adopt operating rules for each transaction described in section 1173(a)(2) of the Social Security Act (42 U.S.C. 1320d-2(a))

(b) OPERATING RULES DEVELOPMENT.—In adopting such rules, the Secretary shall take into account the development of operating rules that have been developed by a nonprofit entity that meets the following criteria:

(1) The entity focuses its mission on administrative simplification.

(2) The entity demonstrates a established multi-stakeholder process that creates consensus based operating rules using a voting policy with balanced representation by the critical stakeholders (including health plans and health care providers) so that no one group dominates the entity and shall include others such as standards development organizations, and relevant Federal agencies.

(3) The entity has in place a public set of guiding principles that ensure the operating rules and process are open and transparent.

(4) The entity shall coordinate its activities with the HIT Policy Committee and the HIT Standards Committee (established under title XXX of the Public Health Service Act) and complements the efforts of the Office of the National Healthcare Coordinator and its related health information exchange goals.

(5) The entity incorporates national standards, including the transaction standards issued under Health Insurance Portability and Accountability Act of 1996.

(6) The entity uses existing market research and proven best practices.

(7) The entity has a set of measures that allow for the evaluation of their market impact and public reporting of aggregate stakeholder impact.

(8) The entity supports nondiscrimination and conflict of interest policies that demonstrate a commitment to open, fair, and nondiscriminatory practices.

(9) The entity allows for public reviews and updates of the operating rules.

(c) IMPLEMENTATION.—The Secretary shall adopt operating rules under this section, by regulation or otherwise, only after taking into account the rules developed by the entity under subsection (b) and having ensured consultation with providers. The first set of operating rules for the transactions for eligibility for health plan and health claims status under this section shall be adopted not later than October 1, 2011, in a manner such that such set of rules is effective beginning not later than January 1, 2013. The second set of operating rules for the remainder of the transactions described in section 1173(a)(2) of the Social Security Act (42 U.S.C. 1320d-2(a)) shall be adopted not later than October 1, 2012, in a manner such that such set of rules is effective beginning not later than January 1, 2014.

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PROCESSING PAYMENT TRANSACTIONS BY FINANCIAL INSTITUTIONS

SEC. 1179. To the extent that an entity is engaged in activities of a financial institution (as defined in section 1101 of the Right to Financial Privacy Act of 1978) *on behalf of an individual*, [or is engaged] *and is engaged* in authorizing, processing, clearing, settling, billing, transferring, reconciling, or collecting payments, for a financial institution *(other than as a business associate for a covered entity) on behalf of an individual*, this part, and any standard adopted under this part, shall not apply to the entity with respect to such activities, including the following:

(1) * * *

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PART D—COMPARATIVE EFFECTIVENESS RESEARCH

COMPARATIVE EFFECTIVENESS RESEARCH

SEC. 1181. (a) CENTER FOR COMPARATIVE EFFECTIVENESS RESEARCH ESTABLISHED.—

(1) IN GENERAL.—The Secretary shall establish within the Agency for Healthcare Research and Quality a Center for Comparative Effectiveness Research (in this section referred to as the "Center") to conduct, support, and synthesize research (including research conducted or supported under section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003) with respect to the outcomes, effectiveness, and appropriateness of health care services and procedures in order to identify the manner in which diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically.

(2) DUTIES.—The Center shall—

(A) conduct, support, and synthesize research relevant to the comparative effectiveness of the full spectrum of health care items, services and systems, including pharmaceuticals, medical devices, medical and surgical procedures, and other medical interventions;

(B) conduct and support systematic reviews of clinical research, including original research conducted subsequent to the date of the enactment of this section;

(C) continuously develop rigorous scientific methodologies for conducting comparative effectiveness studies, and use such methodologies appropriately;

(D) submit to the Comparative Effectiveness Research Commission, the Secretary, and Congress appropriate relevant reports described in subsection (d)(2); and

(E) encourage, as appropriate, the development and use of clinical registries and the development of clinical effectiveness research data networks from electronic health records, post marketing drug and medical device surveillance efforts, and other forms of electronic health data.

(3) POWERS.—

(A) OBTAINING OFFICIAL DATA.—The Center may secure directly from any department or agency of the United States information necessary to enable it to carry out this section. Upon request of the Center, the head of that depart-

ment or agency shall furnish that information to the Center on an agreed upon schedule.

(B) DATA COLLECTION.—In order to carry out its functions, the Center shall—

(i) utilize existing information, both published and unpublished, where possible, collected and assessed either by its own staff or under other arrangements made in accordance with this section,

(ii) carry out, or award grants or contracts for, original research and experimentation, where existing information is inadequate, and

(iii) adopt procedures allowing any interested party to submit information for the use by the Center and Commission under subsection (b) in making reports and recommendations.

(C) ACCESS OF GAO TO INFORMATION.—The Comptroller General shall have unrestricted access to all deliberations, records, and nonproprietary data of the Center and Commission under subsection (b), immediately upon request.

(D) PERIODIC AUDIT.—The Center and Commission under subsection (b) shall be subject to periodic audit by the Comptroller General.

(b) OVERSIGHT BY COMPARATIVE EFFECTIVENESS RESEARCH COMMISSION.—

(1) IN GENERAL.—The Secretary shall establish an independent Comparative Effectiveness Research Commission (in this section referred to as the "Commission") to oversee and evaluate the activities carried out by the Center under subsection (a), subject to the authority of the Secretary, to ensure such activities result in highly credible research and information resulting from such research.

(2) DUTIES.—The Commission shall—

(A) determine national priorities for research described in subsection (a) and in making such determinations consult with a broad array of public and private stakeholders, including patients and health care providers and payers;

(B) monitor the appropriateness of use of the CERTF described in subsection (g) with respect to the timely production of comparative effectiveness research determined to be a national priority under subparagraph (A);

(C) identify highly credible research methods and standards of evidence for such research to be considered by the Center;

(D) review the methodologies developed by the center under subsection (a)(2)(C);

(E) not later than one year after the date of the enactment of this section, enter into an arrangement under which the Institute of Medicine of the National Academy of Sciences shall conduct an evaluation and report on standards of evidence for such research;

(F) support forums to increase stakeholder awareness and permit stakeholder feedback on the efforts of the Center to advance methods and standards that promote highly credible research;

(G) make recommendations for policies that would allow for public access of data produced under this section, in accordance with appropriate privacy and proprietary practices, while ensuring that the information produced through such data is timely and credible;

(H) appoint a clinical perspective advisory panel for each research priority determined under subparagraph (A), which shall consult with patients and advise the Center on research questions, methods, and evidence gaps in terms of clinical outcomes for the specific research inquiry to be examined with respect to such priority to ensure that the information produced from such research is clinically relevant to decisions made by clinicians and patients at the point of care;

(I) make recommendations for the priority for periodic reviews of previous comparative effectiveness research and studies conducted by the Center under subsection (a);

(J) routinely review processes of the Center with respect to such research to confirm that the information produced by such research is objective, credible, consistent with standards of evidence established under this section, and developed through a transparent process that includes consultations with appropriate stakeholders; and

(K) make recommendations to the center for the broad dissemination of the findings of research conducted and supported under this section that enables clinicians, patients, consumers, and payers to make more informed health care decisions that improve quality and value.

(3) COMPOSITION OF COMMISSION.—

(A) IN GENERAL.—The members of the Commission shall consist of—

(i) the Director of the Agency for Healthcare Research and Quality;

(ii) the Chief Medical Officer of the Centers for Medicare & Medicaid Services; and

(iii) 15 additional members who shall represent broad constituencies of stakeholders including clinicians, patients, researchers, third-party payers, consumers of Federal and State beneficiary programs.

Of such members, at least 9 shall be practicing physicians, health care practitioners, consumers, or patients.

(B) QUALIFICATIONS.—

(i) DIVERSE REPRESENTATION OF PERSPECTIVES.—The members of the Commission shall represent a broad range of perspectives and shall collectively have experience in the following areas:

(I) Epidemiology.

(II) Health services research.

(III) Bioethics.

(IV) Decision sciences.

(V) Health disparities.

(VI) Economics.

(ii) DIVERSE REPRESENTATION OF HEALTH CARE COMMUNITY.—At least one member shall represent each of the following health care communities:

(I) Patients.

(II) Health care consumers.

(III) Practicing Physicians, including surgeons.

(IV) Other health care practitioners engaged in clinical care.

(V) Employers.

(VI) Public payers.

(VII) Insurance plans.

(VIII) Clinical researchers who conduct research on behalf of pharmaceutical or device manufacturers.

(C) LIMITATION.—No more than 3 of the Members of the Commission may be representatives of pharmaceutical or device manufacturers and such representatives shall be clinical researchers described under subparagraph (B)(ii)(VIII).

(4) APPOINTMENT.—

(A) IN GENERAL.—The Secretary shall appoint the members of the Commission.

(B) CONSULTATION.—In considering candidates for appointment to the Commission, the Secretary may consult with the Government Accountability Office and the Institute of Medicine of the National Academy of Sciences.

(5) CHAIRMAN; VICE CHAIRMAN.—The Secretary shall designate a member of the Commission, at the time of appointment of the member, as Chairman and a member as Vice Chairman for that term of appointment, except that in the case of vacancy of the Chairmanship or Vice Chairmanship, the Secretary may designate another member for the remainder of that member's term. The Chairman shall serve as an ex officio member of the National Advisory Council of the Agency for Health Care Research and Quality under section 931(c)(3)(B) of the Public Health Service Act.

(6) TERMS.—

(A) IN GENERAL.—Except as provided in subparagraph (B), each member of the Commission shall be appointed for a term of 4 years.

(B) TERMS OF INITIAL APPOINTEES.—Of the members first appointed—

(i) 8 shall be appointed for a term of 4 years; and

(ii) 7 shall be appointed for a term of 3 years.

(7) COORDINATION.—To enhance effectiveness and coordination, the Secretary is encouraged, to the greatest extent possible, to seek coordination between the Commission and the National Advisory Council of the Agency for Healthcare Research and Quality.

(8) CONFLICTS OF INTEREST.—

(A) IN GENERAL.—In appointing the members of the Commission or a clinical perspective advisory panel described in paragraph (2)(H), the Secretary or the Commission, respectively, shall take into consideration any financial interest (as defined in subparagraph (D)), consistent with this paragraph, and develop a plan for managing any identified conflicts.

(B) EVALUATION AND CRITERIA.—When considering an appointment to the Commission or a clinical perspective advisory panel described paragraph (2)(H) the Secretary or the Commission shall review the expertise of the individual and the financial disclosure report filed by the individual pursuant to the Ethics in Government Act of 1978 for each individual under consideration for the appointment, so as to reduce the likelihood that an appointed individual will later require a written determination as referred to in section 208(b)(1) of title 18, United States Code, a written certification as referred to in section 208(b)(3) of title 18, United States Code, or a waiver as referred to in subparagraph (D)(iii) for service on the Commission at a meeting of the Commission.

(C) DISCLOSURES; PROHIBITIONS ON PARTICIPATION; WAIVERS.—

(i) DISCLOSURE OF FINANCIAL INTEREST.—Prior to a meeting of the Commission or a clinical perspective advisory panel described in paragraph (2)(H) regarding a "particular matter" (as that term is used in section 208 of title 18, United States Code), each member of the Commission or the clinical perspective advisory panel who is a full-time Government employee or special Government employee shall disclose to the Secretary financial interests in accordance with subsection (b) of such section 208.

(ii) PROHIBITIONS ON PARTICIPATION.—Except as provided under clause (iii), a member of the Commission or a clinical perspective advisory panel described in paragraph (2)(H) may not participate with respect to a particular matter considered in meeting of the Commission or the clinical perspective advisory panel if such member (or an immediate family member of such member) has a financial interest that could be affected by the advice given to the Secretary with respect to such matter, excluding interests exempted in regulations issued by the Director of the Office of Government Ethics as too remote or inconsequential to affect the integrity of the services of the Government officers or employees to which such regulations apply.

(iii) WAIVER.—If the Secretary determines it necessary to afford the Commission or a clinical perspective advisory panel described in paragraph 2(H) essential expertise, the Secretary may grant a waiver of the prohibition in clause (ii) to permit a member described in such subparagraph to—

(I) participate as a non-voting member with respect to a particular matter considered in a Commission or a clinical perspective advisory panel meeting; or

(II) participate as a voting member with respect to a particular matter considered in a Commission or a clinical perspective advisory panel meeting.

(iv) LIMITATION ON WAIVERS AND OTHER EXCEPTIONS.—

(I) DETERMINATION OF ALLOWABLE EXCEPTIONS FOR THE COMMISSION.—The number of waivers granted to members of the Commission cannot exceed one-half of the total number of members for the Commission.

(II) PROHIBITION ON VOTING STATUS ON CLINICAL PERSPECTIVE ADVISORY PANELS.—No voting member of any clinical perspective advisory panel shall be in receipt of a waiver. No more than two nonvoting members of any clinical perspective advisory panel shall receive a waiver.

(D) FINANCIAL INTEREST DEFINED.—For purposes of this paragraph, the term "financial interest" means a financial interest under section 208(a) of title 18, United States Code.

(9) COMPENSATION.—While serving on the business of the Commission (including travel time), a member of the Commission shall be entitled to compensation at the per diem equivalent of the rate provided for level IV of the Executive Schedule under section 5315 of title 5, United States Code; and while so serving away from home and the member's regular place of business, a member may be allowed travel expenses, as authorized by the Director of the Commission.

(10) AVAILABILITY OF REPORTS.—The Commission shall transmit to the Secretary a copy of each report submitted under this subsection and shall make such reports available to the public.

(11) DIRECTOR AND STAFF; EXPERTS AND CONSULTANTS.—Subject to such review as the Secretary deems necessary to assure the efficient administration of the Commission, the Commission may—

(A) appoint an Executive Director (subject to the approval of the Secretary) and such other personnel as Federal employees under section 2105 of title 5, United States Code, as may be necessary to carry out its duties (without regard to the provisions of title 5, United States Code, governing appointments in the competitive service);

(B) seek such assistance and support as may be required in the performance of its duties from appropriate Federal departments and agencies;

(C) enter into contracts or make other arrangements, as may be necessary for the conduct of the work of the Commission (without regard to section 3709 of the Revised Statutes (41 U.S.C. 5));

(D) make advance, progress, and other payments which relate to the work of the Commission;

(E) provide transportation and subsistence for persons serving without compensation; and

(F) prescribe such rules and regulations as it deems necessary with respect to the internal organization and operation of the Commission.

(c) RESEARCH REQUIREMENTS.—Any research conducted, supported, or synthesized under this section shall meet the following requirements:

(1) ENSURING TRANSPARENCY, CREDIBILITY, AND ACCESS.—

(A) The establishment of the agenda and conduct of the research shall be insulated from inappropriate political or stakeholder influence.

(B) Methods of conducting such research shall be scientifically based.

(C) All aspects of the prioritization of research, conduct of the research, and development of conclusions based on the research shall be transparent to all stakeholders.

(D) The process and methods for conducting such research shall be publicly documented and available to all stakeholders.

(E) Throughout the process of such research, the Center shall provide opportunities for all stakeholders involved to review and provide public comment on the methods and findings of such research.

(2) USE OF CLINICAL PERSPECTIVE ADVISORY PANELS.—The research shall meet a national research priority determined under subsection (b)(2)(A) and shall consider advice given to the Center by the clinical perspective advisory panel for the national research priority.

(3) STAKEHOLDER INPUT.—

(A) IN GENERAL.—The Commission shall consult with patients, health care providers, health care consumer representatives, and other appropriate stakeholders with an interest in the research through a transparent process recommended by the Commission.

(B) SPECIFIC AREAS OF CONSULTATION.—Consultation shall include where deemed appropriate by the Commission—

(i) recommending research priorities and questions;

(ii) recommending research methodologies; and

(iii) advising on and assisting with efforts to disseminate research findings.

(C) OMBUDSMAN.—The Secretary shall designate a patient ombudsman. The ombudsman shall—

(i) serve as an available point of contact for any patients with an interest in proposed comparative effectiveness studies by the Center; and

(ii) ensure that any comments from patients regarding proposed comparative effectiveness studies are reviewed by the Commission.

(4) TAKING INTO ACCOUNT POTENTIAL DIFFERENCES.—Research shall—

(A) be designed, as appropriate, to take into account the potential for differences in the effectiveness of health care items and services used with various subpopulations such as racial and ethnic minorities, women, different age groups (including children, adolescents, adults, and seniors), and individuals with different comorbidities; and—

(B) seek, as feasible and appropriate, to include members of such subpopulations as subjects in the research.

(d) PUBLIC ACCESS TO COMPARATIVE EFFECTIVENESS INFORMATION.—

(1) IN GENERAL.—Not later than 90 days after receipt by the Center or Commission, as applicable, of a relevant report de-

scribed in paragraph (2) made by the Center, Commission, or clinical perspective advisory panel under this section, appropriate information contained in such report shall be posted on the official public Internet site of the Center and of the Commission, as applicable.

(2) RELEVANT REPORTS DESCRIBED.—For purposes of this section, a relevant report is each of the following submitted by the Center or a grantee or contractor of the Center:

(A) Any interim or progress reports as deemed appropriate by the Secretary.

(B) Stakeholder comments.

(C) A final report.

(e) DISSEMINATION AND INCORPORATION OF COMPARATIVE EFFECTIVENESS INFORMATION.—

(1) DISSEMINATION.—The Center shall provide for the dissemination of appropriate findings produced by research supported, conducted, or synthesized under this section to health care providers, patients, vendors of health information technology focused on clinical decision support, appropriate professional associations, and Federal and private health plans, and other relevant stakeholders. In disseminating such findings the Center shall—

(A) convey findings of research so that they are comprehensible and useful to patients and providers in making health care decisions;

(B) discuss findings and other considerations specific to certain sub-populations, risk factors, and comorbidities as appropriate;

(C) include considerations such as limitations of research and what further research may be needed, as appropriate;

(D) not include any data that the dissemination of which would violate the privacy of research participants or violate any confidentiality agreements made with respect to the use of data under this section; and

(E) assist the users of health information technology focused on clinical decision support to promote the timely incorporation of such findings into clinical practices and promote the ease of use of such incorporation.

(2) DISSEMINATION PROTOCOLS AND STRATEGIES.—The Center shall develop protocols and strategies for the appropriate dissemination of research findings in order to ensure effective communication of findings and the use and incorporation of such findings into relevant activities for the purpose of informing higher quality and more effective and efficient decisions regarding medical items and services. In developing and adopting such protocols and strategies, the Center shall consult with stakeholders concerning the types of dissemination that will be most useful to the end users of information and may provide for the utilization of multiple formats for conveying findings to different audiences, including dissemination to individuals with limited English proficiency.

(f) REPORTS TO CONGRESS.—

(1) ANNUAL REPORTS.—Beginning not later than one year after the date of the enactment of this section, the Director of the Agency of Healthcare Research and Quality and the Com-

mission shall submit to Congress an annual report on the activities of the Center and the Commission, as well as the research, conducted under this section. Each such report shall include a discussion of the Center's compliance with subsection (c)(4)(B), including any reasons for lack of complicance with such subsection.

(2) RECOMMENDATION FOR FAIR SHARE PER CAPITA AMOUNT FOR ALL-PAYER FINANCING.—Beginning not later than December 31, 2011, the Secretary shall submit to Congress an annual recommendation for a fair share per capita amount described in subsection (c)(1) of section 9511 of the Internal Revenue Code of 1986 for purposes of funding the CERTF under such section.

(3) ANALYSIS AND REVIEW.—Not later than December 31, 2013, the Secretary, in consultation with the Commission, shall submit to Congress a report on all activities conducted or supported under this section as of such date. Such report shall include an evaluation of the overall costs of such activities and an analysis of the backlog of any research proposals approved by the Commission but not funded.

(g) FUNDING OF COMPARATIVE EFFECTIVENESS RESEARCH.—For fiscal year 2010 and each subsequent fiscal year, amounts in the Comparative Effectiveness Research Trust Fund (referred to in this section as the "CERTF") under section 9511 of the Internal Revenue Code of 1986 shall be available, without the need for further appropriations and without fiscal year limitation, to the Secretary to carry out this section.

(h) CONSTRUCTION.—Nothing in this section shall be construed to permit the Commission or the Center to mandate coverage, reimbursement, or other policies for any public or private payer.

(i) RESEARCH NOT TO BE USED TO DENY OR RATION CARE.—In no case may any research conducted, supported, or developed by the Center, the Commission, or the Federal Coordinating Council for Comparative Effectiveness Research be used by the federal government to deny or ration care.

(j) APPLICATION OF FEDERALLY FUNDED CLINICAL COMPARATIVE EFFECTIVENESS RESEARCH.—The Centers for Medicare & Medicaid Services may not use Federally funded clinical comparative effectiveness research data under this section to make coverage determinations for medical treatments, services, or items under title XVIII on the basis of cost.

(k) CONDITIONS ON RECOMMENDATIONS OF STANDARDS OR PROTOCOLS.—

(1) IN GENERAL.—The work performed by the Commission or the Center shall be based upon consultation with, and review by, the specialty colleges and academies of medicine to determine best practices within their field of specialty. Any recommendations made or best practices developed by the Commission or the Center —

(A) shall be based upon evidence-based medicine; and

(B) shall not violate standards and protocols of clinical excellence of the specialty colleges and academies.

(2) DEFINITIONS.—For purposes of this subsection:

(A) SPECIALTY COLLEGES AND ACADEMIES OF MEDICINE.—The term "specialty colleges and academies of medicine" means the trade associations and professional membership

societies that represent physicians based on the field of medicine in which each such physician practices or is board certified.

(B) STANDARDS AND PROTOCOLS OF CLINICAL EXCELLENCE.—The term "standards and protocols of clinical excellence" means clinical or practice guidelines that consist of a set of directions or principles that is based on evidence and is designed to assist a health care practitioner with decisions about appropriate diagnostic, therapeutic, or other clinical procedures for specific clinical circumstances.

PART E—QUALITY IMPROVEMENT

ESTABLISHMENT OF NATIONAL PRIORITIES FOR PERFORMANCE IMPROVEMENT

SEC. 1191. (a) ESTABLISHMENT OF NATIONAL PRIORITIES BY THE SECRETARY.—The Secretary shall establish and periodically update, not less frequently than triennially, national priorities for performance improvement.

(b) RECOMMENDATIONS FOR NATIONAL PRIORITIES.—In establishing and updating national priorities under subsection (a), the Secretary shall solicit and consider recommendations from multiple outside stakeholders.

(c) CONSIDERATIONS IN SETTING NATIONAL PRIORITIES.—With respect to such priorities, the Secretary shall ensure that priority is given to areas in the delivery of health care services in the United States that—

(1) contribute to a large burden of disease, including those that address the health care provided to patients with prevalent, high-cost chronic diseases;

(2) have the greatest potential to decrease morbidity and mortality in this country, including those that are designed to eliminate harm to patients;

(3) have the greatest potential for improving the performance, affordability, and patient-centeredness of health care, including those due to variations in care;

(4) address health disparities across groups and areas; and

(5) have the potential for rapid improvement due to existing evidence, standards of care or other reasons.

(d) DEFINITIONS.—In this part:

(1) CONSENSUS-BASED ENTITY.—The term "consensus-based entity" means an entity with a contract with the Secretary under section 1890.

(2) QUALITY MEASURE.—The term "quality measure" means a national consensus standard for measuring the performance and improvement of population health, or of institutional providers of services, physicians, and other health care practitioners in the delivery of health care services.

(e) FUNDING.—

(1) IN GENERAL.—The Secretary shall provide for the transfer, from the Federal Hospital Insurance Trust Fund under section 1817 and the Federal Supplementary Medical Insurance Trust Fund under section 1841 (in such proportion as the Secretary determines appropriate), of $2,000,000, for the activities under this section for each of the fiscal years 2010 through 2014.

(2) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out the provisions of this section, in addition to funds otherwise available, out of any funds in the Treasury not otherwise appropriated, there are appropriated to the Secretary of Health and Human Services $2,000,000 for each of the fiscal years 2010 through 2014.

SEC. 1192. DEVELOPMENT OF NEW QUALITY MEASURES.

(a) AGREEMENTS WITH QUALIFIED ENTITIES.—

(1) IN GENERAL.—The Secretary shall enter into agreements with qualified entities to develop quality measures for the delivery of health care services in the United States.

(2) FORM OF AGREEMENTS.—The Secretary may carry out paragraph (1) by contract, grant, or otherwise.

(3) RECOMMENDATIONS OF CONSENSUS-BASED ENTITY.—In carrying out this section, the Secretary shall—

(A) seek public input; and

(B) take into consideration recommendations of the consensus-based entity with a contract with the Secretary under section 1890(a).

(b) DETERMINATION OF AREAS WHERE QUALITY MEASURES ARE REQUIRED.—Consistent with the national priorities established under this part and with the programs administered by the Centers for Medicare & Medicaid Services and in consultation with other relevant Federal agencies, the Secretary shall determine areas in which quality measures for assessing health care services in the United States are needed.

(c) DEVELOPMENT OF QUALITY MEASURES.—

(1) PATIENT-CENTERED AND POPULATION-BASED MEASURES.—Quality measures developed under agreements under subsection (a) shall be designed—

(A) to assess outcomes, presence of impairment, and functional status of patients;

(B) to assess the continuity and coordination of care and care transitions for patients across providers and health care settings, including end of life care;

(C) to assess patient experience and patient engagement;

(D) to assess the safety, effectiveness, and timeliness of care;

(E) to assess health disparities including those associated with individual race, ethnicity, age, gender, place of residence or language;

(F) to assess the efficiency and resource use in the provision of care;

(G) to the extent feasible, to be collected as part of health information technologies supporting better delivery of health care services;

(H) to be available free of charge to users for the use of such measures; and

(I) to assess delivery of health care services to individuals regardless of age.

(2) AVAILABILITY OF MEASURES.—The Secretary shall make quality measures developed under this section available to the public.

(3) TESTING OF PROPOSED MEASURES.—The Secretary may use amounts made available under subsection (f) to fund the

testing of proposed quality measures by qualified entities. Testing funded under this paragraph shall include testing of the feasibility and usability of proposed measures.

(4) UPDATING OF ENDORSED MEASURES.—The Secretary may use amounts made available under subsection (f) to fund the updating (and testing, if applicable) by consensus-based entities of quality measures that have been previously endorsed by such an entity as new evidence is developed, in a manner consistent with section 1890(b)(3).

(d) QUALIFIED ENTITIES.—Before entering into agreements with a qualified entity, the Secretary shall ensure that the entity is a public, nonprofit or academic institution with technical expertise in the area of health quality measurement.

(e) APPLICATION FOR GRANT.—A grant may be made under this section only if an application for the grant is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this section.

(f) FUNDING.—

(1) IN GENERAL.—The Secretary shall provide for the transfer, from the Federal Hospital Insurance Trust Fund under section 1817 and the Federal Supplementary Medical Insurance Trust Fund under section 1841 (in such proportion as the Secretary determines appropriate), of $25,000,000, to the Secretary for purposes of carrying out this section for each of the fiscal years 2010 through 2014.

(2) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out the provisions of this section, in addition to funds otherwise available, out of any funds in the Treasury not otherwise appropriated, there are appropriated to the Secretary of Health and Human Services $25,000,000 for each of the fiscal years 2010 through 2014.

SEC. 1193. GAO EVALUATION OF DATA COLLECTION PROCESS FOR QUALITY MEASUREMENT.

(a) GAO EVALUATIONS.—The Comptroller General of the United States shall conduct periodic evaluations of the implementation of the data collection processes for quality measures used by the Secretary.

(b) CONSIDERATIONS.—In carrying out the evaluation under subsection (a), the Comptroller General shall determine—

(1) whether the system for the collection of data for quality measures provides for validation of data as relevant and scientifically credible;

(2) whether data collection efforts under the system use the most efficient and cost-effective means in a manner that minimizes administrative burden on persons required to collect data and that adequately protects the privacy of patients' personal health information and provides data security;

(3) whether standards under the system provide for an appropriate opportunity for physicians and other clinicians and institutional providers of services to review and correct findings; and

(4) the extent to which quality measures are consistent with section 1192(c)(1) or result in direct or indirect costs to users of such measures.

(c) REPORT.—The Comptroller General shall submit reports to Congress and to the Secretary containing a description of the findings and conclusions of the results of each such evaluation.

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TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND DISABLED

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MEDICARE PAYMENT ADVISORY COMMISSION

SEC. 1805. (a) * * *

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(c) MEMBERSHIP.—

(1) * * *

(2) QUALIFICATIONS.—

(A) IN GENERAL.—The membership of the Commission shall include individuals with national recognition for their expertise in health finance and economics, actuarial science, health facility management, health plans and integrated delivery systems, reimbursement of health facilities, allopathic and osteopathic physicians, and other providers of health services, and other related fields, who provide a mix of different professionals, broad geographic representation, and a balance between urban and rural representatives *consistent with subparagraph (E)*.

* * * * * * *

(E) PROPORTIONAL REPRESENTATION OF INTERESTS OF RURAL AREAS.—In order to provide a balance between urban and rural representatives under subparagraph (A), the proportion of members of the Commission who represent the interests of health care providers and Medicare beneficiaries located in rural areas shall be no less than the proportion of the total number of Medicare beneficiaries who reside in rural areas.

* * * * * * *

PROVISIONS RELATING TO ADMINISTRATION

SEC. 1808. (a) * * *

* * * * * * *

(d) MULTI-STAKEHOLDER PRE-RULEMAKING INPUT INTO SELECTION OF QUALITY MEASURES.—

(1) LIST OF MEASURES.—Not later than December 1 before each year (beginning with 2011), the Secretary shall make public a list of measures being considered for selection for quality measurement by the Secretary in rulemaking with respect to payment systems under this title beginning in the payment year beginning in such year and for payment systems beginning in the calendar year following such year, as the case may be.

(2) CONSULTATION ON SELECTION OF ENDORSED QUALITY MEASURES.—A consensus-based entity that has entered into a contract under section 1890 shall, as part of such contract, convene multi-stakeholder groups to provide recommendations on

the selection of individual or composite quality measures, for use in reporting performance information to the public or for use in public health care programs.

(3) MULTI-STAKEHOLDER INPUT.—Not later than February 1 of each year (beginning with 2011), the consensus-based entity described in paragraph (2) shall transmit to the Secretary the recommendations of multi-stakeholder groups provided under paragraph (2). Such recommendations shall be included in the transmissions the consensus-based entity makes to the Secretary under the contract provided for under section 1890.

(4) REQUIREMENT FOR TRANSPARENCY IN PROCESS.—

(A) IN GENERAL.—In convening multi-stakeholder groups under paragraph (2) with respect to the selection of quality measures, the consensus-based entity described in such paragraph shall provide for an open and transparent process for the activities conducted pursuant to such convening.

(B) SELECTION OF ORGANIZATIONS PARTICIPATING IN MULTI-STAKEHOLDER GROUPS.—The process under paragraph (2) shall ensure that the selection of representatives of multi-stakeholder groups includes provision for public nominations for, and the opportunity for public comment on, such selection.

(5) USE OF INPUT.—The respective proposed rule shall contain a summary of the recommendations made by the multi-stakeholder groups under paragraph (2), as well as other comments received regarding the proposed measures, and the extent to which such proposed rule follows such recommendations and the rationale for not following such recommendations.

(6) MULTI-STAKEHOLDER GROUPS.—For purposes of this subsection, the term "multi-stakeholder groups" means, with respect to a quality measure, a voluntary collaborative of organizations representing persons interested in or affected by the use of such quality measure, such as the following:

(A) Hospitals and other institutional providers.

(B) Physicians.

(C) Health care quality alliances.

(D) Nurses and other health care practitioners.

(E) Health plans.

(F) Patient advocates and consumer groups.

(G) Employers.

(H) Public and private purchasers of health care items and services.

(I) Labor organizations.

(J) Relevant departments or agencies of the United States.

(K) Biopharmaceutical companies and manufacturers of medical devices.

(L) Licensing, credentialing, and accrediting bodies.

(7) FUNDING.—

(A) IN GENERAL.—The Secretary shall provide for the transfer, from the Federal Hospital Insurance Trust Fund under section 1817 and the Federal Supplementary Medical Insurance Trust Fund under section 1841 (in such proportion as the Secretary determines appropriate), of $1,000,000, to the Secretary for purposes of carrying out

this subsection for each of the fiscal years 2010 through 2014.

(B) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out the provisions of this subsection, in addition to funds otherwise available, out of any funds in the Treasury not otherwise appropriated, there are appropriated to the Secretary of Health and Human Services $1,000,000 for each of the fiscal years 2010 through 2014.

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PART A—HOSPITAL INSURANCE BENEFITS FOR THE AGED AND DISABLED

* * * * * * *

CONDITIONS OF AND LIMITATIONS ON PAYMENT FOR SERVICES

SEC. 1814. (a) REQUIREMENT OF REQUESTS AND CERTIFICATIONS.—Except as provided in subsections (d) and (g) and in section 1876, payment for services furnished an individual may be made only to providers of services which are eligible therefor under section 1866 and only if—

(1) written request, signed by such individual, except in cases in which the Secretary finds it impracticable for the individual to do so, is filed for such payment in such form, in such manner, and by such person or persons as the Secretary may by regulation prescribe, no later than the close of the ❙period of 3 calendar years following the year in which such services are furnished (deeming any services furnished in the last 3 calendar months of any calendar year to have been furnished in the succeeding calendar year) except that where the Secretary deems that efficient administration so requires, such period may be reduced to not less than 1 calendar year;❙ *period of 1 calendar year from which such services are furnished; and*

(2) a physician, *in the case of services described in subparagraph (C), a physician enrolled under section 1866(j) or an eligible professional under section 1848(k)(3)(B),* or, in the case of services described in subparagraph (B), a physician, or a nurse practitioner or clinical nurse specialist who does not have a direct or indirect employment relationship with the facility but is working in collaboration with a physician, certifies (and recertifies, where such services are furnished over a period of time, in such cases, with such frequency, and accompanied by such supporting material, appropriate to the case involved, as may be provided by regulations, except that the first of such recertifications shall be required in each case of inpatient hospital services not later than the 20th day of such period) that—

(A) * * *

* * * * * * *

(C) in the case of home health services, such services are or were required because the individual is or was confined to his home (except when receiving items and services referred to in section 1861(m)(7)) and needs or needed skilled nursing care (other than solely venipuncture for the purpose of obtaining a blood sample) on an intermittent basis

or physical or speech therapy or, in the case of an individual who has been furnished home health services based on such a need and who no longer has such a need for such care or therapy, continues or continued to need occupational therapy; a plan for furnishing such services to such individual has been established and is periodically reviewed by a physician; [and such services] *such services* are or were furnished while the individual was under the care of a physician*, and, in the case of a certification or recertification made by a physician after January 1, 2010, prior to making such certification the physician must document that the physician has had a face-to-face encounter (including through use of telehealth and other than with respect to encounters that are incident to services involved) with the individual during the 6-month period preceding such certification, or other reasonable timeframe as determined by the Secretary*; or

* * * * * * *

To the extent provided by regulations, the certification and recertification requirements of paragraph (2) shall be deemed satisfied where, at a later date, a physician, nurse practitioner, or clinical nurse specialist (as the case may be) makes certification of the kind provided in subparagraph (A), (B), (C), or (D) of paragraph (2) (whichever would have applied), but only where such certification is accompanied by such medical and other evidence as may be required by such regulations. With respect to the physician certification required by paragraph (2) for home health services furnished to any individual by a home health agency (other than an agency which is a governmental entity) and with respect to the establishment and review of a plan for such services, the Secretary shall prescribe regulations which shall become effective no later than July 1, 1981, and which prohibit a physician who has a significant ownership interest in, or a significant financial or contractual relationship with, such home health agency from performing such certification and from establishing or reviewing such plan, except that such prohibition shall not apply with respect to a home health agency which is a sole community home health agency (as determined by the Secretary). For purposes of the preceding sentence, service by a physician as an uncompensated officer or director of a home health agency shall not constitute having a significant ownership interest in, or a significant financial or contractual relationship with, such agency. For purposes of paragraph (2)(C), an individual shall be considered to be "confined to his home" if the individual has a condition, due to an illness or injury, that restricts the ability of the individual to leave his or her home except with the assistance of another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be bedridden to be considered "confined to his home", the condition of the individual should be such that there exists a normal inability to leave home and that leaving home requires a considerable and taxing effort by the individual. Any absence of an individual from the home attributable to the need to receive health care treatment, including regular absences for the purpose of participating in thera-

peutic, psychosocial, or medical treatment in an adult day-care program that is licensed or certified by a State, or accredited, to furnish adult day-care services in the State shall not disqualify an individual from being considered to be "confined to his home". Any other absence of an individual from the home shall not so disqualify an individual if the absence is of infrequent or of relatively short duration. For purposes of the preceding sentence, any absence for the purpose of attending a religious service shall be deemed to be an absence of infrequent or short duration. *In applying paragraph (1), the Secretary may specify exceptions to the 1 calendar year period specified in such paragraph.*

* * * * * * *

Payment for Hospice Care

(i)(1)(A) * * *

(C)(i) * * *

(ii) With respect to routine home care and other services included in hospice care furnished during a subsequent fiscal year, the payment rates for such care and services shall be the payment rates in effect under this subparagraph during the previous fiscal year increased by—

(I) * * *

* * * * * * *

(VII) for a subsequent fiscal year, the market basket percentage increase *(which is subject to the productivity adjustment described in section 1886(b)(3)(B)(iii)(II))* for the fiscal year.

* * * * * * *

(l) PAYMENT FOR INPATIENT CRITICAL ACCESS HOSPITAL SERVICES.—(1) * * *

* * * * * * *

(5) The adjustment factor described in section 1886(p)(3) shall apply to payments with respect to a critical access hospital with respect to a cost reporting period beginning in fiscal year 2012 and each subsequent fiscal year (after application of paragraph (4) of this subsection) in a manner similar to the manner in which such section applies with respect to a fiscal year to an applicable hospital as described in section 1886(p)(2).

[(5)**]** *(6)* There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of—

(A) * * *

* * * * * * *

(C) the specification of EHR reporting periods under section 1886(n)(6)(B) as applied under paragraphs (3) and (4); **[**and**]**

(D) the identification of costs for purposes of paragraph (3)(C)**[**.**]***; and*

(E) the methodology for determining the adjustment factor under paragraph (5), including the determination of aggregate payments for actual and expected readmissions, applicable periods, applicable conditions and measures of readmissions.

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FEDERAL HOSPITAL INSURANCE TRUST FUND

SEC. 1817. (a) * * *

* * * * * * *

(k) HEALTH CARE FRAUD AND ABUSE CONTROL ACCOUNT.—

(1) * * *

* * * * * * *

(4) APPROPRIATED AMOUNTS TO ACCOUNT FOR MEDICARE INTEGRITY PROGRAM.—

(A) IN GENERAL.—There are hereby appropriated to the Account from the Trust Fund for each fiscal year such amounts as are necessary *for activities described in paragraph (3)(C) and* to carry out the Medicare Integrity Program under section 1893, subject to subparagraphs (B), (C), and (D) and to be available without further appropriation *until expended*.

* * * * * * *

(7) ADDITIONAL FUNDING.—In addition to the funds otherwise appropriated to the Account from the Trust Fund under paragraphs (3) and (4) and for purposes described in paragraphs (3)(C) and (4)(A), there are hereby appropriated an additional $100,000,000 to such Account from such Trust Fund for each fiscal year beginning with 2011. The funds appropriated under this paragraph shall be allocated in the same proportion as the total funding appropriated with respect to paragraphs (3)(A) and (4)(A) was allocated with respect to fiscal year 2010, and shall be available without further appropriation until expended.

* * * * * * *

REQUIREMENTS FOR, AND ASSURING QUALITY OF CARE IN, SKILLED NURSING FACILITIES

SEC. 1819. (a) * * *

(b) REQUIREMENTS RELATING TO PROVISION OF SERVICES.—

(1) QUALITY OF LIFE.—

(A) * * *

(B) QUALITY ASSESSMENT AND [ASSURANCE] *ASSURANCE AND QUALITY ASSURANCE AND PERFORMANCE IMPROVEMENT PROGRAM.*—

(i) IN GENERAL.—A skilled nursing facility must maintain a quality assessment and assurance committee, consisting of the director of nursing services, a physician designated by the facility, and at least 3 other members of the facility's staff, which [(i)] *(I)* meets at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary and [(ii)] *(II)* develops and implements appropriate plans of action to correct identified quality deficiencies.

(ii) QUALITY ASSURANCE AND PERFORMANCE IMPROVEMENT PROGRAM.—

(I) IN GENERAL.—Not later than December 31, 2011, the Secretary shall establish and implement a quality assurance and performance improvement

program (in this clause referred to as the "QAPI program") for skilled nursing facilities, including multi-unit chains of such facilities. Under the QAPI program, the Secretary shall establish standards relating to such facilities and provide technical assistance to such facilities on the development of best practices in order to meet such standards. Not later than 1 year after the date on which the regulations are promulgated under subclause (II), a skilled nursing facility must submit to the Secretary a plan for the facility to meet such standards and implement such best practices, including how to coordinate the implementation of such plan with quality assessment and assurance activities conducted under clause (i).

(II) REGULATIONS.—The Secretary shall promulgate regulations to carry out this clause.

* * * * * * *

(8) INFORMATION ON NURSE STAFFING.—

(A) * * *

* * * * * * *

(C) SUBMISSION OF STAFFING INFORMATION BASED ON PAYROLL DATA IN A UNIFORM FORMAT.—Beginning not later than 2 years after the date of the enactment of this subparagraph, and after consulting with State long-term care ombudsman programs, consumer advocacy groups, provider stakeholder groups, employees and their representatives, and other parties the Secretary deems appropriate, the Secretary shall require a skilled nursing facility to electronically submit to the Secretary direct care staffing information (including information with respect to agency and contract staff) based on payroll and other verifiable and auditable data in a uniform format (according to specifications established by the Secretary in consultation with such programs, groups, and parties). Such specifications shall require that the information submitted under the preceding sentence—

(i) specify the category of work a certified employee performs (such as whether the employee is a registered nurse, licensed practical nurse, licensed vocational nurse, certified nursing assistant, therapist, or other medical personnel);

(ii) include resident census data and information on resident case mix;

(iii) include a regular reporting schedule; and

(iv) include information on employee turnover and tenure and on the hours of care provided by each category of certified employees referenced in clause (i) per resident per day.

Nothing in this subparagraph shall be construed as preventing the Secretary from requiring submission of such information with respect to specific categories, such as nursing staff, before other categories of certified employees. Information under this subparagraph with respect to agency

and contract staff shall be kept separate from information on employee staffing.

(c) REQUIREMENTS RELATING TO RESIDENTS' RIGHTS.—

(1) * * *

* * * * * * *

(7) NOTIFICATION OF FACILITY CLOSURE.—

(A) IN GENERAL.—Any individual who is the administrator of a skilled nursing facility must—

(i) submit to the Secretary, the State long-term care ombudsman, residents of the facility, and the legal representatives of such residents or other responsible parties, written notification of an impending closure—

(I) subject to subclause (II), not later than the date that is 60 days prior to the date of such closure; and

(II) in the case of a facility where the Secretary terminates the facility's participation under this title, not later than the date that the Secretary determines appropriate;

(ii) ensure that the facility does not admit any new residents on or after the date on which such written notification is submitted; and

(iii) include in the notice a plan for the transfer and adequate relocation of the residents of the facility by a specified date prior to closure that has been approved by the State, including assurances that the residents will be transferred to the most appropriate facility or other setting in terms of quality, services, and location, taking into consideration the needs and best interests of each resident.

(B) RELOCATION.—

(i) IN GENERAL.—The State shall ensure that, before a facility closes, all residents of the facility have been successfully relocated to another facility or an alternative home and community-based setting.

(ii) CONTINUATION OF PAYMENTS UNTIL RESIDENTS RELOCATED.—The Secretary may, as the Secretary determines appropriate, continue to make payments under this title with respect to residents of a facility that has submitted a notification under subparagraph (A) during the period beginning on the date such notification is submitted and ending on the date on which the resident is successfully relocated.

(d) REQUIREMENTS RELATING TO ADMINISTRATION AND OTHER MATTERS.—

(1) ADMINISTRATION.—

(A) * * *

[(B) REQUIRED NOTICES.—If a change occurs in—

[(i) the persons with an ownership or control interest (as defined in section 1124(a)(3)) in the facility,

[(ii) the persons who are officers, directors, agents, or managing employees (as defined in section 1126(b)) of the facility,

[(iii) the corporation, association, or other company responsible for the management of the facility, or

[(iv) the individual who is the administrator or director of nursing of the facility,—the skilled nursing facility must provide notice to the State agency responsible for the licensing of the facility, at the time of the change, of the change and of the identity of each new person, company, or individual described in the respective clause.]

[(C)] *(B)* SKILLED NURSING FACILITY ADMINISTRATOR.—The administrator of a skilled nursing facility must meet standards established by the Secretary under subsection (f)(4).

(C) COMPLIANCE AND ETHICS PROGRAMS.—

(i) REQUIREMENT.—On or after the date that is 36 months after the date of the enactment of this subparagraph, a skilled nursing facility shall, with respect to the entity that operates the facility (in this subparagraph referred to as the "operating organization" or "organization"), have in operation a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations under this Act and in promoting quality of care consistent with regulations developed under clause (ii).

(ii) DEVELOPMENT OF REGULATIONS.—

(I) IN GENERAL.—Not later than the date that is 2 years after such date of the enactment, the Secretary, in consultation with the Inspector General of the Department of Health and Human Services, shall promulgate regulations for an effective compliance and ethics program for operating organizations, which may include a model compliance program.

(II) DESIGN OF REGULATIONS.—Such regulations with respect to specific elements or formality of a program may vary with the size of the organization, such that larger organizations should have a more formal and rigorous program and include established written policies defining the standards and procedures to be followed by its employees. Such requirements shall specifically apply to the corporate level management of multi-unit nursing home chains.

(III) EVALUATION.—Not later than 3 years after the date of promulgation of regulations under this clause, the Secretary shall complete an evaluation of the compliance and ethics programs required to be established under this subparagraph. Such evaluation shall determine if such programs led to changes in deficiency citations, changes in quality performance, or changes in other metrics of resident quality of care. The Secretary shall submit to Congress a report on such evaluation and shall include in such report such recommendations regarding changes in the requirements for such programs as the Secretary determines appropriate.

(iii) REQUIREMENTS FOR COMPLIANCE AND ETHICS PROGRAMS.—In this subparagraph, the term "compliance and ethics program" means, with respect to a skilled nursing facility, a program of the operating organization that—

(I) has been reasonably designed, implemented, and enforced so that it generally will be effective in preventing and detecting criminal, civil, and administrative violations under this Act and in promoting quality of care; and

(II) includes at least the required components specified in clause (iv).

(iv) REQUIRED COMPONENTS OF PROGRAM.—The required components of a compliance and ethics program of an organization are the following:

(I) The organization must have established compliance standards and procedures to be followed by its employees, contractors, and other agents that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations under this Act.

(II) Specific individuals within high-level personnel of the organization must have been assigned overall responsibility to oversee compliance with such standards and procedures and have sufficient resources and authority to assure such compliance.

(III) The organization must have used due care not to delegate substantial discretionary authority to individuals whom the organization knew, or should have known through the exercise of due diligence, had a propensity to engage in criminal, civil, and administrative violations under this Act.

(IV) The organization must have taken steps to communicate effectively its standards and procedures to all employees and other agents, such as by requiring participation in training programs or by disseminating publications that explain in a practical manner what is required.

(V) The organization must have taken reasonable steps to achieve compliance with its standards, such as by utilizing monitoring and auditing systems reasonably designed to detect criminal, civil, and administrative violations under this Act by its employees and other agents and by having in place and publicizing a reporting system whereby employees and other agents could report violations by others within the organization without fear of retribution.

(VI) The standards must have been consistently enforced through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect an offense.

(VII) After an offense has been detected, the organization must have taken all reasonable steps to respond appropriately to the offense and to prevent further similar offenses, including repayment of any funds to which it was not entitled and any necessary modification to its program to prevent and detect criminal, civil, and administrative violations under this Act.

(VIII) The organization must periodically undertake reassessment of its compliance program to identify changes necessary to reflect changes within the organization and its facilities.

(v) COORDINATION.—The provisions of this subparagraph shall apply with respect to a skilled nursing facility in lieu of section 1874(d).

(D) AVAILABILITY OF SURVEY, CERTIFICATION, AND COMPLAINT INVESTIGATION REPORTS.—A skilled nursing facility must—

(i) have reports with respect to any surveys, certifications, and complaint investigations made respecting the facility during the 3 preceding years available for any individual to review upon request; and

(ii) post notice of the availability of such reports in areas of the facility that are prominent and accessible to the public.

The facility shall not make available under clause (i) identifying information about complainants or residents.

* * * * * * *

(e) STATE REQUIREMENTS RELATING TO SKILLED NURSING FACILITY REQUIREMENTS.—The requirements, referred to in section 1864(d), with respect to a State are as follows:

(1) * * *

* * * * * * *

(6) COMPLAINT PROCESSES AND WHISTLE-BLOWER PROTECTION.—

(A) COMPLAINT FORMS.—The State must make the standardized complaint form developed under subsection (f)(9) available upon request to—

(i) a resident of a skilled nursing facility;

(ii) any person acting on the resident's behalf; and

(iii) any person who works at a skilled nursing facility or is a representative of such a worker.

(B) COMPLAINT RESOLUTION PROCESS.—The State must establish a complaint resolution process in order to ensure that a resident, the legal representative of a resident of a skilled nursing facility, or other responsible party is not retaliated against if the resident, legal representative, or responsible party has complained, in good faith, about the quality of care or other issues relating to the skilled nursing facility, that the legal representative of a resident of a skilled nursing facility or other responsible party is not denied access to such resident or otherwise retaliated against if such representative party has complained, in good faith, about the quality of care provided by the facility or other

issues relating to the facility, and that a person who works at a skilled nursing facility is not retaliated against if the worker has complained, in good faith, about quality of care or services or an issue relating to the quality of care or services provided at the facility, whether the resident, legal representative, other responsible party, or worker used the form developed under subsection (f)(9) or some other method for submitting the complaint. Such complaint resolution process shall include—

(i) procedures to assure accurate tracking of complaints received, including notification to the complainant that a complaint has been received;

(ii) procedures to determine the likely severity of a complaint and for the investigation of the complaint;

(iii) deadlines for responding to a complaint and for notifying the complainant of the outcome of the investigation; and

(iv) procedures to ensure that the identity of the complainant will be kept confidential.

(C) WHISTLEBLOWER PROTECTION.—

(i) PROHIBITION AGAINST RETALIATION.—No person who works at a skilled nursing facility may be penalized, discriminated, or retaliated against with respect to any aspect of employment, including discharge, promotion, compensation, terms, conditions, or privileges of employment, or have a contract for services terminated, because the person (or anyone acting at the person's request) complained, in good faith, about the quality of care or services provided by a nursing facility or about other issues relating to quality of care or services, whether using the form developed under subsection (f)(9) or some other method for submitting the complaint.

(ii) RETALIATORY REPORTING.—A skilled nursing facility may not file a complaint or a report against a person who works (or has worked at the facility with the appropriate State professional disciplinary agency because the person (or anyone acting at the person's request) complained in good faith, as described in clause (i).

(iii) COMMENCEMENT OF ACTION.—Any person who believes the person has been penalized, discriminated , or retaliated against or had a contract for services terminated in violation of clause (i) or against whom a complaint has been filed in violation of clause (ii) may bring an action at law or equity in the appropriate district court of the United States, which shall have jurisdiction over such action without regard to the amount in controversy or the citizenship of the parties, and which shall have jurisdiction to grant complete relief, including, but not limited to, injunctive relief (such as reinstatement, compensatory damages (which may include reimbursement of lost wages, compensation, and benefits), costs of litigation (including reasonable attorney and expert witness fees), exemplary damages where

appropriate, and such other relief as the court deems just and proper.

(iv) RIGHTS NOT WAIVABLE.—The rights protected by this paragraph may not be diminished by contract or other agreement, and nothing in this paragraph shall be construed to diminish any greater or additional protection provided by Federal or State law or by contract or other agreement.

(v) REQUIREMENT TO POST NOTICE OF EMPLOYEE RIGHTS.—Each skilled nursing facility shall post conspicuously in an appropriate location a sign (in a form specified by the Secretary) specifying the rights of persons under this paragraph and including a statement that an employee may file a complaint with the Secretary against a skilled nursing facility that violates the provisions of this paragraph and information with respect to the manner of filing such a complaint.

(D) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed as preventing a resident of a skilled nursing facility (or a person acting on the resident's behalf) from submitting a complaint in a manner or format other than by using the standardized complaint form developed under subsection (f)(9) (including submitting a complaint orally).

(E) GOOD FAITH DEFINED.—For purposes of this paragraph, an individual shall be deemed to be acting in good faith with respect to the filing of a complaint if the individual reasonably believes—

(i) the information reported or disclosed in the complaint is true; and

(ii) the violation of this title has occurred or may occur in relation to such information.

(f) RESPONSIBILITIES OF SECRETARY RELATING TO SKILLED NURSING FACILITY REQUIREMENTS.—

(1) * * *

* * * * * * *

(2) REQUIREMENTS FOR NURSE AIDE TRAINING AND COMPETENCY EVALUATION PROGRAMS AND FOR NURSE AIDE COMPETENCY EVALUATION PROGRAMS.—

(A) IN GENERAL.—For purposes of subsections (b)(5) and (e)(1)(A), the Secretary shall establish, by not later than September 1, 1988—

(i) requirements for the approval of nurse aide training and competency evaluation programs, including requirements relating to (I) the areas to be covered in such a program (including at least basic nursing skills, personal care skills, recognition of mental health and social service needs, care of cognitively impaired residents, basic restorative services, and residents' rights) and content of the curriculum *(including, in the case of initial training and, if the Secretary determines appropriate, in the case of ongoing training, dementia management training and resident abuse prevention training)*, (II) minimum hours of initial and ongoing training and retraining (including not less than 75

hours in the case of initial training), (III) qualifications of instructors, and (IV) procedures for determination of competency;

* * * * * * *

(8) SPECIAL FOCUS FACILITY PROGRAM.—

(A) IN GENERAL.—The Secretary shall conduct a special focus facility program for enforcement of requirements for skilled nursing facilities that the Secretary has identified as having substantially failed to meet applicable requirement of this Act.

(B) PERIODIC SURVEYS.—Under such program the Secretary shall conduct surveys of each facility in the program not less than once every 6 months.

(9) STANDARDIZED COMPLAINT FORM.—The Secretary shall develop a standardized complaint form for use by a resident (or a person acting on the resident's behalf) in filing a complaint with a State survey and certification agency and a State long-term care ombudsman program with respect to a skilled nursing facility.

(g) SURVEY AND CERTIFICATION PROCESS.—

(1) * * *

* * * * * * *

(5) DISCLOSURE OF RESULTS OF INSPECTIONS AND ACTIVITIES.—

(A) * * *

* * * * * * *

(E) SUBMISSION OF SURVEY AND CERTIFICATION INFORMATION TO THE SECRETARY.—In order to improve the timeliness of information made available to the public under subparagraph (A) and provided on the Nursing Home Compare Medicare website under subsection (i), each State shall submit information respecting any survey or certification made respecting a skilled nursing facility (including any enforcement actions taken by the State) to the Secretary not later than the date on which the State sends such information to the facility. The Secretary shall use the information submitted under the preceding sentence to update the information provided on the Nursing Home Compare Medicare website as expeditiously as practicable but not less frequently than quarterly.

(h) ENFORCEMENT PROCESS.—

(1) * * *

(2) SECRETARIAL AUTHORITY.—

(A) * * *

(B) SPECIFIED REMEDIES.—The Secretary may take the following actions with respect to a finding that a facility has not met an applicable requirement:

(i) * * *

[(ii) AUTHORITY WITH RESPECT TO CIVIL MONEY PENALTIES.—The Secretary may impose a civil money penalty in an amount not to exceed $10,000 for each day of noncompliance. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a

civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).]

(ii) AUTHORITY WITH RESPECT TO CIVIL MONEY PENALTIES.—

(I) AMOUNT.—The Secretary may impose a civil money penalty in the applicable per instance or per day amount (as defined in subclause (II) and (III)) for each day or instance, respectively, of noncompliance (as determined appropriate by the Secretary).

(II) APPLICABLE PER INSTANCE AMOUNT.—In this clause, the term "applicable per instance amount" means—

(aa) in the case where the deficiency is found to be a direct proximate cause of death of a resident of the facility, an amount not to exceed $100,000;

(bb) in each case of a deficiency where the facility is cited for actual harm or immediate jeopardy, an amount not less than $3,050 and not more than $25,000; and

(cc) in each case of any other deficiency, an amount not less than $250 and not to exceed $3050.

(III) APPLICABLE PER DAY AMOUNT.—In this clause, the term "applicable per day amount" means—

(aa) in each case of a deficiency where the facility is cited for actual harm or immediate jeopardy, an amount not less than $3,050 and not more than $25,000; and

(bb) in each case of any other deficiency, an amount not less than $250 and not to exceed $3,050.

(IV) REDUCTION OF CIVIL MONEY PENALTIES IN CERTAIN CIRCUMSTANCES.—Subject to subclauses (V) and (VI), in the case where a facility self-reports and promptly corrects a deficiency for which a penalty was imposed under this clause not later than 10 calendar days after the date of such imposition, the Secretary may reduce the amount of the penalty imposed by not more than 50 percent.

(V) PROHIBITION ON REDUCTION FOR CERTAIN DEFICIENCIES.—

(aa) REPEAT DEFICIENCIES.—The Secretary may not reduce under subclause (IV) the amount of a penalty if the deficiency is a repeat deficiency.

(bb) CERTAIN OTHER DEFICIENCIES.—The Secretary may not reduce under subclause (IV) the amount of a penalty if the penalty is imposed for a deficiency described in subclause (II)(aa) or (III)(aa) and the actual harm or widespread harm immediately jeopardizes the

health or safety of a resident or residents of the facility, or if the penalty is imposed for a deficiency described in subclause (II)(bb).

(VI) LIMITATION ON AGGREGATE REDUCTIONS.—The aggregate reduction in a penalty under subclause (IV) may not exceed 35 percent on the basis of self-reporting, on the basis of a waiver or an appeal (as provided for under regulations under section 488.436 of title 42, Code of Federal Regulations), or on the basis of both.

(VII) COLLECTION OF CIVIL MONEY PENALTIES.—In the case of a civil money penalty imposed under this clause, the Secretary—

(aa) subject to item (cc), shall, not later than 30 days after the date of imposition of the penalty, provide the opportunity for the facility to participate in an independent informal dispute resolution process which generates a written record prior to the collection of such penalty, but such opportunity shall not affect the responsibility of the State survey agency for making final recommendations for such penalties;

(bb) in the case where the penalty is imposed for each day of noncompliance, shall not impose a penalty for any day during the period beginning on the initial day of the imposition of the penalty and ending on the day on which the informal dispute resolution process under item (aa) is completed;

(cc) may provide for the collection of such civil money penalty and the placement of such amounts collected in an escrow account under the direction of the Secretary on the earlier of the date on which the informal dispute resolution process under item (aa) is completed or the date that is 90 days after the date of the imposition of the penalty;

(dd) may provide that such amounts collected are kept in such account pending the resolution of any subsequent appeals;

(ee) in the case where the facility successfully appeals the penalty, may provide for the return of such amounts collected (plus interest) to the facility; and

(ff) in the case where all such appeals are unsuccessful, may provide that some portion of such amounts collected may be used to support activities that benefit residents, including assistance to support and protect residents of a facility that closes (voluntarily or involuntarily) or is decertified (including offsetting costs of relocating residents to home and community-based settings or another facility), projects that support resident and family

councils and other consumer involvement in assuring quality care in facilities, and facility improvement initiatives approved by the Secretary (including joint training of facility staff and surveyors, technical assistance for facilities under quality assurance programs, the appointment of temporary management, and other activities approved by the Secretary).

(VIII) PROCEDURE.—The provisions of section 1128A (other than subsections (a) and (b) and except to the extent that such provisions require a hearing prior to the imposition of a civil money penalty) shall apply to a civil money penalty under this clause in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

* * * * * * *

(4) IMMEDIATE TERMINATION OF PARTICIPATION FOR FACILITY WHERE SECRETARY FINDS NONCOMPLIANCE AND IMMEDIATE JEOPARDY.—If the Secretary finds that a skilled nursing facility has not met a requirement of subsection (b), (c), or (d), and finds that the failure immediately jeopardizes the health or safety of its residents, the Secretary shall take immediate action to remove the jeopardy and correct the deficiencies through the remedy specified in paragraph (2)(B)(iii), or [the Secretary shall terminate] *the Secretary, subject to subsection (c)(7), shall terminate* the facility's participation under this title. If the facility's participation under this title is terminated, the State shall provide for the safe and orderly transfer of the residents eligible under this title consistent with the requirements of [subsection (c)(2)] *paragraphs (2) and (7) of subsection (c)*.

(5) CONSTRUCTION.—The remedies provided under this subsection are in addition to those otherwise available under State or Federal law and shall not be construed as limiting such other remedies, including any remedy available to an individual at common law. The remedies described in clauses (i), *(ii),* and (iii) of paragraph (2)(B) may be imposed during the pendency of any hearing.

* * * * * * *

(i) NURSING HOME COMPARE WEBSITE.—

(1) INCLUSION OF ADDITIONAL INFORMATION.—

(A) IN GENERAL.—The Secretary shall ensure that the Department of Health and Human Services includes, as part of the information provided for comparison of nursing homes on the official Internet website of the Federal Government for Medicare beneficiaries (commonly referred to as the "Nursing Home Compare" Medicare website) (or a successor website), the following information in a manner that is prominent, easily accessible, readily understandable to consumers of long-term care services, and searchable:

(i) Information that is reported to the Secretary under section 1124(c)(4).

(ii) Information on the "Special Focus Facility program" (or a successor program) established by the Centers for Medicare and Medicaid Services, according to procedures established by the Secretary. Such procedures shall provide for the inclusion of information with respect to, and the names and locations of, those facilities that, since the previous quarter—

(I) were newly enrolled in the program;

(II) are enrolled in the program and have failed to significantly improve;

(III) are enrolled in the program and have significantly improved;

(IV) have graduated from the program; and

(V) have closed voluntarily or no longer participate under this title.

(iii) Staffing data for each facility (including resident census data and data on the hours of care provided per resident per day) based on data submitted under subsection (b)(8)(C), including information on staffing turnover and tenure, in a format that is clearly understandable to consumers of long-term care services and allows such consumers to compare differences in staffing between facilities and State and national averages for the facilities. Such format shall include—

(I) concise explanations of how to interpret the data (such as a plain English explanation of data reflecting "nursing home staff hours per resident day");

(II) differences in types of staff (such as training associated with different categories of staff);

(III) the relationship between nurse staffing levels and quality of care; and

(IV) an explanation that appropriate staffing levels vary based on patient case mix.

(iv) Links to State Internet websites with information regarding State survey and certification programs, links to Form 2567 State inspection reports (or a successor form) on such websites, information to guide consumers in how to interpret and understand such reports, and the facility plan of correction or other response to such report.

(v) The standardized complaint form developed under subsection (f)(8), including explanatory material on what complaint forms are, how they are used, and how to file a complaint with the State survey and certification program and the State long-term care ombudsman program.

(vi) Summary information on the number, type, severity, and outcome of substantiated complaints.

(vii) The number of adjudicated instances of criminal violations by employees of a a nursing facility—

(I) that were committed inside the facility;

(II) with respect to such instances of violations or crimes committed inside of the facility that were the violations or crimes of abuse, neglect, and ex-

ploitation, criminal sexual abuse, or other violations or crimes that resulted in serious bodily injury; and

(III) the number of civil monetary penalties levied against the facility, employees, contractors, and other agents.

(B) DEADLINE FOR PROVISION OF INFORMATION.—

(i) IN GENERAL.—Except as provided in clause (ii), the Secretary shall ensure that the information described in subparagraph (A) is included on such website (or a successor website) not later than 1 year after the date of the enactment of this subsection.

(ii) EXCEPTION.—The Secretary shall ensure that the information described in subparagraph (A)(i) and (A)(iii) is included on such website (or a successor website) not later than the date on which the requirements under section 1124(c)(4) and subsection (b)(8)(C)(ii) are implemented.

(2) REVIEW AND MODIFICATION OF WEBSITE.—

(A) IN GENERAL.—The Secretary shall establish a process—

(i) to review the accuracy, clarity of presentation, timeliness, and comprehensiveness of information reported on such website as of the day before the date of the enactment of this subsection; and

(ii) not later than 1 year after the date of the enactment of this subsection, to modify or revamp such website in accordance with the review conducted under clause (i).

(B) CONSULTATION.—In conducting the review under subparagraph (A)(i), the Secretary shall consult with—

(i) State long-term care ombudsman programs;

(ii) consumer advocacy groups;

(iii) provider stakeholder groups; and

(iv) any other representatives of programs or groups the Secretary determines appropriate.

[(i)**]** *(j)* CONSTRUCTION.—Where requirements or obligations under this section are identical to those provided under section 1919 of this Act, the fulfillment of those requirements or obligations under section 1919 shall be considered to be the fulfillment of the corresponding requirements or obligations under this section.

SEC. 1819A. ASSURING QUALITY OF CARE IN HOSPICE CARE.

(a) IN GENERAL.—If the Secretary determines on the basis of a survey or otherwise, that a hospice program that is certified for participation under this title has demonstrated a substandard quality of care and failed to meet such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are provided care and services by the agency or organization involved and determines—

(1) that the deficiencies involved immediately jeopardize the health and safety of the individuals to whom the program furnishes items and services, the Secretary shall take immediate action to remove the jeopardy and correct the deficiencies through the remedy specified in subsection (b)(2)(A)(iii) or terminate the certification of the program, and may provide, in

addition, for 1 or more of the other remedies described in subsection (b)(2)(A); or

(2) that the deficiencies involved do not immediately jeopardize the health and safety of the individuals to whom the program furnishes items and services, the Secretary may—

(A) impose intermediate sanctions developed pursuant to subsection (b), in lieu of terminating the certification of the program; and

(B) if, after such a period of intermediate sanctions, the program is still not in compliance with such requirements, the Secretary shall terminate the certification of the program.

If the Secretary determines that a hospice program that is certified for participation under this title is in compliance with such requirements but, as of a previous period, was not in compliance with such requirements, the Secretary may provide for a civil money penalty under subsection (b)(2)(A)(i) for the days in which it finds that the program was not in compliance with such requirements.

(b) INTERMEDIATE SANCTIONS.—

(1) DEVELOPMENT AND IMPLEMENTATION.—The Secretary shall develop and implement, by not later than July 1, 2012—

(A) a range of intermediate sanctions to apply to hospice programs under the conditions described in subsection (a), and

(B) appropriate procedures for appealing determinations relating to the imposition of such sanctions.

(2) SPECIFIED SANCTIONS.—

(A) IN GENERAL.—The intermediate sanctions developed under paragraph (1) may include—

(i) civil money penalties in an amount not to exceed $10,000 for each day of noncompliance or, in the case of a per instance penalty applied by the Secretary, not to exceed $25,000,

(ii) denial of all or part of the payments to which a hospice program would otherwise be entitled under this title with respect to items and services furnished by a hospice program on or after the date on which the Secretary determines that intermediate sanctions should be imposed pursuant to subsection (a)(2),

(iii) the appointment of temporary management to oversee the operation of the hospice program and to protect and assure the health and safety of the individuals under the care of the program while improvements are made,

(iv) corrective action plans, and

(v) in-service training for staff.

The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under clause (i) in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a). The temporary management under clause (iii) shall not be terminated until the Secretary has determined that the program has the management capability to ensure continued compliance with all requirements referred to in that clause.

(B) CLARIFICATION.—The sanctions specified in subparagraph (A) are in addition to sanctions otherwise available under State or Federal law and shall not be construed as limiting other remedies, including any remedy available to an individual at common law.

(C) COMMENCEMENT OF PAYMENT.—A denial of payment under subparagraph (A)(ii) shall terminate when the Secretary determines that the hospice program no longer demonstrates a substandard quality of care and meets such other requirements as the Secretary may find necessary in the interest of the health and safety of the individuals who are provided care and services by the agency or organization involved.

(3) SECRETARIAL AUTHORITY.—The Secretary shall develop and implement, by not later than July 1, 2011, specific procedures with respect to the conditions under which each of the intermediate sanctions developed under paragraph (1) is to be applied, including the amount of any fines and the severity of each of these sanctions. Such procedures shall be designed so as to minimize the time between identification of deficiencies and imposition of these sanctions and shall provide for the imposition of incrementally more severe fines for repeated or uncorrected deficiencies.

* * * * * * *

PART B—SUPPLEMENTARY MEDICAL INSURANCE BENEFITS FOR THE AGED AND DISABLED

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SCOPE OF BENEFITS

SEC. 1832. (a) The benefits provided to an individual by the insurance program established by this part shall consist of—

(1) * * *

(2) entitlement to have payment made on his behalf (subject to the provisions of this part) for—

(A) * * *

(B) medical and other health services (other than items described in subparagraph (G) or subparagraph (I)) furnished by a provider of services or by others under arrangement with them made by a provider of services, excluding—

(i) * * *

* * * * * * *

(iv) services of a nurse practitioner or clinical nurse specialist but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services; [and]

(v) marriage and family therapist services; and

(vi) mental health counselor services;

* * * * * * *

PAYMENT OF BENEFITS

SEC. 1833. (a) Except as provided in section 1876, and subject to the succeeding provisions of this section, there shall be paid from the Federal Supplementary Medical Insurance Trust Fund, in the case of each individual who is covered under the insurance program established by this part and incurs expenses for services with respect to which benefits are payable under this part, amounts equal to—

(1) in the case of services described in section 1832(a)(1)—80 percent of the reasonable charges for the services; except that (A) an organization which provides medical and other health services (or arranges for their availability) on a prepayment basis (and either is sponsored by a union or employer, or does not provide, or arrange for the provision of, any inpatient hospital services) may elect to be paid 80 percent of the reasonable cost of services for which payment may be made under this part on behalf of individuals enrolled in such organization in lieu of 80 percent of the reasonable charges for such services if the organization undertakes to charge such individuals no more than 20 percent of such reasonable cost plus any amounts payable by them as a result of subsection (b), (B) with respect to items and services described in section [1861(s)(10)(A)] *1861(s)(10)*, the amounts paid shall be 100 percent of the reasonable charges for such items and services, (C) with respect to expenses incurred for those physicians' services for which payment may be made under this part that are described in section 1862(a)(4), the amounts paid shall be subject to such limitations as may be prescribed by regulations, (D) with respect to clinical diagnostic laboratory tests for which payment is made under this part (i) on the basis of a fee schedule under subsection (h)(1) or section 1834(d)(1), the amount paid shall be equal to 80 percent (or 100 percent, in the case of such tests for which payment is made on an assignment-related basis) of the lesser of the amount determined under such fee schedule, the limitation amount for that test determined under subsection (h)(4)(B), or the amount of the charges billed for the tests, or (ii) on the basis of a negotiated rate established under subsection (h)(6), the amount paid shall be equal to 100 percent of such negotiated rate,, (E) with respect to services furnished to individuals who have been determined to have end stage renal disease, the amounts paid shall be determined subject to the provisions of section 1881, (F) with respect to clinical social worker services under section 1861(s)(2)(N), the amounts paid shall be 80 percent of the lesser of (i) the actual charge for the services or (ii) 75 percent of the amount determined for payment of a psychologist under clause (L),

(G) * * *

(H) with respect to services of a certified registered nurse anesthetist under section 1861(s)(11), the amounts paid shall be 80 percent of the least of the actual charge, the prevailing charge that would be recognized (or, for services furnished on or after January 1, 1992, the fee schedule amount provided under section 1848) if the services had been performed by an

anesthesiologist, or the fee schedule for such services established by the Secretary in accordance with subsection (l), (I) with respect to covered items (described in section 1834(a)(13)), the amounts paid shall be the amounts described in section 1834(a)(1), and (J) with respect to expenses incurred for radiologist services (as defined in section 1834(b)(6)), subject to section 1848, the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount provided under the fee schedule established under section 1834(b), (K) with respect to certified nurse-midwife services under section 1861(s)(2)(L), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph **[**(but in no event shall such fee schedule exceed 65 percent of the prevailing charge that would be allowed for the same service performed by a physician, or, for services furnished on or after January 1, 1992, 65 percent of the fee schedule amount provided under section 1848 for the same service performed by a physician)**]**, (L) with respect to qualified psychologist services under section 1861(s)(2)(M), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary for the purposes of this subparagraph, (M) with respect to prosthetic devices and orthotics and prosthetics (as defined in section 1834(h)(4)), the amounts paid shall be the amounts described in section 1834(h)(1), (N) with respect to expenses incurred for physicians' services (as defined in section 1848(j)(3)), the amounts paid shall be 80 percent of the payment basis determined under section 1848(a)(1), (O) with respect to services described in section 1861(s)(2)(K) (relating to services furnished by physician assistants, nurse practitioners, or clinic nurse specialists), the amounts paid shall be equal to 80 percent of (i) the lesser of the actual charge or 85 percent of the fee schedule amount provided under section 1848, or (ii) in the case of services as an assistant at surgery, the lesser of the actual charge or 85 percent of the amount that would otherwise be recognized if performed by a physician who is serving as an assistant at surgery, (P) with respect to surgical dressings, the amounts paid shall be the amounts determined under section 1834(i), (Q) with respect to items or services for which fee schedules are established pursuant to section 1842(s), the amounts paid shall be 80 percent of the lesser of the actual charge or the fee schedule established in such section, (R) with respect to ambulance services, (i) the amounts paid shall be 80 percent of the lesser of the actual charge for the services or the amount determined by a fee schedule established by the Secretary under section 1834(l) and (ii) with respect to ambulance services described in section 1834(l)(8), the amounts paid shall be the amounts determined under section 1834(g) for outpatient critical access hospital services, (S) with respect to drugs and biologicals (including intravenous immune globulin (as defined in section 1861(zz))) not paid on a cost or prospective payment basis as otherwise provided in this part (other than items and services described in subparagraph (B)), the amounts paid

shall be 80 percent of the lesser of the actual charge or the payment amount established in section 1842(o) (or, if applicable, under section 1847, 1847A, or 1847B), (T) with respect to medical nutrition therapy services (as defined in section 1861(vv)), the amount paid shall be 80 percent of the lesser of the actual charge for the services or 85 percent of the amount determined under the fee schedule established under section 1848(b) for the same services if furnished by a physician, (U) with respect to facility fees described in section 1834(m)(2)(B), the amounts paid shall be 80 percent of the lesser of the actual charge or the amounts specified in such section, (V) notwithstanding subparagraphs (I) (relating to durable medical equipment), (M) (relating to prosthetic devices and orthotics and prosthetics), and (Q) (relating to 1842(s) items), with respect to competitively priced items and services (described in section 1847(a)(2)) that are furnished in a competitive area, the amounts paid shall be the amounts described in section 1847(b)(5), ⟦and⟧ (W) with respect to additional preventive services (as defined in section 1861(ddd)(1)), the amount paid shall be (i) in the case of such services which are clinical diagnostic laboratory tests, the amount determined under subparagraph (D), and (ii) in the case of all other such services, 80 percent of the lesser of the actual charge for the service or the amount determined under a fee schedule established by the Secretary for purposes of this subparagraph*, (X) with respect to marriage and family therapist services under section 1861(s)(2)(GG), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or 75 percent of the amount determined for payment of a psychologist under clause (L), (Y) with respect to mental health counselor services under section 1861(s)(2)(HH), the amounts paid shall be 80 percent of the lesser of the actual charge for the services or 75 percent of the amount determined for payment of a psychologist under clause (L), and (Z) with respect to services described in section 1861(s)(2)(II) (relating to services furnished by a respiratory therapist) that are furnished by a respiratory therapist (as defined in section 1861(mmm)), the amount paid shall be equal to 80 percent of the lesser of the actual charge for the services or 85 percent of the fee schedule amount provided under section 1848 for the same services if furnished by a physician*;

(2) in the case of services described in section 1832(a)(2) (except those services described in subparagraphs (C), (D), (E), (F), (G), (H), and (I) of such section and unless otherwise specified in section 1881)—

(A) * * *

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(F) with respect to a covered osteoporosis drug (as defined in section 1861(kk)) furnished by a home health agency, 80 percent of the reasonable cost of such service, as determined under section 1861(v); ⟦and⟧

(G) with respect to items and services described in section ⟦1861(s)(10)(A)⟧ *1861(s)(10)*, the lesser of—

(i) * * *

* * * * * * *

or, if such services are furnished by a public provider of services, or by another provider which demonstrates to the satisfaction of the Secretary that a significant portion of its patients are low-income (and requests that payment be made under this provision), free of charge or at nominal charges to the public, the amount determined in accordance with section 1814(b)(2); *and*

(H) with respect to additional preventive services (as defined in section 1861(ddd)) furnished by an outpatient department of a hospital, the amount determined under paragraph (1)(W);

(3) in the case of services described in section 1832(a)(2)(D)—

(A) except as provided in subparagraph (B), the costs which are reasonable and related to the cost of furnishing such services or which are based on such other tests of reasonableness as the Secretary may prescribe in regulations, including those authorized under section 1861(v)(1)(A), less the amount a provider may charge as described in clause (ii) of section 1866(a)(2)(A), but in no case may the payment for such services (other than for items and services described in section ⟦1861(s)(10)(A)⟧ *1861(s)(10)*) exceed 80 percent of such costs; or

* * * * * * *

With respect to Medicare covered preventive services, in any case in which the payment rate otherwise provided under this part is computed as a percent of less than 100 percent of an actual charge, fee schedule rate, or other rate, such percentage shall be increased to 100 percent.

(b) Before applying subsection (a) with respect to expenses incurred by an individual during any calendar year, the total amount of the expenses incurred by such individual during such year (which would, except for this subsection, constitute incurred expenses from which benefits payable under subsection (a) are determinable) shall be reduced by a deductible of $75 for calendar years before 1991, $100 for 1991 through 2004, $110 for 2005, and for a subsequent year the amount of such deductible for the previous year increased by the annual percentage increase in the monthly actuarial rate under section 1839(a)(1) ending with such subsequent year (rounded to the nearest $1); except that (1) such total amount shall not include expenses incurred for ⟦items and services described in section 1861(s)(10)(A)⟧ *Medicare covered preventive services (as defined in section 1861(iii))*, (2) such deductible shall not apply with respect to home health services (other than a covered osteoporosis drug (as defined in section 1861(kk))), (3) such deductible shall not apply with respect to clinical diagnostic laboratory tests for which payment is made under this part (A) under subsection (a)(1)(D)(i) or (a)(2)(D)(i) on an assignment-related basis, or to a provider having an agreement under section 1866, or (B) on the basis of a negotiated rate determined under subsection (h)(6), (4) such deductible shall not apply to Federally qualified health center services, ⟦(5) such deductible shall not apply with respect to screening mammography (as described in section 1861(jj)), (6) such deductible shall not apply with respect to screening pap smear and screening pelvic exam (as described in section 1861(nn)), (7) such deductible shall not apply with respect to ultrasound screening for

abdominal aortic aneurysm (as defined in section 1861(bbb)), (8) such deductible shall not apply with respect to colorectal cancer screening tests (as described in section 1861(pp)(1)), and (9)] *and (5)* such deductible shall not apply with respect to an initial preventive physical examination (as defined in section 1861(ww)). The total amount of the expenses incurred by an individual as determined under the preceding sentence shall, after the reduction specified in such sentence, be further reduced by an amount equal to the expenses incurred for the first three pints of whole blood (or equivalent quantities of packed red blood cells, as defined under regulations) furnished to the individual during the calendar year, except that such deductible for such blood shall in accordance with regulations be appropriately reduced to the extent that there has been a replacement of such blood (or equivalent quantities of packed red blood cells, as so defined); and for such purposes blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual shall be deemed replaced when the institution or other person furnishing such blood (or such equivalent quantities of packed red blood cells, as so defined) is given one pint of blood for each pint of blood (or equivalent quantities of packed red blood cells, as so defined) furnished such individual with respect to which a deduction is made under this sentence. The deductible under the previous sentence for blood or blood cells furnished an individual in a year shall be reduced to the extent that a deductible has been imposed under section 1813(a)(2) to blood or blood cells furnished the individual in the year. *Clause (1) of the first sentence of this subsection shall apply with respect to a colorectal cancer screening test regardless of the code that is billed for the establishment of a diagnosis as a result of the test, or for the removal of tissue or other matter or other procedure that is furnished in connection with, as a result of, and in the same clinical encounter as, the screening test.*

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(g)(1) * * *

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(5) With respect to expenses incurred during the period beginning on January 1, 2006, and ending on [December 31, 2009] *December 31, 2011*, for services, the Secretary shall implement a process under which an individual enrolled under this part may, upon request of the individual or a person on behalf of the individual, obtain an exception from the uniform dollar limitation specified in paragraph (2), for services described in paragraphs (1) and (3) if the provision of such services is determined to be medically necessary. Under such process, if the Secretary does not make a decision on such a request for an exception within 10 business days of the date of the Secretary's receipt of the request, the Secretary shall be deemed to have found the services to be medically necessary.

(h)(1) * * *

(2)(A)(i) Except as provided in paragraph (4), the Secretary shall set the fee schedules at 60 percent (or, in the case of a test performed by a qualified hospital laboratory (as defined in paragraph (1)(D)) for outpatients of such hospital, 62 percent) of the prevailing charge level determined pursuant to the third and fourth sentences

of section 1842(b)(3) for similar clinical diagnostic laboratory tests for the applicable region, State, or area for the 12-month period beginning July 1, 1984, adjusted annually (to become effective on January 1 of each year) by a percentage increase or decrease equal to the percentage increase or decrease in the Consumer Price Index for All Urban Consumers (United States city average) minus, **[**for each of the years 2009 through 2013**]** *for 2009*, 0.5 percentage points, and subject to such other adjustments as the Secretary determines are justified by technological changes.

(ii) Notwithstanding clause (i)—

(I) * * *

* * * * * * *

(III) the annual adjustment in the fee schedules determined under clause (i) for each of the years 1991, 1992, and 1993 shall be 2 percent, **[**and**]**

(IV) the annual adjustment in the fee schedules determined under clause (i) for each of the years 1994 and 1995, 1998 through 2002, and 2004 through 2008 shall be 0 percent**[**.**]***; and*

(V) the annual adjustment in the fee schedules determined under clause (i) for years beginning with 2010 shall be subject to the productivity adjustment described in section 1886(b)(3)(B)(iii)(II).

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(i)(1) * * *

(2)(A) * * *

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(D)(i) * * *

* * * * * * *

(v) In implementing the system described in clause (i), for services furnished during 2010 or any subsequent year, to the extent that an annual percentage change factor applies, such factor shall be subject to the productivity adjustment described in section 1886(b)(3)(B)(iii)(II).

[(v)**]** *(vi)* There shall be no administrative or judicial review under section 1869, 1878, or otherwise, of the classification system, the relative weights, payment amounts, and the geographic adjustment factor, if any, under this subparagraph.

* * * * * * *

(7)(A) * * *

(B) Except as the Secretary may otherwise provide, *subject to subparagraph (C),* the provisions of subparagraphs (B), (C), (D), and (E) of paragraph (17) of section 1833(t) shall apply with respect to services of ambulatory surgical centers under this paragraph in a similar manner to the manner in which they apply under such paragraph and, for purposes of this subparagraph, any reference to a hospital, outpatient setting, or outpatient hospital services is deemed a reference to an ambulatory surgical center, the setting of such a center, or services of such a center, respectively.

(C) Under subparagraph (B) the Secretary shall require the reporting of such additional data relating to quality of services fur-

nished in an ambulatory surgical facility, including data on health care associated infections, as the Secretary may specify.

(8) The Secretary shall require, as a condition of the agreement described in section 1832(a)(2)(F)(i), the submission of such cost report as the Secretary may specify, taking into account the requirements for such reports under section 1815 in the case of a hospital.

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(m)(1) * * *

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(4) The provisions of this subsection shall not be taken into account in applying subsections (m) or (u) and any payment under such subsections shall not be taken into account in computing payments under this subsection.

[(4)**]** *(5)* There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, respecting—

(A) * * *

* * * * * * *

(p) PRIMARY CARE PAYMENT INCENTIVES.—

(1) IN GENERAL.—In the case of primary care services (as defined in paragraph (2)) furnished on or after January 1, 2011, by a primary care practitioner (as defined in paragraph (3)) for which amounts are payable under section 1848, in addition to the amount otherwise paid under this part there shall also be paid to the practitioner (or to an employer or facility in the cases described in clause (A) of section 1842(b)(6)) (on a monthly or quarterly basis) from the Federal Supplementary Medical Insurance Trust Fund an amount equal 5 percent (or 10 percent if the practitioner predominately furnishes such services in an area that is designated (under section 332(a)(1)(A) of the Public Health Service Act) as a primary care health professional shortage area.

(2) PRIMARY CARE SERVICES DEFINED.—In this subsection, the term "primary care services"—

(A) means services which are evaluation and management services as defined in section 1848(j)(5)(A); and

(B) includes services furnished by another health care professional that would be described in subparagraph (A) if furnished by a physician.

(3) PRIMARY CARE PRACTITIONER DEFINED.—In this subsection, the term "primary care practitioner"—

(A) means a physician or other health care practitioner (including a nurse practitioner) who—

(i) specializes in family medicine, general internal medicine, general pediatrics, geriatrics, or obstetrics and gynecology; and

(ii) has allowed charges for primary care services that account for at least 50 percent of the physician's or practitioner's total allowed charges under section 1848, as determined by the Secretary for the most recent period for which data are available; and

(B) includes a physician assistant who is under the supervision of a physician described in subparagraph (A).

(4) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, respecting—

(A) any determination or designation under this subsection;

(B) the identification of services as primary care services under this subsection; and

(C) the identification of a practitioner as a primary care practitioner under this subsection.

(5) COORDINATION WITH OTHER PAYMENTS.—

(A) WITH OTHER PRIMARY CARE INCENTIVES.—The provisions of this subsection shall not be taken into account in applying subsections (m) and (u) and any payment under such subsections shall not be taken into account in computing payments under this subsection.

(B) WITH QUALITY INCENTIVES.—Payments under this subsection shall not be taken into account in determining the amounts that would otherwise be paid under this part for purposes of section 1834(g)(2)(B).

* * * * * * *

(t) PROSPECTIVE PAYMENT SYSTEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES.—

(1) AMOUNT OF PAYMENT.—

(A) * * *

(B) DEFINITION OF COVERED OPD SERVICES.—For purposes of this subsection, the term "covered OPD services"—

(i) * * *

* * * * * * *

(iv) does not include any therapy services described in subsection (a)(8) or ambulance services, for which payment is made under a fee schedule described in section 1834(k) or section 1834(l) and does not include ⟦screening mammography (as defined in section 1861(jj)) and diagnostic mammography⟧ *diagnostic mammograms and Medicare covered preventive services (as defined in section 1861(iii)(1))*.

* * * * * * *

(3) CALCULATION OF BASE AMOUNTS.—

(A) * * *

* * * * * * *

(C) CALCULATION OF CONVERSION FACTORS.—

(i) * * *

* * * * * * *

(iv) OPD FEE SCHEDULE INCREASE FACTOR.—For purposes of this subparagraph, subject to paragraph (17), the "OPD fee schedule increase factor" for services furnished in a year is equal to the market basket percentage increase applicable under section 1886(b)(3)(B)(iii) *(which is subject to the productivity adjustment described in subclause (II) of such section)* to hospital discharges occurring during the fiscal year

ending in such year, reduced *(but not below 0)* by 1 percentage point for such factor for services furnished in each of 2000 and 2002. In applying the previous sentence for years beginning with 2000, the Secretary may substitute for the market basket percentage increase an annual percentage increase that is computed and applied with respect to covered OPD services furnished in a year in the same manner as the market basket percentage increase is determined and applied to inpatient hospital services for discharges occurring in a fiscal year.

* * * * * * *

(7) TRANSITIONAL ADJUSTMENT TO LIMIT DECLINE IN PAYMENT.—

(A) * * *

* * * * * * *

(D) HOLD HARMLESS PROVISIONS.—

(i) TEMPORARY TREATMENT FOR CERTAIN RURAL HOSPITALS.—(I) * * *

(II) In the case of a hospital located in a rural area and that has not more than 100 beds and that is not a sole community hospital (as defined in section 1886(d)(5)(D)(iii)), for covered OPD services furnished on or after January 1, 2006, and before January 1, ⟦2010⟧ *2012*, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by the applicable percentage of the amount of such difference. For purposes of the preceding sentence, the applicable percentage shall be 95 percent with respect to covered OPD services furnished in 2006, 90 percent with respect to such services furnished in 2007, and 85 percent with respect to such services furnished in 2008 ⟦or 2009⟧*, 2009, 2010, or 2011*.

(III) In the case of a sole community hospital (as defined in section 1886(d)(5)(D)(iii)) that has not more than 100 beds, for covered OPD services furnished on or after January 1, 2009, and before ⟦January 1, 2010⟧ *January 1, 2012*, for which the PPS amount is less than the pre-BBA amount, the amount of payment under this subsection shall be increased by 85 percent of the amount of such difference.

* * * * * * *

(16) MISCELLANEOUS PROVISIONS.—

(A) * * *

* * * * * * *

(C) PAYMENT FOR DEVICES OF BRACHYTHERAPY AND THERAPEUTIC RADIOPHARMACEUTICALS AT CHARGES ADJUSTED TO COST.—Notwithstanding the preceding provisions of this subsection, for a device of brachytherapy consisting of a seed or seeds (or radioactive source) furnished on or after January 1, 2004, and before ⟦January 1, 2010⟧ *January 1, 2012*, and for therapeutic radiopharmaceuticals

furnished on or after January 1, 2008, and before January 1, 2010, the payment basis for the device or therapeutic radiopharmaceutical under this subsection shall be equal to the hospital's charges for each device or therapeutic radiopharmaceutical furnished, adjusted to cost. Charges for such devices or therapeutic radiopharmaceuticals shall not be included in determining any outlier payment under this subsection.

(17) QUALITY REPORTING.—

(A) * * *

* * * * * * *

(F) USE OF ENDORSED QUALITY MEASURES.—The provisions of clause (x) of section 1886(b)(3)(C) shall apply to quality measures for covered OPD services under this paragraph in the same manner as such provisions apply to quality measures for inpatient hospital services.

(18) AUTHORIZATION OF ADJUSTMENT FOR CANCER HOSPITALS.—

(A) STUDY.—The Secretary shall conduct a study to determine if, under the system under this subsection, costs incurred by hospitals described in section 1886(d)(1)(B)(v) with respect to ambulatory payment classification groups exceed those costs incurred by other hospitals furnishing services under this subsection (as determined appropriate by the Secretary).

(B) AUTHORIZATION OF ADJUSTMENT.—Insofar as the Secretary determines under subparagraph (A) that costs incurred by hospitals described in section 1886(d)(1)(B)(v) exceed those costs incurred by other hospitals furnishing services under this subsection, the Secretary shall provide for an appropriate adjustment under paragraph (2)(E) to reflect those higher costs effective for services furnished on or after January 1, 2011.

* * * * * * *

(x) INCENTIVE PAYMENTS FOR EFFICIENT AREAS.—

(1) IN GENERAL.—In the case of services furnished under the physician fee schedule under section 1848 on or after January 1, 2011, and before January 1, 2013, by a supplier that is paid under such fee schedule in an efficient area (as identified under paragraph (2)), in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid (on a monthly or quarterly basis) an amount equal to 5 percent of the payment amount for the services under this part.

(2) IDENTIFICATION OF EFFICIENT AREAS.—

(A) IN GENERAL.—Based upon available data, the Secretary shall identify those counties or equivalent areas in the United States in the lowest fifth percentile of utilization based on per capita spending under this part and part A for services provided in the most recent year for which data are available as of the date of the enactment of this subsection, as standardized to eliminate the effect of geographic adjustments in payment rates.

(B) IDENTIFICATION OF COUNTIES WHERE SERVICE IS FURNISHED.—For purposes of paying the additional amount specified in paragraph (1), if the Secretary uses the 5-digit postal ZIP Code where the service is furnished, the dominant county of the postal ZIP Code (as determined by the United States Postal Service, or otherwise) shall be used to determine whether the postal ZIP Code is in a county described in subparagraph (A).

(C) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, respecting—

(i) the identification of a county or other area under subparagraph (A); or

(ii) the assignment of a postal ZIP Code to a county or other area under subparagraph (B).

(D) PUBLICATION OF LIST OF COUNTIES; POSTING ON WEBSITE.—With respect to a year for which a county or area is identified under this paragraph, the Secretary shall identify such counties or areas as part of the proposed and final rule to implement the physician fee schedule under section 1848 for the applicable year. The Secretary shall post the list of counties identified under this paragraph on the Internet website of the Centers for Medicare & Medicaid Services.

SPECIAL PAYMENT RULES FOR PARTICULAR ITEMS AND SERVICES

SEC. 1834. (a) PAYMENT FOR DURABLE MEDICAL EQUIPMENT.—

(1) * * *

* * * * * * *

(5) PAYMENT FOR OXYGEN AND OXYGEN EQUIPMENT.—

(A) * * *

* * * * * * *

(F) RENTAL CAP.—

(i) * * *

(ii) PAYMENTS AND RULES AFTER RENTAL CAP.—[After the] *Except as provided in clause (iii), after the* 36th continuous month during which payment is made for the equipment under this paragraph—

(I) * * *

* * * * * * *

(iii) CONTINUATION OF SUPPLY.—In the case of a supplier furnishing such equipment to an individual under this subsection as of the 27th month of the 36 months described in clause (i), the supplier furnishing such equipment as of such month shall continue to furnish such equipment to such individual (either directly or though arrangements with other suppliers of such equipment) during any subsequent period of medical need for the remainder of the reasonable useful lifetime of the equipment, as determined by the Secretary, regardless of the location of the individual, unless another supplier has accepted responsibility for con-

tinuing to furnish such equipment during the remainder of such period.

(iv) EXCEPTION FOR BANKRUPTCY.—If a supplier of oxygen to an individual is declared bankrupt and its assets are liquidated and at the time of such declaration and liquidation more than 24 months of rental payments have been made, the individual may begin under this subparagraph a new 36-month rental period with another supplier of oxygen.

* * * * * * *

(7) PAYMENT FOR OTHER ITEMS OF DURABLE MEDICAL EQUIPMENT.—

(A) PAYMENT.—In the case of an item of durable medical equipment not described in paragraphs (2) through (6), the following rules shall apply:

(i) * * *

(ii) OWNERSHIP AFTER [RENTAL.—On] *RENTAL.—*

(I) IN GENERAL.—Except as provided in subclause (II), on the first day that begins after the 13th continuous month during which payment is made for the rental of an item under clause (i), the supplier of the item shall transfer title to the item to the individual.

(II) OPTION TO ACCEPT OR REJECT TRANSFER OF TITLE TO GROUP 3 SUPPORT SURFACE.—

(aa) IN GENERAL.—During the 10th continuous month during which payment is made for the rental of a Group 3 Support Surface under clause (i), the supplier of such item shall offer the individual the option to accept or reject transfer of title to a Group 3 Support Surface after the 13th continuous month during which payment is made for the rental of the Group 3 Support Surface under clause (i). Such title shall be transferred to the individual only if the individual notifies the supplier not later than 1 month after the supplier makes such offer that the individual agrees to accept transfer of the title to the Group 3 Support Surface. Unless the individual accepts transfer of title to the Group 3 Support Surface in the manner set forth in this subclause, the individual shall be deemed to have rejected transfer of title. If the individual agrees to accept the transfer of the title to the Group 3 Support Surface, the supplier shall transfer such title to the individual on the first day that begins after the 13th continuous month during which payment is made for the rental of the Group 3 Support Surface under clause (i). If the supplier transfers title to the Group 3 Support Surface under this subclause, payments for maintenance and servicing after the transfer of title shall be made in accordance with clause (iv). If the individual rejects trans-

fer of title under this subclause, payments for maintenance and servicing after the end of the period of medical need during which payment is made under clause (i) shall be made in accordance with clause (v).

(bb) SPECIAL RULE.—If, on the effective date of this subclause, an individual's rental period for a Group 3 Support Surface has exceeded 10 continuous months, but the first day that begins after the 13th continuous month during which payment is made for the rental under clause (i) has not been reached, the supplier shall, within 1 month following such effective date, offer the individual the option to accept or reject transfer of title to a Group 3 Support Surface. Such title shall be transferred to the individual only if the individual notifies the supplier not later than 1 month after the supplier makes such offer that the individual agrees to accept transfer of title to the Group 3 Support Surface. Unless the individual accepts transfer of title to the Group 3 Support Surface in the manner set forth in this subclause, the individual shall be deemed to have rejected transfer of title. If the individual agrees to accept the transfer of the title to the Group 3 Support Surface, the supplier shall transfer such title to the individual on the first day that begins after the 13th continuous month during which payment is made for the rental of the Group 3 Support Surface under clause (i) unless that day has passed, in which case the supplier shall transfer such title to the individual not later than 1 month after notification that the individual accepts transfer of title. If the supplier transfers title to the Group 3 Support Surface under this subclause, payments for maintenance and servicing after the transfer of title shall be made in accordance with clause (iv). If the individual rejects transfer of title under this subclause, payments for maintenance and servicing after the end of the period of medical need during which payment is made under clause (i) shall be made in accordance with clause (v).

(iii) PURCHASE AGREEMENT OPTION FOR *CERTAIN COMPLEX REHABILITATIVE* POWER-DRIVEN WHEELCHAIRS.—In the case of a [power-driven wheelchair] *complex rehabilitative power-driven wheelchair recognized by the Secretary as classified within group 3 or higher*, at the time the supplier furnishes the item, the supplier shall offer the individual the option to purchase the item, and payment for such item shall be

made on a lump-sum basis if the individual exercises such option.

(iv) MAINTENANCE AND SERVICING *AFTER TRANSFER OF TITLE*.—After the supplier transfers title to the item under clause (ii) or in the case of a power-driven wheelchair for which a purchase agreement has been entered into under clause (iii), maintenance and servicing payments shall, if the Secretary determines such payments are reasonable and necessary, be made (for parts and labor not covered by the supplier's or manufacturer's warranty, as determined by the Secretary to be appropriate for the particular type of durable medical equipment), and such payments shall be in an amount determined to be appropriate by the Secretary.

(v) MAINTENANCE AND SERVICING OF GROUP 3 SUPPORT SURFACE IF INDIVIDUAL REJECTS TRANSFER OF TITLE.—In the case of a Group 3 Support Surface for which the individual has rejected transfer of title under subclause (ii)(II)—

(I) during the first 6-month period of medical need that follows the period of medical need during which payment is made under clause (i), no payment shall be made for rental or maintenance and servicing of the Group 3 Support Surface; and

(II) during the first month of each succeeding 6-month period of medical need, a maintenance and servicing payment may be made (for parts and labor not covered by the supplier's or manufacturer's warranty, as determined by the Secretary to be appropriate for the Group 3 Support Surface) and the amount recognized for each such 6-month period is the lower of—

(aa) a reasonable and necessary maintenance and servicing fee or fees established by the Secretary; or

(bb) 10 percent of the total of the purchase price recognized under paragraph (8) with respect to the Group 3 Support Surface.

* * * * * * *

(11) IMPROPER BILLING AND REQUIREMENT OF PHYSICIAN ORDER.—

(A) * * *

(B) REQUIREMENT OF PHYSICIAN ORDER.—The Secretary is authorized to require, for specified covered items, that payment may be made under this subsection with respect to the item only if a [physician] *physician enrolled under section 1866(j) or an eligible professional under section 1848(k)(3)(B)* has communicated to the supplier, before delivery of the item, a written order for the item *and shall require that such an order be written pursuant to the physician documenting that the physician has had a face-to-face encounter (including through use of telehealth and other than with respect to encounters that are incident to services involved) with the individual involved during the 6-month*

period preceding such written order, or other reasonable timeframe as determined by the Secretary.

* * * * * * *

(14) COVERED ITEM UPDATE.—In this subsection, the term "covered item update" means, with respect to a year—

(A) * * *

* * * * * * *

(K) for 2010, 2011, 2012, and 2013, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of the previous year*, subject to the productivity adjustment described in section 1886(b)(3)(B)(iii)(II), -0.5 percent*;

(L) for 2014—

(i) in the case of items and services described in subparagraph (J)(i) for which a payment adjustment has not been made under subsection (a)(1)(F)(ii) in any previous year, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June 2013, *subject to the productivity adjustment described in section 1886(b)(3)(B)(iii)(II),* plus 2.0 percentage points; or

(ii) in the case of other items and services, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June 2013*, subject to the productivity adjustment described in section 1886(b)(3)(B)(iii)(II)*; and

(M) for a subsequent year, the percentage increase in the consumer price index for all urban consumers (U.S. urban average) for the 12-month period ending with June of the previous year*, subject to the productivity adjustment described in section 1886(b)(3)(B)(iii)(II)*.

* * * * * * *

(16) DISCLOSURE OF INFORMATION AND SURETY BOND.—The Secretary shall not provide for the issuance (or renewal) of a provider number for a supplier of durable medical equipment, for purposes of payment under this part for durable medical equipment furnished by the supplier, unless the supplier provides the Secretary on a continuing basis—

(A) * * *

* * * * * * *

The Secretary may waive the requirement of a bond under subparagraph (B) in the case of a supplier that provides a comparable surety bond under State law. The Secretary, at the Secretary's discretion, may impose the requirements of the first sentence with respect to some or all providers of items or services under part A or some or all suppliers or other persons (other than physicians or other practitioners, as defined in section 1842(b)(18)(C)) who furnish items or services under this part. *The requirement for a surety bond described in subparagraph (B) shall not apply in the case of a pharmacy (i) that has*

been enrolled under section 1866(j) as a supplier of durable medical equipment, prosthetics, orthotics, and supplies and has been issued (which may include renewal of) a provider number (as described in the first sentence of this paragraph) for at least 5 years, and (ii) for which a final adverse action (as defined in section 424.57(a) of title 42, Code of Federal Regulations) has never been imposed.

* * * * * * *

(20) IDENTIFICATION OF QUALITY STANDARDS.—

(A) * * *

* * * * * * *

(F) APPLICATION OF ACCREDITATION REQUIREMENT.—In implementing quality standards under this paragraph—

(i) subject to [clause (ii)] *clauses (ii) and (iii)*, the Secretary shall require suppliers furnishing items and services described in subparagraph (D) on or after October 1, 2009, directly or as a subcontractor for another entity, to have submitted to the Secretary evidence of accreditation by an accreditation organization designated under subparagraph (B) as meeting applicable quality standards; [and]

(ii) in applying such standards and the accreditation requirement of clause (i) with respect to eligible professionals (as defined in section 1848(k)(3)(B)), and including such other persons, such as orthotists and prosthetists, as specified by the Secretary, furnishing such items and services—

(I) * * *

(II) the Secretary may exempt such professionals and persons from such standards and requirement if the Secretary determines that licensing, accreditation, or other mandatory quality requirements apply to such professionals and persons with respect to the furnishing of such items and services[.]*; and*

(iii) the requirement for accreditation described in clause (i) shall not apply for purposes of supplying diabetic testing supplies, canes, and crutches in the case of a pharmacy that is enrolled under section 1866(j) as a supplier of durable medical equipment, prosthetics, orthotics, and supplies.

Any supplier that has submitted an application for accreditation before August 1, 2009, shall be deemed as meeting applicable standards and accreditation requirement under this subparagraph until such time as the independent accreditation organization takes action on the supplier's application.

* * * * * * *

(d) FREQUENCY LIMITS AND PAYMENT FOR COLORECTAL CANCER SCREENING TESTS.—

(1) * * *

(2) SCREENING FLEXIBLE SIGMOIDOSCOPIES.—

(A) * * *

* * * * * * *

(C) FACILITY PAYMENT LIMIT.—

(i) * * *

[(ii) LIMITATION ON COINSURANCE.—Notwithstanding any other provision of this title, in the case of a beneficiary who receives the services described in clause (i)—

[(I) in computing the amount of any applicable copayment, the computation of such coinsurance shall be based upon the fee schedule under which payment is made for the services, and

[(II) the amount of such coinsurance is equal to 25 percent of the payment amount under the fee schedule described in subclause (I).]

(ii) NO COINSURANCE.—In the case of a beneficiary who receives services described in clause (i), there shall be no coinsurance applied.

* * * * * * *

(3) SCREENING COLONOSCOPY.—

(A) * * *

* * * * * * *

(C) FACILITY PAYMENT LIMIT.—

(i) * * *

[(ii) LIMITATION ON COINSURANCE.—Notwithstanding any other provision of this title, in the case of a beneficiary who receives the services described in clause (i)—

[(I) in computing the amount of any applicable coinsurance, the computation of such coinsurance shall be based upon the fee schedule under which payment is made for the services, and

[(II) the amount of such coinsurance is equal to 25 percent of the payment amount under the fee schedule described in subclause (I).]

(ii) NO COINSURANCE.—In the case of a beneficiary who receives services described in clause (i), there shall be no coinsurance applied.

* * * * * * *

(h) PAYMENT FOR PROSTHETIC DEVICES AND ORTHOTICS AND PROSTHETICS.—

(1) GENERAL RULE FOR PAYMENT.—

(A) * * *

* * * * * * *

(H) SPECIAL PAYMENT RULE FOR POSTMASTECTOMY EXTERNAL BREAST PROSTHESIS GARMENTS.—Payment for postmastectomy external breast prosthesis garments shall be made regardless of whether such items are supplied to the beneficiary prior to or after the mastectomy procedure or other breast cancer surgical procedure. The Secretary shall develop policies to ensure appropriate beneficiary access and utilization safeguards for such items supplied to

a beneficiary prior to the mastectomy or other breast cancer surgical procedure.

[(H)] *(I)* APPLICATION OF COMPETITIVE ACQUISITION TO ORTHOTICS; LIMITATION OF INHERENT REASONABLENESS AUTHORITY.—In the case of orthotics described in paragraph (2)(C) of section 1847(a) furnished on or after January 1, 2009, that are included in a competitive acquisition program in a competitive acquisition area under such section—

(i) * * *

* * * * * * *

(l) ESTABLISHMENT OF FEE SCHEDULE FOR AMBULANCE SERVICES.—

(1) * * *

* * * * * * *

(3) SAVINGS.—In establishing such fee schedule, the Secretary shall—

(A) * * *

(B) set the payment amounts provided under the fee schedule for services furnished in 2001 and each subsequent year at amounts equal to the payment amounts under the fee schedule for services furnished during the previous year, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for the 12-month period ending with June of the previous year reduced in the case of 2002 by 1.0 percentage points *and, in the case of years beginning with 2010, subject to the productivity adjustment described in section 1886(b)(3)(B)(iii)(II).*

* * * * * * *

(13) TEMPORARY INCREASE FOR GROUND AMBULANCE SERVICES.—

(A) IN GENERAL.—After computing the rates with respect to ground ambulance services under the other applicable provisions of this subsection, in the case of such services furnished on or after July 1, 2004, and before January 1, 2007, and for such services furnished on or after July 1, 2008, and [before January 1, 2010] *before January 1, 2012* for which the transportation originates in—

(i) a rural area described in paragraph (9) or in a rural census tract described in such paragraph, the fee schedule established under this section shall provide that the rate for the service otherwise established, after the application of any increase under paragraphs (11) and (12), shall be increased by 2 percent (or 3 percent if such service is furnished on or after July 1, 2008, and [before January 1, 2010] *before January 1, 2012*); and

(ii) an area not described in clause (i), the fee schedule established under this subsection shall provide that the rate for the service otherwise established, after the application of any increase under paragraph (11), shall be increased by 1 percent (or 2 percent if

such service is furnished on or after July 1, 2008, and [before January 1, 2010] *before January 1, 2012*).

* * * * * * *

(m) PAYMENT FOR TELEHEALTH SERVICES.—

(1) * * *

* * * * * * *

(4) DEFINITIONS.—For purposes of this subsection:

(A) * * *

* * * * * * *

(C) ORIGINATING SITE.—

(i) * * *

(ii) SITES DESCRIBED.—The sites referred to in clause (i) are the following sites:

(I) * * *

* * * * * * *

(IX) A renal dialysis facility.

* * * * * * *

(F) TELEHEALTH SERVICE.—

(i) * * *

* * * * * * *

(iii) RECOMMENDATIONS OF THE TELEHEALTH ADVISORY COMMITTEE.—In making determinations under clauses (i) and (ii), the Secretary shall take into account the recommendations of the Telehealth Advisory Committee (established under section 1868(c)) when adding or deleting services (and HCPCS codes) and in establishing policies of the Centers for Medicare & Medicaid Services regarding the delivery of telehealth services. If the Secretary does not implement such a recommendation, the Secretary shall publish in the Federal Register a statement regarding the reason such recommendation was not implemented.

PROCEDURE FOR PAYMENT OF CLAIMS OF PROVIDERS OF SERVICES

SEC. 1835. (a) Except as provided in subsections (b), (c), and (e), payment for services described in section 1832(a)(2) furnished an individual may be made only to providers of services which are eligible therefor under section 1866(a), and only if—

(1) written request, signed by such individual, except in cases in which the Secretary finds it impracticable for the individual to do so, is filed for such payment in such form, in such manner and by such person or persons as the Secretary may by regulation prescribe, no later than the close of the [period of 3 calendar years following the year in which such services are furnished (deeming any services furnished in the last 3 calendar months of any calendar year to have been furnished in the succeeding calendar year) except that, where the Secretary deems that efficient administration so requires, such period may be reduced to not less than 1 calendar year; and] *period of 1 calendar year from which such services are furnished; and*

(2) a physician*, or in the case of services described in subparagraph (A), a physician enrolled under section 1866(j) or an*

eligible professional under section 1848(k)(3)(B), certifies (and recertifies, where such services are furnished over a period of time, in such cases, with such frequency, and accompanied by such supporting material, appropriate to the case involved, as may be provided by regulations) that—

(A) in the case of home health services (i) such services are or were required because the individual is or was confined to his home (except when receiving items and services referred to in section 1861(m)(7)) and needs or needed skilled nursing care (other than solely venipuncture for the purpose of obtaining a blood sample) on an intermittent basis or physical or speech therapy or, in the case of an individual who has been furnished home health services based on such a need and who no longer has such a need for such care or therapy, continues or continued to need occupational therapy, (ii) a plan for furnishing such services to such individual has been established and is periodically reviewed by a physician, ⟦and⟧ (iii) such services are or were furnished while the individual is or was under the care of a physician*, and (iv) in the case of a certification or recertification after January 1, 2010, prior to making such certification the physician must document that the physician has had a face-to-face encounter (including through use of telehealth and other than with respect to encounters that are incident to services involved) with the individual during the 6-month period preceding such certification or recertification, or other reasonable timeframe as determined by the Secretary*;

* * * * * * *

To the extent provided by regulations, the certification and recertification requirements of paragraph (2) shall be deemed satisfied where, at a later date, a physician makes a certification of the kind provided in subparagraph (A) or (B) of paragraph (2) (whichever would have applied), but only where such certification is accompanied by such medical and other evidence as may be required by such regulations. With respect to the physician certification required by paragraph (2) for home health services furnished to any individual by a home health agency (other than an agency which is a governmental entity) and with respect to the establishment and review of a plan for such services, the Secretary shall prescribe regulations which shall become effective no later than July 1, 1981, and which prohibit a physician who has a significant ownership interest in, or a significant financial or contractual relationship with, such home health agency from performing such certification and from establishing or reviewing such plan, except that such prohibition shall not apply with respect to a home health agency which is a sole community home health agency (as determined by the Secretary). For purposes of the preceding sentence, service by a physician as an uncompensated officer or director of a home health agency shall not constitute having a significant ownership interest in, or a significant financial or contractual relationship with, such agency. For purposes of paragraph (2)(A), an individual shall be considered to be "confined to his home" if the individual has a condition, due to an illness or injury, that restricts the ability of the individual to leave his or her home except with the assistance of

another individual or the aid of a supportive device (such as crutches, a cane, a wheelchair, or a walker), or if the individual has a condition such that leaving his or her home is medically contraindicated. While an individual does not have to be bedridden to be considered "confined to his home", the condition of the individual should be such that there exists a normal inability to leave home and that leaving home requires a considerable and taxing effort by the individual. Any absence of an individual from the home attributable to the need to receive health care treatment, including regular absences for the purpose of participating in therapeutic, psychosocial, or medical treatment in an adult day-care program that is licensed or certified by a State, or accredited, to furnish adult day-care services in the State shall not disqualify an individual from being considered to be "confined to his home". Any other absence of an individual from the home shall not so disqualify an individual if the absence is of infrequent or of relatively short duration. For purposes of the preceding sentence, any absence for the purpose of attending a religious service shall be deemed to be an absence of infrequent or short duration. *In applying paragraph (1), the Secretary may specify exceptions to the 1 calendar year period specified in such paragraph.*

* * * * * * *

ELIGIBLE INDIVIDUALS

SEC. 1836. **[**Every individual who**]** *(a) IN GENERAL.—Every individual who—*

(1) * * *

* * * * * * *

(b) SPECIAL RULES APPLICABLE TO INDIVIDUALS ONLY ELIGIBLE FOR COVERAGE OF IMMUNOSUPPRESSIVE DRUGS.—

(1) IN GENERAL.—In the case of an individual whose eligibility for benefits under this title has ended on or after January 1, 2012, except for the coverage of immunosuppressive drugs by reason of section 226A(b)(2), the following rules shall apply:

(A) The individual shall be deemed to be enrolled under this part for purposes of receiving coverage of such drugs.

(B) The individual shall be responsible for providing for payment of the portion of the premium under section 1839 which is not covered under the Medicare savings program (as defined in section 1144(c)(7)) in order to receive such coverage.

(C) The provision of such drugs shall be subject to the application of—

(i) the deductible under section 1833(b); and

(ii) the coinsurance amount applicable for such drugs (as determined under this part).

(D) If the individual is an inpatient of a hospital or other entity, the individual is entitled to receive coverage of such drugs under this part.

(2) ESTABLISHMENT OF PROCEDURES IN ORDER TO IMPLEMENT COVERAGE.—The Secretary shall establish procedures for—

(A) identifying individuals that are entitled to coverage of immunosuppressive drugs by reason of section 226A(b)(2); and

(B) distinguishing such individuals from individuals that are enrolled under this part for the complete package of benefits under this part.

ENROLLMENT PERIODS

SEC. 1837. (a) * * *

* * * * * * *

(l)(1) In the case of any individual who is a covered beneficiary (as defined in section 1072(5) of title 10, United States Code) at the time the individual is entitled to hospital insurance benefits under part A under section 226(b) or section 226A and who is eligible to enroll but who has elected not to enroll (or to be deemed enrolled) during the individual's initial enrollment period, there shall be a special enrollment period described in paragraph (2).

(2) The special enrollment period described in this paragraph, with respect to an individual, is the 12-month period beginning on the day after the last day of the initial enrollment period of the individual or, if later, the 12-month period beginning with the month the individual is notified of enrollment under this section.

(3) In the case of an individual who enrolls during the special enrollment period provided under paragraph (1), the coverage period under this part shall begin on the first day of the month in which the individual enrolls or, at the option of the individual, on the first day of the second month following the last month of the individual's initial enrollment period.

(4) The Secretary of Defense shall establish a method for identifying individuals described in paragraph (1) and providing notice to them of their eligibility for enrollment during the special enrollment period described in paragraph (2).

* * * * * * *

AMOUNTS OF PREMIUMS

SEC. 1839. (a) * * *

(b) In the case of an individual whose coverage period began pursuant to an enrollment after his initial enrollment period (determined pursuant to subsection (c) or (d) of section 1837) and not pursuant to a special enrollment period under [section 1837(i)(4)] *subsection (i)(4) or (l) of section 1837*, the monthly premium determined under subsection (a) (without regard to any adjustment under subsection (i)) shall be increased by 10 percent of the monthly premium so determined for each full 12 months (in the same continuous period of eligibility) in which he could have been but was not enrolled. For purposes of the preceding sentence, there shall be taken into account (1) the months which elapsed between the close of his initial enrollment period and the close of the enrollment period in which he enrolled, plus (in the case of an individual who reenrolls) (2) the months which elapsed between the date of termination of a previous coverage period and the close of the enrollment period in which he reenrolled, but there shall not be taken into account months for which the individual can demonstrate that the individual was enrolled in a group health plan described in section 1862(b)(1)(A)(v) by reason of the individual's (or the individual's spouse's) current employment or months during which the individual has not attained the age of 65 and for which the indi-

vidual can demonstrate that the individual was enrolled in a large group health plan as an active individual (as those terms are defined in section 1862(b)(1)(B)(iii)) or months for which the individual can demonstrate that the individual was an individual described in section 1837(k)(3). Any increase in an individual's monthly premium under the first sentence of this subsection with respect to a particular continuous period of eligibility shall not be applicable with respect to any other continuous period of eligibility which such individual may have. No increase in the premium shall be effected for a month in the case of an individual who enrolls under this part during 2001, 2002, 2003, or 2004 and who demonstrates to the Secretary before December 31, 2004, that the individual is a covered beneficiary (as defined in section 1072(5) of title 10, United States Code). The Secretary of Health and Human Services shall consult with the Secretary of Defense in identifying individuals described in the previous sentence.

* * * * * * *

(i) REDUCTION IN PREMIUM SUBSIDY BASED ON INCOME.—

(1) * * *

* * * * * * *

(4) MODIFIED ADJUSTED GROSS INCOME.—

(A) * * *

* * * * * * *

(C) USE OF MORE RECENT TAXABLE YEAR.—

(i) * * *

(ii) STANDARD FOR GRANTING REQUESTS.—A request under clause (i)(I) to use a more recent taxable year may be granted only if—

(I) * * *

(II) the individual's modified adjusted gross income for such year is significantly less than such income for the taxable year determined under subparagraph (B) by reason of the death of such individual's spouse, the marriage or divorce of such individual, *sale of primary residence,* or other major life changing events specified in regulations prescribed by the Commissioner in consultation with the Secretary.

* * * * * * *

PROVISIONS RELATING TO THE ADMINISTRATION OF PART B

SEC. 1842. (a) * * *

(b)(2) * * *

* * * * * * *

(18)(A) * * *

* * * * * * *

(C) A practitioner described in this subparagraph is any of the following:

(i) * * *

* * * * * * *

(vii) A marriage and family therapist (as defined in section 1861(jjj)(2)).

(viii) A mental health counselor (as defined in section 1861(kkk)(2)).

* * * * * * *

(h)(1) * * *

* * * * * * *

(10) The Secretary may disenroll, for a period of not more than one year for each act, a physician or supplier under section 1866(j) if such physician or supplier fails to maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by such physician or supplier under this title, as specified by the Secretary.

* * * * * * *

(o)(1) If a physician's, supplier's, or any other person's bill or request for payment for services includes a charge for a drug or biological for which payment may be made under this part and the drug or biological is not paid on a cost or prospective payment basis as otherwise provided in this part, the amount payable for the drug or biological is equal to the following:

(A) In the case of any of the following drugs or biologicals, 95 percent of the average wholesale price:

(i) * * *

* * * * * * *

(iv) A vaccine described in [subparagraph (A) or (B) of] section 1861(s)(10) furnished on or after January 1, 2004 *and before January 1, 2011, and influenza vaccines furnished on or after January 1, 2011.*

* * * * * * *

USE OF AVERAGE SALES PRICE PAYMENT METHODOLOGY

SEC. 1847A. (a) * * *

* * * * * * *

(c) MANUFACTURER'S AVERAGE SALES PRICE.—

(1) * * *

* * * * * * *

(3) SALE PRICE NET OF DISCOUNTS.—In calculating the manufacturer's average sales price under this subsection, such price shall include volume discounts, prompt pay discounts *(other than, for drugs and biologicals that are sold on or after January 1, 2011, and before January 1, 2016, customary prompt pay discounts extended to wholesalers, but only to the extent such discounts do not exceed 2 percent of the wholesale acquisition cost)*, cash discounts, free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1927). For years after 2004, the Secretary may include in such price other price concessions *(other than, for drugs and biologicals that are sold on or after January 1, 2011, and before January 1, 2016, customary prompt pay*

discounts extended to wholesalers, but only to the extent such discounts do not exceed 2 percent of the wholesale acquisition cost), which may be based on recommendations of the Inspector General, that would result in a reduction of the cost to the purchaser.

* * * * * * *

(6) DEFINITIONS AND OTHER RULES.—In this section:

(A) * * *

* * * * * * *

[(G) INCLUSION OF VACCINES.—In applying provisions of section 1927 under this section, "other than a vaccine" is deemed deleted from section 1927(k)(2)(B).]

(G) IMPLEMENTATION.—Chapter 35 of title 44, United States Code shall not apply to manufacturer provision of information pursuant to section 1927(b)(3)(A)(iii) for purposes of implementation of this section.

* * * * * * *

PAYMENT FOR PHYSICIANS' SERVICES

SEC. 1848. (a) * * *

(b) ESTABLISHMENT OF FEE SCHEDULES.—

(1) * * *

* * * * * * *

(4) SPECIAL RULE FOR IMAGING SERVICES.—

(A) * * *

(B) IMAGING SERVICES DESCRIBED.—For purposes of [subparagraph (A)] *this paragraph*, imaging services described in this subparagraph are imaging and computer-assisted imaging services, including X-ray, ultrasound (including echocardiography), nuclear medicine (including positron emission tomography), magnetic resonance imaging, computed tomography, and fluoroscopy, but excluding diagnostic and screening mammography.

(C) ADJUSTMENT IN PRACTICE EXPENSE TO REFLECT HIGHER PRESUMED UTILIZATION.—In computing the number of practice expense relative value units under subsection (c)(2)(C)(ii) with respect to advanced diagnostic imaging services (as defined in section 1834(e)(1)(B)), the Secretary shall adjust such number of units so it reflects a 75 percent (rather than 50 percent) presumed rate of utilization of imaging equipment.

(D) ADJUSTMENT IN TECHNICAL COMPONENT DISCOUNT ON SINGLE-SESSION IMAGING INVOLVING CONSECUTIVE BODY PARTS.—The Secretary shall increase the reduction in expenditures attributable to the multiple procedure payment reduction applicable to the technical component for imaging under the final rule published by the Secretary in the Federal Register on November 21, 2005 (part 405 of title 42, Code of Federal Regulations) from 25 percent to 50 percent.

* * * * * * *

(c) DETERMINATION OF RELATIVE VALUES FOR PHYSICIANS' SERVICES.—

(1) * * *

(2) DETERMINATION OF RELATIVE VALUES.—

(A) * * *

(B) PERIODIC REVIEW AND ADJUSTMENTS IN RELATIVE VALUES.—

(i) * * *

* * * * * * *

(v) EXEMPTION OF CERTAIN REDUCED EXPENDITURES FROM BUDGET-NEUTRALITY CALCULATION.—The following reduced expenditures, as estimated by the Secretary, shall not be taken into account in applying clause (ii)(II):

(I) * * *

(II) OPD PAYMENT CAP *AND OTHER PROVISIONS* FOR IMAGING SERVICES.—Effective for fee schedules established beginning with 2007, reduced expenditures attributable to subsection (b)(4).

* * * * * * *

(K) POTENTIALLY MISVALUED CODES.—

(i) IN GENERAL.—The Secretary shall—

(I) periodically identify services as being potentially misvalued using criteria specified in clause (ii); and

(II) review and make appropriate adjustments to the relative values established under this paragraph for services identified as being potentially misvalued under subclause (I).

(ii) IDENTIFICATION OF POTENTIALLY MISVALUED CODES.—For purposes of identifying potentially misvalued services pursuant to clause (i)(I), the Secretary shall examine (as the Secretary determines to be appropriate) codes (and families of codes as appropriate) for which there has been the fastest growth; codes (and families of codes as appropriate) that have experienced substantial changes in practice expenses; codes for new technologies or services within an appropriate period (such as three years) after the relative values are initially established for such codes; multiple codes that are frequently billed in conjunction with furnishing a single service; codes with low relative values, particularly those that are often billed multiple times for a single treatment; codes which have not been subject to review since the implementation of the RBRVS (the so-called "Harvard-valued codes"); and such other codes determined to be appropriate by the Secretary.

(iii) REVIEW AND ADJUSTMENTS.—

(I) The Secretary may use existing processes to receive recommendations on the review and appropriate adjustment of potentially misvalued services described clause (i)(II).

(II) The Secretary may conduct surveys, other data collection activities, studies, or other analyses

as the Secretary determines to be appropriate to facilitate the review and appropriate adjustment described in clause (i)(II).

(III) The Secretary may use analytic contractors to identify and analyze services identified under clause (i)(I), conduct surveys or collect data, and make recommendations on the review and appropriate adjustment of services described in clause (i)(II).

(IV) The Secretary may coordinate the review and appropriate adjustment described in clause (i)(II) with the periodic review described in subparagraph (B).

(V) As part of the review and adjustment described in clause (i)(II), including with respect to codes with low relative values described in clause (ii), the Secretary may make appropriate coding revisions (including using existing processes for consideration of coding changes) which may include consolidation of individual services into bundled codes for payment under the fee schedule under subsection (b).

(VI) The provisions of subparagraph (B)(ii)(II) shall apply to adjustments to relative value units made pursuant to this subparagraph in the same manner as such provisions apply to adjustments under subparagraph (B)(ii)(II).

(L) VALIDATING RELATIVE VALUE UNITS.—

(i) IN GENERAL.—The Secretary shall establish a process to validate relative value units under the fee schedule under subsection (b).

(ii) COMPONENTS AND ELEMENTS OF WORK.—The process described in clause (i) may include validation of work elements (such as time, mental effort and professional judgment, technical skill and physical effort, and stress due to risk) involved with furnishing a service and may include validation of the pre, post, and intra-service components of work.

(iii) SCOPE OF CODES.—The validation of work relative value units shall include a sampling of codes for services that is the same as the codes listed under subparagraph (K)(ii)

(iv) METHODS.—The Secretary may conduct the validation under this subparagraph using methods described in subclauses (I) through (V) of subparagraph (K)(iii) as the Secretary determines to be appropriate.

(v) ADJUSTMENTS.—The Secretary shall make appropriate adjustments to the work relative value units under the fee schedule under subsection (b). The provisions of subparagraph (B)(ii)(II) shall apply to adjustments to relative value units made pursuant to this subparagraph in the same manner as such provisions apply to adjustments under subparagraph (B)(ii)(II).

* * * * * * *

(d) CONVERSION FACTORS.—

(1) ESTABLISHMENT.—

(A) IN GENERAL.—[The conversion factor]

(i) APPLICATION OF SINGLE CONVERSION FACTOR.—Subject to clause (ii), the conversion factor for each year shall be the conversion factor established under this subsection for the previous year (or, in the case of 1992, specified in subparagraph (B)) adjusted by the update (established under paragraph (3)) for the year involved (for years before 2001) and, for years beginning with 2001, multiplied by the update (established under paragraph (4)) for the year involved.

(ii) APPLICATION OF MULTIPLE CONVERSION FACTORS BEGINNING WITH 2011.—

(I) IN GENERAL.—In applying clause (i) for years beginning with 2011, separate conversion factors shall be established for each service category of physicians' services (as defined in subsection (j)(5)) and any reference in this section to a conversion factor for such years shall be deemed to be a reference to the conversion factor for each of such categories.

(II) INITIAL CONVERSION FACTORS.—Such factors for 2011 shall be based upon the single conversion factor for the previous year multiplied by the update established under paragraph (11) for such category for 2011.

(III) UPDATING OF CONVERSION FACTORS.—Such factor for a service category for a subsequent year shall be based upon the conversion factor for such category for the previous year and adjusted by the update established for such category under paragraph (11) for the year involved.

* * * * * * *

(D) SPECIAL RULES FOR ANESTHESIA SERVICES.—The separate conversion factor for anesthesia services for a year shall be equal to 46 percent of the single conversion factor established for [other physicians' services] *physicians' services described in the service category described in subsection (j)(5)(B)*, except as adjusted for changes in work, practice expense, or malpractice relative value units.

(E) PUBLICATION AND DISSEMINATION OF INFORMATION.—The Secretary shall—

(i) * * *

(ii) make available to the Medicare Payment Advisory Commission and the public by March 1 of each year (beginning with 2000) an estimate of the sustainable *or target* growth rate and of the conversion factor which will apply to physicians' services for the succeeding year and data used in making such estimate.

* * * * * * *

(4) UPDATE FOR YEARS BEGINNING WITH 2001.—

(A) * * *

(B) UPDATE ADJUSTMENT FACTOR.—For purposes of subparagraph (A)(ii), subject to [subparagraph (D)] *subpara-*

graphs (D) and (G) and the succeeding paragraphs of this subsection, the "update adjustment factor" for a year is equal (as estimated by the Secretary) to the sum of the following:

(i) * * *

(ii) CUMULATIVE ADJUSTMENT COMPONENT.—An amount determined by—

(I) * * *

(II) dividing that difference by actual expenditures for such services for the prior year as increased by the sustainable *or target* growth rate under subsection (f) for the year for which the update adjustment factor is to be determined; and

* * * * * * *

(C) DETERMINATION OF ALLOWED EXPENDITURES.—For purposes of this paragraph:

(i) * * *

* * * * * * *

(iii) YEARS BEGINNING WITH 2000.—**[**The allowed**]** *Subject to paragraph (11)(B), the allowed* expenditures for a year (beginning with 2000) is equal to the allowed expenditures for physicians' services for the previous year, increased by the sustainable growth rate under subsection (f) for the year involved.

* * * * * * *

(G) REBASING USING 2009 FOR FUTURE UPDATE ADJUSTMENTS.—In determining the update adjustment factor under subparagraph (B) for 2011 and subsequent years—

(i) the allowed expenditures for 2009 shall be equal to the amount of the actual expenditures for physicians' services during 2009; and

(ii) the reference in subparagraph (B)(ii)(I) to "April 1, 1996" shall be treated as a reference to "January 1, 2009 (or, if later, the first day of the fifth year before the year involved)".

* * * * * * *

(10) UPDATE FOR 2010.—The update to the single conversion factor established in paragraph (1)(C) for 2010 shall be the percentage increase in the MEI (as defined in section 1842(i)(3)) for that year.

(11) UPDATES FOR SERVICE CATEGORIES BEGINNING WITH 2011.—

(A) IN GENERAL.—In applying paragraph (4) for a year beginning with 2011, the following rules apply:

(i) APPLICATION OF SEPARATE UPDATE ADJUSTMENTS FOR EACH SERVICE CATEGORY.—Pursuant to paragraph (1)(A)(ii)(I), the update shall be made to the conversion factor for each service category (as defined in subsection (j)(5)) based upon an update adjustment factor for the respective category and year and the update adjustment factor shall be computed, for a year, separately for each service category.

(ii) COMPUTATION OF ALLOWED AND ACTUAL EXPENDITURES BASED ON SERVICE CATEGORIES.—In computing the prior year adjustment component and the cumulative adjustment component under clauses (i) and (ii) of paragraph (4)(B), the following rules apply:

(I) APPLICATION BASED ON SERVICE CATEGORIES.—The allowed expenditures and actual expenditures shall be the allowed and actual expenditures for the service category, as determined under subparagraph (B).

(II) APPLICATION OF CATEGORY SPECIFIC TARGET GROWTH RATE.—The growth rate applied under clause (ii)(II) of such paragraph shall be the target growth rate for the service category involved under subsection (f)(5).

(B) DETERMINATION OF ALLOWED EXPENDITURES.—In applying paragraph (4) for a year beginning with 2010, notwithstanding subparagraph (C)(iii) of such paragraph, the allowed expenditures for a service category for a year is an amount computed by the Secretary as follows:

(i) FOR 2010.—For 2010:

(I) TOTAL 2009 ACTUAL EXPENDITURES FOR ALL SERVICES INCLUDED IN SGR COMPUTATION FOR EACH SERVICE CATEGORY.—Compute total actual expenditures for physicians' services (as defined in subsection (f)(4)(A)) for 2009 for each service category.

(II) INCREASE BY GROWTH RATE TO OBTAIN 2010 ALLOWED EXPENDITURES FOR SERVICE CATEGORY.—Compute allowed expenditures for the service category for 2010 by increasing the allowed expenditures for the service category for 2009 computed under subclause (I) by the target growth rate for such service category under subsection (f) for 2010.

(ii) FOR SUBSEQUENT YEARS.—For a subsequent year, take the amount of allowed expenditures for such category for the preceding year (under clause (i) or this clause) and increase it by the target growth rate determined under subsection (f) for such category and year.

(e) GEOGRAPHIC ADJUSTMENT FACTORS.—

(1) ESTABLISHMENT OF GEOGRAPHIC INDICES.—

(A) * * *

* * * * * * *

(E) FLOOR AT 1.0 ON WORK GEOGRAPHIC INDEX.—After calculating the work geographic index in subparagraph (A)(iii), for purposes of payment for services furnished on or after January 1, 2004, and [before January 1, 2010] *before January 1, 2012*, the Secretary shall increase the work geographic index to 1.00 for any locality for which such work geographic index is less than 1.00.

* * * * * * *

(6) TRANSITION TO USE OF MSAS AS FEE SCHEDULE AREAS IN CALIFORNIA.—

(A) IN GENERAL.—

(i) REVISION.—Subject to clause (ii) and notwithstanding the previous provisions of this subsection, for services furnished on or after January 1, 2011, the Secretary shall revise the fee schedule areas used for payment under this section applicable to the State of California using the Metropolitan Statistical Area (MSA) iterative Geographic Adjustment Factor methodology as follows:

(I) The Secretary shall configure the physician fee schedule areas using the Core-Based Statistical Areas-Metropolitan Statistical Areas (each in this paragraph referred to as an "MSA"), as defined by the Director of the Office of Management and Budget, as the basis for the fee schedule areas. The Secretary shall employ an iterative process to transition fee schedule areas. First, the Secretary shall list all MSAs within the State by Geographic Adjustment Factor described in paragraph (2) (in this paragraph referred to as a "GAF") in descending order. In the first iteration, the Secretary shall compare the GAF of the highest cost MSA in the State to the weighted-average GAF of the group of remaining MSAs in the State. If the ratio of the GAF of the highest cost MSA to the weighted-average GAF of the rest of State is 1.05 or greater then the highest cost MSA becomes a separate fee schedule area.

(II) In the next iteration, the Secretary shall compare the MSA of the second-highest GAF to the weighted-average GAF of the group of remaining MSAs. If the ratio of the second-highest MSA's GAF to the weighted-average of the remaining lower cost MSAs is 1.05 or greater, the second-highest MSA becomes a separate fee schedule area. The iterative process continues until the ratio of the GAF of the highest-cost remaining MSA to the weighted-average of the remaining lower-cost MSAs is less than 1.05, and the remaining group of lower cost MSAs form a single fee schedule area. If two MSAs have identical GAFs, they shall be combined in the iterative comparison.

(ii) TRANSITION.—For services furnished on or after January 1, 2011, and before January 1, 2016, in the State of California, after calculating the work, practice expense, and malpractice geographic indices described in clauses (i), (ii), and (iii) of paragraph (1)(A) that would otherwise apply through application of this paragraph, the Secretary shall increase any such index to the county-based fee schedule area value on December 31, 2009, if such index would otherwise be less than the value on January 1, 2010.

(B) SUBSEQUENT REVISIONS.—

(i) PERIODIC REVIEW AND ADJUSTMENTS IN FEE SCHEDULE AREAS.—Subsequent to the process outlined in paragraph (1)(C), not less often than every three

years, the Secretary shall review and update the California Rest-of-State fee schedule area using MSAs as defined by the Director of the Office of Management and Budget and the iterative methodology described in subparagraph (A)(i).

(ii) LINK WITH GEOGRAPHIC INDEX DATA REVISION.—The revision described in clause (i) shall be made effective concurrently with the application of the periodic review of the adjustment factors required under paragraph (1)(C) for California for 2012 and subsequent periods. Upon request, the Secretary shall make available to the public any county-level or MSA derived data used to calculate the geographic practice cost index.

(C) REFERENCES TO FEE SCHEDULE AREAS.—Effective for services furnished on or after January 1, 2010, for the State of California, any reference in this section to a fee schedule area shall be deemed a reference to an MSA in the State.

(f) SUSTAINABLE GROWTH RATE *AND TARGET GROWTH RATE*.—

(1) PUBLICATION.—The Secretary shall cause to have published in the Federal Register not later than—

(A) November 1, 2000, the sustainable growth rate for 2000 and 2001; **[**and**]**

(B) November 1 of each succeeding year *before 2010* the sustainable growth rate for such succeeding year and each of the preceding 2 years**[**.**]***; and*

(C) November 1 of each succeeding year the target growth rate for such succeeding year and each of the 2 preceding years.

(2) SPECIFICATION OF GROWTH RATE.—The sustainable growth rate for all physicians' services for a fiscal year (beginning with fiscal year 1998 and ending with fiscal year 2000) and a year beginning with 2000 *and ending with 2009* shall be equal to the product of—

(A) * * *

* * * * * * *

(4) DEFINITIONS.—In this subsection:

(A) SERVICES INCLUDED IN PHYSICIANS' SERVICES.—The term "physicians' services" includes other items and services **[**(such as clinical diagnostic laboratory tests and radiology services), specified by the Secretary, that are commonly performed or furnished by a physician or in a physician's office**]** *for which payment under this part is made under the fee schedule under this section, for services for practitioners described in section 1842(b)(18)(C) on a basis related to such fee schedule, or for services described in section 1861(p) (other than such services when furnished in the facility of a provider of services)*, but does not include services furnished to a Medicare+Choice plan enrollee.

* * * * * * *

(5) APPLICATION OF SEPARATE TARGET GROWTH RATES FOR EACH SERVICE CATEGORY BEGINNING WITH 2010.—The target growth rate for a year beginning with 2010 shall be computed and applied separately under this subsection for each service category (as defined in subsection (j)(5)) and shall be computed

using the same method for computing the target growth rate except that the factor described in paragraph (2)(C) for—

(A) the service category described in subsection (j)(5)(A) shall be increased by 0.02; and

(B) the service category described in subsection (j)(5)(B) shall be increased by 0.01.

* * * * * * *

(j) DEFINITIONS.—In this section:

(1) * * *

(2) FEE SCHEDULE AREA.—[The term] *Except as provided in subsection (e)(6)(C), the term* "fee schedule area" means a locality used under section 1842(b) for purposes of computing payment amounts for physicians' services.

(3) PHYSICIANS' SERVICES.—The term "physicians' services" includes items and services described in paragraphs (1), (2)(A), (2)(D), (2)(G), (2)(P) (with respect to services described in subparagraphs (A) and (C) of section 1861(oo)(2)), (2)(R) (with respect to services described in suparagraphs (B), (C), and (D) of section 1861(pp)(1)), (2)(S), (2)(W), (2)(AA), (2)(DD), (2)(EE), *(2)(FF),* (3), (4), (13), (14) (with respect to services described in section 1861(nn)(2)), and (15) of section 1861(s) (other than clinical diagnostic laboratory tests and, except for purposes of subsection (a)(3), (g), and (h) such other items and services as the Secretary may specify).

* * * * * * *

(5) SERVICE CATEGORIES.—For services furnished on or after January 1, 2009, each of the following categories of physicians' services (as defined in paragraph (3)) shall be treated as a separate "service category":

(A) Evaluation and management services that are procedure codes (for services covered under this title) for—

(i) services in the category designated Evaluation and Management in the Health Care Common Procedure Coding System (established by the Secretary under subsection (c)(5) as of December 31, 2009, and as subsequently modified by the Secretary); and

(ii) preventive services (as defined in section 1861(iii)) for which payment is made under this section.

(B) All other services not described in subparagraph (A). Service categories established under this paragraph shall apply without regard to the specialty of the physician furnishing the service.

(k) QUALITY REPORTING SYSTEM.—

(1) * * *

(2) USE OF CONSENSUS-BASED QUALITY MEASURES.—

(A) * * *

* * * * * * *

(C) FOR 2010 AND SUBSEQUENT YEARS.—

(i) * * *

(ii) EXCEPTION.—In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not

been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary, such as the AQA alliance. *The Secretary shall submit such a non-endorsed measure to the entity for consideration for endorsement. If the entity considers but does not endorse such a measure and if the Secretary does not phase-out use of such measure, the Secretary shall include the rationale for continued use of such a measure in rulemaking.*

* * * * * * *

(E) PHYSICIAN'S QUALITY REPORTING INITIATIVE.—

(i) IN GENERAL.—For purposes of reporting data on quality measures for covered professional services furnished during 2011 and any subsequent year, to the extent that measures are available, the Secretary shall include quality measures on end of life care and advanced care planning that have been adopted or endorsed by a consensus-based organization, if appropriate. Such measures shall measure both the creation of and adherence to orders for life-sustaining treatment.

(ii) PROPOSED SET OF MEASURES.—The Secretary shall publish in the Federal Register proposed quality measures on end of life care and advanced care planning that the Secretary determines are described in subparagraph (A) and would be appropriate for eligible professionals to use to submit data to the Secretary. The Secretary shall provide for a period of public comment on such set of measures before finalizing such proposed measures.

* * * * * * *

(m) INCENTIVE PAYMENTS FOR QUALITY REPORTING.—

(1) INCENTIVE PAYMENTS.—

(A) IN GENERAL.—For 2007 through [2010] *2012*, with respect to covered professional services furnished during a reporting period by an eligible professional, if—

(i) * * *

* * * * * * *

(B) APPLICABLE QUALITY PERCENT.—For purposes of subparagraph (A), the term "applicable quality percent" means—

(i) * * *

(ii) for [2009 and 2010] *each of the years 2009 through 2012*, 2.0 percent.

* * * * * * *

(5) APPLICATION.—

(A) * * *

(B) COORDINATION WITH OTHER BONUS PAYMENTS.—The provisions of this subsection shall not be taken into account in applying subsections (m)*, (p),* and (u) of section

1833 and any payment under such subsections shall not be taken into account in computing allowable charges under this subsection.

* * * * * * *

(E) LIMITATIONS ON REVIEW.—[There shall be] *Subject to subparagraph (I), there shall be* no administrative or judicial review under 1869, section 1878, or otherwise of

(i) * * *

* * * * * * *

(H) FEEDBACK.—The Secretary shall provide timely feedback to eligible professionals on the performance of the eligible professional with respect to satisfactorily submitting data on quality measures under this subsection.

(I) INFORMAL APPEALS PROCESS.—Notwithstanding subparagraph (E), by not later than January 1, 2011, the Secretary shall establish and have in place an informal process for eligible professionals to appeal the determination that an eligible professional did not satisfactorily submit data on quality measures under this subsection.

* * * * * * *

(7) INTEGRATION OF PHYSICIAN QUALITY REPORTING AND EHR REPORTING.—Not later than January 1, 2012, the Secretary shall develop a plan to integrate clinical reporting on quality measures under this subsection with reporting requirements under subsection (o) relating to the meaningful use of electronic health records. Such integration shall consist of the following:

(A) The development of measures, the reporting of which would both demonstrate—

(i) meaningful use of an electronic health record for purposes of subsection (o); and

(ii) clinical quality of care furnished to an individual.

(B) The collection of health data to identify deficiencies in the quality and coordination of care for individuals eligible for benefits under this part.

(C) Such other activities as specified by the Secretary.

* * * * * * *

(o) INCENTIVES FOR ADOPTION AND MEANINGFUL USE OF CERTIFIED EHR TECHNOLOGY.—

(1) INCENTIVE PAYMENTS.—

(A) * * *

(B) LIMITATIONS ON AMOUNTS OF INCENTIVE PAYMENTS.—

(i) * * *

* * * * * * *

(iv) INCREASE FOR CERTAIN ELIGIBLE PROFESSIONALS.—In the case of an eligible professional who predominantly furnishes services under this part in an area that is designated by the Secretary (under section 332(a)(1)(A) of the Public Health Service Act) as a *primary care* health professional shortage area, the amount that would otherwise apply for a payment year for such professional under subclauses (I)

through (V) of clause (ii) shall be increased by 10 percent. In implementing the preceding sentence, the Secretary may, as determined appropriate, apply provisions of subsections (m) and (u) of section 1833 in a similar manner as such provisions apply under such subsection.

* * * * * * *

(p) PAYMENT MODIFIER FOR CERTAIN EVALUATION AND MANAGEMENT SERVICES.—The Secretary shall establish a payment modifier under the fee schedule under this section for evaluation and management services (as specified in section 1842(b)(16)(B)(ii)) that result in the ordering of additional services (such as lab tests), the prescription of drugs, the furnishing or ordering of durable medical equipment in order to enable better monitoring of claims for payment for such additional services under this title, or the ordering, furnishing, or prescribing of other items and services determined by the Secretary to pose a high risk of waste, fraud, and abuse. The Secretary may require providers of services or suppliers to report such modifier in claims submitted for payment.

PART C—MEDICARE+CHOICE PROGRAM

ELIGIBILITY, ELECTION, AND ENROLLMENT

SEC. 1851. (a) * * *

* * * * * * *

(e) COVERAGE ELECTION PERIODS.—

(1) * * *

(2) OPEN ENROLLMENT AND DISENROLLMENT OPPORTUNITIES.—Subject to paragraph (5)—

(A) * * *

* * * * * * *

[(C) CONTINUOUS OPEN ENROLLMENT AND DISENROLLMENT FOR FIRST 3 MONTHS IN SUBSEQUENT YEARS.—

[(i) IN GENERAL.—Subject to clauses (ii) and (iii) and subparagraph (D), at any time during the first 3 months of a year after 2006, or, if the individual first becomes a Medicare+Choice eligible individual during a year after 2006, during the first 3 months of such year in which the individual is a Medicare+Choice eligible individual, a Medicare+Choice eligible individual may change the election under subsection (a)(1).

[(ii) LIMITATION OF ONE CHANGE DURING OPEN ENROLLMENT PERIOD EACH YEAR.—An individual may exercise the right under clause (i) only once during the applicable 3-month period described in such clause in each year. The limitation under this clause shall not apply to changes in elections effected during an annual, coordinated election period under paragraph (3) or during a special enrollment period under paragraph (4).

[(iii) LIMITATION ON EXERCISE OF RIGHT WITH RESPECT TO PRESCRIPTION DRUG COVERAGE.—Effective for

plan years beginning on or after January 1, 2006, in applying clause (i) (and clause (i) of subparagraph (B)) in the case of an individual who—

[(I) is enrolled in an MA plan that does provide qualified prescription drug coverage, the individual may exercise the right under such clause only with respect to coverage under the original fee-for-service plan or coverage under another MA plan that does not provide such coverage and may not exercise such right to obtain coverage under an MA–PD plan or under a prescription drug plan under part D; or

[(II) is enrolled in an MA–PD plan, the individual may exercise the right under such clause only with respect to coverage under another MA–PD plan (and not an MA plan that does not provide qualified prescription drug coverage) or under the original fee-for-service plan and coverage under a prescription drug plan under part D.]

* * * * * * *

(3) ANNUAL, COORDINATED ELECTION PERIOD.—

(A) * * *

(B) ANNUAL, COORDINATED ELECTION PERIOD.—For purposes of this section, the term "annual, coordinated election period" means—

(i) * * *

* * * * * * *

(iii) with respect to 2006, the period beginning on November 15, 2005, and ending on May 15, 2006; [and]

(iv) with respect to 2007 [and succeeding years], *2008, 2009, and 2010*, the period beginning on November 15 and ending on December 31 of the year before such year[.]*; and*

(v) with respect to 2011 and succeeding years, the period beginning on November 1 and ending on December 15 of the year before such year.

* * * * * * *

(4) SPECIAL ELECTION PERIODS.—Effective as of January 1, 2006, an individual may discontinue an election of a Medicare+Choice plan offered by a Medicare+Choice organization other than during an annual, coordinated election period and make a new election under this section if—

(A) * * *

* * * * * * *

(C) the individual demonstrates (in accordance with guidelines established by the Secretary) that—

(i) * * *

(ii) the organization (or an agent or other entity acting on the organization's behalf) materially misrepresented the plan's provisions in marketing the plan to the individual; [or]

(D) the individual is enrolled in an MA plan and enrollment in the plan is suspended under paragraph (2)(B) or (3)(C) of section 1857(g) because of a failure of the plan to meet applicable requirements; or

[(D)] *(E)* the individual meets such other exceptional conditions as the Secretary may provide*, taking into account the health or well-being of the individual*.

* * * * * * *

(h) APPROVAL OF MARKETING MATERIAL AND APPLICATION FORMS.—

(1) * * *

* * * * * * *

(4) PROHIBITION OF CERTAIN MARKETING PRACTICES.—Each Medicare+Choice organization shall conform to fair marketing standards, in relation to Medicare+Choice plans offered under this part, included in the standards established under section 1856. Such standards—

(A) * * *

* * * * * * *

Beginning on the effective date of the implementation of the regulations under subparagraph (A) or (B) of section 1856(c)(2), each Medicare Advantage organization with respect to a Medicare Advantage plan offered by the organization (and agents of such organization) shall comply with the standardized marketing requirements under section 1856(c).

* * * * * * *

(p) PUBLICATION OF MEDICAL LOSS RATIOS AND OTHER COST-RELATED INFORMATION.—

(1) IN GENERAL.—The Secretary shall publish, not later than November 1 of each year (beginning with 2011), for each MA plan contract, the medical loss ratio of the plan in the previous year.

(2) SUBMISSION OF DATA.—

(A) IN GENERAL.—Each MA organization shall submit to the Secretary, in a form and manner specified by the Secretary, data necessary for the Secretary to publish the medical loss ratio on a timely basis.

(B) DATA FOR 2010 AND 2011.—The data submitted under subparagraph (A) for 2010 and for 2011 shall be consistent in content with the data reported as part of the MA plan bid in June 2009 for 2010.

(C) USE OF STANDARDIZED ELEMENTS AND DEFINITIONS.—The data to be submitted under subparagraph (A) relating to medical loss ratio for a year, beginning with 2012, shall be submitted based on the standardized elements and definitions developed under paragraph (3).

(3) DEVELOPMENT OF DATA REPORTING STANDARDS.—

(A) IN GENERAL.—The Secretary shall develop and implement standardized data elements and definitions for reporting under this subsection, for contract years beginning with 2012, of data necessary for the calculation of the medical loss ratio for MA plans. Not later than December 31,

2010, the Secretary shall publish a report describing the elements and definitions so developed.

(B) CONSULTATION.—The Secretary shall consult with the Health Choices Commissioner, representatives of MA organizations, experts on health plan accounting systems, and representatives of the National Association of Insurance Commissioners, in the development of such data elements and definitions.

(4) MEDICAL LOSS RATIO TO BE DEFINED.—For purposes of this part, the term "medical loss ratio" has the meaning given such term by the Secretary, taking into account the meaning given such term by the Health Choices Commissioner under section 116 of the America's Affordable Health Choices Act of 2009.

BENEFITS AND BENEFICIARY PROTECTIONS

SEC. 1852. (a) BASIC BENEFITS.—

(1) REQUIREMENT.—

(A) IN GENERAL.—Except as provided in section 1859(b)(3) for MSA plans and except as provided in paragraph (6) for MA regional plans, each Medicare+Choice plan shall provide to members enrolled under this part, through providers and other persons that meet the applicable requirements of this title and part A of title XI, benefits under the original medicare fee-for-service program option (and, for plan years before 2006, additional benefits required under section 1854(f)(1)(A)) *with cost-sharing that is no greater (and may be less) than the cost-sharing that would otherwise be imposed under such program option.*

(B) BENEFITS UNDER THE ORIGINAL MEDICARE FEE-FOR-SERVICE PROGRAM OPTION DEFINED.—

(i) IN GENERAL.—For purposes of this part, the term "benefits under the original medicare fee-for-service program option" means those items and services (other than hospice care) for which benefits are available under parts A and B to individuals entitled to benefits under part A and enrolled under part B, with cost-sharing for those services as required under parts A and B ⟦or an actuarially equivalent level of cost-sharing as determined in this part⟧.

⟦(ii) SPECIAL RULE FOR REGIONAL PLANS.—In the case of an MA regional plan in determining an actuarially equivalent level of cost-sharing with respect to benefits under the original medicare fee-for-service program option, there shall only be taken into account, with respect to the application of section 1858(b)(2), such expenses only with respect to subparagraph (A) of such section.⟧

(ii) PERMITTING USE OF FLAT COPAYMENT OR PER DIEM RATE.—Nothing in clause (i) shall be construed as prohibiting a Medicare Advantage plan from using a flat copayment or per diem rate, in lieu of the cost-sharing that would be imposed under part A or B, so long as the amount of the cost-sharing imposed does not exceed the amount of the cost-sharing that would

be imposed under the respective part if the individual were not enrolled in a plan under this part.

* * * * * * *

[(7) LIMITATION ON COST-SHARING FOR DUAL ELIGIBLES AND QUALIFIED MEDICARE BENEFICIARIES.—In the case of an individual who is a full-benefit dual eligible individual (as defined in section 1935(c)(6)) or a qualified medicare beneficiary (as defined in section 1905(p)(1)) and who is enrolled in a specialized Medicare Advantage plan for special needs individuals described in section 1859(b)(6)(B)(ii), the plan may not impose cost-sharing that exceeds the amount of cost-sharing that would be permitted with respect to the individual under title XIX if the individual were not enrolled in such plan.]

(7) LIMITATION ON COST-SHARING FOR DUAL ELIGIBLES AND QUALIFIED MEDICARE BENEFICIARIES.—In the case of a individual who is a full-benefit dual eligible individual (as defined in section 1935(c)(6)) or a qualified medicare beneficiary (as defined in section 1905(p)(1)) who is enrolled in a Medicare Advantage plan, the plan may not impose cost-sharing that exceeds the amount of cost-sharing that would be permitted with respect to the individual under this title and title XIX if the individual were not enrolled with such plan.

* * * * * * *

PAYMENTS TO MEDICARE+CHOICE ORGANIZATIONS

SEC. 1853. (a) PAYMENTS TO ORGANIZATIONS.—

(1) MONTHLY PAYMENTS.—

(A) * * *

* * * * * * *

(C) DEMOGRAPHIC ADJUSTMENT, INCLUDING ADJUSTMENT FOR HEALTH STATUS.—

(i) * * *

(ii) APPLICATION DURING PHASE-OUT OF BUDGET NEUTRALITY FACTOR.—For 2006 [through 2010] *and each subsequent year*:

(I) * * *

(II) In order to ensure payment accuracy, the Secretary shall *periodically* conduct an analysis of the differences described in subclause (I). The Secretary shall complete such analysis by a date necessary to ensure that the results of such analysis are incorporated *on a timely basis* into the risk scores [only for 2008, 2009, and 2010] *for 2008 and subsequent years*. In conducting such analysis, the Secretary shall use data submitted with respect to 2004 and subsequent years, as available.

* * * * * * *

(j) COMPUTATION OF BENCHMARK AMOUNTS.—For purposes of this part, *subject to subsection (o),* the term "MA area-specific non-drug monthly benchmark amount" means for a month in a year—

(1) with respect to—

(A) a service area that is entirely within an MA local area, subject to section 1860C–1(d)(2)(A), an amount equal to 1/12 of the annual MA capitation rate under section 1853(c)(1) (or, [beginning with 2007] *for 2007, 2008, 2009, and 2010*, 1/12 of the applicable amount determined under subsection (k)(1)*, or, beginning with 2011, 1/12 of the blended benchmark amount determined under subsection (n)(1)*) for the area for the year, adjusted as appropriate (for years before 2007) for the purpose of risk adjustment; or

* * * * * * *

(n) DETERMINATION OF BLENDED BENCHMARK AMOUNT.—

(1) IN GENERAL.—For purposes of subsection (j), subject to paragraphs (3) and (4), the term "blended benchmark amount" means for an area—

(A) for 2011 the sum of—

(i) 2/3 of the applicable amount (as defined in subsection (k)) for the area and year; and

(ii) 1/3 of the amount specified in paragraph (2) for the area and year;

(B) for 2012 the sum of—

(i) 1/3 of the applicable amount for the area and year; and

(ii) 2/3 of the amount specified in paragraph (2) for the area and year; and

(C) for a subsequent year the amount specified in paragraph (2) for the area and year.

(2) SPECIFIED AMOUNT.—The amount specified in this paragraph for an area and year is the amount specified in subsection (c)(1)(D)(i) for the area and year adjusted (in a manner specified by the Secretary) to take into account the phase-out in the indirect costs of medical education from capitation rates described in subsection (k)(4).

(3) FEE-FOR-SERVICE PAYMENT FLOOR.—In no case shall the blended benchmark amount for an area and year be less than the amount specified in paragraph (2).

(4) EXCEPTION FOR PACE PLANS.—This subsection shall not apply to payments to a PACE program under section 1894.

(o) QUALITY BASED PAYMENT ADJUSTMENT.—

(1) HIGH QUALITY PLAN ADJUSTMENT.—For years beginning with 2011, in the case of a Medicare Advantage plan that is identified (under paragraph (3)(E)(ii)) as a high quality MA plan with respect to the year, the blended benchmark amount under subsection (n)(1) shall be increased—

(A) for 2011, by 1.0 percent;

(B) for 2012, by 2.0 percent; and

(C) for a subsequent year, by 3.0 percent.

(2) IMPROVED QUALITY PLAN ADJUSTMENT.—For years beginning with 2011, in the case of a Medicare Advantage plan that is identified (under paragraph (3)(E)(iii)) as an improved quality MA plan with respect to the year, blended benchmark amount under subsection (n)(1) shall be increased—

(A) for 2011, by 0.33 percent;

(B) for 2012, by 0.66 percent; and

(C) for a subsequent year, by 1.0 percent.

(3) DETERMINATIONS OF QUALITY.—

(A) QUALITY PERFORMANCE.—The Secretary shall provide for the computation of a quality performance score for each Medicare Advantage plan to be applied for each year beginning with 2010.

(B) COMPUTATION OF SCORE.—

(i) FOR YEARS BEFORE 2014.—For years before 2014, the quality performance score for a Medicare Advantage plan shall be computed based on a blend (as designated by the Secretary) of the plan's performance on—

(I) HEDIS effectiveness of care quality measures;

(II) CAHPS quality measures; and

(III) such other measures of clinical quality as the Secretary may specify.

Such measures shall be risk-adjusted as the Secretary deems appropriate.

(ii) ESTABLISHMENT OF OUTCOME-BASED MEASURES.—By not later than for 2013 the Secretary shall implement reporting requirements for quality under this section on measures selected under clause (iii) that reflect the outcomes of care experienced by individuals enrolled in Medicare Advantage plans (in addition to measures described in clause (i)). Such measures may include—

(I) measures of rates of admission and readmission to a hospital;

(II) measures of prevention quality, such as those established by the Agency for Healthcare Research and Quality (that include hospital admission rates for specified conditions);

(III) measures of patient mortality and morbidity following surgery;

(IV) measures of health functioning (such as limitations on activities of daily living) and survival for patients with chronic diseases;

(V) measures of patient safety; and

(VI) other measure of outcomes and patient quality of life as determined by the Secretary.

Such measures shall be risk-adjusted as the Secretary deems appropriate. In determining the quality measures to be used under this clause, the Secretary shall take into consideration the recommendations of the Medicare Payment Advisory Commission in its report to Congress under section 168 of the Medicare Improvements for Patients and Providers Act of 2008 (Public Law 110–275) and shall provide preference to measures collected on and comparable to measures used in measuring quality under parts A and B.

(iii) RULES FOR SELECTION OF MEASURES.—The Secretary shall select measures for purposes of clause (ii) consistent with the following:

(I) The Secretary shall provide preference to clinical quality measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a).

(II) Prior to any measure being selected under this clause, the Secretary shall publish in the Federal Register such measure and provide for a period of public comment on such measure.

(iv) TRANSITIONAL USE OF BLEND.—For payments for 2014 and 2015, the Secretary may compute the quality performance score for a Medicare Advantage plan based on a blend of the measures specified in clause (i) and the measures described in clause (ii) and selected under clause (iii).

(v) USE OF QUALITY OUTCOMES MEASURES.—For payments beginning with 2016, the preponderance of measures used under this paragraph shall be quality outcomes measures described in clause (ii) and selected under clause (iii).

(C) DATA USED IN COMPUTING SCORE.—Such score for application for—

(i) payments in 2011 shall be based on quality performance data for plans for 2009; and

(ii) payments in 2012 and a subsequent year shall be based on quality performance data for plans for the second preceding year.

(D) REPORTING OF DATA.—Each Medicare Advantage organization shall provide for the reporting to the Secretary of quality performance data described in subparagraph (B) (in order to determine a quality performance score under this paragraph) in such time and manner as the Secretary shall specify.

(E) RANKING OF PLANS.—

(i) INITIAL RANKING.—Based on the quality performance score described in subparagraph (B) achieved with respect to a year, the Secretary shall rank plan performance—

(I) from highest to lowest based on absolute scores; and

(II) from highest to lowest based on percentage improvement in the score for the plan from the previous year.

A plan which does not report quality performance data under subparagraph (D) shall be counted, for purposes of such ranking, as having the lowest plan performance and lowest percentage improvement.

(ii) IDENTIFICATION OF HIGH QUALITY PLANS IN TOP QUINTILE BASED ON PROJECTED ENROLLMENT.—The Secretary shall, based on the scores for each plan under clause (i)(I) and the Secretary's projected enrollment for each plan and subject to clause (iv), identify those Medicare Advantage plans with the highest score that, based upon projected enrollment, are projected to include in the aggregate 20 percent of the total projected enrollment for the year. For purposes of this subsection, a plan so identified shall be referred to in this subsection as a "high quality MA plan".

(iii) IDENTIFICATION OF IMPROVED QUALITY PLANS IN TOP QUINTILE BASED ON PROJECTED ENROLLMENT.—

The Secretary shall, based on the percentage improvement score for each plan under clause (i)(II) and the Secretary's projected enrollment for each plan and subject to clause (iv), identify those Medicare Advantage plans with the greatest percentage improvement score that, based upon projected enrollment, are projected to include in the aggregate 20 percent of the total projected enrollment for the year. For purposes of this subsection, a plan so identified that is not a high quality plan for the year shall be referred to in this subsection as an "improved quality MA plan".

(iv) AUTHORITY TO DISQUALIFY CERTAIN PLANS.—In applying clauses (ii) and (iii), the Secretary may determine not to identify a Medicare Advantage plan if the Secretary has identified deficiencies in the plan's compliance with rules for such plans under this part.

(F) NOTIFICATION.—The Secretary, in the annual announcement required under subsection (b)(1)(B) in 2011 and each succeeding year, shall notify the Medicare Advantage organization that is offering a high quality plan or an improved quality plan of such identification for the year and the quality performance payment adjustment for such plan for the year. The Secretary shall provide for publication on the website for the Medicare program of the information described in the previous sentence.

PREMIUMS AND BID AMOUNTS

SEC. 1854. (a) SUBMISSION OF PROPOSED PREMIUMS, BID AMOUNTS, AND RELATED INFORMATION.—

(1) * * *

* * * * * * *

(5) REVIEW.—

(A) * * *

* * * * * * *

(C) REJECTION OF BIDS.—Nothing in this section shall be construed as requiring the Secretary to accept any or every bid by an MA organization under this subsection.

* * * * * * *

ESTABLISHMENT OF STANDARDS

SEC. 1856. (a) * * *

(b) ESTABLISHMENT OF OTHER STANDARDS.—

(1) IN GENERAL.—The Secretary shall establish by regulation other standards (not described in subsection (a) *or subsection (c)*) for Medicare+Choice organizations and plans consistent with, and to carry out, this part. The Secretary shall publish such regulations by June 1, 1998. In order to carry out this requirement in a timely manner, the Secretary may promulgate regulations that take effect on an interim basis, after notice and pending opportunity for public comment.

* * * * * * *

(3) RELATION TO STATE LAWS.—The standards established under this part shall supersede any State law or regulation (other than State licensing laws [or State], *State* laws relating to plan solvency*, or State laws or regulations enacting the standardized marketing requirements under subsection (c)*) with respect to MA plans which are offered by MA organizations under this part.

* * * * * * *

(c) STANDARDIZED MARKETING REQUIREMENTS.—

(1) DEVELOPMENT BY THE NAIC.—

(A) REQUIREMENTS.—The Secretary shall request the National Association of Insurance Commissioners (in this subsection referred to as the "NAIC") to—

(i) develop standardized marketing requirements for Medicare Advantage organizations with respect to Medicare Advantage plans and PDP sponsors with respect to prescription drug plans under part D; and

(ii) submit a report containing such requirements to the Secretary by not later than the date that is 9 months after the date of the enactment of this subsection.

(B) PROHIBITED ACTIVITIES.—Such requirements shall include prohibitions on the prohibited activities described in section 1851(j)(1).

(C) LIMITATIONS.—Such requirements shall establish limitations that include at least the limitations described in section 1851(j)(2), except for those relating to compensation.

(D) ELECTION FORM.—Such requirements may prohibit a Medicare Advantage organization or a PDP sponsor (or an agent of such an organization or sponsor) from completing any portion of any election form used to carry out elections under section 1851 or 1860D–1 on behalf of any individual.

(E) AGENT AND BROKER COMMISSIONS AND COMPENSATION.—Such requirements shall establish standards—

(i) for fair and appropriate commissions for agents and brokers of Medicare Advantage organizations and PDP sponsors, including a prohibition on extra bonuses or incentives;

(ii) for the disclosure of such commissions; and

(iii) for the use of compensation for agents and brokers other than such commissions.

Such standards shall ensure that the use of compensation creates incentives for agents and brokers to enroll individuals in the Medicare Advantage plan that is intended to best meet their health care needs.

(F) CERTAIN CONDUCT OF AGENTS.—Such requirements shall address the conduct of agents engaged in on-site promotion at a facility of an organization with which the Medicare Advantage organization or PDP sponsor has a co-branding relationship.

(G) OTHER STANDARDS.—Such requirements may establish such other standards relating to unfair trade practices and marketing under Medicare Advantage plans and prescription drug plans under part D as the NAIC determines appropriate.

(2) IMPLEMENTATION OF REQUIREMENTS.—

(A) ADOPTION OF NAIC DEVELOPED REQUIREMENTS.—If the NAIC develops standardized marketing requirements and submits the report pursuant to paragraph (1), the Secretary shall promulgate regulations for the adoption of such requirements. The Secretary shall ensure that such regulations take effect beginning with the first open enrollment period beginning 12 months after the date of the enactment of this subsection.

(B) REQUIREMENTS IF NAIC DOES NOT SUBMIT REPORT.—If the NAIC does not develop standardized marketing requirements and submit the report pursuant to paragraph (1), the Secretary shall promulgate regulations for standardized marketing requirements for Medicare Advantage organizations with respect to Medicare Advantage plans and PDP sponsors with respect to prescription drug plans under part D. Such regulations shall meet the requirements of subparagraphs (B) through (F) of paragraph (1), and may establish such other standards relating to marketing under Medicare Advantage plans and prescription drug plans as the Secretary determines appropriate. The Secretary shall ensure that such regulations take effect beginning with the first open enrollment period beginning 12 months after the date of the enactment of this subsection.

(C) CONSULTATION.—In establishing requirements under this subsection, the NAIC or Secretary (as the case may be) shall consult with a working group composed of representatives of Medicare Advantage organizations and PDP sponsors, consumer groups, and other qualified individuals. Such representatives shall be selected in a manner so as to insure balanced representation among the interested groups.

(3) STATE REPORTING OF VIOLATIONS OF STANDARDIZED MARKETING REQUIREMENTS.—The Secretary shall request that States report any violations of the standardized marketing requirements under the regulations under subparagraph (A) or (B) of paragraph (2) to national and regional offices of the Centers for Medicare & Medicaid Services.

(4) REPORT.—The Secretary shall submit an annual report to Congress on the enforcement of the standardized marketing requirements under the regulations under subparagraph (A) or (B) of paragraph (2), together with such recommendations as the Secretary determines appropriate. Such report shall include—

(A) a list of any alleged violations of such requirements reported to the Secretary by a State, a Medicare Advantage organization, or a PDP sponsor; and

(B) the disposition of such reported violations.

CONTRACTS WITH MEDICARE+CHOICE ORGANIZATIONS

SEC. 1857. (a) * * *

* * * * * * *

(d) PROTECTIONS AGAINST FRAUD AND BENEFICIARY PROTECTIONS.—

(1) PERIODIC AUDITING.—The Secretary shall provide for the annual auditing of the financial records (including data relating to medicare utilization and costs, including allowable costs under section 1858(c)), *and data submitted with respect to risk adjustment under section 1853(a)(3)* of at least one-third of the Medicare+Choice organizations offering Medicare+Choice plans under this part. The Comptroller General shall monitor auditing activities conducted under this subsection.

(2) INSPECTION AND AUDIT.—Each contract under this section shall provide that the Secretary, or any person or organization designated by the Secretary—

(A) shall have the right to *timely* inspect or otherwise evaluate (i) the quality, appropriateness, and timeliness of services performed under the contract, and (ii) the facilities of the organization when there is reasonable evidence of some need for such inspection, and

(B) shall have the right to *timely* audit and inspect any books and records of the Medicare+Choice organization that pertain (i) to the ability of the organization to bear the risk of potential financial losses, or (ii) to services performed or determinations of amounts payable under the contract.

* * * * * * *

(7) PERIOD FOR SUBMISSION OF CLAIMS.—The contract shall require an MA organization or PDP sponsor to require any provider of services under contract with, in partnership with, or affiliated with such organization or sponsor to ensure that, with respect to items and services furnished by such provider to an enrollee of such organization, written request, signed by such enrollee, except in cases in which the Secretary finds it impracticable for the enrollee to do so, is filed for payment for such items and services in such form, in such manner, and by such person or persons as the Secretary may by regulation prescribe, no later than the close of the 1 calendar year period after such items and services are furnished. In applying the previous sentence, the Secretary may specify exceptions to the 1 calendar year period specified.

(e) ADDITIONAL CONTRACT TERMS.—

(1) * * *

* * * * * * *

(4) REQUIREMENT FOR MINIMUM MEDICAL LOSS RATIO.—If the Secretary determines for a contract year (beginning with 2014) that an MA plan has failed to have a medical loss ratio (as defined in section 1851(p)(4)) of at least .85—

(A) the Secretary shall require the Medicare Advantage organization offering the plan to give enrollees a rebate (in the second succeeding contract year) of premiums under this part (or part B or part D, if applicable) by such amount as would provide for a benefits ratio of at least .85;

(B) for 3 consecutive contract years, the Secretary shall not permit the enrollment of new enrollees under the plan for coverage during the second succeeding contract year; and

(C) the Secretary shall terminate the plan contract if the plan fails to have such a medical loss ratio for 5 consecutive contract years.

(5) ENFORCEMENT OF AUDITS AND DEFICIENCIES.—

(A) INFORMATION IN CONTRACT.—The Secretary shall require that each contract with an MA organization under this section shall include terms that inform the organization of the provisions in subsection (d).

(B) ENFORCEMENT AUTHORITY.—The Secretary is authorized, in connection with conducting audits and other activities under subsection (d), to take such actions, including pursuit of financial recoveries, necessary to address deficiencies identified in such audits or other activities.

(f) PROMPT PAYMENT BY MEDICARE+CHOICE ORGANIZATION.—

(1) * * *

* * * * * * *

(3) INCORPORATION OF CERTAIN PRESCRIPTION DRUG PLAN CONTRACT REQUIREMENTS.—The following provisions shall apply to contracts with a Medicare Advantage organization offering an MA–PD plan in the same manner as they apply to contracts with a PDP sponsor offering a prescription drug plan under part D:

(A) * * *

[(B) SUBMISSION OF CLAIMS BY PHARMACIES LOCATED IN OR CONTRACTING WITH LONG-TERM CARE FACILITIES.—Section 1860D–12(b)(5).]

[(C)] *(B)* REGULAR UPDATE OF PRESCRIPTION DRUG PRICING STANDARD.—Section 1860D–12(b)(6).

(C) REPORTING REQUIREMENT RELATED TO REBATE FOR FULL-BENEFIT DUAL ELIGIBLE MEDICARE DRUG PLAN ENROLLEES.—Section 1860D–12(b)(7).

(g) INTERMEDIATE SANCTIONS.—

(1) IN GENERAL.—If the Secretary determines that a Medicare+Choice organization with a contract under this section—

(A) * * *

* * * * * * *

(F) fails to comply with the applicable requirements of section 1852(j)(3) or 1852(k)(2)(A)(ii); [or]

(G) employs or contracts with any individual or entity that is excluded from participation under this title under section 1128 or 1128A for the provision of health care, utilization review, medical social work, or administrative services or employs or contracts with any entity for the provision (directly or indirectly) through such an excluded individual or entity of such services;

(H) fails substantially to provide language services to limited English proficient beneficiaries enrolled in the plan that are required under law;

(I) except as provided under subparagraph (C) or (D) of section 1860D–1(b)(1), enrolls an individual in any plan under this part without the prior consent of the individual or the designee of the individual;

(J) transfers an individual enrolled under this part from one plan to another without the prior consent of the individual or the designee of the individual or solely for the purpose of earning a commission;

(K) fails to comply with marketing restrictions described in subsections (h) and (j) of section 1851 or applicable implementing regulations or guidance; or

(L) employs or contracts with any individual or entity who engages in the conduct described in subparagraphs (A) through (K) of this paragraph;

the Secretary may provide, in addition to any other remedies authorized by law, for any of the remedies described in paragraph (2). *The Secretary may provide, in addition to any other remedies authorized by law, for any of the remedies described in paragraph (2), if the Secretary determines that any employee or agent of such organization, or any provider or supplier who contracts with such organization, has engaged in any conduct described in subparagraphs (A) through (L) of this paragraph.*

(2) REMEDIES.—The remedies described in this paragraph are—

(A) civil money penalties of not more than $25,000 for each determination under paragraph (1) or, with respect to a determination under subparagraph (D) or (E)(i) of such paragraph, of not more than $100,000 for each such determination, *except with respect to a determination under subparagraph (E), an assessment of not more than 3 times the amount claimed by such plan or plan sponsor based upon the misrepresentation or falsified information involved,* plus, with respect to a determination under paragraph (1)(B), double the excess amount charged in violation of such paragraph (and the excess amount charged shall be deducted from the penalty and returned to the individual concerned), and plus, with respect to a determination under paragraph (1)(D), $15,000 for each individual not enrolled as a result of the practice involved,

* * * * * * *

(i) MEDICARE+CHOICE PROGRAM COMPATIBILITY WITH EMPLOYER OR UNION GROUP HEALTH PLANS.—

(1) * * *

(2) EMPLOYER SPONSORED MA PLANS.—To facilitate the offering of MA plans by employers, labor organizations, or the trustees of a fund established by one or more employers or labor organizations (or combination thereof) to furnish benefits to the entity's employees, former employees (or combination thereof) or members or former members (or combination thereof) of the labor organizations, the Secretary may waive or modify requirements that hinder the design of, the offering of, or the enrollment in such MA plans*, but only if 90 percent of the Medicare Advantage eligible individuals enrolled under such plan reside in a county in which the MA organization offers an MA local plan*. Notwithstanding section 1851(g), an MA plan described in the previous sentence may restrict the enrollment of individuals under this part to individuals who are beneficiaries and participants in such plan.

SPECIAL RULES FOR MA REGIONAL PLANS

SEC. 1858. (a) * * *

* * * * * * *

[(e) STABILIZATION FUND.—

[(1) ESTABLISHMENT.—The Secretary shall establish under this subsection an MA Regional Plan Stabilization Fund (in this subsection referred to as the "Fund") which shall be available for two purposes:

[(A) PLAN ENTRY.—To provide incentives to have MA regional plans offered in each MA region under paragraph (3).

[(B) PLAN RETENTION.—To provide incentives to retain MA regional plans in certain MA regions with below-national-average MA market penetration under paragraph (4).

[(2) FUNDING.—

[(A) INITIAL FUNDING.—

[(i) IN GENERAL.—There shall be available to the Fund, for expenditures from the Fund during 2014, $1.

[(ii) PAYMENT FROM TRUST FUNDS.—Such amount shall be available to the Fund, as expenditures are made from the Fund, from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in the proportion specified in section 1853(f).

[(B) ADDITIONAL FUNDING FROM SAVINGS.—

[(i) IN GENERAL.—There shall also be made available to the Fund, 50 percent of savings described in clause (ii).

[(ii) SAVINGS.—The savings described in this clause are 25 percent of the average per capita savings described in section 1854(b)(4)(C) for which monthly rebates are provided under section 1854(b)(1)(C) in the fiscal year involved that are attributable to MA regional plans.

[(iii) AVAILABILITY.—Funds made available under this subparagraph shall be transferred into a special account in the Treasury from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund in the proportion specified in section 1853(f) on a monthly basis.

[(C) OBLIGATIONS.—Amounts in the Fund shall be available in advance of appropriations to MA regional plans in qualifying MA regions only in accordance with paragraph (5).

[(D) ORDERING.—Expenditures from the Fund shall first be made from amounts made available under subparagraph (A).

[(3) PLAN ENTRY FUNDING.—

[(A) IN GENERAL.—Funding is available under this paragraph for a year only as follows:

[(i) NATIONAL PLAN.—For a national bonus payment described in subparagraph (B) for the offering by a single MA organization of an MA regional plan in each

MA region in the year, but only if there was not such a plan offered in each such region in the previous year. Funding under this clause is only available with respect to any individual MA organization for a single year, but may be made available to more than one such organization in the same year.

[(ii) REGIONAL PLANS.—Subject to clause (iii), for an increased amount under subparagraph (C) for an MA regional plan offered in an MA region which did not have any MA regional plan offered in the prior year.

[(iii) LIMITATION ON REGIONAL PLAN FUNDING IN CASE OF NATIONAL PLAN.—In no case shall there be any payment adjustment under subparagraph (C) for a year for which a national payment adjustment is made under subparagraph (B).

[(B) NATIONAL BONUS PAYMENT.—The national bonus payment under this subparagraph shall—

[(i) be available to an MA organization only if the organization offers MA regional plans in every MA region;

[(ii) be available with respect to all MA regional plans of the organization regardless of whether any other MA regional plan is offered in any region; and

[(iii) subject to amounts available under paragraph (5) for a year, be equal to 3 percent of the benchmark amount otherwise applicable for each MA regional plan offered by the organization.

[(C) REGIONAL PAYMENT ADJUSTMENT.—

[(i) IN GENERAL.—The increased amount under this subparagraph for an MA regional plan in an MA region for a year shall be an amount, determined by the Secretary, based on the bid submitted for such plan (or plans) and shall be available to all MA regional plans offered in such region and year. Such amount may be based on the mean, mode, or median, or other measure of such bids and may vary from region to region. The Secretary may not limit the number of plans or bids in a region.

[(ii) MULTI-YEAR FUNDING.—

[(I) IN GENERAL.—Subject to amounts available under paragraph (5), funding under this subparagraph shall be available for a period determined by the Secretary.

[(II) REPORT.—If the Secretary determines that funding will be provided for a second consecutive year with respect to an MA region, the Secretary shall submit to the Congress a report that describes the underlying market dynamics in the region and that includes recommendations concerning changes in the payment methodology otherwise provided for MA regional plans under this part.

[(iii) APPLICATION TO ALL PLANS IN A REGION.—Funding under this subparagraph with respect to an

MA region shall be made available with respect to all MA regional plans offered in the region.

[(iv) LIMITATION ON AVAILABILITY OF PLAN RETENTION FUNDING IN NEXT YEAR.—If an increased amount is made available under this subparagraph with respect to an MA region for a period determined by the Secretary under clause (ii)(I), in no case shall funding be available under paragraph (4) with respect to MA regional plans offered in the region in the year following such period.

[(D) APPLICATION.—Any additional payment under this paragraph provided for an MA regional plan for a year shall be treated as if it were an addition to the benchmark amount otherwise applicable to such plan and year, but shall not be taken into account in the computation of any benchmark amount for any subsequent year.

[(4) PLAN RETENTION FUNDING.—

[(A) IN GENERAL.—Funding is available under this paragraph for a year with respect to MA regional plans offered in an MA region for the increased amount specified in subparagraph (B) but only if the region meets the requirements of subparagraphs (C) and (E).

[(B) PAYMENT INCREASE.—The increased amount under this subparagraph for an MA regional plan in an MA region for a year shall be an amount, determined by the Secretary, that does not exceed the greater of—

[(i) 3 percent of the benchmark amount applicable in the region; or

[(ii) such amount as (when added to the benchmark amount applicable to the region) will result in the ratio of—

[(I) such additional amount plus the benchmark amount computed under section 1854(b)(4)(B)(i) for the region and year, to the adjusted average per capita cost for the region and year, as estimated by the Secretary under section 1876(a)(4) and adjusted as appropriate for the purpose of risk adjustment; being equal to

[(II) the weighted average of such benchmark amounts for all the regions and such year, to the average per capita cost for the United States and such year, as estimated by the Secretary under section 1876(a)(4) and adjusted as appropriate for the purpose of risk adjustment.

[(C) REGIONAL REQUIREMENTS.—The requirements of this subparagraph for an MA region for a year are as follows:

[(i) NOTIFICATION OF PLAN EXIT.—The Secretary has received notice (in such form and manner as the Secretary specifies) before a year that one or more MA regional plans that were offered in the region in the previous year will not be offered in the succeeding year.

[(ii) REGIONAL PLANS AVAILABLE FROM FEWER THAN 2 MA ORGANIZATIONS IN THE REGION.—The Secretary determines that if the plans referred to in clause (i)

are not offered in the year, fewer than 2 MA organizations will be offering MA regional plans in the region in the year involved.

[(iii) PERCENTAGE ENROLLMENT IN MA REGIONAL PLANS BELOW NATIONAL AVERAGE.—For the previous year, the Secretary determines that the average percentage of MA eligible individuals residing in the region who are enrolled in MA regional plans is less than the average percentage of such individuals in the United States enrolled in such plans.

[(D) APPLICATION.—Any additional payment under this paragraph provided for an MA regional plan for a year shall be treated as if it were an addition to the benchmark amount otherwise applicable to such plan and year, but shall not be taken into account in the computation of any benchmark amount for any subsequent year.

[(E) 2-CONSECUTIVE-YEAR LIMITATION.—

[(i) IN GENERAL.—In no case shall any funding be available under this paragraph in an MA region in a period of consecutive years that exceeds 2 years.

[(ii) REPORT.—If the Secretary determines that funding will be provided under this paragraph for a second consecutive year with respect to an MA region, the Secretary shall submit to the Congress a report that describes the underlying market dynamics in the region and that includes recommendations concerning changes in the payment methodology otherwise provided for MA regional plans under this part.

[(5) FUNDING LIMITATION.—

[(A) IN GENERAL.—The total amount expended from the Fund as a result of the application of this subsection through the end of a calendar year may not exceed the amount available to the Fund as of the first day of such year. For purposes of this subsection, amounts that are expended under this title insofar as such amounts would not have been expended but for the application of this subsection shall be counted as amounts expended as a result of such application.

[(B) APPLICATION OF LIMITATION.—The Secretary may obligate funds from the Fund for a year only if the Secretary determines (and the Chief Actuary of the Centers for Medicare & Medicaid Services and the appropriate budget officer certify) that there are available in the Fund at the beginning of the year sufficient amounts to cover all such obligations incurred during the year consistent with subparagraph (A). The Secretary shall take such steps, in connection with computing additional payment amounts under paragraphs (3) and (4) and including limitations on enrollment in MA regional plans receiving such payments, as will ensure that sufficient funds are available to make such payments for the entire year. Funds shall only be made available from the Fund pursuant to an apportionment made in accordance with applicable procedures.

[(6) SECRETARY REPORTS.—Not later than April 1 of each year (beginning in 2008), the Secretary shall submit a report

to Congress and the Comptroller General of the United States that includes—

[(A) a detailed description of—

[(i) the total amount expended as a result of the application of this subsection in the previous year compared to the total amount that would have been expended under this title in the year if this subsection had not been enacted;

[(ii) the projections of the total amount that will be expended as a result of the application of this subsection in the year in which the report is submitted compared to the total amount that would have been expended under this title in the year if this subsection had not been enacted;

[(iii) amounts remaining within the funding limitation specified in paragraph (5); and

[(iv) the steps that the Secretary will take under paragraph (5)(B) to ensure that the application of this subsection will not cause expenditures to exceed the amount available in the Fund; and

[(B) a certification from the Chief Actuary of the Centers for Medicare & Medicaid Services that the description provided under subparagraph (A) is reasonable, accurate, and based on generally accepted actuarial principles and methodologies.]

* * * * * * *

DEFINITIONS; MISCELLANEOUS PROVISIONS

SEC. 1859. (a) * * *

* * * * * * *

(f) REQUIREMENTS REGARDING ENROLLMENT IN SPECIALIZED MA PLANS FOR SPECIAL NEEDS INDIVIDUALS.—

(1) REQUIREMENTS FOR ENROLLMENT.—In the case of a specialized MA plan for special needs individuals (as defined in subsection (b)(6)), notwithstanding any other provision of this part and in accordance with regulations of the Secretary and for periods before [January 1, 2011] *January 1, 2013 (or January 1, 2016, in the case of a plan described in section 1177(b)(1) of the America's Affordable Health Choices Act of 2009)*, the plan may restrict the enrollment of individuals under the plan to individuals who are within one or more classes of special needs individuals.

* * * * * * *

(4) ADDITIONAL REQUIREMENTS FOR SEVERE OR DISABLING CHRONIC CONDITION SNPS.—In the case of a specialized MA plan for special needs individuals described in subsection (b)(6)(B)(iii), the applicable requirements described in this paragraph are as follows:

(A) * * *

* * * * * * *

(C) The plan does not enroll an individual on or after January 1, 2011, other than during an annual, coordinated open enrollment period or when at the time of the diagnosis

of the disease or condition that qualifies the individual as an individual described in subsection (b)(6)(B)(iii).

* * * * * * *

[COMPARATIVE COST ADJUSTMENT (CCA) PROGRAM

[SEC. 1860C–1. (a) ESTABLISHMENT OF PROGRAM.—

[(1) IN GENERAL.—The Secretary shall establish a program under this section (in this section referred to as the "CCA program") for the application of comparative cost adjustment in CCA areas selected under this section.

[(2) DURATION.—The CCA program shall begin January 1, 2010, and shall extend over a period of 6 years, and end on December 31, 2015.

[(3) REPORT.—Upon the completion of the CCA program, the Secretary shall submit a report to Congress. Such report shall include the following, with respect to both this part and the original medicare fee-for-service program:

[(A) An evaluation of the financial impact of the CCA program.

[(B) An evaluation of changes in access to physicians and other health care providers.

[(C) Beneficiary satisfaction.

[(D) Recommendations regarding any extension or expansion of the CCA program.

[(b) REQUIREMENTS FOR SELECTION OF CCA AREAS.—

[(1) CCA AREA DEFINED.—

[(A) IN GENERAL.—For purposes of this section, the term "CCA area" means an MSA that meets the requirements of paragraph (2) and is selected by the Secretary under subsection (c).

[(B) MSA DEFINED.—For purposes of this section, the term "MSA" means a Metropolitan Statistical Area (or such similar area as the Secretary recognizes).

[(2) REQUIREMENTS FOR CCA AREAS.—The requirements of this paragraph for an MSA to be a CCA area are as follows:

[(A) MA ENROLLMENT REQUIREMENT.—For the reference month (as defined under section 1858(f)(4)(B)) with respect to 2010, at least 25 percent of the total number of MA eligible individuals who reside in the MSA were enrolled in an MA local plan described in section 1851(a)(2)(A)(i).

[(B) 2 PLAN REQUIREMENT.—There will be offered in the MSA during the annual, coordinated election period under section 1851(e)(3)(B) before the beginning of 2010 at least 2 MA local plans described in section 1851(a)(2)(A)(i) (in addition to the fee-for-service program under parts A and B), each offered by a different MA organization and each of which met the minimum enrollment requirements of paragraph (1) of section 1857(b) (as applied without regard to paragraph (3) thereof) as of the reference month.

[(c) SELECTION OF CCA AREAS.—

[(1) GENERAL SELECTION CRITERIA.—The Secretary shall select CCA areas from among those MSAs qualifying under subsection (b) in a manner that—

[(A) seeks to maximize the opportunity to test the application of comparative cost adjustment under this title;

[(B) does not seek to maximize the number of MA eligible individuals who reside in such areas; and

[(C) provides for geographic diversity consistent with the criteria specified in paragraph (2).

[(2) SELECTION CRITERIA.—With respect to the selection of MSAs that qualify to be CCA areas under subsection (b), the following rules apply, to the maximum extent feasible:

[(A) MAXIMUM NUMBER.—The number of such MSAs selected may not exceed the lesser of (i) 6, or (ii) 25 percent of the number of MSAs that meet the requirement of subsection (b)(2)(A).

[(B) ONE OF 4 LARGEST AREAS BY POPULATION.—At least one such qualifying MSA shall be selected from among the 4 such qualifying MSAs with the largest total population of MA eligible individuals.

[(C) ONE OF 4 AREAS WITH LOWEST POPULATION DENSITY.—At least one such qualifying MSA shall be selected from among the 4 such qualifying MSAs with the lowest population density (as measured by residents per square mile or similar measure of density).

[(D) MULTISTATE AREA.—At least one such qualifying MSA shall be selected that includes a multi-State area. Such an MSA may be an MSA described in subparagraph (B) or (C).

[(E) LIMITATION WITHIN SAME GEOGRAPHIC REGION.—No more than 2 such MSAs shall be selected that are, in whole or in part, within the same geographic region (as specified by the Secretary) of the United States.

[(F) PRIORITY TO AREAS NOT WITHIN CERTAIN DEMONSTRATION PROJECTS.—Priority shall be provided for those qualifying MSAs that do not have a demonstration project in effect as of the date of the enactment of this section for medicare preferred provider organization plans under this part.

[(d) APPLICATION OF COMPARATIVE COST ADJUSTMENT.—

[(1) IN GENERAL.—In the case of a CCA area for a year—

[(A) for purposes of applying this part with respect to payment for MA local plans, any reference to an MA area-specific non-drug monthly benchmark amount shall be treated as a reference to such benchmark computed as if the CCA area-specific non-drug monthly benchmark amount (as defined in subsection (e)(1)) were substituted for the amount described in section 1853(j)(1)(A) for the CCA area and year involved, as phased in under paragraph (3); and

[(B) with respect to months in the year for individuals residing in the CCA area who are not enrolled in an MA plan, the amount of the monthly premium under section 1839 is subject to adjustment under subsection (f).

[(2) EXCLUSION OF MA LOCAL AREAS WITH FEWER THAN 2 ORGANIZATIONS OFFERING MA PLANS.—

[(A) IN GENERAL.—In no case shall an MA local area that is within an MSA be included as part of a CCA area

unless for 2010 (and, except as provided in subparagraph (B), for a subsequent year) there is offered in each part of such MA local area at least 2 MA local plans described in section 1851(a)(2)(A)(i) each of which is offered by a different MA organization.

[(B) CONTINUATION.—If an MA local area meets the requirement of subparagraph (A) and is included in a CCA area for 2010, such local area shall continue to be included in such CCA area for a subsequent year notwithstanding that it no longer meets such requirement so long as there is at least one MA local plan described in section 1851(a)(2)(A)(i) that is offered in such local area.

[(3) PHASE-IN OF CCA BENCHMARK.—

[(A) IN GENERAL.—In applying this section for a year before 2013, paragraph (1)(A) shall be applied as if the phase-in fraction under subparagraph (B) of the CCA non-drug monthly benchmark amount for the year were substituted for such fraction of the MA area-specific non-drug monthly benchmark amount.

[(B) PHASE-IN FRACTION.—The phase-in fraction under this subparagraph is—

[(i) for 2010 ¼; and

[(ii) for a subsequent year is the phase-in fraction under this subparagraph for the previous year increased by ¼, but in no case more than 1.

[(e) COMPUTATION OF CCA BENCHMARK AMOUNT.—

[(1) CCA NON-DRUG MONTHLY BENCHMARK AMOUNT.—For purposes of this section, the term "CCA non-drug monthly benchmark amount" means, with respect to a CCA area for a month in a year, the sum of the 2 components described in paragraph (2) for the area and year. The Secretary shall compute such benchmark amount for each such CCA area before the beginning of each annual, coordinated election period under section 1851(e)(3)(B) for each year (beginning with 2010) in which the CCA area is so selected.

[(2) 2 COMPONENTS.—For purposes of paragraph (1), the 2 components described in this paragraph for a CCA area and a year are the following:

[(A) MA LOCAL COMPONENT.—The product of the following:

[(i) WEIGHTED AVERAGE OF MEDICARE ADVANTAGE PLAN BIDS IN AREA.—The weighted average of the plan bids for the area and year (as determined under paragraph (3)(A)).

[(ii) NON-FFS MARKET SHARE.—One minus the fee-for-service market share percentage, determined under paragraph (4) for the area and year.

[(B) FEE-FOR-SERVICE COMPONENT.—The product of the following:

[(i) FEE-FOR-SERVICE AREA-SPECIFIC NON-DRUG AMOUNT.—The fee-for-service area-specific non-drug amount (as defined in paragraph (5)) for the area and year.

[(ii) FEE-FOR-SERVICE MARKET SHARE.—The fee-for-service market share percentage, determined under paragraph (4) for the area and year.

[(3) DETERMINATION OF WEIGHTED AVERAGE MA BIDS FOR A CCA AREA.—

[(A) IN GENERAL.—For purposes of paragraph (2)(A)(i), the weighted average of plan bids for a CCA area and a year is, subject to subparagraph (D), the sum of the following products for MA local plans described in subparagraph (C) in the area and year:

[(i) MONTHLY MEDICARE ADVANTAGE STATUTORY NON-DRUG BID AMOUNT.—The accepted unadjusted MA statutory non-drug monthly bid amount.

[(ii) PLAN'S SHARE OF MEDICARE ADVANTAGE ENROLLMENT IN AREA.—The number of individuals described in subparagraph (B), divided by the total number of such individuals for all MA plans described in subparagraph (C) for that area and year.

[(B) COUNTING OF INDIVIDUALS.—The Secretary shall count, for each MA local plan described in subparagraph (C) for an area and year, the number of individuals who reside in the area and who were enrolled under such plan under this part during the reference month for that year.

[(C) EXCLUSION OF PLANS NOT OFFERED IN PREVIOUS YEAR.—For an area and year, the MA local plans described in this subparagraph are MA local plans described in section 1851(a)(2)(A)(i) that are offered in the area and year and were offered in the CCA area in the reference month.

[(D) COMPUTATION OF WEIGHTED AVERAGE OF PLAN BIDS.—In calculating the weighted average of plan bids for a CCA area under subparagraph (A)—

[(i) in the case of an MA local plan that has a service area only part of which is within such CCA area, the MA organization offering such plan shall submit a separate bid for such plan for the portion within such CCA area; and

[(ii) the Secretary shall adjust such separate bid (or, in the case of an MA local plan that has a service area entirely within such CCA area, the plan bid) as may be necessary to take into account differences between the service area of such plan within the CCA area and the entire CCA area and the distribution of plan enrollees of all MA local plans offered within the CCA area.

[(4) COMPUTATION OF FEE-FOR-SERVICE MARKET SHARE PERCENTAGE.—The Secretary shall determine, for a year and a CCA area, the proportion (in this subsection referred to as the "fee-for-service market share percentage") equal to—

[(A) the total number of MA eligible individuals residing in such area who during the reference month for the year were not enrolled in any MA plan; divided by

[(B) the sum of such number and the total number of MA eligible individuals residing in such area who during such reference month were enrolled in an MA local plan described in section 1851(a)(2)(A)(i),

or, if greater, such proportion determined for individuals nationally.

[(5) FEE-FOR-SERVICE AREA-SPECIFIC NON-DRUG AMOUNT.—

[(A) IN GENERAL.—For purposes of paragraph (2)(B)(i) and subsection (f)(2)(A), subject to subparagraph (C), the term "fee-for-service area-specific non-drug amount" means, for a CCA area and a year, the adjusted average per capita cost for such area and year involved, determined under section 1876(a)(4) and adjusted as appropriate for the purpose of risk adjustment for benefits under the original medicare fee-for-service program option for individuals entitled to benefits under part A and enrolled under part B who are not enrolled in an MA plan for the year, but adjusted to exclude costs attributable to payments under section 1886(h).

[(B) USE OF FULL RISK ADJUSTMENT TO STANDARDIZE FEE-FOR-SERVICE COSTS TO TYPICAL BENEFICIARY.—In determining the adjusted average per capita cost for an area and year under subparagraph (A), such costs shall be adjusted to fully take into account the demographic and health status risk factors established under section 1853(a)(1)(A)(iv) so that such per capita costs reflect the average costs for a typical beneficiary residing in the CCA area.

[(C) INCLUSION OF COSTS OF VA AND DOD MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the adjusted average per capita cost under subparagraph (A) for a year, such cost shall be adjusted to include the Secretary's estimate, on a per capita basis, of the amount of additional payments that would have been made in the area involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Veterans Affairs or the Department of Defense.

[(f) PREMIUM ADJUSTMENT.—

[(1) APPLICATION.—

[(A) IN GENERAL.—Except as provided in subparagraph (B), in the case of an individual who is enrolled under part B, who resides in a CCA area, and who is not enrolled in an MA plan under this part, the monthly premium otherwise applied under part B (determined without regard to subsections (b), (f), and (i) of section 1839 or any adjustment under this subsection) shall be adjusted in accordance with paragraph (2), but only in the case of premiums for months during the period in which the CCA program under this section for such area is in effect.

[(B) NO PREMIUM ADJUSTMENT FOR SUBSIDY ELIGIBLE BENEFICIARIES.—No premium adjustment shall be made under this subsection for a premium for a month if the individual is determined to be a subsidy eligible individual (as defined in section 1860D–14(a)(3)(A)) for the month.

[(2) AMOUNT OF ADJUSTMENT.—

[(A) IN GENERAL.—Under this paragraph, subject to the exemption under paragraph (1)(B) and the limitation under subparagraph (B), if the fee-for-service area-specific

non-drug amount (as defined in section (e)(5)) for a CCA area in which an individual resides for a month—

[(i) does not exceed the CCA non-drug monthly benchmark amount (as determined under subsection (e)(1)) for such area and month, the amount of the premium for the individual for the month shall be reduced, by an amount equal to 75 percent of the amount by which such CCA benchmark exceeds such fee-for-service area-specific non-drug amount; or

[(ii) exceeds such CCA non-drug benchmark, the amount of the premium for the individual for the month shall be adjusted to ensure, that—

[(I) the sum of the amount of the adjusted premium and the CCA non-drug benchmark for the area; is equal to

[(II) the sum of the unadjusted premium plus the amount of such fee-for-service area-specific non-drug amount for the area.

[(B) LIMITATION.—In no case shall the actual amount of an adjustment under subparagraph (A) for an area and month in a year result in an adjustment that exceeds the maximum adjustment permitted under subparagraph (C) for the area and year, or, if less, the maximum annual adjustment permitted under subparagraph (D) for the area and year.

[(C) PHASE-IN OF ADJUSTMENT.—The amount of an adjustment under subparagraph (A) for a CCA area and year may not exceed the product of the phase-in fraction for the year under subsection (d)(3)(B) multiplied by the amount of the adjustment otherwise computed under subparagraph (A) for the area and year, determined without regard to this subparagraph and subparagraph (D).

[(D) 5-PERCENT LIMITATION ON ADJUSTMENT.—The amount of the adjustment under this subsection for months in a year shall not exceed 5 percent of the amount of the monthly premium amount determined for months in the year under section 1839 without regard to subsections (b), (f), and (i) of such section and this subsection.]

PART D—VOLUNTARY PRESCRIPTION DRUG BENEFIT PROGRAM

Subpart 1—Part D Eligible Individuals and Prescription Drug Benefits

ELIGIBILITY, ENROLLMENT, AND INFORMATION

SEC. 1860D–1. (a) * * *

(b) ENROLLMENT PROCESS FOR PRESCRIPTION DRUG PLANS.—

(1) ESTABLISHMENT OF PROCESS.—

(A) * * *

* * * * * * *

(C) SPECIAL RULE.—The process established under subparagraph (A) shall include, in the case of a part D eligible individual who is a full-benefit dual eligible individual (as defined in section 1935(c)(6)) who has failed to enroll in a prescription drug plan or an MA–PD plan, for the enroll-

ment in a prescription drug plan that has a monthly beneficiary premium that does not exceed the premium assistance available under section 1860D–14(a)(1)(A)). If there is more than one such plan available, the Secretary shall enroll such an individual on a random basis among all such plans in the PDP region *or through use of an intelligent assignment process that is designed to maximize the access of such individual to necessary prescription drugs while minimizing costs to such individual and to the program under this part to the greatest extent possible. In the case the Secretary enrolls such individuals through use of an intelligent assignment process, such process shall take into account the extent to which prescription drugs necessary for the individual are covered in the case of a PDP sponsor of a prescription drug plan that uses a formulary, the use of prior authorization or other restrictions on access to coverage of such prescription drugs by such a sponsor, and the overall quality of a prescription drug plan as measured by quality ratings established by the Secretary*. Nothing in the previous sentence shall prevent such an individual from declining or changing such enrollment.

(D) SPECIAL RULE FOR SUBSIDY ELIGIBLE INDIVIDUALS.—The process established under subparagraph (A) shall include, in the case of an individual described in subsection (b)(3)(D) who fails to enroll in a prescription drug plan or an MA–PD plan during the special enrollment established under such section applicable to such individual, the application of the assignment process described in subparagraph (C) to such individual in the same manner as such assignment process applies to a part D eligible individual described in such subparagraph (C). Nothing in the previous sentence shall prevent an individual described in such sentence from declining enrollment in a plan determined appropriate by the Secretary (or in the program under this part) or from changing such enrollment.

* * * * * * *

(3) ADDITIONAL SPECIAL ENROLLMENT PERIODS.—The Secretary shall establish special enrollment periods, including the following:

(A) * * *

* * * * * * *

[(D) MEDICAID COVERAGE.—In the case of an individual (as determined by the Secretary) who is a full-benefit dual eligible individual (as defined in section 1935(c)(6)).]

(D) SUBSIDY ELIGIBLE INDIVIDUALS.—In the case of an individual (as determined by the Secretary) who is determined under subparagraph (B) of section 1860D–14(a)(3) to be a subsidy eligible individual.

* * * * * * *

(F) CHANGE IN FORMULARY RESULTING IN INCREASE IN COST-SHARING.—

(i) IN GENERAL.—Except as provided in clause (ii), in the case of an individual enrolled in a prescription

drug plan (or MA–PD plan) who has been prescribed and is using a covered part D drug while so enrolled, if the formulary of the plan is materially changed (other than at the end of a contract year) so to reduce the coverage (or increase the cost-sharing) of the drug under the plan.

(ii) EXCEPTION.—Clause (i) shall not apply in the case that a drug is removed from the formulary of a plan because of a recall or withdrawal of the drug issued by the Food and Drug Administration, because the drug is replaced with a generic drug that is a therapeutic equivalent, or because of utilization management applied to—

(I) a drug whose labeling includes a boxed warning required by the Food and Drug Administration under section 210.57(c)(1) of title 21, Code of Federal Regulations (or a successor regulation); or

(II) a drug required under subsection (c)(2) of section 505–1 of the Federal Food, Drug, and Cosmetic Act to have a Risk Evaluation and Management Strategy that includes elements under subsection (f) of such section.

* * * * * * *

PRESCRIPTION DRUG BENEFITS

SEC. 1860D–2. (a) * * *

(b) STANDARD PRESCRIPTION DRUG COVERAGE.—For purposes of this part and part C, the term "standard prescription drug coverage" means coverage of covered part D drugs that meets the following requirements:

(1) * * *

* * * * * * *

(3) INITIAL COVERAGE LIMIT.—

(A) IN GENERAL.—Except as provided in [paragraph (4)] *paragraphs (4) and (7)*, the coverage has an initial coverage limit on the maximum costs that may be recognized for payment purposes (including the annual deductible)—

(i) * * *

* * * * * * *

(4) PROTECTION AGAINST HIGH OUT-OF-POCKET EXPENDITURES.—

(A) * * *

(B) ANNUAL OUT-OF-POCKET THRESHOLD.—

(i) IN GENERAL.—For purposes of this part, *subject to paragraph (7),* the "annual out-of-pocket threshold" specified in this subparagraph—

(I) * * *

* * * * * * *

(C) APPLICATION.—In applying subparagraph (A)—

(i) incurred costs shall only include costs incurred with respect to covered part D drugs for the annual deductible described in paragraph (1), for cost-sharing described in paragraph (2), and for amounts for which

benefits are not provided because of the application of the initial coverage limit described in paragraph (3), but does not include any costs incurred for covered part D drugs which are not included (or treated as being included) in the plan's formulary; [and]

(ii) [such costs shall be treated as incurred only if] *subject to subsection (g)(2)(C), subject to clause (iii), such costs shall be treated as incurred only if* they are paid by the part D eligible individual (or by another person, such as a family member, on behalf of the individual)[, under section 1860D–14, or under a State Pharmaceutical Assistance Program] and the part D eligible individual (or other person) is not reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement (other than under such section or such a Program) for such costs[.]*; and*

(iii) such costs shall be treated as incurred and shall not be considered to be reimbursed under clause (ii) if such costs are borne or paid—

(I) under section 1860D–14;

(II) under a State Pharmaceutical Assistance Program;

(III) by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act); or

(IV) under an AIDS Drug Assistance Program under part B of title XXVI of the Public Health Service Act.

* * * * * * *

(7) PHASED-IN ELIMINATION OF COVERAGE GAP.—

(A) IN GENERAL.—For each year beginning with 2011, the Secretary shall consistent with this paragraph progressively increase the initial coverage limit (described in subsection (b)(3)) and decrease the annual out-of-pocket threshold from the amounts otherwise computed until there is a continuation of coverage from the initial coverage limit for expenditures incurred through the total amount of expenditures at which benefits are available under paragraph (4).

(B) INCREASE IN INITIAL COVERAGE LIMIT.—For a year beginning with 2011, the initial coverage limit otherwise computed without regard to this paragraph shall be increased by ½ of the cumulative phase-in percentage (as defined in subparagraph (D)(ii) for the year) times the out-of-pocket gap amount (as defined in subparagraph (E)) for the year.

(C) DECREASE IN ANNUAL OUT-OF-POCKET THRESHOLD.—For a year beginning with 2011, the annual out-of-pocket threshold otherwise computed without regard to this paragraph shall be decreased by ½ of the cumulative phase-in percentage of the out-of-pocket gap amount for the year multiplied by 1.75.

(D) PHASE–IN.—For purposes of this paragraph:

(i) ANNUAL PHASE-IN PERCENTAGE.—The term "annual phase-in percentage" means—

(I) for 2011, 13 percent;

(II) for 2012, 2013, 2014, and 2015, 5 percent;

(III) for 2016 through 2018, 7.5 percent; and

(IV) for 2019 and each subsequent year, 10 percent.

(ii) CUMULATIVE PHASE-IN PERCENTAGE.—The term "cumulative phase-in percentage" means for a year the sum of the annual phase-in percentage for the year and the annual phase-in percentages for each previous year beginning with 2011, but in no case more than 100 percent.

(E) OUT-OF-POCKET GAP AMOUNT.—For purposes of this paragraph, the term "out-of-pocket gap amount" means for a year the amount by which—

(i) the annual out-of-pocket threshold specified in paragraph (4)(B) for the year (as determined as if this paragraph did not apply), exceeds

(ii) the sum of—

(I) the annual deductible under paragraph (1) for the year; and

(II) ¼ of the amount by which the initial coverage limit under paragraph (3) for the year (as determined as if this paragraph did not apply) exceeds such annual deductible.

* * * * * * *

(e) COVERED PART D DRUG DEFINED.—

(1) IN GENERAL.—Except as provided in this subsection *and subsections (f)and (g)*, for purposes of this part, the term "covered part D drug" means—

(A) * * *

* * * * * * *

and [such term includes a vaccine licensed under section 351 of the Public Health Service Act (and, for vaccines administered on or after January 1, 2008, its administration) and] any use of a covered part D drug for a medically accepted indication (as defined in paragraph (4)).

* * * * * * *

(f) PRESCRIPTION DRUG REBATE AGREEMENT FOR FULL-BENEFIT DUAL ELIGIBLE INDIVIDUALS.—

(1) IN GENERAL.—In this part, the term "covered part D drug" does not include any drug or biologic that is manufactured by a manufacturer that has not entered into and have in effect a rebate agreement described in paragraph (2).

(2) REBATE AGREEMENT.—A rebate agreement under this subsection shall require the manufacturer to provide to the Secretary a rebate for each rebate period (as defined in paragraph (6)(B)) ending after December 31, 2010, in the amount specified in paragraph (3) for any covered part D drug of the manufacturer dispensed after December 31, 2010, to any full-benefit dual eligible individual (as defined in paragraph (6)(A)) for which payment was made by a PDP sponsor under part D or a MA organization under part C for such period. Such rebate shall be paid by the manufacturer to the Secretary not later

than 30 days after the date of receipt of the information described in section 1860D–12(b)(7), including as such section is applied under section 1857(f)(3).

(3) REBATE FOR FULL-BENEFIT DUAL ELIGIBLE MEDICARE DRUG PLAN ENROLLEES.—

(A) IN GENERAL.—The amount of the rebate specified under this paragraph for a manufacturer for a rebate period, with respect to each dosage form and strength of any covered part D drug provided by such manufacturer and dispensed to a full-benefit dual eligible individual, shall be equal to the product of—

(i) the total number of units of such dosage form and strength of the drug so provided and dispensed for which payment was made by a PDP sponsor under part D or a MA organization under part C for the rebate period (as reported under section 1860D–12(b)(7), including as such section is applied under section 1857(f)(3)); and

(ii) the amount (if any) by which—

(I) the Medicaid rebate amount (as defined in subparagraph (B)) for such form, strength, and period, exceeds

(II) the average Medicare drug program full-benefit dual eligible rebate amount (as defined in subparagraph (C)) for such form, strength, and period.

(B) MEDICAID REBATE AMOUNT.—For purposes of this paragraph, the term "Medicaid rebate amount" means, with respect to each dosage form and strength of a covered part D drug provided by the manufacturer for a rebate period—

(i) in the case of a single source drug or an innovator multiple source drug, the amount specified in paragraph (1)(A)(ii) of section 1927(c) plus the amount, if any, specified in paragraph (2)(A)(ii) of such section, for such form, strength, and period; or

(ii) in the case of any other covered outpatient drug, the amount specified in paragraph (3)(A)(i) of such section for such form, strength, and period.

(C) AVERAGE MEDICARE DRUG PROGRAM FULL-BENEFIT DUAL ELIGIBLE REBATE AMOUNT.—For purposes of this subsection, the term "average Medicare drug program full-benefit dual eligible rebate amount" means, with respect to each dosage form and strength of a covered part D drug provided by a manufacturer for a rebate period, the sum, for all PDP sponsors under part D and MA organizations administering a MA–PD plan under part C, of—

(i) the product, for each such sponsor or organization, of—

(I) the sum of all rebates, discounts, or other price concessions (not taking into account any rebate provided under paragraph (2) for such dosage form and strength of the drug dispensed, calculated on a per-unit basis, but only to the extent that any such rebate, discount, or other price con-

cession applies equally to drugs dispensed to full-benefit dual eligible Medicare drug plan enrollees and drugs dispensed to PDP and MA–PD enrollees who are not full-benefit dual eligible individuals; and

(II) the number of the units of such dosage and strength of the drug dispensed during the rebate period to full-benefit dual eligible individuals enrolled in the prescription drug plans administered by the PDP sponsor or the MA–PD plans administered by the MA–PD organization; divided by

(ii) the total number of units of such dosage and strength of the drug dispensed during the rebate period to full-benefit dual eligible individuals enrolled in all prescription drug plans administered by PDP sponsors and all MA–PD plans administered by MA–PD organizations.

(4) LENGTH OF AGREEMENT.—The provisions of paragraph (4) of section 1927(b) (other than clauses (iv) and (v) of subparagraph (B)) shall apply to rebate agreements under this subsection in the same manner as such paragraph applies to a rebate agreement under such section.

(5) OTHER TERMS AND CONDITIONS.—The Secretary shall establish other terms and conditions of the rebate agreement under this subsection, including terms and conditions related to compliance, that are consistent with this subsection.

(6) DEFINITIONS.—In this subsection and section 1860D–12(b)(7):

(A) FULL-BENEFIT DUAL ELIGIBLE INDIVIDUAL.—The term "full-benefit dual eligible individual" has the meaning given such term in section 1935(c)(6).

(B) REBATE PERIOD.—The term "rebate period" has the meaning given such term in section 1927(k)(8).

(g) REQUIREMENT FOR MANUFACTURER DISCOUNT AGREEMENT FOR CERTAIN QUALIFYING DRUGS.—

(1) IN GENERAL.—In this part, the term "covered part D drug" does not include any drug or biologic that is manufactured by a manufacturer that has not entered into and have in effect for all qualifying drugs (as defined in paragraph (5)(A)) a discount agreement described in paragraph (2).

(2) DISCOUNT AGREEMENT.—

(A) PERIODIC DISCOUNTS.—A discount agreement under this paragraph shall require the manufacturer involved to provide, to each PDP sponsor with respect to a prescription drug plan or each MA organization with respect to each MA-PD plan, a discount in an amount specified in paragraph (3) for qualifying drugs (as defined in paragraph (5)(A)) of the manufacturer dispensed to a qualifying enrollee after December 31, 2010, insofar as the individual is in the original gap in coverage (as defined in paragraph (5)(E)).

(B) DISCOUNT AGREEMENT.—Insofar as not inconsistent with this subsection, the Secretary shall establish terms and conditions of such agreement, including terms and conditions relating to compliance, similar to the terms and

conditions for rebate agreements under paragraphs (2), (3), and (4) of section 1927(b), except that—

(i) discounts shall be applied under this subsection to prescription drug plans and MA-PD plans instead of State plans under title XIX;

(ii) PDP sponsors and MA organizations shall be responsible, instead of States, for provision of necessary utilization information to drug manufacturers; and

(iii) sponsors and MA organizations shall be responsible for reporting information on drug-component negotiated price, instead of other manufacturer prices.

(C) COUNTING DISCOUNT TOWARD TRUE OUT-OF-POCKET COSTS.—Under the discount agreement, in applying subsection (b)(4), with regard to subparagraph (C)(i) of such subsection, if a qualified enrollee purchases the qualified drug insofar as the enrollee is in an actual gap of coverage (as defined in paragraph (5)(D)), the amount of the discount under the agreement shall be treated and counted as costs incurred by the plan enrollee.

(3) DISCOUNT AMOUNT.—The amount of the discount specified in this paragraph for a discount period for a plan is equal to 50 percent of the amount of the drug-component negotiated price (as defined in paragraph (5)(C)) for qualifying drugs for the period involved.

(4) ADDITIONAL TERMS.—In the case of a discount provided under this subsection with respect to a prescription drug plan offered by a PDP sponsor or an MA-PD plan offered by an MA organization, if a qualified enrollee purchases the qualified drug—

(A) insofar as the enrollee is in an actual gap of coverage (as defined in paragraph (5)(D)), the sponsor or plan shall provide the discount to the enrollee at the time the enrollee pays for the drug; and

(B) insofar as the enrollee is in the portion of the original gap in coverage (as defined in paragraph (5)(E)) that is not in the actual gap in coverage, the discount shall not be applied against the negotiated price (as defined in subsection (d)(1)(B)) for the purpose of calculating the beneficiary payment.

(5) DEFINITIONS.—In this subsection:

(A) QUALIFYING DRUG.—The term "qualifying drug" means, with respect to a prescription drug plan or MA-PD plan, a drug or biological product that—

(i)(I) is a drug produced or distributed under an original new drug application approved by the Food and Drug Administration, including a drug product marketed by any cross-licensed producers or distributors operating under the new drug application;

(II) is a drug that was originally marketed under an original new drug application approved by the Food and Drug Administration; or

(III) is a biological product as approved under section 351(a) of the Public Health Services Act;

(ii) is covered under the formulary of the plan; and

(iii) is dispensed to an individual who is in the original gap in coverage.

(B) QUALIFYING ENROLLEE.—The term "qualifying enrollee" means an individual enrolled in a prescription drug plan or MA-PD plan other than such an individual who is a subsidy-eligible individual (as defined in section 1860D–14(a)(3)).

(C) DRUG-COMPONENT NEGOTIATED PRICE.—The term "drug-component negotiated price" means, with respect to a qualifying drug, the negotiated price (as defined in subsection (d)(1)(B)), as determined without regard to any dispensing fee, of the drug under the prescription drug plan or MA-PD plan involved.

(D) ACTUAL GAP IN COVERAGE.—The term "actual gap in coverage" means the gap in prescription drug coverage that occurs between the initial coverage limit (as modified under subparagraph (B) of subsection (b)(7)) and the annual out-of-pocket threshold (as modified under subparagraph (C) of such subsection).

(E) ORIGINAL GAP IN COVERAGE.—The term "original in gap coverage" means the gap in prescription drug coverage that would occur between the initial coverage limit (described in subsection (b)(3)) and the out-of-pocket threshold (as defined in subsection (b)(4)(B)) if subsection (b)(7) did not apply.

* * * * * * *

BENEFICIARY PROTECTIONS FOR QUALIFIED PRESCRIPTION DRUG COVERAGE

SEC. 1860D–4. (a) * * *

* * * * * * *

(m) STANDARDIZED MARKETING REQUIREMENTS.—A PDP sponsor with respect to a prescription drug plan offered by the sponsor (and agents of such sponsor) shall comply with the standardized marketing requirements under section 1856(c).

Subpart 2—Prescription Drug Plans; PDP Sponsors; Financing

PDP REGIONS; SUBMISSION OF BIDS; PLAN APPROVAL

SEC. 1860D–11. (a) * * *

* * * * * * *

(d) REVIEW OF INFORMATION AND NEGOTIATION.—

(1) * * *

* * * * * * *

(3) REJECTION OF BIDS.—Paragraph (5)(C) of section 1854(a) shall apply with respect to bids under this section in the same manner as it applies to bids by an MA organization under such section.

* * * * * * *

[(i) NONINTERFERENCE.—In order to promote competition under this part and in carrying out this part, the Secretary—

[(1) may not interfere with the negotiations between drug manufacturers and pharmacies and PDP sponsors; and

[(2) may not require a particular formulary or institute a price structure for the reimbursement of covered part D drugs.]

(i) NEGOTIATION OF LOWER DRUG PRICES.—

(1) IN GENERAL.—Notwithstanding any other provision of law, the Secretary shall negotiate with pharmaceutical manufacturers the prices (including discounts, rebates, and other price concessions) that may be charged to PDP sponsors and MA organizations for covered part D drugs for part D eligible individuals who are enrolled under a prescription drug plan or under an MA-PD plan.

(2) NO CHANGE IN RULES FOR FORMULARIES.—

(A) IN GENERAL.—Nothing in paragraph (1) shall be construed to authorize the Secretary to establish or require a particular formulary.

(B) CONSTRUCTION.—Subparagraph (A) shall not be construed as affecting the Secretary's authority to ensure appropriate and adequate access to covered part D drugs under prescription drug plans and under MA-PD plans, including compliance of such plans with formulary requirements under section 1860D–4(b)(3).

(3) CONSTRUCTION.—Nothing in this subsection shall be construed as preventing the sponsor of a prescription drug plan, or an organization offering an MA-PD plan, from obtaining a discount or reduction of the price for a covered part D drug below the price negotiated under paragraph (1).

(4) SEMI-ANNUAL REPORTS TO CONGRESS.—Not later than June 1, 2011, and every six months thereafter, the Secretary shall submit to the Committees on Ways and Means, Energy and Commerce, and Oversight and Government Reform of the House of Representatives and the Committee on Finance of the Senate a report on negotiations conducted by the Secretary to achieve lower prices for Medicare beneficiaries, and the prices and price discounts achieved by the Secretary as a result of such negotiations.

* * * * * * *

REQUIREMENTS FOR AND CONTRACTS WITH PRESCRIPTION DRUG PLAN (PDP) SPONSORS

SEC. 1860D–12. (a) * * *

(b) CONTRACT REQUIREMENTS.—

(1) * * *

* * * * * * *

[(5) SUBMISSION OF CLAIMS BY PHARMACIES LOCATED IN OR CONTRACTING WITH LONG-TERM CARE FACILITIES.—Each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan offered by such sponsor shall provide that a pharmacy located in, or having a contract with, a long-term care facility shall have not less than 30 days (but not more than 90 days) to submit claims to the sponsor for reimbursement under the plan.]

[(6)] *(5)* REGULAR UPDATE OF PRESCRIPTION DRUG PRICING STANDARD.—If the PDP sponsor of a prescription drug plan uses a standard for reimbursement of pharmacies based on the cost of a drug, each contract entered into with such sponsor under this part with respect to the plan shall provide that the sponsor shall update such standard not less frequently than once every 7 days, beginning with an initial update on January 1 of each year, to accurately reflect the market price of acquiring the drug.

(6) REPORTING REQUIREMENT FOR THE DETERMINATION AND PAYMENT OF REBATES BY MANUFACTURERS RELATED TO REBATE FOR FULL-BENEFIT DUAL ELIGIBLE MEDICARE DRUG PLAN ENROLLEES.—

(A) IN GENERAL.—For purposes of the rebate under section 1860D–2(f) for contract years beginning on or after January 1, 2011, each contract entered into with a PDP sponsor under this part with respect to a prescription drug plan shall require that the sponsor comply with subparagraphs (B) and (C).

(B) REPORT FORM AND CONTENTS.—Not later than 60 days after the end of each rebate period (as defined in section 1860D–2(f)(6)(B)) within such a contract year to which such section applies, a PDP sponsor of a prescription drug plan under this part shall report to each manufacturer—

(i) information (by National Drug Code number) on the total number of units of each dosage, form, and strength of each drug of such manufacturer dispensed to full-benefit dual eligible Medicare drug plan enrollees under any prescription drug plan operated by the PDP sponsor during the rebate period;

(ii) information on the price discounts, price concessions, and rebates for such drugs for such form, strength, and period;

(iii) information on the extent to which such price discounts, price concessions, and rebates apply equally to full-benefit dual eligible Medicare drug plan enrollees and PDP enrollees who are not full-benefit dual eligible Medicare drug plan enrollees; and

(iv) any additional information that the Secretary determines is necessary to enable the Secretary to calculate the average Medicare drug program full-benefit dual eligible rebate amount (as defined in paragraph (3)(C) of such section), and to determine the amount of the rebate required under this section, for such form, strength, and period.

Such report shall be in a form consistent with a standard reporting format established by the Secretary.

(C) SUBMISSION TO SECRETARY.—Each PDP sponsor shall promptly transmit a copy of the information reported under subparagraph (B) to the Secretary for the purpose of audit oversight and evaluation.

(D) CONFIDENTIALITY OF INFORMATION.—The provisions of subparagraph (D) of section 1927(b)(3), relating to confidentiality of information, shall apply to information reported by PDP sponsors under this paragraph in the same

manner that such provisions apply to information disclosed by manufacturers or wholesalers under such section, except—

(i) that any reference to "this section" in clause (i) of such subparagraph shall be treated as being a reference to this section;

(ii) the reference to the Director of the Congressional Budget Office in clause (iii) of such subparagraph shall be treated as including a reference to the Medicare Payment Advisory Commission; and

(iii) clause (iv) of such subparagraph shall not apply.

(E) OVERSIGHT.—Information reported under this paragraph may be used by the Inspector General of the Department of Health and Human Services for the statutorily authorized purposes of audit, investigation, and evaluations.

(F) PENALTIES FOR FAILURE TO PROVIDE TIMELY INFORMATION AND PROVISION OF FALSE INFORMATION.—In the case of a PDP sponsor—

(i) that fails to provide information required under subparagraph (B) on a timely basis, the sponsor is subject to a civil money penalty in the amount of $10,000 for each day in which such information has not been provided; or

(ii) that knowingly (as defined in section 1128A(i)) provides false information under such subparagraph, the sponsor is subject to a civil money penalty in an amount not to exceed $100,000 for each item of false information.

Such civil money penalties are in addition to other penalties as may be prescribed by law. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(c) WAIVER OF CERTAIN REQUIREMENTS TO EXPAND CHOICE.—

(1) AUTHORIZING WAIVER.—

(A) IN GENERAL.—[In the case] *Subject to paragraph (5), in the case* of an entity that seeks to offer a prescription drug plan in a State, the Secretary shall waive the requirement of subsection (a)(1) that the entity be licensed in that State if the Secretary determines, based on the application and other evidence presented to the Secretary, that any of the grounds for approval of the application described in paragraph (2) have been met.

* * * * * * *

(5) STATE CERTIFICATION REQUIRED.—

(A) IN GENERAL.—The Secretary may only grant a waiver under paragraph (1)(A) if the Secretary has received a certification from the State insurance commissioner that the prescription drug plan has a substantially complete application pending in the State.

(B) REVOCATION OF WAIVER UPON FINDING OF FRAUD AND ABUSE.—The Secretary shall revoke a waiver granted under paragraph (1)(A) if the State insurance commissioner sub-

mits a certification to the Secretary that the recipient of such a waiver—

(i) has committed fraud or abuse with respect to such waiver;

(ii) has failed to make a good faith effort to satisfy State licensing requirements; or

(iii) was determined ineligible for licensure by the State.

* * * * * * *

PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS

SEC. 1860D–14. (a) INCOME-RELATED SUBSIDIES FOR INDIVIDUALS WITH INCOME UP TO 150 PERCENT OF POVERTY LINE.—

(1) INDIVIDUALS WITH INCOME BELOW 135 PERCENT OF POVERTY LINE.—In the case of a subsidy eligible individual (as defined in paragraph (3)) who is determined to have income that is below 135 percent of the poverty line applicable to a family of the size involved and who meets the resources requirement described in paragraph (3)(D) *(or, beginning with 2012, paragraph (3)(E))* or who is covered under this paragraph under paragraph (3)(B)(i), the individual is entitled under this section to the following:

(A) * * *

* * * * * * *

(D) REDUCTION IN COST-SHARING BELOW OUT-OF-POCKET THRESHOLD.—

(i) [INSTITUTIONALIZED INDIVIDUALS.—In] *ELIMINATION OF COST-SHARING FOR CERTAIN FULL-BENEFIT DUAL ELIGIBLE INDIVIDUALS.—*

(I) INSTITUTIONALIZED INDIVIDUALS.—In the case of an individual who is a full-benefit dual eligible individual and who is an institutionalized individual or couple (as defined in section 1902(q)(1)(B)), the elimination of any beneficiary coinsurance described in section 1860D–2(b)(2) (for all amounts through the total amount of expenditures at which benefits are available under section 1860D–2(b)(4)).

(II) CERTAIN OTHER INDIVIDUALS.—In the case of an individual who is a full-benefit dual eligible individual and with respect to whom there has been a determination that but for the provision of home and community based care (whether under section 1915, 1932, or under a waiver under section 1115) the individual would require the level of care provided in a hospital or a nursing facility or intermediate care facility for the mentally retarded the cost of which could be reimbursed under the State plan under title XIX, the elimination of any beneficiary coinsurance described in section 1860D–2(b)(2) (for all amounts through the total amount

of expenditures at which benefits are available under section 1860D–2(b)(4)).

* * * * * * *

(3) DETERMINATION OF ELIGIBILITY.—

(A) * * *

* * * * * * *

(E) ALTERNATIVE RESOURCE STANDARD.—

(i) IN GENERAL.—The resources requirement of this subparagraph is that an individual's resources (as determined under section 1613 for purposes of the supplemental security income program subject to the life insurance policy exclusion provided under subparagraph (G)) do not exceed—

(I) for 2006, $10,000 (or $20,000 in the case of the combined value of the individual's assets or resources and the assets or resources of the individual's spouse); [and]

(II) for a subsequent year *(before 2012)* the dollar amounts specified in this subclause (or subclause (I)) for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year[.]*;*

(III) for 2012, $17,000 (or $34,000 in the case of the combined value of the individual's assets or resources and the assets or resources of the individual's spouse); and

(IV) for a subsequent year, the dollar amounts specified in this subclause (or subclause (III)) for the previous year increased by the annual percentage increase in the consumer price index (all items; U.S. city average) as of September of such previous year.

Any dollar amount established under subclause (II) *or (IV)* that is not a multiple of $10 shall be rounded to the nearest multiple of $10.

* * * * * * *

[(iii) DOCUMENTATION AND SAFEGUARDS.—Under such process—

[(I) the application form shall consist of an attestation under penalty of perjury regarding the level of assets or resources (or combined assets and resources in the case of a married part D eligible individual) and valuations of general classes of assets or resources;

[(II) such form shall be accompanied by copies of recent statements (if any) from financial institutions in support of the application; and

[(III) matters attested to in the application shall be subject to appropriate methods of verification.]

(iii) CERTIFICATION OF INCOME AND RESOURCES.—For purposes of applying this section—

(I) an individual shall be permitted to apply on the basis of self-certification of income and resources; and

(II) matters attested to in the application shall be subject to appropriate methods of verification without the need of the individual to provide additional documentation, except in extraordinary situations as determined by the Commissioner.

* * * * * * *

(b) PREMIUM SUBSIDY AMOUNT.—

(1) * * *

(2) LOW-INCOME BENCHMARK PREMIUM AMOUNT DEFINED.—

(A) * * *

(B) PREMIUM AMOUNTS DESCRIBED.—The premium amounts described in this subparagraph are, in the case of—

(i) * * *

* * * * * * *

(iii) an MA–PD plan, the portion of the MA monthly prescription drug beneficiary premium that is attributable to basic prescription drug benefits (described in section 1852(a)(6)(B)(ii)) *before the application of the monthly rebate computed under section 1854(b)(1)(C)(i) for that plan and year involved.*

* * * * * * *

MEDICARE PRESCRIPTION DRUG ACCOUNT IN THE FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND

SEC. 1860D–16. (a) * * *

* * * * * * *

(c) DEPOSITS INTO ACCOUNT.—

(1) * * *

* * * * * * *

(6) REBATE FOR FULL-BENEFIT DUAL ELIGIBLE MEDICARE DRUG PLAN ENROLLEES.—Amounts paid under a rebate agreement under section 1860D–2(f) shall be deposited into the Account and shall be used to pay for all or part of the gradual elimination of the coverage gap under section 1860D–2(b)(7).

* * * * * * *

PART E—MISCELLANEOUS PROVISIONS

DEFINITIONS OF SERVICES, INSTITUTIONS, ETC.

SEC. 1861. For purposes of this title—

(a) * * *

* * * * * * *

(s) MEDICAL AND OTHER HEALTH SERVICES.—The term "medical and other health services" means any of the following items or services:

(1) * * *

(2)(A) * * *

* * * * * * *

(AA) ultrasound screening for abdominal aortic aneurysm (as defined in subsection (bbb)) for an individual—

(i) * * *

* * * * * * *

(iii) who—

(I) * * *

(II) manifests risk factors included in a beneficiary category recommended for screening by the [United States Preventive Services Task Force] *Task Force on Clinical Preventive Services* regarding abdominal aortic aneurysms;

* * * * * * *

(DD) items and services furnished under an intensive cardiac rehabilitation program (as defined in subsection (eee)(4)); [and]

(EE) kidney disease education services (as defined in subsection (ggg));

(FF) advance care planning consultation (as defined in subsection (hhh)(1));

(GG) marriage and family therapist services (as defined in subsection (jjj));

(HH) mental health counselor services (as defined in subsection (kkk)(1)); and

(II) respiratory therapy services which would be physicians' services if furnished by a physician (as defined in subsection (r)(1)) for the diagnosis and treatment of respiratory illnesses and which are performed by a respiratory therapist (as defined in subsection (mmm)) under the general supervision of a physician and which the respiratory therapist is legally authorized to perform by the State in which the services are performed, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services;

* * * * * * *

[(10)(A) pneumococcal vaccine and its administration and, subject to section 4071(b) of the Omnibus Budget Reconciliation Act of 1987, influenza vaccine and its administration; and

[(B) hepatitis B vaccine and its administration, furnished to an individual who is at high or intermediate risk of contracting hepatitis B (as determined by the Secretary under regulations);]

(10) federally recommended vaccines (as defined in subsection (lll)) and their respective administration;

* * * * * * *

(aa) RURAL HEALTH CLINIC SERVICES AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES.—(1) The term "rural health clinic services" means —

(A) * * *

(B) such services furnished by a physician assistant or a nurse practitioner (as defined in paragraph (5)), by a clinical

psychologist (as defined by the Secretary) [or by a clinical social worker (as defined in subsection (hh)(1)),], *by a clinical social worker (as defined in subsection (hh)(1)), by a marriage and family therapist (as defined in subsection (jjj)(2)), or a mental health counselor (as defined in subsection (kkk)(2)),* and such services and supplies furnished as an incident to his service as would otherwise be covered if furnished by a physician or as an incident to a physician's service, and

* * * * * * *

(hh) CLINICAL SOCIAL WORKER; CLINICAL SOCIAL WORKER SERVICES.—(1) * * *

(2) The term "clinical social worker services" means services performed by a clinical social worker (as defined in paragraph (1)) for the diagnosis and treatment of mental illnesses (other than services furnished to an inpatient of a hospital [and other than services furnished to an inpatient of a skilled nursing facility which the facility is required to provide as a requirement for participation]) which the clinical social worker is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are performed as would otherwise be covered if furnished by a physician or as an incident to a physician's professional service.

* * * * * * *

(qq) DIABETES OUTPATIENT SELF-MANAGEMENT TRAINING SERVICES.—(1) The term "diabetes outpatient self-management training services" means educational and training services furnished (at such times as the Secretary determines appropriate) to an individual with diabetes by a certified provider (as described in paragraph (2)(A)) in an outpatient setting by an individual or entity who meets the quality standards described in paragraph (2)(B) *or by a certified diabetes educator (as defined in paragraph (3))*, but only if the physician who is managing the individual's diabetic condition certifies that such services are needed under a comprehensive plan of care related to the individual's diabetic condition to ensure therapy compliance or to provide the individual with necessary skills and knowledge (including skills related to the self-administration of injectable drugs) to participate in the management of the individual's condition.

* * * * * * *

(3) For purposes of paragraph (1), the term "certified diabetes educator" means an individual who—

(A) is licensed or registered by the State in which the services are performed as a health care professional;

(B) specializes in teaching individuals with diabetes to develop the necessary skills and knowledge to manage the individual's diabetic condition; and

(C) is certified as a diabetes educator by a recognized certifying body (as defined in paragraph (4)).

(4)(A) For purposes of paragraph (3)(C), the term "recognized certifying body" means—

(i) the National Certification Board for Diabetes Educators, or

(ii) a certifying body for diabetes educators, which is recognized by the Secretary as authorized to grant certification of diabetes educators for purposes of this subsection pursuant to standards established by the Secretary, if the Secretary determines such Board or body, respectively, meets the requirement of subparagraph (B).

(B) The National Certification Board for Diabetes Educators or a certifying body for diabetes educators meets the requirement of this subparagraph, with respect to the certification of an individual, if the Board or body, respectively, is incorporated and registered to do business in the United States and requires as a condition of such certification each of the following:

(i) The individual has a qualifying credential in a specified health care profession.

(ii) The individual has professional practice experience in diabetes self-management training that includes a minimum number of hours and years of experience in such training.

(iii) The individual has successfully completed a national certification examination offered by such entity.

(iv) The individual periodically renews certification status following initial certification.

* * * * * * *

(ww) INITIAL PREVENTIVE PHYSICAL EXAMINATION.—(1) * * *

(2) The screening and other preventive services described in this paragraph include the following:

(A) [Pneumococcal, influenza, and hepatitis B vaccine and administration] *Federally recommended vaccines (as defined in subsection (lll)) and their respective administration* under subsection (s)(10).

* * * * * * *

(xx)(1) The term "cardiovascular screening blood test" means a blood test for the early detection of cardiovascular disease (or abnormalities associated with an elevated risk of cardiovascular disease) that tests for the following:

(A) * * *

* * * * * * *

The Secretary may not approve an indication under subparagraph (B) for any individual unless a blood test for such is recommended by the [United States Preventive Services Task Force] *Task Force on Clinical Preventive Services*.

* * * * * * *

(ddd)(1) The term "additional preventive services" means services not otherwise described in this title that identify medical conditions or risk factors and that the Secretary determines are—

(A) * * *

(B) recommended with a grade of A or B by the [United States Preventive Services Task Force] *Task Force on Clinical Preventive Services* ; and

* * * * * * *

Advance Care Planning Consultation

(hhh)(1) Subject to paragraphs (3) and (4), the term "advance care planning consultation" means a consultation between the individual and a practitioner described in paragraph (2) regarding advance care planning, if, subject to paragraph (3), the individual involved has not had such a consultation within the last 5 years. Such consultation shall include the following:

(A) An explanation by the practitioner of advance care planning, including key questions and considerations, important steps, and suggested people to talk to.

(B) An explanation by the practitioner of advance directives, including living wills and durable powers of attorney, and their uses.

(C) An explanation by the practitioner of the role and responsibilities of a health care proxy.

(D) The provision by the practitioner of a list of national and State-specific resources to assist consumers and their families with advance care planning, including the national toll-free hotline, the advance care planning clearinghouses, and State legal service organizations (including those funded through the Older Americans Act of 1965).

(E) An explanation by the practitioner of the continuum of end-of-life services and supports available, including palliative care and hospice, and benefits for such services and supports that are available under this title.

(F)(i) Subject to clause (ii), an explanation of orders regarding life sustaining treatment or similar orders, which shall include—

(I) the reasons why the development of such an order is beneficial to the individual and the individual's family and the reasons why such an order should be updated periodically as the health of the individual changes;

(II) the information needed for an individual or legal surrogate to make informed decisions regarding the completion of such an order; and

(III) the identification of resources that an individual may use to determine the requirements of the State in which such individual resides so that the treatment wishes of that individual will be carried out if the individual is unable to communicate those wishes, including requirements regarding the designation of a surrogate decision-maker (also known as a health care proxy).

(ii) The Secretary shall limit the requirement for explanations under clause (i) to consultations furnished in a State—

(I) in which all legal barriers have been addressed for enabling orders for life sustaining treatment to constitute a set of medical orders respected across all care settings; and

(II) that has in effect a program for orders for life sustaining treatment described in clause (iii).

(iii) A program for orders for life sustaining treatment for a States described in this clause is a program that—

(I) ensures such orders are standardized and uniquely identifiable throughout the State;

(II) distributes or makes accessible such orders to physicians and other health professionals that (acting within the scope of the professional's authority under State law) may sign orders for life sustaining treatment;

(III) provides training for health care professionals across the continuum of care about the goals and use of orders for life sustaining treatment; and

(IV) is guided by a coalition of stakeholders includes representatives from emergency medical services, emergency department physicians or nurses, state long-term care association, state medical association, state surveyors, agency responsible for senior services, state department of health, state hospital association, home health association, state bar association, and state hospice association.

(2) A practitioner described in this paragraph is—

(A) a physician (as defined in subsection (r)(1)); and

(B) a nurse practitioner or physician assistant who has the authority under State law to sign orders for life sustaining treatments.

(3)(A) An initial preventive physical examination under subsection (WW), including any related discussion during such examination, shall not be considered an advance care planning consultation for purposes of applying the 5-year limitation under paragraph (1).

(B) An advance care planning consultation with respect to an individual may be conducted more frequently than provided under paragraph (1) if there is a significant change in the health condition of the individual, including diagnosis of a chronic, progressive, life-limiting disease, a life-threatening or terminal diagnosis or life-threatening injury, or upon admission to a skilled nursing facility, a long-term care facility (as defined by the Secretary), or a hospice program.

(4) A consultation under this subsection may include the formulation of an order regarding life sustaining treatment or a similar order.

(5)(A) For purposes of this section, the term "order regarding life sustaining treatment" means, with respect to an individual, an actionable medical order relating to the treatment of that individual that—

(i) is signed and dated by a physician (as defined in subsection (r)(1)) or another health care professional (as specified by the Secretary and who is acting within the scope of the professional's authority under State law in signing such an order, including a nurse practitioner or physician assistant) and is in a form that permits it to stay with the individual and be followed by health care professionals and providers across the continuum of care;

(ii) effectively communicates the individual's preferences regarding life sustaining treatment, including an indication of the treatment and care desired by the individual;

(iii) is uniquely identifiable and standardized within a given locality, region, or State (as identified by the Secretary); and

(iv) may incorporate any advance directive (as defined in section 1866(f)(3)) if executed by the individual.

(B) The level of treatment indicated under subparagraph (A)(ii) may range from an indication for full treatment to an indication to

limit some or all or specified interventions. Such indicated levels of treatment may include indications respecting, among other items—

(i) the intensity of medical intervention if the patient is pulse less, apneic, or has serious cardiac or pulmonary problems;

(ii) the individual's desire regarding transfer to a hospital or remaining at the current care setting;

(iii) the use of antibiotics; and

(iv) the use of artificially administered nutrition and hydration.

Medicare Covered Preventive Services

(iii)(1) Subject to the succeeding provisions of this subsection, the term "Medicare covered preventive services" means the following:

(A) Prostate cancer screening tests (as defined in subsection (oo)).

(B) Colorectal cancer screening tests (as defined in subsection (pp) and when applicable as described in section 1305).

(C) Diabetes outpatient self-management training services (as defined in subsection (qq)).

(D) Screening for glaucoma for certain individuals (as described in subsection (s)(2)(U)).

(E) Medical nutrition therapy services for certain individuals (as described in subsection (s)(2)(V)).

(F) An initial preventive physical examination (as defined in subsection (ww)).

(G) Cardiovascular screening blood tests (as defined in subsection (xx)(1)).

(H) Diabetes screening tests (as defined in subsection (yy)).

(I) Ultrasound screening for abdominal aortic aneurysm for certain individuals (as described in described in subsection (s)(2)(AA)).

(J) Federally recommended vaccines (as defined in subsection (lll)) and their respective administration.

(K) Screening mammography (as defined in subsection (jj)).

(L) Screening pap smear and screening pelvic exam (as defined in subsection (nn)).

(M) Bone mass measurement (as defined in subsection (rr)).

(N) Kidney disease education services (as defined in subsection (ggg)).

(O) Additional preventive services (as defined in subsection (ddd)).

(2) With respect to specific Medicare covered preventive services, the limitations and conditions described in the provisions referenced in paragraph (1) with respect to such services shall apply.

Marriage and Family Therapist Services

(jjj)(1) The term "marriage and family therapist services" means services performed by a marriage and family therapist (as defined in paragraph (2)) for the diagnosis and treatment of mental illnesses, which the marriage and family therapist is legally authorized to perform under State law (or the State regulatory mechanism provided by State law) of the State in which such services are performed, as would otherwise be covered if furnished by a physician or as incident to a physician's professional service, but only if no fa-

cility or other provider charges or is paid any amounts with respect to the furnishing of such services.

(2) The term "marriage and family therapist" means an individual who—

(A) possesses a master's or doctoral degree which qualifies for licensure or certification as a marriage and family therapist pursuant to State law;

(B) after obtaining such degree has performed at least 2 years of clinical supervised experience in marriage and family therapy; and

(C) is licensed or certified as a marriage and family therapist in the State in which marriage and family therapist services are performed.

Mental Health Counselor Services

(kkk)(1) The term "mental health counselor services" means services performed by a mental health counselor (as defined in paragraph (2)) for the diagnosis and treatment of mental illnesses which the mental health counselor is legally authorized to perform under State law (or the State regulatory mechanism provided by the State law) of the State in which such services are performed, as would otherwise be covered if furnished by a physician or as incident to a physician's professional service, but only if no facility or other provider charges or is paid any amounts with respect to the furnishing of such services.

(2) The term "mental health counselor" means an individual who—

(A) possesses a master's or doctor's degree which qualifies the individual for licensure or certification for the practice of mental health counseling in the State in which the services are performed;

(B) after obtaining such a degree has performed at least 2 years of supervised mental health counselor practice; and

(C) is licensed or certified as a mental health counselor or professional counselor by the State in which the services are performed.

Federally Recommended Vaccines

(lll) The term "federally recommended vaccine" means an approved vaccine recommended by the Advisory Committee on Immunization Practices (an advisory committee established by the Secretary, acting through the Director of the Centers for Disease Control and Prevention).

Respiratory Therapist

(mmm) For purposes of subsection (s)(2)(II) and section 1833(a)(1)(X) only, the term "respiratory therapist" means an individual who—

(1) is credentialed by a national credentialing board recognized by the Secretary;

(2)(A) is licensed to practice respiratory therapy in the State in which the respiratory therapy services are performed, or

(B) in the case of an individual in a State which does not provide for such licensure, is legally authorized to perform res-

piratory therapy services (in the State in which the individual performed such services) under State law (or the State regulatory mechanism provided by State law);

(3) is a registered respiratory therapist; and

(4) holds a bachelor's degree.

* * * * * * *

EXCLUSIONS FROM COVERAGE AND MEDICARE AS SECONDARY PAYER

SEC. 1862. (a) Notwithstanding any other provision of this title, no payment may be made under part A or part B for any expenses incurred for items or services—

(1)(A) * * *

* * * * * * *

(N) in the case of ultrasound screening for abdominal aortic aneurysm which is performed more frequently than is provided for under section 1861(s)(2)(AA), **[**and**]**

(O) in the case of kidney disease education services (as defined in paragraph (1) of section 1861(ggg)), which are furnished in excess of the number of sessions covered under paragraph (4) of such section**[**;**]***, and*

(P) in the case of advance care planning consultations (as defined in section 1861(hhh)(1)), which are performed more frequently than is covered under such section;

* * * * * * *

(7) where such expenses are for routine physical checkups, eyeglasses (other than eyewear described in section 1861(s)(8)) or eye examinations for the purpose of prescribing, fitting, or changing eyeglasses, procedures performed (during the course of any eye examination) to determine the refractive state of the eyes, hearing aids or examinations therefor, or immunizations (except as otherwise allowed under section 1861(s)(10) and subparagraph (B), (F), (G), (H), **[**or (K)**]** *(K), or (P)* of paragraph (1));

* * * * * * *

(23) which are the technical component of advanced diagnostic imaging services described in section 1834(e)(1)(B) for which payment is made under the fee schedule established under section 1848(b) and that are furnished by a supplier (as defined in section 1861(d)), if such supplier is not accredited by an accreditation organization designated by the Secretary under section 1834(e)(2)(B); **[**or**]**

(24) where such expenses are for renal dialysis services (as defined in subparagraph (B) of section 1881(b)(14)) for which payment is made under such section unless such payment is made under such section to a provider of services or a renal dialysis facility for such services**[**.**]***; or*

(25) subject to subsection (h), not later than January 1, 2015, for which the payment is other than by electronic funds transfer (EFT) or an electronic remittance in a form as specified in ASC X12 835 Health Care Payment and Remittance Advice or subsequent standard.

* * * * * * *

(b) MEDICARE AS SECONDARY PAYER.—

(1) REQUIREMENTS OF GROUP HEALTH PLANS.—

(A) * * *

* * * * * * *

(C) INDIVIDUALS WITH END STAGE RENAL DISEASE.—A group health plan (as defined in subparagraph (A)(v))—

(i) * * *

* * * * * * *

except that clause (ii) shall not prohibit a plan from paying benefits secondary to this title when an individual is entitled to or eligible for benefits under this title under section 226A after the end of the 12-month period described in clause (i). Effective for items and services furnished on or after February 1, 1991, and before the date of enactment of the Balanced Budget Act of 1997 (with respect to periods beginning on or after February 1, 1990), this subparagraph shall be applied by substituting "18- month" for "12-month" each place it appears. Effective for items and services furnished on or after the date of enactment of the Balanced Budget Act of 1997, (with respect to periods beginning on or after the date that is 18 months prior to such date), clauses (i) and (ii) shall be applied by substituting "30-month" for "12-month" each place it appears. *With regard to immunosuppressive drugs furnished on or after the date of the enactment of the America's Affordable Health Choices Act of 2009, this subparagraph shall be applied without regard to any time limitation.*

* * * * * * *

(U) in the case of hospitals which furnish inpatient hospital services for which payment may be made under this title, to be a participating provider of medical care both—

(i) * * *

* * * * * * *

in accordance with regulations promulgated by the Secretary regarding admission practices, payment methodology, and rates of payment (including the acceptance of no more than such payment rate as payment in full for such items and services, **[**and**]**

(V) in the case of hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970 (or a State occupational safety and health plan that is approved under 18(b) of such Act), to comply with the Bloodborne Pathogens standard under section 1910.1030 of title 29 of the Code of Federal Regulations (or as subsequently redesignated)**[**.**]**, *and*

(W) maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by the provider under this title, as specified by the Secretary.

* * * * * * *

(2)(A) A provider of services may charge such individual or other person (i) the amount of any deduction or coinsurance amount imposed pursuant to section 1813(a)(1), (a)(3), or (a)(4), section 1833(b), or section 1861(y)(3) with respect to such items and services (not in excess of the amount customarily charged for such items and services by such provider), and (ii) an amount equal to 20 per centum of the reasonable charges for such items and services (*other than for Medicare covered preventive services and* not in excess of 20 per centum of the amount customarily charged for such items and services by such provider) for which payment is made under part B or which are durable medical equipment furnished as home health services (but in the case of items and services furnished to individuals with end-stage renal disease, an amount equal to 20 percent of the estimated amounts for such items and services calculated on the basis established by the Secretary). In the case of items and services described in section 1833(c), clause (ii) of the preceding sentence shall be applied by substituting for 20 percent the proportion which is appropriate under such section. A provider of services may not impose a charge under clause (ii) of the first sentence of this subparagraph with respect to items and services described in section 1861(s)(10)(A) and with respect to clinical diagnostic laboratory tests for which payment is made under part B. Notwithstanding the first sentence of this subparagraph, a home health agency may charge such an individual or person, with respect to covered items subject to payment under section 1834(a), the amount of any deduction imposed under section 1833(b) and 20 percent of the payment basis described in section 1834(a)(1)(B). In the case of items and services for which payment is made under part B under the prospective payment system established under section 1833(t), clause (ii) of the first sentence shall be applied by substituting for 20 percent of the reasonable charge, the applicable copayment amount established under section 1833(t)(5). In the case of services described in section 1833(a)(8) or section 1833(a)(9) for which payment is made under part B under section 1834(k), clause (ii) of the first sentence shall be applied by substituting for 20 percent of the reasonable charge for such services 20 percent of the lesser of the actual charge or the applicable fee schedule amount (as defined in such section) for such services.

* * * * * * *

(j) ENROLLMENT PROCESS FOR PROVIDERS OF SERVICES AND SUPPLIERS.—

(1) ENROLLMENT PROCESS.—

(A) * * *

* * * * * * *

(D) BILLING AGENTS AND CLEARINGHOUSES REQUIRED TO BE REGISTERED UNDER MEDICARE.—Any agent, clearinghouse, or other alternate payee that submits claims on behalf of a health care provider must be registered with the Secretary in a form and manner specified by the Secretary.

* * * * * * *

(3) PROGRAM INTEGRITY.—The provisions of section 1128G(a) apply to enrollments and renewals of enrollments of providers of services and suppliers under this title.

* * * * * * *

HEALTH CARE QUALITY DEMONSTRATION PROGRAM

SEC. 1866C. (a) * * *

(b) DEMONSTRATION PROJECTS.—[The Secretary] *Subject to section 1866D, the Secretary* shall establish a 5-year demonstration program under which the Secretary shall approve demonstration projects that examine health delivery factors that encourage the delivery of improved quality in patient care, including—

(1) * * *

* * * * * * *

CONVERSION OF ACUTE CARE EPISODE DEMONSTRATION TO PILOT PROGRAM AND EXPANSION TO INCLUDE POST ACUTE SERVICES

SEC. 1866D. (a) IN GENERAL.—By not later than January 1, 2011, the Secretary shall, for the purpose of promoting the use of bundled payments to promote efficient and high quality delivery of care—

(1) convert the acute care episode demonstration program conducted under section 1866C to a pilot program; and

(2) subject to subsection (c), expand such program as so converted to include post acute services and such other services the Secretary determines to be appropriate, which may include transitional services.

(b) SCOPE.—The Secretary shall set specific goals for the number of acute and post-acute bundling test sites under the pilot program to ensure that the pilot program is of sufficient size and scope to—

(1) test the approaches under the pilot program in a variety of settings, including urban, rural, and underserved areas;

(2) include geographic areas and additional conditions that account for significant program spending, as defined by the Secretary; and

(3) subject to subsection (d), disseminate the pilot program rapidly on a national basis.

To the extent that the Secretary finds inpatient and post-acute care bundling to be successful in improving quality and reducing costs, the Secretary shall implement such mechanisms and reforms under the pilot program on as large a geographic scale as practical and economical, consistent with subsection (e).

(c) LIMITATION.—The Secretary shall only expand the pilot program under subsection (a)(2) if the Secretary finds that—

(1) the demonstration program under section 1866C and pilot program under this section maintain or increase the quality of care received by individuals enrolled under this title; and

(2) such demonstration program and pilot program reduce program expenditures and, based on the certification under subsection (d), that the expansion of such pilot program would result in estimated spending that would be less than what spending would otherwise be in the absence of this section.

(d) CERTIFICATION.—For purposes of subsection (c), the Chief Actuary of the Centers for Medicare & Medicaid Services shall certify whether expansion of the pilot program under this section would re-

sult in estimated spending that would be less than what spending would otherwise be in the absence of this section.

(e) VOLUNTARY PARTICIPATION.—Nothing in this paragraph shall be construed as requiring the participation of an entity in the pilot program under this section.

ACCOUNTABLE CARE ORGANIZATION PILOT PROGRAM

SEC. 1866E. (a) ESTABLISHMENT.—

(1) IN GENERAL.—The Secretary shall conduct a pilot program (in this section referred to as the "pilot program") to test different payment incentive models, including (to the extent practicable) the specific payment incentive models described in subsection (c), designed to reduce the growth of expenditures and improve health outcomes in the provision of items and services under this title to applicable beneficiaries (as defined in subsection (d)) by qualifying accountable care organizations (as defined in subsection (b)(1)) in order to—

(A) promote accountability for a patient population and coordinate items and services under parts A and B;

(B) encourage investment in infrastructure and redesigned care processes for high quality and efficient service delivery; and

(C) reward physician practices and other physician organizational models for the provision of high quality and efficient health care services.

(2) SCOPE.—The Secretary shall set specific goals for the number of accountable care organizations, participating practitioners, and patients served in the initial tests under the pilot program to ensure that the pilot program is of sufficient size and scope to—

(A) test the approach involved in a variety of settings, including urban, rural, and underserved areas; and

(B) subject to subsection (f)(1), disseminate such approach rapidly on a national basis.

To the extent that the Secretary finds a qualifying accountable care organization model to be successful in improving quality and reducing costs, the Secretary shall attempt to attract at least 10 percent of all eligible providers to act as accountable care organizations and implement such mechanisms and reforms within 5 years after the date of the enactment of this section. If the Secretary further finds such accountable care organization models to be successful, the Secretary shall seek to implement such mechanisms and reforms on as large a geographic scale as practical and economical.

(b) QUALIFYING ACCOUNTABLE CARE ORGANIZATIONS (ACOS).—

(1) QUALIFYING ACO DEFINED.—In this section:

(A) IN GENERAL.—The terms "qualifying accountable care organization" and "qualifying ACO" mean a group of physicians or other physician organizational model (as defined in subparagraph (D)) that—

(i) is organized at least in part for the purpose of providing physicians' services; and

(ii) meets such criteria as the Secretary determines to be appropriate to participate in the pilot program, including the criteria specified in paragraph (2).

(B) INCLUSION OF OTHER PROVIDERS.—Nothing in this subsection shall be construed as preventing a qualifying ACO from including a hospital or any other provider of services or supplier furnishing items or services for which payment may be made under this title that is affiliated with the ACO under an arrangement structured so that such provider or supplier participates in the pilot program and shares in any incentive payments under the pilot program.

(C) PHYSICIAN.—The term "physician" includes, except as the Secretary may otherwise provide, any individual who furnishes services for which payment may be made as physicians' services.

(D) OTHER PHYSICIAN ORGANIZATIONAL MODEL.—The term "other physician organization model" means, with respect to a qualifying ACO any model of organization under which physicians enter into agreements with other providers for the purposes of participation in the pilot program in order to provide high quality and efficient health care services and share in any incentive payments under such program

(E) OTHER SERVICES.—Nothing in this paragraph shall be construed as preventing a qualifying ACO from furnishing items or services, for which payment may not be made under this title, for purposes of achieving performance goals under the pilot program.

(2) QUALIFYING CRITERIA.—The following are criteria described in this paragraph for an organized group of physicians to be a qualifying ACO:

(A) The group has a legal structure that would allow the group to receive and distribute incentive payments under this section.

(B) The group includes a sufficient number of primary care physicians (regardless of specialty) for the applicable beneficiaries for whose care the group is accountable (as determined by the Secretary).

(C) The group reports on quality measures in such form, manner, and frequency as specified by the Secretary (which may be for the group, for providers of services and suppliers, or both).

(D) The group reports to the Secretary (in a form, manner and frequency as specified by the Secretary) such data as the Secretary determines appropriate to monitor and evaluate the pilot program.

(E) The group provides notice to applicable beneficiaries regarding the pilot program (as determined appropriate by the Secretary).

(F) The group contributes to a best practices network or website, that shall be maintained by the Secretary for the purpose of sharing strategies on quality improvement, care coordination, and efficiency that the groups believe are effective.

(G) The group utilizes patient-centered processes of care, including those that emphasize patient and caregiver in-

volvement in planning and monitoring of ongoing care management plan.

(H) The group meets other criteria determined to be appropriate by the Secretary.

(c) SPECIFIC PAYMENT INCENTIVE MODELS.—The specific payment incentive models described in this subsection are the following:

(1) PERFORMANCE TARGET MODEL.—Under the performance target model under this paragraph (in this paragraph referred to as the "performance target model"):

(A) IN GENERAL.—A qualifying ACO qualifies to receive an incentive payment if expenditures for applicable beneficiaries are less than a target spending level or a target rate of growth. The incentive payment shall be made only if savings are greater than would result from normal variation in expenditures for items and services covered under parts A and B.

(B) COMPUTATION OF PERFORMANCE TARGET.—

(i) IN GENERAL.—The Secretary shall establish a performance target for each qualifying ACO comprised of a base amount (described in clause (ii)) increased to the current year by an adjustment factor (described in clause (iii)). Such a target may be established on a per capita basis, as the Secretary determines to be appropriate.

(ii) BASE AMOUNT.—For purposes of clause (i), the base amount in this subparagraph is equal to the average total payments (or allowed charges) under parts A and B (and may include part D, if the Secretary determines appropriate) for applicable beneficiaries for whom the qualifying ACO furnishes items and services in a base period determined by the Secretary. Such base amount may be determined on a per capita basis.

(iii) ADJUSTMENT FACTOR.—For purposes of clause (i), the adjustment factor in this clause may equal an annual per capita amount that reflects changes in expenditures from the period of the base amount to the current year that would represent an appropriate performance target for applicable beneficiaries (as determined by the Secretary). Such adjustment factor may be determined as an amount or rate, may be determined on a national, regional, local, or organization-specific basis, and may be determined on a per capita basis. Such adjustment factor also may be adjusted for risk as determined appropriate by the Secretary.

(iv) REBASING.—Under this model the Secretary shall periodically rebase the base expenditure amount described in clause (ii).

(C) MEETING TARGET.—

(i) IN GENERAL.—Subject to clause (ii), a qualifying ACO that meet or exceeds annual quality and performance targets for a year shall receive an incentive payment for such year equal to a portion (as determined appropriate by the Secretary) of the amount by which payments under this title for such year relative are estimated to be below the performance target for such year,

as determined by the Secretary. The Secretary may establish a cap on incentive payments for a year for a qualifying ACO.

(ii) LIMITATION.—The Secretary shall limit incentive payments to each qualifying ACO under this paragraph as necessary to ensure that the aggregate expenditures with respect to applicable beneficiaries for such ACOs under this title (inclusive of incentive payments described in this subparagraph) do not exceed the amount that the Secretary estimates would be expended for such ACO for such beneficiaries if the pilot program under this section were not implemented.

(D) REPORTING AND OTHER REQUIREMENTS.—In carrying out such model, the Secretary may (as the Secretary determines to be appropriate) incorporate reporting requirements, incentive payments, and penalties related to the physician quality reporting initiative (PQRI), electronic prescribing, electronic health records, and other similar initiatives under section 1848, and may use alternative criteria than would otherwise apply under such section for determining whether to make such payments. The incentive payments described in this subparagraph shall not be included in the limit described in subparagraph (C)(ii) or in the performance target model described in this paragraph.

(2) PARTIAL CAPITATION MODEL.—

(A) IN GENERAL.—Subject to subparagraph (B), a partial capitation model described in this paragraph (in this paragraph referred to as a "partial capitation model") is a model in which a qualifying ACO would be at financial risk for some, but not all, of the items and services covered under parts A and B, such as at risk for some or all physicians' services or all items and services under part B. The Secretary may limit a partial capitation model to ACOs that are highly integrated systems of care and to ACOs capable of bearing risk, as determined to be appropriate by the Secretary.

(B) NO ADDITIONAL PROGRAM EXPENDITURES.—Payments to a qualifying ACO for applicable beneficiaries for a year under the partial capitation model shall be established in a manner that does not result in spending more for such ACO for such beneficiaries than would otherwise be expended for such ACO for such beneficiaries for such year if the pilot program were not implemented, as estimated by the Secretary.

(3) OTHER PAYMENT MODELS.—

(A) IN GENERAL.—Subject to subparagraph (B), the Secretary may develop other payment models that meet the goals of this pilot program to improve quality and efficiency.

(B) NO ADDITIONAL PROGRAM EXPENDITURES.—Subparagraph (B) of paragraph (2) shall apply to a payment model under subparagraph (A) in a similar manner as such subparagraph (B) applies to the payment model under paragraph (2).

(d) APPLICABLE BENEFICIARIES.—

(1) IN GENERAL.—In this section, the term "applicable beneficiary" means, with respect to a qualifying ACO, an individual who—

(A) is enrolled under part B and entitled to benefits under part A;

(B) is not enrolled in a Medicare Advantage plan under part C or a PACE program under section 1894; and

(C) meets such other criteria as the Secretary determines appropriate, which may include criteria relating to frequency of contact with physicians in the ACO

(2) FOLLOWING APPLICABLE BENEFICIARIES.—The Secretary may monitor data on expenditures and quality of services under this title after an applicable beneficiary discontinues receiving services under this title through a qualifying ACO.

(e) IMPLEMENTATION.—

(1) STARTING DATE.—The pilot program shall begin no later than January 1, 2012. An agreement with a qualifying ACO under the pilot program may cover a multi-year period of between 3 and 5 years.

(2) WAIVER.—The Secretary may waive such provisions of this title (including section 1877) and title XI in the manner the Secretary determines necessary in order implement the pilot program.

(3) PERFORMANCE RESULTS REPORTS.—The Secretary shall report performance results to qualifying ACOs under the pilot program at least annually.

(4) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of—

(A) the elements, parameters, scope, and duration of the pilot program;

(B) the selection of qualifying ACOs for the pilot program;

(C) the establishment of targets, measurement of performance, determinations with respect to whether savings have been achieved and the amount of savings;

(D) determinations regarding whether, to whom, and in what amounts incentive payments are paid; and

(E) decisions about the extension of the program under subsection (g), expansion of the program under subsection (h) or extensions under subsection (i).

(5) ADMINISTRATION.—Chapter 35 of title 44, United States Code shall not apply to this section.

(f) EVALUATION; MONITORING.—

(1) IN GENERAL.—The Secretary shall evaluate the payment incentive model for each qualifying ACO under the pilot program to assess impacts on beneficiaries, providers of services, suppliers and the program under this title. The Secretary shall make such evaluation publicly available within 60 days of the date of completion of such report.

(2) MONITORING.—The Inspector General of the Department of Health and Human Services shall provide for monitoring of the operation of ACOs under the pilot program with regard to violations of section 1877 (popularly known as the "Stark law").

(g) EXTENSION OF PILOT AGREEMENT WITH SUCCESSFUL ORGANIZATIONS.—

(1) REPORTS TO CONGRESS.—Not later than 2 years after the date the first agreement is entered into under this section, and biennially thereafter for six years, the Secretary shall submit to Congress and make publicly available a report on the use of authorities under the pilot program. Each report shall address the impact of the use of those authorities on expenditures, access, and quality under this title.

(2) EXTENSION.—Subject to the report provided under paragraph (1), with respect to a qualifying ACO, the Secretary may extend the duration of the agreement for such ACO under the pilot program as the Secretary determines appropriate if—

(A) the ACO receives incentive payments with respect to any of the first 4 years of the pilot agreement and is consistently meeting quality standards or

(B) the ACO is consistently exceeding quality standards and is not increasing spending under the program.

(3) TERMINATION.—The Secretary may terminate an agreement with a qualifying ACO under the pilot program if such ACO did not receive incentive payments or consistently failed to meet quality standards in any of the first 3 years under the program.

(h) EXPANSION TO ADDITIONAL ACOS.—

(1) TESTING AND REFINEMENT OF PAYMENT INCENTIVE MODELS.—Subject to the evaluation described in subsection (f), the Secretary may enter into agreements under the pilot program with additional qualifying ACOs to further test and refine payment incentive models with respect to qualifying ACOs.

(2) EXPANDING USE OF SUCCESSFUL MODELS TO PROGRAM IMPLEMENTATION.—

(A) IN GENERAL.—Subject to subparagraph (B), the Secretary may issue regulations to implement, on a permanent basis, 1 or more models if, and to the extent that, such models are beneficial to the program under this title, as determined by the Secretary.

(B) CERTIFICATION.—The Chief Actuary of the Centers for Medicare & Medicaid Services shall certify that 1 or more of such models described in subparagraph (A) would result in estimated spending that would be less than what spending would otherwise be estimated to be in the absence of such expansion.

(i) TREATMENT OF PHYSICIAN GROUP PRACTICE DEMONSTRATION.—

(1) EXTENSION.—The Secretary may enter in to an agreement with a qualifying ACO under the demonstration under section 1866A, subject to rebasing and other modifications deemed appropriate by the Secretary, until the pilot program under this section is operational.

(2) TRANSITION.—For purposes of extension of an agreement with a qualifying ACO under subsection (g)(2), the Secretary shall treat receipt of an incentive payment for a year by an organization under the physician group practice demonstration pursuant to section 1866A as a year for which an incentive payment is made under such subsection, as long as such practice

group practice organization meets the criteria under subsection (b)(2).

(j) ADDITIONAL PROVISIONS.—

(1) AUTHORITY FOR SEPARATE INCENTIVE ARRANGEMENTS.—The Secretary may create separate incentive arrangements (including using multiple years of data, varying thresholds, varying shared savings amounts, and varying shared savings limits) for different categories of qualifying ACOs to reflect natural variations in data availability, variation in average annual attributable expenditures, program integrity, and other matters the Secretary deems appropriate.

(2) ENCOURAGEMENT OF PARTICIPATION OF SMALLER ORGANIZATIONS.—In order to encourage the participation of smaller accountable care organizations under the pilot program, the Secretary may limit a qualifying ACO's exposure to high cost patients under the program.

(3) TREATMENT OF HIGH-COST BENEFICIARIES WITH CHRONIC DISEASES.—Nothing in this section shall be construed as preventing a qualifying ACO from entering into an arrangement with an Independence at Home Medical Practice or from providing home based services for the treatment of beneficiaries who are eligible for that program.

(4) INVOLVEMENT IN PRIVATE PAYER ARRANGEMENTS.—Nothing in this section shall be construed as preventing qualifying ACOs participating in the pilot program from negotiating similar contracts with private payers.

(5) ANTIDISCRIMINATION LIMITATION.—The Secretary shall not enter into an agreement with an entity to provide health care items or services under the pilot program, or with an entity to administer the program, unless such entity guarantees that it will not deny, limit, or condition the coverage or provision of benefits under the program, for individuals eligible to be enrolled under such program, based on any health status-related factor described in section 2702(a)(1) of the Public Health Service Act.

(6) CONSTRUCTION.—Nothing in this section shall be construed to compel or require an organization to use an organization-specific target growth rate for an accountable care organization under this section for purposes of section 1848.

(7) FUNDING.—For purposes of administering and carrying out the pilot program, other than for payments for items and services furnished under this title and incentive payments under subsection (c)(1), in addition to funds otherwise appropriated, there are appropriated to the Secretary for the Center for Medicare & Medicaid Services Program Management Account $25,000,000 for each of fiscal years 2010 through 2014 and $20,000,000 for fiscal year 2015. Amounts appropriated under this paragraph for a fiscal year shall be available until expended.

MEDICAL HOME PILOT PROGRAM

SEC. 1866F. (a) ESTABLISHMENT AND MEDICAL HOME MODELS.—

(1) ESTABLISHMENT OF PILOT PROGRAM.—The Secretary shall establish a medical home pilot program (in this section referred to as the "pilot program") for the purpose of evaluating the fea-

sibility and advisability of reimbursing qualified patient-centered medical homes for furnishing medical home services (as defined under subsection (b)(1)) to high need beneficiaries (as defined in subsection (d)(1)(C)) and to targeted high need beneficiaries (as defined in subsection (c)(1)(C)).

(2) SCOPE.—Subject to subsection (g), the Secretary shall set specific goals for the number of practices and communities, and the number of patients served, under the pilot program in the initial tests to ensure that the pilot program is of sufficient size and scope to—

(A) test the approach involved in a variety of settings, including urban, rural, and underserved areas; and

(B) subject to subsection (e)(1), disseminate such approach rapidly on a national basis.

To the extent that the Secretary finds a medical home model to be successful in improving quality and reducing costs, the Secretary shall implement such mechanisms and reforms on as large a geographic scale as practical and economical.

(3) MODELS OF MEDICAL HOMES IN THE PILOT PROGRAM.—The pilot program shall evaluate each of the following medical home models:

(A) INDEPENDENT PATIENT-CENTERED MEDICAL HOME MODEL.—Independent patient-centered medical home model under subsection (c).

(B) COMMUNITY-BASED MEDICAL HOME MODEL.—Community-based medical home model under subsection (d).

(4) PARTICIPATION OF NURSE PRACTITIONERS AND PHYSICIAN ASSISTANTS.—

(A) Nothing in this section shall be construed as preventing a nurse practitioner from leading a patient centered medical home so long as—

(i) all the requirements of this section are met; and

(ii) the nurse practitioner is acting consistently with State law.

(B) Nothing in this section shall be construed as preventing a physician assistant from participating in a patient centered medical home so long as—

(i) all the requirements of this section are met; and

(ii) the physician assistant is acting consistently with State law.

(b) DEFINITIONS.—For purposes of this section:

(1) PATIENT-CENTERED MEDICAL HOME SERVICES.—The term "patient-centered medical home services" means services that—

(A) provide beneficiaries with direct and ongoing access to a primary care or principal care by a physician or nurse practitioner who accepts responsibility for providing first contact, continuous and comprehensive care to such beneficiary;

(B) coordinate the care provided to a beneficiary by a team of individuals at the practice level across office, institutional and home settings led by a primary care or principal care physician or nurse practitioner, as needed and appropriate;

(C) provide for all the patient's health care needs or take responsibility for appropriately arranging care with other qualified providers for all stages of life;

(D) provide continuous access to care and communication with participating beneficiaries;

(E) provide support for patient self-management, proactive and regular patient monitoring, support for family caregivers, use patient-centered processes, and coordination with community resources;

(F) integrate readily accessible, clinically useful information on participating patients that enables the practice to treat such patients comprehensively and systematically; and

(G) implement evidence-based guidelines and apply such guidelines to the identified needs of beneficiaries over time and with the intensity needed by such beneficiaries.

(2) PRIMARY CARE.—The term "primary care" means health care that is provided by a physician, nurse practitioner, or physician assistant who practices in the field of family medicine, general internal medicine, geriatric medicine, or pediatric medicine.

(3) PRINCIPAL CARE.—The term "principal care" means integrated, accessible health care that is provided by a physician who is a medical subspecialist that addresses the majority of the personal health care needs of patients with chronic conditions requiring the subspecialist's expertise, and for whom the subspecialist assumes care management.

(c) INDEPENDENT PATIENT-CENTERED MEDICAL HOME MODEL.—

(1) IN GENERAL.—

(A) PAYMENT AUTHORITY.—Under the independent patient-centered medical home model under this subsection, the Secretary shall make payments for medical home services furnished by an independent patient-centered medical home (as defined in subparagraph (B)) pursuant to paragraph (3)(B) for a targeted high need beneficiaries (as defined in subparagraph (C)).

(B) INDEPENDENT PATIENT-CENTERED MEDICAL HOME DEFINED.—In this section, the term "independent patient-centered medical home" means a physician-directed or nurse-practitioner-directed practice that is qualified under paragraph (2) as—

(i) providing beneficiaries with patient-centered medical home services; and

(ii) meets such other requirements as the Secretary may specify.

(C) TARGETED HIGH NEED BENEFICIARY DEFINED.—For purposes of this subsection, the term "targeted high need beneficiary" means a high need beneficiary who, based on a risk score as specified by the Secretary, is generally within the upper 50th percentile of Medicare beneficiaries.

(D) BENEFICIARY ELECTION TO PARTICIPATE.—The Secretary shall determine an appropriate method of ensuring that beneficiaries have agreed to participate in the pilot program.

(E) IMPLEMENTATION.—The pilot program under this subsection shall begin no later than 6 months after the date of the enactment of this section.

(2) STANDARD SETTING AND QUALIFICATION PROCESS FOR PATIENT-CENTERED MEDICAL HOMES.—The Secretary shall review alternative models for standard setting and qualification, and shall establish a process—

(A) to establish standards to enable medical practices to qualify as patient-centered medical homes; and

(B) to initially provide for the review and certification of medical practices as meeting such standards.

(3) PAYMENT.—

(A) ESTABLISHMENT OF METHODOLOGY.—The Secretary shall establish a methodology for the payment for medical home services furnished by independent patient-centered medical homes. Under such methodology, the Secretary shall adjust payments to medical homes based on beneficiary risk scores to ensure that higher payments are made for higher risk beneficiaries.

(B) PER BENEFICIARY PER MONTH PAYMENTS.—Under such payment methodology, the Secretary shall pay independent patient-centered medical homes a monthly fee for each targeted high need beneficiary who consents to receive medical home services through such medical home.

(C) PROSPECTIVE PAYMENT.—The fee under subparagraph (B) shall be paid on a prospective basis.

(D) AMOUNT OF PAYMENT.—In determining the amount of such fee, the Secretary shall consider the following:

(i) The clinical work and practice expenses involved in providing the medical home services provided by the independent patient-centered medical home (such as providing increased access, care coordination, population disease management, and teaching self-care skills for managing chronic illnesses) for which payment is not made under this title as of the date of the enactment of this section.

(ii) Allow for differential payments based on capabilities of the independent patient-centered medical home.

(iii) Use appropriate risk-adjustment in determining the amount of the per beneficiary per month payment under this paragraph in a manner that ensures that higher payments are made for higher risk beneficiaries.

(4) ENCOURAGING PARTICIPATION OF VARIETY OF PRACTICES.—The pilot program under this subsection shall be designed to include the participation of physicians in practices with fewer than 10 full-time equivalent physicians, as well as physicians in larger practices, particularly in underserved and rural areas, as well as federally qualified community health centers, and rural health centers.

(5) NO DUPLICATION IN PILOT PARTICIPATION.—A physician in a group practice that participates in the accountable care organization pilot program under section 1866D shall not be eligible to participate in the pilot program under this subsection, unless

the pilot program under this section has been implemented on a permanent basis under subsection (e)(3).

(d) COMMUNITY-BASED MEDICAL HOME MODEL.—

(1) IN GENERAL.—

(A) AUTHORITY FOR PAYMENTS.—Under the community-based medical home model under this subsection (in this section referred to as the "CBMH model"), the Secretary shall make payments for the furnishing of medical home services by a community-based medical home (as defined in subparagraph (B)) pursuant to paragraph (5)(B) for high need beneficiaries.

(B) COMMUNITY-BASED MEDICAL HOME DEFINED.—In this section, the term "community-based medical home" means a nonprofit community-based or State-based organization that is certified under paragraph (2) as meeting the following requirements:

(i) The organization provides beneficiaries with medical home services.

(ii) The organization provides medical home services under the supervision of and in close collaboration with the primary care or principal care physician, nurse practitioner, or physician assistant designated by the beneficiary as his or her community-based medical home provider.

(iii) The organization employs community health workers, including nurses or other non-physician practitioners, lay health workers, or other persons as determined appropriate by the Secretary, that assist the primary or principal care physician, nurse practitioner, or physician assistant in chronic care management activities such as teaching self-care skills for managing chronic illnesses, transitional care services, care plan setting, medication therapy management services for patients with multiple chronic diseases, or help beneficiaries access the health care and community-based resources in their local geographic area.

(iv) The organization meets such other requirements as the Secretary may specify.

(C) HIGH NEED BENEFICIARY.—In this section, the term "high need beneficiary" means an individual who requires regular medical monitoring, advising, or treatment, including such an individual with cognitive impairment that leads to functional impairment.

(2) QUALIFICATION PROCESS FOR COMMUNITY-BASED MEDICAL HOMES.—The Secretary shall establish a process—

(A) for the initial qualification of community-based or State-based organizations as community-based medical homes; and

(B) to provide for the review and qualification of such community-based and State-based organizations pursuant to criteria established by the Secretary.

(3) DURATION.—The pilot program for community-based medical homes under this subsection shall start no later than 2 years after the date of the enactment of this section. Each demonstration site under the pilot program shall operate for a pe-

riod of up to 5 years after the initial implementation phase, without regard to the receipt of a initial implementation funding under subsection (i).

(4) PREFERENCE.—In selecting sites for the CBMH model, the Secretary shall seek to eliminate racial, ethnic, gender, and geographic health disparities and may give preference to—

(A) applications from geographic areas that propose to coordinate health care services for chronically ill beneficiaries across a variety of health care settings, such as primary care physician practices with fewer than 10 physicians, specialty physicians, nurse practitioner practices, Federally qualified health centers, rural health clinics, and other settings;

(B) applications that include other payors that furnish medical home services for chronically ill patients covered by such payors; and

(C) applications from States that propose to use the medical home model to coordinate health care services for individuals enrolled under this title, individuals enrolled under title XIX, and full-benefit dual eligible individuals (as defined in section 1935(c)(6)) with chronic diseases across a variety of health care settings.

(5) PAYMENTS.—

(A) ESTABLISHMENT OF METHODOLOGY.—The Secretary shall establish a methodology for the payment for medical home services furnished under the CBMH model.

(B) PER BENEFICIARY PER MONTH PAYMENTS.—Under such payment methodology, the Secretary shall make two separate monthly payments for each high need beneficiary who consents to receive medical home services through such medical home, as follows:

(i) PAYMENT TO COMMUNITY-BASED ORGANIZATION.—One monthly payment to a community-based or State-based organization.

(ii) PAYMENT TO PRIMARY OR PRINCIPAL CARE PRACTICE.—One monthly payment to the primary or principal care practice for such beneficiary.

(C) PROSPECTIVE PAYMENT.—The payments under subparagraph (B) shall be paid on a prospective basis.

(D) AMOUNT OF PAYMENT.—In determining the amount of such payment, the Secretary shall consider the following:

(i) The clinical work and practice expenses involved in providing the medical home services provided by the community-based medical home (such as providing increased access, care coordination, care plan setting, population disease management, and teaching self-care skills for managing chronic illnesses) for which payment is not made under this title as of the date of the enactment of this section.

(ii) Use appropriate risk-adjustment in determining the amount of the per beneficiary per month payment under this paragraph.

(6) INITIAL IMPLEMENTATION FUNDING.—The Secretary may make available initial implementation funding to a community based or State-based organization or a State that is partici-

pating in the pilot program under this subsection. Such organization shall provide the Secretary with a detailed implementation plan that includes how such funds will be used. The Secretary shall select a territory of the United States as one of the locations in which to implement the pilot program under this subsection.

(e) EXPANSION OF PROGRAM.—

(1) EVALUATION OF COST AND QUALITY.—The Secretary shall evaluate the pilot program to determine—

(A) the extent to which medical homes result in—

(i) improvement in the quality and coordination of health care services, particularly with regard to the care of complex patients;

(ii) improvement in reducing health disparities;

(iii) reductions in preventable hospitalizations;

(iv) prevention of readmissions;

(v) reductions in emergency room visits;

(vi) improvement in health outcomes, including patient functional status where applicable;

(vii) improvement in patient satisfaction;

(viii) improved efficiency of care such as reducing duplicative diagnostic tests and laboratory tests; and

(ix) reductions in health care expenditures; and

(B) the feasability and advisability of reimbursing medical homes for medical home services under this title on a permanent basis.

(2) REPORT.—Not later than 60 days after the date of completion of the evaluation under paragraph (1), the Secretary shall submit to Congress and make available to the public a report on the findings of the evaluation under paragraph (1).

(3) EXPANSION OF PROGRAM.—

(A) IN GENERAL.—Subject to the results of the evaluation under paragraph (1) and subparagraph (B), the Secretary may issue regulations to implement, on a permanent basis, one or more models, if, and to the extent that such model or models, are beneficial to the program under this title, including that such implementation will improve quality of care, as determined by the Secretary.

(B) CERTIFICATION REQUIREMENT.—The Secretary may not issue such regulations unless the Chief Actuary of the Centers for Medicare & Medicaid Services certifies that the expansion of the components of the pilot program described in subparagraph (A) would result in estimated spending under this title that would be no more than the level of spending that the Secretary estimates would otherwise be spent under this title in the absence of such expansion.

(f) ADMINISTRATIVE PROVISIONS.—

(1) NO DUPLICATION IN PAYMENTS.—During any month, the Secretary may not make payments under this section under more than one model or through more than one medical home under any model for the furnishing of medical home services to an individual.

(2) NO EFFECT ON PAYMENT FOR EVALUATION AND MANAGEMENT SERVICES.—Payments made under this section are in ad-

dition to, and have no effect on the amount of, payment for evaluation and management services made under this title

(3) ADMINISTRATION.—Chapter 35 of title 44, United States Code shall not apply to this section.

(g) FUNDING.—

(1) OPERATIONAL COSTS.—For purposes of administering and carrying out the pilot program (including the design, implementation, technical assistance for and evaluation of such program), in addition to funds otherwise available, there shall be transferred from the Federal Supplementary Medical Insurance Trust Fund under section 1841 to the Secretary for the Centers for Medicare & Medicaid Services Program Management Account $6,000,000 for each of fiscal years 2010 through 2014. Amounts appropriated under this paragraph for a fiscal year shall be available until expended.

(2) PATIENT-CENTERED MEDICAL HOME SERVICES.—In addition to funds otherwise available, there shall be available to the Secretary for the Centers for Medicare & Medicaid Services, from the Federal Supplementary Medical Insurance Trust Fund under section 1841—

(A) $200,000,000 for each of fiscal years 2010 through 2014 for payments for medical home services under subsection (c)(3); and

(B) $125,000,000 for each of fiscal years 2012 through 2016, for payments under subsection (d)(5).

Amounts available under this paragraph for a fiscal year shall be available until expended.

(3) INITIAL IMPLEMENTATION.—In addition to funds otherwise available, there shall be available to the Secretary for the Centers for Medicare & Medicaid Services, from the Federal Supplementary Medical Insurance Trust Fund under section 1841, $2,500,000 for each of fiscal years 2010 through 2012, under subsection (d)(6). Amounts available under this paragraph for a fiscal year shall be available until expended.

(h) TREATMENT OF TRHCA MEDICARE MEDICAL HOME DEMONSTRATION FUNDING.—

(1) In addition to funds otherwise available for payment of medical home services under subsection (c)(3), there shall also be available the amount provided in subsection (g) of section 204 of division B of the Tax Relief and Health Care Act of 2006 (42 U.S.C. 1395b–1 note).

(2) Notwithstanding section 1302(c) of the America's Affordable Health Choices Act of 2009, in addition to funds provided in paragraph (1) and subsection (g)(2)(A), the funding for medical home services that would otherwise have been available if such section 204 medical home demonstration had been implemented (without regard to subsection (g) of such section) shall be available to the independent patient-centered medical home model described in subsection (c).

INDEPENDENCE AT HOME MEDICAL PRACTICE PILOT PROGRAM

SEC. 1866G. (a) IN GENERAL.—The Secretary shall conduct a pilot program (in this section referred to as the "pilot program") to test a payment incentive and service delivery model that utilizes physician and nurse practitioner directed home-based primary care

teams designed to reduce expenditures and improve health outcomes in the provision of items and services under this title to applicable beneficiaries (as defined in subsection (d)). The pilot program tests whether such a model, which is accountable for providing comprehensive, coordinated, continuous, and accessible care to high-need populations at home and coordinating health care across all treatment settings, results in—

(1) reducing preventable hospitalizations;

(2) preventing hospital readmissions;

(3) reducing emergency room visits;

(4) improving health outcomes;

(5) improving the efficiency of care, such as by reducing duplicative diagnostic and laboratory tests;

(6) reducing the cost of health care services covered under this title; and

(7) achieving beneficiary and family caregiver satisfaction.

(b) QUALIFYING INDEPENDENCE AT HOME MEDICAL PRACTICE.—

(1) DEFINITION.—In this section, the term "qualifying independence at home medical practice" means a legal entity comprised of an individual physician or nurse practitioner or group of physicians and nurse practitioners who are certified or have experience and training in providing home-based primary care services to high cost chronically ill beneficiaries as determined appropriate by the Secretary and which has entered into an agreement with the Secretary. Care is provided by a team, including physicians, nurses, physician assistants, pharmacists, and other health and social services staff as appropriate who are certified or have experience providing home-based primary care to applicable beneficiaries, make in-home visits and carry out plans of care that are tailored to the individual beneficiary's chronic conditions and designed to achieve the results in subsection (a) and report the clinical and quality of care outcomes as determined by the Secretary. The pilot program shall be designed to include the participation of physician and nurse practitioner practices with fewer than 10 full-time equivalent physicians, as well as physicians in larger practices, particularly in underserved rural areas.

(2) PARTICIPATION OF NURSE PRACTITIONERS AND PHYSICIAN ASSISTANTS.—Nothing in this section shall be construed to prevent a nurse practitioner or physician assistant from leading a home-based primary care team as part of an Independence at Home Medical Practice if—

(A) all the requirements of this section are met; and

(B) the nurse practitioner or physician assistant, as the case may be, is acting consistently with State law.

(3) INCLUSION OF PROVIDERS AND PRACTITIONERS.—Nothing in this subsection shall be construed as preventing a qualifying Independence at Home Medical Practice from including a provider or participating practitioner that is affiliated with the medical practice under an arrangement structured so that such provider or practitioner participates in the pilot program and shares in any savings under the pilot program.

(c) PAYMENT.—

(1) SHARED SAVINGS.—A qualifying Independence at Home Medical Practice may receive 80 percent of savings in excess of

5 percent if expenditures under this title for applicable beneficiaries participating in the pilot program are at least 5 percent less than a target spending level or a target rate of growth. The shared savings payment shall be made only if savings are at a minimum 5 percent greater than would result from normal variation in expenditures for items and services covered under parts A and B (and part D to the extent the Secretary decides to include such costs).

(2) ESTABLISHMENT OF LEVELS, THRESHOLDS, AND LIMITS.—The Secretary may establish target spending levels, savings thresholds, and limits on shared savings amounts for each participating Independence at Home Medical Practice based upon the size of the practice, characteristics of the enrolled individuals, and such other factors as the Secretary determines appropriate.

(3) INTERIM PAYMENTS.—A qualifying Independence at Home Medical Practice may receive payments for geriatric assessments and monthly care coordination services as determined by the Secretary but in the event that an Independence at Home Medical Practice does not achieve the required savings in this subsection, those payments or a fraction of them, as appropriate, are at risk of being recouped by the Secretary to ensure that no Independence at Home Medical Practice receives Medicare payments in excess of what Medicare otherwise would have paid for the services provided to the beneficiaries receiving medical care from the Independence at Home Medical Practice in the absence of the pilot program.

(4) ASSURANCE OF FINANCIAL SOLVENCY.—In order to receive payments under paragraph (3), a qualifying Independence at Home Medical Practice shall demonstrate to the satisfaction of the Secretary that the organization is able to assume financial risk for the 5 percent savings requirements through available reserves, reinsurance, or withholding of funding provided under this title, or such other means as the Secretary determines appropriate.

(5) NO ADDITIONAL PROGRAM EXPENDITURES.—The Secretary shall limit shared savings payments to each qualifying Independence at Home Medical Practice under this subsection as necessary to ensure that the aggregate expenditures with respect to applicable beneficiaries for such Independence at Home Medical Practice under this title (inclusive of shared savings payments described in this paragraph) do not exceed the amount that the Secretary estimates would be expended for such Independence at Home Medical Practice for such beneficiaries if the pilot program under this section were not implemented.

(d) APPLICABLE BENEFICIARIES.—

(1) DEFINITION.—In this section, the term "applicable beneficiary" means, with respect to a qualifying Independence at Home Medical Practice, an individual who—

(A) is enrolled under part B and entitled to benefits under part A;

(B) is not enrolled in a Medicare Advantage plan under part C or a PACE program under section 1894;

(C) is in the top 20 percent of Medicare patient risk scores;

(D) has two or more chronic illnesses, including congestive heart failure, diabetes, chronic obstructive pulmonary disease, ischemic heart disease, stroke, Alzheimer's Disease and other dementias designated by the Secretary, pressure ulcers, hypertension, neurodegenerative diseases designated by the Secretary which result in high costs under this title including amyotropic lateral sclerosis (ALS), multiple sclerosis, and Parkinson's disease, and other chronic conditions identified by the Secretary that result in high costs when in combination with one or more of the diseases listed in this subparagraph;

(E) had a nonelective hospital admission within the past 12 months;

(F) has received acute or subacute rehabilitation services;

(G) continues to have two or more functional dependencies requiring the assistance of another person (for example, bathing, dressing, toileting, walking, or feeding); and

(H) fulfills such other criteria as the Secretary determines appropriate.

(2) PUBLICATION OF REQUIREMENTS.—The Secretary shall publish eligibility requirements for beneficiaries that are sufficiently clear to be understood by beneficiaries and the individuals providing services to them as part of the pilot program.

(3) PATIENT ELECTION TO PARTICIPATE.—The Secretary shall determine an appropriate method of ensuring that applicable beneficiaries have agreed to participate in an Independence at Home Medical Practice. Participation shall be entirely voluntary.

(4) BENEFICIARY ACCESS TO SERVICES.—Except as provided in subsection (e)(2), nothing in this section shall be construed as encouraging physicians or nurse practitioners to limit beneficiary access to services covered under title XVIII and beneficiaries shall not be required to relinquish access to any benefit under this title as a condition of receiving services from an Independence at Home Medical Practice.

(e) IMPLEMENTATION.—

(1) STARTING DATE.—The pilot program shall begin not later than January 1, 2012. An agreement with a qualifying Independence at Home Medical Practice under the pilot program may cover a 3 year period.

(2) NO DUPLICATION IN PILOT PARTICIPATION.—A physician or nurse practitioner who participates in the accountable care organization pilot program under section 1866D or the medical home pilot program under section 1866E shall not be eligible to participate in the pilot program under this subsection.

(3) PREFERENCE.—In approving an Independence at Home Medical Practice, the Secretary shall give preference to medical practices that are—

(A) located in high cost areas of the country;

(B) have experience in furnishing health care services to applicable beneficiaries in the home; and

(C) use electronic medical records, health information technology, and individualized plans of care.

(4) WAIVER.—The Secretary may waive such provisions of this title (including section 1877) and title XI in the manner the

Secretary determines necessary in order implement the pilot program.

(5) ADMINISTRATION.—Chapter 35 of title 44, United States Code shall not apply to this section.

(f) MINIMUM NUMBER OF SITES.—To the extent practicable, at least two unaffiliated Independence at Home Medical Practices will be established in the 13 highest cost States and the District of Columbia and in 13 additional States that are representative of other regions of the United States and include medically underserved rural and urban areas as determined by the Secretary.

(g) EVALUATION AND MONITORING.—The Secretary shall annually evaluate each qualifying Independence at Home Medical Practice under the pilot program to assess whether it achieved the minimum savings of 5 percent and the results described in subsection (a). The Secretary shall have the discretion to terminate an agreement with an Independence at Home Medical Practice that fails to achieve a preponderance of those results. The Secretary shall make evaluations publicly available within 60 days of the date of completion of such report.

(h) REPORTS TO CONGRESS.—Not later than 2 years after the date the first agreement is entered into under this section, and biennially thereafter until the pilot is completed, the Secretary shall submit to Congress and make publicly available a report on best practices under the pilot program. Each report shall address the impact of such best practices on expenditures, access, and quality under this title.

(i) EXPANSION TO PROGRAM IMPLEMENTATIONS.—

(1) TESTING AND REFINEMENT OF PAYMENT INCENTIVE AND SERVICE DELIVERY MODELS.—Subject to the evaluation described in subsection (f), the Secretary may enter into agreements under the pilot program with additional qualifying Independence at Home Medical Practices to further test and refine models with respect to qualifying Independence at Home Medical Practices.

(2) EXPANDING USE OF SUCCESSFUL MODELS TO PROGRAM IMPLEMENTATION.—

(A) IN GENERAL.—Subject to subparagraph (B), the Secretary may issue regulations to implement, on a permanent basis, the Independence at Home Medical Practice Model if, and to the extent that, such models are beneficial to the program under this title, as determined by the Secretary.

(B) CERTIFICATION.—The Chief Actuary of the Centers for Medicare and Medicaid Services shall certify that the Independence at Home Medical Model described in subparagraph (A) would result in estimated spending that would be less than what spending would otherwise be estimated to be in the absence of such expansion.

(j) FUNDING.—For purposes of administering and carrying out the pilot program, other than for payments for items and services furnished under this title, shared savings and monthly fees, or other payments under subsection (c), in addition to funds otherwise appropriated, there are appropriated to the Secretary for the Center for Medicare and Medicaid Services Program Management Account $5,000,000 for each of fiscal years 2010 through 2014. Amounts ap-

propriated under this paragraph for a fiscal year shall be available until expended.

* * * * * * *

PRACTICING PHYSICIANS ADVISORY COUNCIL; COUNCIL FOR TECHNOLOGY AND INNOVATION *TELEHEALTH ADVISORY COMMITTEE*

SEC. 1868. [(a) PRACTICING PHYSICIANS ADVISORY COUNCIL.—(1) The Secretary shall appoint, based upon nominations submitted by medical organizations representing physicians, a Practicing Physicians Advisory Council (in this subsection referred to as the "Council") to be composed of 15 physicians, each of whom has submitted at least 250 claims for physicians' services under this title in the previous year. At least 11 of the members of the Council shall be physicians described in section 1861(r)(1) and the members of the Council shall include both participating and nonparticipating physicians and physicians practicing in rural areas and underserved urban areas.

[(2) The Council shall meet once during each calendar quarter to discuss certain proposed changes in regulations and carrier manual instructions related to physician services identified by the Secretary. To the extent feasible and consistent with statutory deadlines, such consultation shall occur before the publication of such proposed changes.

[(3) Members of the Council shall be entitled to receive reimbursement of expenses and per diem in lieu of subsistence in the same manner as other members of advisory councils appointed by the Secretary are provided such reimbursement and per diem under this title.]

* * * * * * *

(c) TELEHEALTH ADVISORY COMMITTEE.—

(1) IN GENERAL.—The Secretary shall appoint a Telehealth Advisory Committee (in this subsection referred to as the "Advisory Committee") to make recommendations to the Secretary on policies of the Centers for Medicare & Medicaid Services regarding telehealth services as established under section 1834(m), including the appropriate addition or deletion of services (and HCPCS codes) to those specified in paragraphs (4)(F)(i) and (4)(F)(ii) of such section and for authorized payment under paragraph (1) of such section.

(2) MEMBERSHIP; TERMS.—

(A) MEMBERSHIP.—

(i) IN GENERAL.—The Advisory Committee shall be composed of 9 members, to be appointed by the Secretary, of whom—

(I) 5 shall be practicing physicians;

(II) 2 shall be practicing non-physician health care practitioners; and

(III) 2 shall be administrators of telehealth programs.

(ii) REQUIREMENTS FOR APPOINTING MEMBERS.—In appointing members of the Advisory Committee, the Secretary shall—

(I) ensure that each member has prior experience with the practice of telemedicine or telehealth;

(II) give preference to individuals who are currently providing telemedicine or telehealth services or who are involved in telemedicine or telehealth programs;

(III) ensure that the membership of the Advisory Committee represents a balance of specialties and geographic regions; and

(IV) take into account the recommendations of stakeholders.

(B) TERMS.—The members of the Advisory Committee shall serve for such term as the Secretary may specify.

(C) CONFLICTS OF INTEREST.—An advisory committee member may not participate with respect to a particular matter considered in an advisory committee meeting if such member (or an immediate family member of such member) has a financial interest that could be affected by the advice given to the Secretary with respect to such matter.

(3) MEETINGS.—The Advisory Committee shall meet twice each calendar year and at such other times as the Secretary may provide.

(4) PERMANENT COMMITTEE.—Section 14 of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the Advisory Committee.

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ADMINISTRATION

SEC. 1874. (a) * * *

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(e) COMPLIANCE PROGRAMS FOR PROVIDERS OF SERVICES AND SUPPLIERS.—

(1) IN GENERAL.—The Secretary may disenroll a provider of services or a supplier (other than a physician or a skilled nursing facility) under this title (or may impose any civil monetary penalty or other intermediate sanction under paragraph (4)) if such provider of services or supplier fails to, subject to paragraph (5), establish a compliance program that contains the core elements established under paragraph (2).

(2) ESTABLISHMENT OF CORE ELEMENTS.—The Secretary, in consultation with the Inspector General of the Department of Health and Human Services, shall establish core elements for a compliance program under paragraph (1). Such elements may include written policies, procedures, and standards of conduct, a designated compliance officer and a compliance committee; effective training and education pertaining to fraud, waste, and abuse for the organization's employees and contractors; a confidential or anonymous mechanism, such as a hotline, to receive compliance questions and reports of fraud, waste, or abuse; disciplinary guidelines for enforcement of standards; internal monitoring and auditing procedures, including monitoring and auditing of contractors; procedures for ensuring prompt responses to detected offenses and development of corrective action initiatives, including responses to potential offenses; and procedures to return all identified overpayments to the programs under this title, title XIX, and title XXI.

(3) TIMELINE FOR IMPLEMENTATION.—The Secretary shall determine a timeline for the establishment of the core elements under paragraph (2) and the date on which a provider of services and suppliers (other than physicians) shall be required to have established such a program for purposes of this subsection.

(4) CMS ENFORCEMENT AUTHORITY.—The Administrator for the Centers of Medicare & Medicaid Services shall have the authority to determine whether a provider of services or supplier described in subparagraph (3) has met the requirement of this subsection and to impose a civil monetary penalty not to exceed $50,000 for each violation. The Secretary may also impose other intermediate sanctions, including corrective action plans and additional monitoring in the case of a violation of this subsection.

(5) PILOT PROGRAM.—The Secretary may conduct a pilot program on the application of this subsection with respect to a category of providers of services or suppliers (other than physicians) that the Secretary determines to be a category which is at high risk for waste, fraud, and abuse before implementing the requirements of this subsection to all providers of services and suppliers described in paragraph (3).

* * * * * * *

PAYMENTS TO HEALTH MAINTENANCE ORGANIZATIONS AND COMPETITIVE MEDICAL PLANS

SEC. 1876. (a) * * *

* * * * * * *

(h)(1) * * *

* * * * * * *

(5)(A) * * *

* * * * * * *

(C)(i) * * *

(ii) For any period beginning on or after [January 1, 2010] *January 1, 2012*, a reasonable cost reimbursement contract under this subsection may not be extended or renewed for a service area insofar as such area during the entire previous year was within the service area of—

(I) * * *

* * * * * * *

(iii) A plan described in this clause for a year for a service area is a plan described in section 1851(a)(2)(A)(i) if [the service area for the year] *the portion of the plan's service area for the year that is within the service area of a reasonable cost reimbursement contract* meets the following minimum enrollment requirements:

(I) * * *

* * * * * * *

LIMITATION ON CERTAIN PHYSICIAN REFERRALS

SEC. 1877. (a) * * *

* * * * * * *

(d) ADDITIONAL EXCEPTIONS RELATED ONLY TO OWNERSHIP OR INVESTMENT PROHIBITION.—The following, if not otherwise excepted under subsection (b), shall not be considered to be an ownership or investment interest described in subsection (a)(2)(A):

(1) * * *

(2) RURAL PROVIDERS.—In the case of designated health services furnished in a rural area (as defined in section 1886(d)(2)(D)) by an entity, if—

(A) substantially all of the designated health services furnished by the entity are furnished to individuals residing in such a rural area; **[**and**]**

(B) effective for the 18-month period beginning on the date of the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the entity is not a specialty hospital (as defined in subsection (h)(7))**[**.**]***; and*

(C) in the case where the entity is a hospital, the hospital meets the requirements of paragraph (3)(D).

(3) HOSPITAL OWNERSHIP.—In the case of designated health services provided by a hospital (other than a hospital described in paragraph (1)) if—

(A) * * *

(B) effective for the 18-month period beginning on the date of the enactment of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, the hospital is not a specialty hospital (as defined in subsection (h)(7)); **[**and**]**

(C) the ownership or investment interest is in the hospital itself (and not merely in a subdivision of the hospital)**[**.**]***; and*

(D) the hospital meets the requirements described in subsection (i)(1).

* * * * * * *

[(f) REPORTING REQUIREMENTS.—Each entity providing covered items or services for which payment may be made under this title shall provide the Secretary with the information concerning the entity's ownership, investment, and compensation arrangements, including—

[(1) the covered items and services provided by the entity, and

[(2) the names and unique physician identification numbers of all physicians with an ownership or investment interest (as described in subsection (a)(2)(A)), or with a compensation arrangement (as described in subsection (a)(2)(B)), in the entity, or whose immediate relatives have such an ownership or investment interest or who have such a compensation relationship with the entity.

Such information shall be provided in such form, manner, and at such times as the Secretary shall specify. The requirement of this subsection shall not apply to designated health services provided outside the United States or to entities which the Secretary determines provides services for which payment may be made under this title very infrequently.**]**

(f) REPORTING AND DISCLOSURE REQUIREMENTS.—

(1) IN GENERAL.—Each entity providing covered items or services for which payment may be made under this title shall provide the Secretary with the information concerning the entity's ownership, investment, and compensation arrangements, including—

(A) the covered items and services provided by the entity, and

(B) the names and unique physician identification numbers of all physicians with an ownership or investment interest (as described in subsection (a)(2)(A)), or with a compensation arrangement (as described in subsection (a)(2)(B)), in the entity, or whose immediate relatives have such an ownership or investment interest or who have such a compensation relationship with the entity.

Such information shall be provided in such form, manner, and at such times as the Secretary shall specify. The requirement of this subsection shall not apply to designated health services provided outside the United States or to entities which the Secretary determines provide services for which payment may be made under this title very infrequently.

(2) REQUIREMENTS FOR HOSPITALS WITH PHYSICIAN OWNERSHIP OR INVESTMENT.—In the case of a hospital that meets the requirements described in subsection (i)(1), the hospital shall—

(A) submit to the Secretary an initial report, and periodic updates at a frequency determined by the Secretary, containing a detailed description of the identity of each physician owner and physician investor and any other owners or investors of the hospital;

(B) require that any referring physician owner or investor discloses to the individual being referred, by a time that permits the individual to make a meaningful decision regarding the receipt of services, as determined by the Secretary, the ownership or investment interest, as applicable, of such referring physician in the hospital; and

(C) disclose the fact that the hospital is partially or wholly owned by one or more physicians or has one or more physician investors—

(i) on any public website for the hospital; and

(ii) in any public advertising for the hospital.

The information to be reported or disclosed under this paragraph shall be provided in such form, manner, and at such times as the Secretary shall specify. The requirements of this paragraph shall not apply to designated health services furnished outside the United States or to entities which the Secretary determines provide services for which payment may be made under this title very infrequently.

(3) PUBLICATION OF INFORMATION.—The Secretary shall publish, and periodically update, the information submitted by hospitals under paragraph (2)(A) on the public Internet website of the Centers for Medicare & Medicaid Services.

* * * * * * *

(g) SANCTIONS.—

(1) * * *

* * * * * * *

[(5) FAILURE TO REPORT INFORMATION.—Any person who is required, but fails, to meet a reporting requirement of subsection (f) is subject to a civil money penalty of not more than $10,000 for each day for which reporting is required to have been made. The provisions of section 1128A (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).]

(5) FAILURE TO REPORT OR DISCLOSE INFORMATION.—

(A) REPORTING.—Any person who is required, but fails, to meet a reporting requirement of paragraphs (1) and (2)(A) of subsection (f) is subject to a civil money penalty of not more than $10,000 for each day for which reporting is required to have been made.

(B) DISCLOSURE.—Any physician who is required, but fails, to meet a disclosure requirement of subsection (f)(2)(B) or a hospital that is required, but fails, to meet a disclosure requirement of subsection (f)(2)(C) is subject to a civil money penalty of not more than $10,000 for each case in which disclosure is required to have been made.

(C) APPLICATION.—The provisions of section 1128A (other than the first sentence of subsection (a) and other than subsection (b)) shall apply to a civil money penalty under subparagraphs (A) and (B) in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

* * * * * * *

(i) REQUIREMENTS TO QUALIFY FOR RURAL PROVIDER AND HOSPITAL OWNERSHIP EXCEPTIONS TO SELF-REFERRAL PROHIBITION.—

(1) REQUIREMENTS DESCRIBED.—For purposes of subsection (d)(3)(D), the requirements described in this paragraph are as follows:

(A) PROVIDER AGREEMENT.—The hospital had—

(i) physician ownership or investment on January 1, 2009; and

(ii) a provider agreement under section 1866 in effect on such date.

(B) PROHIBITION ON PHYSICIAN OWNERSHIP OR INVESTMENT.—The percentage of the total value of the ownership or investment interests held in the hospital, or in an entity whose assets include the hospital, by physician owners or investors in the aggregate does not exceed such percentage as of the date of enactment of this subsection.

(C) PROHIBITION ON EXPANSION OF FACILITY CAPACITY.—Except as provided in paragraph (2), the number of operating rooms, procedure rooms, or beds of the hospital at any time on or after the date of the enactment of this subsection are no greater than the number of operating rooms, procedure rooms, or beds, respectively, as of such date.

(D) ENSURING BONA FIDE OWNERSHIP AND INVESTMENT.—

(i) Any ownership or investment interests that the hospital offers to a physician are not offered on more favorable terms than the terms offered to a person who

is not in a position to refer patients or otherwise generate business for the hospital.

(ii) The hospital (or any investors in the hospital) does not directly or indirectly provide loans or financing for any physician owner or investor in the hospital.

(iii) The hospital (or any investors in the hospital) does not directly or indirectly guarantee a loan, make a payment toward a loan, or otherwise subsidize a loan, for any physician owner or investor or group of physician owners or investors that is related to acquiring any ownership or investment interest in the hospital.

(iv) Ownership or investment returns are distributed to each owner or investor in the hospital in an amount that is directly proportional to the ownership or investment interest of such owner or investor in the hospital.

(v) The investment interest of the owner or investor is directly proportional to the owner's or investor's capital contributions made at the time the ownership or investment interest is obtained.

(vi) Physician owners and investors do not receive, directly or indirectly, any guaranteed receipt of or right to purchase other business interests related to the hospital, including the purchase or lease of any property under the control of other owners or investors in the hospital or located near the premises of the hospital.

(vii) The hospital does not offer a physician owner or investor the opportunity to purchase or lease any property under the control of the hospital or any other owner or investor in the hospital on more favorable terms than the terms offered to a person that is not a physician owner or investor.

(viii) The hospital does not condition any physician ownership or investment interests either directly or indirectly on the physician owner or investor making or influencing referrals to the hospital or otherwise generating business for the hospital.

(E) PATIENT SAFETY.—In the case of a hospital that does not offer emergency services, the hospital has the capacity to—

(i) provide assessment and initial treatment for medical emergencies; and

(ii) if the hospital lacks additional capabilities required to treat the emergency involved, refer and transfer the patient with the medical emergency to a hospital with the required capability.

(F) LIMITATION ON APPLICATION TO CERTAIN CONVERTED FACILITIES.—The hospital was not converted from an ambulatory surgical center to a hospital on or after the date of enactment of this subsection.

(2) EXCEPTION TO PROHIBITION ON EXPANSION OF FACILITY CAPACITY.—

(A) PROCESS.—

(i) ESTABLISHMENT.—The Secretary shall establish and implement a process under which a hospital may

apply for an exception from the requirement under paragraph (1)(C).

(ii) OPPORTUNITY FOR COMMUNITY INPUT.—The process under clause (i) shall provide persons and entities in the community in which the hospital applying for an exception is located with the opportunity to provide input with respect to the application.

(iii) TIMING FOR IMPLEMENTATION.—The Secretary shall implement the process under clause (i) on the date that is one month after the promulgation of regulations described in clause (iv).

(iv) REGULATIONS.—Not later than the first day of the month beginning 18 months after the date of the enactment of this subsection, the Secretary shall promulgate regulations to carry out the process under clause (i). The Secretary may issue such regulations as interim final regulations.

(B) FREQUENCY.—The process described in subparagraph (A) shall permit a hospital to apply for an exception up to once every 2 years.

(C) PERMITTED INCREASE.—

(i) IN GENERAL.—Subject to clause (ii) and subparagraph (D), a hospital granted an exception under the process described in subparagraph (A) may increase the number of operating rooms, procedure rooms, or beds of the hospital above the baseline number of operating rooms, procedure rooms, or beds, respectively, of the hospital (or, if the hospital has been granted a previous exception under this paragraph, above the number of operating rooms, procedure rooms, or beds, respectively, of the hospital after the application of the most recent increase under such an exception).

(ii) 100 PERCENT INCREASE LIMITATION.—The Secretary shall not permit an increase in the number of operating rooms, procedure rooms, or beds of a hospital under clause (i) to the extent such increase would result in the number of operating rooms, procedure rooms, or beds of the hospital exceeding 200 percent of the baseline number of operating rooms, procedure rooms, or beds of the hospital.

(iii) BASELINE NUMBER OF OPERATING ROOMS, PROCEDURE ROOMS, OR BEDS.—In this paragraph, the term "baseline number of operating rooms, procedure rooms, or beds" means the number of operating rooms, procedure rooms, or beds of a hospital as of the date of enactment of this subsection.

(D) INCREASE LIMITED TO FACILITIES ON THE MAIN CAMPUS OF THE HOSPITAL.—Any increase in the number of operating rooms, procedure rooms, or beds of a hospital pursuant to this paragraph may only occur in facilities on the main campus of the hospital.

(E) CONDITIONS FOR APPROVAL OF AN INCREASE IN FACILITY CAPACITY.—The Secretary may grant an exception under the process described in subparagraph (A) only to a hospital—

(i) that is located in a county in which the percentage increase in the population during the most recent 5-year period for which data are available is estimated to be at least 150 percent of the percentage increase in the population growth of the State in which the hospital is located during that period, as estimated by Bureau of the Census and available to the Secretary;

(ii) whose annual percent of total inpatient admissions that represent inpatient admissions under the program under title XIX is estimated to be equal to or greater than the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located;

(iii) that does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries;

(iv) that is located in a State in which the average bed capacity in the State is estimated to be less than the national average bed capacity;

(v) that has an average bed occupancy rate that is estimated to be greater than the average bed occupancy rate in the State in which the hospital is located; and

(vi) that meets other conditions as determined by the Secretary.

(F) PROCEDURE ROOMS.—In this subsection, the term "procedure rooms" includes rooms in which catheterizations, angiographies, angiograms, and endoscopies are furnished, but such term shall not include emergency rooms or departments (except for rooms in which catheterizations, angiographies, angiograms, and endoscopies are furnished).

(G) PUBLICATION OF FINAL DECISIONS.—Not later than 120 days after receiving a complete application under this paragraph, the Secretary shall publish on the public Internet website of the Centers for Medicare & Medicaid Services the final decision with respect to such application.

(H) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the exception process under this paragraph, including the establishment of such process, and any determination made under such process.

(3) PHYSICIAN OWNER OR INVESTOR DEFINED.—For purposes of this subsection and subsection (f)(2), the term "physician owner or investor" means a physician (or an immediate family member of such physician) with a direct or an indirect ownership or investment interest in the hospital.

(4) PATIENT SAFETY REQUIREMENT.—In the case of a hospital to which the requirements of paragraph (1) apply, insofar as the hospital admits a patient and does not have any physician available on the premises 24 hours per day, 7 days per week, before admitting the patient—

(A) the hospital shall disclose such fact to the patient; and

(B) following such disclosure, the hospital shall receive from the patient a signed acknowledgment that the patient understands such fact.

(5) CLARIFICATION.—Nothing in this subsection shall be construed as preventing the Secretary from terminating a hospital's provider agreement if the hospital is not in compliance with regulations pursuant to section 1866.

* * * * * * *

MEDICARE COVERAGE FOR END STAGE RENAL DISEASE PATIENTS

SEC. 1881. (a) * * *

(b)(1) * * *

* * * * * * *

(14)(A) * * *

(B) For purposes of this paragraph, the term "renal dialysis services" includes—

(i) * * *

(iii) other drugs and biologicals*, including oral drugs that are not the oral equivalent of an intravenous drug (such as oral phosphate binders and calcimimetics),* that are furnished to individuals for the treatment of end stage renal disease and for which payment was (before the application of this paragraph) made separately under this title, and any oral equivalent form of such drug or biological; and

* * * * * * *

(E)(i) * * *

(ii) A provider of services or renal dialysis facility may make [a one-time election to be excluded from the phase-in] *an election, with respect to 2011, 2012, or 2013, to be excluded from the phase-in (or the remainder of the phase-in)* under clause (i) and be paid entirely based on the payment amount under the payment system under this paragraph *for such year and for each subsequent year during the phase-in described in clause (i).* Such an election shall be made prior to [January 1, 2011] *the first date of such year*, in a form and manner *and at a time* specified by the Secretary, and is final and may not be rescinded.

* * * * * * *

(15) For purposes of evaluating or auditing payments made to renal dialysis facilities for items and services under this section under paragraph (1), each such renal dialysis facility, upon the request of the Secretary, shall provide to the Secretary access to information relating to any ownership or compensation arrangement between such facility and the medical director of such facility or between such facility and any physician.

* * * * * * *

(h) QUALITY INCENTIVES IN THE END-STAGE RENAL DISEASE PROGRAM.—

(1) * * *

(2) MEASURES.—

(A) * * *

(B) USE OF ENDORSED MEASURES.—

(i) * * *

(ii) EXCEPTION.—In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. *The Secretary shall submit such a non-endorsed measure to the entity for consideration for endorsement. If the entity considers but does not endorse such a measure and if the Secretary does not phase-out use of such measure, the Secretary shall include the rationale for continued use of such a measure in rulemaking.*

* * * * * * *

(4) PERFORMANCE STANDARDS.—

(A) * * *

* * * * * * *

(E) SPECIAL RULE.—The Secretary shall initially use as the performance standard for the measures specified under paragraph (2)(A)(i) for a provider of services or a renal dialysis facility the [lesser] *greater* of—

(i) * * *

* * * * * * *

PAYMENT TO HOSPITALS FOR INPATIENT HOSPITAL SERVICES

SEC. 1886. (a) * * *

(b)(1) * * *

* * * * * * *

(3)(A) * * *

(B)(i) * * *

* * * * * * *

[(iii) For purposes of this subparagraph,] *(iii)(I) For purposes of this subparagraph, subject to the productivity adjustment described in subclause (II),* the term "market basket percentage increase" means, with respect to cost reporting periods and discharges occurring in a fiscal year, the percentage, estimated by the Secretary before the beginning of the period or fiscal year, by which the cost of the mix of goods and services (including personnel costs but excluding nonoperating costs) comprising routine, ancillary, and special care unit inpatient hospital services, based on an index of appropriately weighted indicators of changes in wages and prices which are representative of the mix of goods and services included in such inpatient hospital services, for the period or fiscal year will exceed the cost of such mix of goods and services for the preceding 12-month cost reporting period or fiscal year.

(II) The productivity adjustment described in this subclause, with respect to an increase or change for a fiscal year or year or cost reporting period, or other annual period, is a productivity offset equal to the percentage change in the 10-year moving average of annual

economy-wide private nonfarm business multi-factor productivity (as recently published before the promulgation of such increase for the year or period involved). Except as otherwise provided, any reference to the increase described in this clause shall be a reference to the percentage increase described in subclause (I) minus the percentage change under this subclause.

* * * * * * *

(viii)(I) For purposes of clause (i) for fiscal year 2007 and each subsequent fiscal year, in the case of a subsection (d) hospital that does not submit, to the Secretary in accordance with this clause, data required to be submitted on measures selected under this clause with respect to such a fiscal year, the applicable percentage increase under clause (i) for such fiscal year shall be reduced *(but not below zero)* by 2.0 percentage points (or, beginning with fiscal year 2015, by one-quarter). Such reduction shall apply only with respect to the fiscal year involved and the Secretary shall not take into account such reduction in computing the applicable percentage increase under clause (i) for a subsequent fiscal year, and the Secretary and the Medicare Payment Advisory Commission shall carry out the requirements under section 5001(b) of the Deficit Reduction Act of 2005.

* * * * * * *

(ix)(I) For purposes of clause (i) for fiscal year 2015 and each subsequent fiscal year, in the case of an eligible hospital (as defined in subsection (n)(6)(A)) that is not a meaningful EHR user (as defined in subsection (n)(3)) for an EHR reporting period for such fiscal year, three-quarters of the applicable percentage increase otherwise applicable under clause (i) *(determined without regard to clause (iii)(II)* for such fiscal year shall be reduced *(but not below zero)* by 33⅓ percent for fiscal year 2015, 66⅔ percent for fiscal year 2016, and 100 percent for fiscal year 2017 and each subsequent fiscal year. Such reduction shall apply only with respect to the fiscal year involved and the Secretary shall not take into account such reduction in computing the applicable percentage increase under clause (i) for a subsequent fiscal year.

* * * * * * *

(x)(I) Subject to subclause (II), for purposes of reporting data on quality measures for inpatient hospital services furnished during fiscal year 2012 and each subsequent fiscal year, the quality measures specified under clause (viii) shall be measures selected by the Secretary from measures that have been endorsed by the entity with a contract with the Secretary under section 1890(a).

(II) In the case of a specified area or medical topic determined appropriate by the Secretary for which a feasible and practical quality measure has not been endorsed by the entity with a contract under section 1890(a), the Secretary may specify a measure that is not so endorsed as long as due consideration is given to measures that have been endorsed or adopted by a consensus organization identified by the Secretary. The Secretary shall submit such a non-endorsed measure to the entity for consideration for endorsement. If the entity considers but does not endorse such a measure and if the Secretary does not phase-out use of such measure, the Secretary

shall include the rationale for continued use of such a measure in rulemaking.

* * * * * * *

(d)(1) * * *

* * * * * * *

(5)(A) * * *

(B) The Secretary shall provide for an additional payment amount for subsection (d) hospitals with indirect costs of medical education, in an amount computed in the same manner as the adjustment for such costs under regulations (in effect as of January 1, 1983) under subsection (a)(2), except as follows:

(i) * * *

* * * * * * *

[(iv) Effective for discharges occurring on or after October 1, 1997] *(iv)(I) Effective for discharges occurring on or after October 1, 1997, and before July 1, 2009*, all the time spent by an intern or resident in patient care activities under an approved medical residency training program at an entity in a nonhospital setting shall be counted towards the determination of full-time equivalency if the hospital incurs all, or substantially all, of the costs for the training program in that setting.

(II) Effective for discharges occurring on or after July 1, 2009, all the time spent by an intern or resident in patient care activities at an entity in a nonprovider setting shall be counted towards the determination of full-time equivalency if the hospital incurs the costs of the stipends and fringe benefits of the intern or resident during the time the intern or resident spends in that setting.

(v) In determining the adjustment with respect to a hospital for discharges occurring on or after October 1, 1997, the total number of full-time equivalent interns and residents in the fields of allopathic and osteopathic medicine in either a hospital or nonhospital setting may not exceed the number (or, 130 percent of such number in the case of a hospital located in a rural area) of such full-time equivalent interns and residents in the hospital with respect to the hospital's most recent cost reporting period ending on or before December 31, 1996. Rules similar to the rules of subsection (h)(4)(F)(ii) shall apply for purposes of this clause. The provisions of [subsection (h)(7)] *subsections (h)(7) and (h)(8)* shall apply with respect to the first sentence of this clause in the same manner as [it applies] *they apply* with respect to subsection (h)(4)(F)(i).

* * * * * * *

(x) For discharges occurring on or after July 1, 2011, insofar as an additional payment amount under this subparagraph is attributable to resident positions distributed to a hospital under subsection (h)(8)(B), the indirect teaching adjustment factor shall be computed in the same manner as provided under clause (ii) with respect to such resident positions.

(xi)(I) The provisions of subparagraph (I) of subsection (h)(4) shall apply under this subparagraph in the same manner as they apply under such subsection.

(II) In determining the hospital's number of full-time equivalent residents for purposes of this subparagraph, all the time spent by an intern or resident in an approved medical residency training program in nonpatient care activities, such as didactic conferences and seminars, as such time and activities are defined by the Secretary, that occurs in the hospital shall be counted toward the determination of full-time equivalency if the hospital—

(aa) is recognized as a subsection (d) hospital;

(bb) is recognized as a subsection (d) Puerto Rico hospital;

(cc) is reimbursed under a reimbursement system authorized under section 1814(b)(3); or

(dd) is a provider-based hospital outpatient department.

(III) In determining the hospital's number of full-time equivalent residents for purposes of this subparagraph, all the time spent by an intern or resident in an approved medical residency training program in research activities that are not associated with the treatment or diagnosis of a particular patient, as such time and activities are defined by the Secretary, shall not be counted toward the determination of full-time equivalency.

* * * * * * *

(h) PAYMENTS FOR DIRECT GRADUATE MEDICAL EDUCATION COSTS.—

(1) SUBSTITUTION OF SPECIAL PAYMENT RULES.—

(A) IN GENERAL.—Notwithstanding section 1861(v), instead of any amounts that are otherwise payable under this title with respect to the reasonable costs of hospitals for direct graduate medical education costs, the Secretary shall provide for payments for such costs in accordance with paragraph (3) of this subsection. In providing for such payments, the Secretary shall provide for an allocation of such payments between part A and part B (and the trust funds established under the respective parts) as reasonably reflects the proportion of direct graduate medical education costs of hospitals associated with the provision of services under each respective part.

(B) GOALS AND ACCOUNTABILITY FOR APPROVED MEDICAL RESIDENCY TRAINING PROGRAMS.—The goals of medical residency training programs are to foster a physician workforce so that physicians are trained to be able to do the following:

(i) Work effectively in various health care delivery settings, such as nonprovider settings.

(ii) Coordinate patient care within and across settings relevant to their specialties.

(iii) Understand the relevant cost and value of various diagnostic and treatment options.

(iv) Work in inter-professional teams and multi-disciplinary team-based models in provider and nonprovider settings to enhance safety and improve quality of patient care.

(v) Be knowledgeable in methods of identifying systematic errors in health care delivery and in implementing systematic solutions in case of such errors, in-

cluding experience and participation in continuous quality improvement projects to improve health outcomes of the population the physicians serve.

(vi) Be meaningful EHR users (as determined under section 1848(o)(2)) in the delivery of care and in improving the quality of the health of the community and the individuals that the hospital serves.

* * * * * * *

(4) DETERMINATION OF FULL-TIME-EQUIVALENT RESIDENTS.—

(A) * * *

* * * * * * *

(E) COUNTING TIME SPENT IN OUTPATIENT SETTINGS.—[Such rules]

(i) IN GENERAL.—Subject to clause (ii), such rules shall provide that only time spent in activities relating to patient care [shall be counted and that all the time] *shall be counted and that—*

(I) effective for cost reporting periods beginning before July 1, 2009, all the time so spent by a resident under an approved medical residency training program shall be counted towards the determination of full-time equivalency, without regard to the setting in which the activities are performed, if the hospital incurs all, or substantially all, of the costs for the training program in that setting[.]*; and*

(II) effective for cost reporting periods beginning on or after July 1, 2009, all the time so spent by a resident shall be counted towards the determination of full-time equivalency, without regard to the setting in which the activities are performed, if the hospital incurs the costs of the stipends and fringe benefits of the resident during the time the resident spends in that setting.

Any hospital claiming under this subparagraph for time spent in a nonprovider setting shall maintain and make available to the Secretary records regarding the amount of such time and such amount in comparison with amounts of such time in such base year as the Secretary shall specify.

(ii) TREATMENT OF CERTAIN NONPROVIDER AND DIDACTIC ACTIVITIES.—Such rules shall provide that all time spent by an intern or resident in an approved medical residency training program in a nonprovider setting that is primarily engaged in furnishing patient care (as defined in paragraph (5)(K)) in nonpatient care activities, such as didactic conferences and seminars, but not including research not associated with the treatment or diagnosis of a particular patient, as such time and activities are defined by the Secretary, shall be counted toward the determination of full-time equivalency.

(F) LIMITATION ON NUMBER OF RESIDENTS IN ALLOPATHIC AND OSTEOPATHIC MEDICINE.—

(i) IN GENERAL.—Such rules shall provide that for purposes of a cost reporting period beginning on or after October 1, 1997, subject to [paragraph (7)] *paragraphs (7) and (8)*, the total number of full-time equivalent residents before application of weighting factors (as determined under this paragraph) with respect to a hospital's approved medical residency training program in the fields of allopathic medicine and osteopathic medicine may not exceed the number (or, 130 percent of such number in the case of a hospital located in a rural area) of such full-time equivalent residents for the hospital's most recent cost reporting period ending on or before December 31, 1996.

* * * * * * *

(H) SPECIAL RULES FOR APPLICATION OF SUBPARAGRAPHS (F) AND (G).—

(i) NEW FACILITIES.—The Secretary shall, consistent with the principles of subparagraphs (F) and (G) and subject to [paragraph (7)] *paragraphs (7) and (8)*, prescribe rules for the application of such subparagraphs in the case of medical residency training programs established on or after January 1, 1995. In promulgating such rules for purposes of subparagraph (F), the Secretary shall give special consideration to facilities that meet the needs of underserved rural areas.

* * * * * * *

(vi) REDISTRIBUTION OF RESIDENCY SLOTS AFTER A HOSPITAL CLOSES.—

(I) IN GENERAL.—The Secretary shall, by regulation, establish a process consistent with subclauses (II) and (III) under which, in the case where a hospital (other than a hospital described in clause (v)) with an approved medical residency program in a State closes on or after the date that is 2 years before the date of the enactment of this clause, the Secretary shall increase the otherwise applicable resident limit under this paragraph for other hospitals in the State in accordance with this clause.

(II) PROCESS FOR HOSPITALS IN CERTAIN AREAS.—In determining for which hospitals the increase in the otherwise applicable resident limit described in subclause (I) is provided, the Secretary shall establish a process to provide for such increase to one or more hospitals located in the State. Such process shall take into consideration the recommendations submitted to the Secretary by the senior health official (as designated by the chief executive officer of such State) if such recommendations are submitted not later than 180 days after the date of the hospital closure involved (or, in the case of a hospital that closed after the date that is 2 years before the date of the enactment of this clause, 180 days after such date of enactment).

(III) LIMITATION.—The estimated aggregate number of increases in the otherwise applicable resident limits for hospitals under this clause shall be equal to the estimated number of resident positions in the approved medical residency programs that closed on or after the date described in subclause (I).

(I) TREATMENT OF CERTAIN TIME IN APROVED MEDICAL RESIDENCY TRAINING PROGRAM.—In determining the hospital's number of full-time equivalent residents for purposes of this subsection, all the time that is spent by an intern or resident in an approved medical residency training program on vacation, sick leave, or other approved leave, as such time is defined by the Secretary, and that does not prolong the total time the resident is participating in the approved program beyond the normal duration of the program shall be counted toward the determination of full-time equivalency.

(5) DEFINITIONS AND SPECIAL RULES.—As used in this subsection:

(A) * * *

* * * * * * *

(K) NONPROVIDER SETTING THAT IS PRIMARILY ENGAGED IN FURNISHING PATIENT CARE.—The term "nonprovider setting that is primarily engaged in furnishing patient care" means a nonprovider setting in which the primary activity is the care and treatment of patients, as defined by the Secretary.

* * * * * * *

(7) REDISTRIBUTION OF UNUSED RESIDENT POSITIONS.—

(A) * * *

* * * * * * *

(E) JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise, with respect to determinations made under this paragraph *or under paragraph (4)(H)(vi) and paragraph (8).*

(8) ADDITIONAL REDISTRIBUTION OF UNUSED RESIDENCY POSITIONS.—

(A) REDUCTIONS IN LIMIT BASED ON UNUSED POSITIONS.—

(i) PROGRAMS SUBJECT TO REDUCTION.—If a hospital's reference resident level (specified in clause (ii)) is less than the otherwise applicable resident limit (as defined in subparagraph (C)(ii)), effective for portions of cost reporting periods occurring on or after July 1, 2011, the otherwise applicable resident limit shall be reduced by 90 percent of the difference between such otherwise applicable resident limit and such reference resident level.

(ii) REFERENCE RESIDENT LEVEL.—

(I) IN GENERAL.—Except as otherwise provided in a subsequent subclause, the reference resident level specified in this clause for a hospital is the

highest resident level for any of the 3 most recent cost reporting periods (ending before the date of the enactment of this paragraph) of the hospital for which a cost report has been settled (or, if not, submitted (subject to audit)), as determined by the Secretary.

(II) USE OF MOST RECENT ACCOUNTING PERIOD TO RECOGNIZE EXPANSION OF EXISTING PROGRAMS.—If a hospital submits a timely request to increase its resident level due to an expansion, or planned expansion, of an existing residency training program that is not reflected on the most recent settled or submitted cost report, after audit and subject to the discretion of the Secretary, subject to subclause (IV), the reference resident level for such hospital is the resident level that includes the additional residents attributable to such expansion or establishment, as determined by the Secretary. The Secretary is authorized to determine an alternative reference resident level for a hospital that submitted to the Secretary a timely request, before the start of the 2009–2010 academic year, for an increase in its reference resident level due to a planned expansion.

(III) SPECIAL PROVIDER AGREEMENT.—In the case of a hospital described in paragraph (4)(H)(v), the reference resident level specified in this clause is the limitation applicable under subclause (I) of such paragraph.

(IV) PREVIOUS REDISTRIBUTION.—The reference resident level specified in this clause for a hospital shall be increased to the extent required to take into account an increase in resident positions made available to the hospital under paragraph (7)(B) that are not otherwise taken into account under a previous subclause.

(iii) AFFILIATION.—The provisions of clause (i) shall be applied to hospitals which are members of the same affiliated group (as defined by the Secretary under paragraph (4)(H)(ii)) and to the extent the hospitals can demonstrate that they are filling any additional resident slots allocated to other hospitals through an affiliation agreement, the Secretary shall adjust the determination of available slots accordingly, or which the Secretary otherwise has permitted the resident positions (under section 402 of the Social Security Amendments of 1967) to be aggregated for purposes of applying the resident position limitations under this subsection.

(B) REDISTRIBUTION.—

(i) IN GENERAL.—The Secretary shall increase the otherwise applicable resident limit for each qualifying hospital that submits an application under this subparagraph by such number as the Secretary may approve for portions of cost reporting periods occurring on

or after July 1, 2011. The estimated aggregate number of increases in the otherwise applicable resident limit under this subparagraph may not exceed the Secretary's estimate of the aggregate reduction in such limits attributable to subparagraph (A).

(ii) REQUIREMENTS FOR QUALIFYING HOSPITALS.—A hospital is not a qualifying hospital for purposes of this paragraph unless the following requirements are met:

(I) MAINTENANCE OF PRIMARY CARE RESIDENT LEVEL.—The hospital maintains the number of primary care residents at a level that is not less than the base level of primary care residents increased by the number of additional primary care resident positions provided to the hospital under this subparagraph. For purposes of this subparagraph, the "base level of primary care residents" for a hospital is the level of such residents as of a base period (specified by the Secretary), determined without regard to whether such positions were in excess of the otherwise applicable resident limit for such period but taking into account the application of subclauses (II) and (III) of subparagraph (A)(ii).

(II) DEDICATED ASSIGNMENT OF ADDITIONAL RESIDENT POSITIONS TO PRIMARY CARE.—The hospital assigns all such additional resident positions for primary care residents.

(III) ACCREDITATION.—The hospital's residency programs in primary care are fully accredited or, in the case of a residency training program not in operation as of the base year, the hospital is actively applying for such accreditation for the program for such additional resident positions (as determined by the Secretary).

(iii) CONSIDERATIONS IN REDISTRIBUTION.—In determining for which qualifying hospitals the increase in the otherwise applicable resident limit is provided under this subparagraph, the Secretary shall take into account the demonstrated likelihood of the hospital filling the positions within the first 3 cost reporting periods beginning on or after July 1, 2011, made available under this subparagraph, as determined by the Secretary.

(iv) PRIORITY FOR CERTAIN HOSPITALS.—In determining for which qualifying hospitals the increase in the otherwise applicable resident limit is provided under this subparagraph, the Secretary shall distribute the increase to qualifying hospitals based on the following criteria:

(I) The Secretary shall give preference to hospitals that had a reduction in resident training positions under subparagraph (A).

(II) The Secretary shall give preference to hospitals with 3-year primary care residency training

programs, such as family practice and general internal medicine.

(III) The Secretary shall give preference to hospitals insofar as they have in effect formal arrangements (as determined by the Secretary) that place greater emphasis upon training in Federally qualified health centers, rural health clinics, and other nonprovider settings, and to hospitals that receive additional payments under subsection (d)(5)(F) and emphasize training in an outpatient department.

(IV) The Secretary shall give preference to hospitals with a number of positions (as of July 1, 2009) in excess of the otherwise applicable resident limit for such period.

(V) The Secretary shall give preference to hospitals that place greater emphasis upon training in a health professional shortage area (designated under section 332 of the Public Health Service Act) or a health professional needs area (designated under section 2211 of such Act).

(VI) The Secretary shall give preference to hospitals in States that have low resident-to-population ratios (including a greater preference for those States with lower resident-to-population ratios).

(v) LIMITATION.—In no case shall more than 20 full-time equivalent additional residency positions be made available under this subparagraph with respect to any hospital.

(vi) APPLICATION OF PER RESIDENT AMOUNTS FOR PRIMARY CARE.—With respect to additional residency positions in a hospital attributable to the increase provided under this subparagraph, the approved FTE resident amounts are deemed to be equal to the hospital per resident amounts for primary care and nonprimary care computed under paragraph (2)(D) for that hospital.

(vi) DISTRIBUTION.—The Secretary shall distribute the increase in resident training positions to qualifying hospitals under this subparagraph not later than July 1, 2011.

(C) RESIDENT LEVEL AND LIMIT DEFINED.—In this paragraph:

(i) The term "resident level" has the meaning given such term in paragraph (7)(C)(i).

(ii) The term "otherwise applicable resident limit" means, with respect to a hospital, the limit otherwise applicable under subparagraphs (F)(i) and (H) of paragraph (4) on the resident level for the hospital determined without regard to this paragraph but taking into account paragraph (7)(A).

(D) MAINTENANCE OF PRIMARY CARE RESIDENT LEVEL.—In carrying out this paragraph, the Secretary shall require

hospitals that receive additional resident positions under subparagraph (B)—

(i) to maintain records, and periodically report to the Secretary, on the number of primary care residents in its residency training programs; and

(ii) as a condition of payment for a cost reporting period under this subsection for such positions, to maintain the level of such positions at not less than the sum of—

(I) the base level of primary care resident positions (as determined under subparagraph (B)(ii)(I)) before receiving such additional positions; and

(II) the number of such additional positions.

* * * * * * *

(j) PROSPECTIVE PAYMENT FOR INPATIENT REHABILITATION SERVICES.—

(1) * * *

* * * * * * *

(3) PAYMENT RATE.—

(A) * * *

* * * * * * *

(C) INCREASE FACTOR.—For purposes of this subsection for payment units in each fiscal year (beginning with fiscal year 2001), the Secretary shall establish an increase factor. Such factor shall be based on an appropriate percentage increase *(subject to the productivity adjustment described in subsection (b)(3)(B)(iii)(II))* in a market basket of goods and services comprising services for which payment is made under this subsection, which may be the market basket percentage increase described in subsection (b)(3)(B)(iii). The increase factor to be applied under this subparagraph for each of fiscal years 2008 **[**and 2009**]** *through 2010* shall be 0 percent.

* * * * * * *

(m) PROSPECTIVE PAYMENT FOR LONG-TERM CARE HOSPITALS.—

(1) * * *

* * * * * * *

(3) PRODUCTIVITY ADJUSTMENT.—In implementing the system described in paragraph (1) for discharges occurring during the rate year ending in 2010 or any subsequent rate year for a hospital, to the extent that an annual percentage increase factor applies to a base rate for such discharges for the hospital, such factor shall be subject to the productivity adjustment described in subsection (b)(3)(B)(iii)(II).

* * * * * * *

(o) PROSPECTIVE PAYMENT FOR PSYCHIATRIC HOSPITALS.—

(1) REFERENCE TO ESTABLISHMENT AND IMPLEMENTATION OF SYSTEM.—For provisions related to the establishment and implementation of a prospective payment system for payments under this title for inpatient hospital services furnished by psychiatric hospitals (as described in clause (i) of subsection (d)(1)(B)) and psychiatric units (as described in the matter fol-

lowing clause (v) of such subsection), see section 124 of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999.

(2) PRODUCTIVITY ADJUSTMENT.—In implementing the system described in paragraph (1) for discharges occurring during the rate year ending in 2011 or any subsequent rate year for a psychiatric hospital or unit described in such paragraph, to the extent that an annual percentage increase factor applies to a base rate for such discharges for the hospital or unit, respectively, such factor shall be subject to the productivity adjustment described in subsection (b)(3)(B)(iii)(II).

(p) ADJUSTMENT TO HOSPITAL PAYMENTS FOR EXCESS READMISSIONS.—

(1) IN GENERAL.—With respect to payment for discharges from an applicable hospital (as defined in paragraph (5)(C)) occurring during a fiscal year beginning on or after October 1, 2011, in order to account for excess readmissions in the hospital, the Secretary shall reduce the payments that would otherwise be made to such hospital under subsection (d) (or section 1814(b)(3), as the case may be) for such a discharge by an amount equal to the product of—

(A) the base operating DRG payment amount (as defined in paragraph (2)) for the discharge; and

(B) the adjustment factor (described in paragraph (3)(A)) for the hospital for the fiscal year.

(2) BASE OPERATING DRG PAYMENT AMOUNT.—

(A) IN GENERAL.—Except as provided in subparagraph (B), for purposes of this subsection, the term "base operating DRG payment amount" means, with respect to a hospital for a fiscal year, the payment amount that would otherwise be made under subsection (d) for a discharge if this subsection did not apply, reduced by any portion of such amount that is attributable to payments under subparagraphs (B) and (F) of paragraph (5).

(B) ADJUSTMENTS.—For purposes of subparagraph (A), in the case of a hospital that is paid under section 1814(b)(3), the term "base operating DRG payment amount" means the payment amount under such section.

(3) ADJUSTMENT FACTOR.—

(A) IN GENERAL.—For purposes of paragraph (1), the adjustment factor under this paragraph for an applicable hospital for a fiscal year is equal to the greater of—

(i) the ratio described in subparagraph (B) for the hospital for the applicable period (as defined in paragraph (5)(D)) for such fiscal year; or

(ii) the floor adjustment factor specified in subparagraph (C).

(B) RATIO.—The ratio described in this subparagraph for a hospital for an applicable period is equal to 1 minus the ratio of—

(i) the aggregate payments for excess readmissions (as defined in paragraph (4)(A)) with respect to an applicable hospital for the applicable period; and

(ii) the aggregate payments for all discharges (as defined in paragraph (4)(B)) with respect to such applicable hospital for such applicable period.

(C) FLOOR ADJUSTMENT FACTOR.—For purposes of subparagraph (A), the floor adjustment factor specified in this subparagraph for—

(i) fiscal year 2012 is 0.99;

(ii) fiscal year 2013 is 0.98;

(iii) fiscal year 2014 is 0.97; or

(iv) a subsequent fiscal year is 0.95.

(4) AGGREGATE PAYMENTS, EXCESS READMISSION RATIO DEFINED.—For purposes of this subsection:

(A) AGGREGATE PAYMENTS FOR EXCESS READMISSIONS.—The term "aggregate payments for excess readmissions" means, for a hospital for a fiscal year, the sum, for applicable conditions (as defined in paragraph (5)(A)), of the product, for each applicable condition, of—

(i) the base operating DRG payment amount for such hospital for such fiscal year for such condition;

(ii) the number of admissions for such condition for such hospital for such fiscal year; and

(iii) the excess readmissions ratio (as defined in subparagraph (C)) for such hospital for the applicable period for such fiscal year minus 1.

(B) AGGREGATE PAYMENTS FOR ALL DISCHARGES.—The term "aggregate payments for all discharges" means, for a hospital for a fiscal year, the sum of the base operating DRG payment amounts for all discharges for all conditions from such hospital for such fiscal year.

(C) EXCESS READMISSION RATIO.—

(i) IN GENERAL.—Subject to clauses (ii) and (iii), the term "excess readmissions ratio" means, with respect to an applicable condition for a hospital for an applicable period, the ratio (but not less than 1.0) of—

(I) the risk adjusted readmissions based on actual readmissions, as determined consistent with a readmission measure methodology that has been endorsed under paragraph (5)(A)(ii)(I), for an applicable hospital for such condition with respect to the applicable period; to

(II) the risk adjusted expected readmissions (as determined consistent with such a methodology) for such hospital for such condition with respect to such applicable period.

(ii) EXCLUSION OF CERTAIN READMISSIONS.—For purposes of clause (i), with respect to a hospital, excess readmissions shall not include readmissions for an applicable condition for which there are fewer than a minimum number (as determined by the Secretary) of discharges for such applicable condition for the applicable period and such hospital.

(iii) ADJUSTMENT.—In order to promote a reduction over time in the overall rate of readmissions for applicable conditions, the Secretary may provide, beginning with discharges for fiscal year 2014, for the determina-

tion of the excess readmissions ratio under subparagraph (C) to be based on a ranking of hospitals by readmission ratios (from lower to higher readmission ratios) normalized to a benchmark that is lower than the 50th percentile.

(5) DEFINITIONS.—For purposes of this subsection:

(A) APPLICABLE CONDITION.—The term "applicable condition" means, subject to subparagraph (B), a condition or procedure selected by the Secretary among conditions and procedures for which—

(i) readmissions (as defined in subparagraph (E)) that represent conditions or procedures that are high volume or high expenditures under this title (or other criteria specified by the Secretary); and

(ii) measures of such readmissions—

(I) have been endorsed by the entity with a contract under section 1890(a); and

(II) such endorsed measures have appropriate exclusions for readmissions that are unrelated to the prior discharge (such as a planned readmission or transfer to another applicable hospital).

(B) EXPANSION OF APPLICABLE CONDITIONS.—Beginning with fiscal year 2013, the Secretary shall expand the applicable conditions beyond the 3 conditions for which measures have been endorsed as described in subparagraph (A)(ii)(I) as of the date of the enactment of this subsection to the additional 4 conditions that have been so identified by the Medicare Payment Advisory Commission in its report to Congress in June 2007 and to other conditions and procedures which may include an all-condition measure of readmissions, as determined appropriate by the Secretary. In expanding such applicable conditions, the Secretary shall seek the endorsement described in subparagraph (A)(ii)(I) but may apply such measures without such an endorsement.

(C) APPLICABLE HOSPITAL.—The term "applicable hospital" means a subsection (d) hospital or a hospital that is paid under section 1814(b)(3).

(D) APPLICABLE PERIOD.—The term "applicable period" means, with respect to a fiscal year, such period as the Secretary shall specify for purposes of determining excess readmissions.

(E) READMISSION.—The term "readmission" means, in the case of an individual who is discharged from an applicable hospital, the admission of the individual to the same or another applicable hospital within a time period specified by the Secretary from the date of such discharge. Insofar as the discharge relates to an applicable condition for which there is an endorsed measure described in subparagraph (A)(ii)(I), such time period (such as 30 days) shall be consistent with the time period specified for such measure.

(6) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of—

(A) the determination of base operating DRG payment amounts;

(B) the methodology for determining the adjustment factor under paragraph (3), including excess readmissions ratio under paragraph (4)(C), aggregate payments for excess readmissions under paragraph (4)(A), and aggregate payments for all discharges under paragraph (4)(B), and applicable periods and applicable conditions under paragraph (5);

(C) the measures of readmissions as described in paragraph (5)(A)(ii); and

(D) the determination of a targeted hospital under paragraph (8)(B)(i), the increase in payment under paragraph (8)(B)(ii), the aggregate cap under paragraph (8)(C)(i), the hospital-specific limit under paragraph (8)(C)(ii), and the form of payment made by the Secretary under paragraph (8)(D).

(7) MONITORING INAPPROPRIATE CHANGES IN ADMISSIONS PRACTICES.—The Secretary shall monitor the activities of applicable hospitals to determine if such hospitals have taken steps to avoid patients at risk in order to reduce the likelihood of increasing readmissions for applicable conditions. If the Secretary determines that such a hospital has taken such a step, after notice to the hospital and opportunity for the hospital to undertake action to alleviate such steps, the Secretary may impose an appropriate sanction.

(8) ASSISTANCE TO CERTAIN HOSPITALS.—

(A) IN GENERAL.—For purposes of providing funds to applicable hospitals to take steps described in subparagraph (E) to address factors that may impact readmissions of individuals who are discharged from such a hospital, for fiscal years beginning on or after October 1, 2011, the Secretary shall make a payment adjustment for a hospital described in subparagraph (B), with respect to each such fiscal year, by a percent estimated by the Secretary to be consistent with subparagraph (C).

(B) TARGETED HOSPITALS.—Subparagraph (A) shall apply to an applicable hospital that—

(i) received (or, in the case of an 1814(b)(3) hospital, otherwise would have been eligible to receive) $10,000,000 or more in disproportionate share payments using the latest available data as estimated by the Secretary; and

(ii) provides assurances satisfactory to the Secretary that the increase in payment under this paragraph shall be used for purposes described in subparagraph (E).

(C) CAPS.—

(i) AGGREGATE CAP.—The aggregate amount of the payment adjustment under this paragraph for a fiscal year shall not exceed 5 percent of the estimated difference in the spending that would occur for such fiscal year with and without application of the adjustment factor described in paragraph (3) and applied pursuant to paragraph (1).

(ii) HOSPITAL-SPECIFIC LIMIT.—The aggregate amount of the payment adjustment for a hospital under this paragraph shall not exceed the estimated difference in spending that would occur for such fiscal year for such hospital with and without application of the adjustment factor described in paragraph (3) and applied pursuant to paragraph (1).

(D) FORM OF PAYMENT.—The Secretary may make the additional payments under this paragraph on a lump sum basis, a periodic basis, a claim by claim basis, or otherwise.

(E) USE OF ADDITIONAL PAYMENT.—Funding under this paragraph shall be used by targeted hospitals for transitional care activities designed to address the patient noncompliance issues that result in higher than normal readmission rates, such as one or more of the following:

(i) Providing care coordination services to assist in transitions from the targeted hospital to other settings.

(ii) Hiring translators and interpreters.

(iii) Increasing services offered by discharge planners.

(iv) Ensuring that individuals receive a summary of care and medication orders upon discharge.

(v) Developing a quality improvement plan to assess and remedy preventable readmission rates.

(vi) Assigning discharged individuals to a medical home.

(vii) Doing other activities as determined appropriate by the Secretary.

(F) GAO REPORT ON USE OF FUNDS.—Not later than 3 years after the date on which funds are first made available under this paragraph, the Comptroller General of the United States shall submit to Congress a report on the use of such funds.

(G) DISPROPORTIONATE SHARE HOSPITAL PAYMENT.—In this paragraph, the term "disproportionate share hospital payment" means an additional payment amount under subsection (d)(5)(F).

* * * * * * *

PAYMENT TO SKILLED NURSING FACILITIES FOR ROUTINE SERVICE COSTS

SEC. 1888. (a) * * *

* * * * * * *

(e) PROSPECTIVE PAYMENT.—

(1) * * *

(2) DEFINITIONS.—For purposes of this subsection:

(A) COVERED SKILLED NURSING FACILITY SERVICES.—

(i) * * *

(ii) SERVICES EXCLUDED.—Services described in this clause are physicians' services, services described by clauses (i) and (ii) of section 1861(s)(2)(K), certified nurse-midwife services, qualified psychologist services, *clinical social worker services, marriage and family therapist services (as defined in subsection (jjj)(1)),*

mental health counselor services (as defined in section 1861(kkk)(1)), services of a certified registered nurse anesthetist, items and services described in subparagraphs (F) and (O) of section 1861(s)(2), telehealth services furnished under section 1834(m)(4)(C)(ii)(VII), and, only with respect to services furnished during 1998, the transportation costs of electrocardiogram equipment for electrocardiogram test services (HCPCS Code R0076). Services described in this clause do not include any physical, occupational, or speech-language therapy services regardless of whether or not the services are furnished by, or under the supervision of, a physician or other health care professional.

* * * * * * *

(4) FEDERAL PER DIEM RATE.—

(A) * * *

* * * * * * *

(E) UPDATING.—

(i) * * *

(ii) SUBSEQUENT FISCAL YEARS.—The Secretary shall compute an unadjusted Federal per diem rate equal to the Federal per diem rate computed under this subparagraph—

(I) * * *

* * * * * * *

(III) for each of fiscal years 2002 and 2003, the rate computed for the previous fiscal year increased by the skilled nursing facility market basket percentage change for the fiscal year involved minus 0.5 percentage points; ⟦and⟧

(IV) for each of fiscal years 2004 through 2009, the rate computed for the previous fiscal year increased by the skilled nursing facility market basket percentage change for the fiscal year involved;

(V) for fiscal year 2010, the rate computed for the previous fiscal year; and

⟦(IV)⟧ *(VI)* for each subsequent fiscal year, the rate computed for the previous fiscal year increased by the skilled nursing facility market basket percentage change for the fiscal year involved.

* * * * * * *

(5) SKILLED NURSING FACILITY MARKET BASKET INDEX AND PERCENTAGE.—For purposes of this subsection:

(A) * * *

(B) SKILLED NURSING FACILITY MARKET BASKET PERCENTAGE.—The term "skilled nursing facility market basket percentage" means, for a fiscal year or other annual period and as calculated by the Secretary *subject to the productivity adjustment described in section 1886(b)(3)(B)(iii)(II)*, the percentage change in the skilled nursing facility market basket index (established under subparagraph (A))

from the midpoint of the prior fiscal year (or period) to the midpoint of the fiscal year (or other period) involved.

* * * * * * *

(8) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869, 1878, or otherwise of—

(A) the establishment of Federal per diem rates under paragraph (4), including the computation of the standardized per diem rates under paragraph (4)(C), adjustments and corrections for case mix under paragraphs (4)(F) and (4)(G)(i), adjustments for variations in labor-related costs under paragraph (4)(G)(ii), [and] adjustments under paragraph (4)(G)(iii)*, and adjustment under section 1111(b) of the America's Affordable Health Choices Act of 2009*;

(B) the establishment of facility specific rates before July 1, 1999 (except any determination of costs paid under part A of this title); [and]

(C) the establishment of transitional amounts under paragraph (7)[.]*; and*

(D) the establishment of outliers under paragraph (13).

* * * * * * *

(13) OUTLIERS FOR NTA AND THERAPY.—

(A) IN GENERAL.—With respect to outliers because of unusual variations in the type or amount of medically necessary care, beginning with October 1, 2010, the Secretary—

(i) shall provide for an addition or adjustment to the payment amount otherwise made under this section with respect to non-therapy ancillary services in the case of such outliers; and

(ii) may provide for such an addition or adjustment to the payment amount otherwise made under this section with respect to therapy services in the case of such outliers.

(B) OUTLIERS BASED ON AGGREGATE COSTS.—Outlier adjustments or additional payments described in subparagraph (A) shall be based on aggregate costs during a stay in a skilled nursing facility and not on the number of days in such stay.

(C) BUDGET NEUTRALITY.—The Secretary shall reduce estimated payments that would otherwise be made under the prospective payment system under this subsection with respect to a fiscal year by 2 percent. The total amount of the additional payments or payment adjustments for outliers made under this paragraph with respect to a fiscal year may not exceed 2 percent of the total payments projected or estimated to be made based on the prospective payment system under this subsection for the fiscal year.

* * * * * * *

(f) REPORTING OF DIRECT CARE EXPENDITURES.—

(1) IN GENERAL.—For cost reports submitted under this title for cost reporting periods beginning on or after the date that is 3 years after the date of the enactment of this subsection, skilled

nursing facilities shall separately report expenditures for wages and benefits for direct care staff (breaking out (at a minimum) registered nurses, licensed professional nurses, certified nurse assistants, and other medical and therapy staff).

(2) MODIFICATION OF FORM.—The Secretary, in consultation with private sector accountants experienced with skilled nursing facility cost reports, shall redesign such reports to meet the requirement of paragraph (1) not later than 1 year after the date of the enactment of this subsection.

(3) CATEGORIZATION BY FUNCTIONAL ACCOUNTS.—Not later than 30 months after the date of the enactment of this subsection, the Secretary, working in consultation with the Medicare Payment Advisory Commission, the Inspector General of the Department of Health and Human Services, and other expert parties the Secretary determines appropriate, shall take the expenditures listed on cost reports, as modified under paragraph (1), submitted by skilled nursing facilities and categorize such expenditures, regardless of any source of payment for such expenditures, for each skilled nursing facility into the following functional accounts on an annual basis:

(A) Spending on direct care services (including nursing, therapy, and medical services).

(B) Spending on indirect care (including housekeeping and dietary services).

(C) Capital assets (including building and land costs).

(D) Administrative services costs.

(4) AVAILABILITY OF INFORMATION SUBMITTED.—The Secretary shall establish procedures to make information on expenditures submitted under this subsection readily available to interested parties upon request, subject to such requirements as the Secretary may specify under the procedures established under this paragraph.

* * * * * * *

CONTRACT WITH A CONSENSUS-BASED ENTITY REGARDING PERFORMANCE MEASUREMENT

SEC. 1890. (a) * * *

(b) DUTIES.—The duties described in this subsection are the following:

(1) * * *

(2) ENDORSEMENT OF MEASURES.—The entity shall provide for the endorsement of standardized health care performance measures. The endorsement process under the preceding sentence shall consider whether a measure—

(A) * * *

* * * * * * *

If the entity does not endorse a measure, such entity shall explain the reasons and provide suggestions about changes to such measure that might make it a potentially endorsable measure.

* * * * * * *

(d) FUNDING.—For purposes of carrying out this section, the Secretary shall provide for the transfer, from the Federal Hospital In-

surance Trust Fund under section 1817 and the Federal Supplementary Medical Insurance Trust Fund under section 1841 (in such proportion as the Secretary determines appropriate), of $10,000,000 to the Centers for Medicare & Medicaid Services Program Management Account ⟦for each of fiscal years 2009 through 2012⟧ *for fiscal year 2009, and $12,000,000 for each of the fiscal years 2010 through 2012*.

* * * * * * *

MEDICARE INTEGRITY PROGRAM

SEC. 1893. (a) ESTABLISHMENT OF PROGRAM.—There is hereby established the Medicare Integrity Program (in this section referred to as the "Program") under which the Secretary shall promote the integrity of the medicare program by entering into contracts in accordance with this section with eligible entities*, or otherwise,* to carry out the activities described in subsection (b).

* * * * * * *

(c) ELIGIBILITY OF ENTITIES.—An entity is eligible to enter into a contract under the Program to carry out any of the activities described in subsection (b) if—

(1) * * *

* * * * * * *

(3) the entity complies with such conflict of interest standards as are generally applicable to Federal acquisition and procurement; ⟦and⟧

(4) for the contract year beginning in 2011 and each subsequent contract year, the entity provides assurances to the satisfaction of the Secretary that the entity will conduct periodic evaluations of the effectiveness of the activities carried out by such entity under the Program and will submit to the Secretary an annual report on such activities; and

⟦(4)⟧ *(5)* the entity meets such other requirements as the Secretary may impose.

* * * * * * *

PROSPECTIVE PAYMENT FOR HOME HEALTH SERVICES

SEC. 1895. (a) * * *

(b) SYSTEM OF PROSPECTIVE PAYMENT FOR HOME HEALTH SERVICES.—

(1) * * *

* * * * * * *

(3) PAYMENT BASIS.—

(A) INITIAL BASIS.—

(i) IN GENERAL.—Under such system the Secretary shall provide for computation of a standard prospective payment amount (or amounts) as follows:

(I) * * *

* * * * * * *

(III) For periods beginning after the period described in subclause (II) *and before 2011*, such amount (or amounts) shall be equal to the amount

(or amounts) that would have been determined under subclause (I) that would have been made for fiscal year 2001 if the system had not been in effect and if section 1861(v)(1)(L)(ix) had not been enacted but if the reduction in limits described in clause (ii) had been in effect, updated under subparagraph (B).

(IV) Subject to clause (iii)(I), for 2011, such amount (or amounts) shall be adjusted by a uniform percentage determined to be appropriate by the Secretary based on analysis of factors such as changes in the average number and types of visits in an episode, the change in intensity of visits in an episode, growth in cost per episode, and other factors that the Secretary considers to be relevant.

(V) Subject to clause (iii)(II), for a year after 2011, such a amount (or amounts) shall be equal to the amount (or amounts) determined under this clause for the previous year, updated under subparagraph (B).

* * * * * * *

(iii) SPECIAL RULE IN CASE OF INABILITY TO EFFECT TIMELY REBASING.—

(I) APPLICATION OF PROXY AMOUNT FOR 2011.—If the Secretary is not able to compute the amount (or amounts) under clause (i)(IV) so as to permit, on a timely basis, the application of such clause for 2011, the Secretary shall substitute for such amount (or amounts) 95 percent of the amount (or amounts) that would otherwise be specified under clause (i)(III) if it applied for 2011.

(II) ADJUSTMENT FOR SUBSEQUENT YEARS BASED ON DATA.—If the Secretary applies subclause (I), the Secretary before July 1, 2011, shall compare the amount (or amounts) applied under such subclause with the amount (or amounts) that should have been applied under clause (i)(IV). The Secretary shall decrease or increase the prospective payment amount (or amounts) under clause (i)(V) for 2012 (or, at the Secretary's discretion, over a period of several years beginning with 2012) by the amount (if any) by which the amount (or amounts) applied under subclause (I) is greater or less, respectively, than the amount (or amounts) that should have been applied under clause (i)(IV).

(B) ANNUAL UPDATE.—

(i) * * *

(ii) HOME HEALTH APPLICABLE INCREASE PERCENTAGE.—For purposes of this subparagraph, the term "home health applicable increase percentage" means, with respect to—

(I) * * *

* * * * * * *

(IV) 2006, 0 percent; [and]

(V) 2007, 2008, and 2009, subject to clause (v), the home health market basket percentage increase;

(VI) 2010, subject to clause (v), 0 percent; and

[(V)] *(VII)* any subsequent year, subject to clause (v), the home health market basket percentage increase.

(iii) HOME HEALTH MARKET BASKET PERCENTAGE INCREASE.—For purposes of this subsection, the term "home health market basket percentage increase" means, with respect to a fiscal year or year, a percentage (estimated by the Secretary before the beginning of the fiscal year or year) determined and applied with respect to the mix of goods and services included in home health services in the same manner *(including being subject to the productivity adjustment described in section 1886(b)(3)(B)(iii)(II))* as the market basket percentage increase under section 1886(b)(3)(B)(iii) is determined and applied to the mix of goods and services comprising inpatient hospital services for the fiscal year or year.

(iv) ADJUSTMENT FOR CASE MIX CHANGES.—[Insofar as] *Subject to clause (vi), insofar as* the Secretary determines that the adjustments under paragraph (4)(A)(i) for a previous fiscal year or year (or estimates that such adjustments for a future fiscal year or year) did (or are likely to) result in a change in aggregate payments under this subsection during the fiscal year or year that are a result of changes in the coding or classification of different units of services that do not reflect real changes in case mix, the Secretary may adjust the standard prospective payment amount (or amounts) under paragraph (3) for subsequent fiscal years or years so as to eliminate the effect of such coding or classification changes.

(v) ADJUSTMENT IF QUALITY DATA NOT SUBMITTED.—

(I) ADJUSTMENT.—For purposes of clause (ii)(V), for 2007 and each subsequent year, in the case of a home health agency that does not submit data to the Secretary in accordance with subclause (II) with respect to such a year, the home health market basket percentage increase applicable under such clause for such year shall be reduced *(but not below 0)* by 2 percentage points. Such reduction shall apply only with respect to the year involved, and the Secretary shall not take into account such reduction in computing the prospective payment amount under this section for a subsequent year, and the Medicare Payment Advisory Commission shall carry out the requirements under section 5201(d) of the Deficit Reduction Act of 2005.

(vi) SPECIAL RULE FOR CASE MIX CHANGES FOR 2011.—

(I) IN GENERAL.—With respect to the case mix adjustments established in section 484.220(a) of

title 42, Code of Federal Regulations, the Secretary shall apply, in 2010, the adjustment established in paragraph (3) of such section for 2011, in addition to applying the adjustment established in paragraph (2) for 2010.

(II) CONSTRUCTION.—Nothing in this clause shall be construed as limiting the amount of adjustment for case mix for 2010 or 2011 if more recent data indicate an appropriate adjustment that is greater than the amount established in the section described in subclause (I).

* * * * * * *

MEDICARE IMPROVEMENT FUND

SEC. 1898. (a) * * *

(b) FUNDING.—

(1) IN GENERAL.—There shall be available to the Fund, for expenditures from the Fund for services furnished during—

[(A) fiscal year 2014, $22,290,000,000; and**]**

(A) the period beginning with fiscal year 2011 and ending with fiscal year 2019, $8,000,000,000; and

* * * * * * *

STATE PLANS FOR MEDICAL ASSISTANCE

SEC. 1902. (a) A State plan for medical assistance must—

(1) * * *

* * * * * * *

(9) provide—

(A) * * *

(B) for the establishment or designation of a State authority or authorities which shall be responsible for establishing and maintaining standards, other than those relating to health, for such institutions, **[**and**]**

(C) that any laboratory services paid for under such plan must be provided by a laboratory which meets the applicable requirements of section 1861(e)(9) or paragraphs (16) and (17) of section 1861(s), or, in the case of a laboratory which is in a rural health clinic, of section 1861(aa)(2)(G)**[**;**]**, *and*

(D) that the State maintain a consumer-oriented website providing useful information to consumers regarding all skilled nursing facilities and all nursing facilities in the State, including for each facility, Form 2567 State inspection reports (or a successor form), complaint investigation reports, the facility's plan of correction, and such other information that the State or the Secretary considers useful in assisting the public to assess the quality of long term care options and the quality of care provided by individual facilities;

(10) provide—

(A) *subject to section 1903(aa)(2),* for making medical assistance available, including at least the care and services

listed in paragraphs (1) through (5), (17) [and (21)], *(21), and (28)* of section 1905(a), to—

(i) all individuals—

(I) * * *

* * * * * * *

(VI) who are described in subparagraph (C) of subsection (l)(1) and whose family income does not exceed the income level the State is required to establish under subsection (l)(2)(B) for such a family, [or]

(VII) who are described in subparagraph (D) of subsection (l)(1) and whose family income does not exceed the income level the State is required to establish under subsection (l)(2)(C) for such a family;

(VIII) who are under 65 years of age, who are not described in a previous subclause of this clause, and who are in families whose income (determined using methodologies and procedures specified by the Secretary in consultation with the Health Choices Commissioner) does not exceed 133⅓ percent of the income official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved; or

(IX) who are under 65 years of age, who would be eligible for medical assistance under the State plan under one of subclauses (I) through (VII) (based on the income standards, methodologies, and procedures in effect as of June 16, 2009) but for income and who are in families whose income does not exceed 133⅓ percent of the income official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved;

(ii) at the option of the State, to any group or groups of individuals described in section 1905(a) (or, in the case of individuals described in section 1905(a)(i), to any reasonable categories of such individuals) who are not individuals described in clause (i) of this subparagraph but—

(I) * * *

* * * * * * *

(XVIII) who are described in subsection (aa) (relating to certain breast or cervical cancer patients); [or]

(XIX) who are disabled children described in subsection (cc)(1);

(XX) who are described in subsection (hh) (relating to individuals who meet certain income standards); or

(XXI) who are described in subsection (ii) (relating to HIV-infected individuals);

* * * * * * *

(C) that if medical assistance is included for any group of individuals described in section 1905(a) who are not described in subparagraph (A) or (E), then—

(i) * * *

* * * * * * *

(iv) if such medical assistance includes services in institutions for mental diseases or in an intermediate care facility for the mentally retarded (or both) for any such group, it also must include for all groups covered at least the care and services listed in paragraphs (1) through (5) [and (17)]*, (17), and (28)* of section 1905(a) or the care and services listed in any 7 of the paragraphs numbered (1) through (24) of such section;

* * * * * * *

(E)(i) * * *

* * * * * * *

(iv) subject to [sections 1933 and] *section* 1905(p)(4), for making medical assistance available (but only for premiums payable with respect to months during the period beginning with January 1998, and ending with [December 2010] *December 2012*) for medicare cost-sharing described in section 1905(p)(3)(A)(ii) for individuals who would be qualified medicare beneficiaries described in section 1905(p)(1) but for the fact that their income exceeds the income level established by the State under section 1905(p)(2) and is at least 120 percent, but less than 135 percent, of the official poverty line (referred to in such section) for a family of the size involved and who are not otherwise eligible for medical assistance under the State plan;

* * * * * * *

except that (I) the making available of the services described in paragraph (4), (14), or (16) of section 1905(a) to individuals meeting the age requirements prescribed therein shall not, by reason of this paragraph (10), require the making available of any such services, or the making available of such services of the same amount, duration, and scope, to individuals of any other ages, (II) the making available of supplementary medical insurance benefits under part B of title XVIII to individuals eligible therefor (either pursuant to an agreement entered into under section 1843 or by reason of the payment of premiums under such title by the State agency on behalf of such individuals), or provision for meeting part or all of the cost of deductibles, cost sharing, or similar charges under part B of title XVIII for individuals eligible for benefits under such part, shall not, by reason of this paragraph (10), require the making available of any such benefits, or the making available of serv-

ices of the same amount, duration, and scope, to any other individuals, (III) the making available of medical assistance equal in amount, duration, and scope to the medical assistance made available to individuals described in clause (A) to any classification of individuals approved by the Secretary with respect to whom there is being paid, or who are eligible, or would be eligible if they were not in a medical institution, to have paid with respect to them, a State supplementary payment shall not, by reason of this paragraph (10), require the making available of any such assistance, or the making available of such assistance of the same amount, duration, and scope, to any other individuals not described in clause (A), (IV) the imposition of a deductible, cost sharing, or similar charge for any item or service furnished to an individual not eligible for the exemption under section 1916(a)(2) or (b)(2) shall not require the imposition of a deductible, cost sharing, or similar charge for the same item or service furnished to an individual who is eligible for such exemption, (V) the making available to pregnant women covered under the plan of services relating to pregnancy (including prenatal, delivery, and postpartum services) or to any other condition which may complicate pregnancy shall not, by reason of this paragraph (10), require the making available of such services, or the making available of such services of the same amount, duration, and scope, to any other individuals, provided such services are made available (in the same amount, duration, and scope) to all pregnant women covered under the State plan, (VI) with respect to the making available of medical assistance for hospice care to terminally ill individuals who have made a voluntary election described in section 1905(o) to receive hospice care instead of medical assistance for certain other services, such assistance may not be made available in an amount, duration, or scope less than that provided under title XVIII, and the making available of such assistance shall not, by reason of this paragraph (10), require the making available of medical assistance for hospice care to other individuals or the making available of medical assistance for services waived by such terminally ill individuals, (VII) the medical assistance made available to an individual described in subsection (l)(1)(A) who is eligible for medical assistance only because of subparagraph (A)(i)(IV) or (A)(ii)(IX) shall be limited to medical assistance for services related to pregnancy (including prenatal, delivery, postpartum, and family planning services) and to other conditions which may complicate pregnancy, (VIII) the medical assistance made available to a qualified medicare beneficiary described in section 1905(p)(1) who is only entitled to medical assistance because the individual is such a beneficiary shall be limited to medical assistance for medicare cost-sharing (described in section 1905(p)(3)), subject to the provisions of subsection (n) and section 1916(b), (IX) the making available of respiratory care services in accordance with subsection (e)(9) shall not, by reason of this paragraph (10), require the making available of such services, or the making available of such services of the same amount, duration, and scope, to any individuals not included under subsection (e)(9)(A), provided such services are made available (in the

same amount, duration, and scope) to all individuals described in such subsection, (X) if the plan provides for any fixed durational limit on medical assistance for inpatient hospital services (whether or not such a limit varies by medical condition or diagnosis), the plan must establish exceptions to such a limit for medically necessary inpatient hospital services furnished with respect to individuals under one year of age in a hospital defined under the State plan, pursuant to section 1923(a)(1)(A), as a disproportionate share hospital and subparagraph (B) (relating to comparability) shall not be construed as requiring such an exception for other individuals, services, or hospitals, (XI) the making available of medical assistance to cover the costs of premiums, deductibles, coinsurance, and other cost-sharing obligations for certain individuals for private health coverage as described in section 1906 shall not, by reason of paragraph (10), require the making available of any such benefits or the making available of services of the same amount, duration, and scope of such private coverage to any other individuals, (XII) the medical assistance made available to an individual described in subsection (u)(1) who is eligible for medical assistance only because of subparagraph (F) shall be limited to medical assistance for COBRA continuation premiums (as defined in subsection (u)(2)), (XIII) the medical assistance made available to an individual described in subsection (z)(1) who is eligible for medical assistance only because of subparagraph (A)(ii)(XII) shall be limited to medical assistance for TB-related services (described in subsection (z)(2)), **[**and (XIV)**]** *(XIV)* the medical assistance made available to an individual described in subsection (aa) who is eligible for medical assistance only because of subparagraph (A)(10)(ii)(XVIII) shall be limited to medical assistance provided during the period in which such an individual requires treatment for breast or cervical cancer*, and (XV) the medical assistance made available to an individual described in subsection (hh) shall be limited to family planning services and supplies described in section 1905(a)(4)(C) including medical diagnosis and treatment services that are provided pursuant to a family planning service in a family planning setting*;

* * * * * * *

(13) provide—

(A) for a public process for determination of rates of payment under the plan for hospital services, nursing facility services, and services of intermediate care facilities for the mentally retarded under which—

(i) * * *

(iii) final rates, the methodologies underlying the establishment of such rates, and justifications for such final rates are published, **[**and**]**

(iv) in the case of hospitals, such rates take into account (in a manner consistent with section 1923) the situation of hospitals which serve a disproportionate number of low-income patients with special needs**[**; and**]***, and*

(v) in the case of hospitals and at the option of a State, such rates may include, to the extent consistent

with section 1905(bb), payment for graduate medical education; and

(B) for payment for hospice care in amounts no lower than the amounts, using the same methodology, used under part A of title XVIII and for payment of amounts under section 1905(o)(3); except that in the case of hospice care which is furnished to an individual who is a resident of a nursing facility or intermediate care facility for the mentally retarded, and who would be eligible under the plan for nursing facility services or services in an intermediate care facility for the mentally retarded if he had not elected to receive hospice care, there shall be paid an additional amount, to take into account the room and board furnished by the facility, equal to at least 95 percent of the rate that would have been paid by the State under the plan for facility services in that facility for that individual; *and*

(C) payment for primary care services (as defined in section 1848(j)(5)(A), but applied without regard to clause (ii) thereof) furnished by physicians (or for services furnished by other health care professionals that would be primary care services under such section if furnished by a physician) at a rate not less than 80 percent of the payment rate applicable to such services and physicians or professionals (as the case may be) under part B of title XVIII for services furnished in 2010, 90 percent of such rate for services and physicians (or professionals) furnished in 2011, and 100 percent of such payment rate for services and physicians (or professionals) furnished in 2012 or a subsequent year;

* * * * * * *

(23) provide that (A) any individual eligible for medical assistance (including drugs) may obtain such assistance from any institution, agency, community pharmacy, or person, qualified to perform the service or services required (including an organization which provides such services, or arranges for their availability, on a prepayment basis), who undertakes to provide him such services, and (B) an enrollment of an individual eligible for medical assistance in a primary care case-management system (described in section 1915(b)(1)), a medicaid managed care organization, or a similar entity shall not restrict the choice of the qualified person from whom the individual may receive services under section 1905(a)(4)(C), except as provided in subsection (g) and in section 1915, except that this paragraph shall not apply in the case of Puerto Rico, the Virgin Islands, and Guam, and except that nothing in this paragraph shall be construed as requiring a State to provide medical assistance for such services furnished by a person or entity convicted of a felony under Federal or State law for an offense which the State agency determines is inconsistent with the best interests of beneficiaries under the State plan *or by a person to whom or entity to which a moratorium under section 1128G(a)(4) is applied during the period of such moratorium*;

* * * * * * *

(39) provide that the State agency shall exclude any specified individual or entity from participation in the program under the State plan for the period specified by the Secretary, when required by him to do so pursuant to section 1128 or section 1128A, *terminate the participation of any individual or entity in such program if (subject to such exceptions are are permitted with respect to exclusion under sections 1128(b)(3)(C) and 1128(d)(3)(B)) participation of such individual or entity is terminated under title XVIII, any other State plan under this title, or any child health plan under title XXI,* and provide that no payment may be made under the plan with respect to any item or service furnished by such individual or entity during such period;

* * * * * * *

(47) at the option of the State, provide for making ambulatory prenatal care available to pregnant women during a presumptive eligibility period in accordance with section 1920 and provide for making medical assistance for items and services described in subsection (a) of section 1920A available to children during a presumptive eligibility period in accordance with such section and provide for making medical assistance available to individuals described in subsection (a) of section 1920B during a presumptive eligibility period in accordance with such section *and provide for making medical assistance available to individuals described in subsection (a) of section 1920C during a presumptive eligibility period in accordance with such section*;

* * * * * * *

(55) provide for receipt and initial processing of applications of individuals for medical assistance ⟦under subsection (a)(10)(A)(i)(IV), (a)(10)(A)(i)(VI), (a)(10)(A)(i)(VII), or (a)(10)(A)(ii)(IX)⟧ *(including receipt and processing of applications of individuals for affordability credits under subtitle C of title II of division A of the America's Affordable Health Choices Act of 2009 pursuant to a Medicaid memorandum of understanding under section 1943(a)(1))—*

(A) * * *

* * * * * * *

(72) provide that the State will not prevent a Federally-qualified health center from entering into contractual relationships with private practice dental providers in the provision of Federally-qualified health center services; ⟦and⟧

(73) in the case of any State in which 1 or more Indian Health Programs or Urban Indian Organizations furnishes health care services, provide for a process under which the State seeks advice on a regular, ongoing basis from designees of such Indian Health Programs and Urban Indian Organizations on matters relating to the application of this title that are likely to have a direct effect on such Indian Health Programs and Urban Indian Organizations and that—

(A) * * *

(B) may include appointment of an advisory committee and of a designee of such Indian Health Programs and Urban Indian Organizations to the medical care advisory

committee advising the State on its State plan under this title[.]*;*

(74) provide that the State will enforce any determination made by the Secretary under subsection (a) of section 1128G (relating to a significant risk of fraudulent activity with respect to a category of provider or supplier described in such subsection (a) through use of the appropriate procedures described in such subsection (a)) or subsection (b) of such section (relating to disclosure requirements), and that the State will carry out any activities as required by the Secretary for purposes of such subsection (a) and apply any enhanced safeguards, with respect to a provider or supplier described in such subsection (b), as the Secretary determines necessary under such subsection (b);

(75) provide for maintenance of effort under the State child health plan under title XXI in accordance with subsection (gg);

(76) provide that in the case of any youth who is 18 years of age or younger, was enrolled for medical assistance under the State plan immediately before becoming an inmate of a public institution, is 18 years of age or younger upon release from such institution, and is eligible for such medical assistance under the State plan at the time of release from such institution—

(A) during the period such youth is incarcerated in a public institution, the State shall not terminate eligibility for medical assistance under the State plan for such youth;

(B) during the period such youth is incarcerated in a public institution, the State shall establish a process that ensures—

(i) that the State does not claim federal financial participation for services that are provided to such youth and that are excluded under subsection 1905(a)(28)(A); and

(ii) that the youth receives medical assistance for which federal participation is available under this title;

(C) on or before the date such youth is released from such institution, the State ensure that such youth is enrolled for medical assistance under this title, unless and until there is a determination that the individual is no longer eligible to be so enrolled; and

(D) the State shall ensure that enrollment under subparagraph (C) will be completed before such date so that the youth can access medical assistance under this title immediately upon leaving the institution;

(77) provide that any provider or supplier (other than a physician or nursing facility) providing services under such plan shall, subject to paragraph (5) of section 1874(d), establish a compliance program described in paragraph (1) of such section in accordance with such section;

(78) provide that the State agency described in paragraph (9) exclude, with respect to a period, any individual or entity from participation in the program under the State plan if such individual or entity owns, controls, or manages an entity that (or if such entity is owned, controlled, or managed by an individual or entity that)—

(A) has unpaid overpayments under this title during such period determined by the Secretary or the State agency to be delinquent;

(B) is suspended or excluded from participation under or whose participation is terminated under this title during such period; or

(C) is affiliated with an individual or entity that has been suspended or excluded from participation under this title or whose participation is terminated under this title during such period;

(79) provide that any agent, clearinghouse, or other alternate payee that submits claims on behalf of a health care provider must register with the State and the Secretary in a form and manner specified by the Secretary under section 1866(j)(1)(D); and

(80) provide for implementation of the payment models specified by the Secretary under section 1115A(c) for implementation on a nationwide basis unless the State demonstrates to the satisfaction of the Secretary that implementation would not be administratively feasible or appropriate to the health care delivery system of the State.

* * * * * * *

(e)(1)(A) * * *

(B) Subparagraph (A) shall not apply with respect to families that cease to be eligible for aid under part A of title IV during the period beginning on April 1, 1990, and ending on ⟦December 31, 2010⟧ *December 31, 2012*. During such period, for provisions relating to extension of eligibility for medical assistance for certain families who have received aid pursuant to a State plan approved under part A of title IV and have earned income, see section 1925.

* * * * * * *

(14)(A) At the option of the State, in the case of an individual with extremely high prescription drug costs described in subparagraph (B) who has been determined (without the application of this paragraph) to be eligible for medical assistance under this title, the State may, in redetermining the individual's eligibility for medical assistance under this title, disregard any family income of the individual to the extent such income is less than an amount that is specified by the State and does not exceed the amount specified in subparagraph (C), or, if greater, income equal to the cost of the orphan drugs described in subparagraph (B)(iii).

(B) An individual with extremely high prescription drug costs described in this subparagraph for a 12-month period is an individual—

(i) who is covered under health insurance or a health benefits plan that has a maximum lifetime limit of not less than $1,000,000 which includes all prescription drug coverage;

(ii) who has exhausted all available prescription drug coverage under the plan as of the beginning of such period;

(iii) who incurs (or is reasonably expected to incur) on an annual basis during the period costs for orphan drugs in excess of the amount specified in subparagraph (C) for the period; and

(iv) whose annual family income (determined without regard to this paragraph) as of the beginning of the period does not ex-

ceed 75 percent of the amount incurred for such drugs (as described in clause (iii)).

(C) The amount specified in this subparagraph for a 12-month period beginning in—

(i) 2009 or 2010, is $200,000; or

(ii) a subsequent year, is the amount specified in clause (i) (or this subparagraph) for the previous year increased by the annual rate of increase in the medical care component of the consumer price index (U.S. city average) for the 12-month period ending in August of the previous year.

Any amount computed under clause (ii) that is not a multiple of $1,000 shall be rounded to the nearest multiple of $1,000.

(D) In applying this paragraph, amounts incurred for prescription drugs for cosmetic purposes shall not be taken into account.

(E) With respect to an individual described in subparagraph (A), notwithstanding section 1916, the State plan—

(i) shall provide for the application of cost-sharing that is at least nominal as determined under section 1916; and

(ii) may provide, consistent with section 1916A, for such additional cost-sharing as does not exceed a maximum level of cost-sharing that is specified by the Secretary and is adjusted by the Secretary on an annual basis.

(F) A State electing the option under this paragraph shall provide for a determination on an individual's application for continued medical assistance under this title within 30 days of the date the application if filed with the State.

(G) In this paragraph:

(i) The term "orphan drugs" means prescription drugs designated under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) as a drug for a rare disease or condition.

(ii) The term "health benefits plan" includes coverage under a plan offered under a State high risk pool.

* * * * * * *

(j) Notwithstanding any other requirement of this title, the Secretary may waive or modify any requirement of this title with respect to the medical assistance program in [American Samoa and the Northern Mariana Islands] *Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa*, other than a waiver of the Federal medical assistance percentage, the limitation in section 1108(f), or the requirement that payment may be made for medical assistance only with respect to amounts expended by [American Samoa or the Northern Mariana Islands] *Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, or American Samoa* for care and services described in a numbered paragraph of section 1905(a).

* * * * * * *

(gg) CHIP MAINTENANCE OF ELIGIBILITY REQUIREMENT.—

(1) IN GENERAL.—Subject to paragraph (2), as a condition of its State plan under this title under subsection (a)(75) and receipt of any Federal financial assistance under section 1903(a) for calendar quarters beginning after the date of the enactment of this subsection and before CHIP MOE termination date specified in paragraph (3), a State shall not have in effect eligibility

standards, methodologies, or procedures under its State child health plan under title XXI (including any waiver under such title or under section 1115 that is permitted to continue effect) that are more restrictive than the eligibility standards, methodologies, or procedures, respectively, under such plan (or waiver) as in effect on June 16, 2009.

(2) LIMITATION.—Paragraph (1) shall not be construed as preventing a State from imposing a limitation described in section 2110(b)(5)(C)(i)(II) for a fiscal year in order to limit expenditures under its State child health plan under title XXI to those for which Federal financial participation is available under section 2105 for the fiscal year.

(3) CHIP MOE TERMINATION DATE.—In paragraph (1), the "CHIP MOE termination date" for a State is the date that is the first day of Y1 (as defined in section 100(c) of the America's Affordable Health Choices Act of 2009) or, if later, the first day after such date that both of the following determinations have been made:

(A) The Health Choices Commissioner has determined that the Health Insurance Exchange has the capacity to support the participation of CHIP enrollees who are Exchange-eligible individuals (as defined in section 202(b) of the America's Affordable Health Choices Act of 2009),

(B) The Secretary has determined that—

(i) comparable coverage, as specified in section 202(g) of the America's Affordable Health Choices Act of 2009, is available through such Exchange; and

(ii) procedures have been established for transferring CHIP enrollees into acceptable coverage (as defined for purposes of such Act) without interruption of coverage or a written plan of treatment.

The Secretary shall recommend to Congress any legislative changes needed to effectuate this paragraph. In this paragraph, the term "CHIP enrollee" means a targeted low-income child or (if the State has elected the option under section 2112, a targeted low-income pregnant woman) who is or otherwise would be (but for acceptable coverage) eligible for child health assistance or pregnancy-related assistance, respectively, under the State child health plan referred to in paragraph (1).

(hh)(1) Individuals described in this subsection are individuals—

(A) whose income does not exceed an income eligibility level established by the State that does not exceed the highest income eligibility level established under the State plan under this title (or under its State child health plan under title XXI) for pregnant women; and

(B) who are not pregnant.

(2) At the option of a State, individuals described in this subsection may include individuals who, had individuals applied on or before January 1, 2007, would have been made eligible pursuant to the standards and processes imposed by that State for benefits described in clause (XV) of the matter following subparagraph (G) of section subsection (a)(10) pursuant to a waiver granted under section 1115.

(3) At the option of a State, for purposes of subsection (a)(17)(B), in determining eligibility for services under this subsection, the State may consider only the income of the applicant or recipient.

(ii) Individuals described in this subsection are individuals not described in subsection (a)(10)(A)(i)—

(1) who have HIV infection;

(2) whose income (as determined under the State plan under this title with respect to disabled individuals) does not exceed the maximum amount of income a disabled individual described in subsection (a)(10)(A)(i) may have and obtain medical assistance under the plan; and

(3) whose resources (as determined under the State plan under this title with respect to disabled individuals) do not exceed the maximum amount of resources a disabled individual described in subsection (a)(10)(A)(i) may have and obtain medical assistance under the plan.

(jj) REPORT ON MEDICAID PAYMENTS.—Each year, on or before a date determined by the Secretary, a State participating in the Medicaid program under this title shall submit to the Administrator of the Centers for Medicare & Medicaid Services—

(1) information on the determination of rates of payment to providers for covered services under the State plan, including—

(A) the final rates;

(B) the methodologies used to determine such rates; and

(C) justifications for the rates; and

(2) an explanation of the process used by the State to allow providers, beneficiaries and their representatives, and other concerned State residents a reasonable opportunity to review and comment on such rates, methodologies, and justifications before the State made such rates final.

* * * * * * *

PAYMENT TO STATES

SEC. 1903. (a) From the sums appropriated therefor, the Secretary (except as otherwise provided in this section) shall pay to each State which has a plan approved under this title, for each quarter, beginning with the quarter commencing January 1, 1966—

(1) * * *

(2)(A) * * *

* * * * * * *

(E) an amount equal to 75 percent of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to translation or interpretation services in connection with the enrollment of, retention of, and use of services under this title by, children of families *and other individuals* for whom English is not the primary language; plus

* * * * * * *

(d)(1) * * *

(2)(A) * * *

* * * * * * *

(C) For purposes of this subsection, when an overpayment is discovered, which was made by a State to a person or other entity,

the State shall have a period of 60 days *(or of 1 year in the case of overpayments due to fraud)* in which to recover or attempt to recover such overpayment before adjustment is made in the Federal payment to such State on account of such overpayment. Except as otherwise provided in subparagraph (D), the adjustment in the Federal payment shall be made at the end of **[**the 60 days**]** *such period*, whether or not recovery was made.

* * * * * * *

(f)(1) * * *

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(4) The limitations on payment imposed by the preceding provisions of this subsection shall not apply with respect to any amount expended by a State as medical assistance for any individual described in section 1902(a)(10)(A)(i)(III), 1902(a)(10)(A)(i)(IV), 1902(a)(10)(A)(i)(V), 1902(a)(10)(A)(i)(VI), 1902(a)(10)(A)(i)(VII), *1902(a)(10)(A)(i)(VIII), 1902(a)(10)(A)(i)(IX),* 1902(a)(10)(A)(ii)(IX), 1902(a)(10)(A)(ii)(X), 1902(a)(10)(A)(ii)(XIII), 1902(a)(10)(A)(ii)(XIV), or 1902(a)(10)(A)(ii)(XV), 1902(a)(10)(A)(ii)(XVI), 1902(a)(10)(A)(ii)(XVII), 1902(a)(10)(A)(ii)(XVIII), 1902(a)(10)(A)(ii)(XIX), 1905(p)(1) or for any individual—

(A) * * *

* * * * * * *

(i) Payment under the preceding provisions of this section shall not be made—

(1) * * *

* * * * * * *

(23) with respect to amounts expended for medical assistance for covered outpatient drugs (as defined in section 1927(k)(2)) for which the prescription was executed in written (and non-electronic) form unless the prescription was executed on a tamper-resistant pad; **[**or**]**

(24) if a State is required to implement an asset verification program under section 1940 and fails to implement such program in accordance with such section, with respect to amounts expended by such State for medical assistance for individuals subject to asset verification under such section, unless—

(A) * * *

* * * * * * *

(C) not later than 12 months after the date of such submission (and approval), the State fulfills the terms of such corrective action plan**[**.**]***;*

(25) with respect to amounts expended for services related to the presence of a condition that could be identified by a secondary diagnostic code described in section 1886(d)(4)(D)(iv) and for any health care acquired condition determined as a non-covered service under title XVIII;

(26) with respect to any amount paid to a billing agent, clearinghouse, or other alternate payee that is not registered with the State and the Secretary as required under section 1902(a)(79); or

(27) with respect to any amount expended—

(A) on litigation in which a court imposes sanctions on the State, its employees, or its counsel for litigation-related misconduct; or

(B) to reimburse (or otherwise compensate) a managed care entity for payment of legal expenses associated with any action in which a court imposes sanctions on the managed care entity for litigation-related misconduct.

* * * * * * *

(m)(1) * * *

(2)(A) Except as provided in subparagraphs (B), (C), and (G), no payment shall be made under this title to a State with respect to expenditures incurred by it for payment (determined under a prepaid capitation basis or under any other risk basis) for services provided by any entity (including a health insuring organization) which is responsible for the provision (directly or through arrangements with providers of services) of inpatient hospital services and any other service described in paragraph (2), (3), (4), (5), or (7) of section 1905(a) or for the provision of any three or more of the services described in such paragraphs unless—

(i) * * *

* * * * * * *

(xi) such contract provides for maintenance of sufficient patient encounter data to identify the physician who delivers services to patients *and for the provision of such data to the State at a frequency and level of detail to be specified by the Secretary*; **[**and**]**

(xii) such contract, and the entity complies with the applicable requirements of section 1932**[**.**]***;*

(xiii) such contract provides that the entity shall report to the State such information, on such timely and periodic basis as specified by the Secretary, as the State may require in order to include, in the information submitted by the State to a manufacturer under section 1927(b)(2)(A), information on covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled with the entity and for which the entity is responsible for coverage of such drugs under this subsection; and

(xiv) such contract has a medical loss ratio, as determined in accordance with a methodology specified by the Secretary that is a percentage (not less than 85 percent) as specified by the Secretary.

* * * * * * *

(r)(1) In order to receive payments under subsection (a) for use of automated data systems in administration of the State plan under this title, a State must have in operation mechanized claims processing and information retrieval systems that meet the requirements of this subsection and that the Secretary has found—

(A) * * *

(B) are compatible with the claims processing and information retrieval systems used in the administration of title XVIII, and for this purpose—

(i) * * *

(ii) provide liaison between States and carriers and intermediaries with agreements under title XVIII to facilitate timely exchange of appropriate data; [and]

(iii) provide for exchange of data between the States and the Secretary with respect to persons sanctioned under this title or title XVIII; *and*

(iv) effective for claims filed on or after October 1, 2010, incorporate compatible methodologies of the National Correct Coding Initiative administered by the Secretary (or any successor initiative to promote correct coding and to control improper coding leading to inappropriate payment) and such other methodologies of that Initiative (or such other national correct coding methodologies) as the Secretary identifies in accordance with paragraph (3);

* * * * * * *

(F) effective for claims filed on or after January 1, 1999, provide for electronic transmission of claims data in the format specified by the Secretary and consistent with the Medicaid Statistical Information System (MSIS) (including detailed individual enrollee encounter data and other information that the Secretary may find necessary *and including, for data submitted to the Secretary on or after July 1, 2010, data elements from the automated data system that the Secretary determines to be necessary for detection of waste, fraud, and abuse*).

* * * * * * *

(3) Not later than September 1, 2010, the Secretary shall do the following:

(A) Identify those methodologies of the National Correct Coding Initiative administered by the Secretary (or any successor initiative to promote correct coding and to control improper coding leading to inappropriate payment) which are compatible to claims filed under this title.

(B) Identify those methodologies of such Initiative (or such other national correct coding methodologies) that should be incorporated into claims filed under this title with respect to items or services for which States provide medical assistance under this title and no national correct coding methodologies have been established under such Initiative with respect to title XVIII.

(C) Notify States of—

(i) the methodologies identified under subparagraphs (A) and (B) (and of any other national correct coding methodologies identified under subparagraph (B)); and

(ii) how States are to incorporate such methodologies into claims filed under this title.

(D) Submit a report to Congress that includes the notice to States under subparagraph (C) and an analysis supporting the identification of the methodologies made under subparagraphs (A) and (B).

* * * * * * *

(u)(1)(A) * * *

* * * * * * *

(D)(i) * * *

* * * * * * *

(v) In determining the amount of erroneous excess payments, there shall not be included any erroneous payments made for ambulatory prenatal care provided during a presumptive eligibility period (as defined in section 1920(b)(1)), for items and services described in subsection (a) of section 1920A provided to a child during a presumptive eligibility period under such section, [or] for medical assistance provided to an individual described in subsection (a) of section 1920B during a presumptive eligibility period under such section*, or for medical assistance provided to an individual described in subsection (a) of section 1920C during a presumptive eligibility period under such section*.

(vi) In determining the amount of erroneous excess payments, there shall not be included any erroneous payments made that are attributable to an error in an eligibility determination under subtitle C of title II of division A of the America's Affordable Health Choices Act of 2009.

* * * * * * *

(aa) MAINTENANCE OF MEDICAID EFFORT; SIMPLIFYING AND COORDINATING ELIGIBILITY RULES BETWEEN HEALTH INSURANCE EXCHANGE AND MEDICAID.—

(1) MAINTENANCE OF EFFORT.—

(A) IN GENERAL.—Subject to subparagraph (B), a State is not eligible for payment under subsection (a) for a calendar quarter beginning after the date of the enactment of this subsection if eligibility standards, methodologies, or procedures under its plan under this title (including any waiver under this title or under section 1115 that is permitted to continue effect) that are more restrictive than the eligibility standards, methodologies, or procedures, respectively, under such plan (or waiver) as in effect on June 16, 2009. The Secretary shall extend such a waiver (including the availability of Federal financial participation under such waiver) for such period as may be required for a State to meet the requirement of the previous sentence.

(B) EXCEPTION FOR CERTAIN WAIVERS.—In the case of a State waiver under section 1115 in effect on June 16, 2009, that permits childless individuals to be eligible solely to receive a premium or cost-sharing subsidy for individual health insurance coverage, effective for coverage provided in Y1—

(i) the Secretary shall permit the State to amend such waiver to apply more restrictive eligibility standards, methodologies, or procedures with respect to such individuals under such waiver; and

(ii) the application of such more restrictive, standards, methodologies, or procedures under such an amendment shall not be considered in violation of the requirement of subparagraph (A).

(2) REMOVAL OF ASSET TEST FOR CERTAIN ELIGIBILITY CATEGORIES.—

(A) IN GENERAL.—A State is not eligible for payment under subsection (a) for a calendar quarter beginning on or

after the first day of Y1 (as defined in section 100(c) of the America's Affordable Health Choices Act of 2009), if the State applies any asset or resource test in determining (or redetermining) eligibility of any individual on or after such first day under any of the following:

(i) Subclause (I), (III), (IV), or (VI) of section 1902(a)(10)(A)(i).

(ii) Subclause (II), (IX), (XIV) or (XVII) of section 1902(a)(10)(A)(ii).

(iii) Section 1931(b).

(B) OVERRIDING CONTRARY PROVISIONS; REFERENCES.—The provisions of this title that prevent the waiver of an asset or resource test described in subparagraph (A) are hereby waived.

(C) REFERENCES.—Any reference to a provision described in a provision in subparagraph (A) shall be deemed to be a reference to such provision as modified through the application of subparagraphs (A) and (B).

* * * * * * *

DEFINITIONS

SEC. 1905. For purposes of this title—

(a) The term "medical assistance" means payment of part or all of the cost of the following care and services *or the care and services themselves, or both* (if provided in or after the third month before the month in which the recipient makes application for assistance or, in the case of medicare cost-sharing with respect to a qualified medicare beneficiary described in subsection (p)(1), if provided after the month in which the individual becomes such a beneficiary) for individuals, and, with respect to physicians' or dentists' services, at the option of the State, to individuals (other than individuals with respect to whom there is being paid, or who are eligible, or would be eligible if they were not in a medical institution, to have paid with respect to them a State supplementary payment and are eligible for medical assistance equal in amount, duration, and scope to the medical assistance made available to individuals described in section 1902(a)(10)(A)) not receiving aid or assistance under any plan of the State approved under title I, X, XIV, or XVI, or part A of title IV, and with respect to whom supplemental security income benefits are not being paid under title XVI, who are—

(i) * * *

* * * * * * *

(xii) employed individuals with a medically improved disability (as defined in subsection (v)), **[**or**]**

(xiii) individuals described in section 1902(aa),

(xiv) individuals described in section 1902(ii),

(xv) individuals described in section 1902(hh), or

(xvi) individuals described in section 1902(a)(10)(A)(i)(VIII),

but whose income and resources are insufficient to meet all of such cost—

(1) * * *

* * * * * * *

* * * * * * *

(4)(A) nursing facility services (other than services in an institution for mental diseases) for individuals 21 years of age or older; (B) early and periodic screening, diagnostic, and treatment services (as defined in subsection (r)) for individuals who are eligible under the plan and are under the age of 21; **[**and**]** (C) family planning services and supplies furnished (directly or under arrangements with others) to individuals of child-bearing age (including minors who can be considered to be sexually active) who are eligible under the State plan and who desire such services and supplies *; and (D) preventive services described in subsection (z)*;

(5)(A) physicians' services furnished by a physician (as defined in **[**section 1861(r)(1)**]** *paragraphs (1) and (3) of section 1861(r)*), whether furnished in the office, the patient's home, a hospital, or a nursing facility, or elsewhere, **[**and**]** (B) medical and surgical services furnished by a dentist (described in section 1861(r)(2)) to the extent such services may be performed under State law either by a doctor of medicine or by a doctor of dental surgery or dental medicine and would be described in clause (A) if furnished by a physician (as defined in section 1861(r)(1))*, and (C) medical and other health services (as defined in section 1861(s)) as authorized by State law, furnished by an optometrist (described in section 1861(r)(4)) to the extent such services may be performed under State law*;

* * * * * * *

(27) subject to subsection (x), primary and secondary medical strategies and treatment and services for individuals who have Sickle Cell Disease; **[**and**]**

(28) nurse home visitation services (as defined in subsection (aa));

(29) freestanding birth center services (as defined in subsection (l)(3)(A)) and other ambulatory services that are offered by a freestanding birth center (as defined in subsection (l)(3)(B)) and that are otherwise included in the plan;

(30) nonemergency transportation to medically necessary services, consistent with the requirement of section 431.53 of title 42, Code of Federal Regulations, as in effect as of June 1, 2008; and

[(28)**]** *(31)* any other medical care, and any other type of remedial care recognized under State law, specified by the Secretary**[**,**[***;*

* * * * * * *

(b) Subject to section **[**1933(d)**]** *1933(b)*, the term "Federal medical assistance percentage" for any State shall be 100 per centum less the State percentage; and the State percentage shall be that percentage which bears the same ratio to 45 per centum as the square of the per capita income of such State bears to the square of the per capita income of the continental United States (including Alaska) and Hawaii; except that (1) the Federal medical assistance percentage shall in no case be less than 50 per centum or more than 83 per centum, (2) the Federal medical assistance percentage for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa shall be 50 per centum, (3) for purposes of this title and title XXI, the Federal medical assistance per-

centage for the District of Columbia shall be 70 percent, [and] (4) the Federal medical assistance percentage shall be equal to the enhanced FMAP described in section 2105(b) with respect to medical assistance provided to individuals who are eligible for such assistance only on the basis of [section 1902(a)(10)(A)(ii)(XVIII)] *subclause (XVIII) or (XXI) of section 1902(a)(10)(A)(ii), and (5) 100 percent (or 90 percent for periods beginning with 2015) with respect to amounts described in subsection (y)*. The Federal medical assistance percentage for any State shall be determined and promulgated in accordance with the provisions of section 1101(a)(8)(B). Notwithstanding the first sentence of this section, the Federal medical assistance percentage shall be 100 per centum with respect to amounts expended as medical assistance for services which are received through an Indian Health Service facility whether operated by the Indian Health Service or by an Indian tribe or tribal organization (as defined in section 4 of the Indian Health Care Improvement Act). Notwithstanding the first sentence of this subsection, in the case of a State plan that meets the condition described in subsection (u)(1), with respect to expenditures (other than expenditures under section 1923) described in subsection (u)(2)(A) or subsection (u)(3) for the State for a fiscal year, and that do not exceed the amount of the State's available allotment under section 2104, the Federal medical assistance percentage is equal to the enhanced FMAP described in section 2105(b). *Notwithstanding the first sentence of this subsection and any other provision of law, for fiscal years 2011 through 2019, the Federal medical assistance percentage for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa shall be the highest Federal medical assistance percentage applicable to any of the 50 States or the District of Columbia for the fiscal year involved, taking into account the application of subsections (a) and (b)(1) of section 5001 of division B of the American Recovery and Reinvestment Act of 2009 (Public Law 111–5) to such States and the District for calendar quarters during such fiscal years for which such subsections apply.*

* * * * * * *

(l)(1) * * *

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(3)(A) The term "freestanding birth center services" means services furnished to an individual at a freestanding birth center (as defined in subparagraph (B)), including by a licensed birth attendant (as defined in subparagraph (C)) at such center.

(B) The term "freestanding birth center" means a health facility—

(i) that is not a hospital; and

(ii) where childbirth is planned to occur away from the pregnant woman's residence.

(C) The term "licensed birth attendant" means an individual who is licensed or registered by the State involved to provide health care at childbirth and who provides such care within the scope of practice under which the individual is legally authorized to perform such care under State law (or the State regulatory mechanism provided by State law), regardless of whether the individual is under the supervision of, or associated with, a physician or other health care provider. Nothing in this subparagraph shall be construed as

changing State law requirements applicable to a licensed birth attendant.

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(o)(1) * * *

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(4) The provisions of section 1819A shall apply to a hospice program providing hospice care under this title in the same manner as such provisions apply to a hospice program providing hospice care under title XVIII.

(p)(1) The term "qualified medicare beneficiary" means an individual—

(A) * * *

* * * * * * *

(C) whose resources (as determined under section 1613 for purposes of the supplemental security income program) do not exceed twice the maximum amount of resources that an individual may have and obtain benefits under that program or, [effective beginning with January 1, 2010] *effective for the period beginning with January 1, 2010, and ending with December 31, 2011*, whose resources (as so determined) do not exceed the maximum resource level applied for the year under subparagraph (D) of section 1860D–14(a)(3) (determined without regard to the life insurance policy exclusion provided under subparagraph (G) of such section) applicable to an individual or to the individual and the individual's spouse (as the case may be) *or, effective beginning with January 1, 2012, whose resources (as so determined) do not exceed the maximum resource level applied for the year under subparagraph (E) of section 1860D–14(a)(3) (determined without regard to the life insurance policy exclusion provided under subparagraph (G) of such section) applicable to an individual or to the individual and the individual's spouse (as the case may be).*

* * * * * * *

(y) ADDITIONAL EXPENDITURES SUBJECT TO INCREASED FMAP.—For purposes of section 1905(b)(5), the amounts described in this subsection are the following:

(1) Amounts expended for medical assistance for individuals described in subclause (VIII) or (IX) of section 1902(a)(10)(A)(i), and who is not provided medical assistance under section 1943(b)(2) of this title or section 205(d)(1)(B) of the America's Affordable Health Choices Act of 2009.

(2) Amounts expended for medical assistance for children described in section 203(d)(1)(A) of the America's Affordable Health Choices Act of 2009 during the time period specified in such section.

(3)(A) The portion of the amounts expended for medical assistance for services described in section 1902(a)(13)(C) furnished on or after January 1, 2010, that is attributable to the amount by which the minimum payment rate required under such section (or, by application, section 1932(f)) exceeds the payment rate applicable to such services under the State plan as of June 16, 2009.

(B) Subparagraphs (A) shall not be construed as preventing the payment of Federal financial participation based on the Federal medical assistance percentage for amounts in excess of those specified under such subparagraphs.

(z) PREVENTIVE SERVICES.—The preventive services described in this subsection are services not otherwise described in subsection (a) or (r) that the Secretary determines are—

(1)(A) recommended with a grade of A or B by the Task Force for Clinical Preventive Services; or

(B) vaccines recommended for use as appropriate by the Director of the Centers for Disease Control and Prevention; and

(2) appropriate for individuals entitled to medical assistance under this title.

(aa) The term "nurse home visitation services" means home visits by trained nurses to families with a first-time pregnant woman, or a child (under 2 years of age), who is eligible for medical assistance under this title, but only, to the extent determined by the Secretary based upon evidence, that such services are effective in one or more of the following:

(1) Improving maternal or child health and pregnancy outcomes or increasing birth intervals between pregnancies.

(2) Reducing the incidence of child abuse, neglect, and injury, improving family stability (including reduction in the incidence of intimate partner violence), or reducing maternal and child involvement in the criminal justice system.

(3) Increasing economic self-sufficiency, employment advancement, school-readiness, and educational achievement, or reducing dependence on public assistance.

(bb) PAYMENT FOR GRADUATE MEDICAL EDUCATION.—

(1) IN GENERAL.—The term "medical assistance" includes payment for costs of graduate medical education consistent with this subsection, whether provided in or outside of a hospital.

(2) SUBMISSION OF INFORMATION.—For purposes of paragraph (1) and section 1902(a)(13)(A)(v), payment for such costs is not consistent with this subsection unless—

(A) the State submits to the Secretary, in a timely manner and on an annual basis specified by the Secretary, information on total payments for graduate medical education and how such payments are being used for graduate medical education, including—

(i) the institutions and programs eligible for receiving the funding;

(ii) the manner in which such payments are calculated;

(iii) the types and fields of education being supported;

(iv) the workforce or other goals to which the funding is being applied;

(v) State progress in meeting such goals; and

(vi) such other information as the Secretary determines will assist in carrying out paragraphs (3) and (4); and

(B) such expenditures are made consistent with such goals and requirements as are established under paragraph (4).

(3) REVIEW OF INFORMATION.—The Secretary shall make the information submitted under paragraph (2) available to the Advisory Committee on Health Workforce Evaluation and Assessment (established under section 2261 of the Public Health Service Act). The Secretary and the Advisory Committee shall independently review the information submitted under paragraph (2), taking into account State and local workforce needs.

(4) SPECIFICATION OF GOALS AND REQUIREMENTS.—The Secretary shall specify by rule, initially published by not later than December 31, 2011—

(A) program goals for the use of funds described in paragraph (1), taking into account recommendations of the such Advisory Committee and the goals for approved medical residency training programs described in section 1886(h)(1)(B); and

(B) requirements for use of such funds consistent with such goals.

Such rule may be effective on an interim basis pending revision after an opportunity for public comment.

* * * * * * *

USE OF ENROLLMENT FEES, PREMIUMS, DEDUCTIONS, COST SHARING, AND SIMILAR CHARGES

SEC. 1916. (a) Subject to subsections (g) and (i), the State plan shall provide that in the case of individuals described in subparagraph (A) or (E)(i) of section 1902(a)(10) who are eligible under the plan—

(1) * * *

(2) no deduction, cost sharing or similar charge will be imposed under the plan with respect to—

(A) * * *

* * * * * * *

(D) emergency services (as defined by the Secretary), *preventive services described in section 1905(z),* family planning services and supplies described in section 1905(a)(4)(C), or

* * * * * * *

(b) The State plan shall provide that in the case of individuals other than those described in subparagraph (A) or (E) of section 1902(a)(10) who are eligible under the plan—

(1) * * *

(2) no deduction, cost sharing, or similar charge will be imposed under the plan with respect to—

(A) * * *

* * * * * * *

(D) emergency services (as defined by the Secretary), *preventive services described in section 1905(z),* family planning services and supplies described in section 1905(a)(4)(C), or

* * * * * * *

STATE OPTION FOR ALTERNATIVE PREMIUMS AND COST SHARING

SEC. 1916A. (a) STATE FLEXIBILITY.—

(1) IN GENERAL.—Notwithstanding sections 1916 and 1902(a)(10)(B), but subject to paragraph (2), a State, at its option and through a State plan amendment, may impose premiums and cost sharing for any group of individuals (as specified by the State) and for any type of services (other than drugs for which cost sharing may be imposed under subsection (c)*, preventive services described in section 1905(z),* and nonemergency services furnished in a hospital emergency department for which cost sharing may be imposed under subsection (e)), and may vary such premiums and cost sharing among such groups or types, consistent with the limitations established under this section. Nothing in this section shall be construed as superseding (or preventing the application of) subsection (g) or (i) of section 1916.

* * * * * * *

REQUIREMENTS FOR NURSING FACILITIES

SEC. 1919. (a) * * *

(b) REQUIREMENTS RELATING TO PROVISION OF SERVICES.—

(1) QUALITY OF LIFE.—

(A) * * *

(B) QUALITY ASSESSMENT AND ASSURANCE *AND QUALITY ASSURANCE AND PERFORMANCE IMPROVEMENT PROGRAM*.—

(i) IN GENERAL.—A nursing facility must maintain a quality assessment and assurance committee, consisting of the director of nursing services, a physician designated by the facility, and at least 3 other members of the facility's staff, which (i) meets at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary and (ii) develops and implements appropriate plans of action to correct identified quality deficiencies. A State or the Secretary may not require disclosure of the records of such committee except insofar as such disclosure is related to the compliance of such committee with the requirements of this subparagraph.

(ii) QUALITY ASSURANCE AND PERFORMANCE IMPROVEMENT PROGRAM.—

(I) IN GENERAL.—Not later than December 31, 2011, the Secretary shall establish and implement a quality assurance and performance improvement program (in this clause referred to as the "QAPI program") for nursing facilities, including multi-unit chains of such facilities. Under the QAPI program, the Secretary shall establish standards relating to such facilities and provide technical assistance to such facilities on the development of best practices in order to meet such standards. Not later than 1 year after the date on which the regulations are promulgated under subclause (II), a nursing facility must submit to the Secretary a plan for the facility to meet such standards and

implement such best practices, including how to coordinate the implementation of such plan with quality assessment and assurance activities conducted under clause (i).

(II) REGULATIONS.—The Secretary shall promulgate regulations to carry out this clause.

* * * * * * *

(4) PROVISION OF SERVICES AND ACTIVITIES.—

(A) IN GENERAL.—To the extent needed to fulfill all plans of care described in paragraph (2), a nursing facility must provide (or arrange for the provision of)—

(i) * * *

* * * * * * *

The services provided or arranged by the facility must meet professional standards of quality. *With respect to meeting the staffing requirement imposed by the Secretary to carry out clause (iv), the full-time director of food services of the facility, if not a qualified dietitian (as defined in section 483.35(a)(2) of title 42, Code of Federal Regulations, as in effect as of the date of the enactment of this section), shall be a Certified Dietary Manager meeting the requirements of the Certifying Board for Dietary Managers, or a Dietetic Technician, Registered meeting the requirements of the Commission on Dietetic Registration or have equivalent military or academic qualifications (as specified by the Secretary).*

* * * * * * *

(8) INFORMATION ON NURSE STAFFING.—

(A) * * *

* * * * * * *

(C) SUBMISSION OF STAFFING INFORMATION BASED ON PAYROLL DATA IN A UNIFORM FORMAT.—Beginning not later than 2 years after the date of the enactment of this subparagraph, and after consulting with State long-term care ombudsman programs, consumer advocacy groups, provider stakeholder groups, employees and their representatives, and other parties the Secretary deems appropriate, the Secretary shall require a skilled nursing facility to electronically submit to the Secretary direct care staffing information (including information with respect to agency and contract staff) based on payroll and other verifiable and auditable data in a uniform format (according to specifications established by the Secretary in consultation with such programs, groups, and parties). Such specifications shall require that the information submitted under the preceding sentence—

(i) specify the category of work a certified employee performs (such as whether the employee is a registered nurse, licensed practical nurse, licensed vocational nurse, certified nursing assistant, therapist, or other medical personnel);

(ii) include resident census data and information on resident case mix;

(iii) include a regular reporting schedule; and

(iv) include information on employee turnover and tenure and on the hours of care provided by each category of certified employees referenced in clause (i) per resident per day.

Nothing in this subparagraph shall be construed as preventing the Secretary from requiring submission of such information with respect to specific categories, such as nursing staff, before other categories of certified employees. Information under this subparagraph with respect to agency and contract staff shall be kept separate from information on employee staffing.

(c) REQUIREMENTS RELATING TO RESIDENTS' RIGHTS.—

(1) * * *

* * * * * * *

(9) NOTIFICATION OF FACILITY CLOSURE.—

(A) IN GENERAL.—Any individual who is an administrator of a nursing facility must—

(i) submit to the Secretary, the State long-term care ombudsman, residents of the facility, and the legal representatives of such residents or other responsible parties, written notification of an impending closure—

(I) subject to subclause (II), not later than the date that is 60 days prior to the date of such closure; and

(II) in the case of a facility where the Secretary terminates the facility's participation under this title, not later than the date that the Secretary determines appropriate;

(ii) ensure that the facility does not admit any new residents on or after the date on which such written notification is submitted; and

(iii) include in the notice a plan for the transfer and adequate relocation of the residents of the facility by a specified date prior to closure that has been approved by the State, including assurances that the residents will be transferred to the most appropriate facility or other setting in terms of quality, services, and location, taking into consideration the needs and best interests of each resident.

(B) RELOCATION.—

(i) IN GENERAL.—The State shall ensure that, before a facility closes, all residents of the facility have been successfully relocated to another facility or an alternative home and community-based setting.

(ii) CONTINUATION OF PAYMENTS UNTIL RESIDENTS RELOCATED.—The Secretary may, as the Secretary determines appropriate, continue to make payments under this title with respect to residents of a facility that has submitted a notification under subparagraph (A) during the period beginning on the date such notification is submitted and ending on the date on which the resident is successfully relocated.

(d) REQUIREMENTS RELATING TO ADMINISTRATION AND OTHER MATTERS.—

(1) ADMINISTRATION.—

(A) * * *

[(B) REQUIRED NOTICES.—If a change occurs in—

[(i) the persons with an ownership or control interest (as defined in section 1124(a)(3)) in the facility,

[(ii) the persons who are officers, directors, agents, or managing employees (as defined in section 1126(b)) of the facility,

[(iii) the corporation, association, or other company responsible for the management of the facility, or

[(iv) the individual who is the administrator or director of nursing of the facility,

nursing facility must provide notice to the State agency responsible for the licensing of the facility, at the time of the change, of the change and of the identity of each new person, company, or individual described in the respective clause.]

[(C)] *(B)* NURSING FACILITY ADMINISTRATOR.—The administrator of a nursing facility must meet standards established by the Secretary under subsection (f)(4).

(C) COMPLIANCE AND ETHICS PROGRAM.—

(i) REQUIREMENT.—On or after the date that is 36 months after the date of the enactment of this subparagraph, a nursing facility shall, with respect to the entity that operates the facility (in this subparagraph referred to as the "operating organization" or "organization"), have in operation a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations under this Act and in promoting quality of care consistent with regulations developed under clause (ii).

(ii) DEVELOPMENT OF REGULATIONS.—

(I) IN GENERAL.—Not later than the date that is 2 years after such date of the enactment, the Secretary, in consultation with the Inspector General of the Department of Health and Human Services, shall develop regulations for an effective compliance and ethics program for operating organizations, which may include a model compliance program.

(II) DESIGN OF REGULATIONS.—Such regulations with respect to specific elements or formality of a program may vary with the size of the organization, such that larger organizations should have a more formal and rigorous program and include established written policies defining the standards and procedures to be followed by its employees. Such requirements may specifically apply to the corporate level management of multi-unit nursing home chains.

(III) EVALUATION.—Not later than 3 years after the date of promulgation of regulations under this clause the Secretary shall complete an evaluation of the compliance and ethics programs required to be established under this subparagraph. Such

evaluation shall determine if such programs led to changes in deficiency citations, changes in quality performance, or changes in other metrics of resident quality of care. The Secretary shall submit to Congress a report on such evaluation and shall include in such report such recommendations regarding changes in the requirements for such programs as the Secretary determines appropriate.

(iii) REQUIREMENTS FOR COMPLIANCE AND ETHICS PROGRAMS.—In this subparagraph, the term "compliance and ethics program" means, with respect to a nursing facility, a program of the operating organization that—

(I) has been reasonably designed, implemented, and enforced so that it generally will be effective in preventing and detecting criminal, civil, and administrative violations under this Act and in promoting quality of care; and

(II) includes at least the required components specified in clause (iv).

(iv) REQUIRED COMPONENTS OF PROGRAM.—The required components of a compliance and ethics program of an organization are the following:

(I) The organization must have established compliance standards and procedures to be followed by its employees and other agents that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations under this Act.

(II) Specific individuals within high-level personnel of the organization must have been assigned overall responsibility to oversee compliance with such standards and procedures and has sufficient resources and authority to assure such compliance.

(III) The organization must have used due care not to delegate substantial discretionary authority to individuals whom the organization knew, or should have known through the exercise of due diligence, had a propensity to engage in criminal, civil, and administrative violations under this Act.

(IV) The organization must have taken steps to communicate effectively its standards and procedures to all employees and other agents, such as by requiring participation in training programs or by disseminating publications that explain in a practical manner what is required.

(V) The organization must have taken reasonable steps to achieve compliance with its standards, such as by utilizing monitoring and auditing systems reasonably designed to detect criminal, civil, and administrative violations under this Act by its employees and other agents and by having in place and publicizing a reporting system whereby employees and other agents could report viola-

tions by others within the organization without fear of retribution.

(VI) The standards must have been consistently enforced through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect an offense.

(VII) After an offense has been detected, the organization must have taken all reasonable steps to respond appropriately to the offense and to prevent further similar offenses, including repayment of any funds to which it was not entitled and any necessary modification to its program to prevent and detect criminal, civil, and administrative violations under this Act.

(VIII) The organization must periodically undertake reassessment of its compliance program to identify changes necessary to reflect changes within the organization and its facilities.

(v) COORDINATION.—The provisions of this subparagraph shall apply with respect to a nursing facility in lieu of section 1902(a)(77).

(D) AVAILABILITY OF SURVEY, CERTIFICATION, AND COMPLAINT INVESTIGATION REPORTS.—A nursing facility must—

(i) have reports with respect to any surveys, certifications, and complaint investigations made respecting the facility during the 3 preceding years available for any individual to review upon request; and

(ii) post notice of the availability of such reports in areas of the facility that are prominent and accessible to the public.

The facility shall not make available under clause (i) identifying information about complainants or residents.

* * * * * * *

(e) STATE REQUIREMENTS RELATING TO NURSING FACILITY REQUIREMENTS.—As a condition of approval of its plan under this title, a State must provide for the following:

(1) * * *

* * * * * * *

(8) COMPLAINT PROCESSES AND WHISTLEBLOWER PROTECTION.—

(A) COMPLAINT FORMS.—The State must make the standardized complaint form developed under subsection (f)(11) available upon request to—

(i) a resident of a nursing facility;

(ii) any person acting on the resident's behalf; and

(iii) any person who works at a nursing facility or a representative of such a worker.

(B) COMPLAINT RESOLUTION PROCESS.—The State must establish a complaint resolution process in order to ensure that a resident, the legal representative of a resident of a nursing facility, or other responsible party is not retaliated against if the resident, legal representative, or responsible party has complained, in good faith, about the quality of

care or other issues relating to the nursing facility, that the legal representative of a resident of a nursing facility or other responsible party is not denied access to such resident or otherwise retaliated against if such representative party has complained, in good faith, about the quality of care provided by the facility or other issues relating to the facility, and that a person who works at a nursing facility is not retaliated against if the worker has complained, in good faith, about quality of care or services or an issue relating to the quality of care or services provided at the facility, whether the resident, legal representative, other responsible party, or worker used the form developed under subsection (f)(11) or some other method for submitting the complaint. Such complaint resolution process shall include—

(i) procedures to assure accurate tracking of complaints received, including notification to the complainant that a complaint has been received;

(ii) procedures to determine the likely severity of a complaint and for the investigation of the complaint;

(iii) deadlines for responding to a complaint and for notifying the complainant of the outcome of the investigation; and

(iv) procedures to ensure that the identity of the complainant will be kept confidential.

(C) WHISTLEBLOWER PROTECTION.—

(i) PROHIBITION AGAINST RETALIATION.—No person who works at a nursing facility may be penalized, discriminated, or retaliated against with respect to any aspect of employment, including discharge, promotion, compensation, terms, conditions, or privileges of employment, or have a contract for services terminated, because the person (or anyone acting at the person's request) complained, in good faith, about the quality of care or services provided by a nursing facility or about other issues relating to quality of care or services, whether using the form developed under subsection (f)(11) or some other method for submitting the complaint.

(ii) RETALIATORY REPORTING.—A nursing facility may not file a complaint or a report against a person who works (or has worked at the facility with the appropriate State professional disciplinary agency because the person (or anyone acting at the person's request) complained in good faith, as described in clause (i).

(iii) COMMENCEMENT OF ACTION.—Any person who believes the person has been penalized, discriminated, or retaliated against or had a contract for services terminated in violation of clause (i) or against whom a complaint has been filed in violation of clause (ii) may bring an action at law or equity in the appropriate district court of the United States, which shall have jurisdiction over such action without regard to the amount in controversy or the citizenship of the parties, and

which shall have jurisdiction to grant complete relief, including, but not limited to, injunctive relief (such as reinstatement, compensatory damages (which may include reimbursement of lost wages, compensation, and benefits), costs of litigation (including reasonable attorney and expert witness fees), exemplary damages where appropriate, and such other relief as the court deems just and proper.

(iv) RIGHTS NOT WAIVABLE.—The rights protected by this paragraph may not be diminished by contract or other agreement, and nothing in this paragraph shall be construed to diminish any greater or additional protection provided by Federal or State law or by contract or other agreement.

(v) REQUIREMENT TO POST NOTICE OF EMPLOYEE RIGHTS.—Each nursing facility shall post conspicuously in an appropriate location a sign (in a form specified by the Secretary) specifying the rights of persons under this paragraph and including a statement that an employee may file a complaint with the Secretary against a nursing facility that violates the provisions of this paragraph and information with respect to the manner of filing such a complaint.

(D) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed as preventing a resident of a nursing facility (or a person acting on the resident's behalf) from submitting a complaint in a manner or format other than by using the standardized complaint form developed under subsection (f)(11) (including submitting a complaint orally).

(E) GOOD FAITH DEFINED.—For purposes of this paragraph, an individual shall be deemed to be acting in good faith with respect to the filing of a complaint if the individual reasonably believes—

(i) the information reported or disclosed in the complaint is true; and

(ii) the violation of this title has occurred or may occur in relation to such information.

* * * * * * *

(f) RESPONSIBILITIES OF SECRETARY RELATING TO NURSING FACILITY REQUIREMENTS.—

(1) * * *

(2) REQUIREMENTS FOR NURSE AIDE TRAINING AND COMPETENCY EVALUATION PROGRAMS AND FOR NURSE AIDE COMPETENCY EVALUATION PROGRAMS.—

(A) IN GENERAL.—For purposes of subsections (b)(5) and (e)(1)(A), the Secretary shall establish, by not later than September 1, 1988—

(i) requirements for the approval of nurse aide training and competency evaluation programs, including requirements relating to (I) the areas to be covered in such a program (including at least basic nursing skills, personal care skills, recognition of mental health and social service needs, care of cognitively impaired residents, basic restorative services, and residents' rights) and content of the curriculum *(including, in the case*

of initial training and, if the Secretary determines appropriate, in the case of ongoing training, dementia management training and resident abuse prevention training), (II) minimum hours of initial and ongoing training and retraining (including not less than 75 hours in the case of initial training), (III) qualifications of instructors, and (IV) procedures for determination of competency;

* * * * * * *

(10) SPECIAL FOCUS FACILITY PROGRAM.—

(A) IN GENERAL.—The Secretary shall conduct a special focus facility program for enforcement of requirements for nursing facilities that the Secretary has identified as having substantially failed to meet applicable requirements of this Act.

(B) PERIODIC SURVEYS.—Under such program the Secretary shall conduct surveys of each facility in the program not less often than once every 6 months.

(11) STANDARDIZED COMPLAINT FORM.—The Secretary shall develop a standardized complaint form for use by a resident (or a person acting on the resident's behalf) in filing a complaint with a State survey and certification agency and a State long-term care ombudsman program with respect to a nursing facility.

(g) SURVEY AND CERTIFICATION PROCESS.—

(1) * * *

* * * * * * *

(5) DISCLOSURE OF RESULTS OF INSPECTIONS AND ACTIVITIES.—

(A) * * *

* * * * * * *

(E) SUBMISSION OF SURVEY AND CERTIFICATION INFORMATION TO THE SECRETARY.—In order to improve the timeliness of information made available to the public under subparagraph (A) and provided on the Nursing Home Compare Medicare website under subsection (i), each State shall submit information respecting any survey or certification made respecting a nursing facility (including any enforcement actions taken by the State) to the Secretary not later than the date on which the State sends such information to the facility. The Secretary shall use the information submitted under the preceding sentence to update the information provided on the Nursing Home Compare Medicare website as expeditiously as practicable but not less frequently than quarterly.

(h) ENFORCEMENT PROCESS.—

(1) * * *

(2) SPECIFIED REMEDIES.—

(A) LISTING.—Except as provided in subparagraph (B)(ii), each State shall establish by law (whether statute or regulation) at least the following remedies:

(i) * * *

(ii) [A civil money penalty assessed and collected, with interest, for each day in which the facility is or was out of compliance with a requirement of subsection (b), (c), or (d).] *A civil money penalty in accordance with subparagraph (G).* Funds collected by a State as a result of imposition of such a penalty (or as a result of the imposition by the State of a civil money penalty for activities described in subsections (b)(3)(B)(ii)(I), (b)(3)(B)(ii)(II), or (g)(2)(A)(i)) shall be applied to the protection of the health or property of residents of nursing facilities that the State or the Secretary finds deficient, including payment for the costs of relocation of residents to other facilities, maintenance of operation of a facility pending correction of deficiencies or closure, and reimbursement of residents for personal funds lost*, and some portion of such funds may be used to support activities that benefit residents, including assistance to support and protect residents of a facility that closes (voluntarily or involuntarily) or is decertified (including offsetting costs of relocating residents to home and community-based settings or another facility), projects that support resident and family councils and other consumer involvement in assuring quality care in facilities, and facility improvement initiatives approved by the Secretary (including joint training of facility staff and surveyors, providing technical assistance to facilities under quality assurance programs, the appointment of temporary management, and other activities approved by the Secretary).*

* * * * * * *

(G) CIVIL MONEY PENALTIES.—

(i) IN GENERAL.—The State may impose a civil money penalty under subparagraph (A)(ii) in the applicable per instance or per day amount (as defined in subclause (II) and (III)) for each day or instance, respectively, of noncompliance (as determined appropriate by the Secretary).

(ii) APPLICABLE PER INSTANCE AMOUNT.—In this subparagraph, the term "applicable per instance amount" means—

(I) in the case where the deficiency is found to be a direct proximate cause of death of a resident of the facility, an amount not to exceed $100,000.

(II) in each case of a deficiency where the facility is cited for actual harm or immediate jeopardy, an amount not less than $3,050 and not more than $25,000; and

(III) in each case of any other deficiency, an amount not less than $250 and not to exceed $3050.

(iii) APPLICABLE PER DAY AMOUNT.—In this subparagraph, the term "applicable per day amount" means—

(I) in each case of a deficiency where the facility is cited for actual harm or immediate jeopardy, an

amount not less than $3,050 and not more than $25,000 and

(II) in each case of any other deficiency, an amount not less than $250 and not to exceed $3,050.

(iv) REDUCTION OF CIVIL MONEY PENALTIES IN CERTAIN CIRCUMSTANCES.—Subject to clauses (v) and (vi), in the case where a facility self-reports and promptly corrects a deficiency for which a penalty was imposed under subparagraph (A)(ii) not later than 10 calendar days after the date of such imposition, the State may reduce the amount of the penalty imposed by not more than 50 percent.

(v) PROHIBITION ON REDUCTION FOR CERTAIN DEFICIENCIES.—

(I) REPEAT DEFICIENCIES.—The State may not reduce under clause (iv) the amount of a penalty if the State had reduced a penalty imposed on the facility in the preceding year under such clause with respect to a repeat deficiency.

(II) CERTAIN OTHER DEFICIENCIES.—The State may not reduce under clause (iv) the amount of a penalty if the penalty is imposed for a deficiency described in clause (ii)(II) or (iii)(I) and the actual harm or widespread harm that immediately jeopardizes the health or safety of a resident or residents of the facility, or if the penalty is imposed for a deficiency described in clause (ii)(I).

(III) LIMITATION ON AGGREGATE REDUCTIONS.—The aggregate reduction in a penalty under clause (iv) may not exceed 35 percent on the basis of self-reporting, on the basis of a waiver or an appeal (as provided for under regulations under section 488.436 of title 42, Code of Federal Regulations), or on the basis of both.

(vi) COLLECTION OF CIVIL MONEY PENALTIES.—In the case of a civil money penalty imposed under subparagraph (A)(ii), the State—

(I) subject to subclause (III), shall, not later than 30 days after the date of imposition of the penalty, provide the opportunity for the facility to participate in an independent informal dispute resolution process which generates a written record prior to the collection of such penalty, but such opportunity shall not affect the responsibility of the State survey agency for making final recommendations for such penalties;

(II) in the case where the penalty is imposed for each day of noncompliance, shall not impose a penalty for any day during the period beginning on the initial day of the imposition of the penalty and ending on the day on which the informal dispute resolution process under subclause (I) is completed;

(III) may provide for the collection of such civil money penalty and the placement of such amounts collected in an escrow account under the direction of the State on the earlier of the date on which the informal dispute resolution process under subclause (I) is completed or the date that is 90 days after the date of the imposition of the penalty;

(IV) may provide that such amounts collected are kept in such account pending the resolution of any subsequent appeals;

(V) in the case where the facility successfully appeals the penalty, may provide for the return of such amounts collected (plus interest) to the facility; and

(VI) in the case where all such appeals are unsuccessful, may provide that such funds collected shall be used for the purposes described in the second sentence of subparagraph (A)(ii).

(3) SECRETARIAL AUTHORITY.—

(A) * * *

* * * * * * *

(C) SPECIFIED REMEDIES.—The Secretary may take the following actions with respect to a finding that a facility has not met an applicable requirement:

(i) * * *

[(ii) AUTHORITY WITH RESPECT TO CIVIL MONEY PENALTIES.—The Secretary may impose a civil money penalty in an amount not to exceed $10,000 for each day of noncompliance. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under the previous sentence in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).]

(ii) AUTHORITY WITH RESPECT TO CIVIL MONEY PENALTIES.—

(I) AMOUNT.—Subject to subclause (II), the Secretary may impose a civil money penalty in an amount not to exceed $10,000 for each day or each instance of noncompliance (as determined appropriate by the Secretary).

(II) REDUCTION OF CIVIL MONEY PENALTIES IN CERTAIN CIRCUMSTANCES.—Subject to subclause (III), in the case where a facility self-reports and promptly corrects a deficiency for which a penalty was imposed under this clause not later than 10 calendar days after the date of such imposition, the Secretary may reduce the amount of the penalty imposed by not more than 50 percent.

(III) PROHIBITION ON REDUCTION FOR REPEAT DEFICIENCIES.—The Secretary may not reduce the amount of a penalty under subclause (II) if the Secretary had reduced a penalty imposed on the facility in the preceding year under such subclause with respect to a repeat deficiency.

(IV) COLLECTION OF CIVIL MONEY PENALTIES.—In the case of a civil money penalty imposed under this clause, the Secretary—

(aa) subject to item (bb), shall, not later than 30 days after the date of imposition of the penalty, provide the opportunity for the facility to participate in an independent informal dispute resolution process which generates a written record prior to the collection of such penalty;

(bb) in the case where the penalty is imposed for each day of noncompliance, shall not impose a penalty for any day during the period beginning on the initial day of the imposition of the penalty and ending on the day on which the informal dispute resolution process under item (aa) is completed;

(cc) may provide for the collection of such civil money penalty and the placement of such amounts collected in an escrow account under the direction of the Secretary on the earlier of the date on which the informal dispute resolution process under item (aa) is completed or the date that is 90 days after the date of the imposition of the penalty;

(dd) may provide that such amounts collected are kept in such account pending the resolution of any subsequent appeals;

(ee) in the case where the facility successfully appeals the penalty, may provide for the return of such amounts collected (plus interest) to the facility; and

(ff) in the case where all such appeals are unsuccessful, may provide that some portion of such amounts collected may be used to support activities that benefit residents, including assistance to support and protect residents of a facility that closes (voluntarily or involuntarily) or is decertified (including offsetting costs of relocating residents to home and community-based settings or another facility), projects that support resident and family councils and other consumer involvement in assuring quality care in facilities, and facility improvement initiatives approved by the Secretary (including joint training of facility staff and surveyors, technical assistance for facilities under quality assurance programs, the appointment of temporary management, and other activities approved by the Secretary).

(V) PROCEDURE.—The provisions of section 1128A (other than subsections (a) and (b) and except to the extent that such provisions require a hearing prior to the imposition of a civil money penalty) shall apply to a civil money penalty under

this clause in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

* * * * * * *

(8) CONSTRUCTION.—The remedies provided under this subsection are in addition to those otherwise available under State or Federal law and shall not be construed as limiting such other remedies, including any remedy available to an individual at common law. The remedies described in clauses (i), (iii), and (iv) of paragraph (2)(A) *and in paragraph (3)(C)(ii)* may be imposed during the pendency of any hearing. The provisions of this subsection shall apply to a nursing facility (or portion thereof) notwithstanding that the facility (or portion thereof) also is a skilled nursing facility for purposes of title XVIII.

* * * * * * *

(i) NURSING HOME COMPARE WEBSITE.—

(1) INCLUSION OF ADDITIONAL INFORMATION.—

(A) IN GENERAL.—The Secretary shall ensure that the Department of Health and Human Services includes, as part of the information provided for comparison of nursing homes on the official Internet website of the Federal Government for Medicare beneficiaries (commonly referred to as the "Nursing Home Compare" Medicare website) (or a successor website), the following information in a manner that is prominent, easily accessible, readily understandable to consumers of long-term care services, and searchable:

(i) Staffing data for each facility (including resident census data and data on the hours of care provided per resident per day) based on data submitted under subsection (b)(8)(C)(ii), including information on staffing turnover and tenure, in a format that is clearly understandable to consumers of long-term care services and allows such consumers to compare differences in staffing between facilities and State and national averages for the facilities. Such format shall include—

(I) concise explanations of how to interpret the data (such as plain English explanation of data reflecting "nursing home staff hours per resident day");

(II) differences in types of staff (such as training associated with different categories of staff);

(III) the relationship between nurse staffing levels and quality of care; and

(IV) an explanation that appropriate staffing levels vary based on patient case mix.

(ii) Links to State Internet websites with information regarding State survey and certification programs, links to Form 2567 State inspection reports (or a successor form) on such websites, information to guide consumers in how to interpret and understand such reports, and the facility plan of correction or other response to such report.

(iii) The standardized complaint form developed under subsection (f)(10), including explanatory material on what complaint forms are, how they are used, and how to file a complaint with the State survey and certification program and the State long-term care ombudsman program.

(iv) Summary information on the number, type, severity, and outcome of substantiated complaints.

(v) The number of adjudicated instances of criminal violations by employees of a nursing facility—

(I) that were committed inside of the facility; and

(II) with respect to such instances of violations or crimes committed outside of the facility, that were the violations or crimes that resulted in the serious bodily injury of an elder.

(B) DEADLINE FOR PROVISION OF INFORMATION.—

(i) IN GENERAL.—Except as provided in clause (ii), the Secretary shall ensure that the information described in subparagraph (A) is included on such website (or a successor website) not later than 1 year after the date of the enactment of this subsection.

(ii) EXCEPTION.—The Secretary shall ensure that the information described in subparagraph (A)(i) and (A)(iii) is included on such website (or a successor website) not later than the date on which the requirements under section 1124(c)(4) and subsection (b)(8)(C)(ii) are implemented.

(2) REVIEW AND MODIFICATION OF WEBSITE.—

(A) IN GENERAL.—The Secretary shall establish a process—

(i) to review the accuracy, clarity of presentation, timeliness, and comprehensiveness of information reported on such website as of the day before the date of the enactment of this subsection; and

(ii) not later than 1 year after the date of the enactment of this subsection, to modify or revamp such website in accordance with the review conducted under clause (i).

(B) CONSULTATION.—In conducting the review under subparagraph (A)(i), the Secretary shall consult with—

(i) State long-term care ombudsman programs;

(ii) consumer advocacy groups;

(iii) provider stakeholder groups;

(iv) skilled nursing facility employees and their representatives; and

(v) any other representatives of programs or groups the Secretary determines appropriate.

[(i)**]** *(j)* CONSTRUCTION.—Where requirements or obligations under this section are identical to those provided under section 1819 of this Act, the fulfillment of those requirements or obligations under section 1819 shall be considered to be the fulfillment of the corresponding requirements or obligations under this section.

* * * * * * *

PRESUMPTIVE ELIGIBILITY FOR FAMILY PLANNING SERVICES

SEC. 1920C. (a) STATE OPTION.—State plan approved under section 1902 may provide for making medical assistance available to an individual described in section 1902(hh) (relating to individuals who meet certain income eligibility standard) during a presumptive eligibility period. In the case of an individual described in section 1902(hh), such medical assistance shall be limited to family planning services and supplies described in 1905(a)(4)(C) and, at the State's option, medical diagnosis and treatment services that are provided in conjunction with a family planning service in a family planning setting.

(b) DEFINITIONS.—For purposes of this section:

(1) PRESUMPTIVE ELIGIBILITY PERIOD.—The term "presumptive eligibility period" means, with respect to an individual described in subsection (a), the period that—

(A) begins with the date on which a qualified entity determines, on the basis of preliminary information, that the individual is described in section 1902(hh); and

(B) ends with (and includes) the earlier of—

(i) the day on which a determination is made with respect to the eligibility of such individual for services under the State plan; or

(ii) in the case of such an individual who does not file an application by the last day of the month following the month during which the entity makes the determination referred to in subparagraph (A), such last day.

(2) QUALIFIED ENTITY.—

(A) IN GENERAL.—Subject to subparagraph (B), the term "qualified entity" means any entity that—

(i) is eligible for payments under a State plan approved under this title; and

(ii) is determined by the State agency to be capable of making determinations of the type described in paragraph (1)(A).

(B) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed as preventing a State from limiting the classes of entities that may become qualified entities in order to prevent fraud and abuse.

(c) ADMINISTRATION.—

(1) IN GENERAL.—The State agency shall provide qualified entities with—

(A) such forms as are necessary for an application to be made by an individual described in subsection (a) for medical assistance under the State plan; and

(B) information on how to assist such individuals in completing and filing such forms.

(2) NOTIFICATION REQUIREMENTS.—A qualified entity that determines under subsection (b)(1)(A) that an individual described in subsection (a) is presumptively eligible for medical assistance under a State plan shall—

(A) notify the State agency of the determination within 5 working days after the date on which determination is made; and

(B) inform such individual at the time the determination is made that an application for medical assistance is required to be made by not later than the last day of the month following the month during which the determination is made.

(3) APPLICATION FOR MEDICAL ASSISTANCE.—In the case of an individual described in subsection (a) who is determined by a qualified entity to be presumptively eligible for medical assistance under a State plan, the individual shall apply for medical assistance by not later than the last day of the month following the month during which the determination is made.

(d) PAYMENT.—Notwithstanding any other provision of law, medical assistance that—

(1) is furnished to an individual described in subsection (a)—

(A) during a presumptive eligibility period;

(B) by a entity that is eligible for payments under the State plan; and

(2) is included in the care and services covered by the State plan,

shall be treated as medical assistance provided by such plan for purposes of clause (4) of the first sentence of section 1905(b).

* * * * * * *

ADJUSTMENT IN PAYMENT FOR INPATIENT HOSPITAL SERVICES FURNISHED BY DISPROPORTIONATE SHARE HOSPITALS

SEC. 1923. (a) * * *

(b) HOSPITALS DEEMED DISPROPORTIONATE SHARE.—

(1) * * *

* * * * * * *

(4) The Secretary may not restrict a State's authority to designate hospitals as disproportionate share hospitals under this section. The previous sentence shall not be construed to affect the authority of the Secretary to reduce payments pursuant to section 1903(w)(1)(A)(iii) if the Secretary determines that, as a result of such designations, there is in effect a hold harmless provision described in section 1903(w)(4) *or to affect the authority of the Secretary to issue and implement the DSH Health Reform methodology under section 1704(b)(2) of the America's Health Choices Act of 2009*.

* * * * * * *

(d) REQUIREMENTS TO QUALIFY AS DISPROPORTIONATE SHARE HOSPITAL.—

(1) * * *

* * * * * * *

(4) No hospital may be defined or deemed as a disproportionate share hospital, or as an essential access hospital (for purposes of subsection (f)(6)(A)(iv)), under a State plan under this title or subsection (b) of this section (including any waiver under section 1115) unless the hospital—

(A) provides services to beneficiaries under this title without discrimination on the ground of race, color, national origin, creed, source of payment, status as a beneficiary under this title, or any other ground unrelated to such bene-

ficiary's need for the services or the availability of the needed services in the hospital; and

(B) makes arrangements for, and accepts, reimbursement under this title for services provided to eligible beneficiaries under this title.

* * * * * * *

(f) LIMITATION ON FEDERAL FINANCIAL PARTICIPATION.—

(1) * * *

* * * * * * *

(7) SPECIAL RULE FOR FISCAL YEARS 2017, 2018, AND 2019.—

(A) FISCAL YEAR 2017.—Notwithstanding paragraph (2), the total DSH allotments for all States for—

(i) fiscal year 2017, shall be the total DSH allotments that would otherwise be determined under this subsection for such fiscal year decreased by $1,500,000,000;

(ii) fiscal year 2018, shall be the total DSH allotments that would otherwise be determined under this subsection for such fiscal year decreased by $2,500,000,000; and

(iii) fiscal year 2019, shall be the total DSH allotments that would otherwise be determined under this subsection for such fiscal year decreased by $6,000,000,000.

[(7)**]** *(8)* DEFINITION OF STATE.— In this subsection, the term "State" means the 50 States and the District of Columbia.

* * * * * * *

EXTENSION OF ELIGIBILITY FOR MEDICAL ASSISTANCE

SEC. 1925. (a) * * *

* * * * * * *

(f) SUNSET.—This section shall not apply with respect to families that cease to be eligible for aid under part A of title IV after **[**December 31, 2010**]** *December 31, 2012*.

* * * * * * *

ASSURING ADEQUATE PAYMENT LEVELS FOR SERVICES

SEC. 1926. (a) IN GENERAL.—A State plan under this title shall not be considered to meet the requirement of section 1902(a)(30)(A) for a year (beginning with 2011) unless, by not later than April 1 before the beginning of such year, the State submits to the Secretary an amendment to the plan that specifies the payment rates to be used for such services under the plan in such year and includes in such submission such additional data as will assist the Secretary in evaluating the State's compliance with such requirement, including data relating to how rates established for payments to medicaid managed care organizations under sections 1903(m) and 1932 take into account such payment rates.

(b) SECRETARIAL REVIEW.—The Secretary, by not later than 90 days after the date of submission of a plan amendment under subsection (a), shall—

(1) review each such amendment for compliance with the requirement of section 1902(a)(30)(A); and

(2) approve or disapprove each such amendment.

If the Secretary disapproves such an amendment, the State shall immediately submit a revised amendment that meets such requirement.

PAYMENT FOR COVERED OUTPATIENT DRUGS

SEC. 1927. (a) REQUIREMENT FOR REBATE AGREEMENT.—

(1) * * *

* * * * * * *

(5) LIMITATION ON PRICES OF DRUGS PURCHASED BY COVERED ENTITIES.—

(A) AGREEMENT WITH SECRETARY.—A manufacturer meets the requirements of this paragraph if the manufacturer has entered into an agreement with the Secretary that meets the requirements of section 340B of the Public Health Service Act with respect to [covered outpatient drugs] *covered drugs (as defined in section 340B(b)(2) of the Public Health Service Act)* purchased by a covered entity on or after the first day of the first month that begins after the date of the enactment of this paragraph.

* * * * * * *

[(D) EFFECT OF SUBSEQUENT AMENDMENTS.—In determining whether an agreement under subparagraph (A) meets the requirements of section 340B of the Public Health Service Act, the Secretary shall not take into account any amendments to such section that are enacted after the enactment of title VI of the Veterans Health Care Act of 1992.]

(D) STATE RESPONSIBILITY FOR CALCULATING HOSPITAL CREDITS.—The State shall calculate the credits owed by the hospital under paragraph (1) of section 340B(c) of the Public Health Service Act and provide the hospital with both the amounts and an explanation of how it calculated the credits. In performing the calculations specified in paragraphs (2)(A)(ii) and (2)(B)(ii) of such section, the State shall use the average manufacturer price applicable to the calendar quarter in which the drug was purchased by the hospital.

(b) TERMS OF REBATE AGREEMENT.—

(1) PERIODIC REBATES.—

(A) IN GENERAL.—A rebate agreement under this subsection shall require the manufacturer to provide, to each State plan approved under this title, a rebate for a rebate period in an amount specified in subsection (c) for covered outpatient drugs of the manufacturer dispensed after December 31, 1990, for which payment was made under the State plan for such period*, including such drugs dispensed to individuals enrolled with a medicaid managed care organization if the organization is responsible for coverage of such drugs*. Such rebate shall be paid by the manufacturer

not later than 30 days after the date of receipt of the information described in paragraph (2) for the period involved.

* * * * * * *

(2) STATE PROVISION OF INFORMATION.—

(A) * * *

* * * * * * *

(C) REPORTING ON MMCO DRUGS.—On a quarterly basis, each State shall report to the Secretary the total amount of rebates in dollars received from pharmacy manufacturers for drugs provided to individuals enrolled with Medicaid managed care organizations that contract under section 1903(m).

(3) MANUFACTURER PROVISION OF PRICE INFORMATION.—

(A) IN GENERAL.—Each manufacturer with an agreement in effect under this section shall report to the Secretary—

(i) not later than 30 days after the last day of each *month of a* rebate period under the agreement—

(I) * * *

* * * * * * *

(iii) for calendar quarters beginning on or after January 1, 2004, in conjunction with reporting required under clause (i) and by National Drug Code (including package size)—

(I) * * *

* * * * * * *

for a drug or biological described in subparagraph *(A)(iv) (including influenza vaccines furnished on or after January 1, 2011),* (C), (D), (E), or (G) of section 1842(o)(1) or section 1881(b)(13)(A)(ii), and, for calendar quarters beginning on or after January 1, 2007 and only with respect to the information described in subclause (III), for covered outpatient drugs.

(iv) not later than 30 days after the last day of each month of a rebate period under the agreement, on the manufacturer's total number of units that are used to calculate the monthly average manufacturer price for each covered outpatient drug.

Information reported under this subparagraph is subject to audit by the Inspector General of the Department of Health and Human Services. Beginning July 1, 2006, the Secretary shall provide on a monthly basis to States under subparagraph (D)(iv) the most recently reported average manufacturer prices for single source drugs and for multiple source drugs ❚and shall, on at least a quarterly basis, update the information posted on the website under subparagraph (D)(v)❚.

* * * * * * *

(D) CONFIDENTIALITY OF INFORMATION.—Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph or under an agreement with the Secretary of Veterans Affairs described in subsection (a)(6)(A)(ii) (other than the whole-

sale acquisition cost for purposes of carrying out section 1847A) is confidential and shall not be disclosed by the Secretary or the Secretary of Veterans Affairs or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except—

(i) * * *

* * * * * * *

(v) to the Secretary to disclose (through a website accessible to the public) *weighted* average manufacturer prices.

* * * * * * *

(c) DETERMINATION OF AMOUNT OF REBATE.—

(1) BASIC REBATE FOR SINGLE SOURCE DRUGS AND INNOVATOR MULTIPLE SOURCE DRUGS.—

(A) * * *

(B) RANGE OF REBATES REQUIRED.—

(i) MINIMUM REBATE PERCENTAGE.—For purposes of subparagraph (A)(ii)(II), the "minimum rebate percentage" for rebate periods beginning—

(I) * * *

* * * * * * *

(IV) after December 31, 1994, and before January 1, 1996, is 15.2 percent; **[**and**]**

(V) after December 31, 1995, *and before January 1, 2010* is 15.1 percent**[**.**]***; and*

(VI) after December 31, 2009, is 22.1 percent.

* * * * * * *

(2) ADDITIONAL REBATE FOR SINGLE SOURCE AND INNOVATOR MULTIPLE SOURCE DRUGS.—

(A) * * *

* * * * * * *

(C) TREATMENT OF NEW FORMULATIONS.—In the case of a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form, the rebate obligation with respect to such drug under this section shall be the amount computed under this section for such new drug or, if greater, the product of—

(i) the average manufacturer price of the line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form;

(ii) the highest additional rebate (calculated as a percentage of average manufacturer price) under this section for any strength of the original single source drug or innovator multiple source drug; and

(iii) the total number of units of each dosage form and strength of the line extension product paid for under the State plan in the rebate period (as reported by the State).

In this subparagraph, the term "line extension" means, with respect to a drug, an extended release formulation of the drug.

* * * * * * *

(d) LIMITATIONS ON COVERAGE OF DRUGS.—

(1) * * *

(2) LIST OF DRUGS SUBJECT TO RESTRICTION.—The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:

(A) * * *

* * * * * * *

[(E) Agents when used to promote smoking cessation.]

[(F)] *(E)* Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.

[(G)] *(F)* Nonprescription drugs*, except agents approved by the Food and Drug Administration for purposes of promoting, and when used to promote, tobacco cessation*.

[(H)] *(G)* Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.

[(I)] *(H)* Barbiturates.

[(J)] *(I)* Benzodiazepines.

[(K)] *(J)* Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration.

* * * * * * *

(e) TREATMENT OF PHARMACY REIMBURSEMENT LIMITS.—

(1) * * *

* * * * * * *

[(5) USE OF AMP IN UPPER PAYMENT LIMITS.—Effective January 1, 2007, in applying the Federal upper reimbursement limit under paragraph (4) and section 447.332(b) of title 42 of the Code of Federal Regulations, the Secretary shall substitute 250 percent of the average manufacturer price (as computed without regard to customary prompt pay discounts extended to wholesalers) for 150 percent of the published price.]

(5) USE OF AMP IN UPPER PAYMENT LIMITS.—The Secretary shall calculate the Federal upper reimbursement limit established under paragraph (4) as 130 percent of the weighted average (determined on the basis of manufacturer utilization) of monthly average manufacturer prices.

* * * * * * *

(j) [EXEMPTION] *SPECIAL RULES* OF ORGANIZED HEALTH CARE SETTINGS.—(1) Covered outpatient drugs dispensed by health maintenance organizations, including medicaid managed care organizations that contract under section 1903(m), are [not] subject to the requirements of this section.

* * * * * * *

(k) DEFINITIONS.—In the section—

(1) AVERAGE MANUFACTURER PRICE.—

(A) IN GENERAL.—Subject to [subparagraph (B)] *subparagraphs (B) and (D)*, the term "average manufacturer price" means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade.

(B) EXCLUSION OF CUSTOMARY PROMPT PAY DISCOUNTS [EXTENDED TO WHOLESALERS] *AND OTHER PAYMENTS*.—The average manufacturer price for a covered outpatient drug shall be determined without [regard to customary prompt pay discounts extended to wholesalers.] *regard to—*

(i) customary prompt pay discounts extended to wholesalers;

(ii) bona fide service fees paid by manufacturers;

(iii) reimbursement by manufacturers for recalled, damaged, expired, or otherwise unsalable returned goods, including reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction;

(iv) sales directly to, or rebates, discounts, or other price concessions provided to, pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers, mail order pharmacies that are not open to all members of the public, or long term care providers, provided that these rebates, discounts, or price concessions are not passed through to retail pharmacies;

(v) sales directly to, or rebates, discounts, or other price concessions provided to, hospitals, clinics, and physicians, unless the drug is an inhalation, infusion, or injectable drug, or unless the Secretary determines, as allowed for in Agency administrative procedures, that it is necessary to include such sales, rebates, discounts, and price concessions in order to obtain an accurate AMP for the drug. Such a determination shall not be subject to judicial review; or

(vi) rebates, discounts, and other price concessions required to be provided under agreements under subsections (f) and (g) of section 1860D–2(f).

* * * * * * *

(D) CALCULATION FOR COVERED DRUGS.—With respect to a covered drug (as defined in section 340B(b)(2) of the Public Health Service Act), the average manufacturer price shall be determined in accordance with subparagraph (A) except that, in the event a covered drug is not distributed to the retail pharmacy class of trade, it shall mean the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the acute care class of trade, after deducting customary prompt pay discounts.

* * * * * * *

PROGRAM FOR DISTRIBUTION OF PEDIATRIC VACCINES

SEC. 1928. (a) * * *

(b) VACCINE-ELIGIBLE CHILDREN.—For purposes of this section:

(1) * * *

(2) FEDERALLY VACCINE-ELIGIBLE CHILD.—

(A) IN GENERAL.—The term "federally vaccine-eligible child" means any of the following children:

(i) * * *

* * * * * * *

(iii) A child who (I) is administered a qualified pediatric vaccine by a federally-qualified health center (as defined in section 1905(l)(2)(B)) **[**or a rural health clinic**]**, *a rural health clinic* (as defined in section 1905(l)(1)), *or a public health clinic,* and (II) is not insured with respect to the vaccine.

* * * * * * *

(c) PROGRAM-REGISTERED PROVIDERS.—

(1) * * *

(2) PROVIDER AGREEMENT.—A provider agreement for a provider under this paragraph is an agreement (in such form and manner as the Secretary may require) that the provider agrees as follows:

(A) * * *

(B)(i) Subject to clause (ii), the provider will comply with the schedule, regarding the appropriate periodicity, dosage, and contraindications applicable to pediatric vaccines, that is established and periodically reviewed and, as appropriate, revised by **[**the advisory committee referred to in subsection (e)**]** *the Director of the Centers for Disease Control and Prevention*, except in such cases as, in the provider's medical judgment subject to accepted medical practice, such compliance is medically inappropriate.

* * * * * * *

(e) USE OF PEDIATRIC VACCINES LIST.—The Secretary shall use, for the purpose of the purchase, delivery, and administration of pediatric vaccines under this section, the list established (and periodically reviewed and as appropriate revised) by the **[**Advisory Committee on Immunization Practices (an advisory committee established by the Secretary, acting through the Director of the Centers for Disease Control and Prevention).**]** *Director of the Centers for Disease Control and Prevention.*

* * * * * * *

[(g) TERMINATION.—This section, and the requirement of section 1902(a)(62), shall cease to be in effect beginning on such date as may be prescribed in Federal law providing for immunization services for all children as part of a broad-based reform of the national health care system.**]**

* * * * * * *

ASSURING COVERAGE FOR CERTAIN LOW-INCOME FAMILIES

SEC. 1931. (a) * * *

(b) APPLICATION OF PRE-WELFARE-REFORM ELIGIBILITY CRITERIA.—

(1) IN GENERAL.—For purposes of this title, subject to paragraphs (2) and (3) *and section 1903(aa)(2)*, in determining eligibility for medical assistance—

(A) * * *

* * * * * * *

PROVISIONS RELATING TO MANAGED CARE

SEC. 1932. (a) STATE OPTION TO USE MANAGED CARE.—

(1)

* * * * * * *

(2) SPECIAL RULES.—

(A) * * *

* * * * * * *

(D) ENROLLMENT OF NON-TRADITIONAL MEDICAID ELIGIBLES.—A State may not require under paragraph (1) the enrollment in a managed care entity of an individual described in section 1902(a)(10)(A)(i)(VIII) unless the State demonstrates, to the satisfaction of the Secretary, that the entity, through its provider network and other arrangements, has the capacity to meet the health, mental health, and substance abuse needs of such individuals.

* * * * * * *

(f) TIMELINESS OF PAYMENT*; ADEQUACY OF PAYMENT FOR PRIMARY CARE SERVICES*.—A contract under section 1903(m) with a medicaid managed care organization shall provide that the organization shall make payment to health care providers for items and services which are subject to the contract and that are furnished to individuals eligible for medical assistance under the State plan under this title who are enrolled with the organization on a timely basis consistent with the claims payment procedures described in section 1902(a)(37)(A), unless the health care provider and the organization agree to an alternate payment schedule *and, in the case of primary care services described in section 1902(a)(13)(C), consistent with the minimum payment rates specified in such section (regardless of the manner in which such payments are made, including in the form of capitation or partial capitation)*.

* * * * * * *

STATE COVERAGE OF MEDICARE COST-SHARING FOR ADDITIONAL LOW-INCOME MEDICARE BENEFICIARIES

SEC. 1933. (a) IN GENERAL.—A State plan under this title shall provide, under section 1902(a)(10)(E)(iv) and subject to the succeeding provisions of this section and through a plan amendment, for medical assistance for payment of the cost of medicare cost-sharing described in such section on behalf of all individuals described in such section (in this section referred to as "qualifying individuals") **[**who are selected to receive such assistance under subsection (b)**]**.

[(b) SELECTION OF QUALIFYING INDIVIDUALS.—A State shall select qualifying individuals, and provide such individuals with assistance, under this section consistent with the following:

[(1) ALL QUALIFYING INDIVIDUALS MAY APPLY.—The State shall permit all qualifying individuals to apply for assistance during a calendar year.

[(2) SELECTION ON FIRST-COME, FIRST-SERVED BASIS.—

[(A) IN GENERAL.—For each calendar year (beginning with 1998), from (and to the extent of) the amount of the allocation under subsection (c) for the State for the fiscal year ending in such calendar year, the State shall select qualifying individuals who apply for the assistance in the order in which they apply.

[(B) CARRYOVER.—For calendar years after 1998, the State shall give preference to individuals who were provided such assistance (or other assistance described in section 1902(a)(10)(E)) in the last month of the previous year and who continue to be (or become) qualifying individuals.

[(3) LIMIT ON NUMBER OF INDIVIDUALS BASED ON ALLOCATION.—The State shall limit the number of qualifying individuals selected with respect to assistance in a calendar year so that the aggregate amount of such assistance provided to such individuals in such year is estimated to be equal to (but not exceed) the State's allocation under subsection (c) for the fiscal year ending in such calendar year.

[(4) RECEIPT OF ASSISTANCE DURING DURATION OF YEAR.—If a qualifying individual is selected to receive assistance under this section for a month in a year, the individual is entitled to receive such assistance for the remainder of the year if the individual continues to be a qualifying individual. The fact that an individual is selected to receive assistance under this section at any time during a year does not entitle the individual to continued assistance for any succeeding year.

[(c) ALLOCATION.—

[(1) TOTAL ALLOCATION.—The total amount available for allocation under this section for—

[(A) fiscal year 1998 is $200,000,000;

[(B) fiscal year 1999 is $250,000,000;

[(C) fiscal year 2000 is $300,000,000;

[(D) fiscal year 2001 is $350,000,000; and

[(E) each of fiscal years 2002 and 2003 is $400,000,000.

[(2) ALLOCATION TO STATES.—The Secretary shall provide for the allocation of the total amount described in paragraph (1) for a fiscal year, among the States that executed a plan amendment in accordance with subsection (a), based upon the Secretary's estimate of the ratio of—

[(A) an amount equal to the the total number of individuals described in section 1902(a)(10)(E)(iv) in the State; to

[(B) the sum of the amounts computed under subparagraph (A) for all eligible States.]

[(d)] *(b)* APPLICABLE FMAP.—With respect to assistance described in section 1902(a)(10)(E)(iv) [furnished in a State for calendar quarters in a calendar year —

[(1) to the extent that such assistance does not exceed the State's allocation under subsection (c) for the fiscal year ending

in the calendar year, the Federal medical assistance percentage shall be equal to 100 percent; and

[(2) to the extent that such assistance exceeds such allocation, the Federal medical assistance percentage is 0 percent.] *the Federal medical assistance percentage shall be equal to 100 percent.*

[(e) LIMITATION ON ENTITLEMENT.—Except as specifically provided under this section, nothing in this title shall be construed as establishing any entitlement of individuals described in section 1902(a)(10)(E)(iv) to assistance described in such section.]

[(f)] *(c)* COVERAGE OF COSTS THROUGH PART B OF THE MEDICARE PROGRAM.—For each fiscal year, the Secretary shall provide for the transfer from the Federal Supplementary Medical Insurance Trust Fund under section 1841 to the appropriate account in the Treasury that provides for payments under section 1903(a) with respect to medical assistance provided under this section, of an amount equivalent to the total of the amount of payments made under such section that is attributable to this section and such transfer shall be treated as an expenditure from such Trust Fund for purposes of section 1839.

[(g) SPECIAL RULES.—

[(1) IN GENERAL.—With respect to each period described in paragraph (2), a State shall select qualifying individuals, subject to paragraph (3), and provide such individuals with assistance, in accordance with the provisions of this section as in effect with respect to calendar year 2003, except that for such purpose—

[(A) references in the preceding subsections of this section to a year, whether fiscal or calendar, shall be deemed to be references to such period; and

[(B) the total allocation amount under subsection (c) for such period shall be the amount described in paragraph (2) for that period.

[(2) PERIODS AND TOTAL ALLOCATION AMOUNTS DESCRIBED.—For purposes of this subsection—

[(A) for the period that begins on January 1, 2004, and ends on September 30, 2004, the total allocation amount is $300,000,000;

[(B) for the period that begins on October 1, 2004, and ends on December 31, 2004, the total allocation amount is $100,000,000;

[(C) for the period that begins on January 1, 2005, and ends on September 30, 2005, the total allocation amount is $300,000,000;

[(D) for the period that begins on October 1, 2005, and ends on December 31, 2005, the total allocation amount is $100,000,000;

[(E) for the period that begins on January 1, 2006, and ends on September 30, 2006, the total allocation amount is $300,000,000;

[(F) for the period that begins on October 1, 2006, and ends on December 31, 2006, the total allocation amount is $100,000,000;

[(G) for the period that begins on January 1, 2007, and ends on September 30, 2007, the total allocation amount is $300,000,000;

[(H) for the period that begins on October 1, 2007, and ends on December 31, 2007, the total allocation amount is $100,000,000;

[(I) for the period that begins on January 1, 2008, and ends on September 30, 2008, the total allocation amount is $315,000,000;

[(J) for the period that begins on October 1, 2008, and ends on December 31, 2008, the total allocation amount is $130,000,000;

[(K) for the period that begins on January 1, 2009, and ends on September 30, 2009, the total allocation amount is $350,000,000;

[(L) for the period that begins on October 1, 2009, and ends on December 31, 2009, the total allocation amount is $150,000,000;

[(M) for the period that begins on January 1, 2010, and ends on September 30, 2010, the total allocation amount is $412,500,000; and

[(N) for the period that begins on October 1, 2010, and ends on December 31, 2010, the total allocation amount is $150,000,000.]

* * * * * * *

SPECIAL PROVISIONS RELATING TO MEDICARE PRESCRIPTION DRUG BENEFIT

SEC. 1935. (a) REQUIREMENTS RELATING TO MEDICARE PRESCRIPTION DRUG LOW-INCOME SUBSIDIES AND MEDICARE TRANSITIONAL PRESCRIPTION DRUG ASSISTANCE.—As a condition of its State plan under this title under section 1902(a)(66) and receipt of any Federal financial assistance under section 1903(a) subject to subsection (e), a State shall do the following:

(1) * * *

* * * * * * *

(4) CONSIDERATION OF DATA TRANSMITTED BY THE SOCIAL SECURITY ADMINISTRATION FOR PURPOSES OF MEDICARE SAVINGS PROGRAM.—

(A) IN GENERAL.—The State shall accept data transmitted under section 1144(c)(3) and act on such data in the same manner and in accordance with the same deadlines as if the data constituted an initiation of an application for benefits under the Medicare Savings Program (as defined for purposes of such section) that had been submitted directly by the applicant. [The date of the individual's application for the low income subsidy program from which the data have been derived shall constitute the date of filing of such application for benefits under the Medicare Savings Program.]

(B) FURNISHING MEDICAL ASSISTANCE WITH REASONABLE PROMPTNESS.—For the purpose of a State's obligation under section 1902(a)(8) to furnish medical assistance with reasonable promptness, the date of the electronic trans-

mission of low-income subsidy program data, as described in section 1144(c), from the Commissioner of Social Security to the State Medicaid Agency, shall constitute the date of filing of such application for benefits under the Medicare Savings Program.

(C) DETERMINING AVAILABILITY OF MEDICAL ASSISTANCE.—For the purpose of determining when medical assistance will be made available, the State shall consider the date of the individual's application for the low income subsidy program to constitute the date of filing for benefits under the Medicare Savings Program.

* * * * * * *

MEDICAID INTEGRITY PROGRAM

SEC. 1936. (a) * * *

* * * * * * *

(c) ELIGIBLE ENTITY AND CONTRACTING REQUIREMENTS.—

(1) * * *

(2) ELIGIBILITY REQUIREMENTS.—The requirements of this paragraph are the following:

(A) * * *

* * * * * * *

(D) For the contract year beginning in 2011 and each subsequent contract year, the entity provides assurances to the satisfaction of the Secretary that the entity will conduct periodic evaluations of the effectiveness of the activities carried out by such entity under the Program and will submit to the Secretary an annual report on such activities.

[(D)] *(E)* The entity meets such other requirements as the Secretary may impose.

* * * * * * *

STATE FLEXIBILITY IN BENEFIT PACKAGES

SEC. 1937. (a) * * *

(b) BENCHMARK BENEFIT PACKAGES.—

(1) IN GENERAL.—For purposes of subsection (a)(1), *subject to paragraph (5),* each of the following coverages shall be considered to be benchmark coverage:

(A) * * *

* * * * * * *

(2) BENCHMARK-EQUIVALENT COVERAGE.—For purposes of subsection (a)(1),*subject to paragraph (5),* coverage that meets the following requirement shall be considered to be benchmark-equivalent coverage:

(A) * * *

* * * * * * *

(5) MINIMUM STANDARDS.—Effective January 1, 2013, any benchmark benefit package (or benchmark equivalent coverage under paragraph (2)) must meet the minimum benefits and cost-sharing standards of a basic plan offered through the Health Insurance Exchange.

(6) COVERAGE OF FAMILY PLANNING SERVICES AND SUPPLIES.—Notwithstanding the previous provisions of this section, a State may not provide for medical assistance through enrollment of an individual with benchmark coverage or benchmark-equivalent coverage under this section unless such coverage includes for any individual described in section 1905(a)(4)(C), medical assistance for family planning services and supplies in accordance with such section.

* * * * * * *

REQUIREMENTS AND SPECIAL RULES FOR CERTAIN MEDICAID ELIGIBLE INDIVIDUALS

SEC. 1943. (a) COORDINATION WITH NHI EXCHANGE THROUGH MEMORANDUM OF UNDERSTANDING.—

(1) IN GENERAL.—The State shall enter into a Medicaid memorandum of understanding described in section 204(e)(4) of the America's Affordable Health Choices Act of 2009 with the Health Choices Commissioner, acting in consultation with the Secretary, with respect to coordinating the implementation of the provisions of division A of such Act with the State plan under this title in order to ensure the enrollment of Medicaid eligible individuals in acceptable coverage. Nothing in this section shall be construed as permitting such memorandum to modify or vitiate any requirement of a State plan under this title.

(2) ENROLLMENT OF EXCHANGE-REFERRED INDIVIDUALS.—

(A) NON-TRADITIONAL INDIVIDUALS.—Pursuant to such memorandum the State shall accept without further determination the enrollment under this title of an individual determined by the Commissioner to be a non-traditional Medicaid eligible individual. The State shall not do any redeterminations of eligibility for such individuals unless the periodicity of such redeterminations is consistent with the periodicity for redeterminations by the Commissioner of eligibility for affordability credits under subtitle C of title II of division A of the America's Affordable Health Choices Act of 2009, as specified under such memorandum.

(B) TRADITIONAL INDIVIDUALS.—Pursuant to such memorandum, the State shall accept without further determination the enrollment under this title of an individual determined by the Commissioner to be a traditional Medicaid eligible individual. The State may do redeterminations of eligibility of such individual consistent with such section and the memorandum.

(3) DETERMINATIONS OF ELIGIBILITY FOR AFFORDABILITY CREDITS.—If the Commissioner determines that a State Medicaid agency has the capacity to make determinations of eligibility for affordability credits under subtitle C of title II of division A of the America's Affordable Health Choices Act of 2009, under such memorandum—

(A) the State Medicaid agency shall conduct such determinations for any Exchange-eligible individual who requests such a determination;

(B) in the case that a State Medicaid agency determines that an Exchange-eligible individual is not eligible for affordability credits, the agency shall forward the information on the basis of which such determination was made to the Commissioner; and

(C) the Commissioner shall reimburse the State Medicaid agency for the costs of conducting such determinations.

(b) TREATMENT OF CERTAIN NEWBORNS.—

(1) IN GENERAL.—In the case of a child who is deemed under section 205(d)(1) of the America's Affordable Health Choices Act of 2009 to be a non-traditional Medicaid eligible individual and enrolled under this title pursuant to such section, the State shall provide for a determination, by not later than the end of the period referred to in subparagraph (A) of such section, of the child's eligibility for medical assistance under this title.

(2) EXTENDED TREATMENT AS TRADITIONAL MEDICAID ELIGIBLE INDIVIDUAL.—In accordance with subparagraph (B) of section 205(d)(1) of the America's Affordable Health Choices Act of 2009, in the case of a child described in subparagraph (A) of such section who at the end of the period referred to in such subparagraph is not otherwise covered under acceptable coverage, the child shall be deemed (until such time as the child obtains such coverage or the State otherwise makes a determination of the child's eligibility for medical assistance under its plan under this title pursuant to paragraph (1)) to be a traditional Medicaid eligible individual described in section 1902(l)(1)(B).

(c) DEFINITIONS.—In this section:

(1) MEDICAID ELIGIBLE INDIVIDUALS.—In this section, the terms "Medicaid eligible individual", "traditional Medicaid eligible individual", and "non-traditional Medicaid eligible individual" have the meanings given such terms in section 205(e)(5) of the America's Affordable Health Choices Act of 2009.

(2) MEMORANDUM.—The term "memorandum" means a Medicaid memorandum of understanding under section 205(e)(4) of the America's Affordable Health Choices Act of 2009.

(3) Y1.—The term "Y1" has the meaning given such term in section 100(c) of the America's Affordable Health Choices Act of 2009.

* * * * * * *

TITLE XXI—STATE CHILDREN'S HEALTH INSURANCE PROGRAM

* * * * * * *

SEC. 2102. GENERAL CONTENTS OF STATE CHILD HEALTH PLAN; ELIGIBILITY; OUTREACH.

(a) * * *

(b) GENERAL DESCRIPTION OF ELIGIBILITY STANDARDS AND METHODOLOGY.—

(1) ELIGIBILITY STANDARDS.—

(A) * * *

(B) LIMITATIONS ON ELIGIBILITY STANDARDS.—Such eligibility standards—

(i) * * *

* * * * * * *

(iii) may not apply a waiting period (including a waiting period to carry out paragraph (3)(C)) in the case of a targeted low-income pregnant woman provided pregnancy-related assistance under section 2112; [and]

(iv) at State option, may not apply a waiting period in the case of a child provided dental-only supplemental coverage under section 2110(b)(5)[.]*; and*

(v) may not apply a waiting period (including a waiting period to carry out paragraph (3)(C)) in the case of a child described in subparagraph (C).

(C) DESCRIPTION OF CHILDREN NOT SUBJECT TO WAITING PERIOD.—For purposes of this paragraph, a child described in this subparagraph is a child who, on the date an application is submitted for such child for child health assistance under this title, meets any of the following requirements:

(i) INFANTS AND TODDLERS.—The child is under two years of age.

(ii) LOSS OF GROUP HEALTH PLAN COVERAGE.—The child previously had private health insurance coverage through a group health plan or health insurance coverage offered through an employer and lost such coverage due to—

(I) termination of an individual's employment;

(II) a reduction in hours that an individual works for an employer;

(III) elimination of an individual's retiree health benefits; or

(IV) termination of an individual's group health plan or health insurance coverage offered through an employer.

(iii) UNAFFORDABLE PRIVATE COVERAGE.—

(I) IN GENERAL.—The family of the child demonstrates that the cost of health insurance coverage (including the cost of premiums, co-payments, deductibles, and other cost sharing) for such family exceeds 10 percent of the income of such family.

(II) DETERMINATION OF FAMILY INCOME.—For purposes of subclause (I), family income shall be determined in the same manner specified by the State for purposes of determining a child's eligibility for child health assistance under this title.

* * * * * * *

(6) REQUIREMENT FOR 12-MONTH CONTINUOUS ELIGIBILITY.—In the case of a State child health plan that provides child health assistance under this title through a means other than described in section 2101(a)(2), the plan shall provide for implementation under this title of the 12-month continuous eligibility option described in section 1902(e)(12) for targeted low-income

children whose family income is below 200 percent of the poverty line.

* * * * * * *

(d) PROGRAM INTEGRITY.—A State child health plan shall include a description of the procedures to be used by the State—

(1) to enforce any determination made by the Secretary under subsection (a) of section 1128G (relating to a significant risk of fraudulent activity with respect to a category of provider or supplier described in such subsection through use of the appropriate procedures described in such subsection);

(2) to carry out any activities as required by the Secretary for purposes of such subsection; and

(3) to enforce any determination made by the Secretary under subsection (b) of section 1128G (relating to disclosure requirements) and to apply any enhanced safeguards, with respect to a provider or supplier described in such subsection, as the Secretary determines necessary under such subsection.

* * * * * * *

SEC. 2105. PAYMENTS TO STATES.

(a) * * *

* * * * * * *

(c) LIMITATION ON CERTAIN PAYMENTS FOR CERTAIN EXPENDITURES.—

(1) * * *

* * * * * * *

(11) ENHANCED PAYMENTS.—Notwithstanding subsection (b), the enhanced FMAP with respect to payments under subsection (a) for expenditures related to the administration of the payment error rate measurement (PERM) requirements applicable to the State child health plan in accordance with the Improper Payments Information Act of 2002 and parts 431 and 457 of title 42, Code of Federal Regulations (or any related or successor guidance or regulations) shall in no event be less than 90 percent. *Clause (vi) of section 1903(u)(1)(D) shall apply with respect to the application of such requirements under this title and title XIX.*

* * * * * * *

SEC. 2107. STRATEGIC OBJECTIVES AND PERFORMANCE GOALS; PLAN ADMINISTRATION.

(a) * * *

* * * * * * *

(e) APPLICATION OF CERTAIN GENERAL PROVISIONS.—The following sections of this Act shall apply to States under this title in the same manner as they apply to a State under title XIX:

(1) TITLE XIX PROVISIONS.—

(A) Section 1902(a)(4)(C) (relating to conflict of interest standards) *and sections 1902(a)(39) and 1902(a)(78) (relating to exclusion and termination of participation).*

* * * * * * *

(G) Paragraphs (2), (16), [and (17)] *(17), and (25)* of section 1903(i) (relating to limitations on payment).

(H) Section 1903(m)(2)(A)(xiv) (relating to application of minimum loss ratios), with respect to comparable contracts under this title.

[(H)] *(I)* Paragraph (4) of section 1903(v) (relating to optional coverage of categories of lawfully residing immigrant children or pregnant women), but only if the State has elected to apply such paragraph with respect to such category of children or pregnant women under title XIX.

[(I)] *(J)* Section 1903(w) (relating to limitations on provider taxes and donations).

[(J)] *(K)* Section 1920A (relating to presumptive eligibility for children).

[(K)] *(L)* Subsections (a)(2)(C) and (h) of section 1932.

[(L)] *(M)* Section 1942 (relating to authorization to receive data directly relevant to eligibility determinations).

* * * * * * *

SEC. 2114. ASSURING QUALITY OF CARE IN HOSPICE CARE.

The provisions of section 1819A shall apply to a hospice program providing hospice care under this title in the same manner such provisions apply to a hospice program providing hospice care under title XVIII.

* * * * * * *

BALANCED BUDGET ACT OF 1997

SEC. 4505. IMPLEMENTATION OF RESOURCE-BASED METHODOLOGIES.

(a) * * *

* * * * * * *

[(d) REQUIREMENTS FOR DEVELOPING NEW RESOURCE-BASED PRACTICE EXPENSE RELATIVE VALUE UNITS.—

[(1) DEVELOPMENT.—For purposes of section 1848(c)(2)(C)(ii) of the Social Security Act, the Secretary of Health and Human Services shall develop new resource-based relative value units. In developing such units the Secretary shall—

[(A) utilize, to the maximum extent practicable, generally accepted cost accounting principles which (i) recognize all staff, equipment, supplies, and expenses, not just those which can be tied to specific procedures, and (ii) use actual data on equipment utilization and other key assumptions;

[(B) consult with organizations representing physicians regarding methodology and data to be used; and

[(C) develop a refinement process to be used during each of the 4 years of the transition period.

[(2) REPORT.—The Secretary shall transmit a report by March 1, 1998, on the development of resource-based relative value units under paragraph (1) to the Committee on Ways and Means and the Committee on Commerce of the House of Representatives and the Committee on Finance of the Senate. The report shall include a presentation of data to be used in developing the value units and an explanation of the methodology.

[(3) NOTICE OF PROPOSED RULEMAKING.—The Secretary shall publish a notice of proposed rulemaking with the new resource-based relative value units on or before May 1, 1998, and shall allow for a 90-day public comment period.

[(4) ITEMS INCLUDED.—The new proposed rule shall consider the following:

[(A) Impact projections which compare new proposed payment amounts on data on actual physician practice expenses.

[(B) Impact projections for hospital-based and other specialties, geographic payment localities, and urban versus rural localities.]

* * * * * * *

TAX RELIEF AND HEALTH CARE ACT OF 2006

* * * * * * *

DIVISION B—MEDICARE AND OTHER HEALTH PROVISIONS

* * * * * * *

TITLE I—MEDICARE IMPROVED QUALITY AND PROVIDER PAYMENTS

* * * * * * *

SEC. 106. HOSPITAL MEDICARE REPORTS AND CLARIFICATIONS.

(a) CORRECTION OF MID-YEAR RECLASSIFICATION EXPIRATION.—Notwithstanding any other provision of law, in the case of a subsection (d) hospital (as defined for purposes of section 1886 of the Social Security Act (42 U.S.C. 1395ww)) with respect to which a reclassification of its wage index for purposes of such section would (but for this subsection) expire on March 31, 2007, such reclassification of such hospital shall be extended through [September 30, 2009] *September 30, 2011*. The previous sentence shall not be effected in a budget-neutral manner.

* * * * * * *

TITLE II—MEDICARE BENEFICIARY PROTECTIONS

* * * * * * *

[SEC. 204. MEDICARE MEDICAL HOME DEMONSTRATION PROJECT.

[(a) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the "Secretary") shall establish under title XVIII of the Social Security Act a medical home demonstration project (in this section referred to as the "project") to redesign the health care delivery system to provide targeted, accessible, contin-

uous and coordinated, family-centered care to high-need populations and under which—

[(1) care management fees are paid to persons performing services as personal physicians; and

[(2) incentive payments are paid to physicians participating in practices that provide services as a medical home under subsection (d).

For purposes of this subsection, the term "high-need population" means individuals with multiple chronic illnesses that require regular medical monitoring, advising, or treatment.

[(b) DETAILS.—

[(1) DURATION; SCOPE.—Subject to paragraph (3), the project shall operate during a period of three years and shall include urban, rural, and underserved areas in a total of no more than 8 States.

[(2) ENCOURAGING PARTICIPATION OF SMALL PHYSICIAN PRACTICES.—The project shall be designed to include the participation of physicians in practices with fewer than three full-time equivalent physicians, as well as physicians in larger practices particularly in rural and underserved areas.

[(3) EXPANSION.—The Secretary may expand the duration and the scope of the project under paragraph (1), to an extent determined appropriate by the Secretary, if the Secretary determines that such expansion will result in any of the following conditions being met:

[(A) The expansion of the project is expected to improve the quality of patient care without increasing spending under the Medicare program (not taking into account amounts available under subsection (g)).

[(B) The expansion of the project is expected to reduce spending under the Medicare program (not taking into account amounts available under subsection (g)) without reducing the quality of patient care.

[(c) PERSONAL PHYSICIAN DEFINED.—

[(1) IN GENERAL.—For purposes of this section, the term "personal physician" means a physician (as defined in section 1861(r)(1) of the Social Security Act (42 U.S.C. 1395x(r)(1)) who—

[(A) meets the requirements described in paragraph (2); and

[(B) performs the services described in paragraph (3).

Nothing in this paragraph shall be construed as preventing such a physician from being a specialist or subspecialist for an individual requiring ongoing care for a specific chronic condition or multiple chronic conditions (such as severe asthma, complex diabetes, cardiovascular disease, rheumatologic disorder) or for an individual with a prolonged illness.

[(2) REQUIREMENTS.—The requirements described in this paragraph for a personal physician are as follows:

[(A) The physician is a board certified physician who provides first contact and continuous care for individuals under the physician's care.

[(B) The physician has the staff and resources to manage the comprehensive and coordinated health care of each such individual.

[(3) SERVICES PERFORMED.—A personal physician shall perform or provide for the performance of at least the following services:

[(A) Advocates for and provides ongoing support, oversight, and guidance to implement a plan of care that provides an integrated, coherent, cross-discipline plan for ongoing medical care developed in partnership with patients and including all other physicians furnishing care to the patient involved and other appropriate medical personnel or agencies (such as home health agencies).

[(B) Uses evidence-based medicine and clinical decision support tools to guide decision-making at the point-of-care based on patient-specific factors.

[(C) Uses health information technology, that may include remote monitoring and patient registries, to monitor and track the health status of patients and to provide patients with enhanced and convenient access to health care services.

[(D) Encourages patients to engage in the management of their own health through education and support systems.

[(d) MEDICAL HOME DEFINED.—For purposes of this section, the term "medical home" means a physician practice that—

[(1) is in charge of targeting beneficiaries for participation in the project; and

[(2) is responsible for—

[(A) providing safe and secure technology to promote patient access to personal health information;

[(B) developing a health assessment tool for the individuals targeted; and

[(C) providing training programs for personnel involved in the coordination of care.

[(e) PAYMENT MECHANISMS.—

[(1) PERSONAL PHYSICIAN CARE MANAGEMENT FEE.—Under the project, the Secretary shall provide for payment under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) of a care management fee to personal physicians providing care management under the project. Under such section and using the relative value scale update committee (RUC) process under such section, the Secretary shall develop a care management fee code for such payments and a value for such code.

[(2) MEDICAL HOME SHARING IN SAVINGS.—The Secretary shall provide for payment under the project of a medical home based on the payment methodology applied to physician group practices under section 1866A of the Social Security Act (42 U.S.C. 1395cc–1). Under such methodology, 80 percent of the reductions in expenditures under title XVIII of the Social Security Act resulting from participation of individuals that are attributable to the medical home (as reduced by the total care managements fees paid to the medical home under the project) shall be paid to the medical home. The amount of such reductions in expenditures shall be determined by using assumptions with respect to reductions in the occurrence of health complications, hospitalization rates, medical errors, and adverse drug reactions.

[(3) SOURCE.—Payments paid under the project shall be made from the Federal Supplementary Medical Insurance Trust Fund under section 1841 of the Social Security Act (42 U.S.C. 1395t).

[(f) EVALUATIONS AND REPORTS.—

[(1) ANNUAL INTERIM EVALUATIONS AND REPORTS.—For each year of the project, the Secretary shall provide for an evaluation of the project and shall submit to Congress, by a date specified by the Secretary, a report on the project and on the evaluation of the project for each such year.

[(2) FINAL EVALUATION AND REPORT.—The Secretary shall provide for an evaluation of the project and shall submit to Congress, not later than one year after completion of the project, a report on the project and on the evaluation of the project.

[(g) FUNDING FROM SMI TRUST FUND.—There shall be available, from the Federal Supplementary Medical Insurance Trust Fund (under section 1841 of the Social Security Act (42 U.S.C. 1395t)), the amount of $100,000,000 to carry out the project.

[(h) APPLICATION.—Chapter 35 of title 44, United States Code, shall not apply to the conduct of the project.]

* * * * * * *

SECTION 542 OF THE MEDICARE, MEDICAID, AND SCHIP BENEFITS IMPROVEMENT AND PROTECTION ACT OF 2000

SEC. 542. TREATMENT OF CERTAIN PHYSICIAN PATHOLOGY SERVICES UNDER MEDICARE.

(a) * * *

* * * * * * *

(c) EFFECTIVE DATE.—This section shall apply to services furnished during the 2-year period beginning on January 1, 2001, and for services furnished during 2005, 2006, 2007, 2008, [and 2009] *2009, 2010, and 2011.*

MEDICARE IMPROVEMENTS FOR PATIENTS AND PROVIDERS ACT OF 2008

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TITLE I—MEDICARE

* * * * * * *

Subtitle C—Provisions Relating to Part B

PART I—PHYSICIANS' SERVICES

* * * * * * *

SEC. 138. ADJUSTMENT FOR MEDICARE MENTAL HEALTH SERVICES.

(a) PAYMENT ADJUSTMENT.—

(1) IN GENERAL.—For purposes of payment for services furnished under the physician fee schedule under section 1848 of the Social Security Act (42 U.S.C. 1395w–4) during the period beginning on July 1, 2008, and ending on [December 31, 2009] *December 31, 2011*, the Secretary of Health and Human Services shall increase the fee schedule otherwise applicable for specified services by 5 percent.

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PART II—OTHER PAYMENT AND COVERAGE IMPROVEMENTS

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SEC. 146. IMPROVED ACCESS TO AMBULANCE SERVICES.

(a) * * *

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(b) AIR AMBULANCE PAYMENT IMPROVEMENTS.—

(1) TREATMENT OF CERTAIN AREAS FOR PAYMENT FOR AIR AMBULANCE SERVICES UNDER THE AMBULANCE FEE SCHEDULE.—Notwithstanding any other provision of law, for purposes of making payments under section 1834(l) of the Social Security Act (42 U.S.C. 1395m(l)) for air ambulance services furnished during the period beginning on July 1, 2008, and [ending on December 31, 2009] *ending on December 31, 2011*, any area that was designated as a rural area for purposes of making payments under such section for air ambulance services furnished on December 31, 2006, shall be treated as a rural area for purposes of making payments under such section for air ambulance services furnished during such period.

* * * * * * *

MEDICARE PRESCRIPTION DRUG, IMPROVEMENT, AND MODERNIZATION ACT OF 2003

* * * * * * *

TITLE IV—RURAL PROVISIONS

* * * * * * *

Subtitle C—Provisions Relating to Parts A and B

* * * * * * *

SEC. 422. REDISTRIBUTION OF UNUSED RESIDENT POSITIONS.

(a) * * *

(b) CONFORMING PROVISIONS.—(1) * * *

(2) Chapter 35 of title 44, United States Code, shall not apply with respect to applications under [section 1886(h)(7) of the Social Security Act, as added by subsection (a)(3).] *paragraphs (4)(H)(vi),*

(7), and (8) of subsection (h) of section 1886 of the Social Security Act.

* * * * * * *

TITLE VIII—COST CONTAINMENT

[Subtitle A—Cost Containment

[SEC. 801. INCLUSION IN ANNUAL REPORT OF MEDICARE TRUSTEES OF INFORMATION ON STATUS OF MEDICARE TRUST FUNDS.

[(a) DETERMINATIONS OF EXCESS GENERAL REVENUE MEDICARE FUNDING.—

[(1) IN GENERAL.—The Board of Trustees of each medicare trust fund shall include in the annual reports submitted under subsection (b)(2) of sections 1817 and 1841 of the Social Security Act (42 U.S.C. 1395i and 1395t)—

[(A) the information described in subsection (b); and

[(B) a determination as to whether there is projected to be excess general revenue medicare funding (as defined in subsection (c)) for the fiscal year in which the report is submitted or for any of the succeeding 6 fiscal years.

[(2) MEDICARE FUNDING WARNING.—For purposes of section 1105(h) of title 31, United States Code, and this subtitle, an affirmative determination under paragraph (1)(B) in 2 consecutive annual reports shall be treated as a medicare funding warning in the year in which the second such report is made.

[(3) 7-FISCAL-YEAR REPORTING PERIOD.—For purposes of this subtitle, the term "7-fiscal-year reporting period" means, with respect to a year in which an annual report described in paragraph (1) is made, the period of 7 consecutive fiscal years beginning with the fiscal year in which the report is submitted.

[(b) INFORMATION.—The information described in this subsection for an annual report in a year is as follows:

[(1) PROJECTIONS OF GROWTH OF GENERAL REVENUE SPENDING.—A statement of the general revenue medicare funding as a percentage of the total medicare outlays for each of the following:

[(A) Each fiscal year within the 7-fiscal-year reporting period.

[(B) Previous fiscal years and as of 10, 50, and 75 years after such year.

[(2) COMPARISON WITH OTHER GROWTH TRENDS.—A comparison of the trend of such percentages with the annual growth rate in the following:

[(A) The gross domestic product.

[(B) Private health costs.

[(C) National health expenditures.

[(D) Other appropriate measures.

[(3) PART D SPENDING.—Expenditures, including trends in expenditures, under part D of title XVIII of the Social Security Act, as added by section 101.

[(4) COMBINED MEDICARE TRUST FUND ANALYSIS.—A financial analysis of the combined medicare trust funds if general rev-

enue medicare funding were limited to the percentage specified in subsection (c)(1)(B) of total medicare outlays.

[(c) DEFINITIONS.—For purposes of this section:

[(1) EXCESS GENERAL REVENUE MEDICARE FUNDING.—The term "excess general revenue medicare funding" means, with respect to a fiscal year, that—

[(A) general revenue medicare funding (as defined in paragraph (2)), expressed as a percentage of total medicare outlays (as defined in paragraph (4)) for the fiscal year; exceeds

[(B) 45 percent.

[(2) GENERAL REVENUE MEDICARE FUNDING.—The term "general revenue medicare funding" means for a year—

[(A) the total medicare outlays (as defined in paragraph (4)) for the year; minus

[(B) the dedicated medicare financing sources (as defined in paragraph (3)) for the year.

[(3) DEDICATED MEDICARE FINANCING SOURCES.—The term "dedicated medicare financing sources" means the following:

[(A) HOSPITAL INSURANCE TAX.—Amounts appropriated to the Hospital Insurance Trust Fund under the third sentence of section 1817(a) of the Social Security Act (42 U.S.C. 1395i(a)) and amounts transferred to such Trust Fund under section 7(c)(2) of the Railroad Retirement Act of 1974 (45 U.S.C. 231f(c)(2)).

[(B) TAXATION OF CERTAIN OASDI BENEFITS.—Amounts appropriated to the Hospital Insurance Trust Fund under section 121(e)(1)(B) of the Social Security Amendments of 1983 (Public Law 98–21), as inserted by section 13215(c) of the Omnibus Budget Reconciliation Act of 1993 (Public Law 103–66).

[(C) STATE TRANSFERS.—The State share of amounts paid to the Federal Government by a State under section 1843 of the Social Security Act (42 U.S.C. 1395v) or pursuant to section 1935(c) of such Act.

[(D) PREMIUMS.—The following premiums:

[(i) PART A.—Premiums paid by non-Federal sources under sections 1818 and section 1818A (42 U.S.C. 1395i–2 and 1395i–2a) of such Act.

[(ii) PART B.—Premiums paid by non-Federal sources under section 1839 of such Act (42 U.S.C. 1395r), including any adjustments in premiums under such section.

[(iii) PART D.—Monthly beneficiary premiums paid under part D of title XVIII of such Act, as added by section 101, and MA monthly prescription drug beneficiary premiums paid under part C of such title insofar as they are attributable to basic prescription drug coverage.

Premiums under clauses (ii) and (iii) shall be determined without regard to any reduction in such premiums attributable to a beneficiary rebate under section 1854(b)(1)(C) of such title, as amended by section 222(b)(1), and premiums under clause (iii) are deemed to include any amounts paid under section 1860D–13(b) of such title, as added by section 101.

[(E) GIFTS.—Amounts received by the medicare trust funds under section 201(i) of the Social Security Act (42 U.S.C. 401(i)).

[(4) TOTAL MEDICARE OUTLAYS.—The term "total medicare outlays" means total outlays from the medicare trust funds and shall—

[(A) include payments made to plans under part C of title XVIII of the Social Security Act that are attributable to any rebates under section 1854(b)(1)(C) of such Act (42 U.S.C. 1395w–24(b)(1)(C)), as amended by section 222(b)(1);

[(B) include administrative expenditures made in carrying out title XVIII of such Act and Federal outlays under section 1935(b) of such Act, as added by section 103(a)(2); and

[(C) offset outlays by the amount of fraud and abuse collections insofar as they are applied or deposited into a medicare trust fund.

[(5) MEDICARE TRUST FUND.—The term "medicare trust fund" means—

[(A) the Federal Hospital Insurance Trust Fund established under section 1817 of the Social Security Act (42 U.S.C. 1395i); and

[(B) the Federal Supplementary Medical Insurance Trust Fund established under section 1841 of such Act (42 U.S.C. 1395t), including the Medicare Prescription Drug Account under such Trust Fund.

[(d) CONFORMING AMENDMENTS.—

[(1) FEDERAL HOSPITAL INSURANCE TRUST FUND.—Section 1817(b)(2) (42 U.S.C. 1395i(b)(2)) is amended by adding at the end the following: "Each report provided under paragraph (2) beginning with the report in 2005 shall include the information specified in section 801(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.".

[(2) FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND.—Section 1841(b)(2) (42 U.S.C. 1395t(b)(2)) is amended by adding at the end the following: "Each report provided under paragraph (2) beginning with the report in 2005 shall include the information specified in section 801(a) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.".

[(e) NOTICE OF MEDICARE FUNDING WARNING.—Whenever any report described in subsection (a) contains a determination that for any fiscal year within the 7-fiscal-year reporting period there will be excess general revenue medicare funding, Congress and the President should address the matter under existing rules and procedures.

[SEC. 802. PRESIDENTIAL SUBMISSION OF LEGISLATION.

[(a) IN GENERAL.—Section 1105 of title 31, United States Code, is amended by adding at the end the following new subsection:

["(h)(1) If there is a medicare funding warning under section 801(a)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 made in a year, the President shall submit to Congress, within the 15-day period beginning on the date of

the budget submission to Congress under subsection (a) for the succeeding year, proposed legislation to respond to such warning.

[“(2) Paragraph (1) does not apply if, during the year in which the warning is made, legislation is enacted which eliminates excess general revenue medicare funding (as defined in section 801(c) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003) for the 7-fiscal-year reporting period, as certified by the Board of Trustees of each medicare trust fund (as defined in section 801(c)(5) of such Act) not later than 30 days after the date of the enactment of such legislation.”.

[(b) SENSE OF CONGRESS.—It is the sense of Congress that legislation submitted pursuant to section 1105(h) of title 31, United States Code, in a year should be designed to eliminate excess general revenue medicare funding (as defined in section 801(c)) for the 7-fiscal-year period that begins in such year.

[SEC. 803. PROCEDURES IN THE HOUSE OF REPRESENTATIVES.

[(a) INTRODUCTION AND REFERRAL OF PRESIDENT'S LEGISLATIVE PROPOSAL.—

[(1) INTRODUCTION.—In the case of a legislative proposal submitted by the President pursuant to section 1105(h) of title 31, United States Code, within the 15-day period specified in paragraph (1) of such section, the Majority Leader of the House of Representatives (or his designee) and the Minority Leader of the House of Representatives (or his designee) shall introduce such proposal (by request), the title of which is as follows: “A bill to respond to a medicare funding warning.” Such bill shall be introduced within 3 legislative days after Congress receives such proposal.

[(2) REFERRAL.—Any legislation introduced pursuant to paragraph (1) shall be referred to the appropriate committees of the House of Representatives.

[(b) DIRECTION TO THE APPROPRIATE HOUSE COMMITTEES.—

[(1) IN GENERAL.—In the House, in any year during which the President is required to submit proposed legislation to Congress under section 1105(h) of title 31, United States Code, the appropriate committees shall report medicare funding legislation by not later than June 30 of such year.

[(2) MEDICARE FUNDING LEGISLATION.—For purposes of this section, the term “medicare funding legislation” means—

[(A) legislation introduced pursuant to subsection (a)(1), but only if the legislative proposal upon which the legislation is based was submitted within the 15-day period referred to in such subsection; or

[(B) any bill the title of which is as follows: “A bill to respond to a medicare funding warning.”.

[(3) CERTIFICATION.—With respect to any medicare funding legislation or any amendment to such legislation to respond to a medicare funding warning, the chairman of the Committee on the Budget of the House shall certify—

[(A) whether or not such legislation eliminates excess general revenue medicare funding (as defined in section 801(c)) for each fiscal year in the 7-fiscal-year reporting period; and

[(B) with respect to such an amendment, whether the legislation, as amended, would eliminate excess general

revenue medicare funding (as defined in section 801(c)) for each fiscal year in such 7-fiscal-year reporting period.

[(c) FALLBACK PROCEDURE FOR FLOOR CONSIDERATION IF THE HOUSE FAILS TO VOTE ON FINAL PASSAGE BY JULY 30.—

[(1) After July 30 of any year during which the President is required to submit proposed legislation to Congress under section 1105(h) of title 31, United States Code, unless the House of Representatives has voted on final passage of any medicare funding legislation for which there is an affirmative certification under subsection (b)(3)(A), then, after the expiration of not less than 30 calendar days (and concurrently 5 legislative days), it is in order to move to discharge any committee to which medicare funding legislation which has such a certification and which has been referred to such committee for 30 calendar days from further consideration of the legislation.

[(2) A motion to discharge may be made only by an individual favoring the legislation, may be made only if supported by one-fifth of the total membership of the House (a quorum being present), and is highly privileged in the House. Debate thereon shall be limited to not more than one hour, the time to be divided in the House equally between those favoring and those opposing the motion. An amendment to the motion is not in order, and it is not in order to move to reconsider the vote by which the motion is agreed to or disagreed to.

[(3) Only one motion to discharge a particular committee may be adopted under this subsection in any session of a Congress.

[(4) Notwithstanding paragraph (1), it shall not be in order to move to discharge a committee from further consideration of medicare funding legislation pursuant to this subsection during a session of a Congress if, during the previous session of the Congress, the House passed medicare funding legislation for which there is an affirmative certification under subsection (b)(3)(A).

[(d) FLOOR CONSIDERATION IN THE HOUSE OF DISCHARGED LEGISLATION.—

[(1) In the House, not later than 3 legislative days after any committee has been discharged from further consideration of legislation under subsection (c), the Speaker shall resolve the House into the Committee of the Whole for consideration of the legislation.

[(2) The first reading of the legislation shall be dispensed with. All points of order against consideration of the legislation are waived. General debate shall be confined to the legislation and shall not exceed five hours, which shall be divided equally between those favoring and those opposing the legislation. After general debate the legislation shall be considered for amendment under the five-minute rule. During consideration of the legislation, no amendments shall be in order in the House or in the Committee of the Whole except those for which there has been an affirmative certification under subsection (b)(3)(B). All points of order against consideration of any such amendment in the Committee of the Whole are waived. The legislation, together with any amendments which shall be in order, shall be considered as read. During the consideration of

the bill for amendment, the Chairman of the Committee of the Whole may accord priority in recognition on the basis of whether the Member offering an amendment has caused it to be printed in the portion of the Congressional Record designated for that purpose in clause 8 of Rule XVIII of the Rules of the House of Representatives. Debate on any amendment shall not exceed one hour, which shall be divided equally between those favoring and those opposing the amendment, and no pro forma amendments shall be offered during the debate. The total time for debate on all amendments shall not exceed 10 hours. At the conclusion of consideration of the legislation for amendment, the Committee shall rise and report the legislation to the House with such amendments as may have been adopted. The previous question shall be considered as ordered on the legislation and amendments thereto to final passage without intervening motion except one motion to recommit with or without instructions. If the Committee of the Whole rises and reports that it has come to no resolution on the bill, then on the next legislative day the House shall, immediately after the third daily order of business under clause 1 of Rule XIV of the Rules of the House of Representatives, resolve into the Committee of the Whole for further consideration of the bill.

[(3) All appeals from the decisions of the Chair relating to the application of the Rules of the House of Representatives to the procedure relating to any such legislation shall be decided without debate.

[(4) Except to the extent specifically provided in the preceding provisions of this subsection, consideration of any such legislation and amendments thereto (or any conference report thereon) shall be governed by the Rules of the House of Representatives applicable to other bills and resolutions, amendments, and conference reports in similar circumstances.

[(e) LEGISLATIVE DAY DEFINED.—As used in this section, the term "legislative day" means a day on which the House of Representatives is in session.

[(f) RESTRICTION ON WAIVER.—In the House, the provisions of this section may be waived only by a rule or order proposing only to waive such provisions.

[(g) RULEMAKING POWER.—The provisions of this section are enacted by the Congress—

[(1) as an exercise of the rulemaking power of the House of Representatives and, as such, shall be considered as part of the rules of that House and shall supersede other rules only to the extent that they are inconsistent therewith; and

[(2) with full recognition of the constitutional right of that House to change the rules (so far as they relate to the procedures of that House) at any time, in the same manner, and to the same extent as in the case of any other rule of that House.

[SEC. 804. PROCEDURES IN THE SENATE.

[(a) INTRODUCTION AND REFERRAL OF PRESIDENT'S LEGISLATIVE PROPOSAL.—

[(1) INTRODUCTION.—In the case of a legislative proposal submitted by the President pursuant to section 1105(h) of title 31, United States Code, within the 15-day period specified in paragraph (1) of such section, the Majority Leader and Minor-

ity Leader of the Senate (or their designees) shall introduce such proposal (by request), the title of which is as follows: "A bill to respond to a medicare funding warning." Such bill shall be introduced within 3 days of session after Congress receives such proposal.

[(2) REFERRAL.—Any legislation introduced pursuant to paragraph (1) shall be referred to the Committee on Finance.

[(b) MEDICARE FUNDING LEGISLATION.—For purposes of this section, the term "medicare funding legislation" means—

[(1) legislation introduced pursuant to subsection (a)(1), but only if the legislative proposal upon which the legislation is based was submitted within the 15-day period referred to in such subsection; or

[(2) any bill the title of which is as follows: "A bill to respond to a medicare funding warning.".

[(c) QUALIFICATION FOR SPECIAL PROCEDURES.—

[(1) IN GENERAL.—The special procedures set forth in subsections (d) and (e) shall apply to medicare funding legislation, as described in subsection (b), only if the legislation—

[(A) is medicare funding legislation that is passed by the House of Representatives; or

[(B) contains matter within the jurisdiction of the Committee on Finance in the Senate.

[(2) FAILURE TO QUALIFY FOR SPECIAL PROCEDURES.—If the medicare funding legislation does not satisfy paragraph (1), then the legislation shall be considered under the ordinary procedures of the Standing Rules of the Senate.

[(d) DISCHARGE.—

[(1) IN GENERAL.—If the Committee on Finance has not reported medicare funding legislation described in subsection (c)(1) by June 30 of a year in which the President is required to submit medicare funding legislation to Congress under section 1105(h) of title 31, United States Code, then any Senator may move to discharge the Committee of any single medicare funding legislation measure. Only one such motion shall be in order in any session of Congress.

[(2) DEBATE LIMITS.—Debate in the Senate on any such motion to discharge, and all appeals in connection therewith, shall be limited to not more than 2 hours. The time shall be equally divided between, and controlled by, the maker of the motion and the Majority Leader, or their designees, except that in the event the Majority Leader is in favor of such motion, the time in opposition thereto shall be controlled by the Minority Leader or the Minority Leader's designee. A point of order under this subsection may be made at any time. It is not in order to move to proceed to another measure or matter while such motion (or the motion to reconsider such motion) is pending.

[(3) AMENDMENTS.—No amendment to the motion to discharge shall be in order.

[(4) EXCEPTION IF CERTIFIED LEGISLATION ENACTED.—Notwithstanding paragraph (1), it shall not be in order to discharge the Committee from further consideration of medicare funding legislation pursuant to this subsection during a session of a Congress if the chairman of the Committee on the Budget of the Senate certifies that medicare funding legislation has

been enacted that eliminates excess general revenue medicare funding (as defined in section 801(c)) for each fiscal year in the 7-fiscal-year reporting period.

[(e) CONSIDERATION.—After the date on which the Committee on Finance has reported medicare funding legislation described in subsection (c)(1), or has been discharged (under subsection (d)) from further consideration of, such legislation, it is in order (even though a previous motion to the same effect has been disagreed to) for any Member of the Senate to move to proceed to the consideration of such legislation.

[(f) RULES OF THE SENATE.—This section is enacted by the Senate—

[(1) as an exercise of the rulemaking power of the Senate and as such it is deemed a part of the rules of the Senate, but applicable only with respect to the procedure to be followed in the Senate in the case of a bill described in this paragraph, and it supersedes other rules only to the extent that it is inconsistent with such rules; and

[(2) with full recognition of the constitutional right of the Senate to change the rules (so far as relating to the procedure of the Senate) at any time, in the same manner, and to the same extent as in the case of any other rule of the Senate.]

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TITLE XI—ACCESS TO AFFORDABLE PHARMACEUTICALS

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Subtitle B—Federal Trade Commission Review

* * * * * * *

SEC. 1112. NOTIFICATION OF AGREEMENTS.

(a) * * *

* * * * * * *

(c) FILING.—

(1) * * *

(2) OTHER AGREEMENTS.—The parties that are required in subsection (a) or (b) to file an agreement in accordance with this subsection shall file with the Assistant Attorney General and [the Commission the] *the Commission—*

(A) the text of any agreements between the parties that are not described in such subsections and are contingent upon, provide a contingent condition for, or are otherwise related to an agreement that is required in subsection (a) or (b) to be filed in accordance with this subsection[.]*; and*

(B) any other agreement the parties enter into within 30 days of entering into an agreement covered by subsection (a) or (b).

* * * * * * *

(d) CERTIFICATION.—The chief executive officer or the company official responsible for negotiating any agreement required to be filed under subsection (a), (b), or (c) shall execute and file with the Assistant Attorney General and the Commission a certification as follows: "I declare under penalty of perjury that the following is true and correct: The materials filed with the Federal Trade Commission and the Department of Justice under section 1112 of subtitle B of title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, with respect to the agreement referenced in this certification: (1) represent the complete, final, and exclusive agreement between the parties; (2) include any ancillary agreements that are contingent upon, provide a contingent condition for, or are otherwise related to, the referenced agreement; and (3) include written descriptions of any oral agreements, representations, commitments, or promises between the parties that are responsive to subsection (a) or (b) of such section 1112 and have not been reduced to writing.".

* * * * * * *

PERSONAL RESPONSIBILITY AND WORK OPPORTUNITY RECONCILIATION ACT OF 1996

* * * * * * *

TITLE IV—RESTRICTING WELFARE AND PUBLIC BENEFITS FOR ALIENS

* * * * * * *

Subtitle A—Eligibility for Federal Benefits

* * * * * * *

SEC. 402. LIMITED ELIGIBILITY OF QUALIFIED ALIENS FOR CERTAIN FEDERAL PROGRAMS.

(a) * * *

(b) LIMITED ELIGIBILITY FOR DESIGNATED FEDERAL PROGRAMS.—

(1) * * *

(2) EXCEPTIONS.—Qualified aliens under this paragraph shall be eligible for any designated Federal program.

(A) * * *

* * * * * * *

(G) MEDICAID EXCEPTION FOR CITIZENS OF FREELY ASSOCIATED STATES.—With respect to eligibility for benefits for the designated Federal program defined in paragraph (3)(C) (relating to the Medicaid program), section 401(a) and paragraph (1) shall not apply to any individual who lawfully resides in the United States (including territories and possessions of the United States) in accordance with the Compacts of Free Association between the Government of the United States and the Governments of the Federated

States of Micronesia, the Republic of the Marshall Islands, and the Republic of Palau.

* * * * * * *

SEC. 403. FIVE-YEAR LIMITED ELIGIBILITY OF QUALIFIED ALIENS FOR FEDERAL MEANS-TESTED PUBLIC BENEFIT.

(a) * * *

* * * * * * *

(d) BENEFITS FOR CERTAIN GROUPS.—Notwithstanding any other provision of law, the limitations under section 401(a) and subsection (a) shall not apply to—

(1) an individual described in section 402(a)(2)(G), but only with respect to the programs specified in subsections (a)(3) and (b)(3)(C) of section 402; **[**or**]**

(2) an individual, spouse, or dependent described in section 402(a)(2)(K), but only with respect to the specified Federal program described in section 402(a)(3)(B)**[**.**]***; or*

(3) an individual described in section 402(b)(2)(G), but only with respect to the designated Federal program defined in section 402(b)(3)(C).

* * * * * * *

Subtitle D—General Provisions

SEC. 431. DEFINITIONS.

(a) * * *

(b) QUALIFIED ALIEN.—For purposes of this title, the term "qualified alien" means an alien who, at the time the alien applies for, receives, or attempts to receive a Federal public benefit, is—

(1) * * *

* * * * * * *

(6) an alien who is granted conditional entry pursuant to section 203(a)(7) of such Act as in effect prior to April 1, 1980**[**; or**]***,*

(7) an alien who is a Cuban and Haitian entrant (as defined in section 501(e) of the Refugee Education Assistance Act of 1980)**[**.**]***, or*

(8) an individual who lawfully resides in the United States (including territories and possessions of the United States) in accordance with a Compact of Free Association referred to in section 402(b)(2)(G), but only with respect to the designated Federal program defined in section 402(b)(3)(C) (relating to the Medicaid program).

* * * * * * *

DEFICIT REDUCTION ACT OF 2005

* * * * * * *

TITLE V—MEDICARE

Subtitle A—Provisions Relating to Part A

* * * * * * *

SEC. 5007. MEDICARE DEMONSTRATION PROJECTS TO PERMIT GAINSHARING ARRANGEMENTS.

(a) * * *

* * * * * * *

(d) PROGRAM ADMINISTRATION.—

(1) * * *

* * * * * * *

(3) DURATION.—The qualified gainsharing demonstration program under this section shall be conducted for the period beginning on January 1, 2007, and ending on December 31, 2009 *(or September 30, 2011, in the case of a demonstration project in operation as of October 1, 2008)*.

(e) REPORTS.—

(1) * * *

* * * * * * *

(3) QUALITY IMPROVEMENT AND SAVINGS.—By not later than [December 1, 2008] *March 31, 2011*, the Secretary shall submit to Congress a report on quality improvement and savings achieved as a result of the qualified gainsharing demonstration program established under subsection (a).

(4) FINAL REPORT.—By not later than [May 1, 2010] *March 31, 2013*, the Secretary shall submit to Congress a final report on the information described in paragraph (3).

(f) FUNDING.—

(1) IN GENERAL.—Out of any funds in the Treasury not otherwise appropriated, there are appropriated to the Secretary for fiscal year 2006 $6,000,000, *and for fiscal year 2010, $1,600,000,* to carry out this section.

(2) AVAILABILITY.—Funds appropriated under paragraph (1) shall remain available for expenditure through fiscal year [2010] *2014 or until expended*.

* * * * * * *

CHAPTER 5—STATE FINANCING UNDER MEDICAID

TITLE VI—MEDICAID AND SCHIP

Subtitle A—Medicaid

* * * * * * *

CHAPTER 5—STATE FINANCING UNDER MEDICAID

SEC. 6051. MANAGED CARE ORGANIZATION PROVIDER TAX REFORM.

(a) * * *

(b) EFFECTIVE DATE.—

(1) * * *

(2) DELAY IN EFFECTIVE DATE.—

(A) IN GENERAL.—Subject to subparagraph (B), in the case of a State specified in subparagraph (B), the amendment made by subsection (a) shall be effective as of [October 1, 2009] *October 1, 2010*.

* * * * * * *

SECTION 605 OF THE CHILDREN'S HEALTH INSURANCE PROGRAM REAUTHORIZATION ACT OF 2009

SEC. 605. NO FEDERAL FUNDING FOR ILLEGAL ALIENS; DISALLOWANCE FOR UNAUTHORIZED EXPENDITURES.

Nothing in this Act allows Federal payment for individuals who are not [legal residents] *lawfully residing in the United States*. Titles XI, XIX, and XXI of the Social Security Act provide for the disallowance of Federal financial participation for erroneous expenditures under Medicaid and under CHIP, respectively.

INDIAN HEALTH CARE IMPROVEMENT ACT

* * * * * * *

DECLARATION OF HEALTH OBJECTIVES

SEC. 3. (a) * * *

(b) It is the intent of the Congress that the Nation meet the following health status objectives with respect to Indians and urban Indians by the year 2000:

(1) * * *

* * * * * * *

(61) Increase to at least 70 percent the proportion of individuals who have received, as a minimum within the appropriate interval, all of the screening and immunization services and at least one of the counseling services appropriate for their age and gender as recommended by the [United States Preventive Services Task Force] *Task Force on Clinical Preventive Services*.

* * * * * * *

SECTION 126 OF THE MEDICARE, MEDICAID, AND SCHIP BENEFITS IMPROVEMENT AND PROTECTION ACT OF 2000

SEC. 126. STUDIES ON PREVENTIVE INTERVENTIONS IN PRIMARY CARE FOR OLDER AMERICANS.

(a) STUDIES.—The Secretary of Health and Human Services, acting through the [United States Preventive Services Task Force] *Task Force on Clinical Preventive Services*, shall conduct a series of studies designed to identify preventive interventions that can be delivered in the primary care setting and that are most valuable to older Americans.

(b) MISSION STATEMENT.—The mission statement of the [United States Preventive Services Task Force] *Task Force on Clinical Preventive Services* is amended to include the evaluation of services that are of particular relevance to older Americans.

* * * * * * *

SOCIAL SECURITY ACT

TITLE XVIII—HEALTH INSURANCE FOR THE AGED AND DISABLED

* * * * * * *

PART E—MISCELLANEOUS PROVISIONS

DEFINITIONS OF SERVICES, INSTITUTIONS, ETC.

SEC. 1861. For purposes of this title—

(a) * * *

* * * * * * *

(s) MEDICAL AND OTHER HEALTH SERVICES.—The term "medical and other health services" means any of the following items or services:

(1) * * *

(2)(A) * * *

* * * * * * *

(AA) ultrasound screening for abdominal aortic aneurysm (as defined in subsection (bbb)) for an individual—

(i) * * *

* * * * * * *

(iii) who—

(I) * * *

(II) manifests risk factors included in a beneficiary category recommended for screening by the [United States Preventive Services Task Force] *Task Force on Clinical Preventive Services* regarding abdominal aortic aneurysms;

* * * * * * *

(xx)(1) The term "cardiovascular screening blood test" means a blood test for the early detection of cardiovascular disease (or abnormalities associated with an elevated risk of cardiovascular disease) that tests for the following:

(A) * * *

* * * * * * *

The Secretary may not approve an indication under subparagraph (B) for any individual unless a blood test for such is recommended by the [United States Preventive Services Task Force] *Task Force on Clinical Preventive Services*.

* * * * * * *

(ddd)(1) The term "additional preventive services" means services not otherwise described in this title that identify medical conditions or risk factors and that the Secretary determines are—

(A) * * *

(B) recommended with a grade of A or B by the [United States Preventive Services Task Force] *Task Force on Clinical Preventive Services* ; and

* * * * * * *

TITLE XIX—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

* * * * * * *

PAYMENT FOR COVERED OUTPATIENT DRUGS

SEC. 1927. (a) REQUIREMENT FOR REBATE AGREEMENT.—

(1) * * *

* * * * * * *

(5) LIMITATION ON PRICES OF DRUGS PURCHASED BY COVERED ENTITIES.—

(A) AGREEMENT WITH SECRETARY.—A manufacturer meets the requirements of this paragraph if the manufacturer has entered into an agreement with the Secretary that meets the requirements of section 340B of the Public Health Service Act with respect to [covered outpatient drugs] *covered drugs (as defined in section 340B(b)(2) of the Public Health Service Act)* purchased by a covered entity on or after the first day of the first month that begins after the date of the enactment of this paragraph.

* * * * * * *

[(D) EFFECT OF SUBSEQUENT AMENDMENTS.—In determining whether an agreement under subparagraph (A) meets the requirements of section 340B of the Public Health Service Act, the Secretary shall not take into account any amendments to such section that are enacted after the enactment of title VI of the Veterans Health Care Act of 1992.]

(D) STATE RESPONSIBILITY FOR CALCULATING HOSPITAL CREDITS.—The State shall calculate the credits owed by the hospital under paragraph (1) of section 340B(c) of the Public Health Service Act and provide the hospital with both the amounts and an explanation of how it calculated the credits. In performing the calculations specified in paragraphs (2)(A)(ii) and (2)(B)(ii) of such section, the State shall use the average manufacturer price applicable to the calendar quarter in which the drug was purchased by the hospital.

* * * * * * *

(k) DEFINITIONS.—In the section—

(1) AVERAGE MANUFACTURER PRICE.—

(A) IN GENERAL.—Subject to [subparagraph (B)] *subparagraphs (B) and (D)*, the term "average manufacturer price" means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by

wholesalers for drugs distributed to the retail pharmacy class of trade.

* * * * * * *

(D) CALCULATION FOR COVERED DRUGS.—With respect to a covered drug (as defined in section 340B(b)(2) of the Public Health Service Act), the average manufacturer price shall be determined in accordance with subparagraph (A) except that, in the event a covered drug is not distributed to the retail pharmacy class of trade, it shall mean the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the acute care class of trade, after deducting customary prompt pay discounts.

* * * * * * *

HOMELAND SECURITY ACT OF 2002

* * * * * * *

SEC. 2. DEFINITIONS.

In this Act, the following definitions apply:

(1) * * *

* * * * * * *

(6) The term "emergency response providers" includes Federal, State, and local governmental and nongovernmental emergency public safety, fire, law enforcement, emergency response, emergency medical *and dental* (including hospital emergency facilities), and related personnel, agencies, and authorities.

* * * * * * *

TITLE V—NATIONAL EMERGENCY MANAGEMENT

* * * * * * *

SEC. 516. CHIEF MEDICAL OFFICER.

(a) * * *

* * * * * * *

(c) RESPONSIBILITIES.—The Chief Medical Officer shall have the primary responsibility within the Department for medical issues related to natural disasters, acts of terrorism, and other man-made disasters, including—

(1) * * *

* * * * * * *

(5) serving as the Department's primary point of contact for State, local, and tribal governments, the [medical community] *medical and dental communities*, and others within and out-

side the Department, with respect to medical and public health matters;

* * * * * * *

SECTION 653 OF THE POST-KATRINA EMERGENCY MANAGEMENT REFORM ACT OF 2006

SEC. 653. FEDERAL PREPAREDNESS.

(a) * * *

(b) OPERATIONAL PLANS.—An operations plan developed under subsection (a)(4) shall meet the following requirements:

(1) * * *

* * * * * * *

(4) The operations plan shall address, as appropriate, the following matters:

(A) * * *

(B) The preparedness and deployment of [public health and medical] *public health, medical, and dental* resources, including resources to address the needs of evacuees and populations with special needs.

* * * * * * *

FEDERAL FOOD, DRUG, AND COSMETIC ACT

* * * * * * *

CHAPTER III—PROHIBITED ACTS AND PENALTIES

* * * * * * *

PENALTIES

SEC. 303. (a) * * *

* * * * * * *

(f)(1)(A) * * *

(B) Subparagraph (A) shall not apply—

(i) * * *

(ii) to any person who commits minor violations of section 519(e) or [519(g)] *519(h)* (only with respect to correction reports) if such person demonstrates substantial compliance with such section, or

* * * * * * *

CHAPTER IV—FOOD

* * * * * * *

MISBRANDED FOOD

SEC. 403. A food shall be deemed to be misbranded—

(a) * * *

* * * * * * *

(q)(1) * * *

* * * * * * *

(5)(A) Subparagraphs (1), (2), (3), and (4) shall not apply to food—

(i) *except as provided in clause (H)(ii)(III),* which is served in restaurants or other establishments in which food is served for immediate human consumption or which is sold for sale or use in such establishments,

(ii) *except as provided in clause (H)(ii)(III),* which is processed and prepared primarily in a retail establishment, which is ready for human consumption, which is of the type described in subclause (i), and which is offered for sale to consumers but not for immediate human consumption in such establishment and which is not offered for sale outside such establishment,

* * * * * * *

(H) RESTAURANTS, RETAIL FOOD ESTABLISHMENTS, AND VENDING MACHINES.—

(i) GENERAL REQUIREMENTS FOR RESTAURANTS AND SIMILAR RETAIL FOOD ESTABLISHMENTS.—Except for food described in subclause (vii), in the case of food that is a standard menu item that is offered for sale in a restaurant or similar retail food establishment that is part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items, the restaurant or similar retail food establishment shall disclose the information described in subclauses (ii) and (iii).

(ii) INFORMATION REQUIRED TO BE DISCLOSED BY RESTAURANTS AND RETAIL FOOD ESTABLISHMENTS.—Except as provided in subclause (vii), the restaurant or similar retail food establishment shall disclose in a clear and conspicuous manner—

(I)(aa) in a nutrient content disclosure statement adjacent to the name of the standard menu item, so as to be clearly associated with the standard menu item, on the menu listing the item for sale, the number of calories contained in the standard menu item, as usually prepared and offered for sale; and

(bb) a succinct statement concerning suggested daily caloric intake, as specified by the Secretary by regulation and posted prominently on the menu and designed to enable the public to understand, in the context of a total daily diet, the significance of the caloric information that is provided on the menu;

(II)(aa) in a nutrient content disclosure statement adjacent to the name of the standard menu item, so as to be clearly associated with the standard menu item, on the menu board, including a drive-through menu board, the number of calories contained in the standard menu item, as usually prepared and offered for sale; and

(bb) a succinct statement concerning suggested daily caloric intake, as specified by the Secretary by regulation and posted prominently on the menu board, designed to enable the public to understand, in the context of a total daily diet,

the significance of the nutrition information that is provided on the menu board;

(III) in a written form, available on the premises of the restaurant or similar retail establishment and to the consumer upon request, the nutrition information required under clauses (C) and (D) of subparagraph (1); and

(IV) on the menu or menu board, a prominent, clear, and conspicuous statement regarding the availability of the information described in item (III).

(iii) SELF-SERVICE FOOD AND FOOD ON DISPLAY.—Except as provided in subclause (vii), in the case of food sold at a salad bar, buffet line, cafeteria line, or similar self-service facility, and for self-service beverages or food that is on display and that is visible to customers, a restaurant or similar retail food establishment shall place adjacent to each food offered a sign that lists calories per displayed food item or per serving.

(iv) REASONABLE BASIS.—For the purposes of this clause, a restaurant or similar retail food establishment shall have a reasonable basis for its nutrient content disclosures, including nutrient databases, cookbooks, laboratory analyses, and other reasonable means, as described in section 101.10 of title 21, Code of Federal Regulations (or any successor regulation) or in a related guidance of the Food and Drug Administration.

(v) MENU VARIABILITY AND COMBINATION MEALS.—The Secretary shall establish by regulation standards for determining and disclosing the nutrient content for standard menu items that come in different flavors, varieties, or combinations, but which are listed as a single menu item, such as soft drinks, ice cream, pizza, doughnuts, or children's combination meals, through means determined by the Secretary, including ranges, averages, or other methods.

(vi) ADDITIONAL INFORMATION.—If the Secretary determines that a nutrient, other than a nutrient required under subclause (ii)(III), should be disclosed for the purpose of providing information to assist consumers in maintaining healthy dietary practices, the Secretary may require, by regulation, disclosure of such nutrient in the written form required under subclause (ii)(III).

(vii) NONAPPLICABILITY TO CERTAIN FOOD.—

(I) IN GENERAL.—Subclauses (i) through (vi) do not apply to—

(aa) items that are not listed on a menu or menu board (such as condiments and other items placed on the table or counter for general use);

(bb) daily specials, temporary menu items appearing on the menu for less than 60 days per calendar year, or custom orders; or

(cc) such other food that is part of a customary market test appearing on the menu for less than 90 days, under terms and conditions established by the Secretary.

(II) WRITTEN FORMS.—Clause (C) shall apply to any regulations promulgated under subclauses (ii)(III) and (vi).

(viii) VENDING MACHINES.—In the case of an article of food sold from a vending machine that—

(I) does not permit a prospective purchaser to examine the Nutrition Facts Panel before purchasing the article or does not otherwise provide visible nutrition information at the point of purchase; and

(II) is operated by a person who is engaged in the business of owning or operating 20 or more vending machines, the vending machine operator shall provide a sign in close proximity to each article of food or the selection button that includes a clear and conspicuous statement disclosing the number of calories contained in the article.

(ix) VOLUNTARY PROVISION OF NUTRITION INFORMATION.—

(I) IN GENERAL.—An authorized official of any restaurant or similar retail food establishment or vending machine operator not subject to the requirements of this clause may elect to be subject to the requirements of such clause, by registering biannually the name and address of such restaurant or similar retail food establishment or vending machine operator with the Secretary, as specified by the Secretary by regulation.

(II) REGISTRATION.—Within 120 days of the enactment of this clause, the Secretary shall publish a notice in the Federal Register specifying the terms and conditions for implementation of item (I), pending promulgation of regulations.

(III) RULE OF CONSTRUCTION.—Nothing in this subclause shall be construed to authorize the Secretary to require an application, review, or licensing process for any entity to register with the Secretary, as described in such item.

(x) REGULATIONS.—

(I) PROPOSED REGULATION.—Not later than 1 year after the date of the enactment of this clause, the Secretary shall promulgate proposed regulations to carry out this clause.

(II) CONTENTS.—In promulgating regulations, the Secretary shall—

(aa) consider standardization of recipes and methods of preparation, reasonable variation in serving size and formulation of menu items, space on menus and menu boards, inadvertent human error, training of food service workers, variations in ingredients, and other factors, as the Secretary determines; and

(bb) specify the format and manner of the nutrient content disclosure requirements under this subclause.

(III) REPORTING.—The Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a quarterly report that describes the Secretary's progress toward promulgating final regulations under this subparagraph.

(xi) DEFINITION.—In this clause, the term "menu" or "menu board" means the primary writing of the restaurant or other similar retail food establishment from which a consumer makes an order selection.

* * * * * * *

SEC. 403A. (a) Except as provided in subsection (b), no State or political subdivision of a State may directly or indirectly establish

under any authority or continue in effect as to any food in interstate commerce—

(1) * * *

* * * * * * *

(4) any requirement for nutrition labeling of food that is not identical to the requirement of section 403(q), ⟦except a requirement for nutrition labeling of food which is exempt under subclause (i) or (ii) of section 403(q)(5)(A)⟧ *except that this paragraph does not apply to food that is offered for sale in a restaurant or similar retail food establishment that is not part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items unless such restaurant or similar retail food establishment complies with the voluntary provision of nutrition information requirements under section 403(q)(5)(H)(ix)*, or

* * * * * * *

CHAPTER V—DRUGS AND DEVICES

SUBCHAPTER A—DRUGS AND DEVICES

* * * * * * *

NEW DRUGS

SEC. 505. (a) * * *

* * * * * * *

(w) PROTECTING CONSUMER ACCESS TO GENERIC DRUGS.—

(1) UNFAIR AND DECEPTIVE ACTS AND PRACTICES RELATED TO NEW DRUG APPLICATIONS.—

(A) CONDUCT PROHIBITED.—It shall be unlawful for any person to directly or indirectly be a party to any agreement resolving or settling a patent infringement claim in which—

(i) an ANDA filer receives anything of value; and

(ii) the ANDA filer agrees to limit or forego research, development, manufacturing, marketing, or sales, for any period of time, of the drug that is to be manufactured under the ANDA involved and is the subject of the patent infringement claim.

(B) EXCEPTIONS.—Notwithstanding subparagraph (A)(i), subparagraph (A) does not prohibit a resolution or settlement of a patent infringement claim in which the value received by the ANDA filer includes no more than—

(i) the right to market the drug that is to be manufactured under the ANDA involved and is the subject of the patent infringement claim, before the expiration of—

(I) the patent that is the basis for the patent infringement claim; or

(II) any other statutory exclusivity that would prevent the marketing of such drug; and

(ii) the waiver of a patent infringement claim for damages based on prior marketing of such drug.

(C) ENFORCEMENT.—

(i) IN GENERAL.—A violation of subparagraph (A) shall be treated as an unfair and deceptive act or practice and an unfair method of competition in or affecting interstate commerce prohibited under section 5 of the Federal Trade Commission Act and shall be enforced by the Federal Trade Commission in the same manner, by the same means, and with the same jurisdiction as though all applicable terms and provisions of the Federal Trade Commission Act were incorporated into and made a part of this subsection.

(ii) INAPPLICABILITY.—Subchapter A of chapter VII shall not apply with respect to this subsection.

(D) DEFINITIONS.—In this subsection:

(i) AGREEMENT.—The term "agreement" means anything that would constitute an agreement under section 5 of the Federal Trade Commission Act.

(ii) AGREEMENT RESOLVING OR SETTLING.—The term "agreement resolving or settling", in reference to a patent infringement claim, includes any agreement that is contingent upon, provides a contingent condition for, or is otherwise related to the resolution or settlement of the claim.

(iii) ANDA.—The term "ANDA" means an abbreviated new drug application for the approval of a new drug under section (j).

(iv) ANDA FILER.—The term "ANDA filer" means a party that has filed an ANDA with the Food and Drug Administration.

(v) PATENT INFRINGEMENT.—The term "patent infringement" means infringement of any patent or of any filed patent application, extension, reissuance, renewal, division, continuation, continuation in part, reexamination, patent term restoration, patent of addition, or extension thereof.

(vi) PATENT INFRINGEMENT CLAIM.—The term "patent infringement claim" means any allegation made to an ANDA filer, whether or not included in a complaint filed with a court of law, that its ANDA or drug to be manufactured under such ANDA may infringe any patent.

(2) FTC RULEMAKING.—The Federal Trade Commission may, by rule promulgated under section 553 of title 5, United States Code, exempt certain agreements described in paragraph (1) from the requirements of this subsection if the Commission finds such agreements to be in furtherance of market competition and for the benefit of consumers. Consistent with the authority of the Commission, such rules may include interpretive rules and general statements of policy with respect to the practices prohibited under paragraph (1).

* * * * * * *

RECORDS AND REPORTS ON DEVICES

SEC. 519. (a) * * *

* * * * * * *

National Medical Device Registry

(g)(1) The Secretary shall establish a national medical device registry (in this subsection referred to as the "registry") to facilitate analysis of postmarket safety and outcomes data on each device that—

(A) is or has been used in or on a patient; and

(B) is—

(i) a class III device; or

(ii) a class II device that is implantable, life-supporting, or life-sustaining.

(2) In developing the registry, the Secretary shall, in consultation with the Commissioner of Food and Drugs, the Administrator of the Centers for Medicare & Medicaid Services, the head of the Office of the National Coordinator for Health Information Technology, and the Secretary of Veterans Affairs, determine the best methods for—

(A) including in the registry, in a manner consistent with subsection (f), appropriate information to identify each device described in paragraph (1) by type, model, and serial number or other unique identifier;

(B) validating methods for analyzing patient safety and outcomes data from multiple sources and for linking such data with the information included in the registry as described in subparagraph (A), including, to the extent feasible, use of—

(i) data provided to the Secretary under other provisions of this chapter; and

(ii) information from public and private sources identified under paragraph (3);

(C) integrating the activities described in this subsection with—

(i) activities under paragraph (3) of section 505(k) (relating to active postmarket risk identification);

(ii) activities under paragraph (4) of section 505(k) (relating to advanced analysis of drug safety data); and

(iii) other postmarket device surveillance activities of the Secretary authorized by this chapter; and

(D) providing public access to the data and analysis collected or developed through the registry in a manner and form that protects patient privacy and proprietary information and is comprehensive, useful, and not misleading to patients, physicians, and scientists.

(3)(A) To facilitate analyses of postmarket safety and patient outcomes for devices described in paragraph (1), the Secretary shall, in collaboration with public, academic, and private entities, develop methods to—

(i) obtain access to disparate sources of patient safety and outcomes data, including—

(I) Federal health-related electronic data (such as data from the Medicare program under title XVIII of the Social

Security Act or from the health systems of the Department of Veterans Affairs);

(II) private sector health-related electronic data (such as pharmaceutical purchase data and health insurance claims data); and

(III) other data as the Secretary deems necessary to permit postmarket assessment of device safety and effectiveness; and

(ii) link data obtained under clause (i) with information in the registry.

(B) In this paragraph, the term "data" refers to information respecting a device described in paragraph (1), including claims data, patient survey data, standardized analytic files that allow for the pooling and analysis of data from disparate data environments, electronic health records, and any other data deemed appropriate by the Secretary.

(4) Not later than 36 months after the date of the enactment of this subsection, the Secretary shall promulgate regulations for establishment and operation of the registry under paragraph (1). Such regulations—

(A)(i) in the case of devices that are described in paragraph (1) and sold on or after the date of the enactment of this subsection, shall require manufacturers of such devices to submit information to the registry, including, for each such device, the type, model, and serial number or, if required under subsection (f), other unique device identifier; and

(ii) in the case of devices that are described in paragraph (1) and sold before such date, may require manufacturers of such devices to submit such information to the registry, if deemed necessary by the Secretary to protect the public health;

(B) shall establish procedures—

(i) to permit linkage of information submitted pursuant to subparagraph (A) with patient safety and outcomes data obtained under paragraph (3); and

(ii) to permit analyses of linked data;

(C) may require device manufacturers to submit such other information as is necessary to facilitate postmarket assessments of device safety and effectiveness and notification of device risks;

(D) shall establish requirements for regular and timely reports to the Secretary, which shall be included in the registry, concerning adverse event trends, adverse event patterns, incidence and prevalence of adverse events, and other information the Secretary determines appropriate, which may include data on comparative safety and outcomes trends; and

(E) shall establish procedures to permit public access to the information in the registry in a manner and form that protects patient privacy and proprietary information and is comprehensive, useful, and not misleading to patients, physicians, and scientists.

(5) To carry out this subsection, there are authorized to be appropriated such sums as may be necessary for fiscal years 2010 and 2011.

[(g)] *(h)*(1) * * *

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CHAPTER VII—GENERAL AUTHORITY

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SUBCHAPTER C—FEES

* * * * * * *

PART 2—FEES RELATING TO DRUGS

SEC. 735. DEFINITIONS.

For purposes of this part:

(1) The term "human drug application" means an application for—

(A) * * *

(B) licensure of a biological product under section 351 of the Public Health Service Act*, including licensure of a biological product under section 351(k) of such Act*.

* * * * * * *

DISSENTING VIEWS

Republicans believe that the American health care system is the most effective in the world, but that it increasingly delivers services in ways that are uneven and too expensive for people to afford. We believe those problems are serious and that they require an equally serious remedy. As Congress and the President go about the business of devising new health care policies to cure the problems our people face, our own priorities are to ensure that Americans who like their health insurance are able to keep it, and that no system built by politicians in Washington will insert politics, radical social theory or bureaucrats between patients and their doctors. Unfortunately, those flaws are the hallmarks of the current proposal to restructure American health care, H.R. 3200.

We are further concerned over the related matter of a currently popular style of governing in which every problem seems to require a trillion-dollar solution. The deficit for the just completed fiscal year was $1.6 trillion, the greatest annual accumulation of government debt in the history of the United States. The curious response of those in charge of the House is to amass more debt while simultaneously cutting back on the programs that people need, choose and like. Thus H.R. 3200 manages to achieve both more debt and less health care by cutting Medicare by almost $500 billion in order to fund an array of unaffordable new entitlements that will supplant the health coverage that people have already picked for themselves. We believe that policymakers must find ways to make insurance more affordable and health care more accessible without creating an expensive new entitlement and without imposing on innocent Americans a vast new federal bureaucracy that will take away their choices and make their health care decisions for them.

The President has stated he will not sign a bill "that adds one dime to our deficits—either now or in the future." According to the Congressional Budget Office and Joint Committee on Tax, enacting H.R. 3200 would result in a net increase in the federal budget deficit of $239 billion over the 2010–2019 period.

Additionally, H.R. 3200 uses gimmicks that hide the cost to the American taxpayer. Under H.R. 3200, the tax increases and Medicare cuts come first and quickly, but the big spending does not begin for four years. As a result, annual federal deficits associated with H.R. 3200 will grow progressively larger toward the end of the decade and explode in the following decades. H.R. 3200 will increase the deficit by $65 billion in 2019 alone. A new report issued on September 9, 2009, by the Peterson Foundation found that H.R. 3200 would create an additional $1 trillion in deficit spending between 2020 and 2029.

We believe there are other options to fixing our health care system rather than burdening future generations with trillions of dol-

lars in debt and dismantling the health care systems that the vast majority of Americans like.

Division A of the Act would enact sweeping changes to the laws governing health insurance; create a new federal agency called the Health Choices Administration to regulate and sell health insurance through a new process called an Exchange; create a new government health care program for individuals under 65; and require individuals and employers to either pay new taxes or purchase insurance. The heavy regulation of insurance would increase costs and the government-run plan would exacerbate an ongoing cycle of cost shifting from the public sector to the private sector—driving up costs and encouraging private plans to exit the market.

TITLE I—PROTECTIONS AND STANDARDS FOR QUALIFIED HEALTH BENEFITS PLANS

Title I transforms the current legal framework for the regulation of health insurance with new federal rules governing the sale of health insurance. These rules mandate the benefits that insurers must cover and the prices they may charge. At a minimum, policies would need to cover "essential benefits," defined as services for hospitalization; outpatient care; physician care; medical equipment and supplies; prescription drugs; rehabilitative needs; mental health and substance abuse disorders; preventive care; maternity care; and care for children under 21 years of age. In addition, the Act grants a newly created board of federal bureaucrats (the Health Benefits Advisory Committee) and the Secretary of Health and Human Services (HHS) broad authority to mandate that every health plan in the country cover additional benefits not listed in the legislation. These additional benefits could include objectionable services such as abortion or elective procedures that raise the cost of care.

Benefit mandates are a key reason why the current cost of health plans is inflated. According to some estimates, the States have mandated 2,133 benefits and providers that have increased the cost of basic health coverage from a little less than 20% to perhaps 50%, depending on the number of mandates, the benefit design and the cost of the initial premium. The new authority for the Secretary of Health and Human Services to mandate limitless benefits will drive up the cost of coverage.

If the goal of the legislation is to reduce health care costs, then creation of a multitude of new boards, bureaucrats, commissions, and programs is counterproductive to that goal. One of these new bureaucrats will be a new Health Choices Commissioner who will be endowed with unprecedented powers. The Commissioner will have the power to dictate levels of network adequacy and the types of benefits that must be included in every health plan. The Commissioner will have the ability to disenroll any individual from his or her health plan or it can impose draconian civil monetary penalties on health plans. The Commissioner can also decide that a health plan is not qualified and thus anyone enrolled would be subject to a 2.5% tax and any employer offering the plan would be subject to an 8% tax.

The Act provides essentially meaningless "grandfathering" exceptions for existing health plans. These provisions do not implement

the Majority's claim that the bill allows Americans who like the health insurance they have today to choose to keep it. Individual health policies could remain in effect only so long as the carrier does not change any of its terms and conditions or offer new treatments (e.g., new generic drugs) as covered benefits. As a result, this provision effectively will prohibit individuals from keeping their current health coverage. Instead, individuals will have to buy insurance through the new federal bureaucrat-run Exchange (described below). Existing employer-sponsored coverage would be exempt from the Act's new requirements for five years. At that point, it is probable that employers will begin dropping existing coverage instead of complying with the new costly federal mandates and regulations imposed by the Act.

The Minority offered several amendments to protect Americans' ability to choose to keep their existing insurance plan if they like it. Congressman Stearns offered an amendment, which failed 32–26, to strike the requirement that all employer-sponsored health plans comply with the new mandates within five years. Instead, the amendment would have ensured that "nothing in this Act shall be construed to prevent or limit individuals from keeping their current health coverage." In addition, Congressmen Rogers and Gingrey offered an amendment, which failed 33–26, to ensure that Americans with a Health Savings Account or a Flexible Savings Account could continue to keep them if they chose to do so. Currently more than 8 million Americans own a Health Savings Account—which is more than the 7.7 million Americans enrolled in SCHIP and more than the populations of any one of 39 states.

Congressman Buyer offered several amendments to protect veterans and service members from the adverse effects of H.R. 3200. Two amendments were accepted by voice vote during the Committee's markup: one will allow veterans and service members to enroll in the health insurance Exchange created under the bill and another will protect and preserve the authorities of the Departments of Veterans Affairs (VA) and Defense to ensure they retain their authority over their respective health care systems. When the Energy and Commerce Committee reconvened its markup in September, Chairman Waxman included a third amendment offered by Congressman Buyer in his substitute amendment which passed by voice vote. This amendment requires the public plan created under H.R. 3200 to reimburse the VA in the same manner as other private health insurance plans reimburse the VA for treatment of non-service connected conditions.

In a letter to Congressman Buyer and Chairman Bob Filner, the chairmen of the three committees with jurisdiction over H.R. 3200 committed to addressing the concerns covered in another amendment offered by Congressman Buyer. This amendment would ensure that veterans enrolled in the VA health care system are deemed to have acceptable health coverage for the purposes of the individual coverage mandate created by H.R. 3200 and cannot be subjected to the 2.5% individual mandate tax. Finally, in a colloquy with Congressman Buyer, Chairman Waxman issued his commitment to ensuring that guard and reservists called to active duty and returning from active duty are considered by the Secretary of Treasury when the Secretary develops de minimus rules. This will

help to protect guard and reservists from the individual mandate tax should they, for reasons beyond their control, be temporarily without health insurance due to the process of enrolling them into, and out of, Tricare.

TITLE II—HEALTH INSURANCE EXCHANGE AND A NEW GOVERNMENT HEALTH CARE PLAN

Title II creates a new government bureaucracy called a Health Choices Administration, which will regulate all private insurance and sell insurance plans through a new process called the "Exchange." The Health Choices Administration, run by the Commissioner, will have the power to: govern the Exchange; transfer money from a government trust fund to finance the Exchange; prevent citizens from participating in the Exchange; permit (or not permit) employers to join the Exchange; establish benefit standards for Exchange plans (e.g., standards governing permissible amounts of cost-sharing); set standards governing provider networks (i.e., allow the Commissioner to regulate access to doctors); set enrollment periods; reduce co-payments for out-of-network providers; develop an auto-enrollment process for those who do not choose a plan (nothing prevents the Commissioner from auto-enrolling those individuals into the government plan); establish a mechanism for pooling risk; and suspend payments to health plans.

As this lengthy but not exhaustive list shows, the Act gives tremendous power to the Commissioner. This power will allow the Commissioner to impose significant economic costs, displace unnecessary functions provided by the private market, and restrict the health choices of Americans.

Title II also creates a new government health care plan run by the Department of Health and Human Services, which will "compete" with private insurance and be made available for enrollment through the Exchange. The plan would be administered by government bureaucrats who will determine benefits, premiums, and payments to health care providers. Providers who participate in Medicare would have to participate in the government plan unless they asked to opt out.

The Minority does not accept the Majority's premise that a government health care plan is needed to ensure access to care or to drive down costs. To the contrary, estimates suggest that the creation of a government health plan will be enormously disruptive. Under some scenarios, payment levels under the public plan would be 32% less than what private insurers pay for the same services and would be 14% less for physician services.[1] These lower reimbursement rates will come on top of existing government reimbursement rates that are lower than private plans. According to CBO Director Elmendorf, in 2006 Medicare physician reimbursement rates averaged 20% less than private insurance levels; the disparity was 30% for hospitals. In Medicaid, the variation was

[1] The Lewin Group, Cost and Coverage Impacts of the American Affordable Health Choices Act of 2009: The July 15th draft, July 27, 2009, *http://www.lewin.com/content/publications/LewinAnalysisHouseBill2009.pdf.*

greater: a 40% gap in physician payment levels; 35% for hospitals.[2] Lower government rates force hospitals and doctors to shift costs to privately insured individuals; a Milliman study found that these cost shifts add nearly $1,800 annually to the cost of coverage for a family of four.[3] By triggering these cost shifts, the creation of a government plan would cause 88 million people to lose their existing employer-sponsored private insurance and 103.4 million people to join the government plan.

Despite Majority claims that the government-run plan will compete on a level playing field with other health plans, nothing in this bill suggests that there will be a level playing field. That is because—as Congressional Budget Office Director Elmendorf testified before the Committee this spring—it would be "extremely difficult" to create "a system where a public plan could compete on a level playing field" against private coverage.

Under this bill, the government plan will not be subject to a whole host of costs and liabilities that other plans must face. The government plan does not have to finance its start-up costs or pay state premium taxes; state and local property taxes; corporate taxes; and market rates for buildings, equipment, and services. The government plan would have exclusive access to government agency data, special protections from lawsuits, exemption from financial stability requirements, and the implicit financial backing of the entire U.S. Treasury. Finally, the government plan could undercut healthcare providers by only paying for a portion of services, forcing providers to shift costs onto Americans with private health care plans. These provisions are not—as the Majority claims—in the Act to keep private plans honest; they exist to drive them out of business.

To address this situation, Mr. Burgess offered an amendment, which failed 35–24, to strike the public health plan. Mr. Radanovich offered an amendment to mitigate the damage expected from a government plan by requiring it to be subject to the same standards and business environment as private plans. This amendment, which failed 32–23, would have eliminated the exhaustive list of exclusive benefits afforded to the government plan in order to level the playing field with private insurers and ensure that Americans could keep their health insurance plans if they liked them.

The Minority believes that the creation of the government plan likely will lead to a single payer system after private plans gradually are run out of business. Other countries with single-payer systems provide troubling examples of worse health care outcomes relative to those achieved in the United States. For example, the five-year survival rate for breast cancer patients in America is over 90%, more than twelve points higher than the rate in England, which has a centralized, government-run health care system. Congressman Shadegg offered an amendment, which failed 36–22, that would have required the Government Accountability Office (GAO) to regularly gather data on the five-year survival rates for breast

[2] Testimony of Doug Elmendorf, Congressional Budget Office Director, before the Senate Finance Committee on "Options for Expanding Health Insurance Coverage and Controlling Costs," February 25, 2009.

[2] Milliman, "Hospital and Physician Cost Shift Payment Level Comparison of Medicare, Medicaid, and Commercial Payers," December 2008.

cancer patients. If GAO determined that survival rates decreased after the implementation of the government plan, then it would have been discontinued in order to restore the higher survival rate.

The Minority also offered amendments to ensure that the creation of a government-run health plan does not result in federal bureaucrats rationing access to care. Congressman Burgess offered an amendment, which passed by voice vote, to ensure that all qualified health plans (including the government plan) will have a reasonable and accessible utilization review and appeals process. This change will ensure that plans are not allowed to deny needed care and instead will keep medical decisions between a patient and his or her doctor.

The Minority also offered several amendments to offer alternative solutions to reform the Nation's health care system and increase Americans' access to affordable health care, without unnecessarily expanding the scope of government in the system. Congressman Barton offered an amendment to ensure that very sick individuals with pre-existing health conditions have access to care. This amendment, which failed 35–22, would have struck the government plan and instead directed federal help to those who most needed it by providing health coverage to Americans who are "uninsurable" because of pre-existing health conditions. Every State would have been required to put in place either a high risk pool or a reinsurance program; the federal government would have provided sufficient funding to ensure enrollees' access to care.

Congressmen Terry, Gingrey, and Blunt offered an amendment to allow all Americans access to the same health insurance as Members of Congress. Individuals could enroll in the Federal Employee Health Benefits Program, which offers premium coverage and allows enrollees to choose from many private insurance plans. Passage of this amendment would have met President Obama's guarantee that "every uninsured American could get the same kind of health care that Members of Congress give themselves"—without imposing new burdensome insurance regulations and creating the new Exchange and the new government plan. However, this amendment was voted down 31 to 28.

Finally, the Minority believes Americans should have access to the price and quality information they need to make good health care decisions. Currently, Americans lack adequate cost and quality information to inform their health care decision-making. Insurance companies, government-run health programs and health care providers generally do not provide per-service prices or make this information available to patients prior to providing care. A search of existing State and federal government websites suggest that most provide insufficient information; by, for example, only posting proxies for this information in the form of average prices, median prices or price ranges.

Consequently, consumers rarely know the amount of money they must pay for a specific service when they visit a medical provider. The lack of specific information especially hurts the uninsured and individuals whose insurance leaves them with significant out-of-pocket expenses. By cloaking a wide range of price variation, imprecise information hinders consumers' efforts to understand health care costs and decide how to spend money. It also impacts

the entire market because consumers and analysts lack a critical aspect of a functioning market that they use in other purchasing decisions to drive down cost, determine value, reward effective organizations and penalize ineffective ones.

To address this situation, Congressmen Barton and Stupak offered an amendment to create a new independent office within HHS tasked with the sole mission of working with public and private entities to collect, analyze, and publicly disclose all the price and risk-adjusted quality information necessary for consumers to make informed decisions about their health care services. This added transparency would have not only brought to light a greater understanding of the problems in the health care system, but also would have empowered American patients to make fully informed choices and so bring greater competition to the marketplace. In turn, this competition would bring lower prices, greater efficiency, and higher quality. This amendment was voted down by a show of hands, 28 to 18.

The Committee has subsequently approved a second amendment to improve transparency offered by Congressman Barton, Congressman Green, and Congressman Burgess. The amendment permits all insured individuals to be able to learn in advance the amount of cost-sharing they would pay for a specific item or service by a participating provider. In addition, hospitals will need to make publicly available their charges. This added transparency will improve Americans' access to the information they need to make health care decisions.

TITLE III

Title III requires individuals to obtain insurance and employers to pay for 72% percent of the cost of insurance or face new taxes (2.5% for individuals or 8% of payroll for employers). This approach forces employers to choose between creating (or saving) jobs and providing health insurance, especially since the cost of the insurance likely will rise due to all the new benefit mandates imposed by the bill. The Congressional Research Service has concluded that individuals will pay $29 billion in new taxes due to the individual mandate. H.R. 3200 presents a Catch-22 to American workers because the underlying bill will increase the cost of their health insurance and for those people that cannot afford health insurance they will be subject to the 2.5% surtax on their income.

The individual mandate and the employer mandate not only impose an economic hardship to families and an impediment to job growth but they are also designed to empower bureaucrats to control decisions about Americans' health care. Under these provisions, a person could purchase a health policy that they are happy with and fits their needs but still be subject to the new tax because that policy does not meet the specifications that the Health Care Choices Commissioner dictates. An employer who has offered its employees the same policy for years could be required to pay the 8% tax if the Commissioner says the policy does not qualify. We do not believe any bureaucrat should have that type of unlimited power.

An individual mandate also is troubling because it would force Americans to pay for abortion services if the federal government

exercises its authority under this Act and mandates that insurance plans cover abortion services. This means that Americans who do not want to finance abortion due to conscience objections would have to forego heath insurance coverage in order to uphold the claims of their conscience. In addition, it means that their tax dollars would finance these services through the government plan and through the new subsidies for low-income individuals established under the Act.

The Minority offered several bipartisan amendments to address this problem. Congressman Pitts's amendment passed 31 to 27, prohibiting the federal government from mandating the coverage of abortion (except in cases involving danger to the mother's life, rape or incest). However, at the request of Chairman Waxman, this amendment was reconsidered and subsequently defeated on a second vote 30–29. Another amendment offered by Congressmen Pitts and Stupak would have prevented the Act from allowing taxpayer dollars to subsidize abortions, but failed 31–27.

The pay-to-play employment tax will discourage job growth and low-income workers will be especially hurt in the form of lower wages. Additionally, several studies have concluded that the new pay-to-play tax could put millions of Americans in jeopardy of losing their jobs. The CBO estimates this employment tax will cost employers $163 billion in new taxes over ten years. According to a methodology developed by the chair of the White House Council of Economic Advisors, Christina Romer, the mandates under this legislation could cost 4.7 million jobs during the next ten years.

The pay-to-play employment tax is designed to work in concert with the government health care plan and the new burdensome health care rules set forth by the Health Choices Commissioner to effectuate the ultimate desire of many in the Majority who support the federal government's takeover of health care. With the new costly rules that the Health Choices Commissioner could force on employers, as well the fear of excessive civil monetary penalties that the Commissioner can impose on an employer, many companies will reluctantly pay an 8% tax and put their employees in the government plan rather than deal with the new heavy handed government bureaucracy by continuing to offer employees health insurance.

The devastating impact of the pay-to-play employment tax is exacerbated by the legislation's surtax on income. The new income taxes will cost individuals and small businesses over $500 billion by imposing a surcharge on individuals making over $280,000 a year and households making over $350,000 a year. For those making over a million dollars, the surcharge would be 5.4%. The effective federal tax rate for the highest income tax bracket would be over 45% once the tax rates established in 2001 expire. When State income taxes are factored in with the federal income tax rates, some Americans will see effective tax rates that are among the highest in the world. Mr. Barton offered an amendment that would have prevented the surtax from affecting those individuals and small business that make less than $1 million in 2013, but the amendment was defeated on a party line vote.

H.R. 3200 fails to recognize that most small businesses file individual tax returns. We agree with the July 16, 2009, letter sent by

several Democrats to Speaker Pelosi, which pointed out that the surcharge will have a direct negative impact on manufacturers and small businesses. We share these Members' concern that this tax "will discourage entrepreneurial activity and job growth." Like some in the Majority, we believe the anti-economic growth policies in the bill should be rejected and that it is counterproductive to efforts to get this Nation's economy back on track.

Instead of finding new ways to increase costs on employers we should examine ways to bend the curve on health care costs. One way to do that is to allow employers to incentive workers to take more responsibility for their health and promote prevention. On June 15, before the American Medical Association, President Obama stated the following: "building a health care system that promotes prevention rather than just managing diseases will require all of us to do our part. It will take doctors telling us what risk factors we should avoid and what preventive measures we should pursue. And it will take employers following the example of places like Safeway that is rewarding workers for taking better care of their health while reducing health care costs in the process. If you're one of the three quarters of Safeway workers enrolled in their Healthy Measures' program, you can get screened for problems like high cholesterol or high blood pressure. And if you score well, you can pay lower premiums. It's a program that has helped Safeway cut health care spending by over 13 percent and workers save over 20 percent on their premiums. And we are open to doing more to help employers adopt and expand programs like this one."

Congressman Buyer offered an amendment that would have granted greater flexibility to employers to provide individuals with incentives to take control of their health. These types of programs can improve individuals' health while significantly reducing health insurance costs for employers and employees alike. Such an approach can have far reaching positive impacts for the whole health system without costing federal taxpayers a dime. Mr. Buyer's amendment gained the full support of Republican members of the Committee but was rejected by the Majority. Instead, at taxpayers' expense, the Majority adopted an amendment that would create a new federal grant program to employers and an outreach campaign to let employers know about the grants. Like the President, we understand that employers already know about wellness programs and know they work. Employers do not need federal handouts to initiate these programs; instead they need greater flexibility in our laws and regulations which allow them to offer the incentives needed to attract employees to wellness programs and give individuals greater responsibility over their health.

At the American Medical Association conference earlier this year, President Obama acknowledged that defensive medicine leads to more tests and needless costs because doctors must protect themselves from frivolous lawsuits. However, H.R. 3200 fails to even touch on the issue of liability reform.

Congressman Burgess offered an amendment that would institute common-sense liability protections to reduce the costs of "defensive medicine" to the health care system. Defensive medicine procedures are estimated to cost roughly $70 billion a year. Furthermore, studies also show that the system fails injured patients,

with claims taking on average five years to resolve and roughly 60 cents out of every dollar spent in the malpractice system going to lawyers or administrative costs. Modeled after reforms in Texas, which have reduced liability waste every year since 2003, this amendment would place a $750,000 cap on punitive damages, allow for periodic payments of damages, require expert physician witnesses to be practicing doctors, and afford special protections to volunteering good Samaritans. Reforming the flawed liability system will both lower costs by reducing the prevalence of defensive medicine and frivolous lawsuits, and increase the number of health care providers by curtailing one of the key barriers to entry in the industry. Unfortunately, the amendment was defeated largely along party lines.

DIVISION B

Rather than strengthen our health care system, the Majority's bill jeopardizes access to care that Americans, including seniors, currently enjoy. The Majority's bill raids the Medicare Trust Fund to pay for comparative effectiveness research that may never produce any savings, thereby stealing from Medicare's ever-shrinking funds.

Additionally, the Majority's bill makes drastic cuts across Medicare providers. These cuts include: (1) hospitals and facilities receiving Medicare market basket payment updates will be cut $160.5 billion; (2) home health agencies are cut $56.8 billion; and (3) medical equipment such as oxygen tanks, wheelchairs and imaging services are cut $1.2 billion. Such cuts will not enhance access to health care—they may only serve to hinder the ability of providers to continue to offer quality health care and will eliminate the ability of providers to offset the increased costs of serving those who find themselves enrolled in health care by way of a mandate.

Moreover, H.R. 3200 will directly impact seniors' ability to keep their current health insurance. The bill will limit the ability of millions of seniors to continue to have access to the care they have chosen. The Majority's bill cuts the Medicare Advantage benefit by $172 billion. This is money that is used in the program to buy down premiums and eliminate co-pays, provide enhanced benefits such as vision and dental benefits, and provide access to affordable prescription drugs.

Furthermore, the Majority's bill will actually cost seniors money. The CBO found that the Majority's bill will raise Medicare prescription drug premiums for seniors by about 5% in 2011, rising to about 20% in 2019. H.R. 3200 includes a provision that fills in the Medicare Part D prescription drug program "doughnut hole." This is the coverage gap where seniors are responsible for paying out of pocket for 100% of the costs of their Part D drugs, until they hit a catastrophic level of spending (at which time the plan then picks up most of the cost of the drugs). There are two problems with this provision—first, the doughnut hole is largely filled in outside of the 10-year budget window with completion not until 15 years from now. More importantly, seniors will bear the cost of doing so. The CBO estimated that this provision will raise Part D premiums.

In sum, the Majority's bill hinders access to health care by stealing money from the Medicare Trust Fund, which is estimated to be

bankrupt in a few years; cutting payments to Medicare providers and plans; and setting forth policies that increase our seniors' Medicare premiums. It does so with the purpose of creating new entitlements and empowering and enlarging the federal bureaucracy designed to control the health care choices of Americans. Congressman Gingrey offered an amendment that was unfortunately defeated that would have ensured that any cuts to the Medicare program be directed towards beneficiaries and ensuring the future viability of the program. That amendment was defeated largely along party lines.

We believe that rather than exacerbate problems regarding access to care in our current health care system and spending inordinate sums of taxpayer dollars and Medicare funds on a government-run plan, Congress should be focusing on the need to reform our current health care programs. The National Health Care Anti-Fraud Association (NHCAA) estimates conservatively that 3% of all health care spending—or $68 billion—is lost to health care fraud. Other estimates by government and law enforcement agencies place the loss due to health care fraud as high as 10% of our Nation's annual health care expenditure—or a staggering $226 billion—each year. Even though everyone acknowledges the staggering amount of fraud in our current entitlement programs, H.R. 3200 does little to address this abuse of taxpayer funds.

Furthermore, the Majority asserts their bill overhauls the Medicare physician payment system. This bill does not fix the broken Medicare physician payment system. While it is true the bill does replace the scheduled cut for next year, it does not replace the target system that has proved flawed. Rather, it takes the national target system Congress has almost never allowed to operate and breaks it into two national targets.

If the argument for the past decade has been that a national target does not curb physician spending, then we are unsure why two national targets would be better than one. The Medicare system for paying physicians is broken, and the Majority's bill does not change that. Specifically, it does not adjust for how some providers in this country are getting paid under Medicare at rates well below their cost of services. This causes even more concern for us when you consider that the Majority's bill would tie payments for physicians who take patients in the government-run plan to Medicare rates and make taking these patients as a condition of participation in Medicare. Doing so will only jeopardize access to care as providers are forced to lay off health care workers and close clinics.

The Minority is also concerned about the impact of the Medicaid policies in H.R. 3200. During the numerous health-reform hearings that were held by the Committee in the months leading up to the introduction of H.R. 3200, the Committee repeatedly heard testimony from expert witnesses about the numerous problems that plague the Medicaid program. Repeatedly, the Committee heard testimony as to how the low provider reimbursement rates and burdensome administrative requirements have led to significant access problems for Medicaid beneficiaries. The Committee also heard testimony as to how the fee-for-service model that is incorporated by many State Medicaid programs is an inherently flawed model for the delivery of health care that results in lower-quality health

outcomes and higher costs when compared to more-modern health care delivery models. As a result of these numerous flaws in the Medicaid program, almost every witness, both Majority and Minority, before the Committee stated they would not exchange their current health insurance plan for Medicaid coverage if given the option.

However, despite these numerous, inherent flaws and the undeniable need for significant, fundamental reform of the Medicaid program, the authors of H.R. 3200 decided to imprudently utilize a massive, mandated expansion of Medicaid eligibility, enrollment, and spending as a central component of their strategy to increase the number of Americans with health care coverage. This is primarily accomplished by mandating that all States expand their Medicaid eligibility levels to 133.33% of the federal poverty level ($14,440 for an individual and $29,400 for a family of four) for all individuals under the age of 65. Under current law, non-disabled childless adults between the ages of 19 and 64 are not eligible for Medicaid coverage, so the Majority's draft legislation has to create and mandate coverage for a massive new entitlement category to cover these populations. Combining this massive, mandated coverage expansion with provisions requiring an unprecedented automatic enrollment into Medicaid for low-income individuals, analysts project that this legislation could add between 15 and 20 million people to the Medicaid rolls over the next ten years, increasing total Medicaid enrollment to approximately 90 million Americans.

The Minority is concerned about the negative impact that this policy will have on existing Medicaid beneficiaries, individuals who would become enrolled in Medicaid under this legislation, Medicaid participating health care providers, the States, and the American taxpayers. The Minority is concerned that the additional 15 to 20 million Medicaid beneficiaries who would become enrolled under H.R. 3200 would result in State Medicaid programs losing their focus on providing needed medical services to low-income children and the disabled that are already enrolled in the program. The Committee has repeatedly heard testimony regarding the difficulty that States are currently having in providing the required services to their existing Medicaid populations. In fact, it was this difficulty in meeting the demands of the current Medicaid populations that was given as the primary justification of the $90 billion in temporary federal funding increases that were given to the State Medicaid programs in Title V of P.L. 111–5. However, the current financial and caseload strains on State Medicaid programs, was clearly ignored in the drafting H.R. 3200, which is projected to increase federal Medicaid spending by over $400 billion and State Medicaid spending by over $40 billion.

The Minority offered several amendments to improve the Medicaid-related provisions of H.R. 3200, but unfortunately, these amendments were all defeated by the Majority. One of the most important amendments offered by the Minority would have provided all Medicaid and SCHIP beneficiaries with the right to choose the health care coverage that best fits their needs by requiring all State Medicaid and SCHIP programs to give beneficiaries the option of receiving premium assistance for employer-sponsored health insurance coverage or any other participating health insurance

plan that has met the coverage requirements that already exist in current law. The Minority was disappointed that this premium-assistance amendment was defeated, especially after the Majority voted in favor of an amendment offered by Congressman Welch to give a special exemption for the State of Vermont to allow just this one State to continue their current premium-assistance program for Medicaid beneficiaries.

The Minority was also disappointed that an anti-fraud amendment offered by Congressman Deal was defeated by a 28–29 vote. This amendment would have prevented American taxpayers from being forced to finance welfare benefits for illegal aliens by clarifying that all potential Medicaid enrollees must first go through the existing citizenship and identity verification requirements that are in Sections 1903(x) and 1137(d) of the Social Security Act. H.R. 3200 would require States to automatically enroll potentially millions of Medicaid beneficiaries without any guarantees that these new enrollees will be United States citizens or certain legal permanent residents as required in current law. Specifically, Section 1702 of H.R. 3200 requires that "the State shall accept without further determination the enrollment under [the Medicaid program] of an individual determined by the Commissioner to be a non-traditional Medicaid eligible individual." However, nowhere in this bill is the Health Choices Commissioner required to apply the existing citizenship and identity verification requirements that exist in current Medicaid statute. The Minority hopes that this loophole is addressed before this legislation is passed into law.

DIVISION C

The state of our Nation's health depends greatly on the health status of its people. Prevention and wellness programs are worthwhile endeavors; however, the CBO recently stated that "different types of preventative care [has] different effects on spending, the evidence suggests that for most preventative services, expanded utilization leads to higher, now lower, medical spending overall."[4] CBO outlined that because doctors do not know which patients would benefit from the preventative services, mass screenings will lead to higher costs. In order for preventative services to truly lower costs, the services need to be targeted to specific populations. This bill does nothing to target prevention efforts. Instead, it spends billions of dollars on mass prevention measures which may have little to no effect.

We are concerned by the authorization of over $88 billion to create a public health investment fund. This fund is authorized to be used for increasing the public health workforce, increasing allied health professional workforces, increasing physician workforce, and the creation of a new Prevention and Wellness trust fund. While these are worthy goals, we believe that before any money is appropriated, Congress should take a serious look at what funds are already being used for these purposes. An amendment offered by Congressman Sullivan which was adopted by a majority vote stated that any duplicative programs be eliminated. The new Democratic health care proposal creates massive new federal spending pro-

[4] Congressional Budget Office, Letter to Congressman Nathan Deal, August 7, 2009.

grams, many of which are charged with responsibilities already assigned to pre-existing programs. This amendment does not eliminate services, but ensures that services offered under the new system are administered in a more efficient manner. According to the current language, the vast new roster of programs only add to the existing bureaucracy instead of replacing the appropriate portion. This amendment will lower administrative costs and help streamline the greatly expanded government health care system.

The massive size of the bill and the short time period that the Committee had to consider the bill is concerning given the number of new programs the legislation creates. The legislation creates a loan repayment program financed by the federal taxpayers to repay people's loans who get degrees in health policy. We agree that it is important to find ways to train the next generation of individuals who will be on the front line of treating Americans, but it is irresponsible in this time of budget deficits to have loan repayment programs for people who will never see a patient. We are also concerned with the open ended nature of grants that could be funneled to localities to build sidewalks, parks and bike trails. A health reform bill should be about health care, not bike trails.

As the legislative process moves forward, Congress should consider the following amendments offered at the Committee which were not adopted. An amendment offered by Congressman Gingrey would prevent government bureaucrats at the new Center for Quality Improvement from dictating to physicians what treatments they can or can't offer. In the legislation, the Center is tasked with determining what treatments and procedures are most cost effective. This manner of government-sponsored research, in conjunction with the new federal crowd-out health plan, would represent the first step towards implementing a policy of bureaucrat health care rationing. This amendment would have helped prevent this eventuality by ensuring that this new agency cannot take the next dangerous step and put a federal bureaucrat between the American people and their doctors.

An amendment offered by Congressman Rogers, would prevent the federal government's comparative effectiveness research from being used for care rationing or limiting reimbursement levels by any government or private entity. The current legislation creates an Agency for Healthcare Research and Quality (AHRQ) to conduct said research. Under the current legislation, the AHRQ, the Center for Medicare and Medicaid Services, or any other agency could use comparative effectiveness research, including cost-effectiveness research, to make payment and coverage decisions to deny patient care. This amendment would prevent government agencies from rationing availability of life-saving drugs, therapies, and treatments based on government research, or limiting reimbursement for these services.

An amendment offered by Congressman Terry would reauthorize funding for abstinence education in our Nation's schools. Abstinence education programs teach students far more than just how to "say no". Students learn the value of building healthy relationships, they build critical skills in decision-making and self-efficacy, and they gain medically accurate information on contraceptives and sexually transmitted diseases (STDs). Additionally, while achieving

these objectives, these programs have not decreased condom use in sexually active teens. This amendment would not cut funding for Comprehensive Sex Education programs, which receive four times as much funding as abstinence education programs; it will only ensure that teens retain access to an invaluable perspective on their personal and sexual development.

An amendment offered by Congressman Terry would prohibit the creation of a $35.3 billion Community Wellness Fund unless the projected budget deficit for the next fiscal year is less than $1 trillion. Under the current legislation, this money could be given out to any program that is tangentially related to community wellness. This could include building jungle gyms, bike trails, or parks; or even paying people to drink diet soda instead of regular soda. This amendment would require that Congress have the budget in order before it can obligate billions more in new government grant programs.

The Minority is very concerned that the Committee rejected an amendment offered by Congressman Deal that would prohibit the federal government from taxing or withholding benefits from States whose health plans do not comply with the new arbitrary essential benefits mandates that the HHS Secretary is authorized to make under this legislation. These could include mandated coverage of abortion or Botox injections, and if States don't comply they would face an 8% tax on their employee payroll or drastic cuts in federal grants. States are already struggling to balance their budgets. New federal taxes on State governments or restrictions on critical grants could mean the breaking point for stretched-thin State budgets. Due to the rejection of this amendment, State taxpayers could see thier money taken by the federal government because their State government did not want to cover objectionable services.

The Minority would also note that the Committee has never held a hearing to examine the details of H.R. 3200. The Majority claims in the report that three days of legislative hearings were held on the bill. However, when witnesses were asked to comment on specifics of the legislation, Members were told that the witnesses could not comment on specifics because there had not been enough time to review it. We believe that, given the enormity of this issue, it would be important for the Committee to hold a hearing to discuss the implications of the legislation.

JOE BARTON
(Ranking Member).
NATHAN DEAL.
FRED UPTON.
CLIFF STEARNS.
RALPH HALL.
JOHN SHIMKUS.
GEORGE RADANOVICH.
LEE TERRY.
ED WHITFIELD.
GREG WALDEN.
PHIL GINGREY.
MARSHA BLACKBURN.
MIKE ROGERS.
MICHAEL BURGESS.

MARY BONO MACK.
SUE MYRICK.
JOHN SULLIVAN.
JOHN SHADEGG.
STEVE SCALISE.
JOSEPH R. PITTS.
STEVE BUYER.
ROY BLUNT.
TIM MURPHY.

APPENDIX A—TEXT OF MOTION TO INSTRUCT THE CHAIRMAN ON H.R. 3200

Motion to Instruct the Chairman to Transmit to the Committee on Rules Additional Recommended Amendments

(As Approved by the Committee on Energy and Commerce on September 23, 2009; references are to H.R. 3200, as ordered reported by the Committee on Energy and Commerce)

The Committee on Energy and Commerce approved, by a vote of 28-22 on September 23, 2009, the following motion:

Mr. Dingell moves to instruct the Chairman of the Committee on Energy and Commerce to transmit to the Committee on Rules the following additional recommended amendments for consideration, by the Committee on Rules and the House of Representatives, in connection with H.R. 3200, as previously ordered reported by the Committee on Energy and Commerce:

[Baldwin 15:]

In section 1150A(c) of the Social Security Act, as added by section 1905—

(1) redesignate paragraphs (7) and (8) as paragraphs (9) and (10), respectively; and

(2) insert after paragraph (6) the following new paragraphs:

"(7) Support for coordination of State and Federal contracting and oversight for dual coordination programs supportive of the goals described in subsection (b);

"(8) Support for State Medicaid agencies through the provision of technical assistance for Medicare and Medicaid coordination initiatives designed to improve acute and long-term care for dual eligibles;

In section 1150A of the Social Security Act, as added by section 1905—

(1) redesignate subsections (d) and (e) as subsection (f) and (g), respectively;

(2) in subsection (a), strike "as defined in subsection (e)" and insert "as defined in subsection (g)"; and

(3) insert after subsection (c) the following new subsections:

"(d) INTEGRATED REPORTING; BENCHMARKS.—

"(1) IN GENERAL.—The Office or program shall work with relevant State agencies to establish a common set of risk adjusted quality measures and reporting procedures for Medicare and Medicaid reporting that include integration and consolidation of current reporting requirements for—

"(A) annual risk assessment and model of care requirements;

"(B) the Healthcare Effectiveness Data and Information Set (HEDIS), Consumer Assessment of Healthcare Providers and Systems (CAHPS), Health Outcomes Study

(HOS), Quality Improvement Projects (QIP), Chronic Care Improvement Program (CCIP), and any plan organizational structure and quality improvement processes; and

"(C) a common set of risk adjusted benchmarks for Medicare and Medicaid to evaluate performance of for integrated Medicare-Medicaid programs for dual eligibles in serving a comparable group of beneficiaries under the original Medicare fee-for-service program, under the Medicare Advantage program, and under Medicaid managed care, including, to the extent possible, the following outcomes measures: emergency room use, avoidable hospitalizations and inpatient readmissions for ambulatory care sensitive conditions; medication management to prevent adverse drug events and promote adherence; long-term nursing home stays; beneficiary satisfaction; and such other measures as the Secretary deems appropriate.

"(e) CONSULTATION WITH STAKEHOLDERS.—The Office or program shall consult with relevant stakeholders, including representatives for dual eligible beneficiaries, health plans, providers, and State Medicaid agencies, in the development of policies related to integrated Medicare-Medicaid programs for dual eligibles.

In section 1177, strike subsection (b) and insert the following:

(b) EXTENSION OF CERTAIN PLANS.—

(1) PLANS DESCRIBED.—For purposes of Section 1859(f)(1) of the Social Security Act (42 U.S.C. 1395w-28(f)(1)), a plan described in this paragraph is a Medicare Advantage dual eligible special needs plan—

(A) whose sponsoring Medicare Advantage organization, as of the date enactment of America's Affordable Health Choices Act of 2009, has a contract with a State Medicaid Agency that participated in the "Demonstrations Serving Those Dually-Eligible for Medicare and Medicaid" under the Medicare program; and

(B) that has been approved by the Centers for Medicare & Medicaid Services as a dual eligible special needs plan and that offers integrated Medicare and Medicaid services under a contract with the State Medicaid agency.

(2) ANALYSIS; REPORT.—

(A) ANALYSIS.—The Secretary of Health and Human Services shall provide, through a contract with an independent health services evaluation organization, for an analysis of the plans described in paragraph (1) with regard to the impact of such plans on cost, quality of care, patient satisfaction, and other subjects specified by the Secretary. Such report also will identify statutory changes needed to simplify access to needed services, improve coordination of benefits and services and ensure protection for dual eligibles as appropriate.

(B) REPORT.—Not later than December 31, 2011, the Secretary shall submit to the Congress a report on the analysis under subparagraph (A) and shall include in such report such recommendations with regard to the treatment of such plans as the Secretary deems appropriate.

[Barton, Green, Burgess 1:]

Amend section 133 to read as follows:

SEC. 133. REQUIRING INFORMATION TRANSPARENCY AND PLAN DISCLOSURE.

(a) IN GENERAL.—A qualified health benefits plan shall comply with standards established by the Commissioner for the accurate and timely disclosure of plan documents, plan terms and conditions, claims payment policies, practices, and amounts, periodic financial disclosure, and other information as determined appropriate by the Commissioner. The Commissioner shall require that such disclosure be provided in plain language.

(b) COST SHARING TRANSPARENCY.—A qualified health benefits plan shall allow individuals to learn the amount of cost-sharing (including deductibles, copayments, and coinsurance) under the individual's plan or coverage that the individual would be responsible for paying with respect to the furnishing of a specific item or service by a participating provider in a timely manner upon request. At a minimum, this information shall be made available to such individual via an Internet website.

(c) CONTRACTING REIMBURSEMENT.—A qualified health benefits plan shall comply with standards established by the Commissioner to ensure transparency to each health care provider relating to reimbursement arrangements between such plan and such provider.

(d) ADVANCE NOTICE OF PLAN CHANGES.—A change in a qualified health benefits plan shall not be made without reasonable and timely advance notice to enrollees of such change.

Add at the end of subtitle C of title VII of division B the following:

SEC. 1730B. HOSPITAL PRICE AND QUALITY TRANSPARENCY.

(a) IN GENERAL.—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)), as amended by sections 1631(b), 1703(a), 1729, 1753, 1757(a), 1759(a), and 1910(b), is amended—

(1) by striking "and" at the end of paragraph (79);

(2) by striking the period at the end of paragraph (80) and inserting "; and"; and

(3) by inserting after paragraph (80) the following new paragraph:

"(81) provide that the State will establish and maintain laws, in accordance with the requirements of section 1921A, to require disclosure of information on hospital charges and quality and to make such information available to the public and the Secretary."; and

(4) by inserting after section 1921 the following new section:

"HOSPITAL PRICE TRANSPARENCY

"SEC. 1921A. (a) IN GENERAL.—The requirements referred to in section 1902(a)(81) are that the laws of a State must—

"(1) require reporting to the State (or its agent) by each hospital located therein, of information on—

"(A) the charges for the most common inpatient and outpatient hospital services;

"(B) the Medicare and Medicaid reimbursement amount for such services; and

"(C) if the hospital allows for or provides reduced charges for individuals based on financial need, the factors considered in making determinations for reductions in charges, including any formula for such determination and the contact information for the specific department of a hospital that responds to such inquiries;

"(2) provide for notice to individuals seeking or requiring such services of the availability of information on charges described in paragraph (1);

"(3) provide for timely access to such information, including at least through an Internet website, by individuals seeking or requiring such services; and

"(4) provide for timely access to information regarding the quality of care at each hospital made publicly available in accordance with section 501 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173), section 1139A, or section 1139B.

The Secretary shall consult with stakeholders (including those entities in section 1808(d)(6) and the National Governors Association) through a formal process to obtain guidance prior to issuing implementing policies under this section.

"(b) HOSPITAL DEFINED.—For purposes of this section, the term 'hospital' means an institution that meets the requirements of paragraphs (1) and (7) of section 1861(e) and includes those to which section 1820(c) applies.".

(b) EFFECTIVE DATE; ADMINISTRATION.—

(1) IN GENERAL.—Except as provided in paragraphs (2) and (3)(B), the amendments made by subsection (a) shall take effect on October 1, 2010.

(2) EXCEPTION.—In the case of a State plan for medical assistance under title XIX of the Social Security Act which the Secretary of Health and Human Services determines requires State legislation (other than legislation appropriating funds) in order for the plan to meet the additional requirements imposed by the amendments made by subsection (a), the State plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet these additional requirements before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of the enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of such session shall be deemed to be a separate regular session of the State legislature.

(3) EXISTING PROGRAMS.—

(A) IN GENERAL.—The Secretary of Health and Human Services shall establish a process by which a State with an existing program may certify to the Secretary that its program satisfies the requirements of section 1921A of the Social Security Act, as inserted by subsection (a).

(B) 2-YEAR PERIOD TO BECOME IN COMPLIANCE.—States that, as of the date of the enactment of this Act, administer hospital price transparency policies that do not meet such requiremens shall have 2 years from such date to

make necessary modifications to come into compliance and shall not be regarded as failing to comply with such requirements during such 2-year period.

[Butterfield 2:]

At the end of section 122, add the following new subsection:

(f) REPORT REGARDING INCLUSION OF ORAL HEALTH CARE IN ESSENTIAL BENEFITS PACKAGE.—Not later than one year after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to Congress a report containing the results of a study determining the need and cost of providing accessible and affordable oral health care to adults as part of the essential benefits package.

[Buyer Health09\005:]

In subtitle A of title II of division A, add at the end the following new section:

SEC. 209. REIMBURSEMENT OF SECRETARY OF VETERANS AFFAIRS.

The Secretary of Health and Human Services shall seek to enter into a memorandum of understanding with the Secretary of Veterans Affairs regarding the recovery of costs related to non-service-connected care or services provided by the Secretary of Veterans Affairs to an individual covered under the public health insurance option in a manner consistent with recovery of costs related to non-service-connected care from private health insurance plans.

[Castor 7_001:]

In title XXXI of the Public Health Service Act, added by section 2301(a), redesignate subtitle G (and section 3171) as subtitle H (and section 3181, respectively), and insert after subtitle F the following new subtitle (and conform cross-references accordingly): [review if this should go into part 2 of subtitle B of title V of division C]:

"Subtitle G—Wellness Program Grants

"SEC. 3171. WELLNESS PROGRAM GRANTS.

"(a) ALLOWANCE OF GRANT.—

"(1) IN GENERAL.—For purposes of this section, the Secretary shall award wellness grants as determined under this section. Wellness program grants shall be awarded to qualified employers for any plan year in an amount equal to 50 percent of the costs paid or incurred by the employer in connection with a qualified wellness program during the plan year. For purposes of the preceding sentence, in the case of any qualified wellness program offered as part of an employment-based health plan, only costs attributable to the qualified wellness program and not to the health plan, or health insurance coverage offered in connection with such a plan, may be taken into account.

"(2) LIMITATION.—The amount of the grant allowed under paragraph (1) for any plan year shall not exceed the sum of—

"(A) the product of $200 and the number of employees of the employer not in excess of 200 employees; plus

"(B) the product of $100 and the number of employees of the employer in excess of 200 employees.

The wellness grants awarded to an employer under this section shall be for up to 3 years and shall not exceed $50,000.

"(b) QUALIFIED WELLNESS PROGRAM.—For purposes of this section:

"(1) QUALIFIED WELLNESS PROGRAM.—The term 'qualified wellness program' means a program that —

"(A) includes any 3 wellness components described in subsection (c); and

"(B) is certified by the Secretary, in coordination with the Health Choices Commissioner and the Director of the Center for Disease Control and Prevention, as a qualified wellness program under this section.

"(2) PROGRAMS MUST BE CONSISTENT WITH RESEARCH AND BEST PRACTICES.—

"(A) IN GENERAL.—The Secretary shall not certify a program as a qualified wellness program unless the program—

"(i) is newly established or in existence on the date of enactment of this Act but not yet meeting the requirements of this section;

"(ii) is consistent with evidenced-based researched and best practices, as identified by persons with expertise in employer health promotion and wellness programs;

"(iii) includes multiple, evidenced-based strategies which are based on the existing and emerging research and careful scientific reviews, including the Guide to Community Preventative Services, the Guide to Clinical Preventative Services, and the National Registry for Effective Programs, and

"(iv) includes strategies which focus on prevention and support for employee populations at risk of poor health outcomes.

"(B) PERIODIC UPDATING AND REVIEW.—The Secretary, in consultation with other appropriate agencies shall establish procedures for periodic review, evaluation, and update of the programs under this subsection.

"(3) HEALTH LITERACY/ACCESSIBILITY.—The Secretary shall, as part of the certification process—

"(A) ensure that employers make the programs culturally competent. physically and programmatically accessible (including for individuals with disabilities), and appropriate to the health literacy needs of the employees covered by the programs;

"(B) require a health literacy component to provide special assistance and materials to employees with low literacy skills, limited English and from under-served populations; and

"(C) require the Secretary , in consultation with Secretary of Labor, to compile and disseminate to employer health plans info on model health literacy curricula, instructional programs, and effective intervention strategies.

"(c) WELLNESS PROGRAM COMPONENTS.—For purposes of this section, the wellness program components described in this subsection are the following:

"(1) HEALTH AWARENESS COMPONENT.—A health awareness component which provides for the following:

"(A) HEALTH EDUCATION.—The dissemination of health information which addresses the specific needs and health risks of employees.

"(B) HEALTH SCREENINGS.—The opportunity for periodic screenings for health problems and referrals for appropriate follow up measures.

"(2) EMPLOYEE ENGAGEMENT COMPONENT.—An employee engagement component which provides for the active engagement of employees in worksite wellness programs through worksite assessments and program planning, onsite delivery, evaluation, and improvement efforts.

"(3) BEHAVIORAL CHANGE COMPONENT.—A behavioral change component which provides for altering employee lifestyles to encourage healthy living through counseling, seminars, on-line programs, or self-help materials which provide technical assistance and problem solving skills. such component may include programs relating to—

"(A) tobacco use;

"(B) obesity;

"(C) stress management;

"(D) physical fitness;

"(E) nutrition;

"(F) substance abuse;

"(G) depression; and

"(H) mental health promotion (including anxiety).

"(4) SUPPORTIVE ENVIRONMENT COMPONENT.—A supportive environment component which includes the following:

"(A) ON-SITE POLICIES.—Policies and services at the worksite which promote a healthy lifestyle, including policies relating to—

"(i) tobacco use at the worksite;

"(ii) the nutrition of food available at the worksite through cafeterias and vending options;

"(iii) minimizing stress and promoting positive mental health in the workplace; and

"(iv) the encouragement of physical activity before, during, and after work hours.

"(d) PARTICIPATION REQUIREMENT.—No grant shall be allowed under subsection (a) unless the Secretary in consultation with other appropriate agencies, certifies, as a part of any certification described in subsection (b), that each wellness program component of the qualified wellness program—

"(1) shall be available to all employees of the employer;

"(2) shall not mandate participation by employees; and

"(3) shall not require participation by individual employees as a condition to obtain a premium discount, rebate, deductible reduction, or other financial reward.

"(e) PRIVACY PROTECTIONS.—Any employee health information collected through participation in an employer wellness program

shall be confidential and available only to appropriately trained health professions as defined by the Secretary. Employers or employees of the employer sponsoring a wellness program shall have no access to employee health data. All entities offering employer-sponsored wellness programs shall be considered 'business associates' pursuant to the American Reinvestment and Recovery Act and must comply with privacy protections restricting the release of personal medical information.

"(f) DEFINITIONS AND SPECIAL RULES.—For purposes of this section:

"(1) QUALIFIED EMPLOYER.—The term 'qualified employer' means an employer that offers a qualified health benefits plan to every employee (including each employee required to be offered coverage under a qualified health benefits plan under subtitle B of title III of division A of the America's Affordable Health Choices Act of 2009), and meets the health coverage participation requirements as defined in section 312 of such Act.

"(2) CERTAIN COSTS NOT INCLUDED.—Costs paid or incurred by an employer for food or health insurance shall not be taken into account under subsection (a).

"(g) OUTREACH.—

"(1) IN GENERAL.—The Secretary, in conjunction with other appropriate agencies and members of the business community, shall institute an outreach program to inform businesses about the availability of the wellness program grant as well as to educate businesses on how to develop programs according to recognized and promising practices and on how to measure the success of implemented programs.

"(h) EFFECTIVE DATE.—This section shall take effect on January 1, 2013.

"(i) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary to carry out this section.".

[Christensen 23_001:]

In section 123(a)(5), strike "an expert on children's health" and insert "an expert in child and adolescent health".

[Degette/SarbanesMcNerney 3_001:]

In section 123(a)(5), after "experts in heath care financing and delivery," insert "experts in oral health care,".

[GreenTX 6_002:]

In the subparagraph (C) added by section 1176, insert before the period at the end the following: "or, in the case of an individual described in such subsection who is eligible for benefits under part A on the basis of section 226A, during the 1-year period beginning on the first day of such individual's eligibility for such benefits".

[GreenTX 7_001:]

Add at the end of part 2 of subtitle B of title V of division C the following:

SEC. 2532. GRANTS TO STRENGTHEN THE EFFECTIVENESS, EFFICIENCY, AND COORDINATION OF SERVICES.

(a) IN GENERAL.—The Secretary shall award grants to assist in the development of integrated health care delivery systems to serve defined communities of individuals—

(1) to improve the efficiency of and coordination among the providers providing services through such systems;

(2) to assist local communities in developing programs targeted toward preventing and managing chronic diseases; and

(3) to expand and enhance the services provided through such systems.

(b) ELIGIBLE ENTITIES.—To be eligible to receive a grant under this section, an entity shall be an entity that—

(1) represents a balanced consortium—

(A) whose principal purpose is to ensure the sustainable capacity for the provision of a broad range of coordinated services for all residents within a community defined in the entity's grant application as described in paragraph (2); and

(B) that includes at least one of each of the following providers that serve the community (unless such provider does not exist within the community, declines or refuses to participate, or places unreasonable conditions on their participation)—

(i) a Federally qualified health center (as defined in section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa)));

(ii) rural health clinics and rural health networks (as defined in sections 1861(aa) and 1820(d) of the Social Security Act, respectively (42 U.S.C. 1395x(aa), 1395i–4(d)));

(iii) a hospital with a low-income utilization rate that is greater than 25 percent (as defined in section 1923(b)(3) of the Social Security Act (42 U.S.C. 1396r-4(b)(3))) or a critical access hospital (as defined in section 1820(c)(2) of the Social Security Act (42 U.S.C. 1395i–4(c)(2)));

(iv) a public health department; and

(v) an interested public or private sector health care provider or an organization that has traditionally served the medically uninsured and low-income individuals; and

(2) submits to the Secretary an application, in such form and manner as the Secretary shall prescribe, that—

(A) clearly defines the community to be served;

(B) identifies the providers who will participate in the community coalition under the grant and specifies each provider's contribution to the care of individuals in the community;

(C) describes the activities that the applicant and the community coalition propose to perform under the grant to further the objectives of this section;

(D) demonstrates that it is an established coalition with ability to build on the current system for serving the community by involving providers who have traditionally provided a significant volume of care for uninsured and low-income individuals for that community;

(E) demonstrates the coalition's ability to develop coordinated systems of care that either directly provide or en-

sure the prompt provision of a broad range of high-quality, accessible services, including, as appropriate, primary, secondary, and tertiary services as well as pharmacy, substance abuse, behavioral health and oral health services, in a manner that ensures continuity of care in the community;

(F) provides evidence of community involvement, including the business community, in the development, implementation, and direction of the system of care that the coalition proposes to ensure;

(G) demonstrates the coalition's ability to ensure that participating individuals are enrolled in health care coverage programs, both public and private, for which the individuals are eligible;

(H) presents a plan for leveraging other sources of revenue, which may include State and local sources and private grant funds, and integrating current and proposed new funding sources in a manner to ensure long-term sustainability of the system of care;

(I) describes a plan for evaluation of the activities carried out under the grant, including measurement of progress toward the goals and objectives of the program and the use of evaluation findings to improve system performance;

(J) demonstrates fiscal responsibility through the use of appropriate accounting procedures and management systems;

(K) demonstrates commitment to serve the community without regard to the ability of an individual or family to pay by arranging for or providing free or reduced charge care for the poor; and

(L) includes such other information as the Secretary may prescribe.

(c) LIMITATIONS.—

(1) IN GENERAL.—An eligible entity may receive a grant under this section for 3 consecutive fiscal years and may receive such a grant award for 2 additional years if—

(A) the eligible entity submits to the Secretary a request for a grant for such additional years;

(B) the Secretary determines that current performance justifies the granting of such a request; and

(C) the Secretary determines that granting such request is necessary to further the objectives described in subsection (a).

(d) PRIORITIES.—In awarding grants under this section, the Secretary—

(1) may accord priority to applicants that demonstrate the greatest extent of unmet need in the community for a more coordinated system of care; and

(2) shall accord priority to applicants that best promote the objectives of this section, taking into consideration the extent to which the applicant—

(A) identifies a community whose geographical area has a high or increasing percentage of individuals who are uninsured or low-income;

(B) demonstrates that the applicant has included in its community coalition providers, support systems, and programs that have a tradition of serving individuals and families in the community who are uninsured or earn below 200 percent of the Federal poverty level;

(C) shows evidence that the proposed coalition activities would expand utilization of preventive and primary care services for uninsured and underinsured individuals and families in the community, including pharmaceuticals, behavioral and mental health services, oral health services, or substance abuse services;

(D) proposes approaches that would improve coordination between health care providers and appropriate social service providers;

(E) demonstrates collaboration with State and local governments;

(F) demonstrates that the applicant makes use of non-Federal contributions to the greatest extent possible; or

(G) demonstrates likelihood that the proposed activities will lead to sustainable integrated delivery system as additional efforts of health systems development evolve.

(e) USE OF FUNDS.—

(1) USE BY GRANTEES.—

(A) IN GENERAL.—Except as provided in paragraphs (2) and (3), a grantee may use amounts provided under this section only for—

(i) direct expenses associated with achieving the greater integration of a health care delivery system so that the system either directly provides or ensures the provision of a broad range of culturally competent services, including as appropriate primary, secondary, and tertiary care and oral health, substance abuse, behavioral and mental health, and pharmaceutical services; and

(ii) direct patient care and service expansions to fill identified or documented gaps within an integrated delivery system.

(B) SPECIFIC USES.—The following are examples of purposes for which a grantee may use grant funds under this section, when such use meets the conditions stated in subparagraph (A):

(i) Increases in outreach activities and closing gaps in health care service, including referral to specialty services and prescription drugs and conducting ongoing outreach to health disparity populations.

(ii) Improvements to care management and delivery of patient-centered care, including patient navigation services.

(iii) Improvements to coordination of transportation to health care facilities.

(iv) Development of provider networks and other innovative models to engage physicians in voluntary efforts to serve the medically underserved within a community.

(v) Recruitment, training, and compensation of necessary personnel.

(vi) Coordinate the acquisition or interconnected use of technology within a community for the purpose of coordinating care and improving provider communication, including implementation of shared information systems or shared clinical systems to improve the quality of health care.

(vii) Development of common processes such as mechanisms for determining eligibility for the programs provided through the system, common identification cards, sliding scale discounts, and monitoring and tracking of outcomes.

(viii) Development of specific prevention and disease management tools and processes.

(ix) Language access services.

(x) Facilitating the involvement of community organizations to provide better access to high-quality health care services to individuals at risk for or who have chronic diseases or cancer.

(xi) Helping patients overcome barriers within the health care system to ensure prompt diagnostic and treatment resolution of an abnormal finding of cancer or chronic disease.

(2) DIRECT PATIENT CARE LIMITATION.—Not more than 20 percent of the funds provided under a grant awarded under this section may be used for providing direct patient care and services.

(3) RESERVATION OF FUNDS FOR NATIONAL PROGRAM PURPOSES.—The Secretary may use not more than 7 percent of funds appropriated to carry out this section for providing technical assistance to grantees, obtaining assistance of experts and consultants, holding meetings, developing of tools, disseminating of information, and evaluation.

(f) REPORTING BY GRANTEE.—A grantee under this section shall report to the Secretary annually regarding—

(1) progress in meeting the goals and measurable objectives set forth in the grant application submitted by the grantee under subsection (b); and

(2) the extent to which activities conducted by such grantee have—

(A) improved the effectiveness, efficiency, and coordination of services for uninsured and low-income individuals in the community served by such grantee, using commonly accepted outcome measures;

(B) resulted in the provision of better quality health care for individuals and families in the community served; and

(C) resulted in the provision of health care to such individuals at lower cost than would have been possible in the absence of the activities conducted by such grantee.

(g) MAINTENANCE OF EFFORT.—With respect to activities for which a grant under this section is authorized, the Secretary may award such a grant only if the applicant and each of the participating providers agree that the grantee and each such provider will maintain its expenditures of non-Federal funds for such activities at a level that is not less then the level of such expenditures during the fiscal year immediately preceding the fiscal year for which the applicant is applying to receive such grant.

(h) TECHNICAL ASSISTANCE.—The Secretary may provide any entity that receives a grant under this section with technical and other nonfinancial assistance necessary to meet the requirements of this section. The Secretary may choose to provide such assistance by awarding a grant to, or entering into a contract with, a State or national not-for-profit organization with expertise in building successful community coalitions.

(i) EVALUATION OF PROGRAM.—Not later than September 30, 2014, the Secretary shall prepare and submit to the appropriate committees of Congress a report that describes the extent to which projects funded under this section have been successful in improving the effectiveness, efficiency, and coordination of services in the communities served by such projects, including whether the projects resulted in the provision of better quality health care for such individuals, and whether such care was provided at lower costs than would have been provided in the absence of such projects.

(j) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for fiscal years 2010 through 2014.

[Hill 7_003:]

In the heading of subsection (b) of section 1128H of the Social Security Act, inserted by section 1451(a), strike "IN HOSPITALS AND OTHER ENTITIES THAT BILL MEDICARE".

In section 1128H(b) of the Social Security Act, inserted by section 1451(a), strike "Not later than" and insert the following:

"(1) OWNERSHIP IN HOSPITALS AND OTHER ENTITIES THAT BILL MEDICARE.—Not later than".

In section 1128H(b) of the Social Security Act, inserted by section 1451(a), add at the end the following:

"(2) ADDITIONAL PHYSICIAN OWNERSHIP.—In addition to the requirement under paragraph (a)(1), not later than March 31 of each year (beginning with 2011) any applicable manufacturer, applicable group purchasing organization, or applicable distributor shall submit to the Secretary, in such electronic form as the Secretary shall require, the following information regarding any ownership or investment interest (other than an ownership or investment interest in a publicly traded security and mutual fund, as described in section 1877(c)) held by a physician (or an immediate family member of such physician (as defined for purposes of section 1877(a))) in the applicable manufacturer, applicable group purchasing organization or applicable distributor during the preceding year:

"(A) The dollar amount invested by each physician holding such an ownership or investment interest.

"(B) The value and terms of each such ownership or investment interest.

"(C) Any payment or other transfer of value provided to a physician holding such an ownership or investment interest (or to an entity or individual at the request of or designated on behalf of a physician holding such an ownership or investment interest), including the information described in clauses (i) through (iii) of paragraph (a)(1)(B), and information described in subsection (f)(9)(A) and (f)(9)(B).

"(D) Any other information regarding the ownership or investment interest the Secretary determines appropriate.".

In paragraphs (1)(A), (1)(B), (2)(A), and (2)(B) of section 1128H(d) of the Social Security Act, inserted by section 1451(a), after "applicable manufacturer" insert ", applicable group purchasing organization, or applicable".

In the heading of section 1128H(f)(1) of the Social Security Act, inserted by section 1451(a), strike "; APPLICABLE DISTRIBUTOR".

In section 1128H(f)(1) of the Social Security Act, inserted by section 1451(a), strike ", and" and all that follows and insert a period.

In section 1128H(f) of the Social Security Act, inserted by section 1451(a), amend paragraph (5) to read as follows:

"(5) APPLICABLE DISTRIBUTOR.—The term 'applicable distributor' means an entity, other than an applicable group purchasing organization, that buys and resells, or receives a commission or other similar form of payment, from another seller, for selling or arranging for the sale of a covered drug, device, biological, or medical supply.".

In section 1128H(f) of the Social Security Act, inserted by section 1451(a), add at the end the following:

"(10) APPLICABLE GROUP PURCHASING ORGANIZATION.—The term 'applicable group purchasing organization' means a group purchasing organization (as defined by the Secretary) that purchases, arranges for, or negotiates the purchase of a covered drug, device, biological, or medical supply.".

In section 1128H(f)(9)(C) of the Social Security Act, inserted by section 1451(a), add at the end the following:

"(ix) Payments made to a covered recipient by an applicable manufacturer or by a health plan affiliated with an applicable manufacturer for medical care provided to employees of such manufacturer and their dependents.".

In section 1128H(f)(5) of the Social Security Act, inserted by section 1451(a), strike "(or any subsidiary of or entity affiliated with such entity)" and insert "or any entity under common ownership with such entity and which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, processing, marketing, or distribution of a covered drug, device, biological, or medical supply".

In section 1128H(f)(8) of the Social Security Act, inserted by section 1451(a), strike "(or any subsidiary of or entity affiliated with such entity)" and insert "or any entity under common ownership with such entity and which provides assistance or support to such

entity with respect to the production, preparation, propagation, compounding, conversion, processing, marketing, or distribution of a covered drug, device, biological, or medical supply".

[Markey 4_002:]

Add at the end of section 206(b) the following: "For purposes of the previous sentence, the Commissioner may utilize data regarding enrollee demographics, inpatient and outpatient diagnoses (in a similar manner as such data are used under parts C and D of title XVIII of the Social Security Act), and such other information as the Secretary determines may be necessary, such as the actual medical costs of enrollees during the previous year.".

[Murphy 7_001:]

In section 1866D of the Social Security Act, as being added by section 1152(f)(1) of the bill, strike subsection (b) and insert the following new subsection:

"(b) SCOPE.—

"(1) NUMBER AND PURPOSE OF TEST SITES.—The Secretary shall attempt to attract ten percent of all eligible providers to act as acute and post-acute bundling test sites under the pilot program to ensure that the pilot program is of sufficient size and scope to—

"(A) test the approaches under the pilot program in a variety of settings, including urban, rural, and underserved areas;

"(B) include geographic areas and additional conditions that account for significant program spending, as defined by the Secretary; and

"(C) subject to subsection (d), disseminate the pilot program rapidly on a national basis.

"(2) EXPANSION.—To the extent that the Secretary finds inpatient and post-acute care bundling to be successful in improving quality and reducing costs, the Secretary shall implement such mechanisms and reforms under the pilot program on as large a geographic scale as practical and economical, consistent with subsection (e).".

[Murphy 2_001:]

At the end of title V of division C, insert the following new subtitle::

Subtitle F—Women's Health

SEC. 2591. OFFICE OF WOMEN'S HEALTH.

(a) HEALTH AND HUMAN SERVICES OFFICE ON WOMEN'S HEALTH.—

(1) ESTABLISHMENT.—Part A of title II of the Public Health Service Act (42 U.S.C. 202 et seq.) is amended by adding at the end the following:

"SEC. 229. HEALTH AND HUMAN SERVICES OFFICE ON WOMEN'S HEALTH.

"(a) ESTABLISHMENT OF OFFICE.—There is established within the Office of the Secretary, an Office on Women's Health (referred to in this section as the 'Office'). The Office shall be headed by a Dep-

uty Assistant Secretary for Women's Health who may report to the Secretary.

"(b) DUTIES.—The Secretary, acting through the Office, with respect to the health concerns of women, shall—

"(1) establish short-range and long-range goals and objectives within the Department of Health and Human Services and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Department that relate to disease prevention, health promotion, service delivery, research, and public and health care professional education, for issues of particular concern to women throughout their lifespan;

"(2) provide expert advice and consultation to the Secretary concerning scientific, legal, ethical, and policy issues relating to women's health;

"(3) monitor the Department of Health and Human Services' offices, agencies, and regional activities regarding women's health and identify needs regarding the coordination of activities, including intramural and extramural multidisciplinary activities;

"(4) establish a Department of Health and Human Services Coordinating Committee on Women's Health, which shall be chaired by the Deputy Assistant Secretary for Women's Health and composed of senior level representatives from each of the agencies and offices of the Department of Health and Human Services;

"(5) establish a National Women's Health Information Center to—

"(A) facilitate the exchange of information regarding matters relating to health information, health promotion, preventive health services, research advances, and education in the appropriate use of health care;

"(B) facilitate access to such information;

"(C) assist in the analysis of issues and problems relating to the matters described in this paragraph; and

"(D) provide technical assistance with respect to the exchange of information (including facilitating the development of materials for such technical assistance);

"(6) coordinate efforts to promote women's health programs and policies with the private sector; and

"(7) through publications and any other means appropriate, provide for the exchange of information between the Office and recipients of grants, contracts, and agreements under subsection (c), and between the Office and health professionals and the general public.

"(c) GRANTS AND CONTRACTS REGARDING DUTIES.—

"(1) AUTHORITY.—In carrying out subsection (b), the Secretary may make grants to, and enter into cooperative agreements, contracts, and interagency agreements with, public and private entities, agencies, and organizations.

"(2) EVALUATION AND DISSEMINATION.—The Secretary shall directly or through contracts with public and private entities, agencies, and organizations, provide for evaluations of projects carried out with financial assistance provided under paragraph

(1) and for the dissemination of information developed as a result of such projects.

"(d) REPORTS.—Not later than 1 year after the date of enactment of this section, and every second year thereafter, the Secretary shall prepare and submit to the appropriate committees of Congress a report describing the activities carried out under this section during the period for which the report is being prepared.".

(2) TRANSFER OF FUNCTIONS.—There are transferred to the Office on Women's Health (established under section 229 of the Public Health Service Act, as added by this section), all functions exercised by the Office on Women's Health of the Public Health Service prior to the date of enactment of this section, including all personnel and compensation authority, all delegation and assignment authority, and all remaining appropriations. All orders, determinations, rules, regulations, permits, agreements, grants, contracts, certificates, licenses, registrations, privileges, and other administrative actions that—

(A) have been issued, made, granted, or allowed to become effective by the President, any Federal agency or official thereof, or by a court of competent jurisdiction, in the performance of functions transferred under this paragraph; and

(B) are in effect at the time this section takes effect, or were final before the date of enactment of this section and are to become effective on or after such date;

shall continue in effect according to their terms until modified, terminated, superseded, set aside, or revoked in accordance with law by the President, the Secretary, or other authorized official, a court of competent jurisdiction, or by operation of law.

(b) CENTERS FOR DISEASE CONTROL AND PREVENTION OFFICE OF WOMEN'S HEALTH.—Part A of title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by adding at the end the following:

"SEC. 310A. CENTERS FOR DISEASE CONTROL AND PREVENTION OFFICE OF WOMEN'S HEALTH.

"(a) ESTABLISHMENT.—There is established within the Office of the Director of the Centers for Disease Control and Prevention, an office to be known as the Office of Women's Health (referred to in this section as the 'Office'). The Office shall be headed by a director who shall be appointed by the Director of such Centers.

"(b) PURPOSE.—The Director of the Office shall—

"(1) report to the Director of the Centers for Disease Control and Prevention on the current level of the Centers' activity regarding women's health conditions across, where appropriate, age, biological, and sociocultural contexts, in all aspects of the Centers' work, including prevention programs, public and professional education, services, and treatment;

"(2) establish short-range and long-range goals and objectives within the Centers for women's health and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Centers that relate to prevention, research, education and training, service delivery, and policy development, for issues of particular concern to women;

"(3) identify projects in women's health that should be conducted or supported by the Centers;

"(4) consult with health professionals, nongovernmental organizations, consumer organizations, women's health professionals, and other individuals and groups, as appropriate, on the policy of the Centers with regard to women; and

"(5) serve as a member of the Department of Health and Human Services Coordinating Committee on Women's Health (established under section 229(b)(4)).

"(c) DEFINITION.—As used in this section, the term 'women's health conditions', with respect to women of all age, ethnic, and racial groups, means diseases, disorders, and conditions—

"(1) unique to, significantly more serious for, or significantly more prevalent in women; and

"(2) for which the factors of medical risk or type of medical intervention are different for women, or for which there is reasonable evidence that indicates that such factors or types may be different for women.".

(c) OFFICE OF WOMEN'S HEALTH RESEARCH.—Section 486(a) of the Public Health Service Act (42 U.S.C. 287d(a)) is amended by inserting "and who shall report directly to the Director" before the period at the end thereof.

(d) SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION.—Section 501(f) of the Public Health Service Act (42 U.S.C. 290aa(f)) is amended—

(1) in paragraph (1), by inserting "who shall report directly to the Administrator" before the period;

(2) by redesignating paragraph (4) as paragraph (5); and

(3) by inserting after paragraph (3), the following:

"(4) OFFICE.—Nothing in this subsection shall be construed to preclude the Secretary from establishing within the Substance Abuse and Mental Health Administration an Office of Women's Health.".

(e) AGENCY FOR HEALTHCARE RESEARCH AND QUALITY ACTIVITIES REGARDING WOMEN'S HEALTH..—Part C of title IX of the Public Health Service Act (42 U.S.C. 299c et seq.) is amended—

(1) by redesignating sections 927 and 928 as sections 928 and 929, respectively;

(2) by inserting after section 926 the following:

"SEC. 927. ACTIVITIES REGARDING WOMEN'S HEALTH.

"(a) ESTABLISHMENT.—There is established within the Office of the Director, an Office of Women's Health and Gender-Based Research (referred to in this section as the 'Office'). The Office shall be headed by a director who shall be appointed by the Director of Healthcare and Research Quality.

"(b) PURPOSE.—The official designated under subsection (a) shall—

"(1) report to the Director on the current Agency level of activity regarding women's health, across, where appropriate, age, biological, and sociocultural contexts, in all aspects of Agency work, including the development of evidence reports and clinical practice protocols and the conduct of research into patient outcomes, delivery of health care services, quality of care, and access to health care;

"(2) establish short-range and long-range goals and objectives within the Agency for research important to women's health and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Agency that relate to health services and medical effectiveness research, for issues of particular concern to women;

"(3) identify projects in women's health that should be conducted or supported by the Agency;

"(4) consult with health professionals, nongovernmental organizations, consumer organizations, women's health professionals, and other individuals and groups, as appropriate, on Agency policy with regard to women; and

"(5) serve as a member of the Department of Health and Human Services Coordinating Committee on Women's Health (established under section 229(b)(4)).";; and

(3) by adding at the end of section 928 (as redesignated by paragraph (1)) the following:

"(e) WOMEN'S HEALTH.—For the purpose of carrying out section 927 regarding women's health, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2010 through 2014.".

(f) HEALTH RESOURCES AND SERVICES ADMINISTRATION OFFICE OF WOMEN'S HEALTH.—Title VII of the Social Security Act (42 U.S.C. 901 et seq.) is amended by adding at the end the following:

"SEC. 713. OFFICE OF WOMEN'S HEALTH.

"(a) ESTABLISHMENT.—The Secretary shall establish within the Office of the Administrator of the Health Resources and Services Administration, an office to be known as the Office of Women's Health. The Office shall be headed by a director who shall be appointed by the Administrator.

"(b) PURPOSE.—The Director of the Office shall—

"(1) report to the Administrator on the current Administration level of activity regarding women's health across, where appropriate, age, biological, and sociocultural contexts;

"(2) establish short-range and long-range goals and objectives within the Health Resources and Services Administration for women's health and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Administration that relate to health care provider training, health service delivery, research, and demonstration projects, for issues of particular concern to women;

"(3) identify projects in women's health that should be conducted or supported by the bureaus of the Administration;

"(4) consult with health professionals, nongovernmental organizations, consumer organizations, women's health professionals, and other individuals and groups, as appropriate, on Administration policy with regard to women; and

"(5) serve as a member of the Department of Health and Human Services Coordinating Committee on Women's Health (established under section 229(b)(4) of the Public Health Service Act).

"(c) CONTINUED ADMINISTRATION OF EXISTING PROGRAMS.—The Director of the Office shall assume the authority for the development, implementation, administration, and evaluation any projects

carried out through the Health Resources and Services Administration relating to women's health on the date of enactment of this section.

"(d) DEFINITIONS.—For purposes of this section:

"(1) ADMINISTRATION.—The term 'Administration' means the Health Resources and Services Administration.

"(2) ADMINISTRATOR.—The term 'Administrator' means the Administrator of the Health Resources and Services Administration.

"(3) OFFICE.—The term 'Office' means the Office of Women's Health established under this section in the Administration.".

(g) FOOD AND DRUG ADMINISTRATION OFFICE OF WOMEN'S HEALTH.—Chapter IX of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

"SEC. 911. OFFICE OF WOMEN'S HEALTH.

"(a) ESTABLISHMENT.—There is established within the Office of the Commissioner, an office to be known as the Office of Women's Health (referred to in this section as the 'Office'). The Office shall be headed by a director who shall be appointed by the Commissioner of Food and Drugs.

"(b) PURPOSE.—The Director of the Office shall—

"(1) report to the Commissioner of Food and Drugs on current Food and Drug Administration (referred to in this section as the 'Administration') levels of activity regarding women's participation in clinical trials and the analysis of data by sex in the testing of drugs, medical devices, and biological products across, where appropriate, age, biological, and sociocultural contexts;

"(2) establish short-range and long-range goals and objectives within the Administration for issues of particular concern to women's health within the jurisdiction of the Administration, including, where relevant and appropriate, adequate inclusion of women and analysis of data by sex in Administration protocols and policies;

"(3) provide information to women and health care providers on those areas in which differences between men and women exist;

"(4) consult with pharmaceutical, biologics, and device manufacturers, health professionals with expertise in women's issues, consumer organizations, and women's health professionals on Administration policy with regard to women;

"(5) make annual estimates of funds needed to monitor clinical trials and analysis of data by sex in accordance with needs that are identified; and

"(6) serve as a member of the Department of Health and Human Services Coordinating Committee on Women's Health (established under section 229(b)(4) of the Public Health Service Act).".

(h) NO NEW REGULATORY AUTHORITY.—Nothing in this section and the amendments made by this section may be construed as establishing regulatory authority or modifying any existing regulatory authority.

(i) LIMITATION ON TERMINATION.—Notwithstanding any other provision of law, a Federal office of women's health (including the Office of Research on Women's Health of the National Institutes of Health) or Federal appointive position with primary responsibility over women's health issues (including the Associate Administrator for Women's Services under the Substance Abuse and Mental Health Services Administration) that is in existence on the date of enactment of this section shall not be terminated, reorganized, or have any of it's powers or duties transferred unless such termination, reorganization, or transfer is approved by Congress through the adoption of a concurrent resolution of approval.

(j) RULE OF CONSTRUCTION.—Nothing in this section (or the amendments made by this section) shall be construed to limit the authority of the Secretary of Health and Human Services with respect to women's health, or with respect to activities carried out through the Department of Health and Human Services on the date of enactment of this section.

[Pallone Inf-Mortality_001:]

Add at the end of part 2 of subtitle B of title V of division C the following:

SEC. 2533. INFANT MORTALITY PILOT PROGRAMS.

(a) IN GENERAL.—The Secretary, acting through the Director, shall award grants to eligible entities to create, implement, and oversee infant mortality pilot programs.

(b) PERIOD OF A GRANT.—The period of a grant under this section shall be 5 consecutive fiscal years.

(c) PREFERENCE.—In awarding grants under this section, the Secretary shall give preference to eligible entities proposing to serve any of the 15 counties or groups of counties with the highest rates of infant mortality in the United States in the past 3 years.

(d) USE OF FUNDS.—Any infant mortality pilot program funded under this section may—

(1) include the development of a plan that identifies the individual needs of each community to be served and strategies to address those needs;

(2) provide outreach to at-risk mothers through programs deemed appropriate by the Director;

(3) develop and implement standardized systems for improved access, utilization, and quality of social, educational, and clinical services to promote healthy pregnancies, full term births, and healthy infancies delivered to women and their infants, such as—

(A) counseling on infant care, feeding, and parenting;

(B) postpartum care;

(C) prevention of premature delivery; and

(D) additional counseling for at-risk mothers, including smoking cessation programs, drug treatment programs, alcohol treatment programs, nutrition and physical activity programs, postpartum depression and domestic violence programs, social and psychological services, dental care, and parenting programs;

(4) establish a rural outreach program to provide care to at-risk mothers in rural areas;

(5) establish a regional public education campaign, including a campaign to—

(A) prevent preterm births; and

(B) educate the public about infant mortality; and

(6) provide for any other activities, programs, or strategies as identified by the community plan.

(e) LIMITATION.—Of the funds received through a grant under this section for a fiscal year, an eligible entity shall not use more than 10 percent for program evaluation.

(f) REPORTS ON PILOT PROGRAMS.—

(1) IN GENERAL.—Not later than 1 year after receiving a grant, and annually thereafter for the duration of the grant period, each entity that receives a grant under subsection (a) shall submit a report to the Secretary detailing its infant mortality pilot program.

(2) CONTENTS OF REPORT.—The reports required under paragraph (1) shall include information such as the methodology of, and outcomes and statistics from, the grantee's infant mortality pilot program.

(3) EVALUATION.—The Secretary shall use the reports required under paragraph (1) to evaluate, and conduct statistical research on, infant mortality pilot programs funded through this section.

(g) DEFINITIONS.—For the purposes of this section:

(1) DIRECTOR.—The term "Director" means the Director of the Centers for Disease Control and Prevention.

(2) ELIGIBLE ENTITY.—The term "eligible entity" means a State, county, city, territorial, or tribal health department that has submitted a proposal to the Secretary that the Secretary deems likely to reduce infant mortality rates within the standard metropolitan statistical area involved.

(3) TRIBAL.—The term "tribal" refers to an Indian tribe, a Tribal organization, or an Urban Indian organization, as such terms are defined in section 4 of the Indian Health Care Improvement Act.

(h) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated $10,000,000 for each of fiscal years 2010 through 2014.

[Pallone ECD1_005:**]**

In section 100(c) (relating to general definitions) redesignate paragraphs (14) through (25) as paragraphs (16) through (27), respectively.

In section 100(c), after paragraph 13, insert the following new paragraphs:

(14) INDIAN.—The term "Indian" has the meaning given such term in section 4 of the Indian Health Care Improvement Act (24 U.S.C. 1603).

(15) INDIAN HEALTH CARE PROVIDER.—The term "Indian health care provider" means a health care program operated by the Indian Health Service, an Indian tribe, tribal organization, or urban Indian organization as such terms are defined in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603).

In section 204(b) (relating to standards for QHBP offering entities) redesignate paragraph (8) as paragraph (9).

In section 204(b), after paragraph (7), insert the following new paragraph:

(8) SPECIAL RULES WITH RESPECT TO INDIAN ENROLLEES AND INDIAN HEALTH CARE PROVIDERS.—

(A) CHOICE OF PROVIDERS.—The entity shall—

(i) demonstrate to the satisfaction of the Commissioner that it has contracted with a sufficient number of Indian health care providers to ensure timely access to covered services furnished by such providers to individual Indians through the entity's Exchange-participating health benefits plan; and

(ii) agree to pay Indian health care providers, whether such providers are participating or non-participating providers with respect to the entity, for covered services provided to those enrollees who are eligible to receive services from such providers at a rate that is not less than the level and amount of payment which the entity would make for the services of a participating provider which is not an Indian health care provider.

(B) SPECIAL RULE RELATING TO DISCRIMINATION.—Provision of services by an Indian health care provider exclusively to Indians and their dependents shall not constitute discrimination under this Act.

In section 204(c), add at the end the following new paragraph:

(5) SPECIAL RULE RELATED TO COST-SHARING AND INDIAN HEALTH CARE PROVIDERS.—The contract under this section with a QHBP offering entity for a health benefits plan shall provide that if an individual who is an Indian is enrolled in such a plan and such individual receives a covered item or service from an Indian health care provider (regardless of whether such provider is in the plan's provider network), the cost sharing for such item or service shall be equal to the amount of cost-sharing that would be imposed if such item or service—

(A) had been furnished by another provider in the plan's provider network; or

(B) in the case that the plan has no such network, was furnished by a non-Indian provider.

In section 225 (relating to provider participation) strike subsection (b) and insert the following subsection:

(b) LICENSURE OR CERTIFICATION.—

(1) IN GENERAL.—Except as provided in paragraph (2), the Secretary shall not allow a health care provider to participate in the public health insurance option unless such provider is appropriately licensed or certified under State law.

(2) SPECIAL RULE FOR IHS FACILITIES AND PROVIDERS .—The requirements under paragraph (1) shall not apply to—

(A) a facility that is operated by the Indian Health Service;

(B) a facility operated by an Indian Tribe or tribal organization under the Indian Self Determination Act (Public Law 93-638);

(C) a health care professional employed by the Indian Health Service; or

(D) A health care professional—

(i) who is employed to provide health care services in a facility operated by an Indian Tribe or tribal organization under the Indian Self Determination Act; and

(ii) who is licensed or certified in any State.

[Ross16_001:]

Add at the end of subtitle F of title I of division A the following new section:

SEC. 158. STATE PROHIBITIONS ON DISCRIMINATION AGAINST HEALTH CARE PROVIDERS.

Notwithstanding any other provision of this Act (or any amendment made by this Act), this Act (and any amendment made by this Act) shall not supersede laws, as they now or hereinafter exist, of any State or jurisdiction designed to prohibit a health plan or insurer from discriminating with respect to participation, reimbursement, covered services, indemnification, or related requirements under a health plan or other health insurance coverage against a health care provider who is acting within the scope of that provider's license or certification under applicable State law.

[Rush_003:]

At the end of part 2 of subtitle B of title V of division C, add the following new section:

SEC. 2534. SECONDARY SCHOOL HEALTH SCIENCES TRAINING PROGRAM.

(a) PROGRAM.—The Secretary of Health and Human Services, acting through the Administrator of the Health Resources and Services Administration, and in consultation with the Secretary of Education, may establish a health sciences training program consisting of awarding grants and contracts under subsection (b) to prepare secondary school students for careers in health professions.

(b) DEVELOPMENT AND IMPLEMENTATION OF HEALTH SCIENCES CURRICULA.—The Secretary may make grants to, or enter into contracts with, eligible entities—

(1) to plan, develop, or implement secondary school health sciences curricula, including curricula in biology, chemistry, physiology, mathematics, nutrition, and other courses deemed appropriate by the Secretary to prepare students for associate's or bachelor's degree programs in health professions or bachelor's degree programs in health professions-related majors; and

(2) to increase the interest of secondary school students in applying to, and enrolling in, accredited associate's or bachelor's degree programs in health professions or bachelor's degree programs in health professions-related majors, including through—

(A) work-study programs;

(B) programs to increase awareness of careers in health professions; and

(C) other activities to increase such interest.

(c) ELIGIBILITY.—To be eligible for a grant or contract under subsection (b), an entity shall—

(1) be a local educational agency; and

(2) provide assurances that activities under the grant or contract will be carried out in partnership with an accredited health professions school or program, public or nonprofit private hospital, or public or private nonprofit entity.

(d) PREFERENCE.—In awarding grants and contracts under subsection (b), the Secretary shall give preference to entities that have a demonstrated record of the following:

(1) Graduating the greatest percentage, or significantly improving the percentage, of students who have exhibited mastery in secondary school State science standards.

(2) Graduating students of minority or disadvantaged backgrounds who are underrepresented in—

(A) associate's or bachelor's degree programs in health professions or bachelor's degree programs in health professions-related majors; or

(B) health professions.

(e) REPORT.—The Secretary shall submit to the Congress an annual report on the program carried out under this section.

(f) DEFINITIONS.—In this section:

(1) The term "health profession" means the profession of any member of the health workforce, as defined in section 764(i) of the Public Health Service Act, as added by section 2261.

(2) The term "local educational agency" has the meaning given to the term in section 9101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801).

(3) The term "secondary school"—

(A) means a secondary school, as defined in section 9101 of the Elementary and Secondary Education Act of 1965 (20 U.S.C. 7801); and

(B) includes any such school that is a middle school.

(g) AUTHORIZATION OF APPROPRIATIONS.—To carry out this section, there are authorized to be appropriated such sums as may be necessary for each of fiscal years 2010 through 2014.

[Rush 11__001:]

Add at the end of part 2 of subtitle B of title V of division C the following:

SEC. 2535. COLLABORATIVE CARE NETWORKS.

(a) PURPOSE.—The purpose of this section is to establish and provide assistance to collaborative care networks—

(1) to reduce the use of emergency departments, inpatient and other expensive resources of hospitals and other providers; and

(2) to provide more comprehensive and coordinated care to low-income vulnerable individuals without health insurance coverage.

(b) CREATION OF THE COLLABORATIVE CARE NETWORK PROGRAM.— Part D of title III of the Public Health Service Act (42 U.S.C. 254b et seq.), as amended by sections 2211 and 2231, is amended by inserting after subpart XII the following new subpart:

"Subpart XIII—Collaborative Care Network Program

"SEC. 340O. COLLABORATIVE CARE NETWORK PROGRAM.

"(a) IN GENERAL.—The Secretary may award grants to eligible entities for the purpose of establishing model projects to accomplish the following goals:

"(1) To reduce unnecessary use of items and services furnished in emergency departments of hospitals (especially to ensure that individuals without health insurance coverage or with inadequate health insurance coverage do not use the services of such department instead of the services of a primary care physician) through methods such as—

"(A) screening individuals who seek emergency department services for possible eligibility under relevant governmental health programs or for subsidies under such programs; and

"(B) providing such individuals with referrals for follow-up care and chronic condition care.

"(2) To manage chronic conditions to reduce their severity, negative health outcomes, and expense.

"(3) To encourage health care providers to coordinate their efforts so that the most vulnerable patient populations seek and obtain primary care.

"(4) To provide more comprehensive and coordinated care to vulnerable low income individuals and individuals without health insurance coverage or with inadequate coverage.

"(5) To provide mechanisms for improving both quality and efficiency of care for low-in come individuals and families, with an emphasis on those most likely to remain uninsured despite the existence of government programs to make health insurance more affordable.

"(6) To increase preventive services, including screening and counseling, to those who would otherwise not receive such screening, in order to improve health status and reduce long term complications and costs.

"(7) To ensure the availability of community-wide safety net services, including emergency and trauma care.

"(b) ELIGIBILITY AND PARTICIPANT SELECTION.—

"(1) ELIGIBLE PROGRAM PARTICIPANT.—For purposes of this section, the term 'eligible program participant' means a safety net hospital that provides services to a high volume of low-income patients, as determined by the Secretary, and that is to be a member of a collaborative care network described in subsection (d) and selected by the Secretary under paragraph (3) of this subsection.

"(2) APPLICATION.—An eligible program participant representing a collaborative care network described in subsection (d) shall submit to the Secretary an application in such form and manner and containing such information as specified by the Secretary. Such information shall at least—

"(A) identify the health care providers participating in the collaborative care network proposed by the applicant and in the case a Federally qualified health center is not

included as such a participant, the reason such a center is not so included;

"(B) include a description of how the providers plan to collaborate to provide comprehensive and integrated care for low-income individuals, including uninsured and underinsured individuals;

"(C) include a description of the organizational and joint governance structure of the collaborative care network in a manner so that it is clear how decisions will be made;

"(D) define the geographic areas and populations that the network intends to serve;

"(E) define the scope of services that the network intends to provide and identify any reasons why such services would not include a suggested core service identified by the Secretary under paragraph (4);

"(F) demonstrate the network's ability to meet the requirements of this section; and

"(G) provide assurances that (and include a plan demonstrating how) grant funds received by an eligible program participant shall be appropriately distributed among all health care providers participating in the collaborative care network.

"(3) SELECTION OF PARTICIPANTS.—

"(A) IN GENERAL.—The Secretary shall select eligible program participants to receive grants from applications submitted under paragraph (2) on the basis of quality of the proposal involved, geographic diversity (including different States and regions served and urban and rural diversity), and the number of low-income and uninsured individuals that the proposal intends to serve.

"(B) PRIORITY.—The Secretary shall give priority to proposals from eligible program participants that serve a high volume of low-income individuals.

"(C) RENEWAL.—In subsequent years, the Secretary may provide renewal grants to prior year grant recipients.

"(4) SUGGESTED CORE SERVICES.—For purposes of paragraph (2)(E), the Secretary shall develop a list of suggested core services to be provided by a collaborative care network. The Secretary may select an eligible program participant under paragraph (3), the application of which does not include all such services, if such application provides a reasonable explanation why such services are not proposed to be included, and the Secretary determines that the application is otherwise high quality.

"(5) TERMINATION AUTHORITY.—The Secretary may terminate selection of a collaborative care network under this section for good cause. Such good cause shall include a determination that the network has failed—

"(A) has failed to provide a comprehensive range of coordinated and integrated health care services as required under subsection (d)(3);

"(B) had failed to meet reasonable quality standards;

"(C) has misappropriated funds provided under this section; or

"(D) has failed to make progress toward accomplishing goals set out in subsection (a).

"(c) USE OF GRANT FUNDS.—Grant funds provided under the collaborative care network program shall be available to an eligible program participant (or consortium of participants) to create and support collaborative care networks (described in subsection (d)) that would carry out the following activities:

"(1) Assist low-income individuals without adequate health care coverage to—

"(A) access and appropriately use health services;

"(B) enroll in applicable public or private health insurance programs;

"(C) obtain referrals to and see a primary care provider in case such an individual does not have a primary care provider; and

"(D) obtain appropriate care for chronic conditions.

"(2) Improve heath care by providing case management, application assistance, and appropriate referrals such as through methods to—

"(A) create and meaningfully use a health information network to track patients across collaborative providers;

"(B) perform health outreach, such as by using neighborhood health workers who may inform individuals about the availability of safety net and primary care available through the collaborative care network;

"(C) provide for follow-up outreach to remind patients of appointments or follow-up care instructions;

"(D) provide transportation to individuals to and from the site of care;

"(E) expand the capacity to provide care at any provider participating in the collaborative care network, including through hiring new staff, opening new clinics or other provider sites after-hours, on weekends, or otherwise providing an urgent care alternative to an emergency department; and

"(F) provide a primary care provider or medical home for each network patient.

"(d) COLLABORATIVE CARE NETWORKS.—

"(1) IN GENERAL.—

"(A) DESCRIPTION.—A collaborative care network described in this subsection is a consortium of health care providers with a joint governance structure that provides a comprehensive range of coordinated and integrated health care services for low-income patient populations or medically underserved communities (whether or not such individuals receive benefits under title XVIII, XIX, or XXI of the Social Security Act, private or other health insurance or are uninsured or underinsured) that complies with any applicable minimum eligibility requirements that the Secretary may determine appropriate.

"(B) REQUIRED INCLUSION.—Each such network shall include

"(i) at least one eligible program participant; and

"(ii) at least one Federally qualified health center (as defined in section 1905(l)(2)(B) of such Act), unless no such a center serves the geographic area proposed to be served by the network, a center exists but refuses to participate, or a center places unreasonable conditions on such participation.

"(C) ADDITIONAL INCLUSIONS.—Each such network may include any of the following additional providers:

"(i) A hospital.

"(ii) A county or municipal department of health.

"(iii) A rural health clinic.

"(iv) A community clinic, including a mental health clinic, substance abuse clinic, or a reproductive health clinic.

"(v) A private practice physician or group practice.

"(vi) A nurse or physician assistant or group practice.

"(vii) An adult day care center.

"(viii) A home health provider.

"(ix) Any other type of provider specified by the Secretary, which has a desire to serve low-income and uninsured patients.

"(D) CONSTRUCTION.—Nothing in this section shall prohibit a single entity from qualifying as collaborative care network so long as such single entity meets the criteria of a collaborative care network. If the network does not include at least one Federally qualified health center (as defined in section 1905(l)(2)(B) of the Social Security Act), the application must explain the reason pursuant to subsection (b)(2)(A).

"(2) COMPREHENSIVE RANGE OF COORDINATED AND INTEGRATED HEALTH CARE SERVICES.—The Secretary may define criteria for evaluating the services offered by a collaborative care network. Such criteria may include the following:

"(A) Requiring collaborative care networks to include at least the suggested core services identified under subsection (b)(4), or whichever subset of the suggested core services is applicable to a particular network.

"(B) Requiring such networks to assign each patient of the network to a primary care provider responsible for managing that patient's care.

"(C) Requiring the services provided by a collaborative care network to include support services appropriate to meet the health needs of low-income populations in the network's community, which may include chronic care management, nutritional counseling, transportation, language services, enrollment counselors, social services and other services as proposed by the network.

"(D) Providing that the services provided by a collaborative care network may also include long term care services and other services not specified in this subsection.

"(E) Providing for the approval by the Secretary of a scope of collaborative care network services for each network that addresses an appropriate minimum scope of

work consistent with the setting of the network and the health professionals available in the community the network serves.

"(3) CLARIFICATION.—Participation in a collaborative care network shall not disqualify a health care provider from reimbursement under title XVIII, XIX, or XXI of the Social Security Act with respect to services otherwise reimbursable under such title. Nothing in this section shall prevent a collaborative care network that is otherwise eligible to contract with Medicare, a private health insurer, or any other appropriate entity to provide care under Medicare, under health insurance coverage offered by the insurer, or otherwise.

"(e) EVALUATIONS.—

"(1) PARTICIPANT REPORTS.—Beginning in the third year following an initial grant, each eligible program participant shall submit to the Secretary, with respect to each year the participant has received a grant, an evaluation on the activities carried out by the collaborative care network of such participant under the collaborative care network program and shall include—

"(A) the number of people served;

"(B) the most common health problems treated;

"(C) any reductions in emergency department use;

"(D) an accounting of how amounts received were used; and

"(E) to the extent requested by the Secretary, any quality measures or any other measures specified by the Secretary.

"(2) PROGRAM REPORTS.—The Secretary shall submit to Congress an annual evaluation (beginning not later than 6 months after the first reports under paragraph (1) are submitted) on the extent to which emergency department use was reduced as a result of the activities carried out by the participant under the program. Each such evaluation shall also include information on—

"(A) the prevalence of certain chronic conditions in various populations, including a comparison of such prevalence in the general population versus in the population of individuals with inadequate health insurance coverage;

"(B) demographic characteristics of the population of uninsured and underinsured individuals served by the collaborative care network involved; and

"(C) the conditions of such individuals for whom services were requested at such emergency departments of participating hospitals.

"(3) AUDIT AUTHORITY.—The Secretary may conduct periodic audits and request periodic spending reports of participants under the collaborative care network program.

"(f) CLARIFICATION.—Nothing in this section requires a provider to report individually identifiable information of an individual to government agencies unless the individual consents, consistent with HIPAA privacy and security law, as defined in section 3009(a)(2).

"(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2010 through 2015.".

[Sarbanes/Dingell Medicaid-FQHC_001:]

Add at the end of subtitle C of title VII of division B the following:

SEC. 1730C. FQHC COVERAGE.

Section 1905(l)(2)(B) of the Social Security Act (42 U.S.C. 1396d(l)(2)(B)) is amended—

(1) by striking "or" at the end of clause (iii);

(2) by striking the semicolon at the end of clause (iv) and inserting ", and"; and

(3) by inserting after clause (iv) the following new clause:

"(v) is receiving a grant under section 399Z–1 of the Public Health Service Act;".

[Sarbanes1_001:]

In part 1 of subtitle D of title I of division B, add at the end the following new section:

SEC. 1169A. MEDICARE SENIOR HOUSING PLANS.

Section 1859 of the Social Security Act (42 U.S.C. 1395w–28) is amended by adding at the end the following new subsection:

"(g) SPECIAL RULES FOR SENIOR HOUSING FACILITY PLANS.—

"(1) IN GENERAL.—Notwithstanding any other provision of this part, in the case of a Medicare Advantage senior housing facility plan described in paragraph (2), the service area of such plan may be limited to a senior housing facility in a geographic area.

"(2) MEDICARE ADVANTAGE SENIOR HOUSING FACILITY PLAN DESCRIBED.—For purposes of this subsection, a Medicare Advantage senior housing facility plan is a Medicare Advantage plan that—

"(A)(i) restricts enrollment of individuals under this part to individuals who reside in a continuing care retirement community (as defined in section 1852(l)(4)(B));

"(ii) provides primary care services onsite and has a ratio of accessible providers to beneficiaries that the Secretary determines is adequate, taking into consideration the number of residents onsite, the health needs of those residents, and the accessibility of providers offsite;

"(iii) provides transportation services for beneficiaries to providers outside of the facility; and

"(iv) makes meaningful use of health information technology (as defined in section 3000(5) of the Public Health Service Act (42 U.S.C. 300jj(5)); and

"(B) is offered by a Medicare Advantage organization that has offered at least 1 plan described in subparagraph (A) for at least 1 year prior to January 1, 2010, under a demonstration project established by the Secretary.

"(3) BUDGET NEUTRALITY.—The Secretary of Health and Human Services shall ensure that payments made to qualified health plans described in this Section are no greater than the payments that would have been made before the date of the enactment of this subsection, or that would have been made

had these beneficiaries been enrolled in the traditional fee for service Medicare program."

[Stupak_009:]

In section 1743(b)(3), strike subparagraph (B) and insert the following:

(B) in paragraph (1), by striking "are not subject to the requirements of this section" and inserting "are subject to the requirements of this section unless such drugs are subject to discounts under section 340B of the Public Health Service Act".

[Sutton 22_001:]

In section 144(b)(1), after "by individuals" insert the following: "through means such as the mail, by telephone, electronically, and in person".

[Waxman 340B-Integrity_001:]

Amend the heading of subtitle A of title V of division C to read:

Subtitle A—Drug Discount for Rural and Other Hospitals; 340B Program Integrity

After the heading of subtitle A of title V of division C, insert the following:

PART 1—DRUG DISCOUNT FOR RURAL AND OTHER HOSPITALS

At the end of subtitle A of title V of division C, add the following:

PART 2—340B PROGRAM INTEGRITY

SEC. 2505. IMPROVEMENTS TO 340B PROGRAM INTEGRITY.

(a) INTEGRITY IMPROVEMENTS.—Subsection (d) of section 340B (42 U.S.C. 256b) is amended to read as follows:

"(d) IMPROVEMENTS IN PROGRAM INTEGRITY.—

"(1) MANUFACTURER COMPLIANCE.—

"(A) IN GENERAL.—From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by manufacturers with the requirements of this section in order to prevent overcharges and other violations of the discounted pricing requirements specified in this section.

"(B) IMPROVEMENTS.—The improvements described in subparagraph (A) shall include the following:

"(i) The establishment of a process to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities, which shall include the following:

"(I) Developing and publishing, through an appropriate policy or regulatory issuance, standards and methodology for the calculation of ceiling prices under such subsection.

"(II) Comparing regularly the ceiling prices calculated by the Secretary with the quarterly pricing data that is reported by manufacturers to the Secretary.

"(III) Conducting periodic monitoring of sales transactions to covered entities.

"(IV) Inquiring into any discrepancies between ceiling prices and manufacturer pricing data that may be identified and taking, or requiring manufacturers to take, corrective action in response to such discrepancies.

"(ii) The establishment of procedures for the issuance of refunds to covered entities by manufacturers in the event that the Secretary finds there has been an overcharge, including the following:

"(I) Submission to the Secretary by manufacturers of an explanation of why and how the overcharge occurred, how the refunds will be calculated, and to whom the refunds will be issued.

"(II) Oversight by the Secretary to ensure that the refunds are issued accurately and within a reasonable period of time.

"(iii) Notwithstanding any other provision of law prohibiting the disclosure of ceiling prices or data used to calculate the ceiling price, the provision of access to covered entities through an Internet website of the Department of Health and Human Services or contractor to the applicable ceiling prices for covered drugs as calculated and verified by the Secretary in a manner that ensures protection of privileged pricing data from unauthorized disclosure.

"(iv) The development of a mechanism by which—

"(I) rebates, discounts, or other price concessions provided by manufacturers to other purchasers subsequent to the sale of covered drugs to covered entities are reported to the Secretary; and

"(II) appropriate credits and refunds are issued to covered entities if such rebates, discounts, or other price concessions have the effect of lowering the applicable ceiling price for the relevant quarter for the drugs involved.

"(v) The selective auditing of manufacturers and wholesalers by the Secretary or the Secretary's contractor to ensure the integrity of the drug discount program under this section.

"(vi) The establishment of a requirement that manufacturers and wholesalers use the identification system developed by the Secretary for purposes of facilitating the ordering, purchasing, and delivery of covered drugs under this section, including the processing of chargebacks for such drugs.

"(vii) The imposition of sanctions in the form of civil monetary penalties, which—

"(I) shall be assessed according to standards and procedures established in regulations to be promulgated by the Secretary within one year of the date of the enactment of the America's Affordable Health Choices Act of 2009;

"(II) shall not exceed $5,000 for each instance of overcharging a covered entity that may have occurred; and

"(III) shall apply to any manufacturer with an agreement under this section that knowingly charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price under subsection (a)(1) or that knowingly violates any other provision of this section.

"(2) COVERED ENTITY COMPLIANCE.—

"(A) IN GENERAL.—From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by covered entities with the requirements of this section in order to prevent diversion and violations of the duplicate discount provision and other requirements under subsection (a)(5).

"(B) IMPROVEMENTS.—The improvements described in subparagraph (A) shall include the following:

"(i) The development of procedures to enable and require covered entities to update at least annually the information on the Internet website of the Department of Health and Human Services relating to this section.

"(ii) The development of procedures for the Secretary to verify the accuracy of information regarding covered entities that is listed on the website described in clause (i).

"(iii) The development of more detailed guidance describing methodologies and options available to covered entities for billing covered drugs to State Medicaid agencies in a manner that avoids duplicate discounts pursuant to subsection (a)(5)(A).

"(iv) The establishment of a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, covered entities, and the Secretary for purposes of facilitating the ordering, purchasing, and delivery of covered drugs under this section, including the processing of chargebacks for such drugs.

"(v) The imposition of sanctions in the form of civil monetary penalties, which—

"(I) shall be assessed according to standards and procedures established in regulations promulgated by the Secretary;

"(II) shall not exceed $5,000 for each violation; and

"(III) shall apply to any covered entity that knowingly violates subparagraph (a)(5)(B) or knowingly and violates any other provision of this section.

"(vi) The exclusion of a covered entity from participation in the program under this section, for a period of time to be determined by the Secretary, in cases in which the Secretary determines, in accordance with standards and procedures established in regulations, that—

"(I) a violation of a requirement of this section was repeated and knowing; and

"(II) imposition of a monetary penalty would be insufficient to reasonably ensure compliance.

"(vii) The referral of matters as appropriate to the Food and Drug Administration, the Office of Inspector General of Department of Health and Human Services, or other Federal agencies.

"(3) ADMINISTRATIVE DISPUTE RESOLUTION PROCESS.—From amounts appropriated under paragraph (4), the Secretary may establish and implement an administrative process for the resolution of the following:

"(A) Claims by covered entities that manufacturers have violated the terms of their agreement with the Secretary under subsection (a)(1).

"(B) Claims by manufacturers that covered entities have violated subsection (a)(5)(A) or (a)(5)(B).

"(4) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection, such sums as may be necessary for fiscal year 2010 and each succeeding fiscal year.".

(b) CONFORMING AMENDMENTS.—Section 340B(a) (42 U.S.C. 256b(a)) is amended—

(1) by adding at the end of paragraph (1) the following: "Such agreement shall require that the manufacturer offer each covered entity covered drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price. Notwithstanding any other provision of law, if the Secretary requests a manufacturer to enter into a new agreement that complies with current law, the manufacturer will have the option of signing a new agreement or being determined to not have entered into an agreement with the Secretary that meets the requirements of this section."; and

(2) by adding at the end the following paragraph:

"(11) QUARTERLY REPORTS.—An agreement described in paragraph (1) shall require that the manufacturer furnish the Secretary with reports on a quarterly basis that include the following information:

"(A) The price for each covered drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the 'ceiling price').

"(B) The component information used to calculate the ceiling price as determined necessary to administer the requirements of the program under this section.

"(C) Rebates, discounts, and other price concessions provided by manufacturers to other purchasers subsequent to the sale of covered drugs to covered entities.".

[Welch 9_001:]

Amend paragraph (2) of section 1128H(h) of the Social Security Act, added by section 1451(a), to read as follows:

"(2) NO PREEMPTION OF ADDITIONAL REQUIREMENTS.—Paragraph (1) shall not preempt any statute or regulation of a State or political subdivision of a State that requires any of the following:

"(A) The disclosure or reporting of information not of the type required to be disclosed or reported under this section.

"(B) The disclosure or reporting , in any format, of information described in subsection (f)(9)(C), except in the case of information described in clause (i) of subsection (f)(9)(C).

"(C) The disclosure or reporting by any person or entity other than an applicable manufacturer (as so defined) or a covered recipient (as defined in subsection (f)).

"(D) The disclosure or reporting, in any format, of the type of information required to be disclosed or reported under this section to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes.

Nothing in paragraph (1) shall be construed to limit the discovery or admissibility of information described in this paragraph in a criminal, civil, or administrative proceeding.".

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