MEDICARE PRESCRIPTION DRUG AND MODERNIZATION ACT OF 2003

JUNE 25, 2003.—Ordered to be printed

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

REPORT

together with

DISSENTING AND ADDITIONAL VIEWS

[To accompany H.R. 2473]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 2473) to amend title XVIII of the Social Security Act to provide for a voluntary program for prescription drug coverage under the Medicare Program, to modernize the Medicare Program, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

	Page
Amendment	1
Purpose and Summary	151
Background and Need for Legislation	152
Hearings	152
Committee Consideration	152
Committee Votes	152
Committee Oversight Findings	183
Statement of General Performance Goals and Objectives	183
New Budget Authority, Entitlement Authority, and Tax Expenditures	183
Committee Cost Estimate	183
Congressional Budget Office Estimate	183
Federal Mandates Statement	183
Advisory Committee Statement	183
Constitutional Authority Statement	183
Applicability to Legislative Branch	183
Section-by-Section Analysis of the Legislation	183
Changes in Existing Law Made by the Bill, as Reported	238
Dissenting and Additional Views	239

AMENDMENT

The amendment is as follows:

Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; AMENDMENTS TO SOCIAL SECURITY ACT; REFERENCES TO BIPA AND SECRETARY; TABLE OF CONTENTS.

- (a) SHORT TITLE.—This Act may be cited as the "Medicare Prescription Drug and Modernization Act of 2003'
- (b) AMENDMENTS TO SOCIAL SECURITY ACT.—Except as otherwise specifically provided, whenever in this Act an amendment is expressed in terms of an amendment to or repeal of a section or other provision, the reference shall be considered to be made to that section or other provision of the Social Security Act.

 - (c) BIPA; Secretary.—In this Act:

 (1) BIPA.—The term "BIPA" means 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.
 (2) Secretary.—The term "Secretary" means the Secretary of Health and
 - Human Services.
- (d) Table of Contents.—The table of contents of this Act is as follows: Sec. 1. Short title; amendments to Social Security Act; references to BIPA and Secretary; table of contents.

TITLE I—MEDICARE PRESCRIPTION DRUG BENEFIT

Sec. 101. Establishment of a medicare prescription drug benefit.

"PART D-VOLUNTARY PRESCRIPTION DRUG BENEFIT PROGRAM

- "Sec. 1860D-1. Benefits; eligibility; enrollment; and coverage period.

 "Sec. 1860D-2. Requirements for qualified prescription drug coverage.
 "Sec. 1860D-3. Beneficiary protections for qualified prescription drug coverage.
 "Sec. 1860D-5. Process for and contracts with prescription drug plan (PDP) sponsors.
 "Sec. 1860D-6. Submission of bids and premiums.
 "Sec. 1860D-6. Submission of bids and premiums.
 "Sec. 1860D-7. Premium and cost-sharing subsidies for low-income individuals.
 "Sec. 1860D-9. Medicare Prescription Drug Trust Fund.
 "Sec. 1860D-9. Medicare Prescription Drug Trust Fund.
 "Sec. 1860D-10. Definitions; application to medicare advantage and EFFS programs; treatment of references to provisions in part C.
 Sec. 102. Offering of qualified prescription drug coverage under Medicare Advantage and enhanced fee-for-service (EFFS) program.
 Sec. 103. Medicaid amendments.
 "Sec. 1935. Special provisions relating to medicare prescription drug benefit.
 Sec. 104. Medigap transition.
 Sec. 105. Medicare prescription drug discount card and assistance program.
 Sec. 106. Disclosure of return information for purposes of carrying out medicare catastrophic prescription drug program. program.
 Sec. 107. State pharmaceutical assistance transition commission.

TITLE II—MEDICARE ENHANCED FEE-FOR-SERVICE AND MEDICARE ADVANTAGE PROGRAMS; MEDICARE COMPETITION

Sec. 200. Medicare modernization and revitalization.

Subtitle A-Medicare Enhanced Fee-for-Service Program

Sec. 201. Establishment of enhanced fee-for-service (EFFS) program under medicare

"PART E—ENHANCED FEE-FOR-SERVICE PROGRAM

"Sec. 1860E-1. Offering of enhanced fee-for-service plans throughout the United States.
"Sec. 1860E-2. Offering of enhanced fee-for-service (EFFS) plans.
"Sec. 1860E-3. Submission of bids; beneficiary savings; payment of plans.
"Sec. 1860E-4. Premiums; organizational and financial requirements; establishment of standards; contracts with EFFS organizations.

Subtitle B-Medicare Advantage Program

CHAPTER 1—IMPLEMENTATION OF PROGRAM

- Sec. 211. Implementation of medicare advantage program. Sec. 212. Medicare advantage improvements.

CHAPTER 2—IMPLEMENTATION OF COMPETITION PROGRAM

Sec. 221. Competition program beginning in 2006.

CHAPTER 3—ADDITIONAL REFORMS

- Sec. 231. Making permanent change in medicare advantage reporting deadlines and annual, coordinated election period.

 Sec. 232. Avoiding duplicative State regulation.
- Sec. 233. Specialized medicare advantage plans for special needs beneficiaries.
 Sec. 234. Medicare MSAs.
 Sec. 235. Extension of reasonable cost contracts.

Subtitle C-Application of FEHBP-Style Competitive Reforms

Sec. 241. Application of FEHBP-style competitive reform beginning in 2010.

TITLE III—COMBATTING WASTE, FRAUD, AND ABUSE

- Sec. 301. Medicare secondary payor (MSP) provisions.
 Sec. 302. Competitive acquisition of certain items and services.
 Sec. 303. Competitive acquisition of covered outpatient drugs and biologicals.
 Sec. 304. Demonstration project for use of recovery audit contractors.

TITLE IV—RURAL HEALTH CARE IMPROVEMENTS

- Sec. 401. Enhanced disproportionate share hospital (DSH) treatment for rural hospitals and urban hospitals with fewer than 100 beds.

 Sec. 402. Immediate establishment of uniform standardized amount in rural and small urban areas.

- Sec. 402. Immediate establishment of uniform standardized amount in rural and small urban areas.
 Sec. 403. Establishment of essential rural hospital classification.
 Sec. 404. More frequent update in weights used in hospital market basket.
 Sec. 405. Improvements to critical access hospital program.
 Sec. 406. Redistribution of unused resident positions.
 Sec. 407. Two-year extension of hold harmless provisions for small rural hospitals and sole community hospitals under prospective payment system for hospital outpatient department services.
 Sec. 408. Exclusion of certain rural health clinic and federally qualified health center services from the prospective payment system for skilled nursing facilities.
 Sec. 409. Recognition of attending nurse practitioners as attending physicians to serve hospice patients.
 Sec. 410. Improvement in payments to retain emergency capacity for ambulance services in rural areas.
 Sec. 411. Providing safe harbor for certain collaborative efforts that benefit medically underserved populations.
 Sec. 412. GAO study of geographic differences in payments for physicians' services.
 Sec. 413. Treatment of missing cost reporting periods for sole community hospitals.
 Sec. 414. Extension of telemedicine demonstration project.
 Sec. 415. Two-year increase for home health services furnished in a rural area.

TITLE V-PROVISIONS RELATING TO PART A

Subtitle A-Inpatient Hospital Services

- Sec. 501. Sec. 502. Sec. 503. Sec. 504. Sec. 505. 501. Revision of acute care hospital payment updates.
 502. Recognition of new medical technologies under inpatient hospital PPS.
 503. Increase in Federal rate for hospitals in Puerto Rico.
 504. Wage index adjustment reclassification reform .
 505. MedPAC report on specialty hospitals.

Subtitle B-Other Provisions

- Sec. 511. Payment for covered skilled nursing facility services. Sec. 512. Coverage of hospice consultation services.

TITLE VI-PROVISIONS RELATING TO PART B

Subtitle A-Physicians' Services

- Sec. 601. Revision of updates for physicians' services.
 Sec. 602. Studies on access to physicians' services.
 Sec. 603. MedPAC report on payment for physicians' services.
 Sec. 604. Inclusion of podiatrists and dentists under private contracting authority.
 Sec. 605. Establishment of floor on work geographic adjustment.

SUBTITLE B—PREVENTIVE SERVICES

- Sec. 611. Coverage of an initial preventive physical examination. Sec. 612. Coverage of cholesterol and blood lipid screening. Sec. 613. Waiver of deductible for colorectal cancer screening tests. Sec. 614. Improved payment for certain mammography services. Sec. 615. Medicare coverage of diabetes laboratory diagnostic tests.

Subtitle C—Other Services

- Sec. 621. Hospital outpatient department (HOPD) payment reform. Sec. 622. Payment for ambulance services. Sec. 623. Renal dialysis services.

- Sec. 623. Renal dialysis services.
 Sec. 624. One-year moratorium on therapy caps; provisions relating to reports.
 Sec. 625. Adjustment to payments for services furnished in ambulatory surgical centers.
 Sec. 626. Payment for certain shoes and inserts under the fee schedule for orthotics and prosthetics.
 Sec. 627. Waiver of part B late enrollment penalty for certain military retirees; special enrollment period.
 Sec. 628. Part B deductible.
 Sec. 629. Demonstration project for coverage of self-injected biologics for rheumatoid arthritis.

TITLE VII—PROVISIONS RELATING TO PARTS A AND B

Subtitle A—Home Health Services

Subtitle B-Direct Graduate Medical Education

- 701. Update in home health services.702. MedPAC study on medicare margins of home health agencies703. Demonstration project to clarify the definition of homebound.

Sec. 711. Extension of update limitation on high cost programs.

- Subtitle C-Chronic Care Improvement
- 721. Voluntary chronic care improvement under traditional fee-for-service.
 722. Chronic care improvement under medicare advantage and enhanced fee-for-service programs.
 723. Institute of Medicine report.
 724. MedPAC report.

Subtitle D-Other Provisions

- Sec. 731. Modifications to medicare payment advisory commission (MedPAC). Sec. 732. Demonstration project for medical adult day care services.

Sec. 733. Improvements in national and local coverage determination process to respond to changes in technology.

Sec. 734. Treatment of certain physician pathology services.

Sec. 735. Medicare pancreatic islet cell transplant demonstration project.

Sec. 736. Demonstration project for consumer-directed chronic outpatient services. TITLE VIII—MEDICARE BENEFITS ADMINISTRATION Sec. 801. Establishment of Medicare Benefits Administration. TITLE IX—REGULATORY REDUCTION AND CONTRACTING REFORM Subtitle A-Regulatory Reform Sec. 901. Construction; definition of supplier. "Supplier Sec. 902. Issuance of regulations. Sec. 903. Compliance with changes in regulations and policies. Sec. 904. Reports and studies relating to regulatory reform. Sec. 911. Increased flexibility in medicare administration. Sec. 912. Requirements for information security for medicare administrative contractors. Subtitle C-Education and Outreach Sec. 921. Provider education and technical assistance.

"Sec. 1889. Provider education and technical assistance.

Sec. 922. Small provider technical assistance demonstration program.

Sec. 923. Medicare Provider Ombudsman; Medicare Beneficiary Ombudsman.

Sec. 924. Beneficiary outreach demonstration program.

Sec. 925. Inclusion of additional information in notices to beneficiaries about skilled nursing facility benefits.

Sec. 926. Information on medicare-certified skilled nursing facilities in hospital discharge plans. Subtitle D-Appeals and Recovery Transfer of responsibility for medicare appeals.

Process for expedited access to review.
Revisions to medicare appeals process.
Prepayment review.
Recovery of overpayments.
Provider enrollment process; right of appeal.
Process for correction of minor errors and omissions without pursuing appeals process.
Prior determination process for certain items and services; advance beneficiary notices. Subtitle V-Miscellaneous Provisions Subtitle V—Miscellaneous Provisions

Sec. 941. Policy development regarding evaluation and management (E & M) documentation guidelines.

Sec. 942. Improvement in oversight of technology and coverage.

Sec. 943. Treatment of hospitals for certain services under medicare secondary payor (MSP) provisions.

Sec. 944. EMTALA improvements.

Sec. 945. Emergency Medical Treatment and Active Labor Act (EMTALA) technical advisory group.

Sec. 946. Authorizing use of arrangements to provide core hospice services in certain circumstances.

Sec. 947. Application of osha bloodborne pathogens standard to certain hospitals.

Sec. 948. BIPA-related technical amendments and corrections.

Sec. 949. Conforming authority to waive a program exclusion.

Sec. 950. Treatment of certain dental claims.

Sec. 951. Furnishing hospitals with information to compute dsh formula.

Sec. 952. Revisions to reassignment provisions.

Sec. 953. Other provisions.

TITLE X-MEDICAID

Sec. 1001. Medicaid disproportionate share hospital (DSH) payments.
 Sec. 1002. Clarification of inclusion of inpatient drug prices charged to certain public hospitals in the best price exemptions for the medicaid drug rebate program.

TITLE I—MEDICARE PRESCRIPTION DRUG **BENEFIT**

SEC. 101. ESTABLISHMENT OF A MEDICARE PRESCRIPTION DRUG BENEFIT.

- (a) IN GENERAL.—Title XVIII is amended-

 - (1) by redesignating part D as part F; and (2) by inserting after part C the following new part:

"PART D-VOLUNTARY PRESCRIPTION DRUG BENEFIT PROGRAM

"SEC. 1860D-1. BENEFITS; ELIGIBILITY; ENROLLMENT; AND COVERAGE PERIOD.

"(a) Provision of Qualified Prescription Drug Coverage Through Enroll-MENT IN PLANS.—Subject to the succeeding provisions of this part, each individual who is entitled to benefits under part A or is enrolled under part B is entitled to obtain qualified prescription drug coverage (described in section 1860D-2(a)) as fol-

"(1) MEDICARE-RELATED PLANS.—

"(A) MEDICARE ADVANTAGE.—If the individual is eligible to enroll in a Medicare Advantage plan that provides qualified prescription drug coverage under section 1851(j), the individual may enroll in such plan and obtain

coverage through such plan.

"(B) EFFS PLANS.—If the individual is eligible to enroll in an EFFS plan that provides qualified prescription drug coverage under part E under section 1860E–2(d), the individual may enroll in such plan and obtain coverage

through such plan.

"(C) MA-EFFS PLAN; MA-EFFS RX PLAN.—For purposes of this part, the term 'MA-EFFS plan' means a Medicare Advantage plan under part C and an EFFS plan under part E and the term 'MA-EFFS Rx plan' means a MA-EFFS plan insofar as such plan provides qualified prescription drug cov-

"(2) PRESCRIPTION DRUG PLAN.—If the individual is not enrolled in a MA-EFFS plan, the individual may enroll under this part in a prescription drug plan (as defined in section 1860D–10(a)(5)).

Such individuals shall have a choice of such plans under section 1860D–5(d).

(b) General Election Procedures

"(1) IN GENERAL.—An individual eligible to make an election under subsection (a) may elect to enroll in a prescription drug plan under this part, or elect the option of qualified prescription drug coverage under a MA-EFFS Rx plan under part C or part E, and to change such election only in such manner and form as may be prescribed by regulations of the Administrator of the Medicare Benefits Administration (appointed under section 1809(b)) (in this part referred to as the 'Medicare Benefits Administrator') and only during an election period prescribed in or under this subsection.

(2) ELECTION PERIODS.

"(A) IN GENERAL.—Except as provided in this paragraph, the election periods under this subsection shall be the same as the coverage election periods under the Medicare Advantage and EFFS programs under section 1851(e), including-

(i) annual coordinated election periods; and

"(ii) special election periods.

In applying the last sentence of section 1851(e)(4) (relating to discontinuance of an election during the first year of eligibility) under this subparagraph, in the case of an election described in such section in which the individual had elected or is provided qualified prescription drug coverage at the time of such first enrollment, the individual shall be permitted to enroll in a prescription drug plan under this part at the time of the election of coverage under the original fee-for-service plan.

"(B) Initial election periods.

"(i) Individuals currently covered.—In the case of an individual who is entitled to benefits under part A or enrolled under part B as of October 1, 2005, there shall be an initial election period of 6 months beginning on that date.

(ii) INDIVIDUAL COVERED IN FUTURE.—In the case of an individual who is first entitled to benefits under part A or enrolled under part B after such date, there shall be an initial election period which is the same as the initial enrollment period under section 1837(d).

"(C) ADDITIONAL SPECIAL ELECTION PERIODS.—The Administrator shall es-

tablish special election periods-

(i) in cases of individuals who have and involuntarily lose prescription drug coverage described in subsection (c)(2)(C);

"(ii) in cases described in section 1837(h) (relating to errors in enroll-

ment), in the same manner as such section applies to part B;
"(iii) in the case of an individual who meets such exceptional condi-

tions (including conditions provided under section 1851(e)(4)(D)) as the Administrator may provide; and

(iv) in cases of individuals (as determined by the Administrator) who become eligible for prescription drug assistance under title XIX under section 1935(d).

"(3) Information on Plans.—Information described in section 1860D-3(b)(1) on prescription drug plans shall be made available during election periods. "(c) GUARANTEED ISSUE; COMMUNITY RATING; AND NONDISCRIMINATION.

"(1) GUARANTEED ISSUE.

"(A) IN GENERAL.—An eligible individual who is eligible to elect qualified prescription drug coverage under a prescription drug plan or MA-EFFS Rx plan at a time during which elections are accepted under this part with respect to the plan shall not be denied enrollment based on any health statusrelated factor (described in section 2702(a)(1) of the Public Health Service Act) or any other factor.

"(B) MEDICARE ADVANTAGE LIMITATIONS PERMITTED.—The provisions of paragraphs (2) and (3) (other than subparagraph (C)(i), relating to default enrollment) of section 1851(g) (relating to priority and limitation on termination of election) shall apply to PDP sponsors under this subsection.

"(2) COMMUNITY-RATED PREMIUM.-

"(A) IN GENERAL.—In the case of an individual who enrolls under a prescription drug plan or in a MA-EFFS Rx plan during the individual's initial enrollment period under this part or maintains (as determined under sub-paragraph (C)) continuous prescription drug coverage since the date the in-dividual first qualifies to elect prescription drug coverage under this part, a PDP sponsor or entity offering a prescription drug plan or MA-EFFS Rx plan and in which the individual is enrolled may not deny, limit, or condition the coverage or provision of covered prescription drug benefits or vary or increase the premium under the plan based on any health status-related factor described in section 2702(a)(1) of the Public Health Service Act or any other factor.

(B) LATE ENROLLMENT PENALTY.—In the case of an individual who does not maintain such continuous prescription drug coverage (as described in subparagraph (C)), a PDP sponsor or an entity offering a MA-EFFS Rx plan may (notwithstanding any provision in this title) adjust the premium otherwise applicable or impose a pre-existing condition exclusion with respect to qualified prescription drug coverage in a manner that reflects additional actuarial risk involved. Such a risk shall be established through an appropriate actuarial opinion of the type described in subparagraphs (A) through

(C) of section 2103(c)(4).

"(C) CONTINUOUS PRESCRIPTION DRUG COVERAGE.—An individual is considered for purposes of this part to be maintaining continuous prescription drug coverage on and after the date the individual first qualifies to elect prescription drug coverage under this part if the individual establishes that as of such date the individual is covered under any of the following prescription drug coverage and before the date that is the last day of the 63day period that begins on the date of termination of the particular prescription drug coverage involved (regardless of whether the individual subsequently obtains any of the following prescription drug coverage):

(i) COVERAGE UNDER PRESCRIPTION DRUG PLAN OR MA-EFFS RX PLAN.—Qualified prescription drug coverage under a prescription drug plan or under a MA-EFFS Rx plan.

"(ii) MEDICAID PRESCRIPTION DRUG COVERAGE.—Prescription drug coverage under a medicaid plan under title XIX, including through the Program of All-inclusive Care for the Elderly (PACE) under section 1934, through a social health maintenance organization (referred to in section 4104(c) of the Balanced Budget Act of 1997), or through a demonstration project under part C that demonstrates the application of capitation payment rates for frail elderly medicare beneficiaries through the use of an interdisciplinary team and through the provision of primary care services to such beneficiaries by means of such a team at the nursing facility involved.

"(iii) Prescription drug coverage under group health plan.— Any outpatient prescription drug coverage under a group health plan, including a health benefits plan under the Federal Employees Health Benefit Plan under chapter 89 of title 5, United States Code, and a qualified retiree prescription drug plan as defined in section 1860D–8(f)(1), but only if (subject to subparagraph (E)(ii)) the coverage provides benefits at least equivalent to the benefits under a qualified pre-

scription drug plan.

"(iv) Prescription drug coverage under certain medigap poli-CIES.—Coverage under a medicare supplemental policy under section 1882 that provides benefits for prescription drugs (whether or not such coverage conforms to the standards for packages of benefits under section 1882(p)(1)), but only if the policy was in effect on January 1, 2006, and if (subject to subparagraph (E)(ii)) the coverage provides benefits at least equivalent to the benefits under a qualified prescription drug

"(v) STATE PHARMACEUTICAL ASSISTANCE PROGRAM.—Coverage of prescription drugs under a State pharmaceutical assistance program, but only if (subject to subparagraph (E)(ii)) the coverage provides benefits at least equivalent to the benefits under a qualified prescription drug

"(vi) VETERANS' COVERAGE OF PRESCRIPTION DRUGS.—Coverage of prescription drugs for veterans under chapter 17 of title 38, United States Code, but only if (subject to subparagraph (E)(ii)) the coverage provides benefits at least equivalent to the benefits under a qualified prescription drug plan.

"(D) CERTIFICATION.—For purposes of carrying out this paragraph, the certifications of the type described in sections 2701(e) of the Public Health Service Act and in section 9801(e) of the Internal Revenue Code shall also include a statement for the period of coverage of whether the individual involved had prescription drug coverage described in subparagraph (C).

(E) Disclosure.

"(i) IN GENERAL.—Each entity that offers coverage of the type described in clause (iii), (iv), (v), or (vi) of subparagraph (C) shall provide for disclosure, consistent with standards established by the Administrator, of whether such coverage provides benefits at least equivalent to the benefits under a qualified prescription drug plan.

"(ii) WAIVER OF LIMITATIONS.—An individual may apply to the Administrator to waive the requirement that coverage of such type provide benefits at least equivalent to the benefits under a qualified prescription drug plan, if the individual establishes that the individual was not adequately informed that such coverage did not provide such level of benefits.

"(F) CONSTRUCTION.—Nothing in this section shall be construed as preventing the disenrollment of an individual from a prescription drug plan or a MA-EFFS Rx plan based on the termination of an election described in section 1851(g)(3), including for non-payment of premiums or for other reasons specified in subsection (d)(3), which takes into account a grace period described in section 1851(g)(3)(B)(i).

"(3) NONDISCRIMINATION.—A PDP sponsor that offers a prescription drug plan in an area designated under section 1860D–4(b)(5) shall make such plan available to all eligible individuals residing in the area without regard to their health or economic status or their place of residence within the area.

"(d) Effective Date of Elections.

"(1) IN GENERAL.—Except as provided in this section, the Administrator shall provide that elections under subsection (b) take effect at the same time as the Administrator provides that similar elections under section 1851(e) take effect under section 1851(f).

(2) NO ELECTION EFFECTIVE BEFORE 2006.—In no case shall any election take

effect before January 1, 2006.

"(3) TERMINATION.—The Administrator shall provide for the termination of an election in the case of-

(A) termination of coverage under both part A and part B; and

"(B) termination of elections described in section 1851(g)(3) (including failure to pay required premiums).

"SEC. 1860D-2. REQUIREMENTS FOR QUALIFIED PRESCRIPTION DRUG COVERAGE.

"(a) REQUIREMENTS.—

"(1) IN GENERAL.—For purposes of this part and part C and part E, the term 'qualified prescription drug coverage' means either of the following:

'(A) STANDARD COVERAGE WITH ACCESS TO NEGOTIATED PRICES.—Standard coverage (as defined in subsection (b)) and access to negotiated prices under subsection (d).

"(B) ACTUARIALLY EQUIVALENT COVERAGE WITH ACCESS TO NEGOTIATED PRICES.—Coverage of covered outpatient drugs which meets the alternative coverage requirements of subsection (c) and access to negotiated prices under subsection (d), but only if it is approved by the Administrator, as provided under subsection (c).

"(2) PERMITTING ADDITIONAL OUTPATIENT PRESCRIPTION DRUG COVERAGE.

"(A) IN GENERAL.—Subject to subparagraph (B), nothing in this part shall be construed as preventing qualified prescription drug coverage from including coverage of covered outpatient drugs that exceeds the coverage required under paragraph (1), but any such additional coverage shall be limited to coverage of covered outpatient drugs.

"(B) DISAPPROVAL AUTHORITY.—The Administrator shall review the offering of qualified prescription drug coverage under this part or part C or E. If the Administrator finds, in the case of a qualified prescription drug coverage under a prescription drug plan or a MA-EFFS Rx plan, that the organization or sponsor offering the coverage is engaged in activities intended to discourage enrollment of classes of eligible medicare beneficiaries obtaining coverage through the plan on the basis of their higher likelihood of utilizing prescription drug coverage, the Administrator may terminate the con-

tract with the sponsor or organization under this part or part C or E. "(3) APPLICATION OF SECONDARY PAYOR PROVISIONS.—The provisions of section 1852(a)(4) shall apply under this part in the same manner as they apply under

part C.

"(b) STANDARD COVERAGE.—For purposes of this part, the 'standard coverage' is coverage of covered outpatient drugs (as defined in subsection (f)) that meets the following requirements: "(1) DEDUCTIBLE.-

DEDUCTIBLE.—The coverage has an annual deductible— '(A) for 2006, that is equal to \$250; or

"(B) for a subsequent year, that is equal to the amount specified under this paragraph for the previous year increased by the percentage specified in paragraph (5) for the year involved. Any amount determined under subparagraph (B) that is not a multiple of \$10

shall be rounded to the nearest multiple of \$10.

"(2) 80:20 BENEFIT STRUCTURE.

"(A) 20 PERCENT COINSURANCE.—The coverage has cost-sharing (for costs above the annual deductible specified in paragraph (1) and up to the initial coverage limit under paragraph (3)) that is—

"(i) equal to 20 percent; or

"(ii) is actuarially equivalent (using processes established under subsection (e)) to an average expected payment of 20 percent of such costs. "(B) USE OF TIERS.—Nothing in this part shall be construed as preventing a PDP sponsor from applying tiered copayments, so long as such tiered co-

payments are consistent with subparagraph (A).

"(3) INITIAL COVERAGE LIMIT.—Subject to paragraph (4), the coverage has an initial coverage limit on the maximum costs that may be recognized for pay-

ment purposes

"(A) for 2006, that is equal to \$2,000; or

"(B) for a subsequent year, that is equal to the amount specified in this paragraph for the previous year, increased by the annual percentage increase described in paragraph (5) for the year involved.

Any amount determined under subparagraph (B) that is not a multiple of \$25 shall be rounded to the nearest multiple of \$25.

"(4) CATASTROPHIC PROTECTION.

"(A) IN GENERAL.—Notwithstanding paragraph (3), the coverage provides benefits with no cost-sharing after the individual has incurred costs (as described in subparagraph (C)) for covered outpatient drugs in a year equal to the annual out-of-pocket threshold specified in subparagraph (B).

(B) ANNUAL OUT-OF-POCKET THRESHOLD.

"(i) IN GENERAL.—For purposes of this part, the 'annual out-of-pocket threshold' specified in this subparagraph is equal to \$3,500 (subject to

adjustment under clause (ii) and subparagraph (D)).

"(ii) Inflation increase.—For a year after 2006, the dollar amount specified in clause (i) shall be increased by the annual percentage increase described in paragraph (5) for the year involved. Any amount determined under the previous sentence that is not a multiple of \$100 shall be rounded to the nearest multiple of \$100.

"(C) APPLICATION.—In applying subparagraph (A)—
"(i) incurred costs shall only include costs incurred for the annual deductible (described in paragraph (1)), cost-sharing (described in paragraph (2)), and amounts for which benefits are not provided because of the application of the initial coverage limit described in paragraph (3); and

(ii) such costs shall be treated as incurred only if they are paid by the individual (or by another individual, such as a family member, on behalf of the individual), under section 1860D-7, under title XIX, or under a State pharmaceutical assistance program and the individual (or other individual) is not reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement (other than under such title or such program) for such costs.

"(D) ADJUSTMENT OF ANNUAL OUT-OF-POCKET THRESHOLDS.

(i) IN GENERAL.—For each enrollee in a prescription drug plan or in a MA-EFFS Rx plan whose adjusted gross income exceeds the income threshold as defined in clause (ii) for a year, the annual out-of-pocket threshold otherwise determined under subparagraph (B) for such year shall be increased by an amount equal to the percentage specified in clause (iii), multiplied by the lesser of— "(I) the amount of such excess; or

"(II) the amount by which the income threshold limit exceeds the income threshold.

Any amount determined under the previous sentence that is not a multiple of \$100 shall be rounded to the nearest multiple of \$100.

"(ii) INCOME THRESHOLD.—For purposes of clause (i)—
"(I) IN GENERAL.—Subject to subclause (II), the term 'income threshold' means \$60,000 and the term 'income threshold limit' means \$200,000.

"(II) INCOME INFLATION ADJUSTMENT.—In the case of a year beginning after 2006, each of the dollar amounts in subclause (I) shall be increased by an amount equal to such dollar amount multiplied by the cost-of-living adjustment determined under section 1(f)(3) of the Internal Revenue Code of 1986 for such year, determined by substituting 'calendar year 2005' for 'calendar year 1992', If any amount increased under the previous sentence is not a multiple of \$100, such amount shall be rounded to the nearest multiple of \$100.

"(iii) Percentage.—The percentage specified in this clause for a year

is a fraction (expressed as a percentage) equal to— "(I) the annual out-of-pocket threshold for a year under subparagraph (B) (determined without regard to this subparagraph), divided by

"(II) the income threshold under clause (ii) for that year.

If any percentage determined under the previous sentence that is not a multiple of ½10th of 1 percentage point, such percentage shall be rounded to the nearest multiple of ½10th of 1 percentage point.

(iv) Use of most recent return information.—For purposes of clause (i) for an enrollee for a year, except as provided in clause (v), the adjusted gross income of an individual shall be based on the most recent information disclosed to the Secretary under section 6109(1)(19) of the Internal Revenue Code of 1986 before the beginning of that year.

(v) Individual election to present most recent information re-GARDING INCOME.—The Secretary shall provide, in coordination with the Secretary of the Treasury, a procedure under which, for purposes of applying this subparagraph for a calendar year, instead of using the information described in clause (iv), an enrollee may elect to use more recent information, including information with respect to a taxable year ending in such calendar year. Such process shall-

"(I) require the enrollee to provide the Secretary with a copy of the relevant portion of the more recent return to be used under

this clause;

"(II) provide for the Medicare Beneficiary Ombudsman (under section 1810) offering assistance to such enrollees in presenting such information and the toll-free number under such section being a point of contact for beneficiaries to inquire as to how to present such information;

"(III) provide for the verification of the information in such return by the Secretary of the Treasury under section 6103(l)(19) of the Internal Revenue Code of 1986; and

"(IV) provide for the payment by the Secretary (in a manner specified by the Secretary) to the enrollee of an amount equal to the excess of the benefit payments that would have been payable under the plan if the more recent return information were used,

over the benefit payments that were made under the plan. In the case of a payment under subclause (III) for an enrollee under a prescription drug plan, the PDP sponsor of the plan shall pay to the Secretary the amount so paid, less the applicable reinsurance amount that would have applied under section 1860D-8(c)(1)(B) if such payment had been treated as an allowable cost under such section. Such plan payment shall be deposited in the Treasury to the credit of the Medicare Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund (under section 1841).

'(vi) Dissemination of information on process.—The Secretary shall provide, through the annual medicare handbook under section 1804(a), for a general description of the adjustment of annual out-ofpocket thresholds provided under this subparagraph, including the process for adjustment based upon more recent information and the confidentiality provisions of subparagraph (F), and shall provide for dissemination of a table for each year that sets forth the amount of the adjustment that is made under clause (i) based on the amount of an enrollee's adjusted gross income.

"(E) REQUESTING INFORMATION ON ENROLLEES.-

(i) IN GENERAL.—The Secretary shall, periodically as required to carry out subparagraph (D), transmit to the Secretary of the Treasury a list of the names and TINs of enrollees in prescription drug plans (or in MA-EFFS Rx plans) and request that such Secretary disclose to the Secretary information under subparagraph (A) of section 6103(l)(19) of the Internal Revenue Code of 1986 with respect to those enrollees for a specified taxable year for application in a particular calendar year. "(ii) DISCLOSURE TO PLAN SPONSORS.—In the case of a specified tax-

payer (as defined in section 6103(l)(19)(B) of the Internal Revenue Code of 1986) who is enrolled in a prescription drug plan or in an MA-EFFS Rx plan, the Secretary shall disclose to the entity that offers the plan the annual out-of-pocket threshold applicable to such individual under

subparagraph (D).

"(F) Maintaining confidentiality of information.—

"(i) IN GENERAL.—The amount of any increase in an annual out-ofpocket threshold under subparagraph (D) may not be disclosed by the Secretary except to a PDP sponsor or entity that offers a MA-EFFS Rx

plan to the extent necessary to carry out this part.

"(ii) CRIMINAL AND CIVIL PENALTIES FOR UNAUTHORIZED DISCLO-SURE.—A person who makes an unauthorized disclosure of information disclosed under section 6103(l)(19) of the Internal Revenue Code of 1986 (including disclosure of any increase in an annual out-of-pocket threshold under subparagraph (D)) shall be subject to penalty to the extent provided under-

"(I) section 7213 of such Code (relating to criminal penalty for

unauthorized disclosure of information);

"(II) section 7213A of such Code (relating to criminal penalty for

unauthorized inspection of returns or return information);

(III) section 7431 of such Code (relating to civil damages for unauthorized inspection or disclosure of returns and return informa-

"(IV) any other provision of the Internal Revenue Code of 1986;

"(V) any other provision of law.

"(iii) APPLICATION OF ADDITIONAL CIVIL MONETARY PENALTY FOR UN-AUTHORIZED DISCLOSURES.—In addition to any penalty otherwise provided under law, any person who makes an unauthorized disclosure of such information shall be subject to a civil monetary penalty of not to exceed \$10,000 for each such unauthorized disclosure. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to civil money penalties under this subparagraph in the same manner as they

apply to a penalty or proceeding under section 1128A(a). "(5) ANNUAL PERCENTAGE INCREASE.—For purposes of this part, the annual percentage increase specified in this paragraph for a year is equal to the annual percentage increase in average per capita aggregate expenditures for covered outpatient drugs in the United States for medicare beneficiaries, as determined by the Administrator for the 12-month period ending in July of the previous

year.

"(c) ALTERNATIVE COVERAGE REQUIREMENTS.—A prescription drug plan or MA-EFFS Rx plan may provide a different prescription drug benefit design from the standard coverage described in subsection (b) so long as the Administrator determines (based on an actuarial analysis by the Administrator) that the following requirements are met and the plan applies for, and receives, the approval of the Administrator for such benefit design:

"(1) Assuring at least actuarially equivalent coverage.—

"(A) Assuring equivalent value of total coverage.—The actuarial value of the total coverage (as determined under subsection (e)) is at least

equal to the actuarial value (as so determined) of standard coverage.

"(B) Assuring equivalent unsubsidized value of coverage.—The unsubsidized value of the coverage is at least equal to the unsubsidized value of standard coverage. For purposes of this subparagraph, the unsubsidized value of coverage is the amount by which the actuarial value of the coverage (as determined under subsection (e)) exceeds the actuarial value of the subsidy payments under section 1860D–8 with respect to such coverage. "(C) Assuring standard payment for costs at initial coverage

LIMIT.—The coverage is designed, based upon an actuarially representative pattern of utilization (as determined under subsection (e)), to provide for the payment, with respect to costs incurred that are equal to the initial coverage limit under subsection (b)(3), of an amount equal to at least the prod-

"(i) the amount by which the initial coverage limit described in subsection (b)(3) exceeds the deductible described in subsection (b)(1); and "(ii) 100 percent minus the cost-sharing percentage specified in subsection (b)(2)(A)(i).

"(2) CATASTROPHIC PROTECTION.—The coverage provides for beneficiaries the catastrophic protection described in subsection (b)(4).

"(d) Access to Negotiated Prices

"(1) IN GENERAL.—Under qualified prescription drug coverage offered by a PDP sponsor or an entity offering a MA-EFFS Rx plan, the sponsor or entity shall provide beneficiaries with access to negotiated prices (including applicable discounts) used for payment for covered outpatient drugs, regardless of the fact that no benefits may be payable under the coverage with respect to such drugs because of the application of cost-sharing or an initial coverage limit (described in subsection (b)(3)). Insofar as a State elects to provide medical assistance under title XIX for a drug based on the prices negotiated by a prescribin of drugs and the prices of the process of the table to such a subsection (b)(3). plan or MA-EFFS Rx plan under this part, the requirements of section 1927 shall not apply to such drugs. The prices negotiated by a prescription drug plan under this part, by a MA-EFFS Rx plan with respect to covered outpatient drugs, or by a qualified retiree prescription drug plan (as defined in section 1860D-8(f)(1)) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B, shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1927(c)(1)(C).

"(2) DISCLOSURE.—The PDP sponsor or entity offering a MA-EFFS Rx plan shall disclose to the Administrator (in a manner specified by the Administrator) the extent to which discounts or rebates or other remuneration or price concessions made available to the sponsor or organization by a manufacturer are passed through to enrollees through pharmacies and other dispensers or otherwise. The provisions of section 1927(b)(3)(D) shall apply to information disclosed to the Administrator under this paragraph in the same manner as such provi-

sions apply to information disclosed under such section.

"(3) AUDITS AND REPORTS.—To protect against fraud and abuse and to ensure proper disclosures and accounting under this part, in addition to any protections against fraud and abuse provided under section 1860D-4(b)(3)(C), the Administrator may periodically audit the financial statements and records of PDP sponsor or entities offering a MA-EFFS Rx plan.

"(e) Actuarial VALUATION; DETERMINATION OF ANNUAL PERCENTAGE IN-CREASES

'(1) Processes.—For purposes of this section, the Administrator shall establish processes and methods

(A) for determining the actuarial valuation of prescription drug coverage,

including-

(i) an actuarial valuation of standard coverage and of the reinsurance subsidy payments under section 1860D-8:

"(ii) the use of generally accepted actuarial principles and methodolo-

gies; and

"(iii) applying the same methodology for determinations of alternative coverage under subsection (c) as is used with respect to determinations of standard coverage under subsection (b); and

"(B) for determining annual percentage increases described in subsection

"(2) USE OF OUTSIDE ACTUARIES.—Under the processes under paragraph (1)(A), PDP sponsors and entities offering MA-EFFS Rx plans may use actuarial opinions certified by independent, qualified actuaries to establish actuarial values, but the Administrator shall determine whether such actuarial values meet the requirements under subsection (c)(1).

"(f) COVERED OUTPATIENT DRUGS DEFINED. "(1) In general.—Except as provided in this subsection, for purposes of this part, the term 'covered outpatient drug' means-

"(A) a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i) or (A)(ii) of section 1927(k)(2); or

"(B) a biological product described in clauses (i) through (iii) of subparagraph (B) of such section or insulin described in subparagraph (C) of such section and medical supplies associated with the injection of insulin (as de-

fined in regulations of the Secretary), and such term includes a vaccine licensed under section 351 of the Public Health Service Act and any use of a covered outpatient drug for a medically accepted indication (as defined in section 1927(k)(6)).

(2) Exclusions.

(A) IN GENERAL.—Such term does not include drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1927(d)(2), other than subparagraph (E) thereof (re-

lating to smoking cessation agents), or under section 1927(d)(3). "(B) AVOIDANCE OF DUPLICATE COVERAGE.—A drug prescribed for an individual that would otherwise be a covered outpatient drug under this part shall not be so considered if payment for such drug is available under part A or B for an individual entitled to benefits under part A and enrolled under part B.

"(3) APPLICATION OF FORMULARY RESTRICTIONS.—A drug prescribed for an individual that would otherwise be a covered outpatient drug under this part shall not be so considered under a plan if the plan excludes the drug under a plan if the plan excludes the drug under a plan if the plan excludes the drug under a plan if the plan excludes the drug under a plan if the plan excludes the drug under a plan if the plan excludes the drug under a plan if the plan excludes the drug under a plan in the plan excludes the plan excludes the drug under formulary and such exclusion is not successfully appealed under section 1860D-

3(f)(2). "(4) Application of general exclusion provisions.—A prescription drug plan or MA-EFFS Rx plan may exclude from qualified prescription drug coverage any covered outpatient drug—

"(A) for which payment would not be made if section 1862(a) applied to

part D; or

"(B) which are not prescribed in accordance with the plan or this part. Such exclusions are determinations subject to reconsideration and appeal pursuant to section 1860D-3(f).

"SEC. 1860D-3. BENEFICIARY PROTECTIONS FOR QUALIFIED PRESCRIPTION DRUG COV-

"(a) Guaranteed Issue, Community-Rated Premiums, Access to Negotiated PRICES, AND NONDISCRIMINATION.—For provisions requiring guaranteed issue, community-rated premiums, access to negotiated prices, and nondiscrimination, see sections 1860D–1(c)(1), 1860D–1(c)(2), 1860D–2(d), and 1860D–6(b), respectively.

(b) Dissemination of Information.

"(1) GENERAL INFORMATION.—A PDP sponsor shall disclose, in a clear, accurate, and standardized form to each enrollee with a prescription drug plan offered by the sponsor under this part at the time of enrollment and at least annually thereafter, the information described in section 1852(c)(1) relating to such plan. Such information includes the following:

"(A) Access to specific covered outpatient drugs, including access through

pharmacy networks.

"(B) How any formulary used by the sponsor functions, including the

drugs included in the formulary

"(C) Co-payments and deductible requirements, including the identification of the tiered or other co-payment level applicable to each drug (or class of drugs).

'(D) Grievance and appeals procedures.

Such information shall also be made available upon request to prospective enrollees

"(2) DISCLOSURE UPON REQUEST OF GENERAL COVERAGE, UTILIZATION, AND GRIEVANCE INFORMATION.—Upon request of an individual eligible to enroll under a prescription drug plan, the PDP sponsor shall provide the information described in section 1852(c)(2) (other than subparagraph (D)) to such individual. "(3) RESPONSE TO BENEFICIARY QUESTIONS.—Each PDP sponsor offering a pre-

scription drug plan shall have a mechanism for providing specific information to enrollees upon request. The sponsor shall make available on a timely basis, through an Internet website and in writing upon request, information on specific changes in its formulary.

"(4) CLAIMS INFORMATION.—Each PDP sponsor offering a prescription drug plan must furnish to each enrollee in a form easily understandable to such enrollees an explanation of benefits (in accordance with section 1806(a) or in a comparable manner) and a notice of the benefits in relation to initial coverage limit and the annual out-of-pocket threshold applicable to such enrollee for the current year, whenever prescription drug benefits are provided under this part (except that such notice need not be provided more often than monthly).

"(c) Access to Covered Benefits.-

"(1) Assuring pharmacy access.—

'(A) SECURING SUFFICIENT PARTICIPATION.—

"(i) PARTICIPATION OF ANY WILLING PHARMACY.—A PDP sponsor and an entity offering a MA-EFFS Rx plan shall permit the participation of any pharmacy that meets terms and conditions that the plan has es-

tablished.

"(ii) DISCOUNTS ALLOWED FOR NETWORK PHARMACIES.—A prescription drug plan and a MA-EFFS Rx plan may, notwithstanding clause (i), reduce coinsurance or copayments for its enrolled beneficiaries below the level otherwise provided for covered outpatient drugs dispensed through in-network pharmacies, but in no case shall such a reduction result in an increase in payments made by the Administrator under

section 1860D–8 to a plan.

"(iii) CONVENIENT ACCESS FOR NETWORK PHARMACIES.—The PDP sponsor of the prescription drug plan and the entity offering a MA-EFFS Rx plan shall secure the participation in its network of a sufficient number of pharmacies that dispense (other than by mail order) drugs directly to patients to ensure convenient access (consistent with rules of the Administrator established under subparagraph (B)). The Administrator shall establish convenient access rules under this clause that are no less favorable to enrollees than the rules for convenient access to pharmacies of the Secretary of Defense established as of June 1, 2003, for purposes of the TRICARE Retail Pharmacy (TRRx) program. Such rules shall include adequate emergency access for enrolled beneficiaries.

'(iv) LEVEL PLAYING FIELD.—Such a sponsor shall permit enrollees to receive benefits (which may include a 90-day supply of drugs or biologicals) through a community pharmacy, rather than through mail

order, with any differential in cost paid by such enrollees.

"(v) NOT REQUIRED TO ACCEPT INSURANCE RISK.—The terms and conditions under clause (i) may not require participating pharmacies to accept insurance risk as a condition of participation.

"(2) Use of standardized technology.-

"(A) IN GENERAL.—The PDP sponsor of a prescription drug plan and an entity offering a MA-EFFS Rx plan shall issue (and reissue, as appropriate) such a card (or other technology) that may be used by an enrollee to assure access to negotiated prices under section 1860D-2(d) for the purchase of prescription drugs for which coverage is not otherwise provided under the

"(B) STANDARDS.

(i) DEVELOPMENT.—The Administrator shall provide for the development or utilization of uniform standards relating to a standardized format for the card or other technology referred to in subparagraph (A). Such standards shall be compatible with standards established under part C of title XI.

(ii) APPLICATION OF ADVISORY TASK FORCE.—The advisory task force established under subsection (d)(3)(B)(ii) shall provide recommendations to the Administrator under such subsection regarding the stand-

ards developed under clause (i).

"(3) Requirements on development and application of formularies.—If a PDP sponsor of a prescription drug plan or an entity offering a MA-EFFS Rx plan uses a formulary, the following requirements must be met:

"(A) PHARMACY AND THERAPEUTIC (P&T) COMMITTEE.—The sponsor or enti-

ty must establish a pharmacy and therapeutic committee that develops and reviews the formulary. Such committee shall include at least one practicing physician and at least one practicing pharmacist both with expertise in the care of elderly or disabled persons and a majority of its members shall consist of individuals who are practicing physicians or practicing pharmacists (or both).

"(B) FORMULARY DEVELOPMENT.—In developing and reviewing the for-

mulary, the committee shall-

(i) base clinical decisions on the strength of scientific evidence and standards of practice, including assessing peer-reviewed medical literature, such as randomized clinical trials, pharmacoeconomic studies, outcomes research data, and such other information as the committee determines to be appropriate; and

"(ii) shall take into account whether including in the formulary particular covered outpatient drugs has therapeutic advantages in terms

of safety and efficacy.

"(C) Inclusion of drugs in all therapeutic categories.—The formulary must include drugs within each therapeutic category and class of covered outpatient drugs (although not necessarily for all drugs within such categories and classes). In establishing such classes, the committee shall take into account the standards published in the United States Pharmacopeia-Drug Information. The committee shall make available to the enrollees under the plan through the Internet or otherwise the clinical bases for the coverage of any drug on the formulary.

(D) PROVIDER AND PATIENT EDUCATION.—The committee shall establish policies and procedures to educate and inform health care providers and en-

rollees concerning the formulary.

"(E) NOTICE BEFORE REMOVING DRUG FROM FORMULARY FOR CHANGING PREFERRED OR TIER STATUS OF DRUG.—Any removal of a covered outpatient drug from a formulary and any change in the preferred or tier cost-sharing status of such a drug shall take effect only after appropriate notice is made available to beneficiaries and physicians.

"(F) PERIODIC EVALUATION OF PROTOCOLS.—In connection with the for-

mulary, a prescription drug plan shall provide for the periodic evaluation

and analysis of treatment protocols and procedures.

GRIEVANCES AND APPEALS TO APPLICATION OF RELATING FORMULARIES.-For provisions relating to grievances and appeals of cov-

erage, see subsections (e) and (f).

"(d) Cost and Utilization Management; Quality Assurance; Medication

THERAPY MANAGEMENT PROGRAM.—

"(1) IN GENERAL.—The PDP sponsor or entity offering a MA-EFFS Rx plan shall have in place, directly or through appropriate arrangements, with respect to covered outpatient drugs

"(A) an effective cost and drug utilization management program, including medically appropriate incentives to use generic drugs and therapeutic

interchange, when appropriate;

(B) quality assurance measures and systems to reduce medical errors and adverse drug interactions, including side-effects, and improve medication use, including a medication therapy management program described in paragraph (2) and for years beginning with 2007, an electronic prescription program described in paragraph (3); and

(C) a program to control fraud, abuse, and waste.

Nothing in this section shall be construed as impairing a PDP sponsor or entity from utilizing cost management tools (including differential payments) under all methods of operation.

"(2) Medication therapy management program.—

(A) IN GENERAL.—A medication therapy management program described in this paragraph is a program of drug therapy management and medication administration that may be furnished by a pharmacy provider and that is designed to assure, with respect to beneficiaries at risk for potential medication problems, such as beneficiaries with complex or chronic diseases (such as diabetes, asthma, hypertension, and congestive heart failure) or multiple prescriptions, that covered outpatient drugs under the prescription drug plan are appropriately used to optimize therapeutic outcomes through improved medication use and reduce the risk of adverse events, including adverse drug interactions. Such programs may distinguish between services in ambulatory and institutional settings.

(B) ELEMENTS.—Such program may include—

"(i) enhanced beneficiary understanding to promote the appropriate use of medications by beneficiaries and to reduce the risk of potential adverse events associated with medications, through beneficiary education, counseling, case management, disease state management programs, and other appropriate means;
"(ii) increased beneficiary adherence with prescription medication

regimens through medication refill reminders, special packaging, and

other compliance programs and other appropriate means; and

"(iii) detection of patterns of overuse and underuse of prescription drugs

"(C) DEVELOPMENT OF PROGRAM IN COOPERATION WITH LICENSED PHAR-MACISTS.—The program shall be developed in cooperation with licensed and practicing pharmacists and physicians.

"(D) CONSIDERATIONS IN PHARMACY FEES.—The PDP sponsor of a pre-scription drug program and an entity offering a MA-EFFS Rx plan shall take into account, in establishing fees for pharmacists and others providing services under the medication therapy management program, the resources

and time used in implementing the program. Each such sponsor or entity shall disclose to the Administrator upon request the amount of any such management or dispensing fees.

"(3) ELECTRONIC PRESCRIPTION PROGRAM.—

"(A) IN GENERAL.—An electronic prescription drug program described in this paragraph is a program that includes at least the following components, consistent with uniform standards established under subparagraph

(i) ELECTRONIC TRANSMITTAL OF PRESCRIPTIONS.—Prescriptions must be written and transmitted electronically (other than by facsimile), except in emergency cases and other exceptional circumstances recognized by the Administrator.

(ii) Provision of information to prescribing health care pro-FESSIONAL.—The program provides for the electronic transmittal to the prescribing health care professional of information that includes—

"(I) information (to the extent available and feasible) on the drug or drugs being prescribed for that patient and other information relating to the medical history or condition of the patient that may be relevant to the appropriate prescription for that patient

'(II) cost-effective alternatives (if any) for the use of the drug

prescribed; and

'(III) information on the drugs included in the applicable for-

mulary

To the extent feasible, such program shall permit the prescribing health care professional to provide (and be provided) related information on an interactive, real-time basis.

'(B) Standards.

(i) Development.—The Administrator shall provide for the development of uniform standards relating to the electronic prescription drug program described in subparagraph (A). Such standards shall be compatible with standards established under part C of title XI.

"(ii) ADVISORY TASK FORCE.—In developing such standards and the standards described in subsection (c)(2)(B)(i) the Administrator shall establish a task force that includes representatives of physicians, hospitals, pharmacies, beneficiaries, pharmacy benefit managers, individuals with expertise in information technology, and pharmacy benefit experts of the Departments of Veterans Affairs and Defense and other appropriate Federal agencies to provide recommendations to the Administrator on such standards, including recommendations relating to

"(I) The range of available computerized prescribing software and

hardware and their costs to develop and implement.

"(II) The extent to which such standards and systems reduce medication errors and can be readily implemented by physicians, pharmacies, and hospitals.

"(III) Efforts to develop uniform standards and a common software platform for the secure electronic communication of medication history, eligibility, benefit, and prescription information.

"(IV) Efforts to develop and promote universal connectivity and interoperability for the secure electronic exchange of such informa-

"(V) The cost of implementing such systems in the range of hospital and physician office settings and pharmacies, including hardware, software, and training costs.

"(VI) Implementation issues as they relate to part C of title XI, and current Federal and State prescribing laws and regulations and their impact on implementation of computerized prescribing. "(iii) Deadlines

"(I) The Administrator shall constitute the task force under clause (ii) by not later than April 1, 2004. "(II) Such task force shall submit recommendations to Adminis-

trator by not later than January 1, 2005

"(III) The Administrator shall provide for the development and promulgation, by not later than January 1, 2006, of national standards relating to the electronic prescription drug program described in clause (ii). Such standards shall be issued by a standards organization accredited by the American National Standards Institute (ANSI) and shall be compatible with standards established under part C of title XI.

"(4) Treatment of accreditation.—Section 1852(e)(4) (relating to treatment of accreditation) shall apply to prescription drug plans under this part with respect to the following requirements, in the same manner as they apply to plans under part C with respect to the requirements described in a clause of section 1852(e)(4)(B):

"(A) Paragraph (1) (including quality assurance), including medication

therapy management program under paragraph (2).

"(B) Subsection (c)(1) (relating to access to covered benefits).
"(C) Subsection (g) (relating to confidentiality and accuracy of enrollee

records).

"(5) Public DISCLOSURE OF PHARMACEUTICAL PRICES FOR EQUIVALENT DRUGS.—Each PDP sponsor and each entity offering a MA-EFFS Rx plan shall provide that each pharmacy or other dispenser that arranges for the dispensing of a covered outpatient drug shall inform the beneficiary at the time of purchase of the drug of any differential between the price of the prescribed drug to the enrollee and the price of the lowest cost available generic drug covered under the plan that is therapeutically equivalent and bioequivalent.

"(e) GRIEVANCE MECHANISM, COVERAGE DETERMINATIONS, AND RECONSIDER-

ATIONS.—

"(1) IN GENERAL.—Each PDP sponsor shall provide meaningful procedures for hearing and resolving grievances between the organization (including any entity or individual through which the sponsor provides covered benefits) and enrollees with prescription drug plans of the sponsor under this part in accordance with section 1852(f).

"(2) APPLICATION OF COVERAGE DETERMINATION AND RECONSIDERATION PROVI-

SIONS.—A PDP sponsor shall meet the requirements of paragraphs (1) through (3) of section 1852(g) with respect to covered benefits under the prescription drug plan it offers under this part in the same manner as such requirements apply to an organization with respect to benefits it offers under a plan under

part C.

"(3) Request for review of tiered formulary determinations.—In the case of a prescription drug plan offered by a PDP sponsor or a MA-EFFS Rx plan that provides for tiered cost-sharing for drugs included within a formulary and provides lower cost-sharing for preferred drugs included within the formulary, an individual who is enrolled in the plan may request coverage of a nonpreferred drug under the terms applicable for preferred drugs if the prescribing physician determines that the preferred drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual or both.

"(f) Appeals. "(1) IN GENERAL.—Subject to paragraph (2), a PDP sponsor shall meet the requirements of paragraphs (4) and (5) of section 1852(g) with respect to drugs (including a determination related to the application of tiered cost-sharing described in subsection (e)(3)) in the same manner as such requirements apply to

an organization with respect to benefits it offers under a plan under part C.

"(2) FORMULARY DETERMINATIONS.—An individual who is enrolled in a prescription drug plan offered by a PDP sponsor or in a MA-EFFS Rx plan may appeal to obtain coverage for a covered outpatient drug that is not on a formulary of the sponsor or entity offering the plan if the prescribing physician determines that the formulary drug for treatment of the same condition either would not be as effective for the individual or would have adverse effects for the individual or both.

"(g) Confidentiality and Accuracy of Enrollee Records.—A PDP sponsor that offers a prescription drug plan shall meet the requirements of section 1852(h) with respect to enrollees under the plan in the same manner as such requirements apply to an organization with respect to enrollees under part C. A PDP sponsor shall be treated as a covered entity for purposes of the provisions of subpart E of part 164 of title 45, Code of Federal Regulations, adopted pursuant to the authority of the Secretary under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S. C. 1320d-2 note).

"SEC. 1860D-4, REQUIREMENTS FOR AND CONTRACTS WITH PRESCRIPTION DRUG PLAN (PDP) SPONSORS.

"(a) GENERAL REQUIREMENTS.—Each PDP sponsor of a prescription drug plan shall meet the following requirements:

"(1) LICENSURE.—Subject to subsection (c), the sponsor is organized and licensed under State law as a risk-bearing entity eligible to offer health insurance or health benefits coverage in each State in which it offers a prescription

 $\widetilde{P}(2)$ Assumption of financial risk for unsubsidized coverage.—

"(A) In general.—Subject to subparagraph (B) and section 1860D–5(d)(2), the entity assumes full financial risk on a prospective basis for qualified prescription drug coverage that it offers under a prescription drug plan and that is not covered under section 1860D-8.

"(B) REINSURANCE PERMITTED.—The entity may obtain insurance or make

other arrangements for the cost of coverage provided to any enrollee.

"(3) SOLVENCY FOR UNLICENSED SPONSORS.—In the case of a sponsor that is not described in paragraph (1), the sponsor shall meet solvency standards established by the Administrator under subsection (d).

"(b) CONTRACT REQUIREMENTS.—

"(1) IN GENERAL.—The Administrator shall not permit the election under section 1860D—1 of a prescription drug plan offered by a PDP sponsor under this part, and the sponsor shall not be eligible for payments under section 1860D—2 on 1860D—2 whose the Administrator has an entered into a contract under this 7 or 1860D-8, unless the Administrator has entered into a contract under this subsection with the sponsor with respect to the offering of such plan. Such a contract with a sponsor may cover more than one prescription drug plan. Such contract shall provide that the sponsor agrees to comply with the applicable requirements and standards of this part and the terms and conditions of payment as provided for in this part.

"(2) NEGOTIATION REGARDING TERMS AND CONDITIONS.—The Administrator shall have the same authority to negotiate the terms and conditions of prescription drug plans under this part as the Director of the Office of Personnel Management has with respect to health benefits plans under chapter 89 of title 5, United States Code. In negotiating the terms and conditions regarding premiums for which information is submitted under section 1860D-6(a)(2), the Administrator shall take into account the subsidy payments under section 1860D-

"(3) Incorporation of Certain Medicare advantage contract requirements.—The following provisions of section 1857 shall apply, subject to subsection (c)(5), to contracts under this section in the same manner as they apply to contracts under section 1857(a):

"(A) MINIMUM ENROLLMENT.—Paragraphs (1) and (3) of section 1857(b). "(B) CONTRACT PERIOD AND EFFECTIVENESS.—Paragraphs (1) through (3) and (5) of section 1857(c).

"(C) Protections against fraud and beneficiary protections.—Section 1857(d).

"(D) Additional contract terms.—Section 1857(e); except that in applying section 1857(e)(2) under this part-

"(i) such section shall be applied separately to costs relating to this part (from costs under part C and part E);

"(ii) in no case shall the amount of the fee established under this subparagraph for a plan exceed 20 percent of the maximum amount of the fee that may be established under subparagraph (B) of such section; and

"(iii) no fees shall be applied under this subparagraph with respect to MA-EFFS Rx plans.

"(E) Intermediate sanctions.—Section 1857(g).

"(F) PROCEDURES FOR TERMINATION.—Section 1857(h).

"(4) RULES OF APPLICATION FOR INTERMEDIATE SANCTIONS.—In applying paragraph (3)(E)-(A) the reference in section 1857(g)(1)(B) to section 1854 is deemed a ref-

erence to this part; and "(B) the reference in section 1857(g)(1)(F) to section 1852(k)(2)(A)(ii) shall

not be applied.

"(5) SERVICE AREA REQUIREMENT.—For purposes of this part, the Administrator shall designate at least 10 areas covering the entire United States and to the extent practicable shall be consistent with EFFS regions established under section 1860E-1(a)(2).

"(c) WAIVER OF CERTAIN REQUIREMENTS TO EXPAND CHOICE.—

"(1) IN GENERAL.—In the case of an entity that seeks to offer a prescription drug plan in a State, the Administrator shall waive the requirement of subsection (a)(1) that the entity be licensed in that State if the Administrator determines, based on the application and other evidence presented to the Administrator, that any of the grounds for approval of the application described in paragraph (2) have been met.

(2) GROUNDS FOR APPROVAL.—The grounds for approval under this paragraph are the grounds for approval described in subparagraph (B), (C), and (D) of section 1855(a)(2), and also include the application by a State of any grounds

other than those required under Federal law.

"(3) APPLICATION OF WAIVER PROCEDURES.—With respect to an application for a waiver (or a waiver granted) under this subsection, the provisions of subpara-

graphs (E), (F), and (G) of section 1855(a)(2) shall apply.

(4) LICENSURE DOES NOT SUBSTITUTE FOR OR CONSTITUTE CERTIFICATION.— The fact that an entity is licensed in accordance with subsection (a)(1) does not deem the entity to meet other requirements imposed under this part for a PDP

"(5) REFERENCES TO CERTAIN PROVISIONS.—For purposes of this subsection, in applying provisions of section 1855(a)(2) under this subsection to prescription drug plans and PDP sponsors-

(A) any reference to a waiver application under section 1855 shall be treated as a reference to a waiver application under paragraph (1); and

"(B) any reference to solvency standards shall be treated as a reference to solvency standards established under subsection (d).

"(d) Solvency Standards for Non-Licensed Sponsors.—
"(1) Establishment.—The Administrator shall establish, by not later than October 1, 2004, financial solvency and capital adequacy standards that an entity that does not meet the requirements of subsection (a)(1) must meet to qualify as a PDP sponsor under this part.

"(2) Compliance with standards.—Each PDP sponsor that is not licensed by a State under subsection (a)(1) and for which a waiver application has been approved under subsection (c) shall meet solvency and capital adequacy standards established under paragraph (1). The Administrator shall establish certification procedures for such PDP sponsors with respect to such solvency standards in the manner described in section 1855(c)(2).

"(e) Relation to State Laws.-

"(1) IN GENERAL.—The standards established under this part shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency, except as provided in subsection (d)) with respect to prescription drug plans which are offered by PDP sponsors under this part.

"(2) Prohibition of state imposition of premium taxes.—No State may impose a premium tax or similar tax with respect to premiums paid to PDP sponsors for prescription drug plans under this part, or with respect to any payments made to such a sponsor by the Administrator under this part.

"SEC. 1860D-5. PROCESS FOR BENEFICIARIES TO SELECT QUALIFIED PRESCRIPTION DRUG COVERAGE.

"(a) In General.--The Administrator shall establish a process for the selection of the prescription drug plan or MA-EFFS Rx plan through which eligible individuals elect qualified prescription drug coverage under this part. "(b) Elements.—Such process shall include the following:

"(1) Annual, coordinated election periods, in which such individuals can change the qualifying plans through which they obtain coverage, in accordance with section 1860D–1(b)(2).

"(2) Active dissemination of information to promote an informed selection among qualifying plans based upon price, quality, and other features, in the manner described in (and in coordination with) section 1851(d), including the provision of annual comparative information, maintenance of a toll-free hotline, and the use of non-Federal entities.

"(3) Coordination of elections through filing with the entity offering a MA-EFFS Rx plan or a PDP sponsor, in the manner described in (and in coordination with) section 1851(c)(2).

"(4) Informing each enrollee before the beginning of each year of the annual out-of-pocket threshold applicable to the enrollee for that year under section

1860D-2(b)(4) at such time.

"(c) MA-EFFS RX ENROLLEE MAY ONLY OBTAIN BENEFITS THROUGH THE PLAN.— An individual who is enrolled under a MA-EFFS Rx plan may only elect to receive qualified prescription drug coverage under this part through such plan.

"(d) ASSURING ACCESS TO A CHOICE OF QUALIFIED PRESCRIPTION DRUG COV-

ERAGE.—

"(1) CHOICE OF AT LEAST TWO PLANS IN EACH AREA.—

"(A) IN GENERAL.—The Administrator shall assure that each individual

"(A) In GENERAL.—The Administrator shall assure that each individual assure that each individual to the shareful to the share is residing in an area in the United States has available, consistent with subparagraph (B), a choice of enrollment in at least two qualifying plans (as defined in paragraph (5)) in the area in which the individual resides, at least one of which is a prescription drug plan.

"(B) REQUIREMENT FOR DIFFERENT PLAN SPONSORS.—The requirement in subparagraph (A) is not satisfied with respect to an area if only one PDP sponsor or one entity that offers a MA-EFFS Rx plan offers all the quali-

fying plans in the area.

"(2) Guaranteeing access to coverage.—In order to assure access under paragraph (1) and consistent with paragraph (3), the Administrator may provide partial underwriting of risk for a PDP sponsor to expand the service area under an existing prescription drug plan to adjoining or additional areas or to establish such a plan (including offering such a plan on a regional or nationwide basis), but only so long as (and to the extent) necessary to assure the access guaranteed under paragraph (1).

"(3) LIMITATION ON AUTHORITY.—In exercising authority under this sub-

section, the Administrator

"(A) shall not provide for the full underwriting of financial risk for any PDP sponsor; and

"(B) shall seek to maximize the assumption of financial risk by PDP spon-

sors or entities offering a MA-EFFS Rx plan.

"(4) REPORTS.—The Administrator shall, in each annual report to Congress under section 1809(f), include information on the exercise of authority under this subsection. The Administrator also shall include such recommendations as may be appropriate to minimize the exercise of such authority, including minimizing the assumption of financial risk.

(5) QUALIFYING PLAN DEFINED.—For purposes of this subsection, the term

'qualifying plan' means a prescription drug plan or a MA-EFFS Rx plan.

"SEC. 1860D-6. SUBMISSION OF BIDS AND PREMIUMS.

"(a) Submission of Bids, Premiums, and Related Information.-

"(1) IN GENERAL.—Each PDP sponsor shall submit to the Administrator the information described in paragraph (2) in the same manner as information is submitted by an organization under section 1854(a)(1).

(2) INFORMATION SUBMITTED.—The information described in this paragraph

is the following:

"(A) COVERAGE PROVIDED.—Information on the qualified prescription drug coverage to be provided.

"(B) ACTUARIAL VALUE.—Information on the actuarial value of the cov-

"(C) BID AND PREMIUM.—Information on the bid and the premium for the coverage, including an actuarial certification of—

"(i) the actuarial basis for such bid and premium;

"(ii) the portion of such bid and premium attributable to benefits in excess of standard coverage:

"(iii) the reduction in such bid resulting from the reinsurance subsidy payments provided under section 1860D-8(a)(2); and

(iv) the reduction in such premium resulting from the direct and reinsurance subsidy payments provided under section 1860D-8.

"(D) ADDITIONAL INFORMATION.—Such other information as the Adminis-

trator may require to carry out this part.

"(3) REVIEW OF INFORMATION; NEGOTIATION AND APPROVAL OF PREMIUMS.— "(A) IN GENERAL.—Subject to subparagraph (B), the Administrator shall review the information filed under paragraph (2) for the purpose of conducting negotiations under section 1860D-4(b)(2) (relating to using OPMlike authority under the FEHBP). The Administrator, using the information provided (including the actuarial certification under paragraph (2)(C)) shall approve the premium submitted under this subsection only if the premium accurately reflects both (i) the accuarial value of the benefits provided, and (ii) the 73 percent average subsidy provided under section 1860D-8 for the standard benefit. The Administrator shall apply actuarial principles to approval of a premium under this part in a manner similar to the manner in which those principles are applied in establishing the monthly part B premium under section 1839.

"(B) EXCEPTION.—In the case of a plan described in section 1851(a)(2)(C), the provisions of subparagraph (A) shall not apply and the provisions of paragraph (5)(B) of section 1854(a), prohibiting the review, approval, or disapproval of amounts described in such paragraph, shall apply to the negotiation and rejection of the monthly bid amounts and proportion referred to

in subparagraph (A).

"(b) Uniform Bid and Premium.—

"(1) IN GENERAL.—The bid and premium for a prescription drug plan under this section may not vary among enrollees in the plan in the same service area.

"(2) Construction.—Nothing in paragraph (1) shall be construed as preventing the imposition of a late enrollment penalty under section 1860D-1(c)(2)(B).

"(c) COLLECTION.

"(1) Beneficiary's option of payment through withholding from social SECURITY PAYMENT OR USE OF ELECTRONIC FUNDS TRANSFER MECHANISM.—In accordance with regulations, a PDP sponsor shall permit each enrollee, at the enrollee's option, to make payment of premiums under this part to the sponsor through withholding from benefit payments in the manner provided under section 1840 with respect to monthly premiums under section 1839 or through an electronic funds transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account) or otherwise. All premium payments that are withheld under this paragraph shall be credited to the Medicare Prescription Drug Trust Fund and shall be paid to the PDP sponsor involved.

"(2) OFFSETTING.—Reductions in premiums for coverage under parts A and B as a result of a selection of a MA-EFFS Rx plan may be used to reduce the pre-

mium otherwise imposed under paragraph (1).

"(d) Acceptance of Reference Premium Amount as Full Premium for Sub-SIDIZED LOW-INCOME INDIVIDUALS IF NO STANDARD (OR EQUIVALENT) COVERAGE IN AN AREA

(1) IN GENERAL.—If there is no standard prescription drug coverage (as defined in paragraph (2)) offered in an area, in the case of an individual who is eligible for a premium subsidy under section 1860D-7 and resides in the area, the PDP sponsor of any prescription drug plan offered in the area (and any entity offering a MA-EFFS Rx plan in the area) shall accept the reference premium amount (under paragraph (3)) as payment in full for the premium charge for qualified prescription drug coverage.

"(2) STANDARD PRESCRIPTION DRUG COVERAGE DEFINED.—For purposes of this subsection, the term 'standard prescription drug coverage' means qualified prescription drug coverage that is standard coverage or that has an actuarial value

equivalent to the actuarial value for standard coverage.

(3) Reference Premium amount defined.—For purposes of this subsection, the term 'reference premium amount' means, with respect to qualified prescription drug coverage offered under-

'(A) a prescription drug plan that—

"(i) provides standard coverage (or alternative prescription drug coverage the actuarial value of which is equivalent to that of standard cov-

erage), the plan's PDP premium; or

"(ii) provides alternative prescription drug coverage the actuarial value of which is greater than that of standard coverage, the plan's PDP premium multiplied by the ratio of (I) the actuarial value of standard coverage, to (II) the actuarial value of the alternative coverage; "(B) an EFFS plan, the EFFS monthly prescription drug beneficiary premium (as defined in section 1860E–4(a)(3)(B)); or

"(C) a Medicare Advantage, the Medicare Advantage monthly prescription drug beneficiary premium (as defined in section 1854(b)(2)(B)).

For purposes of subparagraph (A), the term 'PDP premium' means, with respect to a prescription drug plan, the premium amount for enrollment under the plan under this part (determined without regard to any low-income subsidy under section 1860D–7 or any late enrollment penalty under section 1860D–1(c)(2)(B)).

"SEC. 1860D-7. PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-INCOME INDIVIDUALS.

"(a) Income-Related Subsidies for Individuals With Income Below 150 Per-CENT OF FEDERAL POVERTY LEVEL.

"(1) Full premium subsidy and reduction of cost-sharing for individ-UALS WITH INCOME BELOW 135 PERCENT OF FEDERAL POVERTY LEVEL.—In the case of a subsidy eligible individual (as defined in paragraph (4)) who is determined to have income that does not exceed 135 percent of the Federal poverty level, the individual is entitled under this section

"(A) to an income-related premium subsidy equal to 100 percent of the

amount described in subsection (b)(1); and

"(B) subject to subsection (c), to the substitution for the beneficiary costsharing described in paragraphs (1) and (2) of section 1860D-2(b) (up to the initial coverage limit specified in paragraph (3) of such section) of amounts that do not exceed \$2 for a multiple source or generic drug (as described in section 1927(k)(7)(A)) and \$5 for a non-preferred drug.

"(2) SLIDING SCALE PREMIUM SUBSIDY FOR INDIVIDUALS WITH INCOME ABOVE 135, BUT BELOW 150 PERCENT, OF FEDERAL POVERTY LEVEL.—In the case of a subsidy eligible individual who is determined to have income that exceeds 135 percent, but does not exceed 150 percent, of the Federal poverty level, the individual is entitled under this section to an income-related premium subsidy determined on a linear sliding scale ranging from 100 percent of the amount described in subsection (b)(1) for individuals with incomes at 135 percent of such level to 0 percent of such amount for individuals with incomes at 150 percent of such level.

"(3) CONSTRUCTION.—Nothing in this section shall be construed as preventing a PDP sponsor or entity offering a MA-EFFS Rx plan from reducing to 0 the (4) DETERMINATION OF ELIGIBILITY.—

"(A) SUBSIDY ELIGIBLE INDIVIDUAL DEFINED.—For purposes of this section, subject to subparagraph (D), the term 'subsidy eligible individual' means an individual who

(i) is eligible to elect, and has elected, to obtain qualified prescrip-

tion drug coverage under this part;
"(ii) has income below 150 percent of the Federal poverty line; and "(iii) meets the resources requirement described in subparagraph (D)

"(B) DETERMINATIONS.—The determination of whether an individual residing in a State is a subsidy eligible individual and the amount of such individual's income shall be determined under the State medicaid plan for the State under section 1935(a) or by the Social Security Administration. In the case of a State that does not operate such a medicaid plan (either under title XIX or under a statewide waiver granted under section 1115), such determination shall be made under arrangements made by the Administrator. There are authorized to be appropriated to the Social Security Administration such sums as may be necessary for the determination of eligibility under this subparagraph.

"(C) INCOME DETERMINATIONS.—For purposes of applying this section— (i) income shall be determined in the manner described in section

1905(p)(1)(B); and

"(ii) the term 'Federal poverty line' means the 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.

"(D) RESOURCE STANDARD APPLIED TO BE BASED ON TWICE SSI RESOURCE STANDARD.—The resource requirement of this subparagraph is that an individual's resources (as determined under section 1613 for purposes of the supplemental security income program) do not exceed-

(i) for 2006 twice the maximum amount of resources that an indi-

vidual may have and obtain benefits under that program; and

(ii) for a subsequent year the resource limitation established under this clause 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 resource limitation established under clause (ii) that is not a multiple of \$10 shall be rounded to the nearest multiple of \$10.

"(E) TREATMENT OF TERRITORIAL RESIDENTS.—In the case of an individual who is not a resident of the 50 States or the District of Columbia, the individual is not eligible to be a subsidy eligible individual but may be eligible for financial assistance with prescription drug expenses under section

"(F) TREATMENT OF CONFORMING MEDIGAP POLICIES.—For purposes of this section, the term 'qualified prescription drug coverage' includes a medicare supplemental policy described in section 1860D–8(b)(4).

"(5) INDEXING DOLLAR AMOUNTS.—
"(A) FOR 2007.—The dollar amounts applied under paragraphs (1)(B) for 2007 shall be the dollar amounts specified in such paragraph increased by the annual percentage increase described in section 1860D-2(b)(5) for 2007.

"(B) FOR SUBSEQUENT YEARS.—The dollar amounts applied under paragraph (1)(B) for a year after 2007 shall be the amounts (under this paragraph).

graph) applied under paragraph (1)(B) for the preceding year increased by the annual percentage increase described in section 1860D–2(b)(5) (relating to growth in medicare prescription drug costs per beneficiary) for the year involved.

"(b) Premium Subsidy Amount.—

"(1) IN GENERAL.—The premium subsidy amount described in this subsection for an individual residing in an area is the benchmark premium amount (as defined in paragraph (2)) for qualified prescription drug coverage offered by the prescription drug plan or the MA-EFFS Rx plan in which the individual is en-

"(2) BENCHMARK PREMIUM AMOUNT DEFINED.—For purposes of this subsection, the term 'benchmark premium amount' means, with respect to qualified prescription drug coverage offered under

"(A) a prescription drug plan that—

"(i) provides standard coverage (or alternative prescription drug coverage the actuarial value of which is equivalent to that of standard coverage), the premium amount for enrollment under the plan under this part (determined without regard to any subsidy under this section or any late enrollment penalty under section 1860D–1(c)(2)(B)); or

"(ii) provides alternative prescription drug coverage the actuarial value of which is greater than that of standard coverage, the premium amount described in clause (i) multiplied by the ratio of (I) the actuarial value of standard coverage, to (II) the actuarial value of the alter-

native coverage; or

"(B) a MA-EFFS Rx plan, the portion of the premium amount that is attributable to st 1853(a)(1)(A)(ii)(II)). statutory drug benefits (described

"(c) Rules in Applying Cost-Sharing Subsidies.-

(1) IN GENERAL.—In applying subsection (a)(1)(B), nothing in this part shall be construed as preventing a plan or provider from waiving or reducing the amount of cost-sharing otherwise applicable.

"(2) LIMITATION ON CHARGES.—In the case of an individual receiving cost-sharing subsidies under subsection (a)(1)(B), the PDP sponsor or entity offering

a MA-EFFS Rx plan may not charge more than \$5 per prescription.

"(3) APPLICATION OF INDEXING RULES.—The provisions of subsection (a)(5) shall apply to the dollar amount specified in paragraph (2) in the same manner as they apply to the dollar amounts specified in subsections (a)(1)(B).

"(d) ADMINISTRATION OF SUBSIDY PROGRAM.—The Administrator shall provide a process whereby, in the case of an individual who is determined to be a subsidy eligible individual and who is enrolled in prescription drug plan or is enrolled in a MA-EFFS Rx plan-

"(1) the Administrator provides for a notification of the PDP sponsor or the entity offering the MA-EFFS Rx plan involved that the individual is eligible for a subsidy and the amount of the subsidy under subsection (a);

"(2) the sponsor or entity involved reduces the premiums or cost-sharing otherwise imposed by the amount of the applicable subsidy and submits to the Administrator information on the amount of such reduction; and

(3) the Administrator periodically and on a timely basis reimburses the spon-

sor or entity for the amount of such reductions.

The reimbursement under paragraph (3) with respect to cost-sharing subsidies may be computed on a capitated basis, taking into account the actuarial value of the subsidies and with appropriate adjustments to reflect differences in the risks actually involved

(e) Relation to Medicaid Program.—

"(1) IN GENERAL.—For provisions providing for eligibility determinations, and additional financing, under the medicaid program, see section 1935.

(2) MEDICAID PROVIDING WRAP AROUND BENEFITS.—The coverage provided under this part is primary payor to benefits for prescribed drugs provided under the medicaid program under title XIX consistent with section 1935(d)(1).

"(3) COORDINATION.—The Administrator shall develop and implement a plan for the coordination of prescription drug benefits under this part with the benefits provided under the medicaid program under title XIX, with particular attention to insuring coordination of payments and prevention of fraud and abuse. In developing and implementing such plan, the Administrator shall involve the Secretary, the States, the data processing industry, pharmacists, and pharmaceutical manufacturers, and other experts.

"SEC. 1860D-8. SUBSIDIES FOR ALL MEDICARE BENEFICIARIES FOR QUALIFIED PRESCRIP-TION DRUG COVERAGE.

"(a) Subsidy Payment.—In order to reduce premium levels applicable to qualified prescription drug coverage for all medicare beneficiaries consistent with an overall subsidy level of 73 percent, to reduce adverse selection among prescription drug plans and MA-EFFS Rx plans, and to promote the participation of PDP sponsors under this part, the Administrator shall provide in accordance with this section for payment to a qualifying entity (as defined in subsection (b)) of the following subsidies:

"(1) DIRECT SUBSIDY.—In the case of an enrollee enrolled for a month in a prescription drug plan or a MA-EFFS Rx plan, a direct subsidy equal to 43 percent of the national average monthly bid amount (computed under subsection (g)) for that month.

"(2) Subsidy through reinsurance.—In the case of an enrollee enrolled for a month in a prescription drug plan or a MA-EFFS Rx plan, the reinsurance payment amount (as defined in subsection (c)), which in the aggregate is 30 percent of the total payments made by qualifying entities for standard coverage under the respective plan, for excess costs incurred in providing qualified prescription drug coverage—

"(A) for enrollees with a prescription drug plan under this part; and

"(B) for enrollees with a MA-EFFS Rx plan.

"(3) EMPLOYER AND UNION FLEXIBILITY.—In the case of an individual who is a participant or beneficiary in a qualified retiree prescription drug plan (as defined in subsection (f)(1)) and who is not enrolled in a prescription drug plan or in a MA-EFFS Rx plan, the special subsidy payments under subsection (f)(3). This section constitutes budget authority in advance of appropriations Acts and represents the obligation of the Administrator to provide for the payment of amounts provided under this section. In applying the percentages under paragraphs (1) and (2), there shall be taken into account under the respective paragraphs the portion of the employer and union special subsidy payments under subsection (f)(3) that reflect payments that would have been made under the respective paragraphs if such paragraphs had applied to qualified retiree prescription drug plans instead of paragraph (3).

"(b) QUALIFYING ENTITY DEFINED.—For purposes of this section, the term 'qualifying entity' means any of the following that has entered into an agreement with the Administrator to provide the Administrator with such information as may be re-

quired to carry out this section:

"(1) A PDP sponsor offering a prescription drug plan under this part.

"(2) An entity that offers a MA-EFFS Rx plan.

"(3) The sponsor of a qualified retiree prescription drug plan (as defined in subsection (f)).

"(c) REINSURANCE PAYMENT AMOUNT.—

"(1) IN GENERAL.—Subject to subsection (d)(1)(B) and paragraph (4), the reinsurance payment amount under this subsection for a qualifying covered individual (as defined in paragraph (5)) for a coverage year (as defined in subsection (h)(2)) is equal to the sum of the following:

"(A) REINSURANCE BETWEEN INITIAL REINSURANCE THRESHOLD AND THE INITIAL COVERAGE LIMIT.—For the portion of the individual's gross covered prescription drug costs (as defined in paragraph (3)) for the year that exceeds the initial reinsurance threshold specified in paragraph (4), but does not exceed the initial coverage limit specified in section 1860D–2(b)(3), an amount equal to 20 percent of the allowable costs (as defined in paragraph (2)) attributable to such gross covered prescription drug costs.

"(B) REINSURANCE ABOVE ANNUAL OUT-OF-POCKET THRESHOLD.—For the portion of the individual's gross covered prescription drug costs for the year that exceeds the annual out-of-pocket threshold specified in 1860D—2(b)(4)(B), an amount equal to 80 percent of the allowable costs attributable

to such gross covered prescription drug costs.

"(2) ALLOWABLE COSTS.—For purposes of this section, the term 'allowable costs' means, with respect to gross covered prescription drug costs under a plan described in subsection (b) offered by a qualifying entity, the part of such costs that are actually paid (net of discounts, chargebacks, and average percentage rebates) under the plan, but in no case more than the part of such costs that would have been paid under the plan if the prescription drug coverage under the plan were standard coverage.

"(3) GROSS COVERED PRESCRIPTION DRUG COSTS.—For purposes of this section, the term 'gross covered prescription drug costs' means, with respect to an enrollee with a qualifying entity under a plan described in subsection (b) during a coverage year, the costs incurred under the plan (including costs attributable to administrative costs) for covered prescription drugs dispensed during the year, including costs relating to the deductible, whether paid by the enrollee or under the plan, regardless of whether the coverage under the plan exceeds standard coverage and regardless of when the payment for such drugs is maded.

"(4) INITIAL REINSURANCE THRESHOLD.—The initial reinsurance threshold specified in this paragraph—

"(A) for 2006, is equal to \$1,000; or

"(B) for a subsequent year, is equal to the payment threshold specified in this paragraph for the previous year, increased by the annual percentage increase described in section 1860D–2(b)(5) for the year involved.

Any amount determined under subparagraph (B) that is not a multiple of \$10 shall be rounded to the nearest multiple of \$10.

"(5) QUALIFYING COVERED INDIVIDUAL DEFINED.—For purposes of this subsection, the term 'qualifying covered individual' means an individual who—

"(A) is enrolled with a prescription drug plan under this part; or

"(B) is enrolled with a MA-EFFS Rx plan.

"(d) Adjustment of Payments.

(1) ADJUSTMENT OF REINSURANCE PAYMENTS TO ASSURE 30 PERCENT LEVEL OF SUBSIDY THROUGH REINSURANCE.

(A) ESTIMATION OF PAYMENTS.—The Administrator shall estimate

"(i) the total payments to be made (without regard to this subsection) during a year under subsections (a)(2) and (c); and

"(ii) the total payments to be made by qualifying entities for standard coverage under plans described in subsection (b) during the year.

"(B) ADJUSTMENT.—The Administrator shall proportionally adjust the payments made under subsections (a)(2) and (c) for a coverage year in such manner so that the total of the payments made under such subsections (and under subsection (f)(3) insofar as such payments reflect payments that would have been made under such subsections if such subsections had applied to qualified retiree prescription drug plans instead of subsections (a)(3) and (f)(3)) for the year is equal to 30 percent of the total payments described in subparagraph (A)(ii).

"(2) RISK ADJUSTMENT FOR DIRECT SUBSIDIES.—To the extent the Administrator determines it appropriate to avoid risk selection, the payments made for direct subsidies under subsection (a)(1) are subject to adjustment based upon risk factors specified by the Administrator. Any such risk adjustment shall be designed in a manner as to not result in a change in the aggregate payments

made under such subsection. "(e) PAYMENT METHODS.

"(1) IN GENERAL.—Payments under this section shall be based on such a method as the Administrator determines. The Administrator may establish a payment method by which interim payments of amounts under this section are made during a year based on the Administrator's best estimate of amounts that will be payable after obtaining all of the information.

"(2) SOURCE OF PAYMENTS.—Payments under this section shall be made from

the Medicare Prescription Drug Trust Fund.

"(f) Rules Relating to Qualified Retiree Prescription Drug Plan.-

"(1) DEFINITION.—For purposes of this section, the term 'qualified retiree prescription drug plan' means employment-based retiree health coverage (as defined in paragraph (4)(A)) if, with respect to an individual who is a participant or beneficiary under such coverage and is eligible to be enrolled in a prescription drug plan or a MA-EFFS Rx plan under this part, the following requirements are met:

"(A) ACTUARIAL EQUIVALENCE TO STANDARD COVERAGE.—The Administrator determines (based on an actuarial analysis by the Administrator) that coverage provides at least the same actuarial value as standard cov-

erage. Such determination may be made on an annual basis.

"(B) AUDITS.—The sponsor (and the plan) shall maintain, and afford the Administrator access to, such records as the Administrator may require for purposes of audits and other oversight activities necessary to ensure the

adequacy of prescription drug coverage and the accuracy of payments made. "(C) Provision of Certification of Prescription drug coverage.—The sponsor of the plan shall provide for issuance of certifications of the type

described in section 1860D-1(c)(2)(D).

"(2) LIMITATION ON BENEFIT ELIGIBILITY.—No payment shall be provided under this section with respect to a participant or beneficiary in a qualified retiree prescription drug plan unless the individual is-

(A) is covered under the plan; and

"(B) is eligible to obtain qualified prescription drug coverage under section 1860D-1 but did not elect such coverage under this part (either through a prescription drug plan or through a MA-EFFS Rx plan).

"(3) EMPLOYER AND UNION SPECIAL SUBSIDY AMOUNTS.

"(A) IN GENERAL.—For purposes of subsection (a), the special subsidy payment amount under this paragraph for a qualifying covered retiree(as defined in paragraph (6)) for a coverage year (as defined in subsection (h)) enrolled in a qualifying entity described in subsection (b)(3) under a qualified retiree prescription drug plan is, for the portion of the individual's gross covered prescription drug costs for the year that exceeds the deductible amount specified in subparagraph (B), an amount equal to, subject to subparagraph (D), 28 percent of the allowable costs attributable to such gross covered prescription drug costs, but only to the extent such costs exceed the deductible under subparagraph (B) and do not exceed the cost limit under such subparagraph in the case of any such individual for the plan year.

"(B) DEDUCTIBLE AND COST LIMIT APPLICABLE.—Subject to subparagraph

(C)—

"(i) the deductible under this subparagraph is equal to \$250 for plan years that end in 2006; and

"(ii) the cost limit under this subparagraph is equal to \$5,000 for

plan years that end in 2006.

"(C) INDEXING.—The deductible and cost limit amounts specified in subparagraphs (B) for a plan year that ends after 2006 shall be adjusted in the same manner as the annual deductible under section 1860D–2(b)(1) is

annually adjusted under such section.

"(D) ADJUSTMENT CONTINGENCY.—The Secretary may adjust the percentage specified in subparagraph (A) with respect to plan years that end in a year in a manner so that the aggregate expenditures in the year under this section are the same as the aggregate expenditures that would have been made under this section (taking into account the effect of any adjustment under subsection (d)(1)(B)) if paragraphs (1) and (2) of subsection (a) had applied to qualified prescription drug coverage instead of this paragraph and subsection (a)(3).

"(4) RELATED DEFINITIONS.—As used in this section:

"(A) EMPLOYMENT-BASED RETIREE HEALTH COVERAGE.—The term 'employment-based retiree health coverage' means health insurance or other coverage of health care costs for individuals eligible to enroll in a prescription drug plan or MA-EFFS Rx plan under this part (or for such individuals and their spouses and dependents) under a group health plan (including such a plan that is established or maintained under or pursuant to one or more collective bargaining agreements) based on their status as retired participants in such plan.

"(B) QUALIFYING COVERED RETIREE.—The term 'qualifying covered retiree' means an individual who is eligible to obtain qualified prescription drug coverage under section 1860D—1 but did not elect such coverage under this part (either through a prescription drug plan or through a MA-EFFS Rx plan) but is covered under a qualified retiree prescription drug plan.

"(C) Sponsor.—The term sponsor means a plan sponsor, as defined in section 3(16)(B) of the Employee Retirement Income Security Act of 1974. "(5) Construction.—Nothing in this subsection shall be construed as—

"(A) precluding an individual who is covered under employment-based retiree health coverage from enrolling in a prescription drug plan or in a MA-EFFS plan;

"(B) precluding such employment-based retiree health coverage or an employer or other person from paying all or any portion of any premium required for coverage under such a prescription drug plan or MA-EFFS plan on behalf of such an individual; or

"(C) preventing such employment-based retiree health coverage from pro-

viding coverage for retirees—

"(i) who are covered under a qualified retiree prescription plan that

is better than standard coverage; or

"(ii) who are not covered under a qualified retiree prescription plan but who are enrolled in a prescription drug plan or a MA-EFFS Rx plan, that is supplemental to the benefits provided under such prescription drug plan or MA-EFFS Rx plan, except that any such supplemental coverage (not including payment of any premium referred to in subparagraph (B)) shall be treated as primary coverage to which section 1862(b)(2)(A)(i) is deemed to apply.

"(g) Computation of National Average Monthly Bid Amount.—

"(1) IN GENERAL.—For each year (beginning with 2006) the Administrator shall compute a national average monthly bid amount equal to the average of the benchmark bid amounts for each prescription drug plan and for each MA-EFFS Rx plan (as computed under paragraph (2), but excluding plans described in section 1851(a)(2)(C))) adjusted under paragraph (4) to take into account reinsurance payments.

 $\mbox{``(2)}$ Benchmark bid amount defined.—For purposes of this subsection, the term 'benchmark bid amount' means, with respect to qualified prescription drug coverage offered under—

"(A) a prescription drug plan that—

"(i) provides standard coverage (or alternative prescription drug coverage the actuarial value is equivalent to that of standard coverage), the PDP bid; or

"(ii) provides alternative prescription drug coverage the actuarial value of which is greater than that of standard coverage, the PDP bid multiplied by the ratio of (I) the actuarial value of standard coverage,

to (II) the actuarial value of the alternative coverage; or

"(B) a MA-EFFS Rx plan, the portion of the bid amount that is attributable to statutory drug benefits (described in section 1853(a)(1)(A)(ii)(II)). For purposes of subparagraph (A), the term 'PDP bid' means, with respect to a prescription drug plan, the bid amount for enrollment under the plan under this part (determined without regard to any low-income subsidy under section 1860D-7 or any late enrollment penalty under section 1860D-1(c)(2)(B)).

"(3) WEIGHTED AVERAGE.—

"(A) IN GENERAL.—The monthly national average monthly bid amount computed under paragraph (1) shall be a weighted average, with the weight for each plan being equal to the average number of beneficiaries enrolled under such plan in the previous year.

under such plan in the previous year.

"(B) Special rule for 2006.—For purposes of applying this subsection for 2006, the Administrator shall establish procedures for determining the

weighted average under subparagraph (A) for 2005.

"(4) ADJUSTMENT TO ADD BACK IN VALUE OF REINSURANCE SUBSIDIES.—The adjustment under this paragraph, to take into account reinsurance payments under subsection (c) making up 30 percent of total payments, is such an adjustment as will make the national average monthly bid amount represent represent 100 percent, instead of representing 70 percent, of average payments under this part.

"(h) COVERAGE YEAR DEFINED.—For purposes of this section, the term 'coverage year' means a calendar year in which covered outpatient drugs are dispensed if a claim for payment is made under the plan for such drugs, regardless of when the

claim is paid.

"SEC. 1860D-9. MEDICARE PRESCRIPTION DRUG TRUST FUND.

"(a) IN GENERAL.—There is created on the books of the Treasury of the United States a trust fund to be known as the 'Medicare Prescription Drug Trust Fund' (in this section referred to as the 'Trust Fund'). The Trust Fund shall consist of such gifts and bequests as may be made as provided in section 201(i)(1), and such amounts as may be deposited in, or appropriated to, such fund as provided in this part. Except as otherwise provided in this section, the provisions of subsections (b) through (i) of section 1841 shall apply to the Trust Fund in the same manner as they apply to the Federal Supplementary Medical Insurance Trust Fund under such section.

"(b) PAYMENTS FROM TRUST FUND.—

"(1) IN GENERAL.—The Managing Trustee shall pay from time to time from the Trust Fund such amounts as the Administrator certifies are necessary to make—

"(A) payments under section 1860D-7 (relating to low-income subsidy payments);

"(B) payments under section 1860D-8 (relating to subsidy payments); and "(C) payments with respect to administrative expenses under this part in

accordance with section 201(g).

"(2) Transfers to medical account for increased administrative costs.—The Managing Trustee shall transfer from time to time from the Trust Fund to the Grants to States for Medicaid account amounts the Administrator certifies are attributable to increases in payment resulting from the application of a higher Federal matching percentage under section 1935(b). "(c) Deposits Into Trust Fund.—

"(1) LOW-INCOME TRANSFER.—There is hereby transferred to the Trust Fund, from amounts appropriated for Grants to States for Medicaid, amounts equivalent to the aggregate amount of the reductions in payments under section 1903(a)(1) attributable to the application of section 1935(c).

"(2) APPROPRIATIONS TO COVER GOVERNMENT CONTRIBUTIONS.—There are authorized to be appropriated from time to time, 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), reduced

by the amount transferred to the Trust Fund under paragraph (1).

"(d) RELATION TO SOLVENCY REQUIREMENTS.—Any provision of law that relates to the solvency of the Trust Fund under this part shall take into account the Trust Fund and amounts receivable by, or payable from, the Trust Fund.

"SEC. 1860D-10. DEFINITIONS; APPLICATION TO MEDICARE ADVANTAGE AND EFFS PRO-GRAMS; TREATMENT OF REFERENCES TO PROVISIONS IN PART C.

"(a) Definitions.—For purposes of this part:
"(1) Covered outpatient drugs' is de-

fined in section 1860D-2(f).

"(2) INITIAL COVERAGE LIMIT.—The term 'initial coverage limit' means such limit as established under section 1860D-2(b)(3), or, in the case of coverage that is not standard coverage, the comparable limit (if any) established under the

"(3) Medicare prescription drug trust fund.—The term 'Medicare Prescription Drug Trust Fund' means the Trust Fund created under section

1860D-9(a).

"(4) PDP SPONSOR.—The term 'PDP sponsor' means an entity that is certified under this part as meeting the requirements and standards of this part for such

(5) Prescription drug plan.—The term 'prescription drug plan' means

health benefits coverage that-

"(A) is offered under a policy, contract, or plan by a PDP sponsor pursuant to, and in accordance with, a contract between the Administrator and the sponsor under section 1860D-4(b);

"(B) provides qualified prescription drug coverage; and

"(C) meets the applicable requirements of the section 1860D-3 for a prescription drug plan.

"(6) QUALIFIED PRESCRIPTION DRUG COVERAGE.—The term 'qualified prescription drug coverage' is defined in section 1860D-2(a).

"(7) STANDARD COVERAGE.—The term 'standard coverage' is defined in section

1860D-2(b).

"(b) OFFER OF QUALIFIED PRESCRIPTION DRUG COVERAGE UNDER MEDICARE ADVANTAGE AND EFFS PROGRAMS.—

"(1) AS PART OF MEDICARE ADVANTAGE PLAN.—Medicare Advantage organizations are required to offer Medicare Advantage plans that include qualified pre-"(2) As Part of Effs Plan.—Effs organizations are required to offer Effs

plans that include qualified prescription drug coverage under part E pursuant

to section 1860E-2(d).

(c) APPLICATION OF PART C PROVISIONS UNDER THIS PART.—For purposes of applying provisions of part C under this part with respect to a prescription drug plan and a PDP sponsor, unless otherwise provided in this part such provisions shall be applied as if-

"(1) any reference to a Medicare Advantage or other plan included a reference to a prescription drug plan;

"(2) any reference to a provider-sponsored organization included a reference

to a PDP sponsor;

"(3) any reference to a contract under section 1857 included a reference to a contract under section 1860D-4(b); and

(4) any reference to part C included a reference to this part.

"(d) Report on Pharmacy Services Provided to Nursing Facility Patients.— "(1) REVIEW.—Within 6 months after the date of the enactment of this section, the Secretary shall review the current standards of practice for pharmacy services provided to patients in nursing facilities.

"(2) EVALUATIONS AND RECOMMENDATIONS.—Specifically in the review under

paragraph (1), the Secretary shall-

"(A) assess the current standards of practice, clinical services, and other service requirements generally utilized for pharmacy services in the longterm care setting; "(B) evaluate the impact of those standards with respect to patient safety,

reduction of medication errors and quality of care; and

"(C) recommend (in the Secretary's report under paragraph (3)) necessary actions and appropriate reimbursement to ensure the provision of prescription drugs to medicare beneficiaries residing in nursing facilities in a manner consistent with existing patient safety and quality of care standards under applicable State and Federal laws.

"(3) Report.—The Secretary shall submit a report to the Congress on the Secretary's findings and recommendations under this subsection, including a detailed description of the Secretary's plans to implement this part in a manner consistent with applicable State and Federal laws designed to protect the safety and quality of care of nursing facility patients.".

(b) Additional Conforming Changes.

(1) Conforming references to previous part d.—Any reference in law (in effect before the date of the enactment of this Act) to part D of title XVIII of the Social Security Act is deemed a reference to part F of such title (as in effect after such date).

(2) Conforming amendment permitting waiver of cost-sharing.—Section

(2) COMMING AMELINEAN FAMILY OF COST-SHARING.—Section 1128B(b)(3) (42 U.S.C. 1320a-7b(b)(3)) is amended—

(A) by striking "and" at the end of subparagraph (E);

(B) by striking the period at the end of subparagraph (F) and inserting

"; and"; and

(C) by adding at the end the following new subparagraph: "(G) the waiver or reduction of any cost-sharing imposed under part D of title XVIII.".

(3) Submission of Legislative Proposal.—Not later than 6 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit to the appropriate committees of Congress a legislative proposal providing for such technical and conforming amendments in the law as are required by the provisions of this subtitle.

(c) STUDY ON TRANSITIONING PART B PRESCRIPTION DRUG COVERAGE.—Not later than January 1, 2005, the Medicare Benefits Administrator shall submit a report to Congress that makes recommendations regarding methods for providing benefits under part D of title XVIII of the Social Security Act for outpatient prescription

drugs for which benefits are provided under part B of such title.

SEC. 102. OFFERING OF QUALIFIED PRESCRIPTION DRUG COVERAGE UNDER MEDICARE AD-VANTAGE AND ENHANCED FEE-FOR-SERVICE (EFFS) PROGRAM.

(a) Medicare Advantage.—Section 1851 (42 U.S.C. 1395w-21) is amended by adding at the end the following new subsection:

(j) Availability of Prescription Drug Benefits and Subsidies.-

"(1) Offering of qualified prescription drug coverage.—A Medicare Ad-

vantage organization on and after January 1, 2006-

"(A) may not offer a Medicare Advantage plan described in section 1851(a)(2)(A) in an area unless either that plan (or another Medicare Advantage plan offered by the organization in that area) includes qualified prescription drug coverage; and

"(B) may not offer the prescription drug coverage (other than that required under parts A and B) to an enrollee under a Medicare Advantage plan, unless such drug coverage is at least qualified prescription drug coverage and unless the requirements of this subsection with respect to such

coverage are met.

"(2) REQUIREMENT FOR ELECTION OF PART D COVERAGE TO OBTAIN QUALIFIED PRESCRIPTION DRUG COVERAGE.—For purposes of this part, an individual who has not elected qualified prescription drug coverage under section 1860D-1(b) shall be treated as being ineligible to enroll in a Medicare Advantage plan

under this part that offers such coverage.

"(3) COMPLIANCE WITH CERTAIN ADDITIONAL BENEFICIARY PROTECTIONS FOR PRESCRIPTION DRUG COVERAGE.—With respect to the offering of qualified prescription drug coverage by a Medicare Advantage organization under this part on and after January 1, 2006, the organization and plan shall meet the requirements of subsections (a) through (d) of section 1860D-3 in the same manner as they apply to a PDP sponsor and a prescription drug plan under part D and shall submit to the Administrator the information described in section 1860D-6(a)(2). The Administrator shall waive such requirements to the extent the Administrator determines that such requirements duplicate requirements otherwise applicable to the organization or plan under this part.

"(4) Availability of Premium and Cost-Sharing Subsidies.—In the case of low-income individuals who are enrolled in a Medicare Advantage plan that provides qualified prescription drug coverage, premium and cost-sharing subsidies

are provided for such coverage under section 1860D-7.

"(5) AVAILABILITY OF DIRECT AND REINSURANCE SUBSIDIES TO REDUCE BIDS AND PREMIUMS.—Medicare Advantage organizations are provided direct and reinsurance subsidy payments for providing qualified prescription drug coverage under this part under section 1860D–8.

"(6) Consolidation of drug and non-drug premiums.—In the case of a Medicare Advantage plan that includes qualified prescription drug coverage, with respect to an enrollee in such plan there shall be a single premium for both drug and non-drug coverage provided under the plan.

"(7) Transition in initial enrollment period.—Notwithstanding any other provision of this part, the annual, coordinated election period under subsection (e)(3)(B) for 2006 shall be the 6-month period beginning with November 2005.

"(8) QUALIFIED PRESCRIPTION DRUG COVERAGE; STANDARD COVERAGE.—For purposes of this part, the terms 'qualified prescription drug coverage' and 'standard coverage' have the meanings given such terms in section 1860D-2.".

(b) APPLICATION TO EFFS PLANS.—Subsection (d) of section 1860E-2, as added by

section 201(a), is amended to read as follows:

"(d) Availability of Prescription Drug Benefits and Subsidies.—

"(1) OFFERING OF QUALIFIED PRESCRIPTION DRUG COVERAGE.—An EFFS organization—

"(A) may not offer an EFFS plan in an area unless either that plan (or another EFFS plan offered by the organization in that area) includes qualified prescription drug coverage; and

"(B) may not offer the prescription drug coverage (other than that required under parts A and B) to an enrollee under an EFFS plan, unless such drug coverage is at least qualified prescription drug coverage and unless the requirements of this subsection with respect to such coverage are met.

"(2) REQUIREMENT FOR ELECTION OF PART D COVERAGE TO OBTAIN QUALIFIED PRESCRIPTION DRUG COVERAGE.—For purposes of this part, an individual who has not elected qualified prescription drug coverage under section 1860D–1(b) shall be treated as being ineligible to enroll in an EFFS plan under this part that offers such coverage.

"(3) COMPLIANCE WITH CERTAIN ADDITIONAL BENEFICIARY PROTECTIONS FOR PRESCRIPTION DRUG COVERAGE.—With respect to the offering of qualified prescription drug coverage by an EFFS organization under this part, the organization and plan shall meet the requirements of subsections (a) through (d) of section 1860D—3 in the same manner as they apply to a PDP sponsor and a prescription drug plan under part D and shall submit to the Administrator the information described in section 1860D—6(a)(2). The Administrator shall waive such requirements to the extent the Administrator determines that such requirements duplicate requirements otherwise applicable to the organization or plan under this part.

"(4) AVAILABILITY OF PREMIUM AND COST-SHARING SUBSIDIES.—In the case of low-income individuals who are enrolled in an EFFS plan that provides qualified prescription drug coverage, premium and cost-sharing subsidies are provided for such coverage under section 1860D–7.

"(5) AVAILABILITY OF DIRECT AND REINSURANCE SUBSIDIES TO REDUCE BIDS AND PREMIUMS.—EFFS organizations are provided direct and reinsurance subsidy payments for providing qualified prescription drug coverage under this part under section 1860D–8.

"(6) CONSOLIDATION OF DRUG AND NON-DRUG PREMIUMS.—In the case of an EFFS plan that includes qualified prescription drug coverage, with respect to an enrollee in such plan there shall be a single premium for both drug and non-drug coverage provided under the plan.

drug coverage provided under the plan.

"(7) QUALIFIED PRESCRIPTION DRUG COVERAGE; STANDARD COVERAGE.—For purposes of this part, the terms 'qualified prescription drug coverage' and 'standard coverage' have the meanings given such terms in section 1860D–2.".

(c) CONFORMING AMENDMENTS.—Section 1851 (42 U.S.C. 1395w–21) is amended—

(1) in subsection (a)(1)—

(A) by inserting "(other than qualified prescription drug benefits)" after "benefits";

(B) by striking the period at the end of subparagraph (B) and inserting a comma; and

(C) by adding after and below subparagraph (B) the following:

"and may elect qualified prescription drug coverage in accordance with section 1860D-1."; and

(2) in subsection (g)(1), by inserting "and section 1860D–1(c)(2)(B)" after "in this subsection".

(d) Effective Date.—The amendments made by this section apply to coverage provided on or after January 1, 2006.

SEC. 103. MEDICAID AMENDMENTS.

- (a) DETERMINATIONS OF ELIGIBILITY FOR LOW-INCOME SUBSIDIES.—
 - (1) REQUIREMENT.—Section 1902(a) (42 U.S.C. 1396a(a)) is amended—(A) by striking "and" at the end of paragraph (64);
 - (B) by striking the period at the end of paragraph (65) and inserting "; and"; and

- (C) by inserting after paragraph (65) the following new paragraph: "(66) provide for making eligibility determinations under section 1935(a).". (2) NEW SECTION.—Title XIX is further amended—

 - (A) by redesignating section 1935 as section 1936; and (B) by inserting after section 1934 the following new section:

"SPECIAL PROVISIONS RELATING TO MEDICARE PRESCRIPTION DRUG BENEFIT

"Sec. 1935. (a) Requirement for Making Eligibility Determinations for Low-INCOME SUBSIDIES.—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), a State shall-

"(1) make determinations of eligibility for premium and cost-sharing subsidies under (and in accordance with) section 1860D-7;
"(2) inform the Administrator of the Medicare Benefits Administration of such

determinations in cases in which such eligibility is established; and

"(3) otherwise provide such Administrator with such information as may be required to carry out part D of title XVIII (including section 1860D-7).

"(b) PAYMENTS FOR ADDITIONAL ADMINISTRATIVE COSTS.

"(1) IN GENERAL.—The amounts expended by a State in carrying out subsection (a) are, subject to paragraph (2), expenditures reimbursable under the appropriate paragraph of section 1903(a); except that, notwithstanding any other provision of such section, the applicable Federal matching rates with respect to such appropriate paragraph of section, the applicable Federal matching rates with respect to such appropriate paragraph of section applicable formula appropriate paragraph of section appropriate paragraph of section applicable formula appropriate paragraph of section appropriate paragraph of section applicable formula appropriate paragraph of section applicable formula appropriate paragraph of section appropriate par spect to such expenditures under such section shall be increased as follows (but in no case shall the rate as so increased exceed 100 percent):

"(A) For expenditures attributable to costs incurred during 2005, the otherwise applicable Federal matching rate shall be increased by 6-½ percent of the percentage otherwise payable (but for this subsection) by the State. "(B)(i) For expenditures attributable to costs incurred during 2006 and each subsequent year through 2018, the otherwise applicable Federal matching rate shall be increased by the applicable percent (as defined in clause (ii)) of the percentage otherwise payable (but for this subsection) by the State. the State.

"(ii) For purposes of clause (i), the 'applicable percent' for—
"(I) 2006 is 13-1/3 percent; or
"(II) a subsequent year is the applicable percent under this clause for the previous year increased by 6-2/3 percentage points.
"(C) For expenditures attributable to costs incurred after 2018, the otherwise applicable Federal matching rate shall be increased to 100 percent.

"(2) COORDINATION.—The State shall provide the Administrator with such information as may be necessary to properly allocate administrative expenditures described in paragraph (1) that may otherwise be made for similar eligibility determinations.".

(b) Phased-In Federal Assumption of Medicaid Responsibility for Premium AND COST-SHARING SUBSIDIES FOR DUALLY ELIGIBLE INDIVIDUALS.

(1) IN GENERAL.—Section 1903(a)(1) (42 U.S.C. 1396b(a)(1)) is amended by inserting before the semicolon the following: ", reduced by the amount computed under section 1935(c)(1) for the State and the quarter".

(2) AMOUNT DESCRIBED.—Section 1935, as inserted by subsection (a)(2), is amended by adding at the end the following new subsection:

"(c) FEDERAL ASSUMPTION OF MEDICAID PRESCRIPTION DRUG COSTS FOR DUALLY-

ELIGIBLE BENEFICIARIES.

"(1) IN GENERAL.—For purposes of section 1903(a)(1), for a State that is one of the 50 States or the District of Columbia for a calendar quarter in a year (beginning with 2005) the amount computed under this subsection is equal to the product of the following:

(A) MEDICARE SUBSIDIES.—The total amount of payments made in the quarter under section 1860D-7 (relating to premium and cost-sharing prescription drug subsidies for low-income medicare beneficiaries) that are attributable to individuals who are residents of the State and are entitled to benefits with respect to prescribed drugs under the State plan under this title (including such a plan operating under a waiver under section 1115).

"(B) STATE MATCHING RATE.—A proportion computed by subtracting from 100 percent the Federal medical assistance percentage (as defined in sec-

tion 1905(b)) applicable to the State and the quarter. "(C) Phase-out proportion.—The phase-out proportion (as defined in

paragraph (2)) for the quarter.

"(2) Phase-out proportion.—For purposes of paragraph (1)(C), the 'phaseout proportion' for a calendar quarter in-

"(A) 2006 is $93-\frac{1}{3}$ percent;

"(B) a subsequent year before 2021, is the phase-out proportion for calendar quarters in the previous year decreased by 6-3/3 percentage points;

or
"(C) a year after 2020 is 0 percent.".

(c) MEDICAID PROVIDING WRAP-AROUND BENEFITS.—Section 1935, as so inserted and amended, is further amended by adding at the end the following new sub-

"(d) Additional Provisions.—

(1) MEDICAID AS SECONDARY PAYOR.—In the case of an individual who is entitled to qualified prescription drug coverage under a prescription drug plan under part D of title XVIII (or under a MA-EFFS Rx plan under part C or E of such title) and medical assistance for prescribed drugs under this title, medical assistance shall continue to be provided under this title for prescribed drugs to the extent payment is not made under the prescription drug plan or MA-EFFS Rx plan selected by the individual.

(2) CONDITION.—A State may require, as a condition for the receipt of medical assistance under this title with respect to prescription drug benefits for an individual eligible to obtain qualified prescription drug coverage described in paragraph (1), that the individual elect qualified prescription drug coverage

under section 1860D-1.

(d) Treatment of Territories.—

- (1) IN GENERAL.—Section 1935, as so inserted and amended, is further amended
 - (A) in subsection (a) in the matter preceding paragraph (1), by inserting "subject to subsection (e)" after "section 1903(a)"

(B) in subsection (c)(1), by inserting "subject to subsection (e)" after "1903(a)(1)"; and

(C) by adding at the end the following new subsection: "(e) TREATMENT OF TERRITORIES.—

"(1) IN GENERAL.—In the case of a State, other than the 50 States and the District of Columbia-

'(A) the previous provisions of this section shall not apply to residents of such State; and

"(B) if the State establishes a plan described in paragraph (2) (for providing medical assistance with respect to the provision of prescription drugs to medicare beneficiaries), the amount otherwise determined under section 1108(f) (as increased under section 1108(g)) for the State shall be increased by the amount specified in paragraph (3).

"(2) PLAN.—The plan described in this paragraph is a plan that-

- "(A) provides medical assistance with respect to the provision of covered outpatient drugs (as defined in section 1860D–2(f)) to low-income medicare beneficiaries; and
- "(B) assures that additional amounts received by the State that are attributable to the operation of this subsection are used only for such assistance.

"(3) Increased amount.—

"(A) IN GENERAL.—The amount specified in this paragraph for a State for a year is equal to the product of-

"(i) the aggregate amount specified in subparagraph (B); and

"(ii) the amount specified in section 1108(g)(1) for that State, divided by the sum of the amounts specified in such section for all such States. "(B) AGGREGATE AMOUNT.—The aggregate amount specified in this subparagraph for-

(i) 2006, is equal to \$25,000,000; or

- "(ii) a subsequent year, is equal to the aggregate amount specified in this subparagraph for the previous year increased by annual percentage increase specified in section 1860D-2(b)(5) for the year involved.
- "(4) REPORT.—The Administrator shall submit to Congress a report on the application of this subsection and may include in the report such recommendations as the Administrator deems appropriate."
- (2) CONFORMING AMENDMENT.—Section 1108(f) (42 U.S.C. 1308(f)) is amended by inserting "and section 1935(e)(1)(B)" after "Subject to subsection (g)".

 (e) AMENDMENT TO BEST PRICE.—Section 1927(c)(1)(C)(i) (42 U.S.C. 1396r—
- 8(c)(1)(C)(i)) is amended-

- (1) by striking "and" at the end of subclause (III); (2) by striking the period at the end of subclause (IV) and inserting "; and"; and
 - (3) by adding at the end the following new subclause:

"(V) any prices charged which are negotiated by a prescription drug plan under part D of title XVIII, by a MA-EFFS Rx plan under part C or E of such title with respect to covered outpatient drugs, or by a qualified retiree prescription drug plan (as defined in section 1860D-8(f)(1)) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of such title.".

SEC. 104. MEDIGAP TRANSITION.

(a) IN GENERAL.—Section 1882 (42 U.S.C. 1395ss) is amended by adding at the end the following new subsection:

"(v) COVERAGE OF PRESCRIPTION DRUGS.—

"(1) IN GENERAL.—Notwithstanding any other provision of law, except as provided in paragraph (3) no new medicare supplemental policy that provides coverage of expenses for prescription drugs may be issued under this section on or after January 1, 2006, to an individual unless it replaces a medicare supplemental policy that was issued to that individual and that provided some coverage of expenses for prescription drugs. Nothing in this subsection shall be construed as preventing the policy holder of a medicare supplemental policy issued before January 1, 2006, from continuing to receive benefits under such policy on and after such date.

"(2) Issuance of substitute policies for beneficiaries enrolled with a

PLAN UNDER PART D.-

"(A) IN GENERAL.—The issuer of a medicare supplemental policy-

"(i) may not deny or condition the issuance or effectiveness of a medicare supplemental policy that has a benefit package classified as 'A', 'B', 'C', 'D', 'E', F', or 'G' (under the standards established under subsection (p)(2)) and that is offered and is available for issuance to new enrollees by such issuer;

"(ii) may not discriminate in the pricing of such policy, because of health status, claims experience, receipt of health care, or medical con-

dition; and

"(iii) may not impose an exclusion of benefits based on a pre-existing

condition under such policy,

in the case of an individual described in subparagraph (B) who seeks to enroll under the policy not later than 63 days after the date of the termination of enrollment described in such paragraph and who submits evidence of the date of termination or disenrollment along with the application for such medicare supplemental policy.

"(B) INDIVIDUAL COVERED.—An individual described in this subparagraph

is an individual who-

"(i) enrolls in a prescription drug plan under part D; and

"(ii) at the time of such enrollment was enrolled and terminates enrollment in a medicare supplemental policy which has a benefit package classified as 'H', T, or 'J' under the standards referred to in subparagraph (A)(i) or terminates enrollment in a policy to which such standards do not apply but which provides benefits for prescription

"(C) Enforcement.—The provisions of paragraph (4) of subsection (s) shall apply with respect to the requirements of this paragraph in the same

manner as they apply to the requirements of such subsection.

"(3) NEW STANDARDS.—In applying subsection (p)(1)(E) (including permitting the NAIC to revise its model regulations in response to changes in law) with respect to the change in benefits resulting from title I of the Medicare Prescription Drug and Modernization Act of 2003, with respect to policies issued to individuals who are enrolled in a plan under part D, the changes in standards shall only provide for substituting (for the benefit packages described in paragraph (2)(B)(ii) that included coverage for prescription drugs) two benefit packages that may provide for coverage of cost-sharing (other than the prescription drug deductible) with respect to qualified prescription drug coverage under such part.

The two benefit packages shall be consistent with the following:

"(A) FIRST NEW POLICY.—The policy described in this subparagraph has the following benefits, notwithstanding any other provision of this section

relating to a core benefit package:

"(i) Coverage of 50 percent of the cost-sharing otherwise applicable under parts A and B, except coverage of 100 percent of any cost-sharing otherwise applicable for preventive benefits.

"(ii) No coverage of the part B deductible.

"(iii) Coverage for all hospital coinsurance for long stays (as in the

current core benefit package).

"(iv) A limitation on annual out-of-pocket expenditures under parts A and B to \$4,000 in 2005 (or, in a subsequent year, to such limitation for the previous year increased by an appropriate inflation adjustment specified by the Secretary).

"(B) SECOND NEW POLICY.—The policy described in this subparagraph has the same benefits as the policy described in subparagraph (A), except as fol-

"(i) Substitute '75 percent' for '50 percent' in clause (i) of such subparagraph.

"(ii) Substitute '\$2,000' for '\$4,000' in clause (iv) of such subpara-

graph.
"(4) CONSTRUCTION.—Any provision in this section or in a medicare supplemental policy relating to guaranteed renewability of coverage shall be deemed to have been met through the offering of other coverage under this subsection.".

(b) NAIC REPORT TO CONGRESS ON MEDIGAP MODERNIZATION.—The Secretary shall request the National Association of Insurance Commissioners to submit to Congress, not later than 18 months after the date of the enactment of this Act, a report that includes recommendations on the modernization of coverage under the medigap program under section 1882 of the Social Security Act (42 U.S.C. 1395ss).

SEC. 105. MEDICARE PRESCRIPTION DRUG DISCOUNT CARD AND ASSISTANCE PROGRAM.

(a) IN GENERAL.—Title XVIII is amended by inserting after section 1806 the following new sections:

"MEDICARE PRESCRIPTION DRUG DISCOUNT CARD ENDORSEMENT AND ASSISTANCE PROGRAM

"Sec. 1807. (a) Establishment of Program.-

"(1) IN GENERAL.—The Secretary (or the Medicare Benefits Administrator pur-

suant to section 1809(c)(3)(C)) shall establish a program-

'(A) to endorse prescription drug discount card programs (each such program referred to as an 'endorsed program') that meet the requirements of this section in order to provide access to prescription drug discounts through an eligible entity for medicare beneficiaries throughout the United States; and

"(B) to provide for prescription drug accounts and public contributions

into such accounts.

The Secretary shall make available to medicare beneficiaries information regarding endorsed programs and accounts under this section.

"(2) LIMITED PERIOD OF OPERATION.—The Secretary shall begin—
"(A) the card endorsement part of the program under paragraph (1)(A) as soon as possible, but in no case later than 90 days after the date of the enactment of this section; and

"(B) the prescription drug account part of the program under paragraph (1)(B) as soon as possible, but in no case later than September 2004.

"(3) TRANSITION.—The program under this section shall continue through 2005 throughout the United States. The Secretary shall provide for an appropriate transition and discontinuation of such program at the time medicare prescription drug benefits become available under part D.

"(4) VOLUNTARY NATURE OF PROGRAM.—Nothing in this section shall be construed as requiring an eligible beneficiary to enroll in the program under this

"(b) ELIGIBLE BENEFICIARY; ELIGIBLE ENTITY; PRESCRIPTION DRUG ACCOUNT.—For purposes of this section:

"(1) ELIGIBLE BENEFICIARY.—The term 'eligible beneficiary' means an individual who is eligible for benefits under part A or enrolled under part B and who is not enrolled in a prescription drug plan or MA-EFFS Rx plan, but who may be enrolled in a Medicare Advantage plan that does not offer qualified prescription drug coverage.

(2) ELIGIBLE ENTITY.—The term 'eligible entity' means any entity that the Secretary determines to be appropriate to provide the benefits under this sec-

tion, including-

- "(A) pharmaceutical benefit management companies;
- "(B) wholesale and retail pharmacy delivery systems;

"(C) insurers;

"(D) Medicare Advantage or EFFS organizations;

"(E) other entities; or

"(F) any combination of the entities described in subparagraphs (A)

through (E).

"(3) Prescription drug account.—The term 'prescription drug account' means, with respect to an eligible beneficiary, an account established for the benefit of that beneficiary under section 1807A.

"(c) ENROLLMENT IN ENDORSED PLAN. "(1) Establishment of process.

"(A) IN GENERAL.—The Secretary shall establish a process through which an eligible beneficiary may make an election to enroll under this section with an endorsed program.

"(B) REQUIREMENT OF ENROLLMENT.—An eligible beneficiary must enroll under this section for a year in order to be eligible to receive the benefits under this section for that year.

"(C) LIMITATION ON ENROLLMENT.-

"(i) IN GENERAL.—Except as provided under this subparagraph and under such exceptional circumstances as the Secretary may provide, an eligible individual shall have the opportunity to enroll under this section during an initial, general enrollment period as soon as possible after the date of the enactment of this section and annually thereafter. The Secretary shall specify the form, manner, and timing of such election but shall permit the exercise of such election at the time the individual is eligible to enroll. The annual open enrollment periods shall be coordinated with those provided under the Medicare Advantage and EFFS programs under parts C and E as well as under the prescription drug program under part D.

"(ii) Reelection after termination of enrollment in a medicare

ADVANTAGE PLAN.—In the case of an individual who is enrolled under this section and who subsequently enrolls in a Medicare Advantage plan that provides qualified prescription drug coverage under part C, the individual shall be given the opportunity to reenroll under this section at the time the individual discontinues the enrollment under such

"(iii) Late enrollment.—The Secretary shall permit individuals to elect to enroll under this section at times other than as permitted under the previous provisions of this paragraph.

"(D) TERMINATION OF ENROLLMENT.—An enrollee under this section shall

"(i) upon enrollment in a prescription drug plan under part D or a Medicare Advantage or EFFS plan under part C or E that provides qualified prescription drug coverage;

"(ii) upon failure to pay the applicable enrollment fee under subsection (f);

"(iii) upon termination of coverage under part A or part B; or "(iv) upon notice submitted to the Secretary in such form, manner, and time as the Secretary shall provide.

Terminations of enrollment under this subparagraph shall be effective as specified by the Secretary in regulations.

"(2) ENROLLMENT PERIODS.

"(A) IN GENERAL.—Except as provided under this paragraph, an eligible beneficiary may not enroll in the program under this part during any period after the beneficiary's initial enrollment period under part B (as determined under section 1837).

"(B) OPEN ENROLLMENT PERIOD FOR CURRENT BENEFICIARIES.—The Secretary shall establish a period, which shall begin on the date on which the Secretary first begins to accept elections for enrollment under this section and shall end not earlier than 3 months later, during which any eligible beneficiary may enroll under this section.

"(C) SPECIAL ENROLLMENT PERIOD IN CASE OF TERMINATION OF COVERAGE UNDER A GROUP HEALTH PLAN.—The Secretary shall provide for a special enrollment period under this section in the same manner as is provided under section 1837(i) with respect to part B, except that for purposes of this subparagraph any reference to 'by reason of the individual's (or the individual's spouse's) current employment status' shall be treated as being deleted.

"(3) Period of Coverage.

"(A) IN GENERAL.—Except as provided in subparagraph (B) and subject to subparagraph (C), an eligible beneficiary's coverage under the program under this section shall be effective for the period provided under section 1838, as if that section applied to the program under this section.

"(B) ENROLLMENT DURING OPEN AND SPECIAL ENROLLMENT.—Subject to subparagraph (C), an eligible beneficiary who enrolls under the program under this section under subparagraph (B) or (C) of paragraph (2) shall be entitled to the benefits under this section beginning on the first day of the month following the month in which such enrollment occurs.

"(d) SELECTION OF AN ELIGIBLE ENTITY FOR ACCESS TO NEGOTIATED PRICES.—

'(1) Process.

"(A) IN GENERAL.—The Secretary shall establish a process through which an eligible beneficiary who is enrolled under this section shall select any eligible entity, that has been awarded a contract under this section and serves the State in which the beneficiary resides, to provide access to nego-

tiated prices under subsection (i).

"(B) RULES.—In establishing the process under subparagraph (A), the Secretary shall use rules similar to the rules for enrollment and disenrollment with a Medicare Advantage plan under section 1851 (including the special election periods under subsection (e)(4) of such section), including that—

"(i) an individual may not select more than one eligible entity at any

time; and

"(ii) an individual shall only be permitted (except for unusual circumstances) to change the selection of the entity once a year.

In carrying out clause (ii), the Secretary may consider a change in residential setting (such as placement in a nursing facility) to be an unusual circumstance.

(C) Default selection.—In establishing such process, the Secretary shall provide an equitable method for selecting an eligible entity for individuals who enroll under this section and fail to make such a selection.

"(2) COMPETITION.—Eligible entities with a contract under this section shall compete for beneficiaries on the basis of discounts, formularies, pharmacy networks, and other services provided for under the contract

"(e) Providing Enrollment, Selection, and Coverage Information to Bene-

FICIARIES.

"(1) ACTIVITIES.—The Secretary shall provide for activities under this section to broadly disseminate information to eligible beneficiaries (and prospective eligible beneficiaries) regarding enrollment under this section, the selection of eligible entities, and the prescription drug coverage made available by eligible entities with a contract under this section.

"(2) Special rule for first enrollment under the program.—To the extent practicable, the activities described in paragraph (1) shall ensure that eligible beneficiaries are provided with such information at least 60 days prior to the first enrollment period described in subsection (c).

"(f) ENROLLMENT FEE.

"(1) AMOUNT.-

"(A) IN GENERAL.—Except as provided in paragraph (3), enrollment under the program under this section is conditioned upon payment of an annual enrollment fee of \$30 for 2004 (including any portion of 2003 in which the

program is implemented under this section).

"(B) ANNUAL PERCENTAGE INCREASE IN ENROLLMENT FEE.—In the case of any calendar year beginning after 2004, the dollar amount of the enrollment fee in subparagraph (A) shall be the dollar amount of such fee for the previous year increased by the annual percentage increase in the consumer price index for all urban consumers (U.S. city average; all items) as of September before the beginning of the year involved. If any increase determined under the previous sentence is not a multiple of \$1, such increase shall be rounded to the nearest multiple of \$1.

"(2) COLLECTION OF ENROLLMENT FEE.—The annual enrollment fee shall be

collected and credited to the Federal Supplementary Medical Insurance Trust Fund in the same manner as the monthly premium determined under section 1839 is collected and credited to such Trust Fund under section 1840, except

that it shall be collected only 1 time per year.

"(3) PAYMENT OF ENROLLMENT FEE BY STATE FOR CERTAIN BENEFICIARIES.—
"(A) IN GENERAL.—The Secretary shall establish an arrangement under which a State may provide for payment of some or all of the enrollment fee for some or all low income enrollees in the State, as specified by the State under the arrangement. Insofar as such a payment arrangement is made with respect to an enrollee, the amount of the enrollment fee shall be paid directly by the State and shall not be collected under paragraph (2). In carrying out this paragraph, the Secretary may apply procedures similar to that applied under state agreements under section 1843.

"(B) NO FEDERAL MATCHING AVAILABLE UNDER MEDICAID OR SCHIP.—Expenditures made by a State described in subparagraph (A) shall not be treated as State expenditures for purposes of Federal matching payments under titles XIX and XXI insofar as such expenditures are for an enrollment fee under this subsection.

"(4) DISTRIBUTION OF PORTION OF ENROLLMENT FEE.—Of the enrollment fee collected by the Secretary under this subsection with respect to a beneficiary, 3 of that fee shall be made available to the eligible entity selected by the eligible beneficiary.

"(g) ISSUANCE OF CARD AND COORDINATION.—Each eligible entity shall—
"(1) issue, in a uniform standard format specified by the Secretary, to each enrolled beneficiary a card and an enrollment number that establishes proof of enrollment and that can be used in a coordinated manner—

'(A) to identify the eligible entity selected to provide access to negotiated

prices under subsection (i); and

"(B) to make deposits to and withdrawals from a prescription drug account under section 1807A; and

"(2) provide for electronic methods to coordinate with the accounts established under section 1807A.

"(h) ENROLLEE PROTECTIONS.-

"(1) GUARANTEED ISSUE AND NONDISCRIMINATION.—

(A) GUARANTEED ISSUE.

"(i) IN GENERAL.—An eligible beneficiary who is eligible to select an eligible entity under subsection (b) for prescription drug coverage under this section at a time during which selections are accepted under this section with respect to the coverage shall not be denied selection based on any health status-related factor (described in section 2702(a)(1) of the Public Health Service Act) or any other factor and may not be charged any selection or other fee as a condition of such acceptance.

"(ii) MEDICARE+CHOICE LIMITATIONS PERMITTED.—The provisions of paragraphs (2) and (3) (other than subparagraph (C)(i), relating to default enrollment) of section 1851(g) (relating to priority and limitation on termination of election) shall apply to selection of eligible entities

under this paragraph.

"(B) NONDISCRIMINATION.—An eligible entity offering prescription drug coverage under this section shall not establish a service area in a manner that would discriminate based on health or economic status of potential en-

"(C) COVERAGE OF ALL PORTIONS OF A STATE.—If an eligible entity with a contract under this section serves any part of a State it shall serve the entire State.

"(2) Dissemination of Information.-

(A) GENERAL INFORMATION.—An eligible entity with a contract under this section shall disclose, in a clear, accurate, and standardized form to each eligible beneficiary who has selected the entity to provide access to negotiated prices under this section at the time of selection and at least annually thereafter, the information described in section 1852(c)(1) relating to such prescription drug coverage. Such information includes the following (in a manner designed to permit and promote competition among eligible entities):

"(i) Summary information regarding negotiated prices (including discounts) for covered outpatient drugs.

"(ii) Access to such prices through pharmacy networks.
"(iii) How any formulary used by the eligible entity functions.
"(B) DISCLOSURE UPON REQUEST OF GENERAL COVERAGE, UTILIZATION, AND GRIEVANCE INFORMATION.—Upon request of an eligible beneficiary, the eligible provides the information described in the control of the c ble entity shall provide the information described in section 1852(c)(2) (other than subparagraph (D)) to such beneficiary.

"(C) RESPONSE TO BENEFICIARY QUESTIONS.—Each eligible entity offering prescription drug coverage under this section shall have a mechanism (including a toll-free telephone number) for providing upon request specific information (such as negotiated prices, including discounts) to individuals who have selected the entity. The entity shall make available, through an Internet website and in writing upon request, information on specific changes in its formulary.

"(D) COORDINATION WITH PRESCRIPTION DRUG ACCOUNT BENEFITS.—Each such eligible entity shall provide for coordination of such information as the

Secretary may specify to carry out section 1807A.

"(3) Access to covered benefits.-

"(A) Ensuring pharmacy access.—The provisions of subsection (c)(1) of section 1860D-3 (other than payment provisions under section 1860D-8 with respect to sponsors under such subsection) shall apply to an eligible entity under this section in the same manner as they apply to a PDP sponsor under such section.

"(B) ACCESS TO NEGOTIATED PRICES FOR PRESCRIPTION DRUGS.—For requirements relating to the access of an eligible beneficiary to negotiated

prices (including applicable discounts), see subsection (i).

"(C) REQUIREMENTS ON DEVELOPMENT AND APPLICATION OF FORMULARIES.—Insofar as an eligible entity with a contract under this part uses a formulary, the entity shall comply with the requirements of section 1860D–3(c)(3), insofar as the Secretary determines that such requirements can be implemented on a timely basis.

"(4) Cost and utilization management; quality assurance; medication

THERAPY MANAGEMENT PROGRAM.-

- "(A) IN GENERAL.—For purposes of providing access to negotiated benefits under subsection (i), the eligible entity shall have in place the programs and measure described in section 1860D-3(d), including an effective cost and drug utilization management program, quality assurance measures and systems, and a program to control fraud, abuse, and waste, insofar as the Secretary determines that such provisions can be implemented on a timely
- "(B) TREATMENT OF ACCREDITATION.—Section 1852(e)(4) (relating to treatment of accreditation) shall apply to the requirements for an endorsed program under this section with respect to the following requirements, in the same manner as they apply to Medicare Advantage plans under part C with respect to the requirements described in a clause of section 1852(e)(4)(B):

(i) Paragraph (3)(A) (relating to access to covered benefits).

"(ii) Paragraph (7) (relating to confidentiality and accuracy of enrollee records).

"(5) GRIEVANCE MECHANISM.—Each eligible entity shall provide meaningful procedures for hearing and resolving grievances between the organization consistent with the requirements of section 1860D-3(e) insofar as they relate to PDP sponsors of prescription drug plans.

"(6) BENEFICIARY SERVICES.—An eligible entity shall provide for its enrollees pharmaceutical support services, such as education and counseling, and services

to prevent adverse drug interactions.

(7) COVERAGE DETERMINATIONS AND RECONSIDERATIONS.—An eligible entity shall meet the requirements of section 1852(g) with respect to covered benefits under the prescription drug coverage it offers under this section in the same manner as such requirements apply to a Medicare Advantage organization with respect to benefits it offers under a Medicare Advantage plan under part C.

"(8) CONFIDENTIALITY AND ACCURACY OF ENROLLEE RECORDS.—An eligible entitle abell most the available property of the Accuracy of Enroller Records.

tity shall meet the requirements of section 1852(h) with respect to enrollees under this section in the same manner as such requirements apply to a Medicare Advantage organization with respect to enrollees under part C. The eligible entity shall implement policies and procedures to safeguard the use and disclosure of enrollees' individually identifiable health information in a manner consistent with the Federal regulations (concerning the privacy of individually identifiable health information) promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996. The eligible entity shall be treated as a covered entity for purposes of the provisions of subpart E of part 164 of title 45, Code of Federal Regulations, adopted pursuant to the authority of the Secretary under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S. C. 1320d-2 note).

"(9) PERIODIC REPORTS AND OVERSIGHT.—The eligible entity shall submit to the Secretary periodic reports on performance, utilization, finances, and such other matters as the Secretary may specify. The Secretary shall provide appropriate oversight to ensure compliance of eligible entities with the requirements

of this subsection, including verification of the discounts and services provided.

"(10) ADDITIONAL BENEFICIARY PROTECTIONS.—The eligible entity meets such additional requirements as the Secretary identifies to protect and promote the interest of enrollees, including requirements that ensure that enrollees are not charged more than the lower of the negotiated retail price or the usual and cus-

(i) Benefits Under the Program Through Savings to Enrollees Through NEGOTIATED PRICES.

"(1) IN GENERAL.—Subject to paragraph (2), each eligible entity with a contract under this section shall provide each eligible beneficiary enrolled with the entity with access to negotiated prices (including applicable discounts). For purposes of this paragraph, the term 'prescription drugs' is not limited to covered outpatient drugs, but does not include any over-the-counter drug that is not a covered outpatient drug. The prices negotiated by an eligible entity under this paragraph shall (notwithstanding any other provision of law) not be taken into account for the purposes of establishing the best price under section 1927(c)(1)(C).

"(2) FORMULARY RESTRICTIONS.—Insofar as an eligible entity with a contract under this part uses a formulary, the negotiated prices (including applicable discounts) for prescription drugs shall only be available for drugs included in

such formulary

"(3) PROHIBITION ON APPLICATION ONLY TO MAIL ORDER.—The negotiated prices under this subsection shall apply to prescription drugs that are available

other than solely through mail order.

"(4) Prohibition on charges for required services.—An eligible entity (and any pharmacy contracting with such entity for the provision of a discount under this section) may not charge a beneficiary any amount for any services required to be provided by the entity under this section.

"(5) DISCLOSURE.—The eligible entity offering the endorsed program shall dis-

close to the Secretary (in a manner specified by the Secretary) the extent to which discounts or rebates or other remuneration or price concessions made available to the entity by a manufacturer are passed through to enrollees through pharmacies and other dispensers or otherwise. The provisions of section 1927(b)(3)(D) shall apply to information disclosed to the Administrator under this paragraph in the same manner as such provisions apply to information disclosed under such section.

"(6) Public disclosure of pharmaceutical prices for equivalent DRUGS.—Each eligible entity shall provide that each pharmacy or other dispenser that arranges for the dispensing of a covered outpatient drug in connection with its endorsed program shall inform the enrollee in that program at the time of purchase of the drug of any differential between the price of the prescribed drug to the enrollee and the price of the lowest cost available generic drug covered under the program that is therapeutically equivalent and bio-

equivalent.

"(j) Contribution Into Prescription Drug Account.—

"(1) IN GENERAL.—In the case of an individual enrolled under this section— '(A) the Secretary shall establish a prescription drug account for the individual under section 1807A; and

"(B) shall deposit into such account on a monthly or other periodic basis an amount that, on an annual basis, is equivalent to the annual Federal contribution amount specified in paragraph (2) for the enrollee involved.

"(2) ANNUAL FEDERAL CONTRIBUTION AMOUNT.

"(A) IN 2004.—Subject to paragraphs (3) and (4), in the case of an accountholder whose modified adjusted gross income is—

"(i) not more than 135 percent of the poverty line, the annual Federal contribution amount for 2004 is \$800;

"(ii) more than 135 percent, but less than 150 percent, of the poverty line, the annual Federal contribution amount for 2004 is \$500; and "(iii) more than 150 percent of the poverty line, the annual Federal contribution amount for 2004 is \$100.

"(B) THEREAFTER.—For periods after 2004, the amounts applicable under subparagraph (A) shall be increased by the annual percentage increase described in section 1860D–2(b)(5) for the period involved.

"(C) ROUNDING.—If an annual Federal contribution amount determined under subparagraph (B) is not a multiple of \$10, it shall be rounded to the nearest multiple of \$10.

"(3) REQUIREMENT FOR INCOME VERIFICATION TO OBTAIN INCREASED CONTRIBU-TION AMOUNT.

"(A) IN GENERAL.—The provisions of subsections clauses (i) and (ii) of sub-paragraphs (A) and (B) of paragraph (2) shall apply to an individual only if the individual-

(i) provides such information as the Secretary may require in order to determine the appropriate category of benefits under the respective provisions; and

"(ii) authorizes in a form and manner specified by the Secretary the verification of the individual's modified adjusted gross income by the Secretary through arrangements with States.

An arrangement with a State under clause (ii) shall provide for the payment by the Secretary under this section of the State's reasonable costs of conducting income verifications under such arrangement.

(B) Penalties for understatement of income.—The provision of false information under_subparagraph (A)(i) is subject to criminal penalties

under section 1128B.

"(C) PROCEDURES FOR DETERMINING MODIFIED ADJUSTED GROSS INCOME.— "(i) IN GENERAL.—The Secretary shall establish procedures for determining the modified adjusted gross income of enrollees. The Secretary shall consult with the Secretary of the Treasury in making such determinations. Income determinations under this subsection shall be valid

for a period (of not less than 1 year) specified by the Secretary.

"(ii) DISCLOSURE OF INFORMATION.—The Secretary of the Treasury may, upon written request from the Secretary, disclose to Secretary such return information as is necessary to make the determinations described in clause (i). Return information disclosed under the preceding sentence may be used by the Secretary only for the purposes of, and

to the extent necessary in, making such determinations.

"(iii) PENALTY FOR UNAUTHORIZED DISCLOSURE.—The provisions of section 1860D-2(b)(4)(F)(ii) shall apply to an unauthorized disclosure of information under clause (ii) in the same manner as those provisions apply to an unauthorized disclosure of information under such section.

"(4) PARTIAL YEAR.—Insofar as the provisions of this subsection and section 1807A are not implemented for all months in 2004, the annual contribution amount under this subsection for 2004 shall be prorated to reflect the portion

of that year in which such provisions are in effect.

"(5) APPROPRIATION TO COVER NET PROGRAM EXPENDITURES.—There are authorized to be appropriated from time to time, out of any moneys in the Treasury not otherwise appropriated, to the Federal Supplementary Medical Insurance Trust Fund established under section 1841, an amount equal to the amount by which the benefits and administrative costs of providing the benefits under this section exceed the sum of the portion of the enrollment fees retained by the Secretary.

"(k) DEFINITIONS.—In this part and section 1807A:

"(1) COVERED OUTPATIÊNT DRUG.-

"(A) IN GENERAL.—Except as provided in this paragraph, for purposes of this section, the term 'covered outpatient drug' means

"(i) a drug that may be dispensed only upon a prescription and that is described in subparagraph (A)(i) or (A)(ii) of section 1927(k)(2); or

"(ii) a biological product described in clauses (i) through (iii) of subparagraph (B) of such section or insulin described in subparagraph (C) of such section and medical supplies associated with the injection of insulin (as defined in regulations of the Secretary),

and such term includes a vaccine licensed under section 351 of the Public Health Service Act and any use of a covered outpatient drug for a medically accepted indication (as defined in section 1927(k)(6)).

"(B) Exclusions.

"(i) IN GENERAL.—Such term does not include drugs or classes of drugs, or their medical uses, which may be excluded from coverage or otherwise restricted under section 1927(d)(2), other than subparagraph (E) thereof (relating to smoking cessation agents), or under section 1927(d)(3).

"(ii) AVOIDANCE OF DUPLICATE COVERAGE.—A drug prescribed for an individual that would otherwise be a covered outpatient drug under this section shall not be so considered if payment for such drug is available under part A or B for an individual entitled to benefits under part

A and enrolled under part B

"(C) APPLICATION OF FORMULARY RESTRICTIONS.—A drug prescribed for an individual that would otherwise be a covered outpatient drug under this section shall not be so considered under an endorsed program if the eligible entity offering the program excludes the drug under a formulary and a review of such exclusion is not successfully resolved under subsection (h)(5).

"(D) APPLICATION OF GENERAL EXCLUSION PROVISIONS.—An eligible entity offering an endorsed program may exclude from qualified prescription drug

coverage any covered outpatient drug—
"(i) for which payment would not be made if section 1862(a) applied

to part D; or
"(ii) which are not prescribed in accordance with the program or this

Such exclusions are determinations subject to review pursuant to subsection (h)(5).

"(2) Income.

"(A) IN GENERAL.—The term 'income' means, with respect to benefits under this section in a year, the modified adjusted gross income of the individual for the taxable year ending in the previous year.

(B) TREATMENT OF JOINT RETURNS.—In the case of a individual who files a joint return (as defined for purposes of the Internal Revenue Code of 1986), the income of the modified adjusted gross income of both individuals

shall be treated as the income of each individual.

(C) TREATMENT OF SEPARATE RETURNS.—In the case of an individual who is married and who does not file a joint return and who is not living separate and apart from the individual's spouse during at least 6 months of the taxable year shall be treated for purposes of this section as having income that exceeds 150 percent of the poverty line.

"(3) DEFINITION OF MODIFIED ADJUSTED GROSS INCOME.—The term 'modified adjusted gross income' means adjusted gross income (as defined in section 62

of the Internal Revenue Code of 1986)-

(A) determined without regard to sections 911, 931, and 933 of such Code; and "(B) increased by—

(i) the amount of interest received or accrued by the taxpayer during the taxable year which is exempt from tax under such Code, and

(ii) the amount of social security benefits not includible in gross in-

come under section 86 of such Code.

"(4) POVERTY LINE.—The term 'poverty line' means 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.

"(1) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section and section 1807A.

(e) Interim, Final Regulatory Authority.—In order to carry out this section and section 1807A in a timely manner, the Secretary may promulgate regulations that take effect on an interim basis, after notice and pending opportunity for public comment.

"PRESCRIPTION DRUG ACCOUNTS

"Sec. 1807A. "(a) Establishment of Accounts.-

"(1) IN GENERAL.—The Secretary shall establish and maintain for each eligible beneficiary who is enrolled under section 1807 at the time of enrollment a prescription drug account (in this section and section 1807 referred to as an 'account').

"(2) RESERVE ACCOUNTS.—In cases described in subsections (b)(3)(A), (b)(3)(B)(i), and (b)(3)(B)(ii)(I), the Secretary shall establish and maintain for each surviving spouse who is not enrolled under section 1807 a reserve prescription drug account (in this section referred to as an 'reserve account').

"(3) ACCOUNTHOLDER DEFINED.—In this section and section 1807A, the term 'accountholder' means an individual for whom an account or reserve account has

been established under this section.

"(4) EXPENDITURES FROM ACCOUNT.—Nothing in this section shall be construed as requiring the Federal Government to obligate funds for amounts in any account until such time as a withdrawal from such account is authorized under this section.

"(b) Use of Accounts.-

"(1) APPLICATION OF ACCOUNT.—Except as provided in this subsection, amounts credited to an account shall only be used for the purchase of covered outpatient drugs for the accountholder. Any amounts remaining at the end of a year remain available for expenditures in succeeding years.

"(2) ACCOUNT RULES FOR PUBLIC AND PRIVATE CONTRIBUTIONS.—The Secretary shall establish a ongoing process for the determination of the amount in each account that is attributable to public and private contributions (including spousal rollover contributions) based on the following rules:

"(A) TREATMENT OF EXPENDITURES.—Expenditures from the account

shall-

"(i) first be counted against any public contribution; and

"(ii) next be counted against private contributions.

"(B) TREATMENT OF SPOUSAL ROLLOVER CONTRIBUTIONS.—With respect to any spousal rollover contribution, the portions of such contribution that were attributable to public and private contributions at the time of its distribution under subsection (b)(3) shall be treated under this paragraph as if it were a direct public or private contribution, respectively, into the account of the spouse

"(3) DEATH OF ACCOUNTHOLDER.—In the case of the death of an accountholder, the balance in any account (taking into account liabilities accrued before the time of death) shall be distributed as follows:

(A) Treatment of public contributions.—If the accountholder is married at the time of death, the amount in the account that is attributable to public contributions shall be credited to the account (if any) of the surviving spouse of the accountholder (or, if the surviving spouse is not an eligible beneficiary, into a reserve account to be held for when that spouse becomes an eligible beneficiary).

(B) TREATMENT OF PRIVATE CONTRIBUTIONS.—The amount in the account

that is attributable to private contributions shall be distributed as follows:

"(i) DESIGNATION OF DISTRIBUTEE.—If the accountholder has made a designation, in a form and manner specified by the Secretary, for the distribution of some or all of such amount, such amount shall be distributed in accordance with the designation. Such designation may provide for the distribution into an account (including a reserve account) of a surviving spouse.

(ii) ABSENCE OF DESIGNATION.—Insofar as the accountholder has not

made such a designation-

"(I) SURVIVING SPOUSE.—If the accountholder was married at the time of death, the remainder shall be credited to an account (including a reserve account) of the accountholder's surviving spouse.

"(II) NO SURVIVING SPOUSE.—If the accountholder was not so married, the remainder shall be distributed to the estate of the accountholder and distributed as provided by law.

"(4) Use of account for premiums for enrollment in a medicare advan-TAGE OR EFFS PLAN.—During any period in which an accountholder is enrolled in a Medicare Advantage plan under part C or an EFFS plan under part E, the balance in the account may be used and applied only to reimburse the amount of the premium (if any) established for enrollment under the plan.

"(5) Application to medicaid expenses in certain cases

"(A) IN GENERAL.—Except as provided in this paragraph, an account shall be treated as an asset for purposes of establishing eligibility for medical assistance under title XIX.

"(B) APPLICATION TOWARDS SPENDDOWN.—In the case of an accountholder who is applying for such medical assistance and who would, but for the application of subparagraph (A), be eligible for such assistance

(i) subparagraph (A) shall not apply; and

"(ii) the account shall be available (in accordance with a procedure established by the Secretary) to the State to reimburse the State for any expenditures made under the plan for such medical assistance.

"(c) AMOUNTS CREDITED IN ACCOUNT.—The Secretary shall credit to a prescription drug account of an eligible beneficiary the following amounts:

"(1) PUBLIC CONTRIBUTIONS.—The following contributions (each referred to in

this section as a 'public contribution'):

(A) FEDERAL CONTRIBUTIONS.—Federal contributions provided under subsection (d).

"(B) STATE CONTRIBUTIONS.—Contributions made by a State under subsection (f).

"(2) SPOUSAL ROLLOVER CONTRIBUTION.—A distribution from a deceased spouse under subsection (b)(3) (referred to in this section as a 'spousal rollover contribution').

"(3) PRIVATE CONTRIBUTIONS.—The following contributions (each referred to in this section as a 'private contribution'):

(A) EMPLOYER AND INDIVIDUAL CONTRIBUTIONS.—Contributions made under subsection (e).

"(B) OTHER INDIVIDUAL CONTRIBUTIONS.—Contributions made accountholder other than under subsection (e). by

(C) CONTRIBUTIONS BY NONPROFIT ORGANIZATIONS.—Contributions made by a charitable, not-for-profit organization (that may be a religious organization).

Except as provided in this subsection, no amounts may be contributed to, or credited

to, a prescription drug account.
"(d) FEDERAL CONTRIBUTION.—For Federal contributions in the case of accountholders, see section 1807(j).

"(e) EMPLOYER AND INDIVIDUAL CONTRIBUTIONS.—

"(1) Employment-related contribution.—

"(A) IN GENERAL.—In the case of any accountholder who is a beneficiary or participant in a group health plan (including a multi-employer plan), whether as an employee, former employee or otherwise, including as a dependent of an employee or former employee, the plan may make a contribution into the accountholder's account (but not into a reserve account of the accountholder).

"(B) LIMITATION.—The total amount that may be contributed under subparagraph (A) under a plan to an account during any year may not exceed

\$5,000.

"(C) CONDITION.—A group health plan may condition a contribution with respect to an accountholder under this paragraph on the accountholder's enrollment under section 1807 with an eligible entity that is recognized or approved by that plan.

"(2) OTHER INDIVIDUALS.

'(A) IN GENERAL.—Any individual may also contribute to the account of that individual or the account of any other individual under this subsection. "(B) LIMITATION.—The total amount that may be contributed to an account under subparagraph (A) during any year may not exceed \$5,000, re-

gardless of who makes such contribution.

"(3) NO CONTRIBUTION PERMITTED TO RESERVE ACCOUNT.—No contribution

may be made under this subsection to a reserve account.

"(4) FORM AND MANNER OF CONTRIBUTION.—The Secretary shall specify the

form and manner of contributions under this subsection.

"(5) INDEXING OF DOLLAR AMOUNTS.—The dollar amounts of the limitation amounts specified in paragraphs (1)(B) and (2)(B) shall be subject to annual increases for each year after 2004 in the same manner as the annual deductible is subject to an annual increase under subparagraph (B) and the last sentence of section 1860D–2(b)(1).

"(f) STATE CONTRIBUTIONS.-

"(1) IN GENERAL.—A State may enter into arrangements with the Secretary for the crediting of amounts for accountholders.

"(2) FORM AND MANNER OF CONTRIBUTION.—The Secretary shall specify the

form and manner of contributions under this subsection.

(3) Medicaid treatment.—Amounts credited under this subsection shall not be treated as medical assistance for purposes of title XIX or child health assistance for purposes of title XXI for individuals who are not qualifying low income enrollees.

(b) EXCLUSION OF COSTS FROM DETERMINATION OF PART B MONTHLY PREMIUM.—Section 1839(g) (42 U.S.C. 1395r(g)) is amended—

(1) by striking "attributable to the application of section" and inserting "at-

tributable to-

"(1) the application of section";

(2) by striking the period and inserting "; and"; and (3) by adding at the end the following new paragraph:

(2) the Voluntary Medicare Outpatient Prescription Drug Discount and Security Program under sections 1807 and 1807A.".

(c) MEDICAID AMENDMENTS.

(1) Verification of eligibility for improved account contributions,-(A) REQUIREMENT.—Section 1902(a) (42 U.S.C. 1396a(a)) is amended—
(i) by striking "and" at the end of paragraph (64);

(ii) by striking the period at the end of paragraph (65) and inserting "; and"; and

(iii) by inserting after paragraph (65) the following new paragraph: "(66) provide for verification of income under section 1807(j)(3).".

(B) NEW SECTION.—Title XIX is further amended—

(i) by redesignating section 1935 as section 1936; and

(ii) by inserting after section 1934 the following new section:

"SPECIAL PROVISIONS RELATING TO MEDICARE PART D BENEFITS

"Sec. 1935. (a) Requirement for Verification of Eligibility Determinations FOR IMPROVED ACCOUNT CONTRIBUTIONS.—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), a State shall provide for verification of income statements in accordance with arrangements under section 1807(j)(1).

"(b) Payments for Additional Administrative Costs.

"(1) IN GENERAL.—The amounts expended by a State in carrying out subsection (a) are, subject to paragraph (2), expenditures reimbursable under the appropriate paragraph of section 1903(a); except that, notwithstanding any

other provision of such section, the applicable Federal matching rates with re-

spect to such expenditures under such section shall be 90 percent.

"(2) COORDINATION.—The State shall provide the Secretary with such information as may be necessary to properly allocate administrative expenditures described in paragraph (1) that may otherwise be made for eligibility determinations."

SEC. 106. DISCLOSURE OF RETURN INFORMATION FOR PURPOSES OF CARRYING OUT MEDICARE CATASTROPHIC PRESCRIPTION DRUG PROGRAM.

(a) IN GENERAL.—Subsection (l) of section 6103 of the Internal Revenue Code of 1986 (relating to disclosure of returns and return information for purposes other than tax administration) is amended by adding at the end the following new paragraph:
"(19) Disclosure of return information for purposes of carrying out

MEDICARE CATASTROPHIC PRESCRIPTION DRUG PROGRAM.-

"(A) IN GENERAL.—The Secretary may, upon written request from the Secretary of Health and Human Services under section 1860D-2(b)(4)(E)(i) of the Social Security Act, disclose to officers and employees of the Department of Health and Human Services with respect to a specified taxpayer for the taxable year specified by the Secretary of Health and Human Services in such request-

"(i) the taxpayer identity information with respect to such taxpayer,

"(ii) the adjusted gross income of such taxpayer for the taxable year (or, if less, the income threshold limit specified in section 1860D–2(b)(4)(D)(ii) for the calendar year specified by such Secretary in such request).

"(B) Specified taxpayer.—For purposes of this paragraph, the term

'specified taxpayer' means any taxpayer who—

"(i) is identified by the Secretary of Health and Human Services in the request referred to in subparagraph (A), and

"(ii) either-

"(I) has an adjusted gross income for the taxable year referred to in subparagraph (A) in excess of the income threshold specified in section 1860D-2(b)(4)(D)(ii) of such Act for the calendar year referred to in such subparagraph, or

"(II) is identified by such Secretary under subparagraph (A) as being an individual who elected to use more recent information

under section 1860D-2(b)(4)(D)(v) of such Act.

"(C) JOINT RETURNS.—In the case of a joint return, the Secretary shall, for purposes of applying this paragraph, treat each spouse as a separate taxpayer having an adjusted gross income equal to one-half of the adjusted

gross income determined with respect to such return.

"(D) RESTRICTION ON USE OF DISCLOSED INFORMATION.—Return information disclosed under subparagraph (A) may be used by officers and employees of the Department of Health and Human Services only for the purpose of administering the prescription drug benefit under title XVIII of the Social Security Act. Such officers and employees may disclose the annual outcial Security Act. Such officers and employees may disclose the annual outof-pocket threshold which applies to an individual under such part to the
entity that offers the plan referred to in section 1860D–2(b)(4)(E)(ii) of such
Act in which such individual is enrolled. Such sponsor may use such information only for purposes of administering such benefit.".

(b) CONFIDENTIALITY.—Paragraph (3) of section 6103(a) of such Code is amended
by striking "or (16)" and inserting "(16), or (19)".

by striking "or (16)" and inserting "(16), or (19)".

(c) Procedures and Recordkeeping Related to Disclosures.—Subsection (p)(4) of section 6103 of such Code is amended by striking "any other person described in subsection (l)(16) or (17)" each place it appears and inserting "any other person described in subsection (l)(16), (17), or (19)".

(d) Unauthorized Disclosure.—Paragraph (2) of section 7213(a) of such Code is amended by striking "or (16)" and inserting "(16), or (19)".

(e) Unauthorized Inspection.—Subparagraph (B) of section 7213A(a)(1) of such Code is amended by inserting "or (19)" after "subsection (l)(18)".

SEC. 107. STATE PHARMACEUTICAL ASSISTANCE TRANSITION COMMISSION.

(a) ESTABLISHMENT.

(1) IN GENERAL.—There is established, as of the first day of the third month beginning after the date of the enactment of this Act, a State Pharmaceutical Assistance Transition Commission (in this section referred to as the "Commission") to develop a proposal for addressing the unique transitional issues facing State pharmaceutical assistance programs, and program participants, due to the implementation of the medicare prescription drug program under part D of title XVIII of the Social Security Act.

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

(A) STATE PHARMACEUTICAL ASSISTANCE PROGRAM DEFINED.—The term "State pharmaceutical assistance program" means a program (other than the medicaid program) operated by a State (or under contract with a State) that provides as of the date of the enactment of this Act assistance to lowincome medicare beneficiaries for the purchase of prescription drugs.

(B) PROGRAM PARTICIPANT.—The term "program participant" means a low-income medicare beneficiary who is a participant in a State pharma-

ceutical assistance program.

(b) COMPOSITION.—The Commission shall include the following:

- (1) A representative of each governor of each State that the Secretary identifies as operating on a statewide basis a State pharmaceutical assistance program that provides for eligibility and benefits that are comparable or more generous than the low-income assistance eligibility and benefits offered under part D of title XVIII of the Social Security Act.
- (2) Representatives from other States that the Secretary identifies have in operation other State pharmaceutical assistance programs, as appointed by the Secretary.
- (3) Representatives of organizations that have an inherent interest in program participants or the program itself, as appointed by the Secretary but not to exceed the number of representatives under paragraphs (1) and (2).
- (4) Representatives of Medicare Advantage organizations and other private

health insurance plans, as appointed by the Secretary.

(5) The Secretary (or the Secretary's designee) and such other members as the Secretary may specify

The Secretary shall designate a member to serve as chair of the Commission and the Commission shall meet at the call of the chair.

- (c) DEVELOPMENT OF PROPOSAL.—The Commission shall develop the proposal described in subsection (a) in a manner consistent with the following principles:
 - (1) Protection of the interests of program participants in a manner that is the least disruptive to such participants and that includes a single point of contact for enrollment and processing of benefits.
 - (2) Protection of the financial and flexibility interests of States so that States are not financially worse off as a result of the enactment of this title.
- (3) Principles of medicare modernization provided under title II of this Act. (d) REPORT.—By not later than January 1, 2005, the Commission shall submit to the President and the Congress a report that contains a detailed proposal (including specific legislative or administrative recommendations, if any) and such other recommendations as the Commission deems appropriate.
- (e) SUPPORT.—The Secretary shall provide the Commission with the administrative support services necessary for the Commission to carry out its responsibilities under this section.
- (f) TERMINATION.—The Commission shall terminate 30 days after the date of submission of the report under subsection (d).

TITLE II—MEDICARE ENHANCED FEE-FOR-SERVICE AND MEDICARE ADVANTAGE PRO-GRAMS; MEDICARE COMPETITION

SEC. 200. MEDICARE MODERNIZATION AND REVITALIZATION.

This title provides for-

- (1) establishment of the medicare enhanced fee-for-service (EFFS) program under which medicare beneficiaries are provided access to a range of enhanced fee-for-service (EFFS) plans that may use preferred provider networks to offer an enhanced range of benefits;
- (2) establishment of a Medicare Advantage program that offers improved managed care plans with coordinated care; and
- (3) competitive bidding, in the style of the Federal Employees Health Benefits program (FEHBP), among enhanced fee-for-service plans and Medicare Advantage plans in order to promote greater efficiency and responsiveness to medicare beneficiaries.

Subtitle A—Medicare Enhanced Fee-for-Service **Program**

SEC. 201. ESTABLISHMENT OF ENHANCED FEE-FOR-SERVICE (EFFS) PROGRAM UNDER MEDI-

- (a) IN GENERAL.—Title XVIII, as amended by section 101(a), is amended—
 - (1) by redesignating part E as part F; and
 - (2) by inserting after part D the following new part:

"PART E-ENHANCED FEE-FOR-SERVICE PROGRAM

"OFFERING OF ENHANCED FEE-FOR-SERVICE PLANS THROUGHOUT THE UNITED STATES

"Sec. 1860E-1. (a) Establishment of Program.—

"(1) IN GENERAL.—The Administrator shall establish under this part beginning January 1, 2006, an enhanced fee-for-service program under which enhanced fee-for-service plans (as defined in subsection (b)) are offered to EFFSeligible individuals (as so defined) in EFFS regions throughout the United States

"(2) EFFS regions.—For purposes of this part the Administrator shall establish EFFS regions throughout the United States by dividing the entire United States into at least 10 such regions. Before establishing such regions, the Administrator shall conduct a market survey and analysis, including an examination of current insurance markets, to determine how the regions should be established. The regions shall be established in a manner to take into consideration maximizing full access for all EFFS-eligible individuals, especially those residing in rural areas.

"(b) DEFINITIONS.—For purposes of this part:
"(1) EFFS ORGANIZATION.—The 'EFFS organization' means an entity that the Administrator certifies as meeting the requirements and standards applicable

to such organization under this part.

"(2) Enhanced fee-for-service plan; effs plan.—The terms 'enhanced feefor-service plan' and 'EFFS plan' mean health benefits coverage offered under a policy, contract, or plan by an EFFS organization pursuant to and in accordance with a contract pursuant to section 1860E-4(c), but only if the plan provides either fee-for-service coverage described in the following subparagraph (A) or preferred provider coverage described in the following subparagraph (B):

"(A) FEE-FOR-SERVICE COVERAGE.—The plan-

"(i) reimburses hospitals, physicians, and other providers at a rate determined by the plan on a fee-for-service basis without placing the provider at financial risk;

"(ii) does not vary such rates for such a provider based on utilization

relating to such provider; and

"(iii) does not restrict the selection of providers among those who are lawfully authorized to provide the covered services and agree to accept the terms and conditions of payment established by the plan.

"(B) Preferred provider coverage.—The plan-

"(1) has a network of providers that have agreed to a contractually specified reimbursement for covered benefits with the organization offering the plan; and

"(ii) provides for reimbursement for all covered benefits regardless of whether such benefits are provided within such network of providers. "(3) EFFS ELIGIBLE INDIVIDUAL.—The term 'EFFS eligible individual' means an eligible individual described in section 1851(a)(3).

"(4) EFFS REGION.—The term 'EFFS region' means a region established under

subsection (a)(2).

"(c) APPLICATION OF CERTAIN ELIGIBILITY, ENROLLMENT, ETC. REQUIREMENTS.— The provisions of section 1851 (other than subsection (h)(4)(A)) shall apply to EFFS plans offered by an EFFS organization in an EFFS region, including subsection (g) (relating to guaranteed issue and renewal).

"OFFERING OF ENHANCED FEE-FOR-SERVICE (EFFS) PLANS

"Sec. 1860E-2. (a) Plan Requirements.—No EFFS plan may be offered under this part in an EFFS region unless the requirements of this part are met with respect to the plan and EFFS organization offering the plan.

"(b) AVAILABLE TO ALL EFFS BENEFICIARIES IN THE ENTIRE REGION.—With re-

spect to an EFFS plan offered in an EFFS region-

"(1) IN GENERAL.—The plan must be offered to all EFFS-eligible individuals residing in the region.

"(2) Assuring access to services.—The plan shall comply with the require-

ments of section 1852(d)(4). "(c) Benefits.

"(1) IN GENERAL.—Each EFFS plan shall provide to members enrolled in the plan under this part benefits, through providers and other persons that meet the applicable requirements of this title and part A of title XI—

(A) for the items and services described in section 1852(a)(1);

"(B) that are uniform for the plan for all EFFS eligible individuals resid-

ing in the same EFFS region;

"(C) that include a single deductible applicable to benefits under parts A and B and include a catastrophic limit on out-of-pocket expenditures for such covered benefits; and

"(D) that include benefits for prescription drug coverage for each enrollee who elects under part D to be provided qualified prescription drug coverage

through the plan.

"(2) DISAPPROVAL AUTHORITY.—The Administrator shall not approve a plan of an EFFS organization if the Administrator determines (pursuant to the last sentence of section 1852(b)(1)(A)) that the benefits are designed to substantially discourage enrollment by certain EFFS eligible individuals with the organiza-

"(d) OUTPATIENT PRESCRIPTION DRUG COVERAGE.—For rules concerning the offering of prescription drug coverage under EFFS plans, see the amendment made by section 102(b) of the Medicare Prescription Drug and Modernization Act of 2003.

"(e) OTHER ADDITIONAL PROVISIONS.—The provisions of section 1852 (other than subsection (a)(1)) shall apply under this part to EFFS plans. For the application of

chronic care improvement provisions, see the amendment made by section 722(b).

"SUBMISSION OF BIDS; BENEFICIARY SAVINGS; PAYMENT OF PLANS

"Sec. 1860E-3. (a) Submission of Bids.—

"(1) REQUIREMENT.-

"(A) EFFS MONTHLY BID AMOUNT.—For each year (beginning with 2006), an EFFS organization shall submit to the Administrator an EFFS monthly bid amount for each EFFS plan offered in each region. Each such bid is referred to in this section as the 'EFFS monthly bid amount'.

"(B) FORM.—Such bid amounts shall be submitted for each such plan and region in a form and manner and time specified by the Administrator, and

shall include information described in paragraph (3)(A).

"(2) UNIFORM BID AMOUNTS.—Each EFFS monthly bid amount submitted under paragraph (1) by an EFFS organization under this part for an EFFS plan in an EFFS region may not vary among EFFS eligible individuals residing in the EFFS region involved.

"(3) Submission of bid amount information by Effs organizations.-

(A) Information to be submitted.—The information described in this

subparagraph is as follows:

"(i) The EFFS monthly bid amount for provision of all items and services under this part, which amount shall be based on average costs for a typical beneficiary residing in the region, and the actuarial basis for determining such amount.

"(ii) The proportions of such bid amount that are attributable to—
"(I) the provision of statutory non-drug benefits (such portion referred to in this part as the 'unadjusted EFFS statutory non-drug monthly bid amount');

"(II) the provision of statutory prescription drug benefits; and "(III) the provision of non-statutory benefits;

and the actuarial basis for determining such proportions.

"(iii) Such additional information as the Administrator may require to verify the actuarial bases described in clauses (i) and (ii).

"(B) STATUTORY BENEFITS DEFINED.—For purposes of this part:

"(i) The term 'statutory non-drug benefits' means benefits under section 1852(a)(1).

"(ii) The term 'statutory prescription drug benefits' means benefits under part D.

"(iii) The term 'statutory benefits' means statutory prescription drug benefits and statutory non-drug benefits.

"(C) ACCEPTANCE AND NEGOTIATION OF BID AMOUNTS.—The Administrator has the authority to negotiate regarding monthly bid amounts submitted under subparagraph (A) (and the proportion described in subparagraph (A)(ii)), and for such purpose, the Administrator has negotiation authority that the Director of the Office of Personnel Management has with respect to health benefits plans under chapter 89 of title 5, United States Code. The Administrator may reject such a bid amount or proportion if the Administrator determines that such amount or proportion is not supported by the actuarial bases provided under subparagraph (A).

"(D) CONTRACT AUTHORITY.—The Administrator may, taking into account the unadjusted EFFS statutory non-drug monthly bid amounts accepted under subparagraph (C), enter into contracts for the offering of up to 3

EFFS plans in any region.

"(b) Provision of Beneficiary Savings for Certain Plans.—

"(1) BENEFICIARY REBATE RULE.-

"(A) REQUIREMENT.—The EFFS plan shall provide to the enrollee a monthly rebate equal to 75 percent of the average per capita savings (if any) described in paragraph (2) applicable to the plan and year involved. "(B) FORM OF REBATE.—A rebate required under this paragraph shall be

provided-

"(i) through the crediting of the amount of the rebate towards the EFFS monthly prescription drug beneficiary premium (as defined in section 1860E–4(a)(3)(B)) and the EFFS monthly supplemental beneficiary for the section 1860E–4(a)(3)(B) and the EFFS monthly supplemental beneficiary for the section 1860E–4(a)(3)(B). ficiary premium (as defined in section 1860E-4(a)(3)(C));

"(ii) through a direct monthly payment (through electronic funds

transfer or otherwise); or

(iii) through other means approved by the Medicare Benefits Administrator,

or any combination thereof.

"(2) Computation of average per capita monthly savings.—For purposes of paragraph (1)(A), the average per capita monthly savings referred to in such paragraph for an EFFS plan and year is computed as follows:

"(A) DETERMINATION OF REGION-WIDE AVERAGE RISK ADJUSTMENT.

"(i) IN GENERAL.—The Medicare Benefits Administrator shall determine, at the same time rates are promulgated under section 1853(b)(1) (beginning with 2006), for each EFFS region the average of the risk adjustment factors described in subsection (c)(3) to be applied to enrollees under this part in that region. In the case of an EFFS region in which an EFFS plan was offered in the previous year, the Administrator may compute such average based upon risk adjustment factors applied under subsection (c)(3) in that region in a previous year.

"(ii) TREATMENT OF NEW REGIONS.—In the case of a region in which no EFFS plan was offered in the previous year, the Administrator shall estimate such average. In making such estimate, the Administrator may use average risk adjustment factors applied to comparable EFFS

regions or applied on a national basis.

"(B) DETERMINATION OF RISK ADJUSTED BENCHMARK AND RISK-ADJUSTED BID.—For each EFFS plan offered in an EFFS region, the Administrator shall-

"(i) adjust the EFFS region-specific non-drug monthly benchmark amount (as defined in paragraph (3)) by the applicable average risk adjustment factor computed under subparagraph (A); and "(ii) adjust the unadjusted EFFS statutory non-drug monthly bid

amount by such applicable average risk adjustment factor.

"(C) DETERMINATION OF AVERAGE PER CAPITA MONTHLY SAVINGS.—The average per capita monthly savings described in this subparagraph is equal to the amount (if any) by which-

"(i) the risk-adjusted benchmark amount computed under subpara-

 $\begin{array}{l} \text{graph } (B)(i), \text{ exceeds} \\ \text{``(ii) the risk-adjusted bid computed under subparagraph } (B)(ii). \end{array}$

"(3) Computation of Effs region-specific non-drug monthly benchmark AMOUNT.—For purposes of this part, the term 'EFFS region-specific non-drug monthly benchmark amount means, with respect to an EFFS region for a month in a year, an amount equal to $\frac{1}{12}$ of the average (weighted by number of EFFS eligible individuals in each payment area described in section 1853(d)) of the annual capitation rate as calculated under section 1853(c)(1) for that area.

"(c) Payment of Plans Based on Bid Amounts.—

"(1) NON-DRUG BENEFITS.—Under a contract under section 1860E-4(c) and subject to section 1853(g) (as made applicable under subsection (d)), the Administrator shall make monthly payments under this subsection in advance to each

EFFS organization, with respect to coverage of an individual under this part in an EFFS region for a month, in an amount determined as follows:

"(A) PLANS WITH BIDS BELOW BENCHMARK.—In the case of a plan for which there are average per capita monthly savings described in subsection (b)(2)(C), the payment under this subsection is equal to the unadjusted EFFS statutory non-drug monthly bid amount, adjusted under paragraphs (3) and (4), plus the amount of the monthly rebate computed under subsection (b)(1)(A) for that plan and year.

(B) PLANS WITH BIDS AT OR ABOVE BENCHMARK.—In the case of a plan for which there are no average per capita monthly savings described in subsection (b)(2)(C), the payment amount under this subsection is equal to the

section (b)(2)(C), the payment amount under this subsection is equal to the EFFS region-specific non-drug monthly benchmark amount, adjusted under paragraphs (3) and (4).

"(2) FOR FEDERAL DRUG SUBSIDIES.—In the case in which an enrollee who elects under part D to be provided qualified prescription drug coverage through the plan, the EFFS organization offering such plan also is entitled—

"(A) to direct subsidy payment under section 1860D–8(a)(1);

"(B) to reinsurance subsidy payments under section 1860D–8(a)(2); and

"(C) to reimbursement for premium and cost-sharing reductions for low-income individuals under section 1860D-7(c)(3).

"(3) DEMOGRAPHIC RISK ADJUSTMENT, INCLUDING ADJUSTMENT FOR HEALTH STATUS.—The Administrator shall adjust under paragraph (1)(A) the unadjusted EFFS statutory non-drug monthly bid amount and under paragraph (1)(B) the EFFS region-specific non-drug monthly benchmark amount for such risk factors as age, disability status, gender, institutional status, and such other factors as the Administrator determines to be appropriate including adjustment for as age, disability status, gender, institutional status, and such other factors as the Administrator determines to be appropriate, including adjustment for health status under section 1853(a)(3) (as applied under subsection (d)), so as to ensure actuarial equivalence. The Administrator may add to, modify, or substitute for such adjustment factors if such changes will improve the determination of actuarial equivalence.

"(4) Adjustment for intra-regional geographic variations.—The Administrator shall also adjust such amounts in a manner to take into account variations in payments rates under part C among the different payment areas under such part included in each EFFS region.

"(d) APPLICATION OF ADDITIONAL PAYMENT RULES.—The provisions of section 1853

(other than subsections (a)(1)(A), (d), and (e)) shall apply to an EFFS plan under this part, except as otherwise provided in this section.

"PREMIUMS; ORGANIZATIONAL AND FINANCIAL REQUIREMENTS; ESTABLISHMENT OF STANDARDS; CONTRACTS WITH EFFS ORGANIZATIONS

"Sec. 1860E-4. (a) Premiums.-

"(1) IN GENERAL.—The provisions of section 1854 (other than subsections (a)(6)(C) and (h)), including subsection (b)(5) relating to the consolidation of drug and non-drug beneficiary premiums and subsection (c) relating to uniform bids and premiums, shall apply to an EFFS plan under this part, subject to "(2) CROSS-WALK.—In applying paragraph (1), any reference in section 1854(b)(1)(A) or 1854(d) to—

"(A) a Medicare Advantage monthly basic beneficiary premium is deemed a reference to the EFFS monthly basic beneficiary premium (as defined in

paragraph (3)(A));

"(B) a Medicare Advantage monthly prescription drug beneficiary premium is deemed a reference to the EFFS monthly prescription drug beneficiary premium (as defined in paragraph (3)(B)); and

"(C) a Medicare Advantage monthly supplemental beneficiary premium is deemed a reference to the EFFS monthly supplemental beneficiary premium is mium (as defined in paragraph (3)(C)).

"(3) DEFINITIONS.—For purposes of this part:

"(A) EFFS MONTHLY BASIC BENEFICIARY PREMIUM.—The term 'EFFS monthly basic beneficiary premium' means, with respect to an EFFS plan—
"(i) described in section 1860E–3(c)(1)(A) (relating to plans providing

rebates), zero; or

"(ii) described in section 1860E-3(c)(1)(B), the amount (if any) by which the unadjusted EFFS statutory non-drug monthly bid amount exceeds the EFFS region-specific non-drug monthly benchmark amount (as defined in section 1860E-3(b)(3)).

"(B) EFFS MONTHLY PRESCRIPTION DRUG BENEFICIARY PREMIUM.—The term 'EFFS monthly prescription drug beneficiary premium' means, with respect to an EFFS plan, the portion of the aggregate monthly bid amount

submitted under clause (i) of section 1860E-3(a)(3)(A) for the year that is attributable under such section to the provision of statutory prescription

"(C) EFFS MONTHLY SUPPLEMENTAL BENEFICIARY PREMIUM.—The term 'EFFS monthly supplemental beneficiary premium' means, with respect to an EFFS plan, the portion of the aggregate monthly bid amount submitted under clause (i) of section 1860E–3(a)(3)(A) for the year that is attributable under such section to the provision of nonstatutory benefits.

"(b) Organizational and Financial Requirements.—The provisions of section

1855 shall apply to an EFFS plan offered by an EFFS organization under this part. "(c) Contracts with EFFS Organizations.—The provisions of section 1857 shall apply to an EFFS plan offered by an EFFS organization under this part, except that any reference in such section to part C is deemed a reference to this part.

(b) Prohibition on Coverage Under Medigap Plans of Deductible Imposed Under EFFS Plans.—Section 1882 (42 U.S.C. 1395ss), as amended by section

104(a), is amended by adding at the end the following new subsection:

"(w) Prohibition on Coverage of Deductible and Certain Cost-Sharing Im-POSED UNDER EFFS PLANS.—Notwithstanding any other provision of law, no medicare supplemental policy (other than the 2 benefit packages described in subsection (v)(3)) may provide for coverage of the single deductible or more than 50 percent of other cost-sharing imposed under an EFFS plan under part E.".

(c) CONFORMING PROVISIONS.—Section 1882 of the Social Security Act (42 U.S.C.

1395ss) shall be administered as if any reference to a Medicare+Choice organization offering a Medicare+Choice plan under part C of title XVIII of such Act were a reference both to a Medicare Advantage organization offering a Medicare Advantage plan under such part and an EFFS organization offering an EFFS plan under part E of such title.

Subtitle B—Medicare Advantage Program

CHAPTER 1—IMPLEMENTATION OF PROGRAM

SEC. 211. IMPLEMENTATION OF MEDICARE ADVANTAGE PROGRAM.

(a) IN GENERAL.—There is hereby established the Medicare Advantage program. The Medicare Advantage program shall consist of the program under part C of title

XVIII of the Social Security Act, as amended by this title.

(b) REFERENCES.—Any reference to the program under part C of title XVIII of the Social Security Act shall be deemed a reference to the Medicare Advantage program and, with respect to such part, any reference to "Medicare+Choice" is deemed a reference to "Medicare Advantage"

SEC. 212. MEDICARE ADVANTAGE IMPROVEMENTS.

(a) EQUALIZING PAYMENTS WITH FEE-FOR-SERVICE.-

(1) IN GENERAL.—Section 1853(c)(1) (42 U.S.C. 1395w-23(c)(1)) is amended by adding at the end the following:

(D) Based on 100 percent of fee-for-service costs.—

"(i) IN GENERAL.—For 2004, the adjusted average per capita cost for the year involved, determined under section 1876(a)(4) for the Medicare Advantage payment area for services covered under parts A and B for individuals entitled to benefits under part A and enrolled under part B who are not enrolled in a Medicare Advantage under this part for the year, but adjusted to exclude costs attributable to payments under section 1886(h).

(ii) Inclusion of costs of va and dod military facility services TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the adjusted average per capita cost under clause (i) 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.

(2) CONFORMING AMENDMENT.—Such section is further amended, in the matter before subparagraph (A), by striking "or (C)" and inserting "(C), or (D)".

(b) CHANGE IN BUDGET NEUTRALITY FOR BLEND.—Section 1853(c) (42 U.S.C.

1395w-23(c)) is amended-

(1) in paragraph (1)(A), by inserting "(for a year other than 2004)" after "multiplied"; and

(2) in paragraph (5), by inserting "(other than 2004)" after "for each year".

- (c) Increasing Minimum Percentage Increase to National Growth Rate.— (1) IN GENERAL.—Section 1853(c)(1) (42 U.S.C. 1395w-23(c)(1)) is amended-
 - (A) in subparagraph (B)(iv), by striking "and each succeeding year" and inserting ", 2003, and 2004";

(B) in subparagraph (C)(iv), by striking "and each succeeding year" and inserting "and 2003"; and

(C) by adding at the end of subparagraph (C) the following new clause: "(v) For 2004 and each succeeding year, the greater of-

"(I) 102 percent of the annual Medicare Advantage capitation

rate under this paragraph for the area for the previous year; or "(II) the annual Medicare Advantage capitation rate under this paragraph for the area for the previous year increased by the national per capita Medicare Advantage growth percentage, described in paragraph (6) for that succeeding year, but not taking into account any adjustment under paragraph (6)(C) for a year before

(2) Conforming amendment.—Section 1853(c)(6)(C) (42 U.S.C. 1395w-23(c)(6)(C)) is amended by inserting before the period at the end the following: ", except that for purposes of paragraph (1)(C)(v)(II), no such adjustment shall be made for a year before 2004

(d) Inclusion of Costs of DOD and VA Military Facility Services to Medi-CARE-ELIGIBLE BENEFICIARIES IN CALCULATION OF MEDICARE+CHOICE PAYMENT RATES.—Section 1853(c)(3) (42 U.S.C. 1395w-23(c)(3)) is amended—

(1) in subparagraph (A), by striking "subparagraph (B)" and inserting "subparagraphs (B) and (E)", and

- (2) by adding at the end the following new subparagraph:

 "(E) INCLUSION OF COSTS OF DOD AND VA MILITARY FACILITY SERVICES TO MEDICARE-ELIGIBLE BENEFICIARIES.—In determining the area-specific Medicare+Choice capitation rate under subparagraph (A) for a year (beginning with 2004), the annual per capita rate of payment for 1997 determined under section 1876(a)(1)(C) shall be adjusted to include in the rate 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 Defense or the Department of Veterans
- (e) Extending Special Rule for Certain Inpatient Hospital Stays to Reha-BILITATION HOSPITALS.-
 - (1) IN GENERAL.—Section 1853(g) (42 U.S.C. 1395w-23(g)) is amended-
 - (A) by inserting "or from a rehabilitation facility (as defined in section 1886(j)(1)(A))" after "1886(d)(1)(B))"; and
 - (B) in paragraph (2)(B), by inserting "or section 1886(j), as the case may
 - be," after "1886(d)".

 (2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to

contract years beginning on or after January 1, 2004.
(f) APPLICATION OF PRIVACY REGULATIONS.—Section 1852(h) (42 U.S.C. 1395w—

22(h)) is amended by adding after and below paragraph (3) the following: "A Medicare Advantage organization shall be treated as a covered entity for purposes of the provisions of subpart E of part 164 of title 45, Code of Federal Regulations, adopted pursuant to the authority of the Secretary under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S. C. 1320d-2

(g) MedPAC Study of AAPCC.—

(1) STUDY.—The Medicare Payment Advisory Commission shall conduct a study that assesses the method used for determining the adjusted average per that assesses the method used for determining the adjusted average percapita cost (AAPCC) under section 1876(a)(4) of the Social Security Act (42 U.S.C. 1395mm(a)(4)) as applied under section 1853(c)(1)(A) of such Act (as amended by subsection (a)). Such study shall include an examination of—

(A) the bases for variation in such costs between different areas, includ-

ing differences in input prices, utilization, and practice patterns;

(B) the appropriate geographic area for payment under the Medicare Advantage program under part C of title XVIII of such Act; and (C) the accuracy of risk adjustment methods in reflecting differences in

costs of providing care to different groups of beneficiaries served under such

(2) REPORT.—Not later than 18 months after the date of the enactment of this Act, the Commission shall submit to Congress a report on the study conducted under paragraph (1).

(h) REPORT ON IMPACT OF INCREASED FINANCIAL ASSISTANCE TO MEDICARE ADVANTAGE PLANS.—Not later than July 1, 2006, the Medicare Benefits Administrator shall submit to Congress a report that describes the impact of additional financing provided under this Act and other Acts (including the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 and BIPA) on the availability of Medicare Advantage plans in different areas and its impact on lowering premiums and increasing benefits under such plans.

CHAPTER 2—IMPLEMENTATION OF COMPETITION PROGRAM

SEC. 221, COMPETITION PROGRAM BEGINNING IN 2006.

(a) Submission of EFFS-Like Bidding Information Beginning in 2006.—Section 1854 (42 U.S.C. 1395w-24) is amended-

(1) by amending the section heading to read as follows:

"PREMIUMS AND BID AMOUNT":

(2) in subsection (a)(1)(A)—

(A) by striking "(A)" and inserting "(A)(i) if the following year is before 2006,"; and
(B) by inserting before the semicolon at the end the following: "or (ii) if

the following year is 2006 or later, the information described in paragraph (3) or (6)(A) for the type of plan involved"; and (3) by adding at the end of subsection (a) the following:

"(6) Submission of bid amounts by medicare advantage organizations.— "(A) INFORMATION TO BE SUBMITTED.—The information described in this subparagraph is as follows:

"(i) The monthly aggregate bid amount for provision of all items and services under this part, which amount shall be based on average costs for a typical beneficiary residing in the area, and the actuarial basis for determining such amount.

"(ii) The proportions of such bid amount that are attributable to—

"(I) the provision of statutory non-drug benefits (such portion referred to in this part as the 'unadjusted Medicare Advantage statutory non-drug monthly bid amount');

"(II) the provision of statutory prescription drug benefits; and "(III) the provision of non-statutory benefits;

and the actuarial basis for determining such proportions.

"(iii) Such additional information as the Administrator may require to verify the actuarial bases described in clauses (i) and (ii).

"(B) STATUTORY BENEFITS DEFINED.—For purposes of this part:

"(i) The term 'statutory non-drug benefits' means benefits under section 1852(a)(1).

(ii) The term 'statutory prescription drug benefits' means benefits under part D.

"(iii) The term 'statutory benefits' means statutory prescription drug benefits and statutory non-drug benefits.

"(C) ACCEPTANCE AND NEGOTIATION OF BID AMOUNTS.—

"(i) IN GENERAL.—Subject to clause (ii)-

"(I) the Administrator has the authority to negotiate regarding monthly bid amounts submitted under subparagraph (A) (and the proportion described in subparagraph (A)(ii), and for such purpose and subject to such clause, the Administrator has negotiation authority that the Director of the Office of Personnel Management has with respect to health benefits plans under chapter 89 of title

5, United States Code; and
"(II) the Administrator may reject such a bid amount or proportion if the Administrator determines that such amount or proportion is not supported by the actuarial bases provided under sub-

paragraph (A).

"(ii) EXCEPTION.—In the case of a plan described in section 1851(a)(2)(C), the provisions of clause (i) shall not apply and the provisions of paragraph (5)(B), prohibiting the review, approval, or disapproval of amounts described in such paragraph, shall apply to the negotiation and rejection of the monthly bid amounts and proportion referred to in subparagraph (A)."

(b) Providing for Beneficiary Savings for Certain Plans.—
(1) In General.—Section 1854(b) (42 U.S.C. 1395w-24(b)) is amended—

(A) by adding at the end of paragraph (1) the following new subparagraph:

"(C) Beneficiary rebate rule.-

"(i) REQUIREMENT.—The Medicare Advantage plan shall provide to the enrollee a monthly rebate equal to 75 percent of the average per capita savings (if any) described in paragraph (3) applicable to the plan and vear involved.

(iii) FORM OF REBATE.—A rebate required under this subparagraph

shall be provided-

"(Î) through the crediting of the amount of the rebate towards the Medicare Advantage monthly supplementary beneficiary premium or the premium imposed for prescription drug coverage under part D;

"(II) through a direct monthly payment (through electronic funds

transfer or otherwise); or

"(III) through other means approved by the Medicare Benefits Administrator.

or any combination thereof."; and
(B) by adding at the end the following new paragraphs:

"(3) COMPUTATION OF AVERAGE PER CAPITA MONTHLY SAVINGS.—For purposes

"(3) COMPUTATION OF AVERAGE PER CAPITA MONTHLY SAVINGS.—For purposes of paragraph (1)(C)(i), the average per capita monthly savings referred to in such paragraph for a Medicare Advantage plan and year is computed as follows:

"(A) DETERMINATION OF STATE-WIDE AVERAGE RISK ADJUSTMENT.—

"(i) IN GENERAL.—The Medicare Benefits Administrator shall determine, at the same time rates are promulgated under section 1853(b)(1) (beginning with 2006), for each State the average of the risk adjustment factors to be applied under section 1853(a)(1)(A) to payment for enrollees in that State. In the case of a State in which a Medicare Adenrollees in that State. In the case of a State in which a Medicare Advantage plan was offered in the previous year, the Administrator may compute such average based upon risk adjustment factors applied in that State in a previous year.

"(ii) TREATMENT OF NEW STATES.—In the case of a State in which no Medicare Advantage plan was offered in the previous year, the Administrator shall estimate such average. In making such estimate, the Administrator may use average risk adjustment factors applied to com-

parable States or applied on a national basis.

"(B) DETERMINATION OF RISK ADJUSTED BENCHMARK AND RISK-ADJUSTED BID.—For each Medicare Advantage plan offered in a State, the Administrator shall-

"(i) adjust the Medicare Advantage area-specific non-drug monthly benchmark amount (as defined in subsection (j)) by the applicable average risk adjustment factor computed under subparagraph (A); and

'(ii) adjust the unadjusted Medicare Advantage statutory non-drug monthly bid amount by such applicable average risk adjustment factor. "(C) DETERMINATION OF AVERAGE PER CAPITA MONTHLY SAVINGS.—The average per capita monthly savings described in this subparagraph is equal to the amount (if any) by which-

"(i) the risk-adjusted benchmark amount computed under subpara-

graph (B)(i), exceeds

(ii) the risk-adjusted bid computed under subparagraph (B)(ii).

"(D) AUTHORITY TO DETERMINE RISK ADJUSTMENT FOR AREAS OTHER THAN STATES.—The Administrator may provide for the determination and application of risk adjustment factors under this paragraph on the basis of areas other than States.

"(4) BENEFICIARY'S OPTION OF PAYMENT THROUGH WITHHOLDING FROM SOCIAL SECURITY PAYMENT OR USE OF ELECTRONIC FUNDS TRANSFER MECHANISM.—In accordance with regulations, a Medicare Advantage organization shall permit each enrollee, at the enrollee's option, to make payment of premiums under this part to the organization indirectly through withholding from benefit payments in the manner provided under section 1840 with respect to monthly premiums under section 1839 or through an electronic funds transfer mechanism (such as automatic charges of an account at a financial institution or a credit or debit card account) or otherwise. All premium payments that are withheld under this paragraph that are credited to the Federal Supplementary Medical Insurance Drug Trust Fund shall be paid to the Medicare Advantage organization in-

(2) Provision of single consolidated premium.—Section 1854(b) (42 U.S.C. 1395w-24(b)), as amended by paragraph (1), is further amended by adding at the end the following new paragraph:

"(5) SINGLE CONSOLIDATED PREMIUM.—In the case of an enrollee in a Medicare Advantage plan who elects under part D to be provided qualified prescription drug coverage through the plan, the Administrator shall provide a mechanism for the consolidation of the beneficiary premium amount for non-drug benefits under this part with the premium amount for prescription drug coverage under part D provided through the plan.".

(3) COMPUTATION OF MEDICARE ADVANTAGE AREA-SPECIFIC NON-DRUG BENCH-MARK.—Section 1853 (42 U.S.C. 1395w-23) is amended by adding at the end the

following new subsection:

"(j) COMPUTATION OF MEDICARE ADVANTAGE AREA-SPECIFIC NON-DRUG MONTHLY BENCHMARK AMOUNT.—For purposes of this part, the term 'Medicare Advantage area-specific non-drug monthly benchmark amount' means, with respect to a Medicare Advantage payment area for a month in a year, an amount equal to ½12 of the annual Medicare Advantage capitation rate under section 1853(c)(1) for the area for the year."

(c) PAYMENT OF PLANS BASED ON BID AMOUNTS.—

(1) IN GENERAL.—Section 1853(a)(1)(A) (42 U.S.C. 1395w-23) is amended by striking "in an amount" and all that follows and inserting the following: "in an amount determined as follows:

"(i) Payment Before 2006.—For years before 2006, the payment amount shall be equal to $\frac{1}{12}$ of the annual Medicare Advantage capitation rate (as calculated under subsection (c)(1)) with respect to that individual for that area, reduced by the amount of any reduction elected under section 1854(f)(1)(E) and adjusted under clause (iv).

"(ii) PAYMENT FOR STATUTORY NON-DRUG BENEFITS BEGINNING WITH

2006.—For years beginning with 2006—

"(I) PLANS WITH BIDS BELOW BENCHMARK.—In the case of a plan for which there are average per capita monthly savings described in section 1854(b)(3)(C), the payment under this subsection is equal to the unadjusted Medicare Advantage statutory non-drug monthly bid amount, adjusted under clause (iv), plus the amount of the monthly rebate computed under section 1854(b)(1)(C)(i) for that plan and year.

"(II) PLANS WITH BIDS AT OR ABOVE BENCHMARK.—In the case of a plan for which there are no average per capita monthly savings described in section 1854(b)(3)(C), the payment amount under this subsection is equal to the Medicare Advantage area-specific nondrug monthly benchmark amount, adjusted under clause (iv).

"(iii) FOR FEDERAL DRUG SUBSIDIES.—In the case in which an enrollee who elects under part D to be provided qualified prescription drug coverage through the plan, the Medicare Advantage organization offering such plan also is entitled—

"(I) to direct subsidy payment under section 1860D-8(a)(1);

"(II) to reinsurance subsidy payments under section 1860D-8(a)(2); and

"(III) to reimbursement for premium and cost-sharing reductions for low-income individuals under section 1860D–7(c)(3).

"(iv) Demographic adjustment, including adjustment for health status.—The Administrator shall adjust the payment amount under clause (i), the unadjusted Medicare Advantage statutory nondrug monthly bid amount under clause (ii)(I), and the Medicare Advantage area-specific non-drug monthly benchmark amount under clause (ii)(II) for such risk factors as age, disability status, gender, institutional status, and such other factors as the Administrator determines to be appropriate, including adjustment for health status under paragraph (3), so as to ensure actuarial equivalence. The Administrator may add to, modify, or substitute for such adjustment factors if such changes will improve the determination of actuarial equivalence."

(d) CONFORMING AMENDMENTS.—

(1) PROTECTION AGAINST BENEFICIARY SELECTION.—Section 1852(b)(1)(A) (42 U.S.C. 1395w–22(b)(1)(A)) is amended by adding at the end the following: "The Administrator shall not approve a plan of an organization if the Administrator determines that the benefits are designed to substantially discourage enrollment by certain Medicare Advantage eligible individuals with the organization."

(2) Conforming amendment to premium terminology.—Section 1854(b)(2) (42 U.S.C. 1395w–24(b)(2)) is amended by redesignating subparagraph (C) as subparagraph (D) and by striking subparagraphs (A) and (B) and inserting the following:

"(A) MEDICARE ADVANTAGE MONTHLY BASIC BENEFICIARY PREMIUM.—The term 'Medicare Advantage monthly basic beneficiary premium' means, with respect to a Medicare Advantage plan-

"(i) described in section 1853(a)(1)(A)(ii)(I) (relating to plans pro-

viding rebates), zero; or

"(ii) described in section 1853(a)(1)(A)(ii)(II), the amount (if any) by which the unadjusted Medicare Advantage statutory non-drug monthly bid amount exceeds the Medicare Advantage area-specific non-drug monthly benchmark amount:

except that, in the case of a Medicare Advantage private fee-for-service plan, such term means such premium as the plan files with the Adminis-

trator under this section.

(B) MEDICARE ADVANTAGE MONTHLY PRESCRIPTION DRUG BENEFICIARY PREMIUM.—The term 'Medicare Advantage monthly prescription drug beneficiary premium' means, with respect to a Medicare Advantage plan, that portion of the bid amount submitted under clause (i) of subsection (a)(6)(A) for the year that is attributable under such section to the provision of statu-

tory prescription drug benefits.

"(C) Medicare Advantage monthly supplemental beneficiary premium' means, with respect to a Medicare Advantage plan, the portion of the aggregate monthly bid amount submitted under clause (i) of subsection (a)(6)(A) for the year that is attributable under such section to the

provision of nonstatutory benefits.".
(3) REQUIREMENT FOR UNIFORM PREMIUM AND BID AMOUNTS.—Section 1854(c)

(42 U.S.C. 1395w-24(c)) is amended to read as follows:

"(c) Uniform Premium and Bid Amounts.—The Medicare Advantage monthly bid amount submitted under subsection (a)(6), the Medicare Advantage monthly basic, prescription drug, and supplemental beneficiary premiums, and the Medicare Advantage monthly MSA premium charged under subsection (b) of a Medicare Advantage organization under this part may not vary among individuals enrolled in the plan."

(4) PERMITTING BENEFICIARY REBATES

(A) Section 1851(h)(4)(A) (42 U.S.C. 1395w-21(h)(4)(A)) is amended by inserting "except as provided under section 1854(b)(1)(C)" after "or other-

(B) Section 1854(d) (42 U.S.C. 1395w-24(d)) is amended by inserting except as provided under subsection (b)(1)(C)," after "and may not provide". (5) OTHER CONFORMING AMENDMENTS RELATING TO BIDS.—Section 1854 (42) U.S.C. 1395w-24) is amended-

(A) in the heading of subsection (a), by inserting "AND BID AMOUNTS"

after "PREMIUMS"; and

(B) in subsection (a)(5)(A), by inserting "paragraphs (2), (3), and (4) of" after "filed under".

(e) Additional Conforming Amendments.—

(1) Annual determination and announcement of certain factors.—Section 1853(b)(1) (42 U.S.C. 1395w-23(b)(1)) is amended by striking "the respective calendar year" and all that follows and inserting the following: "the calendar year concerned with respect to each Medicare Advantage payment area, the following:

"(A) PRE-COMPETITION INFORMATION.—For years before 2006, the fol-

lowing:
"(i) MEDICARE ADVANTAGE CAPITATION RATES.—The annual Medicare Advantage capitation rate for each Medicare Advantage payment area for the year.

"(ii) ADJUSTMENT FACTORS.—The risk and other factors to be used in

adjusting such rates under subsection (a)(1)(A) for payments for months in that year.

"(B) COMPETITION INFORMATION.—For years beginning with 2006, the fol-

 $\begin{tabular}{ll} lowing: \\ "(i) & BENCHMARK.—The & Medicare & Advantage & area-specific & non-drug \\ \hline \end{tabular}$ benchmark under section 1853(j).

"(ii) ADJUSTMENT FACTORS.—The adjustment factors applied under section 1853(a)(1)(A)(iv) (relating to demographic adjustment), section 1853(a)(1)(B) (relating to adjustment for end-stage renal disease), and section 1853(a)(3) (relating to health status adjustment)."

(2) Repeal of provisions relating to adjusted community rate (acr) (A) IN GENERAL.—Subsections (e) and (f) of section 1854 (42 U.S.C. 1395w-24) are repealed.

(B) CONFORMING AMENDMENTS.—(i) Section 1839(a)(2) (42 U.S.C. 1395r(a)(2)) is amended by striking ", and to reflect" and all that follows

and inserting a period.

(ii) Section 1852(a)(1) (42 U.S.C. 1395w-22(a)(1)) is amended by striking "title XI" and all that follows and inserting the following: "title XI those items and services (other than hospice care) for which benefits are available under parts A and B to individuals residing in the area served by the

(iii) Section 1857(d)(1) (42 U.S.C. 1395w-27(d)(1)) is amended by striking , costs, and computation of the adjusted community rate" and inserting

(f) REFERENCES UNDER PART E.—Section 1859 (42 U.S.C. 1395w-29) is amended

by adding at the end the following new subsection:

"(f) APPLICATION UNDER PART E.—In the case of any reference under part E to a requirement or provision of this part in the relation to an EFFS plan or organization under such part, except as otherwise specified any such requirement or provision shall be applied to such organization or plan in the same manner as such requirement or provision applies to a Medicare Advantage private fee-for-service plan (and the Medicare Advantage organization that offers such plan) under this part.".

(g) EFFECTIVE DATE.—The amendments made by this section shall apply to pay-

ments and premiums for months beginning with January 2006.

CHAPTER 3—ADDITIONAL REFORMS

SEC. 231. MAKING PERMANENT CHANGE IN MEDICARE ADVANTAGE REPORTING DEADLINES AND ANNUAL, COORDINATED ELECTION PERIOD.

- (a) Change in Reporting Deadline.—Section 1854(a)(1) (42 U.S.C. 1395w-24(a)(1)), as amended by section 532(b)(1) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, is amended by striking "2002, 2003, and 2004 (or July 1 of each other year)" and inserting "2002 and each subsequent
- (b) Delay in Annual, Coordinated Election Period.—Section 1851(e)(3)(B) (42 U.S.C. 1395w-21(e)(3)(B)), as amended by section 532(c)(1)(A) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, is amended—

- (1) by striking "and after 2005"; and (2) by striking ", 2004, and 2005" and inserting "and any subsequent year".
- (c) ANNUAL ANNOUNCEMENT OF PAYMENT RATES.—Section 1853(b)(1) (42 U.S.C. 1395w-23(b)(1)), as amended by section 532(d)(1) of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, is amended-

(1) by striking "and after 2005"; and
(2) by striking "and 2005" and inserting "and each subsequent year".
(d) REQUIRING PROVISION OF AVAILABLE INFORMATION COMPARING PLAN OPTIONS.—The first sentence of section 1851(d)(2)(A)(ii) (42 U.S.C. 1395w— 21(d)(2)(A)(ii)) is amended by inserting before the period the following: "to the extent such information is available at the time of preparation of materials for the mail-

SEC. 232. AVOIDING DUPLICATIVE STATE REGULATION.

(a) IN GENERAL.—Section 1856(b)(3) (42 U.S.C. 1395w-26(b)(3)) is amended to read as follows:

"(3) RELATION TO STATE LAWS.—The standards established under this subsection shall supersede any State law or regulation (other than State licensing laws or State laws relating to plan solvency) with respect to Medicare Advantage plans which are offered by Medicare Advantage organizations under this

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

SEC. 233. SPECIALIZED MEDICARE ADVANTAGE PLANS FOR SPECIAL NEEDS BENEFICIARIES.

(a) Treatment as Coordinated Care Plan.—Section 1851(a)(2)(A) (42 U.S.C. 1395w-21(a)(2)(A)) is amended by adding at the end the following new sentence: Specialized Medicare Advantage plans for special needs beneficiaries (as defined in section 1859(b)(4)) may be any type of coordinated care plan."

(b) SPECIALIZED MEDICARE ADVANTAGE PLAN FOR SPECIAL NEEDS BENEFICIARIES DEFINED.—Section 1859(b) (42 U.S.C. 1395w–29(b)) is amended by adding at the

end the following new paragraph:

"(4) SPECIALIZED MEDICARE ADVANTAGE PLANS FOR SPECIAL NEEDS BENE-FICIARIES.-

"(A) IN GENERAL.—The term 'specialized Medicare Advantage plan for special needs beneficiaries' means a Medicare Advantage plan that exclusively serves special needs beneficiaries (as defined in subparagraph (B)).

"(B) SPECIAL NEEDS BENEFICIARY.—The term 'special needs beneficiary' means a Medicare Advantage eligible individual who—

"(i) is institutionalized (as defined by the Secretary);

"(ii) is entitled to medical assistance under a State plan under title

XIX; or
"(iii) meets such requirements as the Secretary may determine would
"meets such requirements as the Secretary may determine would
"Advantage plan" benefit from enrollment in such a specialized Medicare Advantage plan described in subparagraph (A) for individuals with severe or disabling chronic conditions."

(c) RESTRICTION ON ENROLLMENT PERMITTED.—Section 1859 (42 U.S.C. 1395w-29)

is amended by adding at the end the following new subsection:

"(f) RESTRICTION ON ENROLLMENT FOR SPECIALIZED MEDICARE ADVANTAGE PLANS FOR SPECIAL NEEDS BENEFICIARIES.—In the case of a specialized Medicare Advantage plan (as defined in subsection (b)(4)), notwithstanding any other provision of this part and in accordance with regulations of the Secretary and for periods before January 1, 2007, the plan may restrict the enrollment of individuals under the plan to individuals who are within one or more classes of special needs beneficiaries.".

(d) AUTHORITY TO DESIGNATE OTHER PLANS AS SPECIALIZED MEDICARE ADVAN-

TAGE PLANS.—In promulgating regulations to carry out the last sentence of section 1851(a)(2)(A) of the Social Security Act (as added by subsection (a)) and section 1859(b)(4) of such Act (as added by subsection (b)), the Secretary may provide (notwithstanding section 1859(b)(4)(A) of such Act) for the offering of specialized Medicare Advantage plans by Medicare Advantage plans that disproportionately serve special needs beneficiaries who are frail, elderly medicare beneficiaries.

(e) REPORT TO CONGRESS.—Not later than December 31, 2005, the Medicare Benefits Administrator shall submit to Congress a report that assesses the impact of specialized Medicare Advantage plans for special needs beneficiaries on the cost and quality of services provided to enrollees. Such report shall include an assessment of the costs and savings to the medicare program as a result of amendments made

by subsections (a), (b), and (c).

(f) Effective Dates.

(1) IN GENERAL.—The amendments made by subsections (a), (b), and (c) shall

take effect upon the date of the enactment of this Act.

(2) DEADLINE FOR ISSUANCE OF REQUIREMENTS FOR SPECIAL NEEDS BENE-FICIARIES; TRANSITION.—No later than 6 months after the date of the enactment of this Act, the Secretary shall issue interim final regulations to establish requirements for special needs beneficiaries under section 1859(b)(4)(B)(iii) of the Social Security Act, as added by subsection (b).

SEC, 234, MEDICARE MSAS,

(a) Exemption from Reporting Enrollee Encounter Data.-

(1) IN GENERAL.—Section 1852(e)(1) (42 U.S.C. 1395w-22(e)(1)) is amended by inserting "(other than MSA plans)" after "plans"

(2) CONFORMING AMENDMENTS.—Section 1852 (42 U.S.C. 1395w-22) is amend-

(A) in subsection (c)(1)(I), by inserting before the period at the end the following: "if required under such section"; and

(B) in subparagraphs (A) and (B) of subsection (e)(2), by striking ", a non-network MSA plan," and ", NON-NETWORK MSA PLANS," each place it ap-

(b) Making Program Permanent and Eliminating Cap.—Section 1851(b)(4) (42 U.S.C. 1395w-21(b)(4)) is amended-

(1) in the heading, by striking "ON A DEMONSTRATION BASIS";

(2) by striking the first sentence of subparagraph (A); and

(3) by striking the second sentence of subparagraph (C).

(c) APPLYING LIMITATIONS ON BALANCE BILLING.—Section 1852(k)(1) (42 U.S.C. 1395w-22(k)(1)) is amended by inserting "or with an organization offering a MSA plan" after "section 1851(a)(2)(A)'

(d) Additional Amendment.—Section 1851(e)(5)(A) (42 U.S.C. 1395w-21(e)(5)(A)) is amended-

(1) by adding "or" at the end of clause (i); (2) by striking ", or" at the end of clause (ii) and inserting a semicolon; and

(3) by striking clause (iii).

SEC. 235. EXTENSION OF REASONABLE COST CONTRACTS.

Subparagraph (C) of section 1876(h)(5) (42 U.S.C. 1395mm(h)(5)) is amended to read as follows:

"(C)(i) Subject to clause (ii), may be extended or renewed under this subsection indefinitely.

"(ii) For any period beginning on or after January 1, 2008, 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 2 or more plans which were coordinated care Medicare Advantage plans under part C or 2 or more enhanced fee-for-service plans under part E and each of which plan for that previous year for the area involved meets the following minimum enrollment requirements:

"(I) With respect to any portion of the area involved that is within a Metropolitan Statistical Area with a population of more than 250,000 and counties contiguous to such Metropolitan Statistical Area, 5,000 individuals.

"(II) With respect to any other portion of such area, 1,500 individuals.".

Subtitle C—Application of FEHBP-Style Competitive Reforms

SEC. 241. APPLICATION OF FEHBP-STYLE COMPETITIVE REFORM BEGINNING IN 2010.

(a) IDENTIFICATION OF COMPETITIVE EFFS REGIONS; COMPUTATION OF COMPETITIVE EFFS NON-DRUG BENCHMARKS UNDER EFFS PROGRAM.—

(1) IN GENERAL.—Section 1860E-3, as added by section 201(a), is amended by adding at the end the following new subsection:

"(e) APPLICATION OF COMPETITION.—

"(1) DETERMINATION OF COMPETITIVE EFFS REGIONS.—

"(A) In general.—For purposes of this part, the term 'competitive EFFS region' means, for a year beginning with 2010, an EFFS region that the Administrator finds— $\,$

"(i) there will be offered in the region during the annual, coordinated election period under section 1851(e)(3)(B) (as applied under section 1860E-1(c)) before the beginning of the year at least 2 EFFS plans (in addition to the fee-for-service program under parts A and B), each offered by a different EFFS 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 March of the previous year; and

"(ii) during March of the previous year at least the percentage specified in subparagraph (C) of the number of EFFS eligible individuals

who reside in the region were enrolled in an EFFS plan.

"(B) PERCENTAGE SPECIFIED.—

"(i) IN GENERAL.—For purposes of subparagraph (A), subject to clause (ii), the percentage specified in this subparagraph for a year is equal the lesser of 20 percent or to the sum of—

"(I) the percentage, as estimated by the Administrator, of EFFS eligible individuals in the United States who are enrolled in EFFS

plans during March of the previous year; and

"(II) the percentage, as estimated by the Administrator, of Medicare Advantage eligible individuals in the United States who are enrolled in Medicare Advantage plans during March of the previous year.

"(ii) EXCEPTION.—In the case of an EFFS region that was a competitive EFFS region for the previous year, the Medicare Benefits Administrator may continue to treat the region as meeting the requirement of subparagraph (A)(ii) if the region would meet such requirement but for a de minimis reduction below the percentage specified in clause (i).

"(2) COMPETITIVE EFFS NON-DRUG MONTHLY BENCHMARK AMOUNT.—For purposes of this part, the term 'competitive EFFS non-drug monthly benchmark amount' means, with respect to an EFFS region for a month in a year and subject to paragraph (8), the sum of the 2 components described in paragraph (3) for the region and year. The Administrator shall compute such benchmark amount for each competitive EFFS region before the beginning of each annual, coordinated election period under section 1851(e)(3)(B) for each year (beginning with 2010) in which it is designated as such a region.

"(3) 2 COMPONENTS.—For purposes of paragraph (2), the 2 components described in this paragraph for an EFFS region and a year are the following:

"(A) EFFS COMPONENT.—The product of the following:

erage of the EFFS plan bids for the region and year (as determined under paragraph (4)(A)).

"(ii) NON-FFS MARKET SHARE.—1 minus the fee-for-service market share percentage determined under paragraph (5) for the region and

the year.

"(B) FEE-FOR-SERVICE COMPONENT.—The product of the following:

(i) FEE-FOR-SERVICE REGION-SPECIFIC NON-DRUG AMOUNT.—The feefor-service region-specific non-drug amount (as defined in paragraph

(6)) for the region and year.

"(ii) FEE-FOR-SERVICE MARKET SHARE.—The fee-for-service market share percentage (determined under paragraph (5)) for the region and

the vear.

"(4) DETERMINATION OF WEIGHTED AVERAGE EFFS PLAN BIDS FOR A REGION.— "(A) IN GENERAL.—For purposes of paragraph (3)(A)(i), the weighted average of EFFS plan bids for an EFFS region and a year is the sum of the following products for EFFS plans described in subparagraph (C) in the region and year:

"(i) UNADJUSTED EFFS STATUTORY NON-DRUG MONTHLY BID AMOUNT.— The unadjusted EFFS statutory non-drug monthly bid amount (as defined in subsection (a)(3)(A)(ii)(I)) for the region and year.

"(ii) PLAN'S SHARE OF EFFS ENROLLMENT IN REGION.—The number of individuals described in subparagraph (B), divided by the total number of such individuals for all EFFS plans described in subparagraph (C) for that region and year.

"(B) COUNTING OF INDIVIDUALS.—The Administrator shall count, for each EFFS plan described in subparagraph (C) for an EFFS region and year, the number of individuals who reside in the region and who were enrolled under such plan under this part during March of the previous year.

"(C) EXCLUSION OF PLANS NOT OFFERED IN PREVIOUS YEAR.—For an EFFS region and year, the EFFS plans described in this subparagraph are plans that are offered in the region and year and were offered in the region in

March of the previous year.

"(5) COMPUTATION OF FEE-FOR-SERVICE MARKET SHARE PERCENTAGE.—The Administrator shall determine, for a year and an EFFS region, the proportion (in this subsection referred to as the 'fee-for-service market share percentage') of the EFFS eligible individuals who are residents of the region during March of the previous year, of such individuals who were not enrolled in an EFFS plan or in a Medicare Advantage plan (or, if greater, such proportion determined for individuals nationally).

"(6) FEE-FOR-SERVICE REGION-SPECIFIC NON-DRUG AMOUNT.

"(A) IN GENERAL.—For purposes of paragraph (3)(B)(i) and section 1839(h)(2)(A), subject to subparagraph (B), the term 'fee-for-service regionspecific non-drug amount' means, for a competitive EFFS region and a year, the adjusted average per capita cost for the year involved, determined under section 1876(a)(4) for such region for services covered under parts A and B for individuals entitled to benefits under part A and enrolled under this part who are not enrolled in an EFFS plan under part E or a Medicare Advantage plan under part C for the year, but adjusted to exclude costs attributable to payments under section 1886(h).

"(B) 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 Administrator's estimate, on a per capita basis, of the amount of additional payments that would have been made in the region involved under this title if individuals entitled to benefits under this title had not received services from facilities of the Department of Veterans Af-

fairs or the Department of Defense.

"(7) APPLICATION OF COMPETITION.—In the case of an EFFS region that is a competitive EFFS region for a year, for purposes of applying subsections (b) and (c)(1) and section 1860E-4(a), any reference to an EFFS region-specific non-drug monthly benchmark amount shall be treated as a reference to the competitive EFFS non-drug monthly benchmark amount under paragraph (2) for the region and year.

"(8) Phase-in of benchmark for each region.—

"(A) USE OF BLENDED BENCHMARK.—In the case of a region that has not been a competitive EFFS region for each of the previous 4 years, the competitive EFFS non-drug monthly benchmark amount shall be equal to the sum of the following:

"(i) NEW COMPETITIVE COMPONENT.—The product of—

"(I) the weighted average phase-in proportion for that area and year, as specified in subparagraph (B); and

"(II) the competitive EFFS non-drug monthly benchmark amount for the region and year, determined under paragraph (2) without regard to this paragraph.

"(ii) OLD COMPETITIVE COMPONENT.—The product of—

"(I) 1 minus the weighted average phase-in proportion for that region and year; and

(II) the EFFS region-specific non-drug benchmark amount for

the region and the year.

"(B) COMPUTATION OF WEIGHTED AVERAGE PHASE-IN PROPORTION.—For purposes of this paragraph, the 'weighted average phase-in proportion' for an EFFS region for a year shall be determined as follows:

"(i) FIRST YEAR (AND REGION NOT COMPETITIVE REGION IN PREVIOUS

YEAR).—If the area was not a competitive EFFS region in the previous year, the weighted average phase-in proportion for the region for the year is equal to \(\frac{1}{5}\).

"(ii) COMPETITIVE REGION IN PREVIOUS YEAR.—If the region was a competitive EFFS region in the previous year, the weighted average phase-in proportion for the region for the year is equal to the weighted average phase-in proportion determined under this subparagraph for the region for the previous year plus ½, but in no case more than 1.".

(2) Conforming amendments.

(A) Such section 1860E–3 is further amended–

(i) in subsection (b), by adding at the end the following new para-

graph:
"(4) APPLICATION IN COMPETITIVE REGIONS.—For special rules applying this subsection in competitive EFFS regions, see subsection (e)(7).";

(ii) in subsection (c)(1), by inserting "and subsection (e)(7)" after "(as made applicable under subsection (d))"; and (iii) in subsection (d) , by striking "and (e)" and inserting "(e), and

(B) Section 1860E-4(a)(1), as inserted by section 201(a)(2), is amended by inserting ", except as provided in section 1860E-3(e)(7)" after "paragraph

(b) Identification of Competitive Medicare Advantage Areas; Application OF COMPETITIVE MEDICARE ADVANTAGE NON-DRUG BENCHMARKS UNDER MEDICARE Advantage Program.

(1) IN GENERAL.—Section 1853, as amended by section 221(b)(3), is amended by adding at the end the following new subsection:

"(k) APPLICATION OF COMPETITION.-

"(1) Determination of competitive medicare advantage areas.-

"(A) IN GENERAL.—For purposes of this part, the terms 'competitive Medicare Advantage area' and 'CMA area' mean, for a year beginning with 2010, an area (which is a metropolitan statistical area or other area with a substantial number of Medicare Advantage enrollees) that the Administrator finds

"(i) there will be offered during the annual, coordinated election period under section 1851(e)(3)(B) under this part before the beginning of the year at least 2 Medicare Advantage plans (in addition to the fee-for-service program under parts A and B), each offered by a different Medicare Advantage 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 March of the previous year with respect to the area; and

"(ii) during March of the previous year at least the percentage specified in subparagraph (B) of the number of Medicare Advantage eligible individuals who reside in the area were enrolled in a Medicare Advan-

tage plan.

"(B) PERCENTAGE SPECIFIED.—

"(i) IN GENERAL.—For purposes of subparagraph (A), subject to clause (ii), the percentage specified in this subparagraph for a year is equal the lesser of 20 percent or to the sum of-

"(I) the percentage, as estimated by the Administrator, of EFFS eligible individuals in the United States who are enrolled in EFFS plans during March of the previous year; and

"(II) the percentage, as estimated by the Administrator, of Medicare Advantage eligible individuals in the United States who are enrolled in Medicare Advantage plans during March of the previous year.

"(ii) Exception.—In the case of an area that was a competitive area for the previous year, the Medicare Benefits Administrator may continue to treat the area as meeting the requirement of subparagraph (A)(ii) if the area would meet such requirement but for a de minimis reduction below the percentage specified in clause (i).

"(2) Competitive medicare advantage non-drug monthly benchmark AMOUNT.—For purposes of this part, the term 'competitive Medicare Advantage non-drug monthly benchmark amount' means, with respect to a competitive Medicare Advantage area for a month in a year subject to paragraph (8), the sum of the 2 components described in paragraph (3) for the area and year. The Administrator shall compute such benchmark amount for each competitive Medicare Advantage area before the beginning of each annual, coordinated election period under section 1851(e)(3)(B) for each year (beginning with 2010) in which it is designated as such an area.

"(3) 2 COMPONENTS.—For purposes of paragraph (2), the 2 components described in this paragraph for a competitive Medicare Advantage area and a year

are the following:

(A) MEDICARE ADVANTAGE 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 (4)(A)).

"(ii) NON-FFS MARKET SHARE.—1 minus the fee-for-service market share percentage, determined under paragraph (5) for the area and

"(B) FEE-FOR-SERVICE COMPONENT.—The product of the following:
"(i) FEE-FOR-SERVICE AREA-SPECIFIC NON-DRUG AMOUNT.—The fee-forservice area-specific non-drug amount (as defined in paragraph (6)) for the area and year.

(ii) FEE-FOR-SERVICE MARKET SHARE.—The fee-for-service market share percentage, determined under paragraph (5) for the area and

"(4) DETERMINATION OF WEIGHTED AVERAGE MEDICARE ADVANTAGE BIDS FOR

"(A) IN GENERAL.—For purposes of paragraph (3)(A)(i), the weighted average of plan bids for an area and a year is the sum of the following products for Medicare Advantage plans described in subparagraph (C) in the area and year:

"(i) Monthly medicare advantage statutory non-drug bid AMOUNT.—The unadjusted Medicare Advantage statutory non-drug

monthly bid amount.

(ii) P̃lan'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 Medicare Advantage plans

described in subparagraph (C) for that area and year.

"(B) COUNTING OF INDIVIDUALS.—The Administrator shall count, for each Medicare Advantage 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 March of the previous year.

(C) EXCLUSION OF PLANS NOT OFFERED IN PREVIOUS YEAR.—For an area and year, the Medicare Advantage plans described in this subparagraph are plans described in the first sentence of section 1851(a)(2)(A) that are offered in the area and year and were offered in the area in March of the previous

year. "(5) Computation of fee-for-service market share percentage.—The Administrator shall determine, for a year and a competitive Medicare Advantage area, the proportion (in this subsection referred to as the 'fee-for-service market share percentage') of Medicare Advantage eligible individuals residing in the area who during March of the previous year were not enrolled in a Medicare Advantage plan or in an EFFS plan (or, if greater, such proportion determined for individuals nationally).

"(6) FEE-FOR-SERVICE AREA-SPECIFIC NON-DRUG AMOUNT.—

"(A) IN GENERAL.—For purposes of paragraph (3)(B)(i) and section 1839(h)(1)(A), subject to subparagraph (B), the term fee-for-service areaspecific non-drug amount' means, for a competitive Medicare Advantage area and a year, the adjusted average per capita cost for the year involved, determined under section 1876(a)(4) for such area for services covered under parts A and B for individuals entitled to benefits under part A and enrolled under this part who are not enrolled in a Medicare Advantage plan under part C or an EFFS plan under part E for the year, but adjusted to exclude costs attributable to payments under section 1886(h).

"(B) 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 Administrator'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.

"(7) APPLICATION OF COMPETITION.—In the case of an area that is a competitive Medicare Advantage area for a year, for purposes of applying subsection (a)(1)(A)(ii) and sections 1854(b)(2)(A)(ii) and 1854(b)(3)(B)(i), any reference to a Medicare Advantage area-specific non-drug monthly benchmark amount shall be treated as a reference to the competitive Medicare Advantage non-drug monthly benchmark amount under paragraph (2) for the area and year.

"(8) PHASE-IN OF BENCHMARK FOR EACH AREA.

"(A) USE OF BLENDED BENCHMARK.—In the case of an area that has not been a competitive Medicare Advantage area for each of the previous 4 years, the competitive Medicare Advantage non-drug monthly benchmark amount shall be equal to the sum of the following:

"(i) NEW COMPETITIVE COMPONENT.—The product of—

"(I) the weighted average phase-in proportion for that area and year, as specified in subparagraph (B); and
"(II) the competitive Medicare Advantage non-drug monthly benchmark amount for the area and year, determined under paragraph (2) without regard to this paragraph.

"(ii) OLD COMPETITIVE COMPONENT.—The product of—

"(I) 1 minus the weighted average phase-in proportion for that

area and year; and

"(II) the Medicare Advantage area-wide non-drug benchmark

amount for the area and the year.

"(B) COMPUTATION OF WEIGHTED AVERAGE PHASE-IN PROPORTION.—For purposes of this paragraph, the 'weighted average phase-in proportion' for a Medicare Advantage payment area for a year shall be determined as fol-

"(i) FIRST YEAR (AND AREA NOT COMPETITIVE AREA IN PREVIOUS YEAR).—If the area was not a Medicare Advantage competitive area in the previous year, the weighted average phase-in proportion for the

area for the year is equal to ½.

"(ii) COMPETITIVE AREA IN PREVIOUS YEAR.—If the area was a competitive Medicare Advantage area in the previous year, the weighted average phase-in proportion for the area for the year is equal to the weighted average phase-in proportion determined under this subparagraph for the area for the previous year plus ½, but in no case more than 1.

"(C) MEDICARE ADVANTAGE AREA-WIDE NON-DRUG BENCHMARK AMOUNT.— For purposes of subparagraph (A)(ii)(II), the term 'Medicare Advantage area-wide non-drug benchmark amount' means, for an area and year, the weighted average of the amounts described in section 1853(j) for Medicare Advantage payment area or areas included in the area (based on the number of traditional fee-for-service enrollees in such payment area or areas) and vear."

(2) APPLICATION.—Section 1854 (42 U.S.C. 1395w-24) is amended—
(A) in subsection (b)(1)(C)(i), as added by section 221(b)(1)(A), by striking "(i) REQUIREMENT.—The" and inserting "(i) REQUIREMENT FOR NON-COM-PETITIVE AREAS.—In the case of a Medicare Advantage payment area that is not a competitive Medicare Advantage area designated under section 1853(k)(1), the'

(B) in subsection (b)(1)(C), as so added, by inserting after clause (i) the

following new clause:

"(ii) Requirement for competitive medicare advantage areas.-In the case of a Medicare Advantage payment area that is designated as a competitive Medicare Advantage area under section 1853(k)(1), if there are average per capita monthly savings described in paragraph (6) for a Medicare Advantage plan and year, the Medicare Advantage plan shall provide to the enrollee a monthly rebate equal to 75 percent of such savings."; and

(C) by adding at the end of subsection (b), as amended by sections

221(b)(1)(B) and 221(b)(2), the following new paragraph:

"(6) COMPUTATION OF AVERAGE PER CAPITA MONTHLY SAVINGS FOR COMPETI-TIVE MEDICARE ADVANTAGE AREAS.—For purposes of paragraph (1)(C)(ii), the average per capita monthly savings referred to in such paragraph for a Medicare Advantage plan and year shall be computed in the same manner as the average per capita monthly savings is computed under paragraph (3) except that the reference to the Medicare Advantage area-specific non-drug monthly benchmark amount in paragraph (3)(B)(i) (or to the benchmark amount as adjusted under paragraph (3)(C)(i)) is deemed to be a reference to the competitive Medicare Advantage non-drug monthly benchmark amount (or such amount as adjusted in the manner described in paragraph (3)(B)(i)).".

(3) ADDITIONAL CONFORMING AMENDMENTS.—
(A) PAYMENT OF PLANS.—Section 1853(a)(1)(A)(ii), as amended by section 221(c)(1), is amended-

(i) in subclauses (I) and (II), by inserting "(or, insofar as such payment area is a competitive Medicare Advantage area, described in sec-

tion 1854(b)(6))" after "section 1854(b)(3)(C)"; and
(ii) in subclause (II), by inserting "(or, insofar as such payment area is a competitive Medicare Advantage area, the competitive Medicare Advantage non-drug monthly benchmark amount)" after "Medicare Advantage area-specific non-drug monthly benchmark amount"; and

(B) DISCLOSURE OF INFORMATION.—Section 1853(b)(1)(B), as amended by

section 221(e)(1), is amended to read as follows:

"(B) COMPETITION INFORMATION.—For years beginning with 2006, the fol-

lowing:

"(i) BENCHMARKS.—The Medicare Advantage area-specific non-drug benchmark under section 1853(j) and, if applicable, the competitive Medicare Advantage non-drug benchmark under section 1853(k)(2), for the year and competitive Medicare Advantage area involved and the national fee-for-service market share percentage for the area and year.

"(ii) Adjustment factors.—The adjustment factors applied under section 1853(a)(1)(A)(iv) (relating to demographic adjustment), section 1853(a)(1)(B) (relating to adjustment for end-stage renal disease), and

section 1853(a)(3) (relating to health status adjustment).

"(iii) CERTAIN BENCHMARKS AND AMOUNTS.—In the case of a competitive Medicare Advantage area, the Medicare Advantage area-wide nondrug benchmark amount (as defined in subsection (k)(8)(C)) and the fee-for-service area-specific non-drug amount (as defined in section 1853(k)(6)) for the area.

"(iv) Individuals.—The number of individuals counted under subsection (k)(4)(B) and enrolled in each Medicare Advantage plan in the

area."

(C) DEFINITION OF MONTHLY BASIC PREMIUM.—Section 1854(b)(2)(A)(ii), as amended by section 221(d)(2), is amended by inserting "(or, in the case of a competitive Medicare Advantage area, the competitive Medicare Advantage non-drug monthly benchmark amount or, in applying this paragraph under part E in the case of a competitive EFFS region, the competitive EFFS non-drug monthly benchmark amount)" after "benchmark amount".

(c) Premium Adjustment.

(1) IN GENERAL.—Section 1839 (42 U.S.C. 1395r) is amended by adding at the

end the following new subsection:

"(h)(1)(A) In the case of an individual who resides in a competitive Medicare Advantage area under section 1853(k)(1) (regardless of whether such area is in a competitive EFFS region under section 1860E–3(e)) and who is not enrolled in a Medicare Advantage plan under part C or in an EFFS plan under part E, the monthly premium otherwise applied under this part (determined without regard to subsections (b) and (f) or any adjustment under this subsection) shall be adjusted as follows: If the fee-for-service area-specific non-drug amount (as defined in section 1853(k)(6)) for the competitive Medicare Advantage area in which the individual resides for a month

"(i) does not exceed the competitive Medicare Advantage non-drug benchmark (as determined under paragraph (2) of section 1853(k), without regard to paragraph (8) thereof) for such area, the amount of the premium for the individual for the month shall be reduced by an amount equal to the product of the adjust-ment factor under subparagraph (C) and 75 percent of the amount by which such competitive benchmark exceeds such fee-for-service area-specific non-drug

amount; or

"(ii) exceeds such competitive Medicare Advantage non-drug benchmark, the amount of the premium for the individual for the month shall be adjusted to ensure, subject to subparagraph (B), that-

"(I) the sum of the amount of the adjusted premium and the competitive

Medicare Advantage non-drug benchmark for the area, is equal to

"(II) the sum of the unadjusted premium plus amount of the fee-for-serv-

ice area-specific non-drug amount for the area.

"(B) In no case shall the actual amount of an adjustment under subparagraph (A)(ii) exceed the product of the adjustment factor under subparagraph (C) and the amount of the adjustment otherwise computed under subparagraph (A)(ii) without regard to this subparagraph.

(C) The adjustment factor under this subparagraph for an area for a year is

equal to-

"(i) the number of consecutive years (in the 5-year period ending with the year involved) in which such area was a competitive Medicare Advantage area; divided by

"(ii) 5.

"(2)(A) In the case of an individual who resides in an area that is within a competitive EFFS region under section 1860E-3(e) but is not within a competitive Medicare Advantage area under section 1853(k)(1) and who is not enrolled in a Medicare Advantage plan under part C or in an EFFS plan under part E, the monthly premium otherwise applied under this part (determined without regard to subsections (b) and (f) or any adjustment under this subsection) shall be adjusted as follows: If the fee-for-service region-specific non-drug amount (as defined in section 1860E-

3(e)(6)) for a region for a month—

"(i) does not exceed the competitive EFFS non-drug monthly benchmark amount (as determined under paragraph (2) of section 1860E-3(e), without regard to paragraph (8) thereof) for such region, the amount of the premium for the individual for the month shall be reduced by an amount equal to the product of the adjustment factor under subparagraph (C) and 75 percent of the amount by which such competitive benchmark amount exceeds such fee-for-

service region-specific non-drug benchmark amount; or

"(ii) exceeds such competitive EFFS non-drug monthly benchmark amount, the amount of the premium for the individual for the month shall be adjusted to ensure, subject to subparagraph (B), that

'(I) the sum of the amount of the adjusted premium and the competitive EFFS non-drug monthly benchmark amount for the region, is equal to

"(II) the sum of the unadjusted premium plus the amount of the EFFS region-specific non-drug monthly bidfor the region.

"(B) In no case shall the actual amount of an adjustment under subparagraph (A)(ii) exceed the product of the adjustment factor under subparagraph (Ĉ) and the amount of the adjustment otherwise computed under subparagraph (A)(ii) without regard to this subparagraph.

"(C) The adjustment factor under this subparagraph for an EFFS region for a year

is equal to-

(i) the number of consecutive years (in the 5-year period ending with the year involved) in which such region was a competitive EFFS region; divided by

"(3) Nothing in this subsection shall be construed as preventing a reduction under paragraph (1)(A) or paragraph (2)(A) in the premium otherwise applicable under this part to zero or from requiring the provision of a rebate to the extent such premium would otherwise be required to be less than zero.

"(4) The adjustment in the premium under this subsection shall be effected in such manner as the Medicare Benefits Administrator determines appropriate.

"(5) In order to carry out this subsection (insofar as it is effected through the manner of collection of premiums under 1840(a)), the Medicare Benefits Administrator shall transmit to the Commissioner of Social Security-

"(A) at the beginning of each year, the name, social security account number, and the amount of the adjustment (if any) under this subsection for each individual enrolled under this part for each month during the year; and

"(B) periodically throughout the year, information to update the information

previously transmitted under this paragraph for the year.

(2) CONFORMING AMENDMENT.—Section 1844(c) (42 U.S.C. 1395w(c)) is amended by inserting "and without regard to any premium adjustment effected under section 1839(h)" before the period at the end.

(d) EFFECTIVE DATE.—The amendments made by this section shall take effect on January 1, 2010.

TITLE III—COMBATTING WASTE, FRAUD, AND ABUSE

SEC. 301. MEDICARE SECONDARY PAYOR (MSP) PROVISIONS.

- (a) TECHNICAL AMENDMENT CONCERNING SECRETARY'S AUTHORITY TO MAKE CONDITIONAL PAYMENT WHEN CERTAIN PRIMARY PLANS DO NOT PAY PROMPTLY.—
 - (1) IN GENERAL.—Section 1862(b)(2) (42 U.S.C. 1395y(b)(2)) is amended—
 (A) in subparagraph (A)(ii), by striking "promptly (as determined in ac-

cordance with regulations)"; (B) in subparagraph (B)—

- (i) by redesignating clauses (i) through (iii) as clauses (ii) through (iv), respectively; and
- (ii) by inserting before clause (ii), as so redesignated, the following new clause:
- "(i) AUTHORITY TO MAKE CONDITIONAL PAYMENT.—The Secretary may make payment under this title with respect to an item or service if a primary plan described in subparagraph (A)(ii) has not made or cannot reasonably be expected to make payment with respect to such item or service promptly (as determined in accordance with regulations). Any such payment by the Secretary shall be conditioned on reimbursement to the appropriate Trust Fund in accordance with the succeeding provisions of this subsection.".
- (2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall be effective as if included in the enactment of title III of the Medicare and Medicaid Budget Reconciliation Amendments of 1984 (Public Law 98-369).
- (b) CLARIFYING AMENDMENTS TO CONDITIONAL PAYMENT PROVISIONS.—Section 1862(b)(2) (42 U.S.C. 1395y(b)(2)) is further amended—
 - (1) in subparagraph (A), in the matter following clause (ii), by inserting the following sentence at the end: "An entity that engages in a business, trade, or profession shall be deemed to have a self-insured plan if it carries its own risk (whether by a failure to obtain insurance, or otherwise) in whole or in part."; (2) in subparagraph (B)(ii), as redesignated by subsection (a)(2)(B)—
 - (A) by striking the first sentence and inserting the following: "A primary plan, and an entity that receives payment from a primary plan, shall reimburse the appropriate Trust Fund for any payment made by the Secretary under this title with respect to an item or service if it is demonstrated that such primary plan has or had a responsibility to make payment with respect to such item or service. A primary plan's responsibility for such payment may be demonstrated by a judgment, a payment conditioned upon the recipient's compromise, waiver, or release (whether or not there is a determination or admission of liability) of payment for items or services included in a claim against the primary plan or the primary plan's insured, or by other means.": and
 - (B) in the final sentence, by striking "on the date such notice or other information is received" and inserting "on the date notice of, or information related to, a primary plan's responsibility for such payment or other information is received"; and
 - (3) in subparagraph (B)(iii), , as redesignated by subsection (a)(2)(B), by striking the first sentence and inserting the following: "In order to recover payment made under this title for an item or service, the United States may bring an action against any or all entities that are or were required or responsible (directly, as an insurer or self-insurer, as a third-party administrator, as an employer that sponsors or contributes to a group health plan, or large group health plan, or otherwise) to make payment with respect to the same item or service (or any portion thereof) under a primary plan. The United States may, in accordance with paragraph (3)(A) collect double damages against any such entity. In addition, the United States may recover under this clause from any entity that has received payment from a primary plan or from the proceeds of a primary plan's payment to any entity."
 - (c) CLERICAL AMENDMENTS.—Section 1862(b) (42 U.S.C. 1395y(b)) is amended—
 - (1) in paragraph (1)(A), by moving the indentation of clauses (ii) through (v) 2 ems to the left; and
 - (2) in paragraph (3)(A), by striking "such" before "paragraphs".

SEC. 302. COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES.

(a) IN GENERAL.—Section 1847 (42 U.S.C. 1395w-3) is amended to read as follows:

"COMPETITIVE ACQUISITION OF CERTAIN ITEMS AND SERVICES

"Sec. 1847. (a) Establishment of Competitive Acquisition Programs.—

"(1) Implementation of programs.—

"(A) IN GENERAL.—The Secretary shall establish and implement programs under which competitive acquisition areas are established throughout the United States for contract award purposes for the furnishing under this part of competitively priced items and services (described in paragraph (2)) for which payment is made under this part. Such areas may differ for different items and services.

"(B) PHASED-IN IMPLEMENTATION.—The programs shall be phased-in—

"(i) among competitive acquisition areas over a period of not longer than 3 years in a manner so that the competition under the programs occurs in—

"(I) at least ½ of such areas in 2005; and "(II) at least ½ of such areas in 2006; and

"(ii) among items and services in a manner such that the programs apply to the highest cost and highest volume items and services first. "(C) WAIVER OF CERTAIN PROVISIONS.—In carrying out the programs, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this section, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

"(2) ITEMS AND SERVICES DESCRIBED. The items and services referred to in

paragraph (1) are the following:

"(A) DURABLE MEDICAL EQUIPMENT AND MEDICAL SUPPLIES.—Covered items (as defined in section 1834(a)(13)) for which payment is otherwise made under section 1834(a), including items used in infusion and drugs and supplies used in conjunction with durable medical equipment, but excluding class III devices under the Federal Food, Drug, and Cosmetic Act.

"(B) OFF-THE-SHELF ORTHOTICS.—Orthotics (described in section 1861(s)(9)) for which payment is otherwise made under section 1834(h) which require minimal self-adjustment for appropriate use and does not require expertise in trimming, bending, molding, assembling, or customizing to fit to the patient.

"(3) EXCEPTION AUTHORITY.—In carrying out the programs under this section,

the Secretary may exempt—

"(A) rural areas and areas with low population density within urban areas that are not competitive, unless there is a significant national market through mail order for a particular item or service; and

"(B) items and services for which the application of competitive acquisi-

tion is not likely to result in significant savings.

- "(4) SPECIAL RULE FOR CERTAIN RENTED ITEMS OF DURABLE MEDICAL EQUIP-MENT.—In the case of a covered item for which payment is made on a rental basis under section 1834(a), the Secretary shall establish a process by which rental agreements for the covered items entered into before the application of the competitive acquisition program under this section for the item may be continued notwithstanding this section. In the case of any such continuation, the supplier involved shall provide for appropriate servicing and replacement, as required under section 1834(a).
- "(5) PHYSICIAN AUTHORIZATION.—The Secretary may establish a process under which a physician may prescribe a particular brand or mode of delivery of an item or service if the item or service involved is clinically more appropriate than other similar items or services.
- other similar items or services.

 "(6) APPLICATION.—For each competitive acquisition area in which the program is implemented under this subsection with respect to items and services, the payment basis determined under the competition conducted under subsection (b) shall be substituted for the payment basis otherwise applied under section 1834(a).

"(b) Program Requirements.—

"(1) IN GENERAL.—The Secretary shall conduct a competition among entities supplying items and services described in subsection (a)(2) for each competitive acquisition area in which the program is implemented under subsection (a) with respect to such items and services.

"(2) Conditions for awarding contract.—

"(A) IN GENERAL.—The Secretary may not award a contract to any entity under the competition conducted in an competitive acquisition area pursuant to paragraph (1) to furnish such items or services unless the Secretary finds all of the following:

"(i) The entity meets quality and financial standards specified by the Secretary or developed by the Program Advisory and Oversight Committee established under subsection (c).

"(ii) The total amounts to be paid under the contract (including costs associated with the administration of the contract) are expected to be

less than the total amounts that would otherwise be paid.

"(iii) Beneficiary access to a choice of multiple suppliers in the area

is maintained.

(iv) Beneficiary liability is limited to 20 percent of the applicable contract award price, except in such cases where a supplier has furnished an upgraded item and has executed an advanced beneficiary no-

"(B) DEVELOPMENT OF QUALITY STANDARDS FOR DME PRODUCTS.

"(i) IN GENERAL.—The quality standards specified under subparagraph (A)(i) shall not be less than the quality standards that would otherwise apply if this section did not apply and shall include consumer services standards. Not later than July 1, 2004, the Secretary shall establish new quality standards for products subject to competitive acquisition under this section. Such standards shall be applied prospectively and shall be published on the website of the Department of Health and Human Services.

"(ii) CONSULTATION WITH PROGRAM ADVISORY AND OVERSIGHT COM-MITTEE.—The Secretary shall consult with the Program Advisory and Oversight Committee (established under subsection (c)) to review (and advise the Secretary concerning) the quality standards referred to in clause (i).

"(3) Contents of contract.—

"(A) IN GENERAL.—A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify.

"(B) TERM OF CONTRACTS.—The Secretary shall recompete contracts

under this section not less often than once every 3 years.

LIMIT ON NUMBER OF CONTRACTORS.

"(A) IN GENERAL.—The Secretary may limit the number of contractors in a competitive acquisition area to the number needed to meet projected demand for items and services covered under the contracts. In awarding contracts, the Secretary shall take into account the ability of bidding entities to furnish items or services in sufficient quantities to meet the anticipated needs of beneficiaries for such items or services in the geographic area covered under the contract on a timely basis.

"(B) MULTIPLE WINNERS.—The Secretary shall award contracts to mul-

tiple entities submitting bids in each area for an item or service.

"(5) PAYMENT.—Payment under this part for competitively priced items and services described in subsection (a)(2) shall be based on the bids submitted and accepted under this section for such items and services.

"(6) Participating contractors.—Payment shall not be made for items and services described in subsection (a)(2) furnished by a contractor and for which

competition is conducted under this section unless-

'(A) the contractor has submitted a bid for such items and services under

this section: and

"(B) the Secretary has awarded a contract to the contractor for such items and services under this section.

In this section, the term 'bid' means a request for a proposal for an item or service that includes the cost of the item or service, and where appropriate, any services that are attendant to the provision of the item or service.

"(7) Consideration in determining categories for bids.—The Secretary shall consider the similarity of the clinical efficiency and value of specific codes and products, including products that may provide a therapeutic advantage to beneficiaries, before delineating the categories and products that will be subject to bidding.

"(8) AUTHORITY TO CONTRACT FOR EDUCATION, MONITORING, OUTREACH AND COMPLAINT SERVICES.—The Secretary may enter into a contract with an appropriate entity to address complaints from beneficiaries who receive items and services from an entity with a contract under this section and to conduct appropriate education of and outreach to such beneficiaries and monitoring quality

of services with respect to the program.

"(c) PROGRAM ADVISORY AND OVERSIGHT COMMITTEE.—

"(1) ESTABLISHMENT.—There is established a Program Advisory and Oversight Committee (hereinafter in this section referred to as the 'Committee').

"(2) Membership; terms.—The Committee shall consist of such members as the Secretary may appoint who shall serve for such term as the Secretary may specify

(3) DUTIES.—
(A) TECHNICAL ASSISTANCE.—The Committee shall provide advice and technical assistance to the Secretary with respect to the following functions: "(i) The implementation of the program under this section.

"(ii) The establishment of requirements for collection of data.
"(iii) The development of proposals for efficient interaction among manufacturers and distributors of the items and services and providers and beneficiaries.

"(B) ADDITIONAL DUTIES.—The Committee shall perform such additional functions to assist the Secretary in carrying out this section as the Secretary may specify.

"(4) INAPPLICABILITY OF FACA.—The provisions of the Federal Advisory Com-

mittee Act (5 U.S.C. App.) shall not apply.

"(d) Annual Reports.—The Secretary shall submit to Congress an annual management report on the programs under this section. Each such report shall include information on savings, reductions in beneficiary cost-sharing, access to and quality

of items and services, and beneficiary satisfaction.

"(e) DEMONSTRATION PROJECT FOR CLINICAL LABORATORY SERVICES.—

"(1) IN GENERAL.—The Secretary shall conduct a demonstration project on the application of competitive acquisition under this section to clinical diagnostic laboratory tests-

'(A) for which payment is otherwise made under section 1833(h) or

1834(d)(1) (relating to colorectal cancer screening tests); and

"(B) which are furnished by entities that did not have a face-to-face encounter with the individual.

"(2) TERMS AND CONDITIONS.—Such project shall be under the same conditions as are applicable to items and services described in subsection (a)(2).

"(3) Report.—The Secretary shall submit to Congress

"(A) an initial report on the project not later than December 31, 2005;

"(B) such progress and final reports on the project after such date as the Secretary determines appropriate.".

(b) Conforming Amendments.

(1) DURABLE MEDICAL EQUIPMENT; ELIMINATION OF INHERENT REASONABLE-NESS AUTHORITY.—Section 1834(a) (42 U.S.C. 1395m(a)) is amended— (A) in paragraph (1)(B), by striking "The payment basis" and inserting "Subject to subparagraph (E)(i), the payment basis"; (B) in paragraph (1)(C), by striking "This subsection" and inserting "Sub-

ject to subparagraph (E)(ii), this subsection"

(C) by adding at the end of paragraph (1) the following new subpara-

graph:

" $\dot{(E)}$ Application of competitive acquisition; elimination of inherent REASONABLENESS AUTHORITY.—In the case of covered items and services that are included in a competitive acquisition program in a competitive acquisition area under section 1847(a)-

(i) the payment basis under this subsection for such items and services furnished in such area shall be the payment basis determined

under such competitive acquisition program; and

(ii) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847 and in the case of such adjustment, paragraph (10)(B) shall not be applied."; and

(D) in paragraph (10)(B), by inserting "in an area and with respect to covered items and services for which the Secretary does not make a payment amount adjustment under paragraph (1)(E)" after "under this subsection".

(2) OFF-THE-SHELF ORTHOTICS; ELIMINATION OF INHERENT REASONABLENESS AUTHORITY.—Section 1834(h) (42 U.S.C. 1395m(h)) is amended—
(A) in paragraph (1)(B), by striking "and (E)" and inserting ", (E), and

(B) in paragraph (1)(D), by striking "This subsection" and inserting "Subject to subparagraph (H)(ii), this subsection"

(C) by adding at the end of paragraph (1) the following new subpara-

"(H) APPLICATION OF COMPETITIVE ACQUISITION TO ORTHOTICS; ELIMI-NATION OF INHERENT REASONABLENESS AUTHORITY.—In the case of orthotics described in paragraph (2)(B) of section 1847(a) that are included in a competitive acquisition program in a competitive acquisition area under such

"(i) the payment basis under this subsection for such orthotics furnished in such area shall be the payment basis determined under such

competitive acquisition program; and

"(ii) the Secretary may use information on the payment determined under such competitive acquisition programs to adjust the payment amount otherwise recognized under subparagraph (B)(ii) for an area that is not a competitive acquisition area under section 1847, and in the case of such adjustment, paragraphs (8) and (9) of section 1842(b) shall not be applied.

(c) REPORT ON ACTIVITIES OF SUPPLIERS.—The Secretary shall conduct a study to determine the extent to which (if any) suppliers of covered items of durable medical equipment that are subject to the competitive acquisition program under section 1847 of the Social Security Act, as amended by subsection (a), are soliciting physicians to prescribe certain brands or modes of delivery of covered items based on profitability.

(d) GAO STUDY ON SAFE AND EFFECTIVE HOME INFUSION AND INHALATION THER-APY; STANDARDS.

(1) STUDY.—The Comptroller General of the United States shall conduct a study of the standards, professional services, and related functions necessary for the provision of safe and effective home infusion therapy and home inhalation

(2) REPORT.—Not later than May 1, 2004, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1).

(3) Use of findings in developing standards.—In promulgating regulations to carry out section 1847 of the Social Security Act, as amended by subsection (a), the Secretary shall ensure that quality standards developed under subsection (b)(2)(B) of such section reflect the findings of the Comptroller General set forth in the report under paragraph (2).

SEC. 303. COMPETITIVE ACQUISITION OF COVERED OUTPATIENT DRUGS AND BIOLOGICALS.

(a) Adjustment to Physician Fee Schedule.-

(1) Adjustment in practice expense relative value units.—Section 1848(c)(2) (42 U.S.C. 1395w-4(c)(2)) is amended—

(A) in subparagraph (B)-

(i) in clause (ii)(II), by striking "The adjustments" and inserting "Sub-

ject to clause (iv), the adjustments"; and
(ii) by adding at the end of subparagraph (B), the following new

(iv) EXCEPTION TO BUDGET NEUTRALITY.—The additional expenditures attributable to clause (ii) of subparagraph (H) shall not be taken into account in applying clause (ii)(II) for 2005."; and

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

- "(H) ADJUSTMENTS IN PRACTICE EXPENSE RELATIVE VALUE UNITS FOR
 - "(i) IN GENERAL.—As part of the annual process of establishing the physician fee schedule under subsection (b) for 2005, the Secretary shall increase the practice expense relative value units for 2005 consistent with clause (ii).
 - "(ii) USE OF SUPPLEMENTAL SURVEY DATA.—For 2005 for any specialty that submitted survey data that included expenses for the administration of drugs and biologicals for which payment is made under section 1842(o) (or section 1847A), the Secretary shall use such supplemental survey data in carrying out this subparagraph insofar as they are collected and provided by entities and organizations consistent with the criteria established by the Secretary pursuant to section 212(a) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 and insofar as such data are submitted to the Secretary by December 31, 2004.
 - "(iii) Subsequent, budget neutral adjustments permitted.—Nothing in this subparagraph shall be construed as preventing the Secretary from providing for adjustments in practice expense relative value units under (and consistent with) subparagraph (B) for years after 2005.
 - "(iv) Consultation.—Before publishing the notice of proposed rulemaking to carry out this subparagraph, the Secretary shall consult

with the Comptroller General of the United States and with groups

representing the physician specialties involved.

"(v) Treatment as change in law and regulation in sustainable growth rate determination.—The enactment of subparagraph (B)(iv)and this subparagraph shall be treated as a change in law for purposes of applying subsection (f)(2)(D).

(2) Prohibition of administrative and judicial review.—Section 1848(i)(1) (42 U.S.C. 1395w-4(i)(1)) is amended-

(A) by striking "and" at the end of subparagraph (D);

(B) by striking the period at the end of subparagraph (E) and inserting ", and"; and

(C) by adding at the end the following new subparagraph:

"(F) adjustments in practice expense relative value units for 2005 under subsection (c)(2)(H).".

(3) TREATMENT OF OTHER SERVICES CURRENTLY IN THE NON-PHYSICIAN WORK POOL.—The Secretary shall make adjustments to the non-physician work pool methodology (as such term is used in the regulations promulgated by the Secretary in the Federal Register as of December 31, 2002) for determination of practice expense relative value units under the physician fee schedule described in section 1848(c)(2)(C)(ii) of the Social Security Act so that the practice expense relative value units for services determined under such methodology are not disproportionately reduced relative to the practice expense relative value units of other services not determined under such non-physician work pool methodology,

as the result of amendments made by paragraph (1).

(b) PAYMENT BASED ON COMPETITION.—Title XVIII is amended by inserting after section 1847 (42 U.S.C. 1395w-3), as amended by section 302, the following new sec-

"COMPETITIVE ACQUISITION OF COVERED OUTPATIENT DRUGS AND BIOLOGICALS

"Sec. 1847A. (a) IMPLEMENTATION OF COMPETITIVE ACQUISITION.—

"(1) Implementation of program.

"(A) IN GENERAL.—The Secretary shall establish and implement a com-

petitive acquisition program under which-

(i) competitive acquisition areas are established throughout the United States for contract award purposes for acquisition of and payment for categories of covered outpatient drugs and biologicals (as defined in paragraph (2)) under this part;

"(ii) each physician is given the opportunity annually to elect to obtain drugs and biologicals under the program or under section 1847B;

"(iii) each physician who elects to obtain drugs and biologicals under the program makes an annual selection under paragraph (5) of the contractor through which drugs and biologicals within a category of drugs and biologicals will be acquired and delivered to the physician under this part.

"(B) IMPLEMENTATION.—The Secretary shall implement the program so that the program applies to-

(i) the oncology category beginning in 2005; and

"(ii) the non-oncology category beginning in 2006.

This section shall not apply in the case of a physician who elects section

1847B to apply.

"(C) EXCLUSION AUTHORITY.—The Secretary may exclude covered outpatient drugs and biologicals (including a class of such drugs and biologicals) from the competitive bidding system under this section if the drugs or biologicals (or class) are not appropriate for competitive bidding due to low volume of utilization by beneficiaries under this part or a unique mode or method of delivery.

"(2) Covered outpatient drugs and biologicals, categories, program de-

FINED.—For purposes of this section—

"(A) COVERED OUTPATIENT DRUGS AND BIOLOGICALS DEFINED.—The term 'covered outpatient drugs and biologicals' means drugs and biologicals to which section 1842(o) applies and which are not covered under section 1847 (relating to competitive acquisition for items of durable medical equipment). Such term does not include the following:

(i) Blood clotting factors.

"(ii) Drugs and biologicals furnished to individuals in connection with the treatment of end stage renal disease.

"(iii) Radiopharmaceuticals.

"(B) 2 CATEGORIES.—Each of the following shall be a separate category of covered outpatient drugs and biologicals, as identified by the Secretary:

"(i) Oncology category.—A category (in this section referred to as

the 'oncology category') consisting of those covered outpatient drugs and biologicals that, as determined by the Secretary, are typically primarily

billed by oncologists or are otherwise used to treat cancer.

"(ii) NON-ONCOLOGY CATEGORIES.—Such numbers of categories (in this section referred to as the 'non-oncology categories') consisting of covered outpatient drugs and biologicals not described in clause (i), and appropriate subcategories of such drugs and biologicals as the Secretary may specify.

"(C) PROGRAM.—The term 'program' means the competitive acquisition program under this section.

"(D) COMPETITIVE ACQUISITION AREA; AREA.—The terms 'competitive acquisition area' and 'area' mean an appropriate geographic region establishment of the competitive acquisition area, and 'area' mean an appropriate geographic region establishment. "(E) CONTRACTOR.—The term 'contractor' means an entity that has en-

tered into a contract with the Secretary under this section.

"(3) APPLICATION OF PROGRAM PAYMENT METHODOLOGY.—With respect to covered outpatient drugs and biologicals which are supplied under the program in an area and which are prescribed by a physician who has not elected section 1847B to apply—

"(A) the claim for such drugs and biologicals shall be submitted by the

contractor that supplied the drugs and biologicals;

"(B) collection of amounts of any deductible and coinsurance applicable with respect to such drugs and biologicals shall be the responsibility of such contractor and shall not be collected unless the drug or biological is administered to the beneficiary involved; and

"(C) the payment under this section (and related coinsurance amounts)

for such drugs and biologicals-

(i) shall be made only to such contractor;

"(ii) shall be conditioned upon the administration of such drugs and biologicals; and

(iii) shall be based on the average of the bid prices for such drugs

and biologicals in the area, as computed under subsection (d).

The Secretary shall provide a process for recoupment in the case in which payment is made for drugs and biologicals which were billed at the time of dispensing but which were not actually administered.

"(4) Contract required.

"(A) IN GENERAL.—Payment may not be made under this part for covered outpatient drugs and biologicals prescribed by a physician who has not elected section 1847B to apply within a category and a competitive acquisition area with respect to which the program applies unless-

"(i) the drugs or biologicals are supplied by a contractor with a contract under this section for such category of drugs and biologicals and

area; and

"(ii) the physician has elected such contractor under paragraph (5) for

such category and area.

"(B) PHYSICIAN CHOICE.—Subparagraph (A) shall not apply for a category of drugs for an area if the physician prescribing the covered outpatient drug in such category and area has elected to apply section 1847B instead of this section.

"(5) CONTRACTOR SELECTION PROCESS.—

(A) IN GENERAL.—The Secretary shall provide a process for the selection of a contractor, on an annual basis and in such exigent circumstances as the Secretary may provide and with respect to each category of covered outpatient drugs and biologicals for an area, by physicians prescribing such drugs and biologicals in the area of the contractor under this section that will supply the drugs and biologicals within that category and area. Such

selection shall also include the election described in section 1847B(a).

"(B) Information on contractors.—The Secretary shall make available to physicians on an ongoing basis, through a directory posted on the Department's Internet website or otherwise and upon request, a list of the contractors under this section in the different competitive acquisition areas.

"(C) SELECTING PHYSICIAN DEFINED.—For purposes of this section, the term 'selecting physician' means, with respect to a contractor and category and competitive acquisition area, a physician who has not elected section 1847B to apply and has selected to apply under this section such contractor

for such category and area.

"(b) Program Requirements.—

"(1) CONTRACT FOR COVERED OUTPATIENT DRUGS AND BIOLOGICALS.—The Secretary shall conduct a competition among entities for the acquisition of a covered outpatient drug or biological within each HCPCS code within each category for each competitive acquisition area.

"(2) Conditions for awarding contract.—

"(A) IN GENERAL.—The Secretary may not award a contract to any entity under the competition conducted in a competitive acquisition area pursuant to paragraph (1) with respect to the acquisition of covered outpatient drugs and biologicals within a category unless the Secretary finds that the entity meets all of the following with respect to the contract period involved:

"(i) Capacity to supply covered outpatient drug or biological

WITHIN CATEGORY.-

"(I) IN GENERAL.—The entity has sufficient arrangements to acquire and to deliver covered outpatient drugs and biologicals within such category in the area specified in the contract at the bid price specified in the contract for all physicians that may elect such enti-

"(II) SHIPMENT METHODOLOGY.—The entity has arrangements in effect for the shipment at least 5 days each week of covered outpatient drugs and biologicals under the contract and for the timely delivery (including for emergency situations) of such drugs and biologicals in the area under the contract.

"(ii) QUALITY, SERVICE, FINANCIAL PERFORMANCE AND SOLVENCY STANDARDS.—The entity meets quality, service, financial performance, and solvency standards specified by the Secretary, including—

"(I) the establishment of procedures for the prompt response and resolution of physician and beneficiary complaints and inquiries regarding the shipment of covered outpatient drugs and biologicals;

"(II) a grievance process for the resolution of disputes.

"(B) Additional considerations.—The Secretary may refuse to award a contract under this section, and may terminate such a contract, with an entity based upon-

(i) the suspension or revocation, by the Federal Government or a State government, of the entity's license for the distribution of drugs or biologicals (including controlled substances); or

"(ii) the exclusion of the entity under section 1128 from participation

under this title.

"(C) APPLICATION OF MEDICARE PROVIDER OMBUDSMAN.—For provision providing for a program-wide Medicare Provider Ombudsman to review complaints, see section 1868(b), as added by section 923 of the Medicare

Prescription Drug and Modernization Act of 2003.

"(3) AWARDING MULTIPLE CONTRACTS FOR A CATEGORY AND AREA.—In order to provide a choice of at least 2 contractors in each competitive acquisition area for a category of drugs and biologicals, the Secretary may limit (but not below 2) the number of qualified entities that are awarded such contracts for any category and area. The Secretary shall select among qualified entities based on the

"(A) The bid prices for covered outpatient drugs and biologicals within the

category and area.

"(B) Bid price for distribution of such drugs and biologicals.

"(C) Ability to ensure product integrity.

"(D) Customer service.

"(E) Past experience in the distribution of drugs and biologicals, including controlled substances.

"(F) Such other factors as the Secretary may specify.

"(4) TERMS OF CONTRACTS.-

(A) IN GENERAL.—A contract entered into with an entity under the competition conducted pursuant to paragraph (1) is subject to terms and conditions that the Secretary may specify consistent with this section.

"(B) PERIOD OF CONTRACTS.—A contract under this section shall be for a term of 2 years, but may be terminated by the Secretary or the entity with appropriate, advance notice.

(C) INTEGRITY OF DRUG AND BIOLOGICAL DISTRIBUTION SYSTEM.—The Sec-

"(i) shall require that for all drug and biological products distributed by a contractor under this section be acquired directly from the manufacturer or from a distributor that has acquired the products directly from the manufacturer; and

"(ii) may require, in the case of such products that are particularly susceptible to counterfeit or diversion, that the contractor comply with such additional product integrity safeguards as may be determined to

"(D) Implementation of anti-counterfeiting, quality, safety, and RECORD KEEPING REQUIREMENTS.—The Secretary shall require each contractor to implement (through its officers, agents, representatives, and employees) requirements relating to the storage and handling of covered outpatient drugs and biologicals and for the establishment and maintenance of distribution records for such drugs and biologicals. A contract under this section may include requirements relating to the following: "(i) Secure facilities.

- "(ii) Safe and appropriate storage of drugs and biologicals.
 "(iii) Examination of drugs and biologicals received and dispensed.
- "(iv) Disposition of damaged and outdated drugs and biologicals.

"(v) Record keeping and written policies and procedures.

"(vi) Compliance personnel.

- "(E) COMPLIANCE WITH CODE OF CONDUCT AND FRAUD AND ABUSE RULES.— Under the contract-
 - "(i) the contractor shall comply with a code of conduct, specified or recognized by the Secretary, that includes standards relating to conflicts of interest; and

"(ii) the contractor shall comply with all applicable provisions relating to prevention of fraud and abuse, including compliance with applicable guidelines of the Department of Justice and the Inspector Gen-

eral of the Department of Health and Human Services.

"(F) DIRECT DELIVERY OF DRUGS AND BIOLOGICALS TO PHYSICIANS.—Under the contract the contractor shall only supply covered outpatient drugs and biologicals directly to the selecting physicians and not directly to beneficiaries, except under circumstances and settings where a beneficiary currently receives a drug or biological in the beneficiary's home or other non-physician office setting as the Secretary may provide. The contractor shall not deliver drugs and biologicals to a selecting physician except upon receipt of a prescription for such drugs and biologicals, and such necessary data as may be required by the Secretary to carry out this section. This section permits a physician to submit a prescription for each individual treatment but does not change the physician's flexibility in terms of writing a prescription for drugs for a single treatment or a course of treatment.

"(5) PERMITTING ACCESS TO DRUGS AND BIOLOGICALS.—The Secretary shall provide for the reimbursement at the average sales price under section 1847B for drugs and biologicals if the physician demonstrates all of the following:

"(A) The drugs or biologicals are immediately required.

"(B) The physician could not have reasonably anticipated the immediate requirement for the drugs or biologicals.

"(C) The contractor could not deliver to the physician the drugs or

biologicals in a timely manner.

"(6) CONSTRUCTION.—Nothing in this section shall be construed as waiving applicable State requirements relating to licensing of pharmacies. "(c) BIDDING PROCESS.

"(1) IN GENERAL.—In awarding a contract for a category of drugs and biologicals in an area under the program, the Secretary shall consider with respect to each entity seeking to be awarded a contract the prices bid to acquire and supply the covered outpatient drugs and biologicals for that category and area and the other factors referred to in subsection (b)(3).

"(2) PRICES BID.—The prices bid by an entity under paragraph (1) shall be the prices in effect and available for the supply of contracted drugs and biologicals in the area through the entity for the contract period.

"(3) Rejection of contract offer.—The Secretary shall reject the contract offer of an entity with respect to a category of drugs and biologicals for an area if the Secretary estimates that the prices bid, in the aggregate on average, would exceed 120 percent of the average sales price (as determined under section 1847B).

"(4) BIDDING ON A NATIONAL OR REGIONAL BASIS.—Nothing in this section shall be construed as precluding a bidder from bidding for contracts in all areas of the United States or as requiring a bidder to submit a bid for all areas of the United States.

"(5) Uniformity of bids within area.—The amount of the bid submitted under a contract offer for any covered outpatient drug or biological for an area shall be the same for that drug or biological for all portions of that area.

"(6) CONFIDENTIALITY OF BIDS.—The provisions of subparagraph (D) of section 1927(b)(3) shall apply to a bid submitted in a contract offer for a covered outpatient drug or biological under this section in the same manner as it applies to information disclosed under such section, except that any reference

"(A) in that subparagraph to a 'manufacturer or wholesaler' is deemed a reference to a 'bidder' under this section;

"(B) in that section to 'prices charged for drugs' is deemed a reference to a 'bid' submitted under this section; and

"(C) in clause (i) of that section to 'this section', is deemed a reference to 'part B of title XVIII'.

"(7) INCLUSION OF COSTS.—The bid price submitted in a contract offer for a covered outpatient drug or biological shall—

'(A) include all costs related to the delivery of the drug or biological to

the selecting physician (or other point of delivery); and

"(B) include the costs of dispensing (including shipping) of such drug or biological and management fees, but shall not include any costs related to the administration of the drug or biological, or wastage, spillage, or spoil-

"(8) Price adjustments during contract period: disclosure of costs.—

Each contract awarded shall provide for-

"(A) disclosure to the Secretary the contractor's reasonable, net acquisition costs for periods specified by the Secretary, not more often than quarterly, of the contract; and

"(B) appropriate price adjustments over the period of the contract to reflect significant increases or decreases in a contractor's reasonable, net acquisition costs, as so disclosed.

"(d) Computation of Average Bid Prices for a Category and Area.

(1) IN GENERAL.—For each year or other contract period for each covered outpatient drug or biological and area with respect to which a competition is conducted under the program, the Secretary shall compute an area average of the bid prices submitted, in contract offers accepted for the category and area, for that year or other contract period.

"(2) SPECIAL RULES.—The Secretary shall establish rules regarding the use under this section of the alternative payment amount provided under section 1847B to the use of a price for specific covered outpatient drugs and biologicals

in the following cases:

(A) NEW DRUGS AND BIOLOGICALS.—A covered outpatient drug or biological for which an average bid price has not been previously determined.

"(B) OTHER CASES.—Such other exceptional cases as the Secretary may specify in regulations.

(C) EXCLUSION CASES.—A covered outpatient drug or biological that has been excluded under subsection (a)(1)(C).

Such alternative payment amount shall be based upon actual market price information and in no case shall it exceed the average sales price (as determined under section 1847B).

"(e) Coinsurance.-

"(1) IN GENERAL.—Coinsurance under this part with respect to a covered outpatient drug or biological for which payment is payable under this section shall be based on 20 percent of the payment basis under this section.

"(2) COLLECTION.—Such coinsurance shall be collected by the contractor that supplies the drug or biological involved and, subject to subsection (a)(3)(B), in the same manner as coinsurance is collected for durable medical equipment under this part.

"(f) SPECIAL PAYMENT RULES.—
"(1) IN GENERAL.—The Secretary may not provide for an adjustment to reimbursement for covered outpatient drugs and biologicals unless adjustments to the practice expense payment adjustment are made on the basis of supplemental surveys under section 1848(c)(2)(H)(ii) of the Social Security Act, as added by subsection (a)(1)(B).

"(B) USE IN EXCLUSION CASES.—If the Secretary excludes a drug or biological (or class of drugs or biologicals) under subsection (a)(1)(D), the Secretary may provide for reimbursement to be made under this part for such drugs and biologicals (or class) using the payment methodology under section 1847B or other market based pricing system.

"(2) COORDINATION RULES.—The provisions of section 1842(h)(3) shall apply to a contractor with respect to covered outpatients drugs and biologicals supplied by that contractor in the same manner as they apply to a participating supplier. In order to administer this section, the Secretary may condition payment under this part to a person for the administration of a drug or biological supplied under this section upon person's provision of information on such administra-

"(3) APPLICATION OF REQUIREMENT FOR ASSIGNMENT.—For provision requiring assignment of claims for covered outpatient drugs and biologicals, see section 1842(o)(3).

"(4) Protection for beneficiary in case of medical necessity denial.-For protection of beneficiaries against liability in the case of medical necessity determinations, see section 1842(b)(3)(B)(ii)(III).

"(5) Physician Role in Appeals Process.—The Secretary shall establish a procedure under which a physician who prescribes a drug or biological for which payment is made under this section has appeal rights that are similar to those provided to a physician who prescribes durable medical equipment or a laboratory test.

"(g) ADVISORY COMMITTEE.—The Secretary shall establish an advisory committee that includes representatives of parties affected by the program under this section, including physicians, specialty pharmacies, distributors, manufacturers, and beneficiaries. The committee shall advise the Secretary on issues relating to the effective

implementation of this section.

"OPTIONAL USE OF AVERAGE SALES PRICE PAYMENT METHODOLOGY

"Sec. 1847B. (a) Election and Implementation.—

"(1) ELECTION.—In connection with the annual election made by a physician under section 1847A(a)(5), the physician may elect to apply this section to the payment for covered outpatient drugs and biologicals instead of the payment methodology under section 1847A.

"(2) IMPLEMENTATION.—This section shall be implemented with respect to cat-

egories of covered outpatient

"(3) COVERED OUTPATIENT DRUGS AND BIOLOGICALS DEFINED.—For purposes of this section, the term 'covered outpatient drugs and biologicals' has the meaning

this section, the term 'covered outpatient drugs and biologicals' has the meaning given such term in section 1847A(a)(2)(A).

"(b) COMPUTATION OF PAYMENT AMOUNT.—

"(1) IN GENERAL.—If this section applies with respect to a covered outpatient drug or biological, the amount payable for the drug or biological (based on a minimum dosage unit) is, subject to applicable deductible and coinsurance—

"(A) in the case of a multiple source drug (as defined in subsection (c)(6)(C)), 112 percent of the amount determined under paragraph (3); or "(B) in the case of a single source drug (as defined in subsection (c)(6)(D)), 112 percent of the amount determined under paragraph (4)

112 percent of the amount determined under paragraph (4).

"(2) Specification of unit.-

"(A) SPECIFICATION OF UNIT.—

"(A) SPECIFICATION BY MANUFACTURER.—The manufacturer of a covered outpatient drug or biological shall specify the unit associated with each National Drug Code as part of the submission of data under section 1927(b)(3)(A)(iii).

"(B) UNIT DEFINED.—In this section, the term 'unit' means, with respect to a covered outpatient drug or biological, the lowest identifiable quantity (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological that is dispensed, exclusive of any diluent without reference

or biological that is dispensed, exclusive of any difference to volume measures pertaining to liquids.

"(3) MULTIPLE SOURCE DRUG.—For all drug products included within the same multiple source drug, the amount specified in this paragraph is the volume-weighted average of the average sales prices reported under section 1927(b)(3)(A)(iii) computed as follows:

"(A) Compute the sum of the products (for each national drug code assigned translations) of

signed to such drug products) of—

"(i) the manufacturer's average sales price (as defined in subsection (c)); and

"(ii) the total number of units specified under paragraph (2) sold, as reported under section 1927(b)(3)(A)(iii).

"(B) Divide the sum computed under subparagraph (A) by the sum of the total number of units under subparagraph (A)(ii) for all national drug codes assigned to such drug products.

"(4) SINGLE SOURCE DRUG.—The amount specified in this paragraph for a single source drug is the lesser of the following:

"(A) Manufacturer's average sales price.—The manufacturer's average sales price for a national drug code, as computed using the methodology applied under paragraph (3).

"(B) Wholesale acquisition cost (wac).—The wholesale acquisition cost (as defined in subsection (c)(6)(B)) reported for the single source drug.

"(5) BASIS FOR DETERMINATION.—The payment amount shall be determined under this subsection based on information reported under subsection (e) and without regard to any special packaging, labeling, or identifiers on the dosage form or product or package.

"(6) STUDY AND AUTHORIZATION.—Not later than 2 years after the date of the enactment of this section, the Secretary shall conduct and complete a study on the adequacy of the payment rates provided under this subsection, taking into account the acquisition costs for the covered outpatient drugs and biologicals as well as provider-related costs, in rural and urban areas. The Secretary shall submit the results of such study to Congress. For calendar years after the date such results are submitted, the Secretary may adjust the percentage specified in paragraphs (1)(A) and (1)(B) based upon such results.

"(c) MANUFACTURER'S AVERAGE SALES PRICE.—
"(1) IN GENERAL.—For purposes of this subsection, subject to paragraphs (2) and (3), the manufacturer's 'average sales price' means, of a covered outpatient

drug or biological for a NDC code for a calendar quarter for a manufacturer for a unit—

"(A) the manufacturer's total sales (as defined by the Secretary in regulations for purposes of section 1927(c)(1)) in the United States for such drug or biological in the calendar quarter; divided by

"(B) the total number of such units of such drug or biological sold by the

manufacturer in such quarter.

"(2) CERTAIN SALES EXEMPTED FROM COMPUTATION.—In calculating the manufacturer's average sales price under this subsection, the following sales shall be excluded:

"(A) SALES EXEMPT FROM BEST PRICE.—Sales exempt from the inclusion in the determination of 'best price' under section 1927(c)(1)(C)(i).

"(B) SALES AT NOMINAL CHARGE.—Such other sales as the Secretary identifies by regulation as sales to an entity that are nominal in price or do not reflect a market price paid by an entity to which payment is made under

this section.

"(3) SALE PRICE NET OF DISCOUNTS.—In calculating the manufacturer's average sales price under this subsection, such price shall be determined taking into account volume discounts, prompt pay discounts, cash discounts, the free goods that are contingent on any purchase requirement, chargebacks, and rebates (other than rebates under section 1927), that result in a reduction of the cost to the purchaser. A rebate to a payor or other entity that does not take title to a covered outpatient drug or biological shall not be taken into account in determining such price unless the manufacturer has an agreement with the payor or other entity under which the purchaser's price for the drug or biological is reduced as a consequence of such rebate.

"(4) AUTHORITY TO DISREGARD AVERAGE SALES PRICE DURING FIRST QUARTER

"(4) AUTHORITY TO DISREGARD AVERAGE SALES PRICE DURING FIRST QUARTER OF SALES.—In the case of a covered outpatient drug or biological during an initial period (not to exceed a full calendar quarter) in which data on the prices for sales for the drug or biological is not available from the manufacturer to compute an average sales price for the drug or biological, the Secretary may determine the amount payable under this section for the drug or biological without considering the manufacturer's average sales price of that manufacturer for

that drug or biological.

"(5) Frequency of Determinations.—

"(A) IN GENERAL ON A QUARTERLY BASIS.—The manufacturer's average sales price, for a covered outpatient drug or biological of a manufacturer, shall be determined by such manufacturer under this subsection on a quarterly basis. In making such determination insofar as there is a lag in the reporting of the information on rebates and chargebacks under paragraph (3) so that adequate data are not available on a timely basis, the manufacturer shall apply a methodology established by the Secretary based on a 12-month rolling average for the manufacturer to estimate costs attributable to rebates and chargebacks.

"(B) UPDATES IN RATES.—The payment rates under subsection (b)(1) and (b)(2)(A) shall be updated by the Secretary on a quarterly basis and shall be applied based upon the manufacturer's average sales price determined

for the most recent calendar quarter.

"(C) USE OF CONTRACTORS; IMPLEMENTATION.—The Secretary may use a carrier, fiscal intermediary, or other contractor to determine the payment amount under subsection (b). Notwithstanding any other provision of law,

the Secretary may implement, by program memorandum or otherwise, any of the provisions of this section.

"(6) DEFINITIONS AND OTHER RULES.—In this section:

"(A) MANUFACTURER.—The term 'manufacturer' means, with respect to a covered outpatient drug or biological, the manufacturer (as defined in section 1927(k)(5)) whose national drug code appears on such drug or biologi-

"(ii) Wholesale acquisition cost.—The term 'wholesale acquisition cost' means, with respect to a covered outpatient 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 pricing data.

"(C) MULTIPLE SOURCE DRUG.—The term 'multiple source drug' means, for a calendar quarter, a covered outpatient drug or biological for which there

are 2 or more drug products which

(i) are rated as therapeutically equivalent (under the Food and Drug Administration's most recent publication of 'Approved Drug Products with Therapeutic Equivalence Evaluations'),

"(ii) except as provided in subparagraph (E), are pharmaceutically equivalent and bioequivalent, as determined under subparagraph (F) and as determined by the Food and Drug Administration, and

(iii) are sold or marketed in the United States during the quarter. "(D) SINGLE SOURCE DRUG.—The term 'single source drug' means a covered outpatient drug or biological which is not a multiple source drug and which is 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, or which is a biological.

"(E) EXCEPTION FROM PHARMACEUTICAL EQUIVALENCE AND BIOEQUIVA-LENCE REQUIREMENT.—Subparagraph (C)(ii) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (C)(i), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (F).

(F) DETERMINATION OF PHARMACEUTICAL EQUIVALENCE AND BIOEQUIVA-

LENCE.—For purposes of this paragraph-

"(i) drug products are pharmaceutically equivalent if the products contain identical amounts of the same active drug ingredient in the same dosage form and meet compendial or other applicable standards of strength, quality, purity, and identity; and

"(ii) drugs are bioequivalent if they do not present a known or potential bioequivalence problem, or, if they do present such a problem, they

are shown to meet an appropriate standard of bioequivalence.

"(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).

"(d) Authority To Use Alternative Payment in Response to Public Health EMERGENCY.—In the case of a public health emergency under section 319 of the Public Health Service Act in which there is a documented inability to access covered outpatient drugs and biologicals, and a concomitant increase in the price, of a drug or biological which is not reflected in the manufacturer's average sales price for one or more quarters, the Secretary may use the wholesale acquisition cost (or other reasonable measure of drug price) instead of the manufacturer's average sales price for such quarters and for subsequent quarters until the price and availability of the drug or biological has stabilized and is substantially reflected in the applicable manufacturer's average sales price.

(e) Reports.

"(1) QUARTERLY REPORT ON AVERAGE SALES PRICE.—For requirements for reporting the manufacturer's average sales price (and, if required to make payment, the manufacturer's wholesale acquisition cost) for the covered outpatient

drug or biological, see section 1927(b)(3).

"(2) ANNUAL REPORT TO CONGRESS.—The Secretary shall submit to the Committees on Energy and Commerce and Ways and Means of the House of Representatives and the Committee on Finance of the Senate an annual report on the operation of this section and section 1847A. Such report shall include information on the following:

"(A) Information on savings, reductions in cost-sharing, access to covered outpatient drugs and biologicals.

"(B) In the case of section 1847A, the range of choices of contractors available to providers, and beneficiary and provider satisfaction.

"(C) Trends in average sales price under subsection (b).

"(D) Administrative costs associated with compliance with this section.

"(E) Total value of payments made under this section.
"(F) Comparison of the average manufacturer price as applied under section 1927 for a covered outpatient drug or biological with the manufacturer's average sales price for the drug or biological under this section.

"(f) RESTRICTION ON ADMINISTRATIVE AND JUDICIAL REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise, of determinations of manufacturer's average sales price under subsection (c)."

- (c) Continuation of Payment Methodology for Radiopharmaceuticals.— Nothing in the amendments made by this section shall be construed as changing the payment methodology under part B of title XVIII of the Social Security Act for radiopharmaceuticals, including the use by carriers of invoice pricing methodology. (d) Conforming Amendments.
 - (1) IN GENERAL.—Section 1842(o) (42 U.S.C. 1395u(o)) is amended—

(A) in paragraph (1), by inserting ", subject to section 1847A and 1847B," before "the amount payable for the drug or biological"; and

(B) by adding at the end of paragraph (2) the following: "This paragraph shall not apply in the case of payment under section 1847A or 1847B.

- (2) NO CHANGE IN COVERAGE BASIS.—Section 1861(s)(2)(A) (42 U.S.C. 1395x(s)(2)(A)) is amended by inserting "(or would have been so included but for the application of section 1847A or 1847B)" after "included in the physicians" bills"
- (3) PAYMENT.—Section 1833(a)(1)(S) (42 U.S.C. 1395l(a)(1)(S)) is amended by inserting "(or, if applicable, under section 1847A or 1847B)" after "1842(o)"

(4) Consolidated reporting of pricing information.—Section 1927 (42) U.S.C. 1396r-8) is amended-

- (A) in subsection (a)(1), by inserting "or under part B of title XVIII" after "section 1903(a)";
 - (B) in subsection (b)(3)(A)-

(i) in clause (i), by striking "and" at the end; (ii) in clause (ii), by striking the period and inserting "; and"; and

(iii) by adding at the end the following new clause:

"(iii) for calendar quarters beginning on or after April 1, 2004, in conjunction with reporting required under clause (i) and by national drug code (NDC)-

"(I) the manufacturer's average sales price (as defined in section 1847B(c)) and the total number of units specified under section 1847B(b)(2)(A):

"(II) if required to make payment under section 1847B, the manufacturer's wholesale acquisition cost, as defined in subsection (c)(6) of such section; and

"(III) information on those sales that were made at a nominal price or otherwise described in section 1847B(c)(2)(B), which information is subject to audit by the Inspector General of the Department of Health and Human Services;

for a covered outpatient drug or biological for which payment is made under section 1847B.

(C) in subsection (b)(3)(B)-

- (i) in the heading, by inserting "AND MANUFACTURER'S AVERAGE SALES PRICE" after "PRICE"; and
- (ii) by inserting "and manufacturer's average sales prices (including wholesale acquisition cost) if required to make payment" after "manufacturer prices": and
- (D) in subsection (b)(3)(D)(i), by inserting "and section 1847B" after "this section".

(e) GAO STUDY.

- (1) STUDY.—The Comptroller General of the United States shall conduct a study to assess the impact of the amendments made by this section on the delivery of services, including their impact on
 - (A) beneficiary access to drugs and biologicals for which payment is made under part B of title XVIII of the Social Security Act; and
 - (B) the site of delivery of such services.

(2) REPORT.—Not later than 2 years after the year in which the amendment made by subsection (a)(1) first takes effect, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1).

(f) MEDPAC RECOMMENDATIONS ON BLOOD CLOTTING FACTORS.—The Medicare Payment Advisory Commission shall submit to Congress, in its annual report in 2004, specific recommendations regarding a payment amount (or amounts) for blood

clotting factors and its administration under the medicare program.

(g) ESTABLISHMENT OF PHARMACEUTICAL MANAGEMENT FEE WHERE DRUGS PRO-VIDED THROUGH A CONTRACTOR.—Section 1848(a) (42 U.S.C. 1395w-4(a)) is amend-

ed by adding at the end the following new paragraph:

(5) RECOGNITION OF PHARMACEUTICAL MANAGEMENT FEE IN CERTAIN CASES.— In establishing the fee schedule under this section, the Secretary shall provide for a separate payment with respect to physicians' services consisting of the unique administrative and management costs associated with covered drugs and biologicals which are furnished to physicians through a contractor under section 1847A (compared with such costs if such drugs and biologicals were acquired directly by such physicians).". (h) STUDY ON CODES FOR NON-ONCOLOGY CODES.—

(1) STUDY.—The Secretary shall conduct a study to determine the appropriateness of establishing and implementing separate CPT codes for non-oncology infusions that are based on the level of complexity of the administration and resource consumption.

(2) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall submit a report to Congress on the study. To the extent the Secretary determines it to be appropriate, the Secretary may implement appro-

priate changes in the payment methodology for such codes.

SEC. 304. DEMONSTRATION PROJECT FOR USE OF RECOVERY AUDIT CONTRACTORS.

(a) IN GENERAL.—The Secretary of Health and Human Services shall conduct a demonstration project under this section (in this section referred to as the "project") to demonstrate the use of recovery audit contractors under the Medicare Integrity Program in identifying underpayments and overpayments and recouping overpayments under the medicare program for services for which payment is made under part A or part B of title XVIII of the Social Security Act. Under the project—

(1) payment may be made to such a contractor on a contingent basis;

(2) a percentage of the amount recovered may be retained by the Secretary and shall be available to the program management account of the Centers for Medicare & Medicaid Services; and

(3) the Secretary shall examine the efficacy of such use with respect to duplicative payments, accuracy of coding, and other payment policies in which inaccurate payments arise.

(b) Scope and Duration.

- (1) Scope.—The project shall cover at least 2 States that are among the States with-
 - (A) the highest per capita utilization rates of medicare services, and

(B) at least 3 contractors.

(2) DURATION.—The project shall last for not longer than 3 years.

(c) WAIVER.—The Secretary of Health and Human Services shall waive such provisions of title XVIII of the Social Security Act as may be necessary to provide for payment for services under the project in accordance with subsection (a).

(d) QUALIFICATIONS OF CONTRACTORS.—
(1) IN GENERAL.—The Secretary shall enter into a recovery audit contract under this section with an entity only if the entity has staff that has the appropriate clinical knowledge of and experience with the payment rules and regulations under the medicare program or the entity has or will contract with another entity that has such knowledgeable and experienced staff

(2) Ineligibility of Certain Contractors.—The Secretary may not enter into a recovery audit contract under this section with an entity to the extent that the entity is a fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h), a carrier under section 1842 of such Act (42 U.S.C. 1395u), or a Medicare Administrative Contractor under section 1874A of such Act.

(3) Preference for entities with demonstrated proficiency with pri-VATE INSURERS.—In awarding contracts to recovery audit contractors under this section, the Secretary shall give preference to those risk entities that the Secretary determines have demonstrated more than 3 years direct management experience and a proficiency in recovery audits with private insurers or under the medicaid program under title XIX of such Act.

- (e) Construction Relating to Conduct of Investigation of Fraud.—A recovery of an overpayment to a provider by a recovery audit contractor shall not be construed to prohibit the Secretary or the Attorney General from investigating and prosecuting, if appropriate, allegations of fraud or abuse arising from such overpay-
- (f) Report.—The Secretary of Health and Human Services shall submit to Congress a report on the project not later than 6 months after the date of its comple-tion. Such reports shall include information on the impact of the project on savings to the medicare program and recommendations on the cost-effectiveness of extending or expanding the project.

TITLE IV—RURAL HEALTH CARE **IMPROVEMENTS**

SEC. 401. ENHANCED DISPROPORTIONATE SHARE HOSPITAL (DSH) TREATMENT FOR RURAL HOSPITALS AND URBAN HOSPITALS WITH FEWER THAN 100 BEDS.

(a) Doubling the Cap.-

(1) IN GENERAL.—Section 1886(d)(5)(F) (42 U.S.C. 1395ww(d)(5)(F)) is amend-

ed by adding at the end the following new clause: "(xiv)(I) In the case of discharges in a fiscal year beginning on or after October 1, 2003, subject to subclause (II), there shall be substituted for the disproportionate share adjustment percentage otherwise determined under clause (iv) (other than subclause (I)) or under clause (viii), (x), (xi), (xii), or (xiii), the disproportionate share adjustment percentage determined under clause (vii) (relating to large, urban hos-

"(II) Under subclause (I), the disproportionate share adjustment percentage shall not exceed 10 percent for a hospital that is not classified as a rural referral center under subparagraph (C)."

Conforming AMENDMENTS.—Section 1886(d)(5)(F)

1395ww(d)(5)(F)) is amended-

(A) in each of subclauses (II), (III), (IV), (V), and (VI) of clause (iv), by inserting "subject to clause (xiv) and" before "for discharges occurring";

(B) in clause (viii), by striking "The formula" and inserting "Subject to clause (xiv), the formula"; and

(C) in each of clauses (x), (xi), (xii), and (xiii), by striking "For purposes" and inserting "Subject to clause (xiv), for purposes".

(b) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to discharges occurring on or after October 1, 2003.

spect to discharges occurring on or after October 1, 2003.

SEC. 402. IMMEDIATE ESTABLISHMENT OF UNIFORM STANDARDIZED AMOUNT IN RURAL AND SMALL URBAN AREAS.

(a) IN GENERAL.—Section 1886(d)(3)(A) (42 U.S.C. 1395ww(d)(3)(A)) is amended-(1) in clause (iv), by inserting "and ending on or before September 30, 2003," after "October 1, 1995,"; and

(2) by redesignating clauses (v) and (vi) as clauses (vii) and (viii), respectively, and inserting after clause (iv) the following new clauses:

- "(v) For discharges occurring in the fiscal year beginning on October 1, 2003, the average standardized amount for hospitals located in areas other than a large urban area shall be equal to the average standardized amount for hospitals located in a large urban area.".
- (b) Conforming Amendments.
 - (1) Computing drg-specific rates.—Section 1886(d)(3)(D) (42 U.S.C. 1395ww(d)(3)(D)) is amended-
 - (A) in the heading, by striking "IN DIFFERENT AREAS";
 - (B) in the matter preceding clause (i), by striking ", each of";

(C) in clause (i)-

(i) in the matter preceding subclause (I), by inserting "for fiscal years before fiscal year 2004," before "for hospitals"; and (ii) in subclause (II), by striking "and" after the semicolon at the end;

(D) in clause (ii)

(i) in the matter preceding subclause (I), by inserting "for fiscal years before fiscal year 2004," before "for hospitals"; and (ii) in subclause (II), by striking the period at the end and inserting

(E) by adding at the end the following new clause:

"(iii) for a fiscal year beginning after fiscal year 2003, for hospitals located in all areas, to the product of-

"(I) the applicable standardized amount (computed under subparagraph (A)), reduced under subparagraph (B), and adjusted or reduced under subparagraph (C) for the fiscal year; and

"(II) the weighting factor (determined under paragraph (4)(B)) for

that diagnosis-related group.".

TECHNICAL CONFORMING SUNSET.—Section 1886(d)(3) (42 U.S.C. 1395ww(d)(3)) is amended-

(A) in the matter preceding subparagraph (A), by inserting ", for fiscal years before fiscal year 1997," before "a regional adjusted DRG prospective payment rate"; and

(B) in subparagraph (D), in the matter preceding clause (i), by inserting, for fiscal years before fiscal year 1997," before "a regional DRG prospective payment rate for each region,".

SEC. 403. ESTABLISHMENT OF ESSENTIAL RURAL HOSPITAL CLASSIFICATION.

(a) Classification.—Section 1861(mm) (42 U.S.C. 1395x(mm)) is amended—

(1) in the heading by adding "ESSENTIAL RURAL HOSPITALS" at the end; and (2) by adding at the end the following new paragraphs:

"(4)(A) The term 'essential rural hospital' means a subsection (d) hospital (as defined in section 1886(d)(1)(B)) that is located in a rural area (as defined for purposes of section 1886(d)), has more than 25 licensed acute care inpatient beds, has applied to the Secretary for classification as such a hospital, and with respect to which the Secretary has determined that the closure of the hospital would significantly diminish the ability of medicare beneficiaries to obtain essential health care services

"(B) The determination under subparagraph (A) shall be based on the following

criteria:

"(i) HIGH PROPORTION OF MEDICARE BENEFICIARIES RECEIVING CARE FROM HOS-PITAL.—(I) A high percentage of such beneficiaries residing in the area of the hospital who are hospitalized (during the most recent year for which complete data are available) receive basic inpatient medical care at the hospital.

"(II) For a hospital with more than 200 licensed beds, a high percentage of such beneficiaries residing in such area who are hospitalized (during such recent year) receive specialized surgical inpatient care at the hospital.

"(IĬI) Almost all physicians described in section 1861(r)(1) in such area have privileges at the hospital and provide their inpatient services primarily at the hospital.

"(ii) Significant adverse impact in absence of hospital.—If the hospital

were to close-

"(I) there would be a significant amount of time needed for residents to reach emergency treatment, resulting in a potential significant harm to beneficiaries with critical illnesses or injuries;

"(II) there would be an inability in the community to stablize emergency cases for transfers to another acute care setting, resulting in a potential for

significant harm to medicare beneficiaries; and

"(III) any other nearby hospital lacks the physical and clinical capacity to take over the hospital's typical admissions.

"(C) In making such determination, the Secretary may also consider the following: "(i) Free-standing ambulatory surgery centers, office-based oncology care, and imaging center services are insufficient in the hospital's area to handle the outpatient care of the hospital.

"(ii) Beneficiaries in nearby areas would be adversely affected if the hospital were to close as the hospital provides specialized knowledge and services to a

network of smaller hospitals and critical access hospitals.

"(iii) Medicare beneficiaries would have difficulty in accessing care if the hospital were to close as the hospital provides significant subsidies to support ambulatory care in local clinics, including mental health clinics and to support post acute care.

"(iv) The hospital has a committment to provide graduate medical education

in a rural area.

"(C) QUALITY CARE.—The hospital inpatient score for quality of care is not less than the median hospital score for qualify of care for hospitals in the State, as established under standards of the utilization and quality control peer review organization under part B of title XI or other quality standards recognized by the Secretary

A hospital classified as an essential rural hospital may not change such classification and a hospital so classified shall not be treated as a sole community hospital, medicare dependent hospital, or rural referral center for purposes of section 1886.".

(b) Payment Based on 102 Percent of Allowed Costs.

(1) Inpatient hospital services.—Section 1886(d) (42 U.S.C. 1395ww(d)) is

amended by adding at the end the following:

"(11) In the case of a hospital classified as an essential rural hospital under section 1861(mm)(4) for a cost reporting period, the payment under this subsection for inpatient hospital services for discharges occurring during the period shall be based on 102 percent of the reasonable costs for such services. Nothing in this paragraph shall be construed as affecting the application or amount of deductibles or copayments otherwise applicable to such services under part A or as waiving any requirement for billing for such services.'

(2) HOSPITAL OUTPATIENT SERVICES.—Section 1833(t)(13) (42 U.S.C. 1395l(t)(13)) is amended by adding at the end the following new subparagraph: HOSPITAL OUTPATIENT

"(B) SPECIAL RULE FOR ESSENTIAL RURAL HOSPITALS.—In the case of a hospital classified as an essential rural hospital under section 1861(mm)(4) for a cost reporting period, the payment under this subsection for covered OPD services during the period shall be based on 102 percent of the reasonable costs for such services. Nothing in this subparagraph shall be construed as affecting the application or amount of deductibles or copayments otherwise applicable to such services under this part or as waiving any requirement for billing for such services.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to cost

reporting periods beginning on or after October 1, 2004.

SEC. 404. MORE FREQUENT UPDATE IN WEIGHTS USED IN HOSPITAL MARKET BASKET.

(a) More Frequent Updates in Weights.—After revising the weights used in the hospital market basket under section 1886(b)(3)(B)(iii) of the Social Security Act (42 U.S.C. 1395ww(b)(3)(B)(iii)) to reflect the most current data available, the Secretary shall establish a frequency for revising such weights, including the labor share, in such market basket to reflect the most current data available more frequently than once every 5 years.

(b) REPORT.—Not later than October 1, 2004, the Secretary shall submit a report to Congress on the frequency established under subsection (a), including an explanation of the reasons for, and options considered, in determining such frequency.

SEC. 405. IMPROVEMENTS TO CRITICAL ACCESS HOSPITAL PROGRAM.

(a) Increase in Payment Amounts.

(1) IN GENERAL.—Sections 1814(1), 1834(g)(1), and 1883(a)(3) (42 U.S.C. 1395f(1); 1395m(g)(1); 42 U.S.C. 1395tt(a)(3)) are each amended by inserting "equal to 102 percent of" before "the reasonable costs".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to

payments for services furnished during cost reporting periods beginning on or

after October 1, 2003.

(b) Coverage of Costs for Certain Emergency Room On-Call Providers.— (1) IN GENERAL.—Section 1834(g)(5) (42 U.S.C. 1395m(g)(5)) is amended-

(A) in the heading-

(i) by inserting "CERTAIN" before "EMERGENCY"; and

(ii) by striking "PHYSICIANS" and inserting "PROVIDERS";

(B) by striking "emergency room physicians who are on-call (as defined by the Secretary)" and inserting "physicians, physician assistants, nurse practitioners, and clinical nurse specialists who are on-call (as defined by the Secretary) to provide emergency services"; and
(C) by striking "physicians' services" and inserting "services covered

under this title".

- (2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply with respect to costs incurred for services provided on or after January 1, 2004.
 (c) MODIFICATION OF THE ISOLATION TEST FOR COST-BASED CAH AMBULANCE
 - (1) IN GENERAL.—Section 1834(l)(8) (42 U.S.C. 1395m(l)), as added by section 205(a) of BIPA (114 Stat. 2763A-482), is amended by adding at the end the following: "The limitation described in the matter following subparagraph (B) in the previous sentence shall not apply if the ambulance services are furnished by such a provider or supplier of ambulance services who is a first responder to emergencies (as determined by the Secretary).".

 (2) Effective date.—The amendment made by paragraph (1) shall apply to

ambulances services furnished on or after the first cost reporting period that be-

gins after the date of the enactment of this Act. (d) REINSTATEMENT OF PERIODIC INTERIM PAYMENT (PIP).-

(1) IN GENERAL.—Section 1815(e)(2) (42 U.S.C. 1395g(e)(2)) is amended— (A) in the matter before subparagraph (A), by inserting ", in the cases described in subparagraphs (A) through (D)" after "1986"; and (B) by striking "and" at the end of subparagraph (C);

(C) by adding "and" at the end of subparagraph (D); and

(D) by inserting after subparagraph (D) the following new subparagraph:

"(E) inpatient critical access hospital services;"

(2) Dévelopment of alternative methods of periodic interim pay-MENTS.—With respect to periodic interim payments to critical access hospitals for inpatient critical access hospital services under section 1815(e)(2)(E) of the Social Security Act, as added by paragraph (1), the Secretary shall develop alternative methods for such payments that are based on expenditures of the hos-

(3) REINSTATEMENT OF PIP.—The amendments made by paragraph (1) shall

apply to payments made on or after January 1, 2004.

(e) Condition for Application of Special Physician Payment Adjustment.— (1) IN GENERAL.—Section 1834(g)(2) (42 U.S.C. 1395m(g)(2)) is amended by adding after and below subparagraph (B) the following:

"The Secretary may not require, as a condition for applying subparagraph (B) with respect to a critical access hospital, that each physician providing professional services in the hospital must assign billing rights with respect to such services, except that such subparagraph shall not apply to those physicians who

(2) Effective Date.—The amendment made by paragraph (1) shall be effective as if included in the enactment of section 403(d) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (113 Stat. 1501A-371).

(f) Flexibility in Bed Limitation for Hospitals.—Section 1820 (42 U.S.C. 1395i-4) is amended-

(1) in subsection (c)(2)(B)(iii), by inserting "subject to paragraph (3)" after "(iii) provides";

(2) by adding at the end of subsection (c) the following new paragraph:

"(3) INCREASE IN MAXIMUM NUMBER OF BEDS FOR HOSPITALS WITH STRONG SEA-SONAL CENSUS FLUCTUATIONS.

"(A) IN GENERAL.—Subject to subparagraph (C), in the case of a hospital that demonstrates that it meets the standards established under subparagraph (B) and has not made the election described in subsection (f)(2)(A), the bed limitations otherwise applicable under paragraph (2)(B)(iii) and subsection (f) shall be increased by 5 beds.

"(B) STANDARDS.—The Secretary shall specify standards for determining whether a critical access hospital has sufficiently strong seasonal variations in patient admissions to justify the increase in bed limitation provided under subparagraph (A)."; and

(3) in subsection (f)-

(A) by inserting "(1)" after "(f)"; and (B) by adding at the end the following new paragraph:

"(2)(A) A hospital may elect to treat the reference in paragraph (1) to '15 beds' as a reference to '25 beds', but only if no more than 10 beds in the hospital are at any time used for non-acute care services. A hospital that makes such an election is not eligible for the increase provided under subsection (c)(3)(A).

"(B) The limitations in numbers of beds under the first sentence of paragraph (1) are subject to adjustment under subsection (c)(3).".

(4) Effective datasent under subsection (e/s). (4) Effective data.—The amendments made by this subsection shall apply to designations made before, on, or after January 1, 2004.
(g) Additional 5-Year Period of Funding for Grant Program.—
(1) In General.—Section 1820(g) (42 U.S.C. 1395i–4(g)) is amended by adding

at the end the following new paragraph:

"(4) Funding

"(A) IN GENERAL.—Subject to subparagraph (B), payment for grants made under this subsection during fiscal years 2004 through 2008 shall be made from the Federal Hospital Insurance Trust Fund.

"(B) ANNUAL AGGREGATE LIMITATION.—In no case may the amount of payment provided for under subparagraph (A) for a fiscal year exceed \$25,000,000."

(2) CONFORMING AMENDMENT.—Section 1820 (42 U.S.C. 1395i-4) is amended by striking subsection (j).

SEC. 406. REDISTRIBUTION OF UNUSED RESIDENT POSITIONS.

(a) IN GENERAL.—Section 1886(h)(4) (42 U.S.C. 1395ww(h)(4)) is amended-

(1) in subparagraph (F)(i), by inserting "subject to subparagraph (I)," after "October 1, 1997,";

(2) in subparagraph (H)(i), by inserting "subject to subparagraph (I)," after "subparagraphs (F) and (G),"; and

(3) by adding at the end the following new subparagraph:

"(I) REDISTRIBUTION OF UNUSED RESIDENT POSITIONS.—

(i) REDUCTION IN LIMIT BASED ON UNUSED POSITIONS.—

"(I) IN GENERAL.—If a hospital's resident level (as defined in clause (iii)(I)) is less than the otherwise applicable resident limit (as defined in clause (iii)(II)) for each of the reference periods (as defined in subclause (II)), effective for cost reporting periods beginning on or after January 1, 2004, the otherwise applicable resident limit shall be reduced by 75 percent of the difference between such limit and the reference resident level specified in subclause (III) (or subclause (IV) if applicable).

"(II) REFERENCE PERIODS DEFINED.—In this clause, the term 'reference periods' means, for a hospital, the 3 most recent consecutive cost reporting periods of the hospital for which cost reports have been settled (or, if not, submitted) on or before September 30, 2002.

"(III) REFERENCE RESIDENT LEVEL.—Subject to subclause (IV), the reference resident level specified in this subclause for a hospital is the highest resident level for the hospital during any of the reference periods.

"(IV) ADJUSTMENT PROCESS.—Upon the timely request of a hospital, the Secretary may adjust the reference resident level for a hospital to be the resident level for the hospital for the cost report-

ing period that includes July 1, 2003.

"(V) AFFILIATION.—With respect to hospitals which are members of the same affiliated group (as defined by the Secretary under subparagraph (H)(ii)), the provisions of this section shall be applied with respect to such an affiliated group by deeming the affiliated group to be a single hospital.

"(ii) REDISTRIBUTION.—

"(I) IN GENERAL.—The Secretary is authorized to increase the otherwise applicable resident limits for hospitals by an aggregate number estimated by the Secretary that does not exceed the aggregate reduction in such limits attributable to clause (i) (without taking into account any adjustment under subclause (IV) of such clause).

"(II) EFFECTIVE DATE.—No increase under subclause (I) shall be permitted or taken into account for a hospital for any portion of a cost reporting period that occurs before July 1, 2004, or before the date of the hospital's application for an increase under this clause. No such increase shall be permitted for a hospital unless the hospital has applied to the Secretary for such increase by December 31, 2005.

"(III) CONSIDERATIONS IN REDISTRIBUTION.—In determining for which hospitals the increase in the otherwise applicable resident limit is provided under subclause (I), the Secretary shall take into account the need for such an increase by specialty and location in-

volved, consistent with subclause (IV).

"(IV) PRIORITY FOR RURAL AND SMALL URBAN AREAS.—In determining for which hospitals and residency training programs an increase in the otherwise applicable resident limit is provided under subclause (I), the Secretary shall first distribute the increase to programs of hospitals located in rural areas or in urban areas that are not large urban areas (as defined for purposes of subsection (d)) and to programs that have no other program of the same specialty in the same state, on a first-come-first-served basis (as determined by the Secretary) based on a demonstration that the hospital will fill the positions made available under this clause and not to exceed an increase of 25 full-time equivalent positions with respect to any hospital.

to any hospital.

"(V) APPLICATION OF LOCALITY ADJUSTED NATIONAL AVERAGE PER RESIDENT AMOUNT.—With respect to additional residency positions in a hospital attributable to the increase provided under this clause, notwithstanding any other provision of this subsection, the approved FTE resident amount is deemed to be equal to the locality adjusted national average per resident amount computed under

subparagraph (E) for that hospital.

"(VI) Construction.—Nothing in this clause shall be construed as permitting the redistribution of reductions in residency positions attributable to voluntary reduction programs under paragraph (6)

or as affecting the ability of a hospital to establish new medical residency training programs under subparagraph (H).

"(iii) RESIDENT LEVEL AND LIMIT DEFINED.—In this subparagraph:

"(I) RESIDENT LEVEL.—The term 'resident level' means, with respect to a hospital, the total number of full-time equivalent residents, before the application of weighting factors (as determined under this paragraph), in the fields of allopathic and osteopathic medicine for the hospital.

"(II) OTHERWISE APPLICABLE RESIDENT LIMIT.—The term 'otherwise applicable resident limit' means, with respect to a hospital, the limit otherwise applicable under subparagraphs (F)(i) and (H) on the resident level for the hospital determined without regard to this subparagraph.".

- (b) Conforming Amendment to IME.—Section 1886(d)(5)(B)(v) (42 U.S.C. 1395ww(d)(5)(B)(v)) is amended by adding at the end the following: "The provisions of subparagraph (I) of subsection (h)(4) shall apply with respect to the first sentece of this clause in the same manner as it applies with respect to subparagraph (F) of such subsection.
- (c) Report on Extension of Applications Under Redistribution Program.— Not later than July 1, 2005, the Secretary shall submit to Congress a report containing recommendations regarding whether to extend the deadline for applications for an increase in resident limits under section 1886(h)(4)(I)(ii)(II) of the Social Security Act (as added by subsection (a)).

SEC. 407. TWO-YEAR EXTENSION OF HOLD HARMLESS PROVISIONS FOR SMALL RURAL HOS-PITALS AND SOLE COMMUNITY HOSPITALS UNDER PROSPECTIVE PAYMENT SYS-TEM FOR HOSPITAL OUTPATIENT DEPARTMENT SERVICES.

- (a) HOLD HARMLESS PROVISIONS.
 - (1) IN GENERAL.—Section 1833(t)(7)(D)(i) (42 U.S.C. 1395l(t)(7)(D)(i)) is amended-

 - (A) in the heading, by striking "SMALL" and inserting "CERTAIN"; (B) by inserting "or a sole community hospital (as defined in section 1886(d)(5)(D)(iii)) located in a rural area" after "100 beds"; and

(C) by striking "2004" and inserting "2006".

- (2) EFFECTIVE DATE.—The amendment made by subsection (a)(2) shall apply with respect to payment for OPD services furnished on and after January 1, 2004.
- (b) Study; Adjustment.—
 - (1) STUDY.—The Secretary shall conduct a study to determine if, under the prospective payment system for hospital outpatient department services under section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)), costs incurred by rural providers of services by ambulatory payment classification groups (APCs) exceed those costs incurred by urban providers of services.
 - (2) ADJUSTMENT.—Insofar as the Secretary determines under paragraph (1) that costs incurred by rural providers exceed those costs incurred by urban providers of services, the Secretary shall provide for an appropriate adjustment under such section 1833(t) to reflect those higher costs by January 1, 2005.

SEC. 408. EXCLUSION OF CERTAIN RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES FROM THE PROSPECTIVE PAYMENT SYSTEM FOR SKILLED NURSING FACILITIES.

- (a) IN GENERAL.—Section 1888(e)(2)(A) (42 U.S.C. 1395yy(e)(2)(A)) is amended— (1) in clause (i)(II), by striking "clauses (ii) and (iii)" and inserting "clauses (ii), (iii), and (iv)"; and
 - (2) by adding at the end the following new clause:
 - "(iv) EXCLUSION OF CERTAIN RURAL HEALTH CLINIC AND FEDERALLY QUALIFIED HEALTH CENTER SERVICES.—Services described in this clause are-
 - "(I) rural health clinic services (as defined in paragraph (1) of section 1861(aa)); and
 - "(II) Federally qualified health center services (as defined in paragraph (3) of such section);
 - that would be described in clause (ii) if such services were not furnished by an individual affiliated with a rural health clinic or a Federally qualified health center.".
- (b) Effective Date.—The amendments made by subsection (a) shall apply to services furnished on or after January 1, 2004.

SEC. 409. RECOGNITION OF ATTENDING NURSE PRACTITIONERS AS ATTENDING PHYSICIANS TO SERVE HOSPICE PATIENTS.

(a) IN GENERAL.—Section 1861(dd)(3)(B) (42 U.S.C. 1395x(dd)(3)(B)) is amended by inserting "or nurse practitioner (as defined in subsection (aa)(5))" after "the physician (as defined in subsection (r)(1)".

(b) Prohibition on Nurse Practitioner Certifying Need for Hospice.—Section 1814(a)(7)(A)(i)(I) (42 U.S.C. 1395f(a)(7)(A)(i)(I)) is amended by inserting (which for purposes of this subparagraph does not include a nurse practitioner) after "attending physician (as defined in section 1861(dd)(3)(B))".

SEC. 410. IMPROVEMENT IN PAYMENTS TO RETAIN EMERGENCY CAPACITY FOR AMBULANCE SERVICES IN RURAL AREAS.

Section 1834(l) (42 U.S.C. 1395m(l)) is amended—

(1) by redesignating paragraph (8), as added by section 221(a) of BIPA (114 Stat. 2763A-486), as paragraph (9); and

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

"(10) Assistance for rural providers furnishing services in low medi-CARE POPULATION DENSITY AREAS.

"(A) IN GENERAL.—In the case of ground ambulance services furnished on or after January 1, 2004, for which the transportation originates in a qualified rural area (as defined in subparagraph (B)), the Secretary shall provide for an increase in the base rate of the fee schedule for mileage for a trip established under this subsection. In establishing such increase, the Secretary shall, based on the relationship of cost and volume, estimate the average increase in cost per trip for such services as compared with the cost per trip for the average ambulance service.

"(B) QUALIFIED RURAL AREA DEFINED.—For purposes of subparagraph (A), the term 'qualified rural area' is a rural area (as defined in section 1886(d)(2)(D)) with a population density of medicare beneficiaries residing in the area that is in the lowest quartile of all rural county populations.".

SEC. 411. PROVIDING SAFE HARBOR FOR CERTAIN COLLABORATIVE EFFORTS THAT BENEFIT MEDICALLY UNDERSERVED POPULATIONS.

(a) IN GENERAL.—Section 1128B(b)(3) (42 U.S.C. 1320a-7(b)(3)), as amended by section 101(b)(2), is amended-

1) in subparagraph (F), by striking "and" after the semicolon at the end;

(2) in subparagraph (G), by striking the period at the end and inserting "; and"; and

(3) by adding at the end the following new subparagraph:

"(H) any remuneration between a public or nonprofit private health center entity described under clause (i) or (ii) of section 1905(l)(2)(B) and any individual or entity providing goods, items, services, donations or loans, or a combination thereof, to such health center entity pursuant to a contract, lease, grant, loan, or other agreement, if such agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center entity.".

(b) RULEMAKING FOR EXCEPTION FOR HEALTH CENTER ENTITY ARRANGEMENTS.—

(1) Establishment.-

(A) In general.--The Secretary of Health and Human Services (in this subsection referred to as the "Secretary") shall establish, on an expedited basis, standards relating to the exception described in section 1128B(b)(3)(H) of the Social Security Act, as added by subsection (a), for health center entity arrangements to the antikickback penalties.

(B) FACTORS TO CONSIDER.—The Secretary shall consider the following

factors, among others, in establishing standards relating to the exception for health center entity arrangements under subparagraph (A):

(i) Whether the arrangement between the health center entity and the other party results in savings of Federal grant funds or increased revenues to the health center entity.

(ii) Whether the arrangement between the health center entity and

the other party restricts or limits a patient's freedom of choice.

(iii) Whether the arrangement between the health center entity and the other party protects a health care professional's independent medical judgment regarding medically appropriate treatment.

The Secretary may also include other standards and criteria that are consistent with the intent of Congress in enacting the exception established under this section.

(2) INTERIM FINAL EFFECT.—No later than 180 days after the date of enactment of this Act, the Secretary shall publish a rule in the Federal Register consistent with the factors under paragraph (1)(B). Such rule shall be effective and final immediately on an interim basis, subject to such change and revision, after public notice and opportunity (for a period of not more than 60 days) for public comment, as is consistent with this subsection.

SEC. 412. GAO STUDY OF GEOGRAPHIC DIFFERENCES IN PAYMENTS FOR PHYSICIANS' SERV-ICES.

(a) Study.—The Comptroller General of the United States shall conduct a study of differences in payment amounts under the physician fee schedule under section 1848 of the Social Security Act (42 U.S.C. 1395w-4) for physicians' services in different geographic areas. Such study shall include-

(1) an assessment of the validity of the geographic adjustment factors used

for each component of the fee schedule;

(2) an evaluation of the measures used for such adjustment, including the fre-

quency of revisions; and

- (3) an evaluation of the methods used to determine professional liability insurance costs used in computing the malpractice component, including a review of increases in professional liability insurance premiums and variation in such increases by State and physician specialty and methods used to update the geographic cost of practice index and relative weights for the malpractice compo-
- (b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under subsection (a). The report shall include recommendations regarding the use of more current data in computing geographic cost of practice indices as well as the use of data directly representative of physicians' costs (rather than proxy measures of such costs).

SEC. 413. TREATMENT OF MISSING COST REPORTING PERIODS FOR SOLE COMMUNITY HOS-PITALS.

(a) IN GENERAL.—Section 1886(b)(3)(I) (42 U.S.C. 1395ww(b)(3)(I)) is amended by

adding at the end the following new clause:

"(iii) In no case shall a hospital be denied treatment as a sole community hospital or payment (on the basis of a target rate as such as a hospital) because data are unavailable for any cost reporting period due to changes in ownership, changes in fiscal intermediaries, or other extraordinary circumstances, so long as data for at least one applicable base cost reporting period is available."

(b) Effective Date.—The amendment made by subsection (a) shall apply to cost

reporting periods beginning on or after January 1, 2004.

SEC. 414. EXTENSION OF TELEMEDICINE DEMONSTRATION PROJECT.

Section 4207 of Balanced Budget Act of 1997 (Public Law 105-33) is amended—

(1) in subsection (a)(4), by striking "4-year" and inserting "8-year"; and (2) in subsection (d)(3), by striking "\$30,000,000" and inserting "\$60,000,000".

SEC. 415. TWO-YEAR INCREASE FOR HOME HEALTH SERVICES FURNISHED IN A RURAL AREA.

(a) In General.—In the case of home health services furnished in a rural area (as defined in section 1886(d)(2)(D) of the Social Security Act (42 U.S.C. 1395ww(d)(2)(D))) during 2004 and 2005, the Secretary shall increase the payment amount otherwise made under section 1895 of such Act (42 U.S.C. 1395fff) for such services by 5 percent.

(b) WAIVING BUDGET NEUTRALITY.—The Secretary shall not reduce the standard prospective payment amount (or amounts) under section 1895 of the Social Security Act (42 U.S.C. 1395fff) applicable to home health services furnished during a period to offset the increase in payments resulting from the application of subsection (a).

TITLE V—PROVISIONS RELATING TO PART A

Subtitle A—Inpatient Hospital Services

SEC. 501. REVISION OF ACUTE CARE HOSPITAL PAYMENT UPDATES.

Section 1886(b)(3)(B)(i) (42 U.S.C. 1395ww(b)(3)(B)(i)) is amended—

(1) by striking "and" at the end of subclause (XVIII); (2) by striking subclause (XIX); and

(3) by inserting after subclause (XVIII) the following new subclauses:

"(XIX) for each of fiscal years 2004 through 2006, the market basket percentage increase minus 0.4 percentage points for hospitals in all areas; and "(XX) for fiscal year 2007 and each subsequent fiscal year, the market basket

percentage increase for hospitals in all areas.".

SEC. 502. RECOGNITION OF NEW MEDICAL TECHNOLOGIES UNDER INPATIENT HOSPITAL PPS.

(a) IMPROVING TIMELINESS OF DATA COLLECTION.—Section 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)) is amended by adding at the end the following new clause: '(vii) Under the mechanism under this subparagraph, the Secretary shall provide

for the addition of new diagnosis and procedure codes in April 1 of each year, but the addition of such codes shall not require the Secretary to adjust the payment (or diagnosis-related group classification) under this subsection until the fiscal year that begins after such date."

(b) ELIGIBILITY STANDARD FOR TECHNOLOGY OUTLIERS.—

(1) MINIMUM PERIOD FOR RECOGNITION OF NEW TECHNOLOGIES.—Section 1886(d)(5)(K)(vi) (42 U.S.C. 1395ww(d)(5)(K)(vi)) is amended—

(A) by inserting "(I)" after "(vi)"; and

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

"(II) Under such criteria, a service or technology shall not be denied treatment as a new service or technology on the basis of the period of time in which the service or technology has been in use if such period ends before the end of the 2-to-3-year or technology has been in use if such period ends before the end of the 2-to-3-year period that begins on the effective date of implementation of a code under ICD-9-CM (or a successor coding methodology) that enables the identification of specific

discharges in which the service or technology has been used.".

(2) ADJUSTMENT OF THRESHOLD.—Section 1886(d)(5)(K)(ii)(I) (42 U.S.C. 1395ww(d)(5)(K)(ii)(I)) is amended by inserting "(applying a threshold specified by the Secretary that is 75 percent of one standard deviation for the diagnosis-related group involved)" after "is inadequate".

(3) CRITERION FOR SUBSTANTIAL IMPROVEMENT.—Section 1886(d)(5)(K)(vi) (42 U.S.C. 1395ww(d)(5)(K)(vi)), as amended by paragraph (1), is further amended by adding at the end the following subclause:

"(III) The Secretary shall by regulation provide for further clarification of the criteria applied to determine whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment value in medical technology that substantially improves the diagnosis of freatment of beneficiaries. Under such criteria, in determining whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of beneficiaries, the Secretary shall deem a service or technology as meeting such requirement if the service or technology is a drug or biological that is designated under section 506 of the Federal Food, Drug, and Cosmetic Act, approved under section 314.510 or 601.41 of title 21, Code of Federal Regulations or designated for priority regions when the marketing application for such tions, or designated for priority review when the marketing application for such drug or biological was filed or is a medical device for which an exemption has been granted under section 520(m) of such Act, or for which priority review has been provided under section 515(d)(5) of such Act. Nothing in this subclause shall be construed as effecting the authority of the Secretary to determine whether items and services are medically necessary and appropriate under section 1862(a)(1)

(4) PROCESS FOR PUBLIC INPUT.—Section 1886(d)(5)(K)

1395ww(d)(5)(K)), as amended by paragraph (1), is amended-

(A) in clause (i), by adding at the end the following: "Such mechanism shall be modified to meet the requirements of clause (viii)."; and

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

"(viii) The mechanism established pursuant to clause (i) shall be adjusted to provide, before publication of a proposed rule, for public input regarding whether a new service or technology not described in the second sentence of clause (vi)(III) represents an advance in medical technology that substantially improves the diagnosis or treatment of beneficiaries as follows:

"(I) The Secretary shall make public and periodically update a list of all the services and technologies for which an application for additional payment under

this subparagraph is pending.

"(II) The Secretary shall accept comments, recommendations, and data from the public regarding whether the service or technology represents a substantial

improvement.

"(III) The Secretary shall provide for a meeting at which organizations representing hospitals, physicians, medicare beneficiaries, manufacturers, and any other interested party may present comments, recommendations, and data to the clinical staff of the Centers for Medicare & Medicaid Services before publication of a notice of proposed rulemaking regarding whether service or technology represents a substantial improvement."

(c) Preference for Use of DRG Adjustment.—Section 1886(d)(5)(K) (42 U.S.C. 1395ww(d)(5)(K)) is further amended by adding at the end the following new clause:

"(ix) Before establishing any add-on payment under this subparagraph with respect to a new technology, the Secretary shall seek to identify one or more diagnosis-related groups associated with such technology, based on similar clinical or anatomical characteristics and the cost of the technology. Within such groups the Sec-

retary shall assign an eligible new technology into a diagnosis-related group where the average costs of care most closely approximate the costs of care of using the new technology. In such case, the new technology would no longer meet the threshold of exceeding 75 percent of the standard deviation for the diagnosis-related group involved under clause (ii)(I). No add-on payment under this subparagraph shall be made with respect to such new technology and this clause shall not affect the application of paragraph (4)(C)(iii).".

(d) IMPROVEMENT IN PAYMENT FOR NEW TECHNOLOGY.—Section 1886(d)(5)(K)(ii)(III) (42 U.S.C. 1395ww(d)(5)(K)(ii)(III)) is amended by inserting after "the estimated average cost of such service or technology" the following: "(based on the marginal rate applied to costs under subparagraph (A))".

(e) ESTABLISHMENT OF NEW FUNDING FOR HOSPITAL INPATIENT TECHNOLOGY.—Section 1886(d)(5)(K)(ii)(III) (42 U.S.C. 1395ww(d)(5)(K)(ii)(III)) is amended by striking "subject to paragraph (4)(C)(iii),". (f) Effective Date.—

(1) IN GENERAL.—The Secretary shall implement the amendments made by this section so that they apply to classification for fiscal years beginning with fiscal year 2005.

(2) RECONSIDERATIONS OF APPLICATIONS FOR FISCAL YEAR 2003 THAT ARE DE-NIED.—In the case of an application for a classification of a medical service or technology as a new medical service or technology under section 1886(d)(5)(K) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(K)) that was filed for fiscal year 2004 and that is denied—

(A) the Secretary shall automatically reconsider the application as an application for fiscal year 2005 under the amendments made by this section;

(B) the maximum time period otherwise permitted for such classification of the service or technology shall be extended by 12 months.

SEC. 503. INCREASE IN FEDERAL RATE FOR HOSPITALS IN PUERTO RICO.

Section 1886(d)(9) (42 U.S.C. 1395ww(d)(9)) is amended-

(1) in subparagraph (A)-

(A) in clause (i), by striking "for discharges beginning on or after October 1, 1997, 50 percent (and for discharges between October 1, 1987, and September 30, 1997, 75 percent)" and inserting "the applicable Puerto Rico percentage (specified in subparagraph (E))"; and

(B) in clause (ii), by striking "for discharges beginning in a fiscal year beginning on or after October 1, 1997, 50 percent (and for discharges between October 1, 1987, and September 30, 1997, 25 percent)" and inserting "the applicable Federal percentage (specified in subparagraph (E))"; and

(2) by adding at the end the following new subparagraph:

"(E) For purposes of subparagraph (A), for discharges occurring—
"(i) on or after October 1, 1987, and before October 1, 1997, the applicable
Puerto Rico percentage is 75 percent and the applicable Federal percentage is

25 percent; "(ii) on or after October 1, 1997, and before October 1, 2003, the applicable Puerto Rico percentage is 50 percent and the applicable Federal percentage is 50 percent;

"(iii) during fiscal year 2004, the applicable Puerto Rico percentage is 41 percent and the applicable Federal percentage is 59 percent;
"(iv) during fiscal year 2005, the applicable Puerto Rico percentage is 33 percent and the applicable Federal percentage is 67 percent; and
"(v) on or after October 1, 2005, the applicable Puerto Rico percentage is 25 percent and the applicable Federal percentage is 75 percent."

SEC. 504. WAGE INDEX ADJUSTMENT RECLASSIFICATION REFORM .

(a) IN GENERAL.—Section 1886(d) (42 U.S.C. 1395ww(d)) is amended by adding at

the end the following:
"(11)(A) In order to recognize commuting patterns among Metropolitan Statistical Areas and between such Areas and rural areas, the Secretary shall establish a process, upon application of a subsection (d) hospital that establishes that it is a qualifying hospital described in subparagraph (B), for an increase of the wage index applied under paragraph (3)(E) for the hospital in the amount computed under sub-

paragraph (D).

"(B) A qualifying hospital described in this subparagraph is a subsection (d) hos-

pital—

"(i) the average wages of which exceed the average wages for the area in which the hospital is located; and

"(ii) which has at least 10 percent of its employees who reside in one or more higher wage index areas.

"(C) For purposes of this paragraph, the term 'higher wage index area' means, with respect to a hospital, an area with a wage index that exceeds that of the area

in which the hospital is located.

"(D) The increase in the wage index under subparagraph (A) for a hospital shall be equal to the percentage of the employees of the hospital that resides in any higher wage index area multiplied by the sum of the products, for each higher wage index area of-

"(i) the difference between (I) the wage index for such area, and (II) the wage index of the area in which the hospital is located (before the application of this paragraph); and

"(ii) the number of employees of the hospital that reside in such higher wage index area divided by the total number of such employees that reside in all high

wage index areas.

"(E) The process under this paragraph shall be based upon the process used by the Medicare Geographic Classification Review Board under paragraph (10) with respect to data submitted by hospitals to the Board on the location of residence of hospital employees and wages under the applicable schedule established for geographic reclassification.

"(F) A reclassification under this paragraph shall be effective for a period of 3 fiscal years, except that the Secretary shall establish procedures under which a subsection (d) hospital may elect to terminate such reclassification before the end of

such period.

"(G) A hospital that is reclassified under this paragraph for a period is not eligible for reclassification under paragraphs (8) or (10) during that period.

"(H) Any increase in a wage index under this paragraph for a hospital shall not be taken into account for purposes of-

(i) computing the wage index for the area in which the hospital is located

or any other area; or

"(ii) applying any budget neutrality adjustment with respect to such index under paragraph (8)(D).

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall first apply to the wage index for cost reporting period beginning on or after October 1, 2004.

SEC. 505. MEDPAC REPORT ON SPECIALTY HOSPITALS.

- (a) MedPAC Study.—The Medicare Payment Advisory Commission shall conduct a study of specialty hospitals compared with other similar general acute care hospitals under the medicare program. Such study shall examine—
 - 1) whether there are excessive self-referrals;

quality of care furnished;

(3) the impact of specialty hospitals on such general acute care hospitals; and

(4) differences in the scope of services, medicaid utilization, and uncompensated care furnished.

(b) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall submit to Congress a report on the study conducted under subsection (a), and shall include any recommendations for legislation or administrative change as the Secretary determines appropriate.

Subtitle B—Other Provisions

SEC. 511. PAYMENT FOR COVERED SKILLED NURSING FACILITY SERVICES.

(a) ADJUSTMENT TO RUGS FOR AIDS RESIDENTS.—Paragraph (12) of section 1888(e) (42 U.S.C. 1395yy(e)) is amended to read as follows:

"(12) ADJUSTMENT FOR RESIDENTS WITH AIDS.—

"(A) By CONTROL OF THE SERVICES.

(A) IN GENERAL.—Subject to subparagraph (B), in the case of a resident of a skilled nursing facility who is afflicted with acquired immune defi-ciency syndrome (AIDS), the per diem amount of payment otherwise appli-cable shall be increased by 128 percent to reflect increased costs associated with such residents.

"(B) SUNSET.—Subparagraph (A) shall not apply on and after such date as the Secretary certifies that there is an appropriate adjustment in the case mix under paragraph (4)(G)(i) to compensate for the increased costs associated with residents described in such subparagraph.

(b) Effective Date.—The amendment made by paragraph (1) shall apply to services furnished on or after October 1, 2003.

SEC. 512. COVERAGE OF HOSPICE CONSULTATION SERVICES.

(a) Coverage of Hospice Consultation Services.—Section 1812(a) (42 U.S.C. 1395d(a)) is amended-

- (1) by striking "and" at the end of paragraph (3);
- (2) by striking the period at the end of paragraph (4) and inserting "; and";

(3) by inserting after paragraph (4) the following new paragraph:

"(5) for individuals who are terminally ill, have not made an election under subsection (d)(1), and have not previously received services under this paragraph, services that are furnished by a physician who is either the medical director or an employee of a hospice program and that consist of—

"(A) an evaluation of the individual's need for pain and symptom manage-

ment:

"(B) counseling the individual with respect to end-of-life issues and care options; and

"(C) advising the individual regarding advanced care planning.".
(b) PAYMENT.—Section 1814(i) (42 U.S.C. l395f(i)) is amended by adding at the

end the following new paragraph:

"(4) The amount paid to a hospice program with respect to the services under section 1812(a)(5) for which payment may be made under this part shall be equal to an amount equivalent to the amount established for an office or other outpatient visit for evaluation and management associated with presenting problems of moderate severity under the fee schedule established under section 1848(b), other than the portion of such amount attributable to the practice expense component.".

(c) CONFORMING AMENDMENT.—Section 1861(dd)(2)(A)(i) (42 U.S.C. 1395x(dd)(2)(A)(i)) is amended by instance the comma at the end the following from the comma at the end the

lowing: "and services described in section 1812(a)(5)".

(d) Effective Date.—The amendments made by this section shall apply to services provided by a hospice program on or after January 1, 2004.

TITLE VI—PROVISIONS RELATING TO PART B

Subtitle A—Physicians' Services

SEC. 601. REVISION OF UPDATES FOR PHYSICIANS' SERVICES.

(a) Update for 2004 and 2005

(1) IN GENERAL.—Section 1848(d) (42 U.S.C. 1395w-4(d)) is amended by add-

ing at the end the following new paragraph:

"(5) UPDATE FOR 2004 AND 2005.—The update to the single conversion factor established in paragraph (1)(C) for each of 2004 and 2005 shall be not less than 1.5 percent.'

(2) CONFORMING AMENDMENT.—Paragraph (4)(B) of such section is amended, in the matter before clause (i), by inserting "and paragraph (5)" after "subpara-

graph (D)".

- (3) NOT TREATED AS CHANGE IN LAW AND REGULATION IN SUSTAINABLE GROWTH RATE DETERMINATION.—The amendments made by this subsection shall not be treated as a change in law for purposes of applying section 1848(f)(2)(D) of the Social Security Act (42 U.S.C. 1395w–4(f)(2)(D)).
- (b) Use of 10-Year Rolling Average in Computing Gross Domestic Prod-
 - (1) IN GENERAL.—Section 1848(f)(2)(C) (42 U.S.C. 1395w-4(f)(2)(C)) is amended-

- (A) by striking "projected" and inserting "annual average"; and (B) by striking "from the previous applicable period to the applicable period involved" and inserting "during the 10-year period ending with the applicable period involved".

 (2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to
- computations of the sustainable growth rate for years beginning with 2003

SEC. 602. STUDIES ON ACCESS TO PHYSICIANS' SERVICES.

(a) GAO STUDY ON BENEFICIARY ACCESS TO PHYSICIANS' SERVICES.-

(1) STUDY.—The Comptroller General of the United States shall conduct a study on access of medicare beneficiaries to physicians' services under the medicare program. The study shall include

(A) an assessment of the use by beneficiaries of such services through an analysis of claims submitted by physicians for such services under part B of the medicare program;

(B) an examination of changes in the use by beneficiaries of physicians' services over time;

(C) an examination of the extent to which physicians are not accepting new medicare beneficiaries as patients.

(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). The report shall include a determination whether—

(A) data from claims submitted by physicians under part B of the medicare program indicate potential access problems for medicare beneficiaries in certain geographic areas; and

(B) access by medicare beneficiaries to physicians' services may have improved, remained constant, or deteriorated over time.

(b) STUDY AND REPORT ON SUPPLY OF PHYSICIANS.—

(1) STUDY.—The Secretary shall request the Institute of Medicine of the National Academy of Sciences to conduct a study on the adequacy of the supply of physicians (including specialists) in the United States and the factors that affect such supply.

(2) REPORT TO CONGRESS.—Not later than 2 years after the date of enactment of this section, the Secretary shall submit to Congress a report on the results of the study described in paragraph (1), including any recommendations for legislation.

(c) GAO STUDY OF MEDICARE PAYMENT FOR INHALATION THERAPY.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study to examine the adequacy of current reimbursements for inhalation therapy under the medicare program.

(2) REPORT.—Not later than May 1, 2004, the Comptroller General shall submit to Congress a report on the study conducted under paragraph (1).

SEC. 603. MEDPAC REPORT ON PAYMENT FOR PHYSICIANS' SERVICES.

(a) Practice Expense Component.—Not later than 1 year after the date of the enactment of this Act, the Medicare Payment Advisory Commission shall submit to Congress a report on the effect of refinements to the practice expense component of payments for physicians' services, after the transition to a full resource-based payment system in 2002, under section 1848 of the Social Security Act (42 U.S.C. 1395w-4). Such report shall examine the following matters by physician specialty:

(1) The effect of such refinements on payment for physicians' services.

(2) The interaction of the practice expense component with other components of and adjustments to payment for physicians' services under such section.

(3) The appropriateness of the amount of compensation by reason of such refinements.

(4) The effect of such refinements on access to care by medicare beneficiaries to physicians' services.

(5) The effect of such refinements on physician participation under the medi-

care program.

(b) VOLUME OF PHYSICIAN SERVICES.—The Medicare Payment Advisory Commission shall submit to Congress a report on the extent to which increases in the vol-

ume of physicians' services under part B of the medicare program are a result of care that improves the health and well-being of medicare beneficiaries. The study shall include the following:

(1) An analysis of recent and historic growth in the components that the Sec-

(1) An analysis of recent and historic growth in the components that the Secretary includes under the sustainable growth rate (under section 1848(f) of the Social Security Act).

(2) An examination of the relative growth of volume in physician services between medicare beneficiaries and other populations.

(3) An analysis of the degree to which new technology, including coverage determinations of the Centers for Medicare & Medicaid Services, has affected the volume of physicians' services.

(4) An examination of the impact on volume of demographic changes.

(5) An examination of shifts in the site of service of services that influence the number and intensity of services furnished in physicians' offices and the extent to which changes in reimbursement rates to other providers have affected these changes.

(6) An evaluation of the extent to which the Centers for Medicare & Medicaid Services takes into account the impact of law and regulations on the sustainable growth rate.

SEC. 604. INCLUSION OF PODIATRISTS AND DENTISTS UNDER PRIVATE CONTRACTING AUTHORITY.

Section 1802(b)(5)(B) (42 U.S.C. 1395a(b)(5)(B)) is amended by striking "section 1861(r)(1)" and inserting "paragraphs (1), (2), and (3) of section 1861(r)".

SEC. 605. ESTABLISHMENT OF FLOOR ON WORK GEOGRAPHIC ADJUSTMENT.

(a) Minimum Index.-

(1) IN GENERAL.—Section 1848(e)(1) (42 U.S.C. 1395w-4(e)(1)) is amended by

adding at the end the following new subparagraph:

"(E) FLOOR AT 1.0 ON WORK GEOGRAPHIC INDICES.—Subject to section 605(a)(2) of the Medicare Prescription Drug and Modernization Act of 2003, after calculating the work geographic indices in subparagraph (A)(iii), for purposes of payment for services furnished on or after January 1, 2004, and before January 1, 2006, the Secretary shall increase the work geographic index to 1.00 for any locality for which such geographic index is less than

(2) Secretarial discretion.—Section 1848(e)(1)(E), as added by paragraph (1) shall have no force or effect in law if the Secretary determines, taking into account the report of the Comptroller General under subsection (b)(2), that there is no sound economic rationale for the implementation of that section.

(b) GAO REPORT.

- (1) EVALUATION.—As part of the study on geographic differences in payments for physicians' services conducted under section 412, the Comptroller General of the United States shall evaluate the following:
 - (A) Whether there is a sound economic basis for the implementation of the amendment to section 1848(e)(1) under subsection (a)(1) in those areas in which the adjustment applies.

(B) The effect of such adjustment on physician location and retention in

areas affected by such adjustment, taking into account-

(i) differences in recruitment costs and retention rates for physicians, including specialists, between large urban areas and other areas; and (ii) the mobility of physicians, including specialists, over the last decade.

(C) The appropriateness of establishing a floor of 1.0 for the work geo-

graphic index.
(2) REPORT.—By not later than September 1, 2004, the Comptroller General shall submit to Congress and to the Secretary a report on the evaluation conducted under paragraph (1).

Subtitle B—Preventive Services

SEC. 611. COVERAGE OF AN INITIAL PREVENTIVE PHYSICAL EXAMINATION.

(a) COVERAGE.—Section 1861(s)(2) (42 U.S.C. 1395x(s)(2)) is amended—

(1) in subparagraph (U), by striking "and" at the end;(2) in subparagraph (V), by inserting "and" at the end; and

(3) by adding at the end the following new subparagraph: "(W) an initial preventive physical examination (as defined in subsection

(b) Services Described.—Section 1861 (42 U.S.C. 1395x) is amended by adding at the end the following new subsection:

"Initial Preventive Physical Examination

"(ww) The term 'initial preventive physical examination' means physicians' services consisting of a physical examination with the goal of health promotion and disease detection and includes items and services (excluding clinical laboratory tests), as determined by the Secretary, consistent with the recommendations of the United States Preventive Services Task Force.".

(c) WAIVER OF DEDUCTIBLE AND COINSURANCE.—

(1) Deductible.—The first sentence of section 1833(b) (42 U.S.C. 1395l(b)) is amended-

(A) by striking "and" before "(6)", and (B) by inserting before the period at the end the following: ", and (7) such deductible shall not apply with respect to an initial preventive physical examination (as defined in section 1861(ww))'

(2) COINSURANCE.—Section 1833(a)(1) (42 U.S.C. 1395l(a)(1)) is amended-

(A) in clause (N), by inserting "(or 100 percent in the case of an initial preventive physical examination, as defined in section 1861(ww))" after "80 percent"; and

(B) in clause (O), by inserting "(or 100 percent in the case of an initial preventive physical examination, as defined in section 1861(ww))" after "80 percent".

- (d) Payment as Physicians' Services.—Section 1848(j)(3) (42 U.S.C. 1395w-4(j)(3)) is amended by inserting "(2)(W)," after "(2)(S),". (e) Other Conforming Amendments.—Section 1862(a) (42 U.S.C. 1395y(a)) is
- amended-

(1) in paragraph (1)—

(A) by striking "and" at the end of subparagraph (H);
(B) by striking the semicolon at the end of subparagraph (I) and inserting ", and"; and

(C) by adding at the end the following new subparagraph:

"(J) in the case of an initial preventive physical examination, which is performed not later than 6 months after the date the individual's first coverage pe-

riod begins under part B;"; and
(2) in paragraph (7), by striking "or (H)" and inserting "(H), or (J)".
(f) Effective Date.—The amendments made by this section shall apply to services furnished on or after January 1, 2004, but only for individuals whose coverage period begins on or after such date.

SEC. 612. COVERAGE OF CHOLESTEROL AND BLOOD LIPID SCREENING.

(a) COVERAGE.—Section 1861(s)(2) (42 U.S.C. 1395x(s)(2)), as amended by section 611(a), is amended-

(1) in subparagraph (V), by striking "and" at the end;
(2) in subparagraph (W), by inserting "and" at the end; and
(3) by adding at the end the following new subparagraph:

"(X) cholesterol and other blood lipid screening tests (as defined in subsection (XX)):

(b) Services Described.—Section 1861 (42 U.S.C. 1395x), as amended by section 611(b), is amended by adding at the end the following new subsection:

"Cholesterol and Other Blood Lipid Screening Test

"(xx)(1) The term 'cholesterol and other blood lipid screening test' means diagnostic testing of cholesterol and other lipid levels of the blood for the purpose of early detection of abnormal cholesterol and other lipid levels.

"(Ž) The Secretary shall establish standards, in consultation with appropriate organizations, regarding the frequency and type of cholesterol and other blood lipid screening tests, except that such frequency may not be more often than once every 2 years.

(c) Frequency.—Section 1862(a)(1) (42 U.S.C. 1395y(a)(1)), as amended by section

611(e), is amended-

(1) by striking "and" at the end of subparagraph (I);

(2) by striking the semicolon at the end of subparagraph (J) and inserting "; and"; and

- (3) by adding at the end the following new subparagraph:
 "(K) in the case of a cholesterol and other blood lipid screening test (as defined in section 1861(xx)(1)), which is performed more frequently than is covered under section 1861(xx)(2).
- (d) EFFECTIVE DATE.—The amendments made by this section shall apply to tests furnished on or after January 1, 2005.

SEC. 613. WAIVER OF DEDUCTIBLE FOR COLORECTAL CANCER SCREENING TESTS.

(a) In General.—The first sentence of section 1833(b) (42 U.S.C. 1395l(b)), as amended by section 611(c)(1), is amended—
(1) by striking "and" before "(7)"; and

- (2) by inserting before the period at the end the following: ", and (8) such deductible shall not apply with respect to colorectal cancer screening tests (as described in section 1861(pp)(1))".
- (b) CONFORMING AMENDMENTS.—Paragraphs (2)(C)(ii) and (3)(C)(ii) of section 1834(d) (42 U.S.C. 1395m(d)) are each amended—

 (1) by striking "DEDUCTIBLE AND" in the heading; and
 (2) in subclause (I), by striking "deductible or" each place it appears.

 (c) EFFECTIVE DATE.—The amendment made by this section shall apply to items

- and services furnished on or after Janaury 1, 2004.

SEC. 614. IMPROVED PAYMENT FOR CERTAIN MAMMOGRAPHY SERVICES.

(a) Exclusion from OPD Fee Schedule.—Section 1833(t)(1)(B)(iv) (42 U.S.C. 1395l(t)(1)(B)(iv)) is amended by inserting before the period at the end the following: "and does not include screening mammography (as defined in section 1861(jj)) and unilateral and bilateral diagnostic mammography"

(b) ADJUSTMENT TO TECHNICAL COMPONENT.—For diagnostic mammography performed on or after January 1, 2004, for which payment is made under the physician fee schedule under section 1848 of the Social Security Act (42 U.S.C. 1395w–4), the

Secretary, based on the most recent cost data available, shall provide for an appropriate adjustment in the payment amount for the technical component of the diagnostic mammography.

(c) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to mammography performed on or after January 1, 2004.

SEC. 615. MEDICARE COVERAGE OF DIABETES LABORATORY DIAGNOSTIC TESTS.

- (a) COVERAGE.—Section 1861(s)(2) (42 U.S.C. 1395x(s)(2)), as amended by sections 611 and 612, is amended-
 - (1) in subparagraph (W), by striking "and" at the end; (2) in subparagraph (X), by adding "and" at the end; and
 - (3) by adding at the end the following new subparagraph:
 - "(Y) diabetes screening tests and services (as defined in subsection (yy));".
- (b) Services Described.—Section 1861 (42 U.S.C. 1395x), as amended by sections 611 and 612, is further amended by adding at the end the following new subsection:

"Diabetes Screening Tests and Services

"(yy)(1) The term 'diabetes screening tests' means diagnostic testing furnished to an individual at risk for diabetes (as defined in paragraph (2)) for the purpose of early detection of diabetes, including-

"(A) a fasting plasma glucose test; and
"(B) such other tests, and modifications to tests, as the Secretary determines appropriate, in consultation with appropriate organizations.

"(2) For purposes of paragraph (1), the term 'individual at risk for diabetes' means an individual who has any, a combination of, or all of the following risk factors for diabetes:

"(A) A family history of diabetes.

"(B) Overweight defined as a body mass index greater than or equal to 25 kg/ m2.

"(C) Habitual physical inactivity.

- "(D) Belonging to a high-risk ethnic or racial group.
- "(E) Previous identification of an elevated impaired fasting glucose.

"(F) Identification of impaired glucose tolerance.

"(G) Hypertension.

"(H) Dyslipidemia.

"(I) History of gestational diabetes mellitus or delivery of a baby weighing greater than 9 pounds.

"(J) Polycystic ovary syndrome.
"(3) The Secretary shall establish standards, in consultation with appropriate organizations, regarding the frequency of diabetes screening tests, except that such frequency may not be more often than twice within the 12-month period following the date of the most recent diabetes screening test of that individual.

(c) Frequency.—Section 1862(a)(1) (42 U.S.C. 1395y(a)(1)), as amended by sections 611 and 612, is amended—

(1) by striking "and" at the end of subparagraph (J); (2) by striking the semicolon at the end of subparagraph (K) and inserting "; and"; and

(3) by adding at the end the following new subparagraph:

(L) in the case of a diabetes screening tests or service (as defined in section 1861(yy)(1)), which is performed more frequently than is covered under section 1861(yy)(3).

(d) Effective Date.—The amendments made by this section shall apply to tests furnished on or after the date that is 90 days after the date of enactment of this

Subtitle C—Other Services

SEC. 621. HOSPITAL OUTPATIENT DEPARTMENT (HOPD) PAYMENT REFORM.

(a) PAYMENT FOR DRUGS.-

(1) MODIFICATION OF AMBULATORY PAYMENT CLASSIFICATION (APC) GROUPS.—Section 1833(t) (42 U.S.C. 1395l(t)) is amended—

(A) by redesignating paragraph (13) as paragraph (14); and

(B) by inserting after paragraph (12) the following new paragraph:

"(13) DRUG APC PAYMENT RATES.

"(A) IN GENERAL.—With respect to payment for covered OPD services that includes a specified covered outpatient drug (defined in subparagraph (B)),

the amount provided for payment for such drug under the payment system under this subsection for services furnished in—

"(i) 2004, 2005, or 2006, shall in no case—

"(I) exceed 95 percent of the average wholesale price for the drug;

or "(II) be less than the transition percentage (under subparagraph

(C)) of the average wholesale price for the drug; or

"(ii) a subsequent year, shall be equal to the average price for the drug for that area and year established under the competitive acquisition program under section 1847A as calculated and applied by the Secretary for purposes of this paragraph.

"(B) SPECIFIED COVERED OUTPATIENT DRUG DEFINED.—

"(i) IN GENERAL.—In this paragraph, the term 'specified covered outpatient drug' means, subject to clause (ii), a covered outpatient drug (as defined in 1927(k)(2), that is

"(I) a radiopharmaceutical; or

"(II) a drug or biological for which payment was made under paragraph (6) (relating to pass-through payments) on or before December 31, 2002.

"(ii) EXCEPTION.—Such term does not include—

"(I) a drug for which payment is first made on or after January 1, 2003, under paragraph (6); or "(II) a drug for a which a temporary HCPCS code has not been assigned.

"(C) Transition towards historical average acquisition cost.—The transition percentage under this subparagraph for drugs furnished in a year is determined in accordance with the following table:

The transition percentage for—

For the year—	Single source drugs are—	Innovator mul- tiple source drugs are—	Generic drugs are—
2004	83%	81.5%	46%
2005	77%	75%	46%
2006	71%	68%	16%

"(D) PAYMENT FOR NEW DRUGS UNTIL TEMPORARY HCPCS CODE AS-SIGNED.—With respect to payment for covered OPD services that includes a covered outpatient drug (as defined in 1927(k)) for a which a temporary HCPCS code has not been assigned, the amount provided for payment for such drug under the payment system under this subsection shall be equal to 95 percent of the average wholesale price for the drug.

"(E) CLASSES OF DRUGS.—For purposes of this paragraph, each of the fol-

lowing shall be treated as a separate class of drugs:

"(i) SOLE SOURCE DRUGS.—A sole source drug which for purposes of this paragraph means a drug or biological that is not a multiple source drug (as defined in subclauses (I) and (II) of section 1927(k)(7)(A)(i)) and is not a drug approved under an abbreviated new drug application under section 355(j) of the Federal Food, Drug, and Cosmetic Act.

"(ii) INNOVATOR MULTIPLE SOURCE DRUGS.—Innovator multiple source

drugs (as defined in section 1927(k)(7)(A)(ii)).

"(iii) NONINOVATOR MULTIPLE SOURCE DRUGS.—Noninnovator multiple source drugs (as defined in section 1927(k)(7)(A)(iii)).

"(F) INAPPLICABILITY OF EXPENDITURES IN DETERMINING CONVERSION FAC-TORS.—Additional expenditures resulting from this paragraph and paragraph (14)(C) in a year shall not be taken into account in establishing the conversion factor for that year.'

(2) REDUCTION IN THRESHOLD FOR SEPARATE APCS FOR DRUGS.—Section 1833(t)(14), as redesignated by paragraph (1)(A), is amended by adding at the

end the following new subparagraph:

(B) THRESHOLD FOR ESTABLISHMENT OF SEPARATE APCS FOR DRUGS.—The Secretary shall reduce the threshold for the establishment of separate ambulatory procedure classification groups (APCs) with respect to drugs to \$50

per administration.".
(3) Exclusion of Separate Drug APCS FROM OUTLIER PAYMENTS.—Section 1833(t)(5) is amended by adding at the end the following new subparagraph:

"(E) EXCLUSION OF SEPARATE DRUG APCS FROM OUTLIER PAYMENTS.—No additional payment shall be made under subparagraph (A) in the case of

ambulatory procedure codes established separately for drugs.".

(4) PAYMENT FOR PASS THROUGH DRUGS.—Clause (i) of section 1833(t)(6)(D) (42 U.S.C. 1395l(t)(6)(D)) is amended by inserting after "under section 1842(o)" the following: "(or if the drug is covered under a competitive acquisition contract under section 1847A for an area, an amount determined by the Secretary equal to the average price for the drug for that area and year established under such section as calculated and applied by the Secretary for purposes of this paragraph)".

(5) EFFECTIVE DATE.—The amendments made by this subsection shall apply

to services furnished on or after January 1, 2004. (b) Special Payment for Brachytherapy.-

(1) IN GENERAL.—Section 1833(t)(14), as so redesignated and amended by sub-

- section (a)(2), is amended by adding at the end the following new subparagraph: "(C) PAYMENT FOR DEVICES OF BRACHYTHERAPY AT CHARGES ADJUSTED TO COST.—Notwithstanding the preceding provisions of this subsection, for a device of brachytherapy furnished on or after January 1, 2004, and before January 1, 2007, the payment basis for the device under this subsection shall be equal to the hospital's charges for each device furnished, adjusted
- SPECIFICATION OF GROUPS FOR BRACHYTHERAPY DEVICES.—Section 1833(t)(2) (42 U.S.C. 1395l(t)(2) is amended—

 (A) in subparagraph (F), by striking "and" at the end;

 (B) in subparagraph (G), by striking the period at the end and inserting

"; and"; and

(C) by adding at the end the following new subparagraph:

"(H) with respect to devices of brachytherapy, the Secretary shall create additional groups of covered OPD services that classify such devices separately from the other services (or group of services) paid for under this subsection in a manner reflecting the number, isotope, and radioactive intensity of such devices furnished, including separate groups for palladium-103 and iodine-125 devices.".
(3) GAO REPORT.—The Comptroller General of the United States shall con-

duct a study to determine appropriate payment amounts under section 1833(t)(13)(B) of the Social Security Act, as added by paragraph (1), for devices of brachytherapy. Not later than January 1, 2005, the Comptroller General shall submit to Congress and the Secretary a report on the study conducted under this paragraph, and shall include specific recommendations for appropriate payments for such devices.

(c) Application of Functional Equivalence Test.-

(1) IN GENERAL.—Section 1833(t)(6) (42 U.S.C. 1395l(t)(6)) is amended by adding at the end the following new subparagraph:

"(F) LIMITATION ON APPLICATION OF FUNCTIONAL EQUIVALENCE STAND-

"(i) IN GENERAL.—The Secretary may not apply a 'functional equivalence' or similar standard to a drug or biological under this paragraph. "(ii) LIMITED APPLICATION.—Clause (i) shall apply to the application

of a 'functional equivalent' or similar standard to a drug or biological on or after the date of the enactment of this subparagraph, unless-"(I) such application was being made to such drug or biological

before such date; and

"(II) the Secretary applies, or has applied, such 'functional equivalent' or similar standard to such drug or biological only for the purpose of determining the eligibility of such drug or biological for additional payments under this paragraph and not for the purpose of any other payments under this title.

"(iii) RULE OF CONSTRUCTION.—Nothing in this subparagraph shall be construed as affecting the Secretary's authority to deem a particular drug or biological to be identical to another drug or biological if the two drugs or biologicals are pharmaceutically equivalent and bioequivalent,

as determined by the Commissioner of Food and Drugs.".

(d) Hospital Acquisition Cost Study.

(1) IN GENERAL.—The Secretary shall conduct a study on the costs incurred by hospitals in acquiring covered outpatient drugs for which payment is made under section 1833(t) of the Social Security Act (42 U.S.C. 1395l(t)).

(2) DRUGS COVERED.—The study in paragraph (1) shall not include those

drugs for which the acquisition costs is less than \$50 per administration.

(3) Representative sample of hospitals.—In conducting the study under paragraph (1), the Secretary shall collect data from a statistically valid sample of hospitals with an urban/rural stratification.

(4) REPORT.—Not later than January 1, 2006, the Secretary shall submit to Congress a report on the study conducted under paragraph (1), and shall in-

clude recommendations with respect to the following:

(A) Whether the study should be repeated, and if so, how frequently.

(B) Whether the study produced useful data on hospital acquisition cost.
(C) Whether data produced in the study is appropriate for use in making adjustments to payments for drugs and biologicals under section 1847A of the Social Security Act.

(D) Whether separate estimates can made of overhead costs, including

handing and administering costs for drugs.

SEC. 622. PAYMENT FOR AMBULANCE SERVICES.

(a) Phase-In Providing Floor Using Blend of Fee Schedule and Regional Fee Schedules.—Section 1834(l) (42 U.S.C. 1395m(l)), as amended by section 410(a), is amended—

(1) in paragraph (2)(E), by inserting "consistent with paragraph (11)" after "in an efficient and fair manner"; and
(2) by adding at the end the following new paragraph:

"(11) Phase-in providing floor using blend of fee schedule and re-GIONAL FEE SCHEDULES.—In carrying out the phase-in under paragraph (2)(E) for each level of service furnished in a year, the portion of the payment amount that is based on the fee schedule shall be the greater of the amount determined under such fee schedule (without regard to this paragraph) or the following blended rate of the fee schedule under paragraph (1) and of a regional fee schedule for the region involved:

"(A) For 2004, the blended rate shall be based 20 percent on the fee schedule under paragraph (1) and 80 percent on the regional fee schedule. "(B) For 2005, the blended rate shall be based 40 percent on the fee

schedule under paragraph (1) and 60 percent on the regional fee schedule. "(C) For 2006, the blended rate shall be based 60 percent on the fee

schedule under paragraph (1) and 40 percent on the regional fee schedule. "(D) For 2007, 2008, and 2009, the blended rate shall be based 80 percent on the fee schedule under paragraph (1) and 20 percent on the regional fee schedule.

"(E) For 2010 and each succeeding year, the blended rate shall be based 100 percent on the fee schedule under paragraph (1).

For purposes of this paragraph, the Secretary shall establish a regional fee schedule for each of the 9 Census divisions using the methodology (used in establishing the fee schedule under paragraph (1)) to calculate a regional conversion factor and a regional mileage payment rate and using the same payment adjustments and the same relative value units as used in the fee schedule under such paragraph.

(b) Adjustment in Payment for Certain Long Trips.—Section 1834(1), as amended by subsection (a), is further amended by adding at the end the following

new paragraph:

"(12) ADJUSTMENT IN PAYMENT FOR CERTAIN LONG TRIPS.—In the case of ground ambulance services furnished on or after January 1, 2004, and before January 1, 2009, regardless of where the transportation originates, the fee schedule established under this subsection shall provide that, with respect to the payment rate for mileage for a trip above 50 miles the per mile rate otherwise established shall be increased by \(^{1}\)4 of the payment per mile otherwise ap-

plicable to such miles.".
(c) GAO REPORT ON COSTS AND ACCESS.—Not later than December 31, 2005, the Comptroller General of the United States shall submit to Congress an initial report on how costs differ among the types of ambulance providers and on access, supply, and quality of ambulance services in those regions and States that have a reduction in payment under the medicare ambulance fee schedule (under section 1834(l) of the Social Security Act, as amended by this section). Not later than December 31, 2007, the Comptroller General shall submit to Congress a final report on such access and supply.

(d) Effective Date.—The amendments made by this section shall apply to ambu-

lance services furnished on or after January 1, 2004.

SEC. 623. RENAL DIALYSIS SERVICES.

(a) DEMONSTRATION OF ALTERNATIVE DELIVERY MODELS.—

(1) USE OF ADVISORY BOARD.—In carrying out the demonstration project relating to improving care for people with end-stage renal disease through alternative delivery models (as published in the Federal Register of June 4, 2003), the Secretary shall establish an advisory board comprised of representatives described in paragraph (2) to provide advice and recommendations with respect to the establishment and operation of such demonstration project.

(2) Representatives.—Representatives referred to in paragraph (1) include representatives of the following:

(A) Patient organizations.

(B) Clinicians.

(C) The medicare payment advisory commission, established under section 1805 of the Social Security Act (42 U.S.C. 1395b-6).

(D) The National Kidney Foundation.

(E) The National Institute of Diabetes and Digestive and Kidney Diseases of National Institutes of Health.

(F) End-stage renal disease networks.

(G) Medicare contractors to monitor quality of care.
(I) providers of services and renal dialysis facilities furnishing end-stage renal disease services.

(J) Economists. (K) Researchers.

(b) Restoring Composite Rate Exceptions for Pediatric Facilities.—

- (1) IN GENERAL.—Section 422(a)(2) of BIPA is amended—
 (A) in subparagraph (A), by striking "and (C)" and inserting ", (C), and (D)'
 - (B) in subparagraph (B), by striking "In the case" and inserting "Subject to subparagraph (D), in the case"; and (C) by adding at the end the following new subparagraph:

"(D) INAPPLICABILITY TO PEDIATRIC FACILITIES.—Subparagraphs (A) and (B) shall not apply, as of October 1, 2002, to pediatric facilities that do not have an exception rate described in subparagraph (C) in effect on such date. For purposes of this subparagraph, the term 'pediatric facility' means a renal facility at least 50 percent of whose patients are individuals under 18

(2) CONFORMING AMENDMENT.—The fourth sentence of section 1881(b)(7) (42 U.S.C. 1395rr(b)(7)), as amended by subsection (b), is further amended by striking "Until" and inserting "Subject to section 422(a)(2) of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000, and until'

(c) Increase in Renal Dialysis Composite Rate for Services Furnished in 2004.—Notwithstanding any other provision of law, with respect to payment under part B of title XVIII of the Social Security Act for renal dialysis services furnished in 2004, the composite payment rate otherwise established under section 1881(b)(7) of such Act (42 U.S.C. 1395rr(b)(7)) shall be increased by 1.6 percent.

SEC. 624. ONE-YEAR MORATORIUM ON THERAPY CAPS; PROVISIONS RELATING TO REPORTS.

(a) 1-Year Moratorium on Therapy Caps.—Section 1833(g)(4) (42 U.S.C. 13951(g)(4)) is amended by striking "and 2002" and inserting "2002, and 2004".

(b) Prompt Submission of Overdue Reports on Payment and Utilization of Outpatient Therapy Services.—Not later than December 31, 2003, the Secretary shall submit to Congress the reports required under section 4541(d)(2) of the Balanced Budget Act of 1997 (relating to alternatives to a single annual dollar cap on outpatient therapy) and under section 221(d) of the Medicare, Medicaid, and SCHIP Balanced Budget Refinement Act of 1999 (relating to utilization patterns for outpatient therapy).

(c) IDENTIFICATION OF CONDITIONS AND DISEASES JUSTIFYING WAIVER OF THERAPY

(1) STUDY.—The Secretary shall request the Institute of Medicine of the National Academy of Sciences to identify conditions or diseases that should justify conducting an assessment of the need to waite therapy caps under section 1833(g)(4) of the Social Security Act (42 U.S.C. 1395l(g)(4))

(2) Reports to congress.

(A) Preliminary report.—Not later than July 1, 2004, the Secretary shall submit to Congress a preliminary report on the conditions and diseases identified under paragraph (1).

(B) FINAL REPORT.—Not later than September 1, 2004, the Secretary shall submit to Congress a final report on such conditions and diseases.

(C) RECOMMENDATIONS.—Not later than October 1, 2004, the Secretary shall submit to Congress a recommendation of criteria, with respect to such conditions and disease, under which a waiver of the therapy caps would

(d) GAO STUDY OF PATIENT ACCESS TO PHYSICAL THERAPIST SERVICES.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on access to physical therapist services in States authorizing such services without a physician referral and in States that require such a physician referral. The study shall-

(A) examine the use of and referral patterns for physical therapist services for patients age 50 and older in States that authorize such services without a physician referral and in States that require such a physician re-

ferral;

(B) examine the use of and referral patterns for physical therapist serv-

ices for patients who are medicare beneficiaries; (C) examine the potential effect of prohibiting a physician from referring patients to physical therapy services owned by the physician and provided in the physician's office;
(D) examine the delivery of physical therapists' services within the facili-

ties of Department of Defense; and

(E) analyze the potential impact on medicare beneficiaries and on expenditures under the medicare program of eliminating the need for a physician referral and physician certification for physical therapist services under the medicare program.

(2) REPORT.—The Comptroller General shall submit to Congress a report on the study conducted under paragraph (1) by not later than 1 year after the date

of the enactment of this Act.

SEC. 625. ADJUSTMENT TO PAYMENTS FOR SERVICES FURNISHED IN AMBULATORY SUR-GICAL CENTERS.

Section 1833(i)(2)(C) (42 U.S.C. 1395l(i)(2)(C)) is amended in the last sentence by inserting "and each of fiscal years 2004 through 2008" after "In each of the fiscal years 1998 through 2002".

SEC. 626. PAYMENT FOR CERTAIN SHOES AND INSERTS UNDER THE FEE SCHEDULE FOR ORTHOTICS AND PROSTHETICS.

(a) IN GENERAL.—Section 1833(o) (42 U.S.C. 1395l(o)) is amended-

(1) in paragraph (1), by striking "no more than the limits established under paragraph (2)" and inserting "no more than the amount of payment applicable under paragraph (2)"; and
(2) in paragraph (2), to read as follows:

"(2)(A) Except as provided by the Secretary under subparagraphs (B) and (C), the amount of payment under this paragraph for custom molded shoes, extra depth shoes, and inserts shall be the amount determined for such items by the Secretary under section 1834(h).

"(B) The Secretary or a carrier may establish payment amounts for shoes and inserts that are lower than the amount established under section 1834(h) if the Secretary finds that shoes and inserts of an appropriate quality are readily available

at or below the amount established under such section.

- (C) In accordance with procedures established by the Secretary, an individual entitled to benefits with respect to shoes described in section 1861(s)(12) may substitute modification of such shoes instead of obtaining one (or more, as specified by the Secretary) pair of inserts (other than the original pair of inserts with respect to such shoes). In such case, the Secretary shall substitute, for the payment amount established under section 1834(h), a payment amount that the Secretary estimates will assure that there is no net increase in expenditures under this subsection as a result of this subparagraph."
- (b) CONFORMING AMENDMENTS.—(1) Section 1834(h)(4)(C) (42 U.S.C. 1395m(h)(4)(C)) is amended by inserting "(and includes shoes described in section 1861(s)(12))" after "in section 1861(s)(9)".

 (2) Section 1842(s)(2) (42 U.S.C. 1395u(s)(2)) is amended by striking subparagraph

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to items furnished on or after January 1, 2004.

SEC. 627. WAIVER OF PART B LATE ENROLLMENT PENALTY FOR CERTAIN MILITARY RETIR-EES; SPECIAL ENROLLMENT PERIOD.

(a) Waiver of Penalty.-

(1) IN GENERAL.—Section 1839(b) (42 U.S.C. 1395r(b)) is amended by adding at the end the following new sentence: "No increase in the premium shall be effected for a month in the case of an individual who is 65 years of age or older, 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.". (2) Effective date.—The amendment made by paragraph (1) shall apply to premiums for months beginning with January 2003. The Secretary of Health and Human Services shall establish a method for providing rebates of premium penalties paid for months on or after January 2004 for which a penalty does not apply under such amendment but for which a penalty was previously col-

(b) Medicare Part B Special Enrollment Period.—

(1) IN GENERAL.—In the case of any individual who, as of the date of the enactment of this Act, is 65 years of age or older, is eligible to enroll but is not enrolled under part B of title XVIII of the Social Security Act, and is a covered beneficiary (as defined in section 1072(5) of title 10, United States Code), the Secretary of Health and Human Services shall provide for a special enrollment period during which the individual may enroll under such part. Such period shall begin as soon as possible after the date of the enactment of this Act and shall end on December 31, 2004.

(2) COVERAGE PERIOD.—In the case of an individual who enrolls during the special enrollment period provided under paragraph (1), the coverage period under part B of title XVIII of the Social Security Act shall begin on the first day of the month following the month in which the individual enrolls.

SEC. 628. PART B DEDUCTIBLE.

Section 1833(b) (42 U.S.C. 1395l(b)) is amended-

(1) by striking "1991 and" and inserting "1991,"; and (2) by striking "and subsequent years" and inserting "and each subsequent year through 2003, and for a subsequent year after 2003 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)".

SEC. 629. DEMONSTRATION PROJECT FOR COVERAGE OF SELF-INJECTED BIOLOGICS FOR RHEUMATOID ARTHRITIS.

- (a) Demonstration Project.—The Secretary shall conduct a demonstration project under part B of title XVIII of the Social Security Act under which payment is made for self-injected biologics (approved by the Food and Drug Administration) prescribed for the treatment of rheumatoid arthritis that are prescribed as replacements for drugs and biologicals described in section 1861(s)(2)(A) of such Act (42 U.S.C. 1395x(s)(2)(A)) for which payment is made under such part.
- (b) DEMONSTRATION PROJECT SITES.—The project established under this section shall be conducted in 3 States selected by the Secretary.
- (c) DURATION.—The Secretary shall conduct the demonstration project for the 2year period beginning on the date that is 90 days after the date of the enactment
- (d) REPORT.—(1) Not later than January 1, 2006, the Secretary shall submit to Congress a report on the project. The report shall include an evaluation of patient access to care and patient outcomes under the project, as well as an analysis of the cost effectiveness of the project, including an evaluation of the costs savings (if any) to the medicare program attributable to reduced physicians' services and hospital outpatient departments services for administration of the biological.

(2) The Secretary may use findings from the report under paragraph (1) in determining appropriate settings for the administration of biologics (approved by the Food and Drug Administration) prescribed for medicare beneficiaries for the treatment of rheumatoid arthritis.

TITLE VII—PROVISIONS RELATING TO PARTS A AND B

Subtitle A—Home Health Services

SEC. 701. UPDATE IN HOME HEALTH SERVICES.

- (a) Change to Calender Year Update.-
 - (1) IN GENERAL.—Section 1895(b) (42 U.S.C. 1395fff(b)(3)) is amended— (A) in paragraph (3)(B)(i)-
 - (i) by striking "each fiscal year (beginning with fiscal year 2002)" and inserting "fiscal year 2002 and for fiscal year 2003 and for each subsequent year (beginning with 2004)"; and
 - (ii) by inserting "or year" after "the fiscal year";

- (B) in paragraph (3)(B)(ii)(II), by striking "any subsequent fiscal year" and inserting "2004 and any subsequent year";
- (C) in paragraph (3)(B)(iii), by inserting "or year" after "fiscal year" each place it appears;

(D) in paragraph (3)(B)(iv)-

- (i) by inserting "or year" after "fiscal year" each place it appears; and
 (ii) by inserting "or years" after "fiscal years"; and
 (E) in paragraph (5), by inserting "or year" after "fiscal years".

 (2) TRANSITION RULE.—The standard prospective payment amount (or amounts) under section 1895(b)(3) of the Social Security Act for the calendar quarter beginning on October 1, 2003, shall be such amount (or amounts) for the previous calendar quarter.
- (b) CHANGES IN UPDATES FOR 2004, 2005, AND 2006.—Section 1895(b)(3)(B)(ii) (42 U.S.C. 1395fff(b)(3)(B)(ii)), as amended by subsection (a)(1)(B), is amended—

 (1) by striking "or" at the end of subclause (I);
 (2) by redesignating subclause (II) as subclause (III);
 (3) is subclause (III) as a redesignated by striking "2004" and its attempts (III);

- (3) in subclause (III), as so redesignated, by striking "2004" and inserting "2007"; and

(4) by inserting after subclause (I) the following new subclause:

"(II) each of 2004, 2005, and 2006 the home health market basket percentage increase minus 0.4 percentage points; or".

SEC. 702. MEDPAC STUDY ON MEDICARE MARGINS OF HOME HEALTH AGENCIES.

(a) STUDY.—The Medicare Payment Advisory Commission shall conduct a study of payment margins of home health agencies under the home health prospective payment system under section 1895 of the Social Security Act (42 U.S.C. 1395fff). Such study shall examine whether systematic differences in payment margins are related to differences in case mix (as measured by home health resource groups (HHRGs)) among such agencies. The study shall use the partial or full-year cost reports filed by home health agencies.

(b) REPORT.—Not later than 2 years after the date of the enactment of this Act, the Commission shall submit to Congress a report on the study under subsection

SEC. 703. DEMONSTRATION PROJECT TO CLARIFY THE DEFINITION OF HOMEBOUND.

(a) DEMONSTRATION PROJECT.—Not later than 180 days after the date of the enactment of this Act, the Secretary shall conduct a two-year demonstration project under part B of title XVIII of the Social Security Act under which medicare beneficiaries with chronic conditions described in subsection (b) are deemed to be home-

bound for purposes of receiving home health services under the medicare program.

(b) Medicare Beneficiary Described.—For purposes of subsection (a), a medicare beneficiary is eligible to be deemed to be homebound, without regard to the purpose, frequency, or duration of absences from the home, if the beneficiary-

(1) has been certified by one physician as an individual who has a permanent

and severe condition that will not improve;

- (2) requires the individual to receive assistance from another individual with at least 3 out of the 5 activities of daily living for the rest of the individual's
- (3) requires 1 or more home health services to achieve a functional condition that gives the individual the ability to leave home; and

(4) requires technological assistance or the assistance of another person to

leave the home.

(c) DEMONSTRATION PROJECT SITES.—The demonstration project established under this section shall be conducted in 3 States selected by the Secretary to represent the Northeast, Midwest, and Western regions of the United States.

(d) LIMITATION ON NUMBER OF PARTICIPANTS.—The aggregate number of such

beneficiaries that may participate in the project may not exceed 15,000.

(e) Data.—The Secretary shall collect such data on the demonstration project with respect to the provision of home health services to medicare beneficiaries that relates to quality of care, patient outcomes, and additional costs, if any, to the medicare program.

(f) REPORT TO CONGRESS.—Not later than 1 year after the date of the completion

of the demonstration project under this section, the Secretary shall submit to Congress a report on the project using the data collected under subsection (e) and shall include

(1) an examination of whether the provision of home health services to medicare beneficiaries under the project-

(A) adversely effects the provision of home health services under the medicare program; or

(B) directly causes an unreasonable increase of expenditures under the medicare program for the provision of such services that is directly attributable to such clarification;

(2) the specific data evidencing the amount of any increase in expenditures that is a directly attributable to the demonstration project (expressed both in absolute dollar terms and as a percentage) above expenditures that would otherwise have been incurred for home health services under the medicare program; and

(3) specific recommendations to exempt permanently and severely disabled homebound beneficiaries from restrictions on the length, frequency and purpose of their absences from the home to qualify for home health services without in-

curring additional unreasonable costs to the medicare program.

(g) WAIVER AUTHORITY.—The Secretary shall waive compliance with the requirements of title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) to such extent and for such period as the Secretary determines is necessary to conduct demonstration projects.

(h) CONSTRUCTION.—Nothing in this section shall be construed as waiving any applicable civil monetary penalty, criminal penalty, or other remedy available to the Secretary under title XI or title XVIII of the Social Security Act for acts prohibited under such titles, including penalties for false certifications for purposes of receipt of items or services under the medicare program.

(i) AUTHORIZATION OF APPROPRIATIONS.—Payments for the costs of carrying out the demonstration project under this section shall be made from the Federal Supplementary Insurance Trust Fund under section 1841 of such Act (42 U.S.C. 1395t).

(j) DEFINITIONS.—In this section:

(1) MEDICARE BENEFICIARY.—The term "medicare beneficiary" means an individual who is enrolled under part B of title XVIII of the Social Security Act. (2) HOME HEALTH SERVICES.—The term "home health services" has the meaning given such term in section 1861(m) of the Social Security Act (42 U.S.C. 1395x(m)).

(3) ACTIVITIES OF DAILY LIVING DEFINED.—The term "activities of daily living" means eating, toileting, transferring, bathing, and dressing.

(4) Secretary.—The term "Secretary" means the Secretary of Health and

Human Services.

Subtitle B—Direct Graduate Medical Education

SEC. 711. EXTENSION OF UPDATE LIMITATION ON HIGH COST PROGRAMS.

Section 1886(h)(2)(D)(iv) (42 U.S.C. 1395ww(h)(2)(D)(iv)) is amended—

(1) in subclause (I)-

(A) by inserting "AND 2004 THROUGH 2013" after "AND 2002"; and (B) by inserting "or during the period beginning with fiscal year 2004 and ending with fiscal year 2013" after "during fiscal year 2001 or fiscal year

(2) in subclause (II)-

(A) by striking "fiscal year 2004, or fiscal year 2005," and (B) by striking "For a" and inserting "For the".

Subtitle C—Chronic Care Improvement

SEC. 721. VOLUNTARY CHRONIC CARE IMPROVEMENT UNDER TRADITIONAL FEE-FOR-SERV-ICE.

Title XVIII, as amended by section 105(a), is amended by inserting after section 1807 the following new section:

"CHRONIC CARE IMPROVEMENT

"Sec. 1808. (a) IN GENERAL.

"(1) IN GENERAL.—The Secretary shall establish a process for providing chronic care improvement programs in each CCIA region for medicare beneficiaries who are not enrolled under part C or E and who have certain chronic conditions, such as congestive heart failure, diabetes, chronic obstructive pulmonary disease (COPD), stroke, prostate and colon cancer, hypertension, or other disease as identified by the Secretary as appropriate for chronic care improvement. Such a process shall begin to be implemented no later than 1 year after the date of the enactment of this section.

"(2) TERMINOLOGY.—For purposes of this section:

"(A) CCIA REGION.—The term 'CCIA region' means a chronic care improvement administrative region delineated under subsection (b)(2).

"(B) CHRONIC CARE IMPROVEMENT PROGRAM.—The terms 'chronic care improvement program' and 'program' means such a program provided by a contractor under this section.

"(C) CONTRACTOR.—The term 'contractor' means an entity with a contract to provide a chronic care improvement program in a CCIA region under this section.

"(D) Individual plan.—The term 'individual plan' means a chronic care improvement plan established under subsection (c)(5) for an individual.

"(3) CONSTRUCTION.—Nothing in this section shall be construed as expanding the amount, duration, or scope of benefits under this title.

"(b) Competitive Bidding Process.-

"(1) IN GENERAL.—Under this section the Secretary shall award contracts to qualified entities for chronic care improvement programs for each CCIA region under this section through a competitive bidding process.

"(2) Process.—Under such process

"(A) the Secretary shall delineate the United States into multiple chronic

care improvement administrative regions; and

"(B) the Secretary shall select at least 2 winning bidders in each CCIA region on the basis of the ability of each bidder to carry out a chronic care improvement program in accordance with this section, in order to achieve improved health and financial outcomes.

"(3) ELIGIBLE CONTRACTOR.—A contractor may be a disease improvement organization, health insurer, provider organization, a group of physicians, or any other legal entity that the Secretary determines appropriate.

"(c) Chronic Care Improvement Programs.

'(1) IN GENERAL.—Each contract under this section shall provide for the operation of a chronic care improvement program by a contractor in a CCIA region consistent with this subsection.

"(2) IDENTIFICATION OF PROSPECTIVE PROGRAM PARTICIPANTS.—Each contractor shall have a method for identifying medicare beneficiaries in the region to whom it will offer services under its program. The contractor shall identify such beneficiaries through claims or other data and other means permitted consistent with applicable disclosure provisions.

"(3) Initial contact by secretary.—The Secretary shall communicate with each beneficiary identified under paragraph (2) as a prospective participant in one or more programs concerning participation in a program. Such communication may be made by the Secretary (or on behalf of the Secretary) and shall include information on the following:

(A) A description of the advantages to the beneficiary in participating in

a program.

"(B) Notification that the contractor offering a program may contact the beneficiary directly concerning such participation.

(C) Notification that participation in a program is voluntary.

"(D) A description of the method for the beneficiary to select the single program in which the beneficiary wishes to participate and for declining to participate and a method for obtaining additional information concerning such participation.

"(4) PARTICIPATION.—A medicare beneficiary may participate in only one program under this section and may terminate participation at any time in a man-

ner specified by the Secretary.

"(5) Individual chronic care improvement plans.—

(A) IN GENERAL.—For each beneficiary participating in a program of a contractor under this section, the contractor shall develop with the beneficiary an individualized, goal-oriented chronic care improvement plan.

(B) ELEMENTS OF INDIVIDUAL PLAN.—Each individual plan developed under subparagraph (A) shall include a single point of contact to coordinate care and the following, as appropriate:

(i) Self-improvement education for the beneficiary (such as education for disease management through medical nutrition therapy) and support education for health care providers, primary caregivers, and family members.

"(ii) Coordination of health care services, such as application of a pre-

scription drug regimen and home health services.

"(iii) Collaboration with physicians and other providers to enhance communication of relevant clinical information.

"(iv) The use of monitoring technologies that enable patient guidance through the exchange of pertinent clinical information, such as vital signs, symptomatic information, and health self-assessment.
"(v) The provision of information about hospice care, pain and pallia-

tive care, and end-of-life care.

"(C) CONTRACTOR RESPONSIBILITIES.—In establishing and carrying out individual plans under a program, a contractor shall, directly or through subcontractors-

(i) guide participants in managing their health, including all their co-morbidities, and in performing activities as specified under the elements of the plan;

"(ii) use decision support tools such as evidence-based practice guide-

lines or other criteria as determined by the Secretary; and
"(iii) develop a clinical information database to track and monitor

each participant across settings and to evaluate outcomes.

"(6) ADDITIONAL REQUIREMENTS.—The Secretary may establish additional requirements for programs and contractors under this section.

"(7) ACCREDITATION.—The Secretary may provide that programs that are accredited by qualified organizations may be deemed to meet such requirements under this section as the Secretary may specify.

"(c) Contract Terms.-

"(1) IN GENERAL.—A contract under this section shall contain such terms and conditions as the Secretary may specify consistent with this section. The Secretary may not enter into a contract with an entity under this section unless the entity meets such clinical, quality improvement, financial, and other requirements as the Secretary deems to be appropriate for the population to be

"(2) Use of subcontractors permitted.—A contractor may carry out a program directly or through contracts with subcontractors.

"(3) BUDGET NEUTRAL PAYMENT CONDITION.—In entering into a contract with an entity under this subsection, the Secretary shall establish payment rates that assure that there will be no net aggregate increase in payments under this title over any period of 3 years or longer, as agreed to by the Secretary. Under this section, the Secretary shall assure that medicare program outlays plus administrative expenses (that would not have been paid under this title without implementation of this section), including contractor fees, shall not exceed the expenditures that would have been incurred under this title for a comparable population in the absence of the program under this section for the 3-year contract period.

"(4) AT RISK RELATIONSHIP.—For purposes of section 1128B(b)(3)(F), a contract under this section shall be treated as a risk-sharing arrangement referred to

in such section.

"(5) Performance standards.—Payment to contractors under this section shall be subject to the contractor's meeting of clinical and financial performance standards set by the Secretary.

(6) CONTRACTOR OUTCOMES REPORT.—Each contractor offering a program shall monitor and report to the Secretary, in a manner specified by the Secretary, the quality of care and efficacy of such program in terms of-

"(A) process measures, such as reductions in errors of treatment and re-

hospitalization rates;

"(B) beneficiary and provider satisfaction;

"(C) health outcomes; and

"(D) financial outcomes.

"(7) PHASED IN IMPLEMENTATION.—Nothing in this section shall be construed as preventing the Secretary from phasing in the implementation of programs. "(d) BIANNUAL OUTCOMES REPORTS.—The Secretary shall submit to the Congress biannual reports on the implementation of this section. Each such report shall include information on—
"(1) the scope of implementation (in terms of both regions and chronic condi-

tions);

"(2) program design; and

"(3) improvements in health outcomes and financial efficiencies that result

from such implementation.

"(e) CLINICAL TRIALS.—The Secretary shall conduct randomized clinical trials, that compare program participants with medicare beneficiaries who are offered, but decline, to participate, in order to assess the potential of programs to-

(1) reduce costs under this title; and

"(2) improve health outcomes under this title.

"(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary, in appropriate part from the Hospital Insurance Trust Fund and the Supplementary Medical Insurance Trust Fund, such sums as may be necessary to provide for contracts with chronic care improvement programs under this section.

(g) LIMITATION ON FUNDING.—In no case shall the funding under this section ex-

ceed \$100,000,000 over a period of 3 years.".

SEC. 722. CHRONIC CARE IMPROVEMENT UNDER MEDICARE ADVANTAGE AND ENHANCED FEE-FOR-SERVICE PROGRAMS.

(a) Under Medicare Advantage Program.—Section 1852 (42 U.S.C. 1395w-22) is amended-

(1) by amending subsection (e) to read as follows:

"(e) IMPLEMENTATION OF CHRONIC CARE IMPROVEMENT PROGRAMS FOR BENEFICIARIES WITH MULTIPLE OR SUFFICIENTLY SEVERE CHRONIC CONDITIONS.—

"(1) IN GENERAL.—Each Medicare Advantage organization with respect to each Medicare Advantage plan it offers shall have in effect, for enrollees with multiple or sufficiently severe chronic conditions, a chronic care improvement program that is designed to manage the needs of such enrollees and that meets the requirements of this subsection.

"(2) Enrollee with multiple or sufficiently severe chronic condi-TIONS.—For purposes of this subsection, the term 'enrollee with multiple or sufficiently severe chronic conditions' means, with respect to an enrollee in a Medicare Advantage plan of a Medicare Advantage organization, an enrollee in the plan who has one or more chronic conditions, such as congestive heart failure, diabetes, COPD, stroke, prostate and colon cancer, hypertension, or other disease as identified by the organization as appropriate for chronic care improve-

"(3) GENERAL REQUIREMENTS.-

"(A) IN GENERAL.—Each chronic care improvement program under this

subsection shall be conducted consistent with this subsection.

"(B) IDENTIFICATION OF ENROLLEES.—Each such program shall have a method for monitoring and identifying enrollees with multiple or sufficiently severe chronic conditions that meet the organization's criteria for participation under the program.

"(C) DEVELOPMENT OF PLANS.—For an enrollee identified under subparagraph (B) for participation in a program, the program shall develop, with the enrollee's consent, an individualized, goal-oriented chronic care improvement plan for chronic care improvement.

"(D) ELEMENTS OF PLANS.—Each chronic care improvement plan developed under subparagraph (C) shall include a single point of contact to co-

ordinate care and the following, as appropriate:

"(i) Self-improvement education for the enrollee (such as education for disease management through medical nutrition therapy) and support education for health care providers, primary caregivers, and family members.

"(ii) Coordination of health care services, such as application of a pre-

scription drug regimen and home health services

"(iii) Collaboration with physicians and other providers to enhance communication of relevant clinical information.

'(iv) The use of monitoring technologies that enable patient guidance through the exchange of pertinent clinical information, such as vital signs, symptomatic information, and health self-assessment.

"(v) The provision of information about hospice care, pain and pallia-

tive care, and end-of-life care.

"(E) Organization responsibilities.—In establishing and carrying out chronic care improvement plans for participants under this paragraph, a Medicare Advantage organization shall, directly or through subcontrac-

"(i) guide participants in managing their health, including all their co-morbidities, and in performing the activities as specified under the elements of the plan;

"(ii) use decision support tools such as evidence-based practice guide-

lines or other criteria as determined by the Secretary; and

"(iii) develop a clinical information database to track and monitor each participant across settings and to evaluate outcomes.

"(3) ADDITIONAL REQUIREMENTS.—The Secretary may establish additional requirements for chronic care improvement programs under this section.

"(4) ACCREDITATION.—The Secretary may provide that chronic care improvement programs that are accredited by qualified organizations may be deemed to meet such requirements under this subsection as the Secretary may specify.

"(5) Outcomes report.—Each Medicare Advantage organization with respect to its chronic care improvement program under this subsection shall monitor and report to the Secretary information on the quality of care and efficacy of such program as the Secretary may require."; and
(2) by amending subparagraph (I) of subsection (c)(1) to read as follows:

"(I) CHRONIC CARE IMPROVEMENT PROGRAM.—A description of the organization's chronic care improvement program under subsection (e).".

(b) APPLICATION UNDER ENHANCED FEE-FOR-SERVICE PROGRAM.—Section 1860E—2(c)(3), as inserted by section 201(a), is amended by inserting ", including subsection (e) (relating to implementation of chronic care improvement programs)" after "The provisions of section 1852

(c) EFFECTIVE DATE.—The amendments made by this section shall apply for contract years beginning on or after 1 year after the date of the enactment of this Act.

SEC. 723. INSTITUTE OF MEDICINE REPORT.

(a) STUDY.

(1) IN GENERAL.—The Secretary of Health and Human Services shall contract with the Institute of Medicine of the National Academy of Sciences to conduct a study of the barriers to effective integrated care improvement for medicare beneficiaries with multiple or severe chronic conditions across settings and over

time and to submit a report under subsection (b).

(2) Specific items.—The study shall examine the statutory and regulatory barriers to coordinating care across settings for medicare beneficiaries in transition from one setting to another (such as between hospital, nursing facility, home health, hospice, and home). The study shall specifically identify the fol-

- (A) Clinical, financial, or administrative requirements in the medicare program that present barriers to effective, seamless transitions across care
- (B) Policies that impede the establishment of administrative and clinical information systems to track health status, utilization, cost, and quality data across settings.

(C) State-level requirements that may present barriers to better care for

medicare beneficiaries.

(3) CONSULTATION.—The study under this subsection shall be conducted in consultation with experts in the field of chronic care, consumers, and family caregivers, working to integrate care delivery and create more seamless transi-

tions across settings and over time.
(b) REPORT.—The report under this subsection shall be submitted to the Secretary and Congress not later than 18 months after the date of the enactment of this Act.

SEC. 724. MEDPAC REPORT.

(a) EVALUATION.—shall conduct an evaluation that includes a description of the status of the implementation of chronic care improvement programs under section 1808 of the Social Security Act, the quality of health care services provided to individuals in such program, the health status of the participants of such program, and the cost savings attributed to implementation of such program.

(b) Report.—Not later than 2 years after the date of implementation of such

chronic care improvement programs, the Commission shall submit a report on such

evaluation.

Subtitle D—Other Provisions

SEC. 731. MODIFICATIONS TO MEDICARE PAYMENT ADVISORY COMMISSION (MEDPAC).

(a) Examination of Budget Consequences.—Section 1805(b) (42 U.S.C. 1395b-

- 6(b)) is amended by adding at the end the following new paragraph:

 "(8) EXAMINATION OF BUDGET CONSEQUENCES.—Before making any recommendations, the Commission shall examine the budget consequences of such recommendations, directly or through consultation with appropriate expert enti-
- ties.".
 Consideration (b) Consideration of Efficient Provision of Services.—Section 1805(b)(2)(B)(i) (42 U.S.C. 1395b–6(b)(2)(B)(i)) is amended by inserting "the efficient provision of" after "expenditures for".

(c) APPLICATION OF DISCLOSURE REQUIREMENTS.—

(1) IN GENERAL.—Section 1805(c)(2)(D) (42 U.S.C. 1395b-6(c)(2)(D)) is amended by adding at the end the following: "Members of the Commission shall be treated as employees of the Congress for purposes of applying title I of the Ethics in Government Act of 1978 (Public Law 95-521)."

(2) Effective date.—The amendment made by paragraph (1) shall take effect on January 1, 2004.

(d) Additional Reports.

(1) Data needs and sources.—The Medicare Payment Advisory Commission shall conduct a study, and submit a report to Congress by not later than June 1, 2004, on the need for current data, and sources of current data available, to determine the solvency and financial circumstances of hospitals and other medicare providers of services. The Commission shall examine data on uncompensated care, as well as the share of uncompensated care accounted for by the expenses for treating illegal aliens.

(2) Use of tax-related returns.—Using return information provided under Form 990 of the Internal Revenue Service, the Commission shall submit to Con-

gress, by not later than June 1, 2004, a report on the following:

(A) Investments, endowments, and fundraising of hospitals participating under the medicare program and related foundations.

(B) Access to capital financing for private and for not-for-profit hospitals.

SEC. 732. DEMONSTRATION PROJECT FOR MEDICAL ADULT DAY CARE SERVICES.

(a) ESTABLISHMENT.—Subject to the succeeding provisions of this section, the Secretary of Health and Human Services shall establish a demonstration project (in this section referred to as the "demonstration project") under which the Secretary shall, as part of a plan of an episode of care for home health services established for a medicare beneficiary, permit a home health agency, directly or under arrangements with a medical adult day care facility, to provide medical adult day care services as a substitute for a portion of home health services that would otherwise be provided in the beneficiary's home.

(b) PAYMENT.

(1) IN GENERAL.—The amount of payment for an episode of care for home health services, a portion of which consists of substitute medical adult day care services, under the demonstration project shall be made at a rate equal to 95 percent of the amount that would otherwise apply for such home health services under section 1895 of the Social Security Act (42 u.s.c. 1395fff). In no case may a home health agency, or a medical adult day care facility under arrangements with a home health agency, separately charge a beneficiary for medical adult day care services furnished under the plan of care.

(2) BUDGET NEUTRALITY FOR DEMONSTRATION PROJECT.—Notwithstanding any other provision of law, the Secretary shall provide for an appropriate reduction in the aggregate amount of additional payments made under section 1895 of the Social Security Act (42 U.S.C. 1395fff) to reflect any increase in amounts expended from the Trust Funds as a result of the demonstration project conducted

(c) DEMONSTRATION PROJECT SITES.—The project established under this section shall be conducted in not more than 5 States selected by the Secretary that license or certify providers of services that furnish medical adult day care services.

(d) DURATION.—The Secretary shall conduct the demonstration project for a period

of 3 years.

(e) VOLUNTARY PARTICIPATION.—Participation of medicare beneficiaries in the demonstration project shall be voluntary. The total number of such beneficiaries that may participate in the project at any given time may not exceed 15,000.

(f) PREFERENCE IN SELECTING AGENCIES.—In selecting home health agencies to participate under the demonstration project, the Secretary shall give preference to those agencies that are currently licensed or certified through common ownership and control to furnish medical adult day care services.

(g) WAIVER AUTHORITY.—The Secretary may waive such requirements of title XVIII of the Social Security Act as may be necessary for the purposes of carrying out the demonstration project, other than waiving the requirement that an individual be homebound in order to be eligible for benefits for home health services.

(h) EVALUATION AND REPORT.—The Secretary shall conduct an evaluation of the clinical and cost effectiveness of the demonstration project. Not later 30 months after the commencement of the project, the Secretary shall submit to Congress a report on the evaluation, and shall include in the report the following:

(1) An analysis of the patient outcomes and costs of furnishing care to the medicare beneficiaries participating in the project as compared to such outcomes and costs to beneficiaries receiving only home health services for the same health conditions

(2) Such recommendations regarding the extension, expansion, or termination of the project as the Secretary determines appropriate.

(i) DEFINITIONS.—In this section:

- (1) HOME HEALTH AGENCY.—The term "home health agency" has the meaning given such term in section 1861(o) of the Social Security Act (42 U.S.C. 1395x(0)).
- (2) MEDICAL ADULT DAY CARE FACILITY.—The term "medical adult day care facility" means a facility that-

(A) has been licensed or certified by a State to furnish medical adult day care services in the State for a continuous 2-year period;

(B) is engaged in providing skilled nursing services and other therapeutic services directly or under arrangement with a home health agency;

(C) meets such standards established by the Secretary to assure quality of care and such other requirements as the Secretary finds necessary in the interest of the health and safety of individuals who are furnished services in the facility; and

(D) provides medical adult day care services.

- (3) MEDICAL ADULT DAY CARE SERVICES.—The term "medical adult day care services" means
 - (A) home health service items and services described in paragraphs (1) through (7) of section 1861(m) furnished in a medical adult day care facil-
 - (B) a program of supervised activities furnished in a group setting in the
 - (i) meet such criteria as the Secretary determines appropriate; and (ii) is designed to promote physical and mental health of the individ-

(C) such other services as the Secretary may specify.

(4) MEDICARE BENEFICIARY.—The term "medicare beneficiary" means an individual entitled to benefits under part A of this title, enrolled under part B of this title, or both.

SEC. 733. IMPROVEMENTS IN NATIONAL AND LOCAL COVERAGE DETERMINATION PROCESS TO RESPOND TO CHANGES IN TECHNOLOGY.

(a) NATIONAL AND LOCAL COVERAGE DETERMINATION PROCESS.

(1) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is amended-

(A) in the third sentence of subsection (a) by inserting "consistent with subsection (k)" after "the Secretary shall ensure"; and

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

"(k) NATIONAL AND LOCAL COVERAGE DETERMINATION PROCESS.

"(1) Criteria and evidence used in making national coverage deter-MINATIONS.—The Secretary shall make available to the public the criteria the Secretary uses in making national coverage determinations, including how evidence to demonstrate that a procedure or device is reasonable and necessary is considered.

(2) Timeframe for decisions on requests for national coverage deter-MINATIONS.—In the case of a request for a national coverage determination

that—
"(A) does not require a technology assessment from an outside entity or deliberation from the Medicare Coverage Advisory Committee, the decision on the request shall be made not later than 6 months after the date of the request; or "(B) requires such an assessment or deliberation and in which a clinical

trial is not requested, the decision on the request shall be made not later than 12 months after the date of the request.

"(3) PROCESS FOR PUBLIC COMMENT IN NATIONAL COVERAGE DETERMINA-TIONS.—At the end of the 6-month period that begins on the date a request for a national coverage determination is made, the Secretary shall-

(A) make a draft of proposed decision on the request available to the public through the Medicare Internet site of the Department of Health and Human Services or other appropriate means;

"(B) provide a 30-day period for public comment on such draft;

"(C) make a final decision on the request within 60 days of the conclusion of the 30-day period referred to under subparagraph (B);

"(D) include in such final decision summaries of the public comments re-

ceived and responses thereto;

"(E) make available to the public the clinical evidence and other data used in making such a decision when the decision differs from the recommendations of the Medicare Coverage Advisory Committee; and

"(F) in the case of a decision to grant the coverage determination, assign a temporary or permanent code during the 60-day period referred to in subparagraph (C).

"(4) Consultation with outside experts in certain national coverage DETERMINATIONS.—With respect to a request for a national coverage determination for which there is not a review by the Medicare Coverage Advisory Committee, the Secretary shall consult with appropriate outside clinical experts.

"(5) LOCAL COVERAGE DETERMINATION PROCESS.—With respect to local cov-

erage determinations made on or after January 1, 2004-

"(A) Plan to promote consistency of coverage determinations.— The Secretary shall develop a plan to evaluate new local coverage determinations to determine which determinations should be adopted nationally and to what extent greater consistency can be achieved among local coverage determinations.

"(B) CONSULTATION.—The Secretary shall require the fiscal intermediaries or carriers providing services within the same area to consult on

all new local coverage determinations within the area.

"(C) DISSEMINATION OF INFORMATION.—The Secretary should serve as a center to disseminate information on local coverage determinations among fiscal intermediaries and carriers to reduce duplication of effort.

"(6) NATIONAL AND LOCAL COVERAGE DETERMINATION DEFINED.—For purposes of this subsection, the terms 'national coverage determination' and 'local coverage determination' have the meaning given such terms in paragraphs (1)(B) and (2)(B), respectively, of section 1869(f).".

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to

national and local coverage determinations as of January 1, 2004.
(b) Medicare Coverage of Routine Costs Associated With Certain Clinical

TRIALS.

- (1) IN GENERAL.—With respect to the coverage of routine costs of care for beneficiaries participating in a qualifying clinical trial, as set forth on the date of the enactment of this Act in National Coverage Determination 30-1 of the Medicare Coverage Issues Manual, the Secretary shall deem clinical trials conducted in accordance with an investigational device exemption approved under section 520(g) of the Federal Food, Drug, and Cosmetic Act (42 U.S.C. 360j(g)) to be automatically qualified for such coverage.
- (2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed as authorizing or requiring the Secretary to modify the regulations set forth on the date of the enactment of this Act at subpart B of part 405 of title 42, Code of Federal Regulations, or subpart A of part 411 of such title, relating to coverage of, and payment for, a medical device that is the subject of an investigational device exemption by the Food and Drug Administration (except as may be nec-

essary to implement paragraph (1)).

(3) EFFECTIVE DATE.—This subsection shall apply to clinical trials begun before, on, or after the date of the enactment of this Act and to items and services

furnished on or after such date.

(c) ISSUANCE OF TEMPORARY NATIONAL CODES.—Not later than January 1, 2004, the Secretary shall implement revised procedures for the issuance of temporary national HCPCS codes under part B of title XVIII of the Social Security Act.

SEC. 734. TREATMENT OF CERTAIN PHYSICIAN PATHOLOGY SERVICES.

(a) IN GENERAL.—Section 1848(i) (42 U.S.C. 1395w-4(i)) is amended by adding at the end the following new paragraph:

"(4) Treatment of certain inpatient physician pathology services.-

"(A) IN GENERAL.—With respect to services furnished on or after January 1, 2001, if an independent laboratory furnishes the technical component of a physician pathology service to a fee-for-service medicare beneficiary who is an inpatient of a covered hospital, the Secretary shall treat such component as a service for which payment shall be made to the laboratory under this section and not as an inpatient hospital service for which payment is made to the hospital under section 1886(d). "(B) DEFINITIONS.—In this paragraph:

"(i) COVERED HOSPITAL.—

"(I) IN GENERAL.—The term 'covered hospital' means, with respect to an inpatient or outpatient, a hospital that had an arrangement with an independent laboratory that was in effect as of July 22, 1999, under which a laboratory furnished the technical component of physician pathology services to fee-for-service medicare beneficiaries who were hospital inpatients or outpatients, respectively, and submitted claims for payment for such component to a carrier with a contract under section 1842 and not to the hospital.

(II) Change in ownership does not affect determination.-A change in ownership with respect to a hospital on or after the date referred to in subclause (I) shall not affect the determination of whether such hospital is a covered hospital for purposes of such

"(ii) FEE-FOR-SERVICE MEDICARE BENEFICIARY.—The term 'fee-for-service medicare beneficiary' means an individual who is entitled to benefits under part A, or enrolled under this part, or both, but is not enrolled in any of the following:

(I) A Medicare+Choice plan under part C.

"(II) A plan offered by an eligible organization under section

1876.

"(III) A program of all-inclusive care for the elderly (PACE)

"(IV) A social health maintenance organization (SHMO) demonstration project established under section 4018(b) of the Omnibus Budget Reconciliation Act of 1987 (Public Law 100–203)."

(b) CONFORMING AMENDMENT.—Section 542 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (114 Stat. 2763A-550), as enacted into law by section 1(a)(6) of Public Law 106-554, is repealed.

(c) Effective Dates.—The amendments made by this section shall take effect as if included in the enactment of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Appendix F, 114 Stat. 2763A–463), as enacted into law by section 1(a)(6) of Public Law 106–554.

SEC. 735. MEDICARE PANCREATIC ISLET CELL TRANSPLANT DEMONSTRATION PROJECT.

(a) ESTABLISHMENT.—In order to test the appropriateness of pancreatic islet cell transplantation, not later than 120 days after the date of the enactment of this Act, the Secretary shall establish a demonstration project which the Secretary, provides for payment under the medicare program under title XVIII of the Social Security Act for pancreatic islet cell transplantation and related items and services in the case of medicare beneficiaries who have type I (juvenile) diabetes and have end stage renal disease.

(b) DURATION OF PROJECT.—The authority of the Secretary to conduct the demonstration project under this section shall terminate on the date that is 5 years after the date of the establishment of the project.

(c) EVALUATION AND REPORT.—The Secretary shall conduct an evaluation of the outcomes of the demonstration project. Not later than 120 days after the date of the termination of the demonstration project under subsection (b), the Secretary shall submit to Congress a report on the project, including recommendations for such legislative and administrative action as the Secretary deems appropriate.

(d) PAYMENT METHODOLOGY.—The Secretary shall establish an appropriate pay-

ment methodology for the provision of items and services under the demonstration project, which may include a payment methodology that bundles, to the maximum extent feasible, payment for all such items and services.

(e) WAIVER AUTHORITY.—The Secretary may waive compliance with the requirements of title XVIII of the Social Security Act to such extent and for such period as the Secretary determines is necessary to conduct the demonstration project.

SEC. 736. DEMONSTRATION PROJECT FOR CONSUMER-DIRECTED CHRONIC OUTPATIENT

(a) Establishment.-

(1) IN GENERAL.—Subject to the succeeding provisions of this section, the Secretary shall establish demonstration projects (in this section referred to as "demonstration projects") under which the Secretary shall evaluate methods that improve the quality of care provided to medicare beneficiaries with chronic conditions and that reduce expenditures that would otherwise be made under the medicare program on behalf of such individuals for such chronic conditions, such methods to include permitting those beneficiaries to direct their own health care needs and services.

(2) Medicare beneficiaries with Chronic conditions defined.—In this section, the term "medicare beneficiaries with chronic conditions" means an individual entitled to benefits under part A of title XVIII of the Social Security Act, and enrolled under part B of such title, but who is not enrolled under part C of such title who is diagnosed as having one or more chronic conditions (as

defined by the Secretary), such as diabetes.

(b) Design of Projects.

(1) IN GENERAL.—In establishing the demonstration projects under this section, the Secretary shall evaluate practices employed by group health plans and practices under State plans for medical assistance under the medicaid program under title XIX of the Social Security Act that permit patients to self-direct the provision of personal care services.

- (2) Scope of services.—The Secretary shall determine the appropriate scope of personal care services that would apply under the demonstration projects.

 (c) VOLUNTARY PARTICIPATION.—Participation of medicare beneficiaries in the

demonstration projects shall be voluntary

(d) DEMONSTRATION PROJECTS SITES.—Not later than 2 years after the date of the enactment of this Act, the Secretary shall conduct no fewer than 3 demonstration projects established under this section. Of those demonstration projects, the Secretary shall conduct at least one in each of the following areas:

(1) An urban area.

A rural area.

(3) An area that the Secretary determines has a medicare population with rate of incidence of diabetes that significantly exceeds the national average rate of all areas

(e) EVALUATION AND REPORT.—

(1) EVALUATIONS.—The Secretary shall conduct evaluations of the clinical and

cost effectiveness of the demonstration projects.

- (2) REPORTS.—Not later than 2 years after the commencement of the demonstration projects, and biannually thereafter, the Secretary shall submit to Congress a report on the evaluation, and shall include in the report the following:
 - (A) An analysis of the patient outcomes and costs of furnishing care to the medicare beneficiaries participating in the projects as compared to such outcomes and costs to other beneficiaries for the same health conditions.
 - (B) Evaluation of patient satisfaction under the demonstration projects. (C) Such recommendations regarding the extension, expansion, or termination of the projects as the Secretary determines appropriate.

TITLE VIII—MEDICARE BENEFITS ADMINISTRATION

SEC. 801. ESTABLISHMENT OF MEDICARE BENEFITS ADMINISTRATION.

(a) In General.—Title XVIII (42 U.S.C. 1395 et seq.), as amended by sections 105 and 721, is amended by inserting after 1808 the following new section:

"MEDICARE BENEFITS ADMINISTRATION

"Sec. 1809. (a) Establishment.—There is established within the Department of Health and Human Services an agency to be known as the Medicare Benefits Administration.

"(b) Administrator; Deputy Administrator; Chief Actuary.—

(1) Administrator.-

"(A) IN GENERAL.—The Medicare Benefits Administration shall be headed by an administrator to be known as the 'Medicare Benefits Aldministrator' (in this section referred to as the 'Administrator') who shall be appointed the this section referred to as the Administrator) who shall be appointed by the President, by and with the advice and consent of the Senate. The Administrator shall be in direct line of authority to the Secretary.

"(B) COMPENSATION.—The Administrator shall be paid at the rate of basic pay payable for level III of the Executive Schedule under section 5314 of title 5, United States Code.

"(C) TERM OF OFFICE.—The Administrator shall be appointed for a term of 4 years. In any case, in which a successor does not take office at the end

of 4 years. In any case in which a successor does not take office at the end of an Administrator's term of office, that Administrator may continue in office until the entry upon office of such a successor. An Administrator appointed to a term of office after the commencement of such term may serve under such appointment only for the remainder of such term.

"(D) GENERAL AUTHORITY.—The Administrator shall be responsible for the exercise of all powers and the discharge of all duties of the Administra-tion, and shall have authority and control over all personnel and activities

thereof.

(E) RULEMAKING AUTHORITY.—The Administrator may prescribe such rules and regulations as the Administrator determines necessary or appropriate to carry out the functions of the Administration. The regulations prescribed by the Administrator shall be subject to the rulemaking procedures established under section 553 of title 5, United States Code. The Administrator shall provide for the issuance of new regulations to carry out parts

C, D, and E.

"(F) AUTHORITY TO ESTABLISH ORGANIZATIONAL UNITS.—The Administrator may establish, alter, consolidate, or discontinue such organizational units or components within the Administration as the Administrator con-

siders necessary or appropriate, except as specified in this section.

"(G) AUTHORITY TO DELEGATE.—The Administrator may assign duties, and delegate, or authorize successive redelegations of, authority to act and to render decisions, to such officers and employees of the Administration as the Administrator may find necessary. Within the limitations of such delegations, redelegations, or assignments, all official acts and decisions of such officers and employees shall have the same force and effect as though performed or rendered by the Administrator.

"(2) DEPUTY ADMINISTRATOR.

"(A) IN GENERAL.—There shall be a Deputy Administrator of the Medicare Benefits Administration who shall be appointed by the President, by and with the advice and consent of the Senate.

"(B) COMPENSATION.—The Deputy Administrator shall be paid at the rate of basic pay payable for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

"(C) TERM OF OFFICE.—The Deputy Administrator shall be appointed for a term of 4 years. In any case in which a successor does not take office at the end of a Deputy Administrator's term of office, such Deputy Administrator may continue in office until the entry upon office of such a successor. A Deputy Administrator appointed to a term of office after the commencement of such term may serve under such appointment only for the remainder of such term.

"(D) DUTIES.—The Deputy Administrator shall perform such duties and exercise such powers as the Administrator shall from time to time assign or delegate. The Deputy Administrator shall be Acting Administrator of the Administration during the absence or disability of the Administrator and, unless the President designates another officer of the Government as Acting Administrator, in the event of a vacancy in the office of the Administrator.

"(3) CHIEF ACTUARY.-

"(A) IN GENERAL.—There is established in the Administration the position of Chief Actuary. The Chief Actuary shall be appointed by, and in direct line of authority to, the Administrator of such Administration. The Chief Actuary shall be appointed from among individuals who have demonstrated, by their education and experience, superior expertise in the actuarial sciences. The Chief Actuary may be removed only for cause.

"(B) Compensation.—The Chief Actuary shall be compensated at the

highest rate of basic pay for the Senior Executive Service under section 5382(b) of title 5, United States Code.

"(C) DUTIES.—The Chief Actuary shall exercise such duties as are appropriate for the office of the Chief Actuary and in accordance with profes-

sional standards of actuarial independence.

"(4) SECRETARIAL COORDINATION OF PROGRAM ADMINISTRATION.—The Secretary shall ensure appropriate coordination between the Administrator and the Administrator of the Centers for Medicare & Medicaid Services in carrying out the programs under this title.

"(c) DÛTIES; ADMINISTRATIVE PROVISIONS.—

"(1) DUTIES.-

"(A) GENERAL DUTIES.—The Administrator shall carry out parts C, D, and E, including-

"(i) negotiating, entering into, and enforcing, contracts with plans for the offering of Medicare Advantage plans under part C and EFFS plans under part E, including the offering of qualified prescription drug coverage under such plans; and

"(ii) negotiating, entering into, and enforcing, contracts with PDP sponsors for the offering of prescription drug plans under part D.

"(B) OTHER DUTIES.—The Administrator shall carry out any duty provided for under part C, part D, or part E, including demonstration projects carried out in part or in whole under such parts, the programs of all-inclusive care for the elderly (PACE program) under section 1894, the social health maintenance organization (SHMO) demonstration projects (referred to in section 4104(c) of the Balanced Budget Act of 1997), medicare cost contractors under section 1876(h), and through a Medicare Advantage project that demonstrates the application of capitation payment rates for frail elderly medicare beneficiaries through the use of a interdisciplinary team and through the provision of primary care services to such beneficiaries by means of such a team at the nursing facility involved).

"(C) Prescription drug card.—The Administrator shall carry out section 1807 (relating to the medicare prescription drug discount card endorsement program).

"(D) NONINTERFERENCE.—In carrying out its duties with respect to the provision of qualified prescription drug coverage to beneficiaries under this

title, the Administrator may not-

(i) require a particular formulary or institute a price structure for

the reimbursement of covered outpatient drugs;
"(ii) interfere in any way with negotiations between PDP sponsors and Medicare Advantage organizations and EFFS organizations and drug manufacturers, wholesalers, or other suppliers of covered outpatient drugs; and

(iii) otherwise interfere with the competitive nature of providing

such coverage through such sponsors and organizations. "(E) ANNUAL REPORTS.—Not later March 31 of each year, the Administrator shall submit to Congress and the President a report on the administration of parts C, D, and E during the previous fiscal year.

"(2) STAFF.

"(A) IN GENERAL.—The Administrator, with the approval of the Secretary, may employ, without regard to chapter 31 of title 5, United States Code, other than sections 3102 through 3113, 3131, 3133, 3136, 3151, and 3161, such officers and employees as are necessary to administer the activities to be carried out through the Medicare Benefits Administration. The Administrator shall employ staff with appropriate and necessary expertise in negotiating contracts in the private sector.

"(B) FLEXIBILITY WITH RESPECT TO COMPENSATION.—

"(i) IN GENERAL.—The staff of the Medicare Benefits Administration shall, subject to clause (ii), be paid without regard to the provisions of chapter 51 (other than section 5101) and chapter 53 (other than section 5301, sections 5303 through 5305, 5311, and 5372 of such title (relating to classification and schedule pay rates)

"(ii) MAXIMUM RATE.—In no case may the rate of compensation determined under clause (i) exceed the rate of basic pay payable for level IV of the Executive Schedule under section 5315 of title 5, United States

"(C) LIMITATION ON FULL-TIME EQUIVALENT STAFFING FOR CURRENT CMS FUNCTIONS BEING TRANSFERRED.—The Administrator may not employ under this paragraph a number of full-time equivalent employees, to carry out functions that were previously conducted by the Centers for Medicare & Medicaid Services and that are conducted by the Administrator by reason of this section, that exceeds the number of such full-time equivalent employees authorized to be employed by the Centers for Medicare & Medicaid Services to conduct such functions as of the date of the enactment of this Act.

"(3) Redelegation of certain functions of the centers for medicare &

MEDICAID SERVICES.

"(A) IN GENERAL.—The Secretary, the Administrator, and the Administrator of the Centers for Medicare & Medicaid Services shall establish an appropriate transition of responsibility in order to redelegate the administration of part C from the Secretary and the Administrator of the Centers for Medicare & Medicaid Services to the Administrator as is appropriate to carry out the purposes of this section.

"(B) TRANSFER OF DATA AND INFORMATION.—The Secretary shall ensure that the Administrator of the Centers for Medicare & Medicaid Services transfers to the Administrator of the Medicare Benefits Administration such information and data in the possession of the Administrator of the Centers for Medicare & Medicaid Services as the Administrator of the Medicare Benefits Administration requires to carry out the duties described in paragraph (1).

"(C) CONSTRUCTION.—Insofar as a responsibility of the Secretary or the Administrator of the Centers for Medicare & Medicaid Services is redelegated to the Administrator under this section, any reference to the Secretary or the Administrator of the Centers for Medicare & Medicaid Services in this title or title XI with respect to such responsibility is deemed

to be a reference to the Administrator.

"(d) Office of Beneficiary Assistance.-

"(1) ESTABLISHMENT.—The Secretary shall establish within the Medicare Benefits Administration an Office of Beneficiary Assistance to coordinate functions relating to outreach and education of medicare beneficiaries under this title, including the functions described in paragraph (2). The Office shall be separate operating division within the Administration.

"(2) DISSEMINATION OF INFORMATION ON BENEFITS AND APPEALS RIGHTS.-

"(A) DISSEMINATION OF BENEFITS INFORMATION.—The Office of Beneficiary Assistance shall disseminate, directly or through contract, to medicare beneficiaries, by mail, by posting on the Internet site of the Medicare Benefits Administration and through a toll-free telephone number, information with respect to the following:

(i) Benefits, and limitations on payment (including cost-sharing stop-loss provisions, and formulary restrictions) under parts C, D, and

"(ii) Benefits, and limitations on payment under parts A and B, including information on medicare supplemental policies under section

Such information shall be presented in a manner so that medicare beneficiaries may compare benefits under parts A, B, D, and medicare supplemental policies with benefits under Medicare Advantage plans under part

C and EFFS plans under part E.

"(B) DISSEMINATION OF APPEALS RIGHTS INFORMATION.—The Office of Beneficiary Assistance shall disseminate to medicare beneficiaries in the manner provided under subparagraph (A) a description of procedural rights (including grievance and appeals procedures) of beneficiaries under the original medicare fee-for-service program under parts A and B, the Medicare Advantage program under part C, the Voluntary Prescription Drug Benefit Program under part D, and the Enhanced Fee-for-Service program under part E.

"(e) MEDICARE POLICY ADVISORY BOARD.-

(1) ESTABLISHMENT.—There is established within the Medicare Benefits Administration the Medicare Policy Advisory Board (in this section referred to the 'Board'). The Board shall advise, consult with, and make recommendations to the Administrator of the Medicare Benefits Administration with respect to the administration of parts C, D, and E, including the review of payment policies under such parts.

"(2) Reports.

(A) IN GENERAL.—With respect to matters of the administration of parts C, D, and E the Board shall submit to Congress and to the Administrator of the Medicare Benefits Administration such reports as the Board determines appropriate. Each such report may contain such recommendations as the Board determines appropriate for legislative or administrative changes to improve the administration of such parts, including the topics described in subparagraph (B). Each such report shall be published in the Federal Register.

(B) TOPICS DESCRIBED.—Reports required under subparagraph (A) may

include the following topics:

"(i) FOSTERING COMPETITION.—Recommendations or proposals to increase competition under parts C, D, and E for services furnished to medicare beneficiaries.

"(ii) EDUCATION AND ENROLLMENT.—Recommendations for the improvement to efforts to provide medicare beneficiaries information and education on the program under this title, and specifically parts C, D,

and E, and the program for enrollment under the title.

"(iii) IMPLEMENTATION OF RISK-ADJUSTMENT.—Evaluation of the implementation under section 1853(a)(3)(C) of the risk adjustment methodology to payment rates under that section to Medicare Advantage organizations offering Medicare Advantage plans (and the corresponding payment provisions under part E) that accounts for variations in per capita costs based on health status, geography, and other demographic factors

"(iv) RURAL ACCESS.—Recommendations to improve competition and

access to plans under parts C, D, and E in rural areas.

"(C) MAINTAINING INDEPENDENCE OF BOARD.—The Board shall directly submit to Congress reports required under subparagraph (A). No officer or agency of the United States may require the Board to submit to any officer or agency of the United States for approval, comments, or review, prior to the submission to Congress of such reports.

"(3) Duty of administrator of medicare benefits administration.—With respect to any report submitted by the Board under paragraph (2)(A), not later than 90 days after the report is submitted, the Administrator of the Medicare Benefits Administration shall submit to Congress and the President an analysis of recommendations made by the Board in such report. Each such analysis shall be published in the Federal Register.

(4) Membership.

"(A) Appointment.—Subject to the succeeding provisions of this paragraph, the Board shall consist of seven members to be appointed as follows:

"(i) Three members shall be appointed by the President.

"(ii) Two members shall be appointed by the Speaker of the House of Representatives, with the advice of the chairmen and the ranking minority members of the Committees on Ways and Means and on Energy and Commerce of the House of Representatives.

"(iii) Two members shall be appointed by the President pro tempore of the Senate with the advice of the chairman and the ranking minority

member of the Senate Committee on Finance.

"(B) QUALIFICATIONS.—The members shall be chosen on the basis of their integrity, impartiality, and good judgment, and shall be individuals who are, by reason of their education and experience in health care benefits management, exceptionally qualified to perform the duties of members of the Board.

"(C) Prohibition on inclusion of federal employees.—No officer or

employee of the United States may serve as a member of the Board.

"(5) COMPENSATION.—Members of the Board shall receive, for each day (including travel time) they are engaged in the performance of the functions of the board, compensation at rates not to exceed the daily equivalent to the annual rate in effect for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

"(6) TERMS OF OFFICE.—
"(A) IN GENERAL.—The term of office of members of the Board shall be

3 years.

"(B) Terms of initial appointees.—As designated by the President at

the time of appointment, of the members first appointed-

(i) one shall be appointed for a term of 1 year; "(ii) three shall be appointed for terms of 2 years; and

"(iii) three shall be appointed for terms of 3 years.
"(C) REAPPOINTMENTS.—Any person appointed as a member of the Board

may not serve for more than 8 years.

"(D) VACANCY.—Any member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was ap-pointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has taken office. A vacancy in the Board shall be filled in the manner in which the original appointment was made.

"(7) CHAIR.—The Chair of the Board shall be elected by the members. The

term of office of the Chair shall be 3 years.

"(8) MEETINGS.—The Board shall meet at the call of the Chair, but in no event less than three times during each fiscal year.

"(9) Director and Staff.

"(A) APPOINTMENT OF DIRECTOR.—The Board shall have a Director who

shall be appointed by the Chair.

"(B) IN GENERAL.—With the approval of the Board, the Director may appoint, without regard to chapter 31 of title 5, United States Code, such additional personnel as the Director considers appropriate.

"(C) FLEXIBILITY WITH RESPECT TO COMPENSATION

"(i) IN GENERAL.—The Director and staff of the Board shall, subject to clause (ii), be paid without regard to the provisions of chapter 51 and chapter 53 of such title (relating to classification and schedule pay rates)

"(ii) MAXIMUM RATE.—In no case may the rate of compensation determined under clause (i) exceed the rate of basic pay payable for level IV of the Executive Schedule under section 5315 of title 5, United States Code.

"(D) Assistance from the administrator of the medicare benefits ADMINISTRATION.—The Administrator of the Medicare Benefits Administration shall make available to the Board such information and other assistance as it may require to carry out its functions.

"(10) CONTRACT AUTHORITY.—The Board may contract with and compensate government and private agencies or persons to carry out its duties under this subsection, without regard to section 3709 of the Revised Statutes (41 U.S.C. "(f) Funding.—There is authorized to be appropriated, in appropriate part from the Federal Hospital Insurance Trust Fund and from the Federal Supplementary Medical Insurance Trust Fund (including the Medicare Prescription Drug Account), such sums as are necessary to carry out this section.".

(b) Effective Date.-

(1) IN GENERAL.—The amendment made by subsection (a) shall take effect on the date of the enactment of this Act.

(2) DUTIES WITH RESPECT TO ELIGIBILITY DETERMINATIONS AND ENROLL-MENT.—The Administrator of the Medicare Benefits Administration shall carry out enrollment under title XVIII of the Social Security Act, make eligibility determinations under such title, and carry out parts C and E of such title for

years beginning or after January 1, 2006.

(3) Transition.—Before the date the Administrator of the Medicare Benefits

Administration is appointed and assumes responsibilities under this section and section 1807 of the Social Security Act, the Secretary of Health and Human Services shall provide for the conduct of any responsibilities of such Administrator that are otherwise provided under law.

(c) MISCELLANEOUS ADMINISTRATIVE PROVISIONS.-

(1) ADMINISTRATOR AS MEMBER OF THE BOARD OF TRUSTEES OF THE MEDICARE TRUST FUNDS.—Section 1817(b) and section 1841(b) (42 U.S.C. 1395i(b), 1395t(b)) are each amended by striking "and the Secretary of Health and Human Services, all ex officio," and inserting "the Secretary of Health and Human Services, and the Administrator of the Medicare Benefits Administrations of the Medicare Benefits and the Administration of the Medicare Benefits and the Medicare Benefits are the medicare Benefits and the Medicare Bene tion, all ex officio,".

(2) Increase in grade to executive level iii for the administrator of

THE CENTERS FOR MEDICARE & MEDICAID SERVICES; LEVEL FOR MEDICARE BENE-FITS ADMINISTRATOR.

(A) IN GENERAL.—Section 5314 of title 5, United States Code, by adding at the end the following:

"Administrator of the Centers for Medicare & Medicaid Services.

"Administrator of the Medicare Benefits Administration.

(B) CONFORMING AMENDMENT.—Section 5315 of such title is amended by striking "Administrator of the Health Care Financing Administration.

(C) EFFECTIVE DATE.—The amendments made by this paragraph take effect on January 1, 2004.

TITLE IX—REGULATORY REDUCTION AND CONTRACTING REFORM

Subtitle A—Regulatory Reform

SEC. 901. CONSTRUCTION; DEFINITION OF SUPPLIER.

(a) CONSTRUCTION.—Nothing in this title shall be construed—

(1) to compromise or affect existing legal remedies for addressing fraud or abuse, whether it be criminal prosecution, civil enforcement, or administrative remedies, including under sections 3729 through 3733 of title 31, United States Code (known as the False Claims Act); or

(2) to prevent or impede the Department of Health and Human Services in

any way from its ongoing efforts to eliminate waste, fraud, and abuse in the

medicare program.

Furthermore, the consolidation of medicare administrative contracting set forth in this Act does not constitute consolidation of the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund or reflect any position on that issue.

(b) Definition of Supplier.—Section 1861 (42 U.S.C. 1395x) is amended by inserting after subsection (c) the following new subsection:

"Supplier

"(d) The term 'supplier' means, unless the context otherwise requires, a physician or other practitioner, a facility, or other entity (other than a provider of services) that furnishes items or services under this title.".

SEC. 902. ISSUANCE OF REGULATIONS.

(a) REGULAR TIMELINE FOR PUBLICATION OF FINAL RULES.—

(1) IN GENERAL.—Section 1871(a) (42 U.S.C. 1395hh(a)) is amended by adding at the end the following new paragraph:

"(3)(A) The Secretary, in consultation with the Director of the Office of Management and Budget, shall establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation or

an interim final regulation.

"(B) Such timeline may vary among different regulations based on differences in the complexity of the regulation, the number and scope of comments received, and other relevant factors, but shall not be longer than 3 years except under exceptional circumstances. If the Secretary intends to vary such timeline with respect to the publication of a final regulation, the Secretary shall cause to have published in the Federal Register notice of the different timeline by not later than the timeline previously established with respect to such regulation. Such notice shall include a brief explanation of the justification for such variation.

"(C) In the case of interim final regulations, upon the expiration of the regular timeline established under this paragraph for the publication of a final regulation after opportunity for public comment, the interim final regulation shall not continue in effect unless the Secretary publishes (at the end of the regular timeline and, if applicable, at the end of each succeeding 1-year period) a notice of continuation of the regulation that includes an explanation of why the regular timeline (and any the regulation that includes an explanation of why the regular timeline (and any subsequent 1-year extension) was not complied with. If such a notice is published, the regular timeline (or such timeline as previously extended under this paragraph) for publication of the final regulation shall be treated as having been extended for 1 additional year.

"(D) The Secretary shall annually submit to Congress a report that describes the instances in which the Secretary failed to publish a final regulation within the applicable regular timeline under this paragraph and that provides an explanation for

such failures.'

(2) Effective date.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act. The Secretary shall provide for an appropriate transition to take into account the backlog of previously published interim final regulations.

(b) Limitations on New Matter in Final Regulations.-

(1) IN GENERAL.—Section 1871(a) (42 U.S.C. 1395hh(a)), as amended by subsection (a), is amended by adding at the end the following new paragraph:

"(4) If the Secretary publishes a final regulation that includes a provision that is not a logical outgrowth of a previously published notice of proposed rulemaking or interim final rule, such provision shall be treated as a proposed regulation and shall not take effect until there is the further opportunity for public comment and a publication of the provision again as a final regulation.

(2) Effective Date.—The amendment made by paragraph (1) shall apply to final regulations published on or after the date of the enactment of this Act.

SEC. 903. COMPLIANCE WITH CHANGES IN REGULATIONS AND POLICIES.

(a) NO RETROACTIVE APPLICATION OF SUBSTANTIVE CHANGES.-

(1) IN GENERAL.—Section 1871 (42 U.S.C. 1395hh), as amended by section

902(a), is amended by adding at the end the following new subsection:

"(e)(1)(A) A substantive change in regulations, manual instructions, interpretative rules, statements of policy, or guidelines of general applicability under this title shall not be applied (by extrapolation or otherwise) retroactively to items and services furnished before the effective date of the change, unless the Secretary determines that-

"(i) such retroactive application is necessary to comply with statutory requirements; or

"(ii) failure to apply the change retroactively would be contrary to the public interest."

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to substantive changes issued on or after the date of the enactment of this Act. (b) Timeline for Compliance With Substantive Changes After Notice.

(1) IN GENERAL.—Section 1871(e)(1), as added by subsection (a), is amended

by adding at the end the following:

"(B)(i) Except as provided in clause (ii), a substantive change referred to in sub-paragraph (A) shall not become effective before the end of the 30-day period that begins on the date that the Secretary has issued or published, as the case may be,

the substantive change.

"(ii) The Secretary may provide for such a substantive change to take effect on a date that precedes the end of the 30-day period under clause (i) if the Secretary finds that waiver of such 30-day period is necessary to comply with statutory requirements or that the application of such 30-day period is contrary to the public interest. If the Secretary provides for an earlier effective date pursuant to this clause, the Secretary shall include in the issuance or publication of the substantive change a finding described in the first sentence, and a brief statement of the reasons for such finding.

"(C) No action shall be taken against a provider of services or supplier with respect to noncompliance with such a substantive change for items and services furnished before the effective date of such a change."

(2) Effective date—The amendment made by paragraph (1) shall apply to compliance actions undertaken on or after the date of the enactment of this Act. (c) Reliance on Guidance.

(1) IN GENERAL.—Section 1871(e), as added by subsection (a), is further amended by adding at the end the following new paragraph:

"(i) a provider of services or supplier follows the written guidance (which may be transmitted electronically) provided by the Secretary or by a medicare contractor (as defined in section 1889(g)) acting within the scope of the contractor's contract authority, with respect to the furnishing of items or services and submission of a claim for benefits for such items or services with respect to such provider or supplier;

"(ii) the Secretary determines that the provider of services or supplier has accurately presented the circumstances relating to such items, services, and claim

to the contractor in writing; and "(iii) the guidance was in error;

the provider of services or supplier shall not be subject to any sanction (including any penalty or requirement for repayment of any amount) if the provider of services or supplier reasonably relied on such guidance.

"(B) Subparagraph (A) shall not be construed as preventing the recoupment or repayment (without any additional penalty) relating to an overpayment insofar as the overpayment was solely the result of a clerical or technical operational error.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act but shall not apply to any sanction for which notice was provided on or before the date of the enactment of this Act.

SEC. 904. REPORTS AND STUDIES RELATING TO REGULATORY REFORM.

(a) GAO STUDY ON ADVISORY OPINION AUTHORITY

(1) STUDY.—The Comptroller General of the United States shall conduct a study to determine the feasibility and appropriateness of establishing in the Secretary authority to provide legally binding advisory opinions on appropriate interpretation and application of regulations to carry out the medicare program under title XVIII of the Social Security Act. Such study shall examine the appropriate timeframe for issuing such advisory opinions, as well as the need for additional staff and funding to provide such opinions.

(2) REPORT.—The Comptroller General shall submit to Congress a report on the study conducted under paragraph (1) by not later than one year after the

date of the enactment of this Act.

(b) Report on Legal and Regulatory Inconsistencies.—Section 1871 (42 U.S.C. 1395hh), as amended by section 2(a), is amended by adding at the end the

following new subsection: "(f)(1) Not later than 2 years after the date of the enactment of this subsection." and every 2 years thereafter, the Secretary shall submit to Congress a report with respect to the administration of this title and areas of inconsistency or conflict among the various provisions under law and regulation.

"(2) In preparing a report under paragraph (1), the Secretary shall collect— "(A) information from individuals entitled to benefits under part A or enrolled

under part B, or both, providers of services, and suppliers and from the Medicare Beneficiary Ombudsman and the Medicare Provider Ombudsman with respect to such areas of inconsistency and conflict; and

"(B) information from medicare contractors that tracks the nature of written

and telephone inquiries.

"(3) A report under paragraph (1) shall include a description of efforts by the Secretary to reduce such inconsistency or conflicts, and recommendations for legislation or administrative action that the Secretary determines appropriate to further reduce such inconsistency or conflicts."

Subtitle B—Contracting Reform

SEC. 911. INCREASED FLEXIBILITY IN MEDICARE ADMINISTRATION.

(a) Consolidation and Flexibility in Medicare Administration.—

(1) IN GENERAL.—Title XVIII is amended by inserting after section 1874 the following new section:

"CONTRACTS WITH MEDICARE ADMINISTRATIVE CONTRACTORS

"Sec. 1874A. (a) AUTHORITY.—

"(1) AUTHORITY TO ENTER INTO CONTRACTS.—The Secretary may enter into contracts with any eligible entity to serve as a medicare administrative contractor with respect to the performance of any or all of the functions described in paragraph (4) or parts of those functions (or, to the extent provided in a contract, to secure performance thereof by other entities).

"(2) ELIGIBILITY OF ENTITIES.—An entity is eligible to enter into a contract with respect to the performance of a particular function described in paragraph

(4) only if-

"(A) the entity has demonstrated capability to carry out such function; "(B) the entity complies with such conflict of interest standards as are generally applicable to Federal acquisition and procurement;

"(C) the entity has sufficient assets to financially support the performance of such function; and

"(D) the entity meets such other requirements as the Secretary may im-

"(3) MEDICARE ADMINISTRATIVE CONTRACTOR DEFINED.—For purposes of this title and title XI-

"(A) IN GENERAL.—The term 'medicare administrative contractor' means an agency, organization, or other person with a contract under this section.

"(B) APPROPRIATE MEDICARE ADMINISTRATIVE CONTRACTOR.—With respect to the performance of a particular function in relation to an individual entitled to benefits under part A or enrolled under part B, or both, a specific provider of services or supplier (or class of such providers of services or suppliers), the 'appropriate' medicare administrative contractor is the medicare administrative contractor that has a contract under this section with respect to the performance of that function in relation to that individual, provider of services or supplier or class of provider of services or supplier.

"(4) FUNCTIONS DESCRIBED.—The functions referred to in paragraphs (1) and (2) are payment functions, provider services functions, and functions relating to services furnished to individuals entitled to benefits under part A or enrolled

under part B, or both, as follows:

(A) DETERMINATION OF PAYMENT AMOUNTS.—Determining (subject to the provisions of section 1878 and to such review by the Secretary as may be provided for by the contracts) the amount of the payments required pursuant to this title to be made to providers of services, suppliers and individ-

"(B) MAKING PAYMENTS.—Making payments described in subparagraph (A) (including receipt, disbursement, and accounting for funds in making

such payments).

"(C) BENEFICIARY EDUCATION AND ASSISTANCE.—Providing education and outreach to individuals entitled to benefits under part A or enrolled under part B, or both, and providing assistance to those individuals with specific issues, concerns or problems.

"(D) PROVIDER CONSULTATIVE SERVICES.—Providing consultative services to institutions, agencies, and other persons to enable them to establish and maintain fiscal records necessary for purposes of this title and otherwise to

qualify as providers of services or suppliers.

"(E) COMMUNICATION WITH PROVIDERS.—Communicating to providers of services and suppliers any information or instructions furnished to the medicare administrative contractor by the Secretary, and facilitating communication between such providers and suppliers and the Secretary

'(F) Provider education and technical assistance.—Performing the functions relating to provider education, training, and technical assistance.

"(G) Additional functions.—Performing such other functions as are necessary to carry out the purposes of this title.

"(5) RELATIONSHIP TO MIP CONTRACTS.

"(A) NONDUPLICATION OF DUTIES.—In entering into contracts under this section, the Secretary shall assure that functions of medicare administrative contractors in carrying out activities under parts A and B do not duplicate activities carried out under the Medicare Integrity Program under section 1893. The previous sentence shall not apply with respect to the activity described in section 1893(b)(5) (relating to prior authorization of certain items of durable medical equipment under section 1834(a)(15)).

"(B) CONSTRUCTION.—An entity shall not be treated as a medicare administrative contractor merely by reason of having entered into a contract with the Secretary under section 1893.

"(6) APPLICATION OF FEDERAL ACQUISITION REGULATION.—Except to the extent inconsistent with a specific requirement of this title, the Federal Acquisition Regulation applies to contracts under this title.

"(b) Contracting Requirements.

"(1) Use of competitive procedures.-

(A) IN GENERAL.—Except as provided in laws with general applicability to Federal acquisition and procurement or in subparagraph (B), the Secretary shall use competitive procedures when entering into contracts with medicare administrative contractors under this section, taking into account

performance quality as well as price and other factors.

"(B) Renewal of contracts.—The Secretary may renew a contract with a medicare administrative contractor under this section from term to term without regard to section 5 of title 41, United States Code, or any other provision of law requiring competition, if the medicare administrative contractor has met or exceeded the performance requirements applicable with respect to the contract and contractor, except that the Secretary shall provide for the application of competitive procedures under such a contract not less frequently than once every five years.

"(C) TRANSFER OF FUNCTIONS.—The Secretary may transfer functions

among medicare administrative contractors consistent with the provisions of this paragraph. The Secretary shall ensure that performance quality is considered in such transfers. The Secretary shall provide public notice (whether in the Federal Register or otherwise) of any such transfer (including a description of the functions so transferred, a description of the providers of services and suppliers affected by such transfer, and contact infor-

mation for the contractors involved).

'(D) INCENTIVES FOR QUALITY.—The Secretary shall provide incentives for medicare administrative contractors to provide quality service and to promote efficiency.

"(2) COMPLIANCE WITH REQUIREMENTS.—No contract under this section shall be entered into with any medicare administrative contractor unless the Secretary finds that such medicare administrative contractor will perform its obligations under the contract efficiently and effectively and will meet such requirements as to financial responsibility, legal authority, quality of services provided, and other matters as the Secretary finds pertinent.

"(3) Performance requirements.-

"(A) DEVELOPMENT OF SPECIFIC PERFORMANCE REQUIREMENTS.—In developing contract performance requirements, the Secretary shall develop performance requirements applicable to functions described in subsection

(a)(4).

"(B) CONSULTATION.— In developing such requirements, the Secretary may consult with providers of services and suppliers, organizations representing individuals entitled to benefits under part A or enrolled under part B, or both, and organizations and agencies performing functions necessary to carry out the purposes of this section with respect to such performance requirements.

C) INCLUSION IN CONTRACTS.—All contractor performance requirements shall be set forth in the contract between the Secretary and the appropriate medicare administrative contractor. Such performance requirements

"(i) shall reflect the performance requirements developed under subparagraph (A), but may include additional performance requirements; "(ii) shall be used for evaluating contractor performance under the contract; and

"(iii) shall be consistent with the written statement of work provided under the contract.

"(4) INFORMATION REQUIREMENTS.—The Secretary shall not enter into a contract with a medicare administrative contractor under this section unless the contractor agrees

"(A) to furnish to the Secretary such timely information and reports as the Secretary may find necessary in performing his functions under this title; and

"(B) to maintain such records and afford such access thereto as the Secretary finds necessary to assure the correctness and verification of the information and reports under subparagraph (A) and otherwise to carry out the purposes of this title.

"(5) Surety bond.—A contract with a medicare administrative contractor under this section may require the medicare administrative contractor, and any of its officers or employees certifying payments or disbursing funds pursuant to the contract, or otherwise participating in carrying out the contract, to give sur-ety bond to the United States in such amount as the Secretary may deem appropriate.

"(c) Terms and Conditions.—

"(1) IN GENERAL.—A contract with any medicare administrative contractor under this section may contain such terms and conditions as the Secretary finds necessary or appropriate and may provide for advances of funds to the medicare administrative contractor for the making of payments by it under subsection

(a)(4)(B). "(2) Prohibition on mandates for certain data collection.—The Secretary may not require, as a condition of entering into, or renewing, a contract under this section, that the medicare administrative contractor match data obtained other than in its activities under this title with data used in the administration of this title for purposes of identifying situations in which the provisions

of section 1862(b) may apply.

"(d) Limitation on Liability of Medicare Administrative Contractors and

CERTAIN OFFICERS.

"(1) CERTIFYING OFFICER.—No individual designated pursuant to a contract under this section as a certifying officer shall, in the absence of the reckless disregard of the individual's obligations or the intent by that individual to defraud the United States, be liable with respect to any payments certified by the individual under this section.

"(2) DISBURSING OFFICER.—No disbursing officer shall, in the absence of the reckless disregard of the officer's obligations or the intent by that officer to defraud the United States, be liable with respect to any payment by such officer under this section if it was based upon an authorization (which meets the applicable requirements for such internal controls established by the Comptroller General) of a certifying officer designated as provided in paragraph (1) of this subsection.

(3) Liability of medicare administrative contractor.

"(A) IN GENERAL.—No medicare administrative contractor shall be liable to the United States for a payment by a certifying or disbursing officer unless, in connection with such payment, the medicare administrative contractor acted with reckless disregard of its obligations under its medicare administrative contract or with intent to defraud the United States.

"(B) RELATIONSHIP TO FALSE CLAIMS ACT.—Nothing in this subsection shall be construed to limit liability for conduct that would constitute a violation of sections 3729 through 3731 of title 31, United States Code (commonly known as

the 'False Claims Act').

(4) Indemnification by secretary.-

"(A) IN GENERAL.—Subject to subparagraphs (B) and (D), in the case of a medicare administrative contractor (or a person who is a director, officer, or employee of such a contractor or who is engaged by the contractor to participate directly in the claims administration process) who is made a party to any judicial or administrative proceeding arising from or relating directly to the claims administration process under this title, the Secretary may, to the extent the Secretary determines to be appropriate and as specified in the contract with the contractor, indemnify the contractor and such persons

"(B) CONDITIONS.—The Secretary may not provide indemnification under subparagraph (A) insofar as the liability for such costs arises directly from conduct that is determined by the judicial proceeding or by the Secretary to be criminal in nature, fraudulent, or grossly negligent. If indemnification is provided by the Secretary with respect to a contractor before a determination that such costs arose directly from such conduct, the contractor shall reimburse the Secretary for costs of indemnification.

(C) Scope of indemnification.—Indemnification by the Secretary under subparagraph (A) may include payment of judgments, settlements (subject to subparagraph (D)), awards, and costs (including reasonable legal ex-

"(D) WRITTEN APPROVAL FOR SETTLEMENTS.—A contractor or other person described in subparagraph (A) may not propose to negotiate a settlement or compromise of a proceeding described in such subparagraph without the prior written approval of the Secretary to negotiate such settlement or compromise. Any indemnification under subparagraph (A) with respect to amounts paid under a settlement or compromise of a proceeding described

in such subparagraph are conditioned upon prior written approval by the Secretary of the final settlement or compromise.

"(E) CONSTRUCTION.—Nothing in this paragraph shall be construed—

"(i) to change any common law immunity that may be available to a medicare administrative contractor or person described in subpara-

graph (A); or
"(ii) to permit the payment of costs not otherwise allowable, reason-

able, or allocable under the Federal Acquisition Regulations.'

- (2) CONSIDERATION OF INCORPORATION OF CURRENT LAW STANDARDS. veloping contract performance requirements under section 1874A(b) of the Social Security Act, as inserted by paragraph (1), the Secretary shall consider inclusion of the performance standards described in sections 1816(f)(2) of such Act (relating to timely processing of reconsiderations and applications for exemptions) and section 1842(b)(2)(B) of such Act (relating to timely review of determinations and fair hearing requests), as such sections were in effect before the date of the enactment of this Act.
- (b) Conforming Amendments to Section 1816 (Relating to Fiscal Intermediaries).—Section 1816 (42 U.S.C. 1395h) is amended as follows:

(1) The heading is amended to read as follows:

"PROVISIONS RELATING TO THE ADMINISTRATION OF PART A".

(2) Subsection (a) is amended to read as follows:

"(a) The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1874A.".

(3) Subsection (b) is repealed.

(4) Subsection (b) is repealed.
(4) Subsection (c) is amended—
(A) by striking paragraph (1); and
(B) in each of paragraphs (2)(A) and (3)(A), by striking "agreement under this section" and inserting "contract under section 1874A that provides for making payments under this part".
(5) Subsections (d) through (i) are repealed.

(5) Subsections (d) through (i) are repealed.

- (6) Subsections (j) and (k) are each amended—
 (A) by striking "An agreement with an agency or organization under this section" and inserting "A contract with a medicare administrative contractor under section 1874A with respect to the administration of this part";
 - (B) by striking "such agency or organization" and inserting "such medicare administrative contractor" each place it appears.

(7) Subsection (1) is repealed.

(c) Conforming Amendments to Section 1842 (Relating to Carriers).—Section 1842 (42 U.S.C. 1395u) is amended as follows:

(1) The heading is amended to read as follows:

"PROVISIONS RELATING TO THE ADMINISTRATION OF PART B".

(2) Subsection (a) is amended to read as follows:

"(a) The administration of this part shall be conducted through contracts with medicare administrative contractors under section 1874A.".

are administrative contractors under section 1874A.".

(3) Subsection (b) is amended—

(A) by striking paragraph (1);
(B) in paragraph (2)—

(i) by striking subparagraphs (A) and (B);
(ii) in subparagraph (C), by striking "carriers" and inserting "medicare administrative contractors"; and

(iii) by striking subparagraphs (D) and (E);
(C) in paragraph (3)—

(i) in the metter before subparagraph (A) by striking "Fach such cap."

- (i) in the matter before subparagraph (A), by striking "Each such contract shall provide that the carrier" and inserting "The Secretary"; (ii) by striking "will" the first place it appears in each of subparagraphs (A), (B), (F), (G), (H), and (L) and inserting "shall"; (iii) in subparagraph (B), in the matter before clause (i), by striking "to the policyholders and subscribers of the carrier" and inserting "to the policyholders and subscribers of the medicare administrative con-
 - (iv) by striking subparagraphs (C), (D), and (E);

(v) in subparagraph (H)—

(I) by striking "if it makes determinations or payments with respect to physicians' services," in the matter preceding clause (i);

(II) by striking "carrier" and inserting "medicare administrative contractor" in clause (i);

(vi) by striking subparagraph (I); (vii) in subparagraph (L), by striking the semicolon and inserting a period;

(viii) in the first sentence, after subparagraph (L), by striking "and shall contain" and all that follows through the period; and

(ix) in the seventh sentence, by inserting "medicare administrative contractor," after "carrier,"; and

- (D) by striking paragraph (5);
 (E) in paragraph (6)(D)(iv), by striking "carrier" and inserting "medicare administrative contractor"; and
- (F) in paragraph (7), by striking "the carrier" and inserting "the Secretary" each place it appears.

(4) Subsection (c) is amended-

(A) by striking paragraph (1);

(B) in paragraph (2)(A), by striking "contract under this section which provides for the disbursement of funds, as described in subsection (a)(1)(B)," and inserting "contract under section 1874A that provides for making payments under this part"

(C) in paragraph (3)(A), by striking "subsection (a)(1)(B)" and inserting "section 1874A(a)(3)(B)":

(D) in paragraph (4), in the matter preceding subparagraph (A), by strik-(b) in paragraph (4), in the matter preceding subparagraph (A), by striking "carrier" and inserting "medicare administrative contractor"; and (E) by striking paragraphs (5) and (6).

(5) Subsections (d), (e), and (f) are repealed.

(6) Subsection (g) is amended by striking "carrier or carriers" and inserting

"medicare administrative contractor or contractors".

(7) Subsection (h) is amended.

(A) in paragraph (2)-(i) by striking "Each carrier having an agreement with the Secretary under subsection (a)" and inserting "The Secretary"; and (ii) by striking "Each such carrier" and inserting "The Secretary"; (B) in paragraph (3)(A)—

(i) by striking "a carrier having an agreement with the Secretary under subsection (a)" and inserting "medicare administrative contractor having a contract under section 1874A that provides for making payments under this part"; and

(ii) by striking "such carrier" and inserting "such contractor";

(C) in paragraph (3)(B)-

- (i) by striking "a carrier" and inserting "a medicare administrative contractor" each place it appears; and
- (ii) by striking "the carrier" and inserting "the contractor" each place it appears; and
- (D) in paragraphs (5)(A) and (5)(B)(iii), by striking "carriers" and inserting "medicare administrative contractors" each place it appears.

(8) Subsection (1) is amended-

(A) in paragraph (1)(A)(iii), by striking "carrier" and inserting "medicare administrative contractor"; and

(B) in paragraph (2), by striking "carrier" and inserting "medicare administrative contractor"

(9) Subsection (p)(3)(A) is amended by striking "carrier" and inserting "medicare administrative contractor".

(10) Subsection (q)(1)(A) is amended by striking "carrier". (d) Effective Date; Transition Rule.—

(1) Effective date.

(A) IN GENERAL.—Except as otherwise provided in this subsection, the amendments made by this section shall take effect on October 1, 2005, and the Secretary is authorized to take such steps before such date as may be necessary to implement such amendments on a timely basis.

(B) CONSTRUCTION FOR CURRENT CONTRACTS.—Such amendments shall not apply to contracts in effect before the date specified under subparagraph (A) that continue to retain the terms and conditions in effect on such date (except as otherwise provided under this Act, other than under this section) until such date as the contract is let out for competitive bidding under such amendments.

(C) DEADLINE FOR COMPETITIVE BIDDING.—The Secretary shall provide for the letting by competitive bidding of all contracts for functions of medicare administrative contractors for annual contract periods that begin on or after

October 1, 2010.
(D) WAIVER OF PROVIDER NOMINATION PROVISIONS DURING TRANSITION.— During the period beginning on the date of the enactment of this Act and before the date specified under subparagraph (A), the Secretary may enter into new agreements under section 1816 of the Social Security Act (42 U.S.C. 1395h) without regard to any of the provider nomination provisions of such section.

(2) GENERAL TRANSITION RULES.—The Secretary shall take such steps, consistent with paragraph (1)(B) and (1)(C), as are necessary to provide for an appropriate transition from contracts under section 1816 and section 1842 of the Social Security Act (42 U.S.C. 1395h, 1395u) to contracts under section 1874A,

as added by subsection (a)(1).

(3) AUTHORIZING CONTINUATION OF MIP FUNCTIONS UNDER CURRENT CONTRACTS AND AGREEMENTS AND UNDER ROLLOVER CONTRACTS.—The provisions contained in the exception in section 1893(d)(2) of the Social Security Act (42 U.S.C. 1395ddd(d)(2)) shall continue to apply notwithstanding the amendments made by this section, and any reference in such provisions to an agreement or contract shall be deemed to include a contract under section 1874A of such Act, as inserted by subsection (a)(1), that continues the activities referred to in such provisions.

(e) REFERENCES.—On and after the effective date provided under subsection (d)(1), any reference to a fiscal intermediary or carrier under title XI or XVIII of the Social Security Act (or any regulation, manual instruction, interpretative rule, statement of policy, or guideline issued to carry out such titles) shall be deemed a reference to a medicare administrative contractor (as provided under section 1874A of the So-

cial Security Act).

(f) Reports on Implementation.—

(1) Plan for implementation.—By not later than October 1, 2004, the Secretary shall submit a report to Congress and the Comproller General of the United States that describes the plan for implementation of the amendments made by this section. The Comptroller General shall conduct an evaluation of such plan and shall submit to Congress, not later than 6 months after the date the report is received, a report on such evaluation and shall include in such report such recommendations as the Comptroller General deems appropriate.

(2) STATUS OF IMPLEMENTATION.—The Secretary shall submit a report to Congress not later than October 1, 2008, that describes the status of implementation of such amendments and that includes a description of the following:

(A) The number of contracts that have been competitively bid as of such date.

(B) The distribution of functions among contracts and contractors.

(C) A timeline for complete transition to full competition.

(D) A detailed description of how the Secretary has modified oversight and management of medicare contractors to adapt to full competition.

SEC. 912. REQUIREMENTS FOR INFORMATION SECURITY FOR MEDICARE ADMINISTRATIVE CONTRACTORS.

(a) IN GENERAL.—Section 1874A, as added by section 911(a)(1), is amended by adding at the end the following new subsection:

(e) REQUIREMENTS FOR INFORMATION SECURITY.-

"(1) DEVELOPMENT OF INFORMATION SECURITY PROGRAM.—A medicare administrative contractor that performs the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) shall implement a contractor-wide information security program to provide information security for the operation and assets of the contractor with respect to such functions under this title. An information security program under this paragraph shall meet the requirements for information security programs imposed on Federal agencies under paragraphs (1) through (8) of section 3544(b) of title 44, United States Code (other than the requirements under paragraphs (2)(D)(i), (5)(A), and (5)(B) of such section).

(2) Independent audits.

- "(A) PERFORMANCE OF ANNUAL EVALUATIONS.—Each year a medicare administrative contractor that performs the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) shall undergo an evaluation of the information security of the contractor with respect to such functions under this title. The evaluation
 - "(i) be performed by an entity that meets such requirements for independence as the Inspector General of the Department of Health and Human Services may establish; and

"(ii) test the effectiveness of information security control techniques of an appropriate subset of the contractor's information systems (as defined in section 3502(8) of title 44, United States Code) relating to such functions under this title and an assessment of compliance with the requirements of this subsection and related information security policies, procedures, standards and guidelines, including policies and procedures as may be prescribed by the Director of the Office of Management and Budget and applicable information security standards promulgated under section 11331 of title 40, United States Code.

"(B) DEADLINE FOR INITIAL EVALUATION.—

"(i) NEW CONTRACTORS.—In the case of a medicare administrative contractor covered by this subsection that has not previously performed the functions referred to in subparagraphs (A) and (B) of subsection (a)(4) (relating to determining and making payments) as a fiscal intermediary or carrier under section 1816 or 1842, the first independent evaluation conducted pursuant subparagraph (A) shall be completed prior to commencing such functions.

"(ii) OTHER CONTRACTORS.—In the case of a medicare administrative contractor covered by this subsection that is not described in clause (i), the first independent evaluation conducted pursuant subparagraph (A) shall be completed within 1 year after the date the contractor com-

mences functions referred to in clause (i) under this section.

"(C) Reports on evaluations.

"(i) To the department of health and human services.—The results of independent evaluations under subparagraph (A) shall be submitted promptly to the Inspector General of the Department of Health and Human Services and to the Secretary.

(ii) To CONGRESS.—The Inspector General of Department of Health and Human Services shall submit to Congress annual reports on the results of such evaluations, including assessments of the scope and sufficiency of such evaluations.

(iii) AGENCY REPORTING.—The Secretary shall address the results of such evaluations in reports required under section 3544(c) of title 44,

United States Code.".

(b) Application of Requirements to Fiscal Intermediaries and Carriers.— (1) IN GENERAL.—The provisions of section 1874A(e)(2) of the Social Security Act (other than subparagraph (B)), as added by subsection (a), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.
(2) DEADLINE FOR INITIAL EVALUATION.—In the case of such a fiscal inter-

mediary or carrier with an agreement or contract under such respective section in effect as of the date of the enactment of this Act, the first evaluation under section 1874A(e)(2)(A) of the Social Security Act (as added by subsection (a)), pursuant to paragraph (1), shall be completed (and a report on the evaluation submitted to the Secretary) by not later than 1 year after such date.

Subtitle C—Education and Outreach

SEC. 921. PROVIDER EDUCATION AND TECHNICAL ASSISTANCE.

(a) COORDINATION OF EDUCATION FUNDING.-

(1) IN GENERAL.—Title XVIII is amended by inserting after section 1888 the following new section:

"PROVIDER EDUCATION AND TECHNICAL ASSISTANCE

"Sec. 1889. (a) Coordination of Education Funding.—The Secretary shall coordinate the educational activities provided through medicare contractors (as defined in subsection (g), including under section 1893) in order to maximize the effectiveness of Federal education efforts for providers of services and suppliers."

(2) Effective date.—The amendment made by paragraph (1) shall take ef-

fect on the date of the enactment of this Act.

(3) REPORT.—Not later than October 1, 2004, the Secretary shall submit to Congress a report that includes a description and evaluation of the steps taken to coordinate the funding of provider education under section 1889(a) of the Social Security Act, as added by paragraph (1).

(b) INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE.—

(1) IN GENERAL.—Section 1874A, as added by section 911(a)(1) and as amended by section 912(a), is amended by adding at the end the following new subsection:

"(f) INCENTIVES TO IMPROVE CONTRACTOR PERFORMANCE IN PROVIDER EDUCATION AND OUTREACH.—The Secretary shall use specific claims payment error rates or similar methodology of medicare administrative contractors in the processing or reviewing of medicare claims in order to give such contractors an incentive to implement effective education and outreach programs for providers of services and suppliers.

(2) APPLICATION TO FISCAL INTERMEDIARIES AND CARRIERS.—The provisions of section 1874A(f) of the Social Security Act, as added by paragraph (1), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contrac-

tors under such provisions.

(3) GAO REPORT ON ADEQUACY OF METHODOLOGY.—Not later than October 1, 2004, the Comptroller General of the United States shall submit to Congress and to the Secretary a report on the adequacy of the methodology under section 1874A(f) of the Social Security Act, as added by paragraph (1), and shall include in the report such recommendations as the Comptroller General determines ap-

(4) Report on use of methodology.

(A) Report on use of methodology in assessing contractor performance.—Not later than October 1, 2004, the Secretary shall submit to Congress a report that describes how the Secretary intends to use such methodology in assessing medicare contractor performance in implementing effective education and outreach programs, including whether to use such methodology as a basis for performance bonuses. The report shall include an analysis of the sources of identified errors and potential changes in systems of contractors and rules of the Secretary that could reduce claims error rates.

(c) Provision of Access to and Prompt Responses From Medicare Adminis-

TRATIVE CONTRACTORS.-

(1) IN GENERAL.—Section 1874A, as added by section 911(a)(1) and as amended by section 912(a) and subsection (b), is further amended by adding at the end the following new subsection:

"(g) Communications with Beneficiaries, Providers of Services and Sup-

- "(1) COMMUNICATION STRATEGY.—The Secretary shall develop a strategy for communications with individuals entitled to benefits under part A or enrolled under part B, or both, and with providers of services and suppliers under this
- "(2) RESPONSE TO WRITTEN INQUIRIES.—Each medicare administrative contractor shall, for those providers of services and suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A or enrolled under part B, or both, with respect to whom claims are submitted for claims processing, provide general written responses (which may be through electronic transmission) in a clear, concise, and accurate manner to inquiries of providers of services, suppliers and individuals entitled to benefits under part A or enrolled under part B, or both, concerning the programs under this title within 45 business days of the date of receipt of such inquiries.
- "(3) RESPONSE TO TOLL-FREE LINES.—The Secretary shall ensure that each medicare administrative contractor shall provide, for those providers of services and suppliers which submit claims to the contractor for claims processing and for those individuals entitled to benefits under part A or enrolled under part B, or both, with respect to whom claims are submitted for claims processing, a toll-free telephone number at which such individuals, providers of services and suppliers may obtain information regarding billing, coding, claims, coverage, and other appropriate information under this title.

- "(4) MONITORING OF CONTRACTOR RESPONSES.—
 "(A) IN GENERAL.—Each medicare administrative contractor shall, consistent with standards developed by the Secretary under subparagraph
 - "(i) maintain a system for identifying who provides the information referred to in paragraphs (2) and (3); and
 - "(ii) monitor the accuracy, consistency, and timeliness of the information so provided.

"(B) DEVELOPMENT OF STANDARDS.—

"(i) IN GENERAL.—The Secretary shall establish and make public standards to monitor the accuracy, consistency, and timeliness of the

information provided in response to written and telephone inquiries under this subsection. Such standards shall be consistent with the performance requirements established under subsection (b)(3).

(ii) EVALUATION.—In conducting evaluations of individual medicare administrative contractors, the Secretary shall take into account the results of the monitoring conducted under subparagraph (A) taking into account as performance requirements the standards established under clause (i). The Secretary shall, in consultation with organizations representing providers of services, suppliers, and individuals entitled to benefits under part A or enrolled under part B, or both, establish standards relating to the accuracy, consistency, and timeliness of the information so provided.

"(C) DIRECT MONITORING.—Nothing in this paragraph shall be construed as preventing the Secretary from directly monitoring the accuracy, consistency, and timeliness of the information so provided.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take ef-

fect October 1, 2004.

(3) APPLICATION TO FISCAL INTERMEDIARIES AND CARRIERS.—The provisions of section 1874A(g) of the Social Security Act, as added by paragraph (1), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

(d) IMPROVED PROVIDER EDUCATION AND TRAINING.—
(1) IN GENERAL.—Section 1889, as added by subsection (a), is amended by adding at the end the following new subsections: "(b) ENHANCED EDUCATION AND TRAINING.—

"(1) ADDITIONAL RESOURCES.—There are authorized to be appropriated to the Secretary (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) \$25,000,000 for each of fiscal years 2005 and 2006 and such sums as may be necessary for succeeding fiscal years.

"(2) USE.—The funds made available under paragraph (1) shall be used to increase the conduct by medicare contractors of education and training of providers of services and suppliers regarding billing, coding, and other appropriate items and may also be used to improve the accuracy, consistency, and timeliness of contractor responses.

"(c) Tailoring Education and Training Activities for Small Providers or

"(1) IN GENERAL.—Insofar as a medicare contractor conducts education and training activities, it shall tailor such activities to meet the special needs of small providers of services or suppliers (as defined in paragraph (2)).

(2) SMALL PROVIDER OF SERVICES OR SUPPLIER.—In this subsection, the term

'small provider of services or supplier' means-

(A) a provider of services with fewer than 25 full-time-equivalent employees; or

(B) a supplier with fewer than 10 full-time-equivalent employees.

(2) Effective date.—The amendment made by paragraph (1) shall take effect on October 1, 2004.

(e) REQUIREMENT TO MAINTAIN INTERNET SITES.—

- (1) IN GENERAL.—Section 1889, as added by subsection (a) and as amended by subsection (d), is further amended by adding at the end the following new subsection:
- "(d) Internet Sites; FAQs.—The Secretary, and each medicare contractor insofar as it provides services (including claims processing) for providers of services or suppliers, shall maintain an Internet site which—
 - "(1) provides answers in an easily accessible format to frequently asked ques-

tions, and

"(2) includes other published materials of the contractor,

- that relate to providers of services and suppliers under the programs under this title (and title XI insofar as it relates to such programs).
 - (2) Effective date.—The amendment made by paragraph (1) shall take effect on October 1, 2004

(f) Additional Provider Education Provisions.—

- (1) IN GENERAL.—Section 1889, as added by subsection (a) and as amended by subsections (d) and (e), is further amended by adding at the end the following new subsections:
- "(e) Encouragement of Participation in Education Program Activities.—A medicare contractor may not use a record of attendance at (or failure to attend) edu-

cational activities or other information gathered during an educational program conducted under this section or otherwise by the Secretary to select or track providers of services or suppliers for the purpose of conducting any type of audit or prepay-

"(f) Construction.—Nothing in this section or section 1893(g) shall be construed as providing for disclosure by a medicare contractor of information that would compromise pending law enforcement activities or reveal findings of law enforcementrelated audits.

(g) Definitions.—For purposes of this section, the term 'medicare contractor' includes the following:

"(1) A medicare administrative contractor with a contract under section 1874A, including a fiscal intermediary with a contract under section 1816 and a carrier with a contract under section 1842.

"(2) An eligible entity with a contract under section 1893. Such term does not include, with respect to activities of a specific provider of services or supplier an entity that has no authority under this title or title IX with respect to such activities and such provider of services or supplier.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take effect on the date of the enactment of this Act.

SEC. 922. SMALL PROVIDER TECHNICAL ASSISTANCE DEMONSTRATION PROGRAM.

(a) Establishment.-

- (1) IN GENERAL.—The Secretary shall establish a demonstration program (in this section referred to as the "demonstration program") under which technical assistance described in paragraph (2) is made available, upon request and on a voluntary basis, to small providers of services or suppliers in order to improve compliance with the applicable requirements of the programs under medicare program under title XVIII of the Social Security Act (including provisions of title XI of such Act insofar as they relate to such title and are not administered by the Office of the Inspector General of the Department of Health and Human
- (2) FORMS OF TECHNICAL ASSISTANCE.—The technical assistance described in this paragraph is-

(A) evaluation and recommendations regarding billing and related systems; and

(B) information and assistance regarding policies and procedures under the medicare program, including coding and reimbursement.

(3) SMALL PROVIDERS OF SERVICES OR SUPPLIERS.—In this section, the term "small providers of services or suppliers" means-

(A) a provider of services with fewer than 25 full-time-equivalent employ-

(B) a supplier with fewer than 10 full-time-equivalent employees.

(b) QUALIFICATION OF CONTRACTORS.—In conducting the demonstration program, the Secretary shall enter into contracts with qualified organizations (such as peer review organizations or entities described in section 1889(g)(2) of the Social Security Act, as inserted by section 5(f)(1)) with appropriate expertise with billing systems of the full range of providers of services and suppliers to provide the technical assistance. In awarding such contracts, the Secretary shall consider any prior investigations of the entity's work by the Inspector General of Department of Health and Human Services or the Comptroller General of the United States.

(c) DESCRIPTION OF TECHNICAL ASSISTANCE.—The technical assistance provided under the demonstration program shall include a direct and in-person examination of billing systems and internal controls of small providers of services or suppliers to determine program compliance and to suggest more efficient or effective means

of achieving such compliance.

(d) Avoidance of Recovery Actions for Problems Identified as Cor-RECTED.—The Secretary shall provide that, absent evidence of fraud and notwithstanding any other provision of law, any errors found in a compliance review for a small provider of services or supplier that participates in the demonstration program shall not be subject to recovery action if the technical assistance personnel under the program determine that-

(1) the problem that is the subject of the compliance review has been corrected to their satisfaction within 30 days of the date of the visit by such personnel to the small provider of services or supplier; and

(2) such problem remains corrected for such period as is appropriate.

The previous sentence applies only to claims filed as part of the demonstration program and lasts only for the duration of such program and only as long as the small provider of services or supplier is a participant in such program.

(e) GAO EVALUATION.—Not later than 2 years after the date of the date the demonstration program is first implemented, the Comptroller General, in consultation with the Inspector General of the Department of Health and Human Services, shall conduct an evaluation of the demonstration program. The evaluation shall include a determination of whether claims error rates are reduced for small providers of services or suppliers who participated in the program and the extent of improper payments made as a result of the demonstration program. The Comptroller General shall submit a report to the Secretary and the Congress on such evaluation and shall include in such report recommendations regarding the continuation or extension of the demonstration program.

(f) FINANCIAL PARTICIPATION BY PROVIDERS.—The provision of technical assistance to a small provider of services or supplier under the demonstration program is conditioned upon the small provider of services or supplier paying an amount estimated (and disclosed in advance of a provider's or supplier's participation in the program)

to be equal to 25 percent of the cost of the technical assistance.

(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to the Secretary (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) to carry out the demonstration program-

(1) for fiscal year 2005, \$1,000,000, and

(2) for fiscal year 2006, \$6,000,000.

SEC. 923. MEDICARE PROVIDER OMBUDSMAN; MEDICARE BENEFICIARY OMBUDSMAN.

(a) Medicare Provider Ombudsman.—Section 1868 (42 U.S.C. 1395ee) is amended-

(1) by adding at the end of the heading the following: "; MEDICARE PROVIDER OMBUDSMAN":

(2) by inserting "Practicing Physicians Advisory Council.—(1)" after "(a)"; (3) in paragraph (1), as so redesignated under paragraph (2), by striking "in this section" and inserting "in this subsection";

(4) by redesignating subsections (b) and (c) as paragraphs (2) and (3), respec-

tively; and

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

"(b) Medicare Provider Ombudsman.—The Secretary shall appoint within the Department of Health and Human Services a Medicare Provider Ombudsman. The Ombudsman shall-

"(1) provide assistance, on a confidential basis, to providers of services and suppliers with respect to complaints, grievances, and requests for information concerning the programs under this title (including provisions of title XI insofar as they relate to this title and are not administered by the Office of the Inspector General of the Department of Health and Human Services) and in the resolution of unclear or conflicting guidance given by the Secretary and medicare contractors to such providers of services and suppliers regarding such programs

and provisions and requirements under this title and such provisions; and "(2) submit recommendations to the Secretary for improvement in the admin-

istration of this title and such provisions, including-

"(A) recommendations to respond to recurring patterns of confusion in this title and such provisions (including recommendations regarding suspending imposition of sanctions where there is widespread confusion in program administration), and

"(B) recommendations to provide for an appropriate and consistent response (including not providing for audits) in cases of self-identified over-

payments by providers of services and suppliers.

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.

(b) MEDICARE BENEFICIARY OMBUDSMAN.—Title XVIII, as previously amended, is amended by inserting after section 1809 the following new section:

"MEDICARE BENEFICIARY OMBUDSMAN

"SEC. 1810. (a) IN GENERAL.—The Secretary shall appoint within the Department of Health and Human Services a Medicare Beneficiary Ombudsman who shall have expertise and experience in the fields of health care and education of (and assistance to) individuals entitled to benefits under this title.

(b) Duties.—The Medicare Beneficiary Ombudsman shall-

"(1) receive complaints, grievances, and requests for information submitted by individuals entitled to benefits under part A or enrolled under part B, or both, with respect to any aspect of the medicare program;

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

'(A) assistance in collecting relevant information for such individuals, to seek an appeal of a decision or determination made by a fiscal intermediary, carrier, Medicare+Choice organization, or the Secretary

"(B) assistance to such individuals with any problems arising from disenrollment from a Medicare+Choice plan under part C; and

"(C) assistance to such individuals in presenting information under section 1860D-2(b)(4)(D)(v); and

"(3) submit annual reports to Congress and the Secretary that describe the activities of the Office and that include such recommendations for improvement in the administration of this title 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 cov-

erage policies.
"(c) Working With Health Insurance Counseling Programs.—To the extent "(c) WORKING WITH HEALTH INSURANCE COUNSELING PROGRAMS.—To the extent possible, the Ombudsman shall work with health insurance counseling programs (receiving funding under section 4360 of Omnibus Budget Reconciliation Act of 1990) to facilitate the provision of information to individuals entitled to benefits under part A or enrolled under part B, or both regarding Medicare+Choice plans and changes to those plans. Nothing in this subsection shall preclude further collaboration between the Ombudsman and such programs."

(c) DEADLINE FOR APPOINTMENT.—The Secretary shall appoint the Medicare Provider Ombudsman and the Medicare Beneficiary Ombudsman, under the amendments made by subsections (a) and (b), respectively, by not later than 1 year after the date of the enactment of this Act.

(d) Funding.—There are authorized to be appropriated to the Secretary (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) to carry out the provisions of subsection (b) of section 1868 of the Social Security Act (relating to the Medicare Provider Ombudsman), as added by subsection (a)(5) and section 1807 of such Act (relating to the Medicare Beneficiary Ombudsman), as added by subsection (b), such sums as are necessary for fiscal year 2004 and each succeeding fiscal year. (e) USE OF CENTRAL, TOLL-FREE NUMBER (1–800–MEDICARE).-

(1) PHONE TRIAGE SYSTEM; LISTING IN MEDICARE HANDBOOK INSTEAD OF OTHER TOLL-FREE NUMBERS.—Section 1804(b) (42 U.S.C. 1395b-2(b)) is amended by adding at the end the following: "The Secretary shall provide, through the toll-free number 1-800-MEDICARE, for a means by which individuals seeking information about, or assistance with, such programs who phone such toll-free number are transferred (without charge) to appropriate entities for the provision of such information or assistance. Such toll-free number shall be the tollfree number listed for general information and assistance in the annual notice under subsection (a) instead of the listing of numbers of individual contractors.". (2) Monitoring accuracy.

(A) STUDY.—The Comptroller General of the United States shall conduct a study to monitor the accuracy and consistency of information provided to individuals entitled to benefits under part A or enrolled under part B, or both, through the toll-free number 1–800–MEDICARE, including an assessment of whether the information provided is sufficient to answer questions of such individuals. In conducting the study, the Comptroller General shall examine the education and training of the individuals providing information through such number.

tion through such number.

(B) REPORT.—Not later than 1 year after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on the study conducted under subparagraph (A).

SEC. 924. BENEFICIARY OUTREACH DEMONSTRATION PROGRAM.

(a) IN GENERAL.—The Secretary shall establish a demonstration program (in this section referred to as the "demonstration program") under which medicare specialists employed by the Department of Health and Human Services provide advice and assistance to individuals entitled to benefits under part A of title XVIII of the Social Security Act, or enrolled under part B of such title, or both, regarding the medicare program at the location of existing local offices of the Social Security Administra-

(b) Locations.—

(1) IN GENERAL.—The demonstration program shall be conducted in at least 6 offices or areas. Subject to paragraph (2), in selecting such offices and areas, the Secretary shall provide preference for offices with a high volume of visits by individuals referred to in subsection (a).

- (2) Assistance for rural beneficiaries.—The Secretary shall provide for the selection of at least 2 rural areas to participate in the demonstration program. In conducting the demonstration program in such rural areas, the Secretary shall provide for medicare specialists to travel among local offices in a
- rural area on a scheduled basis.

 (c) DURATION.—The demonstration program shall be conducted over a 3-year period

(d) EVALUATION AND REPORT.—

(1) EVALUATION.—The Secretary shall provide for an evaluation of the demonstration program. Such evaluation shall include an analysis of—

(A) utilization of, and satisfaction of those individuals referred to in sub-

section (a) with, the assistance provided under the program; and
(B) the cost-effectiveness of providing beneficiary assistance through outstationing medicare specialists at local offices of the Social Security Administration.

(2) REPORT.—The Secretary shall submit to Congress a report on such evaluation and shall include in such report recommendations regarding the feasibility of permanently out-stationing medicare specialists at local offices of the Social Security Administration.

SEC. 925. INCLUSION OF ADDITIONAL INFORMATION IN NOTICES TO BENEFICIARIES ABOUT SKILLED NURSING FACILITY BENEFITS.

(a) IN GENERAL.—The Secretary shall provide that in medicare beneficiary notices provided (under section 1806(a) of the Social Security Act, 42 U.S.C. 1395b-7(a)) with respect to the provision of post-hospital extended care services under part A of title XVIII of the Social Security Act, there shall be included information on the number of days of coverage of such services remaining under such part for the medicare beneficiary and spell of illness involved

(b) Effective Date.—Subsection (a) shall apply to notices provided during calendar quarters beginning more than 6 months after the date of the enactment of

this Act

SEC. 926. INFORMATION ON MEDICARE-CERTIFIED SKILLED NURSING FACILITIES IN HOS-PITAL DISCHARGE PLANS.

(a) AVAILABILITY OF DATA.—The Secretary shall publicly provide information that enables hospital discharge planners, medicare beneficiaries, and the public to identify skilled nursing facilities that are participating in the medicare program.

(b) Inclusion of Information in Certain Hospital Discharge Plans.—

(1) IN GENERAL.—Section 1861(ee)(2)(D) (42 U.S.C. 1395x(ee)(2)(D)) is amended—

(A) by striking "hospice services" and inserting "hospice care and post-hospital extended care services"; and

(B) by inserting before the period at the end the following: "and, in the case of individuals who are likely to need post-hospital extended care services, the availability of such services through facilities that participate in the program under this title and that serve the area in which the patient resides'

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall apply to discharge plans made on or after such date as the Secretary shall specify, but not later than 6 months after the date the Secretary provides for availability of information under subsection (a).

Subtitle D—Appeals and Recovery

SEC. 931. TRANSFER OF RESPONSIBILITY FOR MEDICARE APPEALS.

(a) Transition Plan.

(1) IN GENERAL.—Not later than October 1, 2004, the Commissioner of Social Security and the Secretary shall develop and transmit to Congress and the Comptroller General of the United States a plan under which the functions of administrative law judges responsible for hearing cases under title XVIII of the Social Security Act (and related provisions in title XI of such Act) are transferred from the responsibility of the Commissioner and the Social Security Administration to the Secretary and the Department of Health and Human Serv-

(2) GAO EVALUATION.—The Comptroller General of the United States shall evaluate the plan and, not later than the date that is 6 months after the date on which the plan is received by the Comptroller General, shall submit to Congress a report on such evaluation.

(b) Transfer of Adjudication Authority.—

(1) IN GENERAL.—Not earlier than July 1, 2005, and not later than October 1, 2005, the Commissioner of Social Security and the Secretary shall implement the transition plan under subsection (a) and transfer the administrative law judge functions described in such subsection from the Social Security Adminis-

tration to the Secretary.

(2) Assuring independence of judges.—The Secretary shall assure the independence of administrative law judges performing the administrative law judge functions transferred under paragraph (1) from the Centers for Medicare & Medicaid Services and its contractors. In order to assure such independence, the Secretary shall place such judges in an administrative office that is organizationally and functionally separate from such Centers. Such judges shall report to, and be under the general supervision of, the Secretary, but shall not report

to, or be subject to supervision by, another other officer of the Department.

(3) Geographic distribution.—The Secretary shall provide for an appropriate geographic distribution of administrative law in the secretary shall provide for an appropriate geographic distribution of administrative law in the secretary shall provide for an appropriate geographic distribution of administrative law in the secretary shall provide for an appropriate geographic distribution of administrative law in the secretary shall provide for an appropriate geographic distribution of administrative law judges performing the administrative law judge functions transferred under paragraph (1) throughout

the United States to ensure timely access to such judges.

(4) HIRING AUTHORITY.—Subject to the amounts provided in advance in approjudges to hear such cases, giving priority to those judges with prior experience in handling medicare appeals and in a manner consistent with paragraph (3), and to hire support staff for such judges.

(5) FINANCING.—Amounts payable under law to the Commissioner for administrative law judges performing the administrative law judge functions transferred under paragraph (1) from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund shall become

payable to the Secretary for the functions so transferred.

(6) Shared resources.—The Secretary shall enter into such arrangements with the Commissioner as may be appropriate with respect to transferred functions of administrative law judges to share office space, support staff, and other resources, with appropriate reimbursement from the Trust Funds described in paragraph (5).

(c) INCREASED FINANCIAL SUPPORT.—In addition to any amounts otherwise appropriated, to ensure timely action on appeals before administrative law judges and the Departmental Appeals Board consistent with section 1869 of the Social Security Act (as amended by section 521 of BIPA, 114 Stat. 2763A-534), there are authorized to be appropriated (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) to the Secretary such sums as are necessary for fiscal year 2005 and each subsequent fiscal year to-

(1) increase the number of administrative law judges (and their staffs) under

subsection (b)(4);

(2) improve education and training opportunities for administrative law judges (and their staffs); and

(3) increase the staff of the Departmental Appeals Board.

(d) Conforming Amendment.—Section 1869(f)(2)(A)(i) (42 U.S.C. 1395ff(f)(2)(A)(i)), as added by section 522(a) of BIPA (114 Stat. 2763A–543), is amended by striking "of the Social Security Administration".

SEC. 932. PROCESS FOR EXPEDITED ACCESS TO REVIEW.

- (a) Expedited Access to Judicial Review.—Section 1869(b) (42 U.S.C. 1395ff(b)) as amended by BIPA, is amended-
 - (1) in paragraph (1)(A), by inserting ", subject to paragraph (2)," before "to judicial review of the Secretary's final decision";

(2) in paragraph (1)(F)-

(A) by striking clause (ii);

(B) by striking "PROCEEDING" and all that follows through "DETERMINA-TION" and inserting "DETERMINATIONS AND RECONSIDERATIONS"; and

(C) by redesignating subclauses (I) and (II) as clauses (i) and (ii) and by moving the indentation of such subclauses (and the matter that follows) 2 ems to the left; and

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

"(2) EXPEDITED ACCESS TO JUDICIAL REVIEW.—
"(A) IN GENERAL.—The Secretary shall establish a process under which a provider of services or supplier that furnishes an item or service or an individual entitled to benefits under part A or enrolled under part B, or both, who has filed an appeal under paragraph (1) may obtain access to judicial review when a review panel (described in subparagraph (D)), on its own motion or at the request of the appellant, determines that no entity in the administrative appeals process has the authority to decide the question of law or regulation relevant to the matters in controversy and that there is no material issue of fact in dispute. The appellant may make such request only once with respect to a question of law or regulation in a case

of an appeal.

"(B) PROMPT DETERMINATIONS.—If, after or coincident with appropriately filing a request for an administrative hearing, the appellant requests a determination by the appropriate review panel that no review panel has the authority to decide the question of law or regulations relevant to the matters in controversy and that there is no material issue of fact in dispute and if such request is accompanied by the documents and materials as the and it such request is accompanied by the documents and indertain to the appropriate review panel shall require for purposes of making such determination, such review panel shall make a determination on the request in writing within 60 days after the date such review panel receives the request and such accompanying documents and materials. Such a determina-tion by such review panel shall be considered a final decision and not subject to review by the Secretary.

"(C) Access to judicial review.-

"(i) IN GENERAL.—If the appropriate review panel—

"(I) determines that there are no material issues of fact in dispute and that the only issue is one of law or regulation that no review panel has the authority to decide; or

"(II) fails to make such determination within the period provided

under subparagraph (B);

then the appellant may bring a civil action as described in this subparagraph.

"(ii) DEADLINE FOR FILING.—Such action shall be filed, in the case de-

scribed in— "(I) clause (i)(I), within 60 days of date of the determination described in such subparagraph; or "(II) clause (i)(II), within 60 days of the end of the period pro-

vided under subparagraph (B) for the determination.

"(iii) VENUE.—Such action shall be brought in the district court of the United States for the judicial district in which the appellant is located (or, in the case of an action brought jointly by more than one applicant, the judicial district in which the greatest number of applicants are located) or in the district court for the District of Columbia.

"(iv) Interest on amounts in controversy.-Where a provider of services or supplier seeks judicial review pursuant to this paragraph, the amount in controversy shall be subject to annual interest beginning on the first day of the first month beginning after the 60-day period as determined pursuant to clause (ii) and equal to the rate of interest on obligations issued for purchase by the Federal Hospital Insurance Trust Fund and by the Federal Supplementary Medical Insurance Trust Fund for the month in which the civil action authorized under this paragraph is commenced, to be awarded by the reviewing court in favor of the prevailing party. No interest awarded pursuant to the preceding sentence shall be deemed income or cost for the purposes of de-termining reimbursement due providers of services or suppliers under

"(D) REVIEW PANELS.—For purposes of this subsection, a 'review panel' is a panel consisting of 3 members (who shall be administrative law judges, members of the Departmental Appeals Board, or qualified individuals associated with a qualified independent contractor (as defined in subsection (c)(2)) or with another independent entity) designated by the Secretary for purposes of making determinations under this paragraph.

(b) APPLICATION TO PROVIDER AGREEMENT DETERMINATIONS.—Section 1866(h)(1) (42 U.S.C. 1395cc(h)(1)) is amended— (1) by inserting "(A)" after "(h)(1)"; and

(2) by adding at the end the following new subparagraph:

"(B) An institution or agency described in subparagraph (A) that has filed for a hearing under subparagraph (A) shall have expedited access to judicial review under this subparagraph in the same manner as providers of services, suppliers, and individuals entitled to benefits under part A or enrolled under part B, or both, may obtain expedited access to judicial review under the process established under section 1869(b)(2). Nothing in this subparagraph shall be construed to affect the application of any remedy imposed under section 1819 during the pendency of an appeal under this subparagraph.".

- (c) EFFECTIVE DATE.—The amendments made by this section shall apply to appeals filed on or after October 1, 2004
 - (d) Expedited Review of Certain Provider Agreement Determinations.—
 - (1) Termination and certain other immediate remedies.—The Secretary shall develop and implement a process to expedite proceedings under sections 1866(h) of the Social Security Act (42 U.S.C. 1395cc(h)) in which the remedy of termination of participation, or a remedy described in clause (i) or (iii) of section 1819(h)(2)(B) of such Act (42 U.S.C. 1395i-3(h)(2)(B)) which is applied on an immediate basis, has been imposed. Under such process priority shall be provided in cases of termination.
 - (2) INCREASED FINANCIAL SUPPORT.—In addition to any amounts otherwise appropriated, to reduce by 50 percent the average time for administrative determinance. minations on appeals under section 1866(h) of the Social Security Act (42 U.S.C. 1395cc(h)), there are authorized to be appropriated (in appropriate part from the Federal Hospital Insurance Trust Fund and the Federal Supplementary Medical Insurance Trust Fund) to the Secretary such additional sums for fiscal year 2005 and each subsequent fiscal year as may be necessary. The purposes for which such amounts are available include increasing the number of administrative law judges (and their staffs) and the appellate level staff at the Departmental Appeals Board of the Department of Health and Human Services and educating such judges and staffs on long-term care issues.

SEC. 933. REVISIONS TO MEDICARE APPEALS PROCESS.

(a) Requiring Full and Early Presentation of Evidence.—
(1) In General.—Section 1869(b) (42 U.S.C. 1395ff(b)), as amended by BIPA and as amended by section 932(a), is further amended by adding at the end the

following new paragraph:

(3) REQUIRING FULL AND EARLY PRESENTATION OF EVIDENCE BY PROVIDERS.— A provider of services or supplier may not introduce evidence in any appeal under this section that was not presented at the reconsideration conducted by the qualified independent contractor under subsection (c), unless there is good cause which precluded the introduction of such evidence at or before that reconsideration."

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall take ef-

fect on October 1, 2004

(b) Use of Patients' Medical Records.—Section 1869(c)(3)(B)(i) (42 U.S.C. 1395ff(c)(3)(B)(i)), as amended by BIPA, is amended by inserting "(including the medical records of the individual involved)" after "clinical experience".

(c) Notice Requirements for Medicare Appeals.

(1) INITIAL DETERMINATIONS AND REDETERMINATIONS.—Section 1869(a) (42 U.S.C. 1395ff(a)), as amended by BIPA, is amended by adding at the end the following new paragraphs:

"(4) REQUIREMENTS OF NOTICE OF DETERMINATIONS.—With respect to an ini-

tial determination insofar as it results in a denial of a claim for benefits-

"(A) the written notice on the determination shall include-"(i) the reasons for the determination, including whether a local med-

ical review policy or a local coverage determination was used;

- "(ii) the procedures for obtaining additional information concerning the determination, including the information described in subparagraph (B); and
- "(iii) notification of the right to seek a redetermination or otherwise appeal the determination and instructions on how to initiate such a redetermination under this section; and
- "(B) the person provided such notice may obtain, upon request, the specific provision of the policy, manual, or regulation used in making the determination.
- "(5) REQUIREMENTS OF NOTICE OF REDETERMINATIONS.—With respect to a redetermination insofar as it results in a denial of a claim for benefits

"(A) the written notice on the redetermination shall include-

(i) the specific reasons for the redetermination;

"(ii) as appropriate, a summary of the clinical or scientific evidence used in making the redetermination;

"(iii) a description of the procedures for obtaining additional information concerning the redetermination; and

(iv) notification of the right to appeal the redetermination and instructions on how to initiate such an appeal under this section;

"(B) such written notice shall be provided in printed form and written in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both; and

"(C) the person provided such notice may obtain, upon request, information on the specific provision of the policy, manual, or regulation used in making the redetermination.".

(2) RECONSIDERATIONS.—Section 1869(c)(3)(E) (42 U.S.C. 1395ff(c)(3)(E)), as

amended by BIPA, is amended-

- (A) by inserting "be written in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both, and shall include (to the extent appropriate)" after "in writing,
- (B) by inserting "and a notification of the right to appeal such determina-tion and instructions on how to initiate such appeal under this section" after "such decision,
- (3) APPEALS.—Section 1869(d) (42 U.S.C. 1395ff(d)), as amended by BIPA, is amended-

- (A) in the heading, by inserting "; NOTICE" after "SECRETARY"; and
 (B) by adding at the end the following new paragraph:
 "(4) NOTICE.—Notice of the decision of an administrative law judge shall be in writing in a manner calculated to be understood by the individual entitled to benefits under part A or enrolled under part B, or both, and shall include-
 - '(A) the specific reasons for the determination (including, to the extent appropriate, a summary of the clinical or scientific evidence used in making the determination);
 "(B) the procedures for obtaining additional information concerning the

decision; and "(C) notification of the right to appeal the decision and instructions on

how to initiate such an appeal under this section."

- (4) SUBMISSION OF RECORD FOR APPEAL.—Section 1869(c)(3)(J)(i) (42 U.S.C. 1395ff(c)(3)(J)(i)) by striking "prepare" and inserting "submit" and by striking "with respect to" and all that follows through "and relevant policies". (d) Qualified Independent Contractors.
 - (1) ELIGIBILITY REQUIREMENTS OF QUALIFIED INDEPENDENT CONTRACTORS.—Section 1869(c)(3) (42 U.S.C. 1395ff(c)(3)), as amended by BIPA, is amended—
 - (A) in subparagraph (A), by striking "sufficient training and expertise in medical science and legal matters" and inserting "sufficient medical, legal, and other expertise (including knowledge of the program under this title) and sufficient staffing"; and

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

"(K) Independence requirements.

- "(i) IN GENERAL.—Subject to clause (ii), a qualified independent contractor shall not conduct any activities in a case unless the entity
 - "(I) is not a related party (as defined in subsection (g)(5)); "(II) does not have a material familial, financial, or professional relationship with such a party in relation to such case; and

"(III) does not otherwise have a conflict of interest with such a

- party.

 "(ii) EXCEPTION FOR REASONABLE COMPENSATION.—Nothing in clause (i) shall be construed to prohibit receipt by a qualified independent contractor of compensation from the Secretary for the conduct of activities under this section if the compensation is provided consistent with clause (iii).
- "(iii) LIMITATIONS ON ENTITY COMPENSATION.—Compensation provided by the Secretary to a qualified independent contractor in connection with reviews under this section shall not be contingent on any decision rendered by the contractor or by any reviewing professional

(2) ELIGIBILITY REQUIREMENTS FOR REVIEWERS.—Section 1869 (42 U.S.C. 1395ff), as amended by BIPA, is amended—

(A) by amending subsection (c)(3)(D) to read as follows:
"(D) QUALIFICATIONS FOR REVIEWERS.—The requirements of subsection (g) shall be met (relating to qualifications of reviewing professionals)."; and

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

"(g) QUALIFICATIONS OF REVIEWERS.

1) IN GENERAL.—In reviewing determinations under this section, a qualified independent contractor shall assure that-

"(A) each individual conducting a review shall meet the qualifications of paragraph (2);

"(B) compensation provided by the contractor to each such reviewer is consistent with paragraph (3); and

'(C) in the case of a review by a panel described in subsection (c)(3)(B) composed of physicians or other health care professionals (each in this sub-

section referred to as a 'reviewing professional'), a reviewing professional meets the qualifications described in paragraph (4) and, where a claim is regarding the furnishing of treatment by a physician (allopathic or osteopathic) or the provision of items or services by a physician (allopathic or osteopathic), each reviewing professional shall be a physician (allopathic or

"(2) Independence.—

"(A) IN GENERAL.—Subject to subparagraph (B), each individual conducting a review in a case shall-

(i) not be a related party (as defined in paragraph (5));

"(ii) not have a material familial, financial, or professional relationship with such a party in the case under review; and

"(iii) not otherwise have a conflict of interest with such a party. "(B) EXCEPTION.—Nothing in subparagraph (A) shall be construed to-

(i) prohibit an individual, solely on the basis of a participation agreement with a fiscal intermediary, carrier, or other contractor, from serving as a reviewing professional if-

"(I) the individual is not involved in the provision of items or

services in the case under review;

"(II) the fact of such an agreement is disclosed to the Secretary and the individual entitled to benefits under part A or enrolled under part B, or both, (or authorized representative) and neither party objects; and

"(III) the individual is not an employee of the intermediary, carrier, or contractor and does not provide services exclusively or primarily to or on behalf of such intermediary, carrier, or contractor; "(ii) prohibit an individual who has staff privileges at the institution

where the treatment involved takes place from serving as a reviewer merely on the basis of having such staff privileges if the existence of such privileges is disclosed to the Secretary and such individual (or authorized representative), and neither party objects; or

"(iii) prohibit receipt of compensation by a reviewing professional from a contractor if the compensation is provided consistent with para-

graph (3).

For purposes of this paragraph, the term 'participation agreement' means an agreement relating to the provision of health care services by the indi-vidual and does not include the provision of services as a reviewer under this subsection.

"(3) LIMITATIONS ON REVIEWER COMPENSATION.—Compensation provided by a qualified independent contractor to a reviewer in connection with a review under this section shall not be contingent on the decision rendered by the re-

"(4) LICENSURE AND EXPERTISE.—Each reviewing professional shall be—
"(A) a physician (allopathic or osteopathic) who is appropriately credentialed or licensed in one or more States to deliver health care services and has medical expertise in the field of practice that is appropriate for the items or services at issue; or

"(B) a health care professional who is legally authorized in one or more States (in accordance with State law or the State regulatory mechanism provided by State law) to furnish the health care items or services at issue and has medical expertise in the field of practice that is appropriate for such items or services.

"(5) RELATED PARTY DEFINED.—For purposes of this section, the term 'related party' means, with respect to a case under this title involving a specific individual entitled to benefits under part A or enrolled under part B, or both, any of the following:

"(A) The Secretary, the medicare administrative contractor involved, or any fiduciary, officer, director, or employee of the Department of Health and Human Services, or of such contractor.

"(B) The individual (or authorized representative). "(C) The health care professional that provides the items or services involved in the case.

"(D) The institution at which the items or services (or treatment) involved in the case are provided.

"(E) The manufacturer of any drug or other item that is included in the items or services involved in the case.

"(F) Any other party determined under any regulations to have a substantial interest in the case involved."

- (3) Reducing minimum number of qualified independent contractors.—Section 1869(c)(4) (42 U.S.C. 1395ff(c)(4)) is amended by striking "not fewer than 12 qualified independent contractors under this subsection" and inserting "with a sufficient number of qualified independent contractors (but not fewer than 4 such contractors) to conduct reconsiderations consistent with the time-frames applicable under this subsection".
- (4) EFFECTIVE DATE.—The amendments made by paragraphs (1) and (2) shall be effective as if included in the enactment of the respective provisions of subtitle C of title V of BIPA. (114 Stat. 2763A–534).
- (5) Transition.—In applying section 1869(g) of the Social Security Act (as added by paragraph (2)), any reference to a medicare administrative contractor shall be deemed to include a reference to a fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and a carrier under section 1842 of such Act (42 U.S.C. 1395u).

SEC. 934. PREPAYMENT REVIEW.

- (a) In General.—Section 1874A, as added by section 911(a)(1) and as amended by sections 912(b), 921(b)(1), and 921(c)(1), is further amended by adding at the end the following new subsection:
 - "(h) CONDUCT OF PREPAYMENT REVIEW.—
 - "(1) CONDUCT OF RANDOM PREPAYMENT REVIEW.—
 - "(A) IN GENERAL.—A medicare administrative contractor may conduct random prepayment review only to develop a contractor-wide or program-wide claims payment error rates or under such additional circumstances as may be provided under regulations, developed in consultation with providers of services and suppliers.
 - "(B) USE OF STANDARD PROTOCOLS WHEN CONDUCTING PREPAYMENT RE-VIEWS.—When a medicare administrative contractor conducts a random prepayment review, the contractor may conduct such review only in accordance with a standard protocol for random prepayment audits developed by the Secretary.
 - "(C) Construction.—Nothing in this paragraph shall be construed as preventing the denial of payments for claims actually reviewed under a random prepayment review.
 - "(D) RANDOM PREPAYMENT REVIEW.—For purposes of this subsection, the term 'random prepayment review' means a demand for the production of records or documentation absent cause with respect to a claim.
 - "(2) LIMITATIONS ON NON-RANDOM PREPAYMENT REVIEW.—
 - "(A) LIMITATIONS ON INITIATION OF NON-RANDOM PREPAYMENT REVIEW.— A medicare administrative contractor may not initiate non-random prepayment review of a provider of services or supplier based on the initial identification by that provider of services or supplier of an improper billing practice unless there is a likelihood of sustained or high level of payment error (as defined in subsection (i)(3)(A)).
 - "(B) TERMINATION OF NON-RANDOM PREPAYMENT REVIEW.—The Secretary shall issue regulations relating to the termination, including termination dates, of non-random prepayment review. Such regulations may vary such a termination date based upon the differences in the circumstances triggering prepayment review.".
 - (b) EFFECTIVE DATE.—
 - (1) IN GENERAL.—Except as provided in this subsection, the amendment made by subsection (a) shall take effect 1 year after the date of the enactment of this Act.
 - (2) DEADLINE FOR PROMULGATION OF CERTAIN REGULATIONS.—The Secretary shall first issue regulations under section 1874A(h) of the Social Security Act, as added by subsection (a), by not later than 1 year after the date of the enactment of this Act.
 - (3) APPLICATION OF STANDARD PROTOCOLS FOR RANDOM PREPAYMENT REVIEW.—Section 1874A(h)(1)(B) of the Social Security Act, as added by subsection (a), shall apply to random prepayment reviews conducted on or after such date (not later than 1 year after the date of the enactment of this Act) as the Secretary shall specify.
- (c) APPLICATION TO FISCAL INTERMEDIARIES AND CARRIERS.—The provisions of section 1874A(h) of the Social Security Act, as added by subsection (a), shall apply to each fiscal intermediary under section 1816 of the Social Security Act (42 U.S.C. 1395h) and each carrier under section 1842 of such Act (42 U.S.C. 1395u) in the same manner as they apply to medicare administrative contractors under such provisions.

SEC. 935. RECOVERY OF OVERPAYMENTS.

(a) IN GENERAL.—Section 1893 (42 U.S.C. 1395ddd) is amended by adding at the end the following new subsection:

"(f) Recovery of Overpayments.

"(1) Use of repayment plans.—

"(A) IN GENERAL.—If the repayment, within 30 days by a provider of services or supplier, of an overpayment under this title would constitute a hardship (as defined in subparagraph (B)), subject to subparagraph (C), upon request of the provider of services or supplier the Secretary shall enter into a plan with the provider of services or supplier for the repayment (through offset or otherwise) of such overpayment over a period of at least 6 months but not longer than 3 years (or not longer than 5 years in the case of extreme hardship, as determined by the Secretary). Interest shall accrue on the balance through the period of repayment. Such plan shall meet terms and conditions determined to be appropriate by the Secretary.

(B) Hardship.

"(i) IN GENERAL.—For purposes of subparagraph (A), the repayment of an overpayment (or overpayments) within 30 days is deemed to constitute a hardship if-

"(I) in the case of a provider of services that files cost reports, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this title to the provider of services for the cost reporting period covered by the most recently submitted cost

report; or
"(II) in the case of another provider of services or supplier, the aggregate amount of the overpayments exceeds 10 percent of the amount paid under this title to the provider of services or supplier

for the previous calendar year.

"(ii) RULE OF APPLICATION.—The Secretary shall establish rules for the application of this subparagraph in the case of a provider of services or supplier that was not paid under this title during the previous year or was paid under this title only during a portion of that year.

"(iii) Treatment of previous overpayments.—If a provider of services or supplier has entered into a repayment plan under subparagraph (A) with respect to a specific overpayment amount, such payment amount under the repayment plan shall not be taken into account under clause (i) with respect to subsequent overpayment amounts.

"(C) EXCEPTIONS.—Subparagraph (A) shall not apply if-

(i) the Secretary has reason to suspect that the provider of services or supplier may file for bankruptcy or otherwise cease to do business or discontinue participation in the program under this title; or

"(ii) there is an indication of fraud or abuse committed against the

program.

"(D) IMMEDIATE COLLECTION IF VIOLATION OF REPAYMENT PLAN.—If a provider of services or supplier fails to make a payment in accordance with a repayment plan under this paragraph, the Secretary may immediately seek to offset or otherwise recover the total balance outstanding (including applicable interest) under the repayment plan.

"(E) RELATION TO NO FAULT PROVISION. -Nothing in this paragraph shall be construed as affecting the application of section 1870(c) (relating to no

adjustment in the cases of certain overpayments). "(2) $\check{\mathbf{L}}$ IMITATION ON RECOUPMENT.-

"(A) IN GENERAL.—In the case of a provider of services or supplier that is determined to have received an overpayment under this title and that seeks a reconsideration by a qualified independent contractor on such determination under section 1869(b)(1), the Secretary may not take any action (or authorize any other person, including any medicare contractor, as defined in subparagraph (C)) to recoup the overpayment until the date the decision on the reconsideration has been rendered. If the provisions of section 1869(b)(1) (providing for such a reconsideration by a qualified independent contractor) are not in effect, in applying the previous sentence any reference to such a reconsideration shall be treated as a reference to a redeter-

mination by the fiscal intermediary or carrier involved. "(B) COLLECTION WITH INTEREST.—Insofar as the determination on such appeal is against the provider of services or supplier, interest on the over-payment shall accrue on and after the date of the original notice of overpayment. Insofar as such determination against the provider of services or supplier is later reversed, the Secretary shall provide for repayment of the amount recouped plus interest at the same rate as would apply under the previous sentence for the period in which the amount was recouped.

(C) MEDICARE CONTRACTOR DEFINED.—For purposes of this subsection, the term 'medicare contractor' has the meaning given such term in section

1889(g).

"(3) LIMITATION ON USE OF EXTRAPOLATION.—A medicare contractor may not use extrapolation to determine overpayment amounts to be recovered by recoupment, offset, or otherwise unless

'(A) there is a sustained or high level of payment error (as defined by the

Secretary by regulation); or

"(B) documented educational intervention has failed to correct the pay-

ment error (as determined by the Secretary).

"(4) Provision of supporting documentation.—In the case of a provider of services or supplier with respect to which amounts were previously overpaid, a medicare contractor may request the periodic production of records or supporting documentation for a limited sample of submitted claims to ensure that the previous practice is not continuing.

(5) Consent settlement reforms.

"(A) IN GENERAL.—The Secretary may use a consent settlement (as de-

fined in subparagraph (D)) to settle a projected overpayment.

"(B) OPPORTUNITY TO SUBMIT ADDITIONAL INFORMATION BEFORE CONSENT SETTLEMENT OFFER.—Before offering a provider of services or supplier a consent settlement, the Secretary shall-

"(i) communicate to the provider of services or supplier-

"(I) that, based on a review of the medical records requested by the Secretary, a preliminary evaluation of those records indicates that there would be an overpayment;

"(II) the nature of the problems identified in such evaluation;

"(III) the steps that the provider of services or supplier should

take to address the problems; and

"(ii) provide for a 45-day period during which the provider of services or supplier may furnish additional information concerning the medical records for the claims that had been reviewed.

"(C) CONSENT SETTLEMENT OFFER.—The Secretary shall review any additional information furnished by the provider of services or supplier under subparagraph (B)(ii). Taking into consideration such information, the Secretary shall determine if there still appears to be an overpayment. If so, the

"(i) shall provide notice of such determination to the provider of services or supplier, including an explanation of the reason for such deter-

mination; and

(ii) in order to resolve the overpayment, may offer the provider of services or supplier-

'(I) the opportunity for a statistically valid random sample; or

"(II) a consent settlement.

The opportunity provided under clause (ii)(I) does not waive any appeal

rights with respect to the alleged overpayment involved.

(D) CONSENT SETTLEMENT DEFINED.—For purposes of this paragraph, the term 'consent settlement' means an agreement between the Secretary and a provider of services or supplier whereby both parties agree to settle a projected overpayment based on less than a statistically valid sample of claims and the provider of services or supplier agrees not to appeal the claims involved.

"(6) NOTICE OF OVER-UTILIZATION OF CODES.—The Secretary shall establish, in consultation with organizations representing the classes of providers of services and suppliers, a process under which the Secretary provides for notice to classes of providers of services and suppliers served by the contractor in cases in which the contractor has identified that particular billing codes may be overutilized by that class of providers of services or suppliers under the programs under this title (or provisions of title XI insofar as they relate to such programs).

"(7) PAYMENT AUDITS.-

"(A) WRITTEN NOTICE FOR POST-PAYMENT AUDITS.—Subject to subparagraph (C), if a medicare contractor decides to conduct a post-payment audit of a provider of services or supplier under this title, the contractor shall provide the provider of services or supplier with written notice (which may be in electronic form) of the intent to conduct such an audit.

"(B) EXPLANATION OF FINDINGS FOR ALL AUDITS.—Subject to subparagraph (C), if a medicare contractor audits a provider of services or supplier under this title, the contractor shall-

"(i) give the provider of services or supplier a full review and explanation of the findings of the audit in a manner that is understandable to the provider of services or supplier and permits the development of an appropriate corrective action plan;

"(ii) inform the provider of services or supplier of the appeal rights under this title as well as consent settlement options (which are at the

discretion of the Secretary)

"(iii) give the provider of services or supplier an opportunity to provide additional information to the contractor; and

"(iv) take into account information provided, on a timely basis, by the

- provider of services or supplier under clause (iii).

 "(C) EXCEPTION.—Subparagraphs (A) and (B) shall not apply if the provision of notice or findings would compromise pending law enforcement activities, whether civil or criminal, or reveal findings of law enforcement-related audits.
- "(8) STANDARD METHODOLOGY FOR PROBE SAMPLING.—The Secretary shall establish a standard methodology for medicare contractors to use in selecting a sample of claims for review in the case of an abnormal billing pattern.". (b) Effective Dates and Deadlines.
 - (1) USE OF REPAYMENT PLANS.—Section 1893(f)(1) of the Social Security Act, as added by subsection (a), shall apply to requests for repayment plans made after the date of the enactment of this Act.
 - (2) LIMITATION ON RECOUPMENT.—Section 1893(f)(2) of the Social Security Act, as added by subsection (a), shall apply to actions taken after the date of the enactment of this Act.
 - (3) USE OF EXTRAPOLATION.—Section 1893(f)(3) of the Social Security Act, as added by subsection (a), shall apply to statistically valid random samples initiated after the date that is 1 year after the date of the enactment of this Act.

 (4) PROVISION OF SUPPORTING DOCUMENTATION.—Section 1893(f)(4) of the So-
 - cial Security Act, as added by subsection (a), shall take effect on the date of the enactment of this Act.
 - (5) CONSENT SETTLEMENT.—Section 1893(f)(5) of the Social Security Act, as added by subsection (a), shall apply to consent settlements entered into after the date of the enactment of this Act.
 - (6) NOTICE OF OVERUTILIZATION.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall first establish the process for notice of overutilization of billing codes under section 1893A(f)(6) of the Social Security Act, as added by subsection (a).
 - (7) PAYMENT AUDITS.—Section 1893A(f)(7) of the Social Security Act, as added by subsection (a), shall apply to audits initiated after the date of the enactment of this Act.
 - (8) STANDARD FOR ABNORMAL BILLING PATTERNS.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall first establish a standard methodology for selection of sample claims for abnormal billing patterns under section 1893(f)(8) of the Social Security Act, as added by subsection (a).

SEC. 936. PROVIDER ENROLLMENT PROCESS; RIGHT OF APPEAL.

- (a) IN GENERAL.—Section 1866 (42 U.S.C. 1395cc) is amended—
 - (1) by adding at the end of the heading the following: "; ENROLLMENT PROC-
 - (2) by adding at the end the following new subsection:
- "(j) Enrollment Process for Providers of Services and Suppliers.—

"(1) Enrollment process.

"(A) IN GENERAL.—The Secretary shall establish by regulation a process for the enrollment of providers of services and suppliers under this title.

"(B) DEADLINES.—The Secretary shall establish by regulation procedures

under which there are deadlines for actions on applications for enrollment (and, if applicable, renewal of enrollment). The Secretary shall monitor the performance of medicare administrative contractors in meeting the dead-lines established under this subparagraph.

(C) CONSULTATION BEFORE CHANGING PROVIDER ENROLLMENT FORMS.— The Secretary shall consult with providers of services and suppliers before making changes in the provider enrollment forms required of such providers and suppliers to be eligible to submit claims for which payment may

be made under this title.

"(2) Hearing rights in cases of denial or non-renewal.—A provider of services or supplier whose application to enroll (or, if applicable, to renew enrollment) under this title is denied may have a hearing and judicial review of such denial under the procedures that apply under subsection (h)(1)(A) to a provider of services that is dissatisfied with a determination by the Secretary.".

(b) Effective Dates.

(1) ENROLLMENT PROCESS.—The Secretary shall provide for the establishment of the enrollment process under section 1866(j)(1) of the Social Security Act, as added by subsection (a)(2), within 6 months after the date of the enactment of this Act.

(2) CONSULTATION.—Section 1866(j)(1)(C) of the Social Security Act, as added by subsection (a)(2), shall apply with respect to changes in provider enrollment forms made on or after January 1, 2004.

(3) HEARING RIGHTS.—Section 1866(j)(2) of the Social Security Act, as added by subsection (a)(2), shall apply to denials occurring on or after such date (not later than 1 year after the date of the enactment of this Act) as the Secretary specifies.

SEC. 937. PROCESS FOR CORRECTION OF MINOR ERRORS AND OMISSIONS WITHOUT PURSUING APPEALS PROCESS.

(a) CLAIMS.—The Secretary shall develop, in consultation with appropriate medicare contractors (as defined in section 1889(g) of the Social Security Act, as inserted by section 301(a)(1)) and representatives of providers of services and suppliers, a process whereby, in the case of minor errors or omissions (as defined by the Secretary) that are detected in the submission of claims under the programs under title XVIII of such Act, a provider of services or supplier is given an opportunity to correct such an error or omission without the need to initiate an appeal. Such process shall include the ability to resubmit corrected claims.

(b) Permitting Use of Corrected and Supplementary Data.—
(1) In general.—Section 1886(d)(10)(D)(vi) (42 U.S.C. 1395ww(d)(10)(D)(vi))

is amended by adding after subclause (II) at the end the following:

"Notwithstanding subclause (I), a hospital may submit, and the Secretary may accept upon verification, data that corrects or supplements the data described in such subclause without regard to whether the corrected or supplementary data relate to a cost report that has been settled.".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to

fiscal years beginning with fiscal year 2004.

(3) Submittal and resubmittal of applications permitted for fiscal YEAR 2004.

(A) In general.—Notwithstanding any other provision of law, a hospital may submit (or resubmit) an application for a change described in section 1886(d)(10)(C)(i)(II) of the Social Security Act for fiscal year 2004 if the hospital demonstrates on a timely basis to the satisfaction of the Secretary that the use of corrected or supplementary data under the amendment made by paragraph (1) would materially affect the approval of such an application.

(B) APPLICATION OF BUDGET NEUTRALITY.—If one or more hospital's applications are approved as a result of paragraph (1) and subparagraph (A) for fiscal year 2004, the Secretary shall make a proportional adjustment in the standardized amounts determined under section 1886(d)(3) of the Social Security Act (42 U.S.C. 1395ww(d)(3)) for fiscal year 2004 to assure that approval of such applications does not result in aggregate payments under section 1886(d) of such Act that are greater or less than those that would otherwise be made if paragraph (1) and subparagraph (A) did not apply.

SEC. 938. PRIOR DETERMINATION PROCESS FOR CERTAIN ITEMS AND SERVICES; ADVANCE BENEFICIARY NOTICES.

(a) In General.—Section 1869 (42 U.S.C. 1395ff(b)), as amended by sections 521 and 522 of BIPA and section 933(d)(2)(B), is further amended by adding at the end the following new subsection:

e following new subsection:

"(h) PRIOR DETERMINATION PROCESS FOR CERTAIN ITEMS AND SERVICES.—

"(1) ESTABLISHMENT OF PROCESS.—

"(A) IN GENERAL.—With respect to a medicare administrative contractor that has a contract under section 1874A that provides for making payments under this title with respect to eligible items and services described in subparagraph (C), the Secretary shall establish a prior determination process that meets the requirements of this subsection and that shall be applied by such contractor in the case of eligible requesters.

"(B) ELIGIBLE REQUESTER.—For purposes of this subsection, each of the

following shall be an eligible requester:

"(i) A physician, but only with respect to eligible items and services for which the physician may be paid directly.
"(ii) An individual entitled to benefits under this title, but only with respect to an item or service for which the individual receives, from the physician who may be paid directly for the item or service, an advance beneficiary notice under section 1879(a) that payment may not be made (or may no longer be made) for the item or service under this title.

"(C) ELIGIBLE ITEMS AND SERVICES.—For purposes of this subsection and subject to paragraph (2), eligible items and services are items and services which are physicians' services (as defined in paragraph (4)(A) of section 1848(f) for purposes of calculating the sustainable growth rate under such

section).

"(2) Secretarial flexibility.—The Secretary shall establish by regulation reasonable limits on the categories of eligible items and services for which a prior determination of coverage may be requested under this subsection. In establishing such limits, the Secretary may consider the dollar amount involved with respect to the item or service, administrative costs and burdens, and other relevant factors.

"(3) Request for prior determination.—

"(A) IN GENERAL.—Subject to paragraph (2), under the process established under this subsection an eligible requester may submit to the contractor a request for a determination before the formal determination of the contractor and the contractor and the contractor are contracted to the contractor and the contractor are contracted to the contractor and contractor are contracted to the contractor are contracted to the contractor and contractor are contracted to the cont request for a determination, before the furnishing of an eligible item or service involved as to whether the item or service is covered under this title consistent with the applicable requirements of section 1862(a)(1)(A) (relat-

ing to medical necessity).

(B) ACCOMPANYING DOCUMENTATION.—The Secretary may require that the request be accompanied by a description of the item or service, supporting documentation relating to the medical necessity for the item or service, and any other appropriate documentation. In the case of a request submitted by an eligible requester who is described in paragraph (1)(B)(ii), the Secretary may require that the request also be accompanied by a copy of the advance beneficiary notice involved.

"(4) Response to request.

"(A) IN GENERAL.—Under such process, the contractor shall provide the eligible requester with written notice of a determination as to whether—

"(i) the item or service is so covered;

"(ii) the item or service is not so covered; or

"(iii) the contractor lacks sufficient information to make a coverage determination.

If the contractor makes the determination described in clause (iii), the contractor shall include in the notice a description of the additional informa-

tion required to make the coverage determination.

"(B) DEADLINE TO RESPOND.—Such notice shall be provided within the same time period as the time period applicable to the contractor providing notice of initial determinations on a claim for benefits under subsection

"(C) Informing beneficiary in case of physician request.—In the case of a request in which an eligible requester is not the individual described in paragraph (1)(B)(ii), the process shall provide that the individual to whom the item or service is proposed to be furnished shall be informed of any determination described in clause (ii) (relating to a determination of non-coverage) and the right (referred to in paragraph (6)(B)) to obtain the item or service and have a claim submitted for the item or service.

"(5) Effect of Determinations.

"(A) BINDING NATURE OF POSITIVE DETERMINATION.—If the contractor makes the determination described in paragraph (4)(A)(i), such determination shall be binding on the contractor in the absence of fraud or evidence of misrepresentation of facts presented to the contractor.

"(B) NOTICE AND RIGHT TO REDETERMINATION IN CASE OF A DENIAL.—
"(i) IN GENERAL.—If the contractor makes the determination de-

scribed in paragraph (4)(A)(ii)—

"(I) the eligible requester has the right to a redetermination by the contractor on the determination that the item or service is not so covered; and

"(II) the contractor shall include in notice under paragraph (4)(A) a brief explanation of the basis for the determination, including on what national or local coverage or noncoverage determination (if any) the determination is based, and the right to such a redetermination.

"(ii) Deadline for redeterminations.—The contractor shall complete and provide notice of such redetermination within the same time period as the time period applicable to the contractor providing notice of redeterminations relating to a claim for benefits under subsection (a)(3)(C)(ii)

"(6) LIMITATION ON FURTHER REVIEW.—
"(A) IN GENERAL.—Contractor determinations described in paragraph (4)(A)(ii) or (4)(A)(iii) (and redeterminations made under paragraph (5)(B)), relating to pre-service claims are not subject to further administrative ap-

peal or judicial review under this section or otherwise.

"(B) DECISION NOT TO SEEK PRIOR DETERMINATION OR NEGATIVE DETER-MINATION DOES NOT IMPACT RIGHT TO OBTAIN SERVICES, SEEK REIMBURSE-MENT, OR APPEAL RIGHTS.—Nothing in this subsection shall be construed as

affecting the right of an individual who—

"(i) decides not to seek a prior determination under this subsection with respect to items or services; or

"(ii) seeks such a determination and has received a determination de-

scribed in paragraph (4)(A)(ii),

from receiving (and submitting a claim for) such items services and from obtaining administrative or judicial review respecting such claim under the other applicable provisions of this section. Failure to seek a prior determination under this subsection with respect to items and services shall not be taken into account in such administrative or judicial review.

"(C) NO PRIOR DETERMINATION AFTER RECEIPT OF SERVICES.—Once an individual is provided items and services, there shall be no prior determina-

tion under this subsection with respect to such items or services.".

(b) Effective Date; Transition

(1) EFFECTIVE DATE.—The Secretary shall establish the prior determination process under the amendment made by subsection (a) in such a manner as to provide for the acceptance of requests for determinations under such process filed not later than 18 months after the date of the enactment of this Act

(2) Transition.—During the period in which the amendment made by subsection (a) has become effective but contracts are not provided under section 1874A of the Social Security Act with medicare administrative contractors, any reference in section 1869(g) of such Act (as added by such amendment) to such a contractor is deemed a reference to a fiscal intermediary or carrier with an agreement under section 1816, or contract under section 1842, respectively, of

(3) LIMITATION ON APPLICATION TO SGR.—For purposes of applying section 1848(f)(2)(D) of the Social Security Act (42 U.S.C. 1395w-4(f)(2)(D)), the amendment made by subsection (a) shall not be considered to be a change in law or regulation.

(c) Provisions Relating to Advance Beneficiary Notices; Report on Prior

DETERMINATION PROCESS.

(1) Data collection.—The Secretary shall establish a process for the collection of information on the instances in which an advance beneficiary notice (as defined in paragraph (5)) has been provided and on instances in which a beneficiary indicates on such a notice that the beneficiary does not intend to seek to have the item or service that is the subject of the notice furnished.

(2) OUTREACH AND EDUCATION.—The Secretary shall establish a program of outreach and education for beneficiaries and providers of services and other persons on the appropriate use of advance beneficiary notices and coverage policies

under the medicare program.

(3) GAO REPORT REPORT ON USE OF ADVANCE BENEFICIARY NOTICES.—Not later than 18 months after the date on which section 1869(g) of the Social Security Act (as added by subsection (a)) takes effect, the Comptroller General of the United States shall submit to Congress a report on the use of advance beneficiary notices under title XVIII of such Act. Such report shall include information concerning the providers of services and other persons that have provided such notices and the response of beneficiaries to such notices.

(4) GAO REPORT ON USE OF PRIOR DETERMINATION PROCESS.—Not later than 18 months after the date on which section 1869(g) of the Social Security Act (as added by subsection (a)) takes effect, the Comptroller General of the United States shall submit to Congress a report on the use of the prior determination

process under such section. Such report shall include-

(A) information concerning the types of procedures for which a prior determination has been sought, determinations made under the process, and changes in receipt of services resulting from the application of such process;

- (B) an evaluation of whether the process was useful for physicians (and other suppliers) and beneficiaries, whether it was timely, and whether the amount of information required was burdensome to physicians and bene-
- (5) ADVANCE BENEFICIARY NOTICE DEFINED.—In this subsection, the term "advance beneficiary notice" means a written notice provided under section 1879(a) of the Social Security Act (42 U.S.C. 1395pp(a)) to an individual entitled to benefits under part A or B of title XVIII of such Act before items or services are furnished under such part in cases where a provider of services or other person that would furnish the item or service believes that payment will not be made for some or all of such items or services under such title.

Subtitle V—Miscellaneous Provisions

SEC. 941. POLICY DEVELOPMENT REGARDING EVALUATION AND MANAGEMENT (E & M) DOC-UMENTATION GUIDELINES.

- (a) In General.—The Secretary may not implement any new documentation guidelines for, or clinical examples of, evaluation and management physician services under the title XVIII of the Social Security Act on or after the date of the enactment of this Act unless the Secretary-
 - (1) has developed the guidelines in collaboration with practicing physicians (including both generalists and specialists) and provided for an assessment of the proposed guidelines by the physician community;
 - (2) has established a plan that contains specific goals, including a schedule,

for improving the use of such guidelines;

- (3) has conducted appropriate and representative pilot projects under subsection (b) to test modifications to the evaluation and management documentation guidelines;
- (4) finds that the objectives described in subsection (c) will be met in the implementation of such guidelines; and

(5) has established, and is implementing, a program to educate physicians on the use of such guidelines and that includes appropriate outreach.

The Secretary shall make changes to the manner in which existing evaluation and management documentation guidelines are implemented to reduce paperwork burdens on physicians.

- (b) PILOT PROJECTS TO TEST EVALUATION AND MANAGEMENT DOCUMENTATION Guidelines
 - (1) IN GENERAL.—The Secretary shall conduct under this subsection appropriate and representative pilot projects to test new evaluation and management
 - (2) LENGTH AND CONSULTATION.—Each pilot project under this subsection shall—

(A) be voluntary;

(B) be of sufficient length as determined by the Secretary to allow for preparatory physician and medicare contractor education, analysis, and use and assessment of potential evaluation and management guidelines; and

(C) be conducted, in development and throughout the planning and operational stages of the project, in consultation with practicing physicians (including both generalists and specialists).

(3) RANGE OF PILOT PROJECTS.—Of the pilot projects conducted under this

- subsection-
 - (A) at least one shall focus on a peer review method by physicians (not employed by a medicare contractor) which evaluates medical record information for claims submitted by physicians identified as statistical outliers relative to definitions published in the Current Procedures Terminology (CPT) code book of the American Medical Association;
 - (B) at least one shall focus on an alternative method to detailed guidelines based on physician documentation of face to face encounter time with a patient;
 - (C) at least one shall be conducted for services furnished in a rural area and at least one for services furnished outside such an area; and
 - (D) at least one shall be conducted in a setting where physicians bill under physicians' services in teaching settings and at least one shall be conducted in a setting other than a teaching setting.
- (4) BANNING OF TARGETING OF PILOT PROJECT PARTICIPANTS.—Data collected under this subsection shall not be used as the basis for overpayment demands or post-payment audits. Such limitation applies only to claims filed as part of

the pilot project and lasts only for the duration of the pilot project and only as long as the provider is a participant in the pilot project.

(5) STUDY OF IMPACT.—Each pilot project shall examine the effect of the new evaluation and management documentation guidelines on-

(A) different types of physician practices, including those with fewer than

10 full-time-equivalent employees (including physicians); and

(B) the costs of physician compliance, including education, implementation, auditing, and monitoring.

(6) PERIODIC REPORTS.—The Secretary shall submit to Congress periodic reports on the pilot projects under this subsection.

(c) OBJECTIVES FOR EVALUATION AND MANAGEMENT GUIDELINES.—The objectives for modified evaluation and management documentation guidelines developed by the Secretary shall be to—

(1) identify clinically relevant documentation needed to code accurately and

assess coding levels accurately;
(2) decrease the level of non-clinically pertinent and burdensome documentation time and content in the physician's medical record;

(3) increase accuracy by reviewers; and (4) educate both physicians and reviewers.

- (d) STUDY OF SIMPLER, ALTERNATIVE SYSTEMS OF DOCUMENTATION FOR PHYSICIAN
 - (1) Study.—The Secretary shall carry out a study of the matters described in paragraph (2).

(2) MATTERS DESCRIBED.—The matters referred to in paragraph (1) are-

(A) the development of a simpler, alternative system of requirements for documentation accompanying claims for evaluation and management physician services for which payment is made under title XVIII of the Social Security Act; and

(B) consideration of systems other than current coding and documenta-

tion requirements for payment for such physician services.

(3) CONSULTATION WITH PRACTICING PHYSICIANS.—In designing and carrying out the study under paragraph (1), the Secretary shall consult with practicing physicians, including physicians who are part of group practices and including both generalists and specialists.

(4) APPLICATION OF HIPAA UNIFORM CODING REQUIREMENTS.—In developing an alternative system under paragraph (2), the Secretary shall consider requirements of administrative simplification under part C of title XI of the Social Se-

curity Act.

(5) REPORT TO CONGRESS.—(A) Not later than October 1, 2005, the Secretary shall submit to Congress a report on the results of the study conducted under paragraph (1).

(B) The Medicare Payment Advisory Commission shall conduct an analysis of the results of the study included in the report under subparagraph (A) and shall

submit a report on such analysis to Congress.

(e) STUDY ON APPROPRIATE CODING OF CERTAIN EXTENDED OFFICE VISITS.—The Secretary shall conduct a study of the appropriateness of coding in cases of extended office visits in which there is no diagnosis made. Not later than October 1, 2005, the Secretary shall submit a report to Congress on such study and shall include recommendations on how to code appropriately for such visits in a manner that takes into account the amount of time the physician spent with the patient.

(f) DEFINITIONS.—In this section—

(1) the term "rural area" has the meaning given that term in section 1886(d)(2)(D) of the Social Security Act, 42 U.S.C. 1395ww(d)(2)(D); and

(2) the term "teaching settings" are those settings described in section 415.150 of title 42, Code of Federal Regulations.

SEC. 942. IMPROVEMENT IN OVERSIGHT OF TECHNOLOGY AND COVERAGE.

(a) COUNCIL FOR TECHNOLOGY AND INNOVATION.—Section 1868 (42 U.S.C. 1395ee). as amended by section 921(a), is amended by adding at the end the following new subsection:

(c) COUNCIL FOR TECHNOLOGY AND INNOVATION.—
(1) ESTABLISHMENT.—The Secretary shall establish a Council for Technology and Innovation within the Centers for Medicare & Medicaid Services (in this section referred to as 'CMS')

"(2) COMPOSITION.—The Council shall be composed of senior CMS staff and clinicians and shall be chaired by the Executive Coordinator for Technology and Innovation (appointed or designated under paragraph (4)).

"(3) DUTIES.—The Council shall coordinate the activities of coverage, coding, and payment processes under this title with respect to new technologies and procedures, including new drug therapies, and shall coordinate the exchange of information on new technologies between CMS and other entities that make similar decisions.

- "(4) EXECUTIVE COORDINATOR FOR TECHNOLOGY AND INNOVATION.—The Secretary shall appoint (or designate) a noncareer appointee (as defined in section 3132(a)(7) of title 5, United States Code) who shall serve as the Executive Coordinator for Technology and Innovation. Such executive coordinator shall report to the Administrator of CMS, shall chair the Council, shall oversee the execution of its duties, and shall serve as a single point of contact for outside groups and entities regarding the coverage, coding, and payment processes under this
- (b) Methods for Determining Payment Basis For New Lab Tests.—Section 1833(h) (42 U.S.C. 1395l(h)) is amended by adding at the end the following:

"(8)(A) The Secretary shall establish by regulation procedures for determining the basis for, and amount of, payment under this subsection for any clinical diagnostic laboratory test with respect to which a new or substantially revised HCPCS code is assigned on or after January 1, 2005 (in this paragraph referred to as 'new tests'). "(B) Determinations under subparagraph (A) shall be made only after the Sec-

retary—

"(i) makes available to the public (through an Internet site and other appropriate mechanisms) a list that includes any such test for which establishment

of a payment amount under this subsection is being considered for a year;
"(ii) on the same day such list is made available, causes to have published in the Federal Register notice of a meeting to receive comments and recommendations (and data on which recommendations are based) from the public on the appropriate basis under this subsection for establishing payment amounts for the tests on such list;

"(iii) not less than 30 days after publication of such notice convenes a meeting, that includes representatives of officials of the Centers for Medicare & Medicaid Services involved in determining payment amounts, to receive such comments and recommendations (and data on which the recommendations are

"(iv) taking into account the comments and recommendations (and accompanying data) received at such meeting, develops and makes available to the public (through an Internet site and other appropriate mechanisms) a list of proposed determinations with respect to the appropriate basis for establishing a payment amount under this subsection for each such code, together with an explanation of the reasons for each such determination, the data on which the determinations are based, and a request for public written comments on the proposed determination; and

v) taking into account the comments received during the public comment pe riod, develops and makes available to the public (through an Internet site and other appropriate mechanisms) a list of final determinations of the payment amounts for such tests under this subsection, together with the rationale for each such determination, the data on which the determinations are based, and

responses to comments and suggestions received from the public.

"(C) Under the procedures established pursuant to subparagraph (A), the Sec-

retary shall—

"(i) set forth the criteria for making determinations under subparagraph (A);

"(ii) make available to the public the data (other than proprietary data) considered in making such determinations.

"(D) The Secretary may convene such further public meetings to receive public comments on payment amounts for new tests under this subsection as the Secretary

deems appropriate.

"(E) For purposes of this paragraph:

"(i) The term 'HCPCS' refers to the Health Care Procedure Coding System. "(ii) A code shall be considered to be 'substantially revised' if there is a substantive change to the definition of the test or procedure to which the code applies (such as a new analyte or a new methodology for measuring an existing analyte-specific test)."

(c) GAO STUDY ON IMPROVEMENTS IN EXTERNAL DATA COLLECTION FOR USE IN THE MEDICARE INPATIENT PAYMENT SYSTEM.

(1) STUDY.—The Comptroller General of the United States shall conduct a study that analyzes which external data can be collected in a shorter time frame by the Centers for Medicare & Medicaid Services for use in computing payments for inpatient hospital services. The study may include an evaluation of the feasibility and appropriateness of using of quarterly samples or special surveys or any other methods. The study shall include an analysis of whether other executive agencies, such as the Bureau of Labor Statistics in the Department of Commerce, are best suited to collect this information.

(2) Report.—By not later than October 1, 2004, the Comptroller General

shall submit a report to Congress on the study under paragraph (1).

(d) Process for Adoption of ICD Codes as Data Standard.—Section 1172(f) (42 U.S.C. 1320d–1(f)) is amended by inserting after the first sentence the following: "Notwithstanding the preceding sentence, if the National Committee on Vital and Health Statistics has not made a recommendation to the Secretary before the date of the enactment of this sentence, with respect to the adoption of the International Classification of Diseases, 10th Revision, Procedure Coding System ('ICD-10-PCS') and the International Classification of Diseases, 10th Revision, Clinical Modification ('ICD–10–CM') as a standard under this part for the reporting of diagnoses, the Secretary may implement ICD-10-PCS only with respect to inpatient services as such a standard.".

SEC. 943. TREATMENT OF HOSPITALS FOR CERTAIN SERVICES UNDER MEDICARE SECONDARY PAYOR (MSP) PROVISIONS.

(a) IN GENERAL.—The Secretary shall not require a hospital (including a critical access hospital) to ask questions (or obtain information) relating to the application of section 1862(b) of the Social Security Act (relating to medicare secondary payor provisions) in the case of reference laboratory services described in subsection (b), if the Secretary does not impose such requirement in the case of such services furnished by an independent laboratory

(b) REFERENCE LABORATORY SERVICES DESCRIBED.—Reference laboratory services described in this subsection are clinical laboratory diagnostic tests (or the interpretation of such tests, or both) furnished without a face-to-face encounter between the individual entitled to benefits under part A or enrolled under part B, or both, and the hospital involved and in which the hospital submits a claim only for such test

or interpretation.

SEC. 944. EMTALA IMPROVEMENTS.

(a) Payment for EMTALA-Mandated Screening and Stabilization Serv-

(1) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is amended by inserting

after subsection (c) the following new subsection:

"(d) For purposes of subsection (a)(1)(A), in the case of any item or service that is required to be provided pursuant to section 1867 to an individual who is entitled to benefits under this title, determinations as to whether the item or service is reasonable and necessary shall be made on the basis of the information available to the treating physician or practitioner (including the patient's presenting symptoms or complaint) at the time the item or service was ordered or furnished by the physician or practitioner (and not on the patient's principal diagnosis). When making such determinations with respect to such an item or service, the Secretary shall not consider the frequency with which the item or service was provided to the patient before or after the time of the admission or visit.

(2) Effective date.—The amendment made by paragraph (1) shall apply to

items and services furnished on or after January 1, 2004.
(b) NOTIFICATION OF PROVIDERS WHEN EMTALA INVESTIGATION CLOSED.—Section 1867(d) (42 U.S.C. 42 U.S.C. 1395dd(d)) is amended by adding at the end the following new paragraph:

(4) NOTICE UPON CLOSING AN INVESTIGATION.—The Secretary shall establish a procedure to notify hospitals and physicians when an investigation under this

section is closed."

(c) PRIOR REVIEW BY PEER REVIEW ORGANIZATIONS IN EMTALA CASES INVOLVING TERMINATION OF PARTICIPATION.

(1) IN GENERAL.—Section 1867(d)(3) (42 U.S.C. 1395dd(d)(3)) is amended—

(A) in the first sentence, by inserting "or in terminating a hospital's participation under this title" after "in imposing sanctions under paragraph

(1)"; and

(B) by adding at the end the following new sentences: "Except in the case in which a delay would jeopardize the health or safety of individuals, the Secretary shall also request such a review before making a compliance determination as part of the process of terminating a hospital's participation under this title for violations related to the appropriateness of a medical screening examination, stabilizing treatment, or an appropriate transfer as required by this section, and shall provide a period of 5 days for such review. The Secretary shall provide a copy of the organization's report to the hospital or physician consistent with confidentiality requirements imposed on the organization under such part B.".

(2) Effective date.—The amendments made by paragraph (1) shall apply to terminations of participation initiated on or after the date of the enactment of this Act.

SEC. 945. EMERGENCY MEDICAL TREATMENT AND ACTIVE LABOR ACT (EMTALA) TECHNICAL ADVISORY GROUP.

- (a) ESTABLISHMENT.—The Secretary shall establish a Technical Advisory Group (in this section referred to as the "Advisory Group") to review issues related to the Emergency Medical Treatment and Labor Act (EMTALA) and its implementation. In this section, the term "EMTALA" refers to the provisions of section 1867 of the Social Security Act (42 U.S.C. 1395dd).
- (b) MEMBERSHIP.—The Advisory Group shall be composed of 19 members, including the Administrator of the Centers for Medicare & Medicaid Services and the Inspector General of the Department of Health and Human Services and of which—
 - (1) 4 shall be representatives of hospitals, including at least one public hospital, that have experience with the application of EMTALA and at least 2 of which have not been cited for EMTALA violations;
 - (2) 7 shall be practicing physicians drawn from the fields of emergency medicine, cardiology or cardiothoracic surgery, orthopedic surgery, neurosurgery, pediatrics or a pediatric subspecialty, obstetrics-gynecology, and psychiatry, with not more than one physician from any particular field;
 - (3) 2 shall represent patients;
 - (4) 2 shall be staff involved in EMTALA investigations from different regional offices of the Centers for Medicare & Medicaid Services; and
 - (5) 1 shall be from a State survey office involved in EMTALA investigations and 1 shall be from a peer review organization, both of whom shall be from areas other than the regions represented under paragraph (4).

In selecting members described in paragraphs (1) through (3), the Secretary shall consider qualified individuals nominated by organizations representing providers and patients.

(c) GENERAL RESPONSIBILITIES.—The Advisory Group—

(1) shall review EMTALA regulations;

- (2) may provide advice and recommendations to the Secretary with respect to those regulations and their application to hospitals and physicians;
- (3) shall solicit comments and recommendations from hospitals, physicians, and the public regarding the implementation of such regulations; and
- (4) may disseminate information on the application of such regulations to hospitals, physicians, and the public.
- (d) Administrative Matters.—
 - (1) CHAIRPERSON.—The members of the Advisory Group shall elect a member to serve as chairperson of the Advisory Group for the life of the Advisory Group.
 - (2) MEETINGS.—The Advisory Group shall first meet at the direction of the Secretary. The Advisory Group shall then meet twice per year and at such other times as the Advisory Group may provide.
- (e) TERMINATION.—The Advisory Group shall terminate 30 months after the date of its first meeting.
- (f) WAIVER OF ADMINISTRATIVE LIMITATION.—The Secretary shall establish the Advisory Group 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. 946. AUTHORIZING USE OF ARRANGEMENTS TO PROVIDE CORE HOSPICE SERVICES IN CERTAIN CIRCUMSTANCES.

- (a) IN GENERAL.—Section 1861(dd)(5) (42 U.S.C. 1395x(dd)(5)) is amended by adding at the end the following:
- ing at the end the following: "(D) In extraordinary, exigent, or other non-routine circumstances, such as unanticipated periods of high patient loads, staffing shortages due to illness or other events, or temporary travel of a patient outside a hospice program's service area, a hospice program may enter into arrangements with another hospice program for the provision by that other program of services described in paragraph (2)(A)(ii)(I). The provisions of paragraph (2)(A)(ii)(II) shall apply with respect to the services provided under such arrangements.
- "(E) A hospice program may provide services described in paragraph (1)(A) other than directly by the program if the services are highly specialized services of a registered professional nurse and are provided non-routinely and so infrequently so that the provision of such services directly would be impracticable and prohibitively expensive."
- (b) CONFORMING PAYMENT PROVISION.—Section 1814(i) (42 U.S.C. 1395f(i)) is amended by adding at the end the following new paragraph:

"(4) In the case of hospice care provided by a hospice program under arrangements under section 1861(dd)(5)(D) made by another hospice program, the hospice program that made the arrangements shall bill and be paid for the hospice care."

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to hospice care provided on or after the date of the enactment of this Act.

SEC. 947. APPLICATION OF OSHA BLOODBORNE PATHOGENS STANDARD TO CERTAIN HOS-PITALS.

- (a) IN GENERAL.—Section 1866 (42 U.S.C. 1395cc) is amended—
 - (1) in subsection (a)(1)-

(A) in subparagraph (R), by striking "and" at the end;

- (B) in subparagraph (S), by striking the period at the end and inserting
- (C) by inserting after subparagraph (S) the following new subparagraph: "(T) in the case of hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970, 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

(2) by adding at the end of subsection (b) the following new paragraph:

"(4)(A) A hospital that fails to comply with the requirement of subsection (a)(1)(T) (relating to the Bloodborne Pathogens standard) is subject to a civil money penalty in an amount described in subparagraph (B), but is not subject to termination of an agreement under this section.

"(B) The amount referred to in subparagraph (A) is an amount that is similar to the amount of civil penalties that may be imposed under section 17 of the Occupational Safety and Health Act of 1970 for a violation of the Bloodborne Pathogens standard referred to in subsection (a)(1)(T) by a hospital that is subject to the provisions of such Act.

"(C) A civil money penalty under this paragraph 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) EFFECTIVE DATE.—The amendments made by this subsection (a) shall apply to hospitals as of July 1, 2004.

SEC. 948. BIPA-RELATED TECHNICAL AMENDMENTS AND CORRECTIONS.

- (a) TECHNICAL AMENDMENTS RELATING TO ADVISORY COMMITTEE UNDER BIPA SECTION 522.—(1) Subsection (i) of section 1114 (42 U.S.C. 1314)-
 - (A) is transferred to section 1862 and added at the end of such section; and (B) is redesignated as subsection (j).
 - (2) Section 1862 (42 U.S.C. 1395y) is amended—
 - (A) in the last sentence of subsection (a), by striking "established under section 1114(f)"; and
 - (B) in subsection (j), as so transferred and redesignated—
- (i) by striking "under subsection (f)"; and
 (ii) by striking "section 1862(a)(1)" and inserting "subsection (a)(1)".

 (b) TERMINOLOGY CORRECTIONS.—(1) Section 1869(c)(3)(I)(ii) (42 U.S.C. 1395ff(c)(3)(I)(ii)), as amended by section 521 of BIPA, is amended—
 - (A) in subclause (III), by striking "policy" and inserting "determination"; and (B) in subclause (IV), by striking "medical review policies" and inserting "cov-
 - erage determinations'
- (2) Section 1852(a)(2)(C) (42 U.S.C. 1395w-22(a)(2)(C)) is amended by striking "policy" and "POLICY" and inserting "determination" each place it appears and "DETERMINATION", respectively.
- (c) REFERENCE CORRECTIONS.—Section 1869(f)(4) (42 U.S.C. 1395ff(f)(4)), as added by section 522 of BIPA, is amended-
 - (1) in subparagraph (A)(iv), by striking "subclause (I), (II), or (III)" and inserting "clause (i), (ii), or (iii)"

 - (2) in subparagraph (B), by striking "clause (i)(IV)" and "clause (i)(III)" and inserting "subparagraph (A)(iv)" and "subparagraph (A)(iii)", respectively; and (3) in subparagraph (C), by striking "clause (i)", "subclause (IV)" and "subparagraph (A)" and inserting "subparagraph (A)", "clause (iv)" and "paragraph (I)(A)", respectively each place it appears.
- (d) OTHER CORRECTIONS.—Effective as if included in the enactment of section 521(c) of BIPA, section 1154(e) (42 U.S.C. 1320c–3(e)) is amended by striking paragraph (5).
- (e) Effective Date.—Except as otherwise provided, the amendments made by this section shall be effective as if included in the enactment of BIPA.

SEC. 949. CONFORMING AUTHORITY TO WAIVE A PROGRAM EXCLUSION.

The first sentence of section 1128(c)(3)(B) (42 U.S.C. 1320a-7(c)(3)(B)) is amended to read as follows: "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, the Secretary may 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.'

SEC. 950. TREATMENT OF CERTAIN DENTAL CLAIMS.

(a) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is amended by adding after sub-

section (g) the following new subsection:

"(h)(1) Subject to paragraph (2), a group health plan (as defined in subsection (a)(1)(A)(v)) providing supplemental or secondary coverage to individuals also entitled to services under this title shall not require a medicare claims determination under this title for dental benefits specifically excluded under subsection (a)(12) as a condition of making a claims determination for such benefits under the group

health plan.

"(2) A group health plan may require a claims determination under this title in cases involving or appearing to involve inpatient dental hospital services or dental services expressly covered under this title pursuant to actions taken by the Sec-

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date that is 60 days after the date of the enactment of this Act.

SEC. 951. FURNISHING HOSPITALS WITH INFORMATION TO COMPUTE DSH FORMULA.

Beginning not later than 1 year after the date of the enactment of this Act, the Secretary shall furnish to subsection (d) hospitals (as defined in section 1886(d)(1)(B) of the Social Security Act, 42 U.S.C. 1395ww(d)(1)(B)) the data necessary for such hospitals to compute the number of patient days described in subclause (II) of section 1886(d)(5)(F)(v) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(F)(v)) used in computing the disproportionate patient percentage under such section for that hospital. Such data shall also be furnished to other hospitals. pitals which would qualify for additional payments under part A of title XVIII of the Social Security Act on the basis of such data.

SEC. 952. REVISIONS TO REASSIGNMENT PROVISIONS.

(a) IN GENERAL.—Section 1842(b)(6)(A) (42 U.S.C. 1395u(b)(6)(A)) is amended by striking "or (ii) (where the service was provided in a hospital, critical access hospital, clinic, or other facility) to the facility in which the service was provided if there is a contractual arrangement between such physician or other person and such facility under which such facility submits the bill for such service," and inserting "or (ii) where the service was provided under a contractual arrangement between such physician or other person and an entity (as defined by the Secretary), to the entity if, under the contractual arrangement, the entity submits the bill for the service and the contractual arrangement meets such other program integrity and other safeguards as the Secretary may determine to be appropriate,

(b) Conforming Amendment.—The second sentence of section 1842(b)(6) (42 U.S.C. 1395u(b)(6)) is amended by striking "except to an employer or facility" and

inserting "except to an employer, entity, or other person".

(c) Effective Date.—The amendments made by section shall apply to payments made on or after the date of the enactment of this Act.

(a) GAO REPORTS ON THE PHYSICIAN COMPENSATION.-

(1) SUSTAINABLE GROWTH RATE AND UPDATES.—Not later than 6 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 appropriateness of the updates in the conversion factor under subsection (d)(3) of section 1848 of the Social Security Act (42 U.S.C. 1395w-4), including the appropriateness of the sustainable growth rate formula under subsection (f) of such section for 2002 and succeeding years. Such report shall examine the stability and predictability of such updates and rate and alternatives for the use of such rate in the updates.

(2) Physician compensation generally.—Not later than 12 months after the date of the enactment of this Act, the Comptroller General shall submit to Congress a report on all aspects of physician compensation for services furnished under title XVIII of the Social Security Act, and how those aspects interact and the effect on appropriate compensation for physician services. Such report shall review alternatives for the physician fee schedule under section 1848 of such title (42 U.S.C. 1395w-4).
(b) Annual Publication of List of National Coverage Determinations.—The

Secretary shall provide, in an appropriate annual publication available to the public, a list of national coverage determinations made under title XVIII of the Social Security Act in the previous year and information on how to get more information with

respect to such determinations.

(c) GAO REPORT ON FLEXIBILITY IN APPLYING HOME HEALTH CONDITIONS OF PARTICIPATION TO PATIENTS WHO ARE NOT MEDICARE BENEFICIARIES.—Not later than 6 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 implications if there were flexibility in the application of the medicare conditions of participation for home health agencies with respect to groups or types of patients who are not medicare beneficiaries. The report shall include an analysis of the potential impact of such flexible application on clinical operations and the recipients of such services and an analysis of methods for menitoring the application of methods for menitoring the application of methods for menitoring the application of the such services and an analysis of methods for menitoring the application of methods for menitoring the application of methods for menitoring the application of the such services and an analysis of methods for menitoring the application of the such services and application of the such services are such services and services are such services and application of the such services are such services and services are such services are such services and services are such services and services are such services are such services and services are such services are such services are such services are such services and services are such services are such services and services are such services are s and an analysis of methods for monitoring the quality of care provided to such re-

(d) OIG REPORT ON NOTICES RELATING TO USE OF HOSPITAL LIFETIME RESERVE DAYS.—Not later than 1 year after the date of the enactment of this Act, the Inspector General of the Department of Health and Human Services shall submit a report

to Congress on-

(1) the extent to which hospitals provide notice to medicare beneficiaries in accordance with applicable requirements before they use the 60 lifetime reserve days described in section 1812(a)(1) of the Social Security Act (42 U.S.C. 1395d(a)(1)); and

(2) the appropriateness and feasibility of hospitals providing a notice to such beneficiaries before they completely exhaust such lifetime reserve days.

TITLE X—MEDICAID

SEC. 1001. MEDICAID DISPROPORTIONATE SHARE HOSPITAL (DSH) PAYMENTS.

Section 1923(f)(3) (42 U.S.C. 1396r-4(f)(3)) is amended-

(1) in subparagraph (A), by striking "subparagraph (B)" and inserting "subparagraphs (B) and (C)"; and

(2) by adding at the end the following new subparagraphs:

"(C) SPECIAL, TEMPORARY INCREASE IN ALLOTMENTS ON A ONE-TIME, Non-cumulative basis.—The DSH allotment for any State—
"(i) for fiscal year 2004 is equal to 106 percent of the DSH allotment

for the State for fiscal year 2003 under this paragraph, notwith-standing subparagraph (B); and

"(ii) for each succeeding fiscal year is equal to the DSH allotment for the State for the previous fiscal year under this subparagraph increased, subject to subparagraph (B), by 1.9 percent or, in the case of fiscal years beginning with the fiscal year specified in subparagraph (D) for that State, the percentage change in the consumer price index for all urban consumers (all items; U.S. city average), for the previous fis-

"(D) FISCAL YEAR SPECIFIED.—For purposes of subparagraph (C)(ii), the fiscal year specified in this subparagraph for a State is the first fiscal year for which the Secretary estimates that the DSH allotment for that State will equal (or no longer exceed) the DSH allotment for that State under the law as in effect before the date of the enactment of this subparagraph."

SEC. 1002. CLARIFICATION OF INCLUSION OF INPATIENT DRUG PRICES CHARGED TO CER-TAIN PUBLIC HOSPITALS IN THE BEST PRICE EXEMPTIONS FOR THE MEDICAID DRUG REBATE PROGRAM.

- (a) In General.—Section 1927(c)(1)(C)(i)(I) (42 U.S.C. 1396r-8(c)(1)(C)(i)(I)) is amended by inserting before the semicolon the following: "(including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the Public Health Service
- (b) EFFECTIVE DATE.—The amendment made by this section shall take effect on the date of the enactment of this Act.

PURPOSE AND SUMMARY

H.R. 2473 is a comprehensive Medicare modernization bill that makes significant changes to the Medicare Program and establishes new outpatient prescription drug coverage for Medicare beneficiaries. The bill creates new Prescription Drug Plans and permits all individuals currently enrolled within Parts A and B to obtain a new benefit.

BACKGROUND AND NEED FOR LEGISLATION

The Medicare program has not provided a comprehensive outpatient prescription drug benefit to beneficiaries since the inception of the program in 1966. At the time, outpatient drug therapy regimens were not considered an integral component of patients' base health insurance benefits. Over the past few decades, outpatient prescription drug coverage has become commonplace in the private sector, yet as many as 25 percent of Medicare beneficiaries in the United States do not have access to third party prescription drug coverage. This lack of a prescription drug benefit has placed a significant burden on those who cannot afford the sometimes substantial out-of-pocket costs associated with the purchase of these medicines.

In addition to providing seniors with access to a Medicare prescription drug benefit, this legislation also creates an option for seniors to obtain their covered Part A and Part B services through enhanced fee-for-service plans. These plans—designed to offer health insurance coverage to Medicare beneficiaries on a regional basis—seek to replicate many of the successes of the Federal Employees Health Benefits Program.

HEARINGS

The Subcommittee on Health held a hearing on Tuesday, April 8, 2003 entitled "Designing a Twenty-First Century Medicare Prescription Drug Benefit." The Subcommittee received testimony from: Dr. Dan Crippen; Roger Feldman, Ph.D., University of Minnesota, Health Services Research/Policy; Mr. David Herman, Executive Director, The Seniors Coalition; Mr. Bruce Vladeck, Professor of Health Policy and Geriatrics, Mt. Sinai University; and Mr. Eric Olsen, On behalf of AARP.

The Subcommittee on Health held a hearing on Wednesday, April 9, 2003 entitled "Strengthening and Improving Medicare." The Subcommittee received testimony from: Mr. Rick Foster, Chief Actuary, Center for Medicare and Medicaid Services; Dr. Robert Berenson, M.D., F.A.C.P., Senior Consultant, Academy Health; Ms. Susan Rawlins, Head of Retiree Markets, Aetna Inc.; Dr. Marilyn Moon, Ph.D., Senior Fellow, The Urban Institute; Ms. Mary Grealy, President, Healthcare Leadership Council; Ms. Barbara Kennelly, President, National Committee to Preserve Social Security and Medicare; and Mr. Robert Buddy.

COMMITTEE CONSIDERATION

On Tuesday, June 17, 2003, Wednesday, June 18, 2003, and Thursday, June 19, 2003, the Full Committee met in open markup session and ordered H.R. 2473 reported to the House, as amended, by a record vote of 29 yeas and 20 nays.

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 thereto. The following are the record votes taken on amendments offered to H.R. 2473, including the names of those Members voting for and against. A motion by Mr. Tauzin to order H.R. 2473 reported to the House, as amended, was agreed to by a record vote of 29 yeas and 20 nays.

BILL: H.R. 2473, Medicare Prescription Drug and Modernization Act.

AMENDMENT: A substitute amendment to the amendment in the nature of a substitute by Mr. Dingell, No. 2, to (1) strike Title I and create an alternative, voluntary Medicare outpatient prescription drug program; (2) to make similar benefits available through Medicare+Choice plans; and, (3) to provide transitional assistance to low-income Medicare beneficiaries.

DISPOSITION: NOT AGREED TO, by a roll call vote of 25 yeas to 27 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Tauzin		X		Mr. Dingell	Х		
Mr. Bilirakis		X		Mr. Waxman	X		
Mr. Barton		Х		Mr. Markey	X		
Mr. Upton		X		Mr. Hall	X		
Mr. Stearns		X		Mr. Boucher	Х		
Mr. Gillmor				Mr. Towns	X		110000
Mr. Greenwood				Mr. Pallone	Х		***************************************
Mr. Cox		X		Mr. Brown	X		
Mr. Deal		X		Mr. Gordon	X		J. A. T. W.
Mr. Burr	-			Mr. Deutsch	X		
Mr. Whitfield		X		Mr. Rush	X		7000
Mr. Norwood		X		Ms. Eshoo			
Mrs. Cubin		X		Mr. Stupak	X		
Mr. Shimkus		X		Mr. Engel	X		***************************************
Mrs. Wilson		X		Mr. Wynn	Х		
Mr. Shadegg				Mr. Green	X		
Mr. Pickering	***************************************	X		Ms. McCarthy	X	10/2011101	
Mr. Fossella		X		Mr. Strickland	Х		
Mr. Blunt		X		Ms. DeGette	X		
Mr. Buyer		X		Ms. Capps	X		
Mr. Radanovich		X		Mr. Doyle	X		
Mr. Bass		X		Mr. John	X		· · · · · · · · · · · · · · · · · · ·
Mr. Pitts		X		Mr. Allen	X		
Ms. Bono		X		Mr. Davis	Х		
Mr. Walden		X		Ms. Schakowsky	X		
Mr. Terry		X		Ms. Solis	Х		***
Mr. Fletcher		Х					-/
Mr. Ferguson		X			-44		
Mr. Rogers		X					****
Mr. Issa		X	***************************************				n militar (#876
Mr. Otter		Х					

BILL: H.R. 2473, Medicare Prescription Drug and Modernization Act.

AMENDMENT: An amendment to the amendment in the nature of a substitute by Mr. Brown, No. 4, to require that the drug benefit offered by BlueCross-BlueShield to current Federal employees be the minimum benefit offered to Medicare beneficiaries.

DISPOSITION: NOT AGREED TO, by a roll call vote of 19 years to 27 nays.

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REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Tauzin		X		Mr. Dingell	Х		
Mr. Bilirakis		X		Mr. Waxman	X		
Mr. Barton		X		Mr. Markey	X		
Mr. Upton		X		Mr. Hali	X		
Mr. Steams		X		Mr. Boucher			
Mr. Gillmor		X		Mr. Towns	X		
Mr. Greenwood		X		Mr. Pallone	X		
Mr. Cox		X		Mr. Brown	Х		
Mr. Deal		X		Mr. Gordon	X		
Mr. Burr		X		Mr. Deutsch			
Mr. Whitfield		X		Mr. Rush	х		
Mr. Norwood		X		Ms. Eshoo			
Mrs. Cubin				Mr. Stupak			
Mr. Shimkus		X		Mr. Engel			
Mrs. Wilson		X		Mr. Wynn			
Mr. Shadegg				Mr. Green	Х		
Mr. Pickering				Ms. McCarthy	X		
Mr. Fossella		X		Mr. Strickland	X		
Mr. Blunt				Ms. DeGette	X		
Mr. Buyer		X		Ms. Capps	X		
Mr. Radanovich		X		Mr. Doyle	x		
Mr. Bass		X		Mr. John	X		
Mr. Pitts		X		Mr. Allen			
Ms. Bono		X		Mr. Davis	X		
Mr. Walden		X		Ms. Schakowsky	x		
Mr. Terry		X		Ms. Solis	X		
Mr. Fletcher		X					,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,
Mr. Ferguson	***************************************	X					
Mr. Rogers		X					
Mr. Issa	***************************************	X					
Mr. Otter		X					

BILL: H.R. 2473, Medicare Prescription Drug and Modernization Act.

AMENDMENT: An amendment to the amendment in the nature of a substitute by Mr. Green, No. 6, to provide limits on cost sharing up to the annual out-of-pocket threshold.

DISPOSITION: NOT AGREED TO, by a roll call vote of 23 yeas to 23 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Tauzin		X		Mr. Dingell	X		
Mr. Bilirakis		X		Mr. Waxman	X		
Mr. Barton		Х		Mr. Markey	X		
Mr. Upton		X		Mr. Hall	х		
Mr. Stearns				Mr. Boucher			
Mr. Gillmor		X		Mr. Towns	X		
Mr. Greenwood		Х		Mr. Pallone	X		
Mr. Cox				Mr. Brown	X		
Mr. Deal		X		Mr. Gordon	X		
Mr. Burr		X		Mr. Deutsch	X		
Mr. Whitfield	-	X		Mr. Rush	X		
Mr. Norwood		Х		Ms. Eshoo	Kimim		
Mrs. Cubin				Mr. Stupak	X		
Mr. Shimkus		X		Mr. Engel	X		
Mrs, Wilson		X		Mr. Wynn	х		
Mr. Shadegg		X		Mr. Green	X		
Mr. Pickering		X		Ms. McCarthy	X		
Mr. Fossella		X		Mr. Strickland	X		
Mr. Blunt				Ms. DeGette	х		
Mr. Buyer		X		Ms. Capps	X		
Mr. Radanovich				Mr. Doyle	x		
Mr. Bass		Х		Mr. John			
Mr. Pitts				Mr. Allen	х		***************************************
Ms. Bono				Mr. Davis	X		11170.00
Mr. Walden		X		Ms. Schakowsky	x		
Mr. Terry		X		Ms. Solis	x		
Mr. Fletcher		Х					
Mr. Ferguson		X					
Mr. Rogers	***************************************	Х					*****
Mr. Issa		170100040					
Mr. Otter		X					P21

BILL: H.R. 2473, Medicare Prescription Drug and Modernization Act.

AMENDMENT: An amendment to the amendment in the nature of a substitute by Mr. Pallone, No. 8, to add a new paragraph to allow the Administrator to negotiate pricing contracts directly with drug manufacturers.

DISPOSITION: NOT AGREED TO, by a roll call vote of 18 yeas to 33 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Tauzin		X		Mr. Dingell	X		44.4
Mr. Bilirakis		X		Mr. Waxman			
Mr. Barton		X		Mr. Markey	X		
Mr. Upton		Х		Mr. Hall		Х	
Mr. Stearns		X		Mr. Boucher			
Mr. Gillmor		X		Mr. Towns			
Mr. Greenwood		X		Mr. Pallone	X		
Mr. Cox		X		Mr. Brown	Х		
Mr. Deal		X		Mr. Gordon	,		
Mr. Burr		X		Mr. Deutsch			
Mr. Whitfield		X		Mr. Rush	Х		
Mr. Norwood		X		Ms. Eshoo			
Mrs. Cubin		X		Mr. Stupak	Х		
Mr. Shimkus	, ,	X		Mr. Engel	X		
Mrs. Wilson	,	Х		Mr. Wynn	х		
Mr. Shadegg		X		Mr. Green	X		
Mr. Pickering		X		Ms. McCarthy	X		
Mr. Fossella		X		Mr. Strickland	X		
Mr. Blunt		X		Ms. DeGette	X		
Mr. Buyer		X		Ms. Capps	X		
Mr. Radanovich		X		Mr. Doyle	x		
Mr. Bass		X		Mr. John		Х	
Mr. Pitts		X		Mr. Allen	X		
Мѕ. Вопо		X		Mr. Davis	X		, O/100000000
Mr. Walden		X		Ms. Schakowsky	X		
Mr. Terry		X	,	Ms. Solis	X		
Mr. Fletcher		X					
Mr. Ferguson		X					
Mr. Rogers		X					
Mr. Issa		X					
Mr. Otter		x					

COMMITTEE ON ENERGY AND COMMERCE $-108 \mathrm{TH}$ CONGRESS ROLL CALL VOTE $\#\,45$

BILL: H.R. 2473, Medicare Prescription Drug and Modernization Act.

AMENDMENT: An amendment to the amendment in the nature of a substitute by Mr. Strickland, No. 11, to require a uniform premium be set at \$35 a month in 2006 and to be adjusted for inflation in subsequent years.

DISPOSITION: NOT AGREED TO, by a roll call vote of 22 yeas to 28 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Tauzin		X		Mr. Dingell	Х		
Mr. Bilirakis		Х		Mr. Waxman	X		
Mr. Barton				Mr. Markey	Х		
Mr. Upton		X		Mr. Hall	-		
Mr. Stearns		X		Mr. Boucher			
Mr. Gillmor		X		Mr. Towns	X		
Mr. Greenwood		X		Mr. Pallone	X		
Mr. Cox		X		Mr. Brown	X		,
Mr. Deal		Х		Mr. Gordon			
Mr. Burr		X		Mr. Deutsch	X		
Mr. Whitfield		X		Mr. Rush	х		
Mr. Norwood		X		Ms. Eshoo	X		
Mrs. Cubin		Х		Mr. Stupak	X		***************************************
Mr. Shimkus	447-	Х		Mr. Engel	X		
Mrs. Wilson		X		Mr. Wynn	х		
Mr. Shadegg		X		Mr. Green	X		
Mr. Pickering		X		Ms. McCarthy			
Mr. Fossella		X		Mr. Strickland	X		
Mr. Blunt				Ms. DeGette	Х		
Mr. Buyer		Х		Ms. Capps	X		
Mr. Radanovich	-7,	X		Mr. Doyle	X		
Mr. Bass		Х		Mr. John	х		
Mr. Pitts		X		Mr. Allen	x		
Ms. Bono		X		Mr. Davis	X		
Mr. Walden	***************************************	X		Ms. Schakowsky	X		
Mr. Terry		X		Ms. Solis	X		
Mr. Fletcher		Х					- Marian
Mr. Ferguson	***************************************	X			*******		
Mr. Rogers	President Control of the Control of	X	,				
Mr. Issa	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,						
Mr. Otter		X					

BILL: H.R. 2473, Medicare Prescription Drug and Modernization Act.

AMENDMENT: An amendment to the amendment in the nature of a substitute by Mr. Green, No. 12, to provide for the inclusion of all expenses made on behalf of Medicare beneficiaries to count towards the total out-of-pocket threshold.

DISPOSITION: NOT AGREED TO, by a roll call vote of 24 yeas to 30 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Tauzin		X		Mr. Dingell	X		
Mr. Bilirakis		X		Mr. Waxman	X		
Mr. Barton				Mr. Markey	X		
Mr. Upton		X		Mr. Hall	X		
Mr. Stearns		X		Mr. Boucher			
Mr. Gillmor		X		Mr. Towns	X		
Mr. Greenwood		X		Mr. Pallone	X		
Mr. Cox		Х		Mr. Brown	X		
Mr. Deal	:	X		Mr. Gordon			
Mr. Burr		Х		Mr. Deutsch	X		
Mr. Whitfield		X		Mr. Rush	X		
Mr. Norwood		X		Ms. Eshoo	X		
Mrs. Cubin		X		Mr. Stupak	X		
Mr. Shimkus		Х		Mr. Engel	X		
Mrs. Wilson		X		Mr. Wynn	X		
Mr. Shadegg		X		Mr. Green	x		
Mr. Pickering		X		Ms. McCarthy	X		
Mr. Fossella		Х		Mr. Strickland	X		
Mr. Blunt		X		Ms. DeGette	X		
Mr. Buyer		X		Ms. Capps	X		
Mr. Radanovich		X		Mr. Doyle	X		
Mr. Bass		Х		Mr. John	Х		
Mr. Pitts		X		Mr. Allen	x		
Ms. Bono		X		Mr. Davis	x		
Mr. Walden		Х		Ms. Schakowsky	X		
Mr. Terry	- *	X		Ms. Solis	X		
Mr. Fletcher		Х					
Mr. Ferguson		X					
Mr. Rogers	10	Х					
Mr. Issa		Х			with the same of t		
Mr. Otter		X					

BILL: H.R. 2473, Medicare Prescription Drug and Modernization Act.

AMENDMENT: An amendment to the amendment in the nature of a substitute by Mr. Pallone, No. 13, to require that qualified prescription drug coverage be only standard coverage, and eliminate the possibility of coverage being only actuarially equivalent to standard coverage.

DISPOSITION: NOT AGREED TO, by a roll call vote of 24 yeas to 30 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Tauzin		X		Mr. Dingell	X		
Mr. Bilirakis		X		Mr. Waxman	X		
Mr. Barton				Mr. Markey	X		
Mr. Upton		х		Mr. Hali	X		
Mr. Stearns		X		Mr. Boucher			
Mr. Gillmor		X		Mr. Towns	X		
Mr. Greenwood		X		Mr. Pallone	X		
Mr. Cox		X		Mr. Brown	X		
Mr. Deal		Х		Mr. Gordon			
Mr. Burr		X		Mr. Deutsch	X		
Mr. Whitfield		Х		Mr. Rush	X		
Mr. Norwood		X		Ms. Eshoo	Х		
Mrs. Cubin		X		Mr. Stupak	X		
Mr. Shimkus		X		Mr. Engel	X		
Mrs. Wilson		X		Mr. Wynn	X		
Mr. Shadegg		X		Mr. Green	X		
Mr. Pickering		X		Ms. McCarthy	X		
Mr. Fossella		Х		Mr. Strickland	X		
Mr. Blunt		·X		Ms. DeGette	X		
Mr. Buyer		Х		Ms. Capps	X		
Mr. Radanovich		X		Mr. Doyle	X		
Mr. Bass		X		Mr. John	X		
Mr. Pitts		X		Mr. Allen	X		
Ms. Bono		X		Mr. Davis	X		
Mr. Walden		X		Ms. Schakowsky	X		
Mr. Terry		Х		Ms. Solis	X		
Mr. Fletcher		х					
Mr. Ferguson		X					
Mr. Rogers		Х					-
Mr. Issa		х					
Mr. Otter		X			17. 17.		

BILL: H.R. 2473, Medicare Prescription Drug and Modernization Act.

AMENDMENT: An amendment to the amendment in the nature of a substitute by Ms. Capps, No. 14, to provide a guaranteed nationwide prescription drug plan.

DISPOSITION: NOT AGREED TO, by a roll call vote of 23 yeas to 30 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Tauzin		X		Mr. Dingell	X		
Mr. Bilirakis		X		Mr. Waxman	X		
Mr. Barton				Mr. Markey	X		
Mr. Upton		X		Mr. Hall	X		
Mr. Stearns		x		Mr. Boucher			
Mr. Gillmor		X		Mr. Towns	X		
Mr. Greenwood		X		Mr. Pallone	X		
Mr. Cox		X		Mr. Brown	X		
Mr. Deal		X		Mr. Gordon			
Mr. Burr		х		Mr. Deutsch	X		
Mr. Whitfield	•	X		Mr. Rush	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,		
Mr. Norwood		X		Ms. Eshoo	X		
Mrs. Cubin		X		Mr. Stupak	X		
Mr. Shimkus	***	Х		Mr. Engel	X		,,,,,
Mrs. Wilson		X		Mr. Wynn	X		
Mr. Shadegg		x		Mr. Green	X		
Mr. Pickering		Х		Ms. McCarthy	X		
Mr. Fossella		X		Mr. Strickland	X		
Mr. Blunt		X		Ms. DeGette	X		
Mr. Buyer		x		Ms. Capps	X		
Mr, Radanovich		X		Mr. Doyle	X		
Mr. Bass		X		Mr. John	X		
Mr. Pitts		X		Mr. Allen	X		
Ms. Bono		X		Mr. Davis	X		
Mr. Walden		X		Ms. Schakowsky	X		
Mr. Terry		X		Ms. Solis	X		
Mr. Fletcher		X					
Mr. Ferguson		X					
Mr. Rogers	-	X					
Mr. Issa		X					
Mr. Otter		X					

BILL: H.R. 2473, Medicare Prescription Drug and Modernization Act.

AMENDMENT: An amendment to the amendment in the nature of a substitute by Ms. Schakowsky, No. 15, to eliminate the means test in determining the threshold for catastrophic coverage.

DISPOSITION: NOT AGREED TO, by a roll call vote of 24 yeas to 29 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Tauzin		X		Mr. Dingell	X		
Mr. Bilirakis		х		Mr. Waxman	X		
Mr. Barton		X		Mr. Markey	X		
Mr. Upton	1100	X		Mr. Hall			
Mr. Stearns		X		Mr. Boucher			
Mr. Gillmor		X		Mr. Towns	X		
Mr. Greenwood	.,	Х		Mr. Pallone	X		
Mr. Cox		X		Mr. Brown	X		
Mr. Deal		Х		Mr. Gordon			
Mr. Burr		X		Mr. Deutsch	Х		
Mr. Whitfield		Х		Mr. Rush	X		
Mr. Norwood		X		Ms. Eshoo	Х		
Mrs. Cubin		х		Mr. Stupak	X		
Mr. Shimkus		Х		Mr. Engel	x		
Mrs. Wilson		x		Mr. Wynn	X		
Mr. Shadegg		X		Mr. Green	X		
Mr. Pickering		Х		Ms. McCarthy	x		
Mr. Fossella				Mr. Strickland	X		
Mr. Blunt		X		Ms. DeGette	X		
Mr. Buyer		Х		Ms. Capps	X		
Mr. Radanovich		X		Mr. Doyle	X		
Mr. Bass		X		Mr. John	X		
Mr. Pitts		X		Mr. Allen	X		
Ms. Bono		X		Mr. Davis	х		
Mr. Walden		Х		Ms. Schakowsky	X		
Mr. Terry		х		Ms. Solis	X		
Mr. Fletcher		X					
Mr. Ferguson	X						
Mr. Rogers	***	X			*****		
Mr. Issa		х					
		1 ^	I	1		1	

BILL: H.R. 2473, Medicare Prescription Drug and Modernization Act.

AMENDMENT: An amendment to the amendment in the nature of a substitute by Ms. Capps, No. 16, to provide limits on cost sharing up to the annual out-of-pocket threshold for individuals with amyotrophic lateral sclerosis (ALS).

DISPOSITION: NOT AGREED TO, by a roll call vote of 22 yeas to 31 nays.

						OPERATOR AND ADDRESS OF THE PERSON NAMED IN COLUMN 1	
REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Tauzin		X		Mr. Dingell	X		
Mr. Bilirakis		X		Mr. Waxman			
Mr. Barton		X		Mr. Markey	х		
Mr. Upton		х		Mr. Hall			
Mr. Stearns		Х		Mr. Boucher			
Mr. Gillmor	.,	X		Mr. Towns	x		
Mr. Greenwood		Х		Mr. Pallone	X		
Mr. Cox		Х		Mr. Brown	Х		
Mr. Deal		X		Mr. Gordon	- 7 (1000)		
Mr. Burr		X		Mr. Deutsch	X		
Mr. Whitfield		X		Mr. Rush	Х		
Mr. Norwood		X		Ms. Eshoo	X		
Mrs. Cubin		X		Mr. Stupak	Х		
Mr. Shimkus		X		Mr. Engel	Х		
Mrs. Wilson		X		Mr. Wynn	Х		
Mr. Shadegg		X		Mr. Green	X		
Mr. Pickering		X		Ms. McCarthy	X		
Mr. Fossella		Х		Mr. Strickland	X		
Mr. Blunt		X		Ms. DeGette	X		
Mr. Buyer		Х		Ms. Capps	x		
Mr. Radanovich		X		Mr. Doyle	X		
Mr. Bass	-	X		Mr. John	Х		
Mr. Pitts		X		Mr. Allen	X		
Ms. Bono		X		Mr. Davis	X		
Mr. Walden		Х		Ms. Schakowsky	X		
Mr. Terry		X		Ms. Solis	X		
Mr. Fletcher		X			, , , , , , , , , , , , , , , , , , , ,		
Mr. Ferguson	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	X					
Mr. Rogers		Х					
Mr. Issa		X					
Mr. Otter		x					

BILL: H.R. 2473, Medicare Prescription Drug and Modernization Act.

AMENDMENT: An amendment to the amendment in the nature of a substitute by Mr. Stupak, No. 19, to allow any Medicare beneficiary enrolled in a PDP plan to be eligible to obtain prescription drugs at prices specified in the Federal Supply Schedule, notwithstanding any other provision of law.

DISPOSITION: NOT AGREED TO, by a roll call vote of 17 yeas to 34 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Tauzin		X		Mr. Dingell	X		
Mr. Bilirakis		X		Mr. Waxman			
Mr. Barton		X		Mr. Markey			
Mr. Upton		X		Mr. Hall			
Mr. Stearns		X		Mr. Boucher			
Mr. Gillmor		X		Mr. Towns			
Mr. Greenwood		X		Mr. Pallone	X		
Mr. Cox		X		Mr. Brown	X		
Mr. Deal		X		Mr. Gordon			
Mr. Burr		Х		Mr. Deutsch	X		
Mr. Whitfield		х		Mr. Rush	X		
Mr. Norwood		X		Ms. Eshoo		Х	
Mrs. Cubin		X		Mr. Stupak	X		
Mr. Shimkus		х		Mr. Engel	X		
Mrs. Wilson		X		Mr. Wynn	X		
Mr. Shadegg		X		Mr. Green	Х		
Mr. Pickering		X		Ms. McCarthy	X		
Mr. Fossella		X		Mr. Strickland	X		
Mr. Blunt		x		Ms. DeGette	X		
Mr. Buyer		X		Ms. Capps	X		
Mr. Radanovich		X		Mr. Doyle	X		
Mr. Bass		X		Mr. John		X	
Mr. Pitts		Х		Mr. Allen	X		
Ms. Bono		x		Mr. Davis		Х	
Mr. Walden		x		Ms. Schakowsky	X		
Mr. Terry		X		Ms. Solis	X		
Mr. Fletcher		X					
Mr. Ferguson		X					
Mr. Rogers		Х					
Mr. Issa		X					
Mr. Otter		X			, , , , , , , , , , , , , , , , , , , ,		

BILL: H.R. 2473, Medicare Prescription Drug and Modernization Act.

AMENDMENT: An amendment to the amendment in the nature of a substitute by Mr. John, No. 20, to require a 2 year contract for prescription drug plans.

DISPOSITION: NOT AGREED TO, by a roll call vote of 22 yeas to 31 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Tauzin		Х		Mr. Dingell	X		
Mr. Bilirakis		X		Mr. Waxman	X		
Mr. Barton		X		Mr. Markey	X		
Mr. Upton		x		Mr. Hall			
Mr. Stearns		X		Mr. Boucher			
Mr. Gillmor		X		Mr. Towns			
Mr. Greenwood		Х		Mr. Pallone	X		
Mr. Cox		X		Mr. Brown	X		
Mr. Deal		Х		Mr. Gordon			
Mr. Burr	-100.7	X		Mr. Deutsch	X		
Mr. Whitfield		X		Mr. Rush	X		
Mr. Norwood	,	X		Ms. Eshoo	X		
Mrs. Cubin		Х		Mr. Stupak	X		
Mr. Shimkus		x		Mr. Engel	X		
Mrs. Wilson		x		Mr. Wynn	X		
Mr. Shadegg		X		Mr. Green	X		
Mr. Pickering		Х		Ms. McCarthy	Х		
Mr. Fossella		x		Mr. Strickland	X		
Mr. Blunt		Х		Ms. DeGette	X		
Mr. Buyer		X		Ms. Capps	X		
Mr. Radanovich	1.72	X		Mr. Doyle	X		
Mr. Bass		X		Mr. John	X		
Mr. Pitts		x		Mr. Allen	X		
Ms. Bono		X		Mr. Davis	X		
Mr. Walden		x		Ms. Schakowsky	X		
Mr. Terry		X		Ms. Solis	X		
Mr. Fletcher	,	X					
Mr. Ferguson		X					
Mr. Rogers		X					
Mr. Issa		X					
Mr. Otter		х					

BILL: H.R. 2473, Medicare Prescription Drug and Modernization Act.

AMENDMENT: An amendment to the amendment in the nature of a substitute by Mr. Waxman, No. 21, to eliminate the asset test used to determine eligibility for subsidies to low-income Medicare beneficiaries.

DISPOSITION: NOT AGREED TO, by a roll call vote of 22 years to 30 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Tauzin		X		Mr. Dingell	X		
Mr. Bilírakis				Mr. Waxman	X		
Mr. Barton		X		Mr. Markey	X		
Mr. Upton		Х		Mr. Hall			
Mr. Stearns		X		Mr. Boucher			
Mr. Gillmor	.,	X		Mr. Towns			
Mr. Greenwood		X		Mr. Pallone	Х		
Mr. Cox		Х		Mr. Brown	X		
Mr. Deal		Х		Mr. Gordon			
Mr. Burr		X		Mr. Deutsch	X		
Mr. Whitfield		X		Mr. Rush	X		
Mr. Norwood		X		Ms. Eshoo	X		
Mrs. Cubin		Х		Mr. Stupak	X		
Mr. Shimkus		X		Mr. Engel	X		
Mrs. Wilson		X		Mr. Wynn	X		
Mr. Shadegg		X		Mr. Green	Х		
Mr. Pickering		Х		Ms. McCarthy	X		
Mr. Fossella		X		Mr. Strickland	X		
Mr. Blunt		Х		Ms. DeGette	X		
Mr. Buyer		X		Ms. Capps	X		
Mr. Radanovich	-,	X		Mr. Doyle	· X		
Mr. Bass		Х		Mr. John	X		
Mr. Pitts		X		Mr. Allen	X		
Ms. Bono		X		Mr. Davis	X		
Mr. Walden	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	X		Ms. Schakowsky	X		
Mr. Terry	,	X		Ms. Solis	X		
Mr. Fletcher		Х					
Mr. Ferguson		Х					
Mr. Rogers		Х			J. J.		
Mr. Issa		X			1711111		
Mr. Otter		Х			. ,		

BILL: H.R. 2473, Medicare Prescription Drug and Modernization Act.

AMENDMENT: An amendment to the amendment in the nature of a substitute by Mr. Allen, No. 23, to require each participating drug manufacturer to charge participating entities prices no greater than the average price that the manufacture charges in foreign nations.

DISPOSITION: NOT AGREED TO, by a roll call vote of 17 yeas to 35 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Tauzin		X		Mr. Dingell	X		
Mr. Bilirakis		X		Mr. Waxman	X		
Mr. Barton		Х		Mr. Markey	X		
Mr. Upton		X		Mr. Hall			
Mr. Stearns		X		Mr. Boucher			
Mr. Gillmor		X		Mr. Towns			
Mr. Greenwood		Х		Mr. Pallone	X		
Mr. Cox		X		Mr. Brown	X		
Mr. Deal		Х		Mr. Gordon			
Mr. Burr		Х		Mr. Deutsch	X		
Mr. Whitfield		X		Mr. Rush		X	
Mr. Norwood				Ms. Eshoo		Х	
Mrs. Cubin		Х		Mr. Stupak	X		
Mr. Shimkus		Х	-	Mr. Engel	X		
Mrs. Wilson		X		Mr. Wynn		Х	
Mr. Shadegg		X		Mr. Green	X		
Mr. Pickering		X		Ms. McCarthy	X		
Mr. Fossella		X		Mr. Strickland	X		
Mr. Blunt		X		Ms. DeGette	X		
Mr. Buyer		X		Ms. Capps	X		
Mr. Radanovich		X		Mr. Doyle	X		
Mr. Bass		Х		Mr. John	74.00	X	
Mr. Pitts		X		Mr. Allen	X		
Ms. Bono		X		Mr. Davis		Х	
Mr. Walden		X		Ms. Schakowsky	X		
Mr. Terry		X		Ms. Solis	X		
Mr. Fletcher		х					
Mr. Ferguson		X					
Mr. Rogers		Х					
Mr. Issa		X			-		
Mr. Otter		Х					

BILL: H.R. 2473, Medicare Prescription Drug and Modernization Act.

AMENDMENT: An amendment to the amendment in the nature of a substitute by Ms. Solis No. 24, to improve Medicare's outreach to certain low-income beneficiaries.

DISPOSITION: NOT AGREED TO, by a roll call vote of 21 yeas to 30 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Tauzin		X		Mr. Dingell	X		
Mr. Bilirakis		X		Mr. Waxman			
Mr. Barton		X		Mr. Markey	X		
Mr. Upton		х		Mr. Hall			
Mr. Stearns		X		Mr. Boucher			
Mr. Gillmor	1.0	Х		Mr. Towns			
Mr. Greenwood		X		Mr. Pallone	X		
Mr. Cox		x		Mr. Brown	X		
Mr. Deal		X		Mr. Gordon			
Mr. Burr		X		Mr. Deutsch	X		
Mr. Whitfield		X		Mr. Rush	X		
Mr. Norwood				Ms. Eshoo	X		
Mrs. Cubin		X	·	Mr. Stupak	X		
Mr. Shimkus		X		Mr. Engel	X		
Mrs, Wilson		x		Mr. Wynn	X		
Mr. Shadegg		X		Mr. Green	X		
Mr. Pickering		X		Ms. McCarthy	X		
Mr. Fossella		X		Mr. Strickland	X		
Mr. Blunt		X		Ms. DeGette	X		
Mr. Buyer		x		Ms. Capps	Х		
Mr. Radanovich		X		Mr. Doyle	X		
Mr. Bass		Х		Mr. John	X		,
Mr. Pitts		X		Mr. Allen	X		
Ms. Bono	·	х		Mr. Davis	X		
Mr. Walden		X		Ms. Schakowsky	X		
Mr. Terry		х		Ms. Solis	Х		
Mr. Fletcher		Х			- Annulai		
Mr. Ferguson		X					
Mr. Rogers		Х					
Mr. Issa		X					
Mr. Otter		X					

COMMITTEE ON ENERGY AND COMMERCE $-108 \mathrm{TH}$ CONGRESS ROLL CALL VOTE $\#\,56$

BILL: H.R. 2473, Medicare Prescription Drug and Modernization Act.

AMENDMENT: An amendment to the amendment in the nature of a substitute by Mr. Markey, No. 25, to prohibit an entity offering an endorsed prescription discount card from the use, sale, or transfer of information gathered in connection with an endorsed prescription drug discount card program for purposes of marketing, eligibility for enrollment, and rates in any prescription drug plan or Medicare Advantage-Enhanced Fee for Service Plan under the Act.

DISPOSITION: NOT AGREED TO, by a roll call vote of 22 yeas to 30 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Tauzin		Х		Mr. Dingell	Х		
Mr. Bilirakis		X		Mr. Waxman	Х		
Mr. Barton		X		Mr. Markey	X		
Mr. Upton		X		Mr. Hall			
Mr. Stearns		Х		Mr. Boucher			
Mr. Gillmor		X		Mr. Towns			
Mr. Greenwood		X		Mr. Pallone	х		
Mr. Cox		X		Mr. Brown	Х		
Mr. Deal		Х		Mr. Gordon	,		
Mr. Burr		Х		Mr. Deutsch	Х		-
Mr. Whitfield		X		Mr. Rush	X		
Mr. Norwood				Ms. Eshoo	X		
Mrs. Cubin		X		Mr. Stupak	Х		
Mr. Shimkus		X		Mr. Engel	X		
Mrs. Wilson		X		Mr. Wynn	X		
Mr. Shadegg		X		Mr. Green	X		
Mr. Pickering		X		Ms. McCarthy	Х		
Mr. Fossella	, — , , , , , , , , , , , , , , , , , ,	X		Mr. Strickland	Х		
Mr. Blunt		X		Ms. DeGette	х		
Mr. Buyer		Х		Ms. Capps	X	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	
Mr. Radanovich		X		Mr. Doyle	X		
Mr. Bass	,	X		Mr. John	X		
Mr. Pitts		Х		Mr. Allen	X		
Ms. Bono	11000000	X		Mr. Davis	X	214	
Mr. Walden		х		Ms. Schakowsky	X		, , , , , , , , , , , , , , , , , , ,
Mr. Terry		Х	,	Ms. Solis	X		
Mr. Fletcher		х					
Mr. Ferguson		Х					
Mr. Rogers		Х				***************************************	
Mr. Issa	~******	X	www.kgtty/	Control of the Contro			AL
Mr. Otter		Х					

BILL: H.R. 2473, Medicare Prescription Drug and Modernization Act.

AMENDMENT: An amendment to the amendment in the nature of a substitute by Mr. Markey, No. 26, to strike the provision authorizing the disclosure to entities that offer an eligible prescription drug plan the annual out-of-pocket threshold available to certain individuals, which is based on income-tax related information.

DISPOSITION: NOT AGREED TO, by a roll call vote of 19 yeas to 28 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Tauzin		X		Mr. Dingell	Х		
Mr. Bilirakis		X		Mr. Waxman			
Mr. Barton		X		Mr. Markey	X		
Mr. Upton		X		Mr. Hall			
Mr. Stearns				Mr. Boucher			
Mr. Gillmor		X		Mr. Towns			
Mr. Greenwood		X		Mr. Pallone	X		
Mr. Cox		x		Mr. Brown			
Mr. Deal		Х		Mr. Gordon			
Mr. Burr		X		Mr. Deutsch	X		
Mr. Whitfield		Х		Mr. Rush	X		
Mr. Norwood				Ms. Eshoo	X		,
Mrs. Cubin		x		Mr. Stupak	X		
Mr. Shimkus		X		Mr. Engel	X		
Mrs. Wilson		X		Mr. Wynn	X		
Mr. Shadegg		Х		Mr. Green	X		
Mr. Pickering	-	X		Ms. McCarthy			
Mr. Fossella		Х		Mr. Strickland	X		
Mr. Blunt		x		Ms. DeGette	X		
Mr. Buyer		X		Ms. Capps	X		
Mr. Radanovich		Х		Mr. Doyle	X		
Mr. Bass		X		Mr. John	X		
Mr. Pitts				Mr. Allen	X		
Ms. Bono		Х		Mr. Davis	X		
Mr. Walden		X		Ms. Schakowsky	X		
Mr. Terry		X		Ms. Solis	X		
Mr. Fletcher		X					
Mr. Ferguson		X					
Mr. Rogers		X					
Mr. Is		X					
Mr. Otter		X					i

COMMITTEE ON ENERGY AND COMMERCE $-108 \mathrm{TH}$ CONGRESS ROLL CALL VOTE $\#\,58$

BILL: H.R. 2473, Medicare Prescription Drug and Modernization Act.

AMENDMENT: An amendment to the amendment in the nature of a substitute by Mr. Brown No. 27, to strike section 241 of the bill.

DISPOSITION: NOT AGREED TO, by a roll call vote of 25 yeas to 29 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Tauzin		Х		Mr. Dingell	X		
Mr. Bilirakis		х		Mr. Waxman	X		
Mr. Barton		Х		Mr. Markey	X		
Mr. Upton		X		Mr. Hall	X		
Mr. Stearns		Х		Mr. Boucher			
Mr. Gillmor		X		Mr. Towns	X		
Mr, Greenwood	.,	Х		Mr. Pallone	X		
Mr. Cox		Х		Mr. Brown	X		
Mr. Deal		x		Mr. Gordon	х		11000
Mr. Burr		X		Mr. Deutsch	X		
Mr. Whitfield		х		Mr. Rush	Х		
Mr. Norwood		X		Ms. Eshoo	X		
Mrs. Cubin				Mr. Stupak	X		
Mr. Shimkus		х		Mr. Engel	x		
Mrs, Wilson		х		Mr. Wynn	X		
Mr. Shadegg		X		Mr. Green	x		
Mr. Pickering		X		Ms. McCarthy	x		
Mr. Fossella		Х		Mr. Strickland	X		
Mr. Blunt				Ms. DeGette	X		
Mr. Buyer		X		Ms. Capps	x		
Mr. Radanovich		X		Mr. Doyle	X		
Mr. Bass		X		Mr. John	X		
Mr. Pitts		х		Mr. Allen	X		
Ms. Bono		X		Mr. Davis	X		
Mr. Walden		X		Ms. Schakowsky	X		
Mr. Terry		X		Ms. Solis	x		
Mr. Fletcher	•	X			real Park		
Mr. Ferguson		Х			466		
Mr. Rogers		X					
Mr. Issa	*	X					
Mr. Otter		х					

BILL: H.R. 2473, Medicare Prescription Drug and Modernization Act.

AMENDMENT: An amendment to the amendment in the nature of a substitute by Mr. Pallone, No. 29, to strike the portion of section 241 that allows for the adjustment of premiums for enrollees in the traditional fee-for-service program in competitive areas.

DISPOSITION: NOT AGREED TO, by a roll call vote of 20 yeas to 27 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Tauzin		X		Mr. Dingell	X		
Mr. Bilirakis		X		Mr. Waxman	X		
Mr. Barton				Mr. Markey	X		
Mr. Upton		X		Mr. Hall	X		
Mr. Stearns		X		Mr. Boucher			
Mr. Gillmor		X		Mr. Towns	X		
Mr. Greenwood		х		Mr. Pallone	X		
Mr. Cox		X		Mr. Brown	X		
Mr. Deal		x		Mr. Gordon			
Mr. Burr		X		Mr. Deutsch	X		
Mr. Whitfield		X		Mr. Rush	X		
Mr. Norwood		Х		Ms. Eshoo	X		
Mrs. Cubin				Mr. Stupak	X		
Mr. Shimkus		x		Mr. Engel	X		
Mrs. Wilson		X		Mr. Wynn			
Mr. Shadegg		X		Mr. Green	x		
Mr. Pickering		x		Ms. McCarthy			
Mr. Fossella		X		Mr. Strickland	X		
Mr. Blunt				Ms. DeGette	X		
Mr. Buyer		X		Ms. Capps	X		
Mr. Radanovich		X		Mr. Doyle	X		
Mr. Bass		X		Mr. John	x		
Mr. Pitts		x		Mr. Allen	,,,,,,		1000
Ms. Bono		X		Mr. Davis			
Mr. Walden		x		Ms. Schakowsky	X		
Mr. Terry		X		Ms. Solis	X		
Mr. Fletcher		X					
Mr. Ferguson		1					
Mr. Rogers		X					
Mr. Issa		X					
Mr. Otter		X					

COMMITTEE ON ENERGY AND COMMERCE $-108 \mathrm{TH}$ CONGRESS ROLL CALL VOTE $\#\,60$

BILL: H.R. 2473, Medicare Prescription Drug and Modernization Act.

AMENDMENT: An amendment to the amendment in the nature of a substitute by Mr. Markey, No.30, to establish a new benefit within the traditional Medicare program by providing catastrophic coverage for all medical costs after a Medicare beneficiary has spent \$2,000 out-of-pocket.

DISPOSITION: NOT AGREED TO, by a roll call vote of 18 yeas to 25 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr, Tauzin		X		Mr. Dingell	X		
Mr. Bilirakis		X		Mr. Waxman			
Mr. Barton		X		Mr. Markey	X		
Mr. Upton		X		Mr. Hall	X		
Mr. Stearns		X		Mr. Boucher			
Mr. Gillmor		X		Mr. Towns	X		
Mr. Greenwood		х		Mr. Pallone	X		
Mr. Cox		X		Mr. Brown	X		
Mr. Deal		Х		Mr. Gordon			
Mr. Burr		X		Mr. Deutsch	X		
Mr. Whitfield				Mr. Rush	X		
Mr. Norwood		Х		Ms. Eshoo	X		
Mrs. Cubin				Mr. Stupak	X		
Mr. Shimkus		X		Mr. Engel	X		
Mrs. Wilson		X		Mr. Wynn			
Mr. Shadegg		X		Mr. Green	X		
Mr. Pickering		X		Ms. McCarthy			
Mr. Fossella		X		Mr. Strickland			
Mr. Blunt				Ms. DeGette			
Mr. Buyer		Х		Ms. Capps	X		
Mr. Radanovich				Mr. Doyle	X		-
Mr. Bass		Х		Mr. John	X		
Mr. Pitts		Х		Mr. Allen	X		
Ms. Bono		Х		Mr. Davis			
Mr. Walden		Х		Ms. Schakowsky	X		
Mr. Terry		X		Ms. Solis	X		
Mr, Fletcher							
Mr. Ferguson		X					
Mr. Rogers		X					
Mr. Issa							
Mr. Otter		Х				1	

BILL: H.R. 2473, Medicare Prescription Drug and Modernization Act.

AMENDMENT: An amendment to the amendment in the nature of a substitute by Mr. Engel, No.31, to prohibit Medicare private plans from imposing cost-sharing requirements any higher than those that currently exist under the traditional fee-for-service program.

DISPOSITION: NOT AGREED TO, by a roll call vote of 21 yeas to 24 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Tauzin		X		Mr. Dingell	X		
Mr. Bilirakis		X		Mr. Waxman	X		
Mr. Barton		X		Mr. Markey	X		
Mr. Upton		Х		Mr. Hall	X		
Mr. Stearns				Mr. Boucher			
Mr. Gillmor		Х		Mr. Towns	X		
Mr. Greenwood		Х		Mr. Pallone	X		
Mr. Cox		X		Mr. Brown	X		
Mr. Deal	,	X		Mr. Gordon	X		
Mr. Burr				Mr. Deutsch	X		
Mr. Whitfield		X		Mr. Rush	X		
Mr. Norwood		X		Ms. Eshoo	Х		
Mrs. Cubin				Mr. Stupak			
Mr. Shimkus		X		Mr. Engel	Х		
Mrs. Wilson		X		Mr. Wynn			
Mr. Shadegg		X		Mr. Green			
Mr. Pickering				Ms. McCarthy	X		
Mr. Fossella		X		Mr. Strickland	X		
Mr. Blunt		***		Ms. DeGette	X		
Mr. Buyer		Х		Ms. Capps	Х		
Mr. Radanovich				Mr. Doyle			
Mr. Bass		X		Mr. John	X		
Mr. Pitts		Х		Mr. Allen	X		
Ms. Bono	·	X		Mr. Davis	Х		
Mr. Walden		X		Ms. Schakowsky	X		
Mr. Terry		X		Ms. Solis	X		
Mr. Fletcher							
Mr. Ferguson		Х					
Mr. Rogers		Х					
Mr. Issa		Х					
Mr. Otter		X					

BILL: H.R. 2473, Medicare Prescription Drug and Modernization Act.

AMENDMENT: An amendment to the amendment in the nature of a substitute by Ms. Eshoo No.32, to strike all of Titles I and II and replace with Titles I and II of the bill reported out of the Senate Finance Committee which (1) establishes a voluntary Medicare prescription drug delivery program; (2) establishes a Medicare prescription drug discount card and transitional assistance for low-income beneficiaries; (3) establishes the criteria for the eligibility, election, and enrollment of eligible individuals for MedicareAdvantage; (4) establishes a MedicareAdvantage Preferred Provider Program Option; and, (5) provides an extension of reasonable cost contracts.

DISPOSITION: NOT AGREED TO, by a roll call vote of 9 yeas to 41 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Tauzin		X		Mr. Dingell		Х	
Mr. Bilirakis		Х		Mr. Waxman		Х	
Mr. Barton		X		Mr. Markey		X	
Mr. Upton		X		Mr. Hall	X		
Mr. Stearns	-	X		Mr. Boucher		Х	
Mr. Gillmor		X		Mr. Towns	X		
Mr. Greenwood		X		Mr. Pallone		X	
Mr. Cox	٠	X		Mr. Brown		X	
Mr. Deal		X		Mr. Gordon			
Mr. Burr	•			Mr. Deutsch		Х	
Mr. Whitfield		X	,	Mr. Rush			
Mr. Norwood		X		Ms. Eshoo	X		
Mrs. Cubin				Mr. Stupak		X	
Mr. Shimkus		X		Mr. Engel	•	X	
Mrs. Wilson		X		Mr. Wynn			
Mr. Shadegg		X		Mr. Green	X		
Mr. Pickering		X		Ms. McCarthy	X		
Mr. Fossella		X		Mr. Strickland		X	, , , , , , , , , , , , , , , , , , , ,
Mr. Blunt				Ms. DeGette	X		
Mr. Buyer		X		Ms. Capps	"	X	
Mr. Radanovich		X	-	Mr. Doyle	X		
Mr. Bass		X		Mr. John	X		
Mr. Pitts		X		Mr. Allen		X	
Ms. Bono		X		Mr. Davis	X		
Mr. Walden		X		Ms. Schakowsky		X	
Мг. Тетгу		X		Ms. Solis		Х	
Mr. Fletcher	,	X					,
Mr. Ferguson		X					
Mr. Rogers		Х					
Mr. Issa		X					
Mr. Otter		х				44.00	

BILL: H.R. 2473, Medicare Prescription Drug and Modernization Act.

AMENDMENT: An amendment to the amendment in the nature of a substitute by Ms. Capps, No.36, to eliminate physicians' ability to obtain Medicare covered drugs through contractors selected through a competitive bidding process.

DISPOSITION: NOT AGREED TO, by a roll call vote of 20 years to 26 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Tauzin		Х		Mr. Dingell	X		
Mr. Bilirakis		Х		Mr. Waxman	X		
Mr. Barton		X		Mr. Markey	X		
Mr. Upton		X		Mr. Hall	X		
Mr. Stearns		Х		Mr. Boucher			
Mr. Gillmor		Х		Mr. Towns			
Mr. Greenwood		X		Mr. Pallone	X		
Mr. Cox				Mr. Brown	X		
Mr. Deal		X		Mr. Gordon			
Mr. Burr		X		Mr. Deutsch	X		
Mr. Whitfield		X		Mr. Rush	X		
Mr. Norwood				Ms. Eshoo			
Mrs. Cubin				Mr. Stupak	X		
Mr. Shimkus		X		Mr. Engel	X		
Mrs. Wilson		X		Mr. Wynn			
Mr. Shadegg		X		Mr. Green	X		
Mr. Pickering		X		Ms. McCarthy	X		
Mr. Fossella				Mr. Strickland	X		
Mr. Blunt		X		Ms. DeGette	X		
Mr. Buyer		Х		Ms. Capps	X		
Mr. Radanovich		X		Mr. Doyle	· X		
Mr. Bass		Х		Mr. John	X		
Mr. Pitts	•	x		Mr. Allen			
Ms. Bono		Х		Mr. Davis	Х		
Mr. Walden		X		Ms. Schakowsky	X		
Mr. Terry		X		Ms. Solis	х		
Mr. Fletcher							
Mr. Ferguson		X			,		
Mr. Rogers		X					
Mr. Issa		X			30-0-1		
Mr. Otter		Х			10.00		

COMMITTEE ON ENERGY AND COMMERCE $-108 \mathrm{TH}$ CONGRESS ROLL CALL VOTE $\#\,64$

BILL: H.R. 2473, Medicare Prescription Drug and Modernization Act.

AMENDMENT: An amendment to the amendment in the nature of a substitute by Ms. Capps, No. 37, to modify the practice expense reimbursements to physician specialties that administer Medicare covered drugs.

DISPOSITION: NOT AGREED TO, by a roll call vote of 22 yeas to 23 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Tauzin		X		Mr. Dingell	Х		
Mr. Bilirakis		Х	-	Mr. Waxman	X		
Mr. Barton		X		Mr. Markey	X		
Mr. Upton				Mr. Hall	х		
Mr. Stearns		X		Mr. Boucher			
Mr. Gillmor				Mr. Towns	x		
Mr. Greenwood		X		Mr. Pallone	X		
Mr. Cox		X		Mr. Brown	X		
Mr. Deal		X		Mr. Gordon	X		
Mr. Burr		X		Mr. Deutsch	х		
Mr. Whitfield		X		Mr. Rush	X		
Mr. Norwood	X			Ms. Eshoo	Х		
Mrs. Cubin				Mr. Stupak			
Mr. Shimkus		X		Mr. Engel			
Mrs. Wilson		Х		Mr. Wynn	X		
Mr. Shadegg		X		Mr. Green	X		***************************************
Mr. Pickering		Х		Ms. McCarthy	X		
Mr. Fossella		X		Mr. Strickland	х		
Mr. Blunt	ON THE REAL PROPERTY OF THE PERSON OF THE PE	- Hologe		Ms. DeGette	Х		
Mr. Buyer		X		Ms. Capps	X		
Mr. Radanovich		Х		Mr. Doyle			
Mr. Bass		X		Mr. John	X		
Mr. Pitts		X		Mr. Allen			
Ms. Bono		X		Mr. Davis	x		
Mr. Walden	~1	X		Ms. Schakowsky	X		
Mr. Terry				Ms. Solis	X		
Mr. Fletcher							
Mr. Ferguson		X					
Mr. Rogers		X					
Mr. Issa							
Mr. Otter		X					

BILL: H.R. 2473, Medicare Prescription Drug and Modernization Act.

AMENDMENT: An amendment to the amendment in the nature of a substitute by Mr. John, No.41, to enhance payments for health care services furnished in rural areas.

DISPOSITION: NOT AGREED TO, by a roll call vote of 22 yeas to 24 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Tauzin		X		Mr. Dingell	X		
Mr. Bilirakis		X		Mr. Waxman	X		
Mr. Barton		x		Mr. Markey	X		
Mr. Upton				Mr. Hall	X		
Mr. Stearns				Mr. Boucher			
Mr. Gillmor		x		Mr. Towns	X		
Mr. Greenwood		Х		Mr. Pallone	X		
Mr. Cox		X		Mr. Brown	X		
Mr. Deal		X		Mr. Gordon	X		
Mr. Burr		X		Mr. Deutsch	X		
Mr. Whitfield		x		Mr. Rush	X		
Mr. Norwood		Х		Ms. Eshoo	X		***
Mrs. Cubin				Mr. Stupak	3.44		
Mr. Shimkus		Х		Mr. Engel	***************************************		
Mrs. Wilson		X		Mr. Wynn	X		
Mr. Shadegg		X		Mr. Green	X		
Mr. Pickering	X			Ms. McCarthy	X		
Mr. Fossella		X		Mr. Strickland	Х		
Mr. Blunt				Ms. DeGette			
Mr. Buyer		X		Ms. Capps	X		
Mr. Radanovich				Mr. Doyle			
Mr. Bass		X		Mr. John	X		
Mr. Pitts		x		Mr. Allen	X		
Ms. Bono		х		Mr. Davis	X		
Mr. Walden		х		Ms. Schakowsky	X		
Mr. Terry		х		Ms. Solis	X		
Mr. Fletcher		X					
Mr. Ferguson							
Mr. Rogers		X					
Mr. Issa		X					
Mr. Otter	- 1400	X					

BILL: H.R. 2473, Medicare Prescription Drug and Modernization Act.

AMENDMENT: An amendment to the amendment in the nature of a substitute by Mr. Tauzin, No.59, to eliminate the establishment of reduced co-payment for a home health service episode of care for certain Medicare beneficiaries.

DISPOSITION: AGREED TO, by a roll call vote of 41 yeas to 5 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Tauzin	X			Mr. Dingell	X		
Mr. Bilírakis	X			Mr. Waxman	X		
Mr. Barton		X		Mr. Markey	X		
Mr. Upton				Mr. Hall	X		
Mr. Stearns	X			Mr. Boucher			
Mr. Gillmor	X			Mr. Towns	X		111
Mr. Greenwood	X			Mr. Pallone	X		
Mr. Cox		x		Mr. Brown	x		
Mr. Deal				Mr. Gordon			
Mr. Burr	х			Mr. Deutsch	X		***************************************
Mr. Whitfield	X			Mr. Rush	X		
Mr. Norwood	X			Ms. Eshoo	x		
Mrs. Cubin				Mr. Stupak	,		
Mr. Shimkus	Х			Mr. Engel			
Mrs. Wilson	X			Mr. Wynn	X		
Mr. Shadegg		X		Mr. Green	х		
Mr. Pickering	X			Ms. McCarthy	X		
Mr. Fossella				Mr. Strickland	X		
Mr. Blunt				Ms. DeGette	X		
Mr. Buyer		X		Ms. Capps	X		
Mr, Radanovich	X			Mr. Doyle			
Mr. Bass	Х			Mr. John			
Mr. Pitts	х			Mr. Allen	X		
Ms. Bono	X			Mr. Davis	x		
Mr. Walden	X			Ms. Schakowsky	X		
Mr. Terry	х			Ms. Solis	X		
Mr. Fletcher	X						
Mr. Ferguson	X						
Mr. Rogers	X						
Mr. Issa	X				Ultimate Control		
Mr. Otter	**	X					

BILL: H.R. 2473, Medicare Prescription Drug and Modernization Act.

AMENDMENT: An amendment to the amendment in the nature of a substitute by Mr. Cox, No.60, to authorize, notwithstanding other provisions under the Medicare program, a physician or practitioner to furnish medical and other health service for a fee that such physician or practitioner, and the patient agree upon, provided that the physician or practitioner, and the patient, shall have voluntarily elected not to seek payment or reimbursement under the Medicare program.

DISPOSITION: NOT AGREED TO, by a roll call vote of 19 yeas to 27 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Tauzin		X		Mr. Dingell		X	
Mr. Bilirakis		X		Mr. Waxman		X	
Mr. Barton	Х			Mr. Markey		X	
Mr. Upton				Mr. Hall	X		
Mr. Stearns	X			Mr. Boucher			117111111111111111111111111111111111111
Mr. Gillmor	х			Mr. Towns		X	
Mr. Greenwood	X			Mr. Pallone		X	707111111111111111111111111111111111111
Mr. Cox	X			Mr. Brown		X	
Mr. Deal				Mr. Gordon			
Mr. Burr	х			Mr. Deutsch		Х	
Mr. Whitfield	Х			Mr. Rush		Х	
Mr. Norwood	х			Ms. Eshoo		X	
Mrs. Cubin				Mr. Stupak			
Mr. Shimkus		X		Mr. Engel			
Mrs. Wilson		Х		Mr. Wynn		Х	
Mr. Shadegg	Х			Mr. Green		Х	
Mr. Pickering	Х			Ms. McCarthy		Х	
Mr. Fossella				Mr. Strickland		X	
Mr. Blunt				Ms. DeGette		X	
Mr. Buyer	Х			Ms. Capps		х	
Mr. Radanovich	X			Mr. Doyle			
Mr. Bass	Х			Mr. John			
Mr. Pitts	х			Mr. Allen		X	
Ms. Bono		X		Mr. Davis		Х	
Mr. Walden		X		Ms. Schakowsky		X	
Мг. Тетгу	X			Ms. Solis		X	
Mr. Fletcher	X			2000	****		
Mr. Ferguson		Х					
Mr. Rogers		X					
Mr. Issa	X						
Mr. Otter	X		.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,				

COMMITTEE ON ENERGY AND COMMERCE -- 108TH CONGRESS ROLL CALL VOTE # 68

BILL: H.R. 2473, Medicare Prescription Drug and Modernization Act.

AMENDMENT: An amendment to the Whitfield amendment by Ms. Degette No.62a, to (1) further increase a States Medicaid Disproportionate Share Hospital (DSH) allotment to those levels that each State had in fiscal year 2002, to (2) decrease subsequent years each states' DSH allotment to reflect current law policies, and to (3) increase the allotments for low DSH states.

DISPOSITION: NOT AGREED TO, by a roll call vote of 22 yeas to 26 nays.

		T		T		7	
REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Tauzin		X		Mr. Dingell	X		35.71
Mr. Bilirakis		X		Mr. Waxman	X		
Mr. Barton		X		Mr. Markey	X		
Mr. Upton				Mr. Hall	X		
Mr. Stearns		X		Mr. Boucher			
Mr. Gillmor		Х		Mr. Towns	X		
Mr. Greenwood		Х		Mr. Pallone	X		
Mr. Cox		X		Mr. Brown	X		
Mr. Deal				Mr. Gordon	, , , , , , , , , , , , , , , , , , , ,		
Mr. Burr		X		Mr. Deutsch	X		
Mr. Whitfield		X		Mr. Rush	X		
Mr. Norwood		Х		Ms. Eshoo	X		
Mrs. Cubin	-			Mr. Stupak			
Mr. Shimkus		Х		Mr. Engel			
Mrs. Wilson	X			Mr. Wynn	X		
Mr. Shadegg		X		Mr. Green	X		
Mr. Pickering		X		Ms. McCarthy	X		
Mr. Fossella		Х		Mr. Strickland	X		
Mr. Blunt		X		Ms. DeGette	X		
Mr. Buyer		X		Ms. Capps	X		
Mr. Radanovich		X		Mr. Doyle			
Mr. Bass		X		Mr. John			
Mr. Pitts		X		Mr. Allen	X		
Ms, Bono	X			Mr. Davis	X		
Mr. Walden		Х		Ms. Schakowsky	X		
Mr. Terry		X		Ms. Solis	· X		
Mr. Fletcher		X					
Mr. Ferguson		X					
Mr. Rogers		X					
Mr. Issa		Х				1	
Mr. Otter		X					
		1					

6/19/2003

COMMITTEE ON ENERGY AND COMMERCE -- 108TH CONGRESS ROLL CALL VOTE # 69

BILL: H.R. 2473, Medicare Prescription Drug and Modernization Act.

 $\textbf{MOTION:} \quad A \ \text{motion by Mr. Tauzin to order H.R. 2473 ordered reported to the House, as amended.}$

DISPOSITION: AGREED TO, by a roll call vote of 29 yeas to 20 nays.

REPRESENTATIVE	YEAS	NAYS	PRESENT	REPRESENTATIVE	YEAS	NAYS	PRESENT
Mr. Tauzin	X			Mr. Dingell		х	
Mr. Bilirakis	X			Mr. Waxman		Х	
Mr. Barton	X			Mr. Markey		X	
Mr. Upton				Mr. Hall	X		
Mr. Stearns	X			Mr. Boucher			
Mr. Gillmor	X			Mr. Towns	, , , , , , ,	Х	
Mr. Greenwood	Х			Mr. Pallone		Х	
Mr. Cox	X			Mr. Brown	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	X	
Mr. Deal				Mr. Gordon			
Mr. Burr	Х			Mr. Deutsch		х	
Mr. Whitfield	X			Mr. Rush		х	
Mr. Norwood	X			Ms. Eshoo		X	
Mrs. Cubin				Mr. Stupak			
Mr. Shimkus	X			Mr. Engel			
Mrs. Wilson	X			Mr. Wynn		Х	
Mr. Shadegg	X			Mr. Green	,	х	
Mr. Pickering	Х			Ms. McCarthy		X	
Mr. Fossella	X			Mr. Strickland		X	
Mr. Blunt	X			Ms. DeGette		X	****
Mr. Buyer	X			Ms. Capps		Х	
Mr. Radanovich	X			Mr. Doyle			
Mr. Bass	X			Mr. John		х	
Mr. Pitts	х			Mr. Allen		X	
Ms. Bono	X			Mr. Davis		x	
Mr. Walden	X			Ms. Schakowsky		X	
Mr. Terry	X			Ms. Solis		X	
Mr. Fletcher	X				11000		
Mr. Ferguson	X						
Mr. Rogers	X						
Mr. Issa	X	1		3000000			A.V.
Mr. Otter	X						

6/19/2003

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee has held oversight hearings on this legislation, and made findings that are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The goal of H.R. 2473 is to create a new Prescription Drug Plan that permits all individuals currently enrolled within Parts A and B to obtain a new benefit.

NEW BUDGET AUTHORITY, ENTITLEMENT AUTHORITY, AND TAX EXPENDITURES

In compliance with clause 3(c)(2) of rule XIII of the Rules of the House of Representatives, the Committee finds that H.R. 2473, the Medicare Prescription Drug and Modernization Act of 2003, would result in changes to budget authority, entitlement authority, and tax expenditures and revenues.

COMMITTEE COST ESTIMATE, CONGRESSIONAL BUDGET OFFICE ESTIMATE, AND FEDERAL MANDATES STATEMENT

The Congressional Budget Office estimate required pursuant to clause 3(c)(3) of rule XIII of the Rules of the House of Representatives, as provided by the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974, and the estimate of Federal mandates required pursuant to section 423 of the Unfunded Mandates Reform Act were requested from the Congressional Budget Office, but were not prepared as of the date of filing of this report.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

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 this legislation is provided in Article I, section 8, clause 3, which grants Congress the power to regulate commerce with foreign nations, among the several States, and with the Indian tribes.

APPLICABILITY TO LEGISLATIVE BRANCH

The Committee finds that the legislation does not relate to the terms and conditions of employment or access to public services or accommodations within the meaning of section 102(b)(3) of the Congressional Accountability Act.

SECTION-BY-SECTION ANALYSIS OF THE LEGISLATION

TITLE I—MEDICARE PRESCRIPTION DRUG BENEFIT

Section 101. Establishment of a Medicare prescription drug benefit

Section 101 establishes a new Voluntary Prescription Drug Benefit Program under a new Part D of title XVIII of the Social Security Act, as follows:

Section 1860D-1. Benefits; eligibility; enrollment; and coverage period

Under new section 1860D–1, all beneficiaries entitled to benefits under Part A or enrolled in Part B of the Medicare program will be eligible to enroll in a qualified prescription drug plan (PDP) or receive prescription drug benefits a Medicare Advantage (MA) plan, or an Enhanced Fee-for-Service (EFFS) plan. Each beneficiary enrolled in Part A and/or Part B will have a choice between two qualified prescription drug plans, at least one of which will be a PDP.

All eligible beneficiaries who elect to enroll in a PDP will not be excluded on the basis of a pre-existing condition or their economic status and will be guaranteed continuous coverage while enrolled in the program. When a beneficiary is not continuously enrolled in a PDP, a qualified retiree plan, or a MA/EFFS plan, the plan may change the premium or impose a pre-existing condition exclusion that is consistent with the risk of enrolling that beneficiary. The initial period of coverage under the program will begin January 1, 2006.

Section 1860D-2. Requirements for qualified prescription drug coverage

Under new section 1860D–2, all PDP plans will be required to make available to their enrollees the benefit of all price discounts. They also will provide coverage for outpatient prescription drugs on the plan's formulary.

Standard coverage under the bill includes an annual deductible of \$250, beneficiary cost sharing 20% of the first \$2,000 of expenditures, and a limitation of total out-of-pocket expenditures of \$3,500. The Committee notes, however, that a PDP or a MA/EFFS plan can provide a benefit different from the standard coverage requirement so long as it is actuarially equivalent in value.

Beneficiaries enrolled in either a PDP, qualified retiree plan or a MA/EFFS plan will have access to negotiated prices that include discounts. The PDP sponsors, qualified retiree plans or the MA/EFFS plans will fully disclose to the Secretary the degree to which discounts and rebates are passed along to the beneficiaries.

A covered outpatient drug includes prescription drugs and/or biologics, defined under section 1927 of Medicaid. If a plan meets the beneficiary protection requirements in section 1860C, it can use a formulary to provide further discounts for certain covered outpatient drugs.

Section 1860D-3. Beneficiary protections for qualified prescription drug coverage

New section 1860D–3 sets forth beneficiary protections for qualified prescription drug coverage. First, plans will be required to provide each enrolled beneficiary information about the plan's benefit structure, its affiliated networks of pharmacy providers, any applicable formulary requirements including any applicable cost-sharing and their right to file grievances and/or seek benefit appeal. Plans will be required to respond to beneficiary inquiries and make available information regarding any changes in the plan's formulary.

The PDP sponsor will also ensure adequate access to a sufficient number of pharmacies that dispense drugs to patients. These requirements shall provide beneficiaries with the same convenient access rules that apply to TRICARE plans. Plans also will be required to accept any pharmacy that is willing to accept the plans' terms and conditions. Every sponsor of a PDP will have a pharmacy and therapeutic committee that will develop and maintain a formulary. In establishing therapeutic categories for the formulary, the plan must take into account standards published in the U.S. Pharmacopeia-Drug Information.

Section 1860D-4. Requirements for and contracts with prescription drug plan (PDP) sponsors

New section 1860D–4 of the legislation outlines the requirements for Prescription Drug Plan (PDP) sponsors. Specifically, sponsors of PDPs will be licensed under state law as risk bearing entities eligible to offer health insurance or coverage in each state in which the plan operates. The plan will assume full risk for the unsubsidized portion of the benefit. The plan also may use reinsurance to ensure coverage for a portion of the benefit.

Section 1860D-5. Process for beneficiaries to select qualified prescription drug coverage

New section 1860D–5 establishes a process for beneficiaries to select qualified prescription drug coverage. The selection process will include annual, coordinated election periods, dissemination of comparative information regarding price, quality and other features, and coordination with MA/EFFS elections. Enrollees in MA/EFFS plans offering prescription drug coverage can only elect to receive drug coverage through that plan.

While ensuring access to coverage the Administrator will provide a choice of at least two qualifying plans in each area. Qualifying plans are defined as Prescription Drug Plans or MA/EFFS plans that include prescription drug coverage. In order to guarantee access to coverage, the Administrator may provide financial incentives to plans. These incentives will ensure that all beneficiaries have access to multiple choices of drug plans.

Section 1860D-6. Submission of bids and premiums

New section 1860D–6 provides that each PDP sponsor will be required to submit specified bid information, in the same manner as MA/EFFS plans. This information will describe the qualified drug coverage to be provided, the actuarial value of the coverage, the monthly premium to be charged for the coverage, the portion of the premium attributable to benefits in excess of the standard coverage and the reduction in the premium resulting from federal subsidies. The Administrator will review this information and use it to negotiate the terms and conditions of PDPs.

Section 1860D-7. Premium and cost-sharing subsidies for low-income individuals

New section 1860D-7 reflects the desire of the Committee to target government resources to those who need it most. Individuals with incomes below 135 percent of the Federal Poverty Level (FPL) will receive a subsidy for the full value of their premium and the deductible. Cost-sharing obligations for these individuals may not exceed \$2 for multiple-source or generic drugs and \$5 for non-pre-

ferred drugs. Individuals with incomes between 135 and 150 percent of FPL will receive a premium subsidy based on an income-

related sliding scale.

The Administrator will notify PDP sponsors or MA/EFFS organizations that an individual is eligible for a subsidy and the amount of the subsidy. The sponsor or organization will then reduce the premiums or cost sharing, which would otherwise be imposed, by the amount of the subsidy. The Administrator will periodically and on a timely basis reimburse the sponsor or organization for the amount of the reductions.

Part D coverage will be the primary payor for drug benefits under Medicaid. The Administrator will coordinate prescription drug benefits under Part D with the benefits provided under Medicaid, with particular focus upon coordination of payments and prevention of fraud and abuse.

Section 1860D-8. Subsidies for all Medicare beneficiaries for qualified prescription drug coverage

In new section 1860D–8, the Administrator will provide subsidies to qualifying entities in order to reduce beneficiary premiums, mitigate adverse selection among PDPs and MA/EFFS plans and promote the participation of PDP sponsors. The section will constitute budget authority in advance of appropriations and represents the obligation of the Administrator to provide payment of amounts provided under this section. The subsidies will include direct subsidies to PDP and MA/EFFS plans equal to a percentage of an amount equal to the actuarial value of the standard drug coverage subsidies through reinsurance for excess costs incurred in providing qualified prescription drug coverage. The section also incorporates special subsidy mechanisms for employers and labor unions.

Section 1860D-9. Medicare Prescription Drug Trust Fund

New section 1860D–9 creates a new trust fund in the United States Treasury. The trust fund will be managed in the same manner as the "Federal Supplementary Medical Insurance Trust Fund." Payments from the trust fund will be made from time to time for the low-income subsidies, the federal subsidies, reinsurance amounts, and administrative expenses.

Section 1860D-10. Definitions; application to Medicare advantage and EFFS programs; treatment of references to provisions in part

New section 1860D-10 directs the Administrator to complete a study and make recommendations to Congress by January 1, 2005 on how to move Medicare part B covered drugs into the new Medicare part D outpatient prescription drug program. It is the Committee's intent to ensure that Part B and Part D benefits will be appropriately coordinated in the future.

In addition, this section directs the Secretary to review the current standards of practice for pharmacy services provided to patients in nursing facilities. It is the intent of the Committee to have the Secretary expand this study to examine long term care facilities, not just nursing homes, as that will more accurately reflect that current issues confronting this sector.

Section 102. Offering of qualified prescription drug coverage under Medicare Advantage (MA) and enhanced fee-for-service (EFFS) program

Section 102 requires MA and EFFS plans to offer at least qualified prescription drug coverage in an area or region, and provide that such coverage is actuarially equivalent to standard coverage. This does not require all MA/EFFS plans offered by an organization in a given area to offer drug coverage, but at least one of their plan offerings in a given area must offer drug coverage. MA/EFFS plans must comply with all the same requirements as those that apply to PDP sponsors, and submit the appropriate information to the Administrator except for information that the Administrator determines is duplicative.

Section 103. Medicaid amendments

Section 103 adds a new section 1935 to the Social Security Act entitled "Special Provisions Relating to Medicare Prescription Drug Benefit." The provision requires states, as a condition of receiving Federal assistance, to make eligibility determinations for premium and cost-sharing assistance for Part D, inform the Medicare Benefits Administrator (MBA) Administrator of cases where eligibility has been established, and otherwise provide information to the MBA Administrator as may be required to carry out Part D. It also allows for enhanced administrative payments for the purpose of determining eligibility for the low-income benefit.

The provision also provides for a phased-in Federal assumption of the costs associated with providing dual-eligible Medicaid beneficiaries qualified drug coverage under Medicare Part D. These costs would be assumed by the Federal government over a period of fifteen years, in increments of 6 2/3% each year, and be assumed through appropriate revisions in the Medicaid matching payments for each state.

The provision includes clarification that in the case of individuals dually entitled to prescription drug coverage under Part D and drug coverage under Medicaid, that those individuals' coverage under Medicare would be primary. The provision allows states to require, as a condition for receipt of Medicaid drug benefits, that a dually-entitled individual elect qualified prescription drug coverage under Medicare.

Residents of Territories are not eligible for regular low-income subsidies. However, Territories would be able to get additional Medicaid funds, beginning at \$25 million a year and escalating by the annual percentage increase in prescription drug costs for Medicare beneficiaries. In order to obtain these funds, Territories would be required to formulate a plan on how they would dedicate the funds to assist low-income Medicare beneficiaries in obtaining covered outpatient prescription drugs.

Section 104. Medigap transition

Section 104 contains specific rules pertaining to Medigap plans. Under the bill, no new Medigap prescription drug policies can be sold after January 1, 2006. Beneficiaries who have current Medigap prescription drug insurance can maintain such coverage. Individuals who currently have Medigap policies with prescription drug coverage, who elect to terminate such coverage and enroll in

Part D, would be able to enroll in a Medigap policy without prescription drug penalty within 63 days of the termination of prior coverage. In providing such plans, the Medigap issuer may not deny or condition the issuance of such plans, may not discriminate in the pricing of such policy based upon health status, claims experience, receipt of health care or medical condition and may not impose an exclusion of benefits based upon a pre-existing condition. Two new Medigap policies will also be created, the first of which will cover 50 percent of the all cost sharing except for preventative benefits, where the percentage of coverage will be 100 percent. This plan will also limit annual out-of-pocket expenditures to \$4,000 in 2005, with that number subsequently adjusted for inflation. The second new plan would be similar to the first plan, but would replace 50 percent cost sharing with 75 percent and set the limit on annual out-of-pocket expenditures at \$2,000.

Section 105. Medicare prescription drug discount card and assistance program

Section 105 directs the Secretary to establish a program to endorse prescription drug discount card programs and provide information regarding such programs to Medicare beneficiaries. Starting in 2004, fee-for-service (FFS) beneficiaries will be able to choose from a wide selection of discount drug cards (drug value cards). The drug value cards will give seniors access to the benefits of bulk prescription drug purchasing and cost management techniques.

The following rules will apply to the program. Any organization is eligible to offer a drug value card: AARP, employers, pharmacist/ pharmacy organizations, pharmacy benefit managers, drug wholesalers, and insurers. The cards will be CMS-approved. Drug card issuers will negotiate discounts from drug manufacturers. Under the legislation, low-income beneficiaries who are not eligible to receive drug benefits under Medicaid will receive Federal assistance to buy prescription drugs. The Federal contributions will be credited to beneficiaries' individual accounts held by the Federal government in the Supplementary Medical Insurance (SMI) (Part B) Trust Fund. The accounts will then be debited every time seniors purchase their drugs. The Federal government will add the following income-related contributions into every account: \$800—for those below 135% of the Federal Poverty Level (FPL); \$500—136-150% of FPL; and \$100 for individuals above 150% of FPL. The contribution amounts will then be indexed to Medicare Drug Spending. Medicare beneficiaries' children and other individuals can also contribute to the accounts. The allowable contribution is capped at \$5,000 per year.

Depending on beneficiaries' income levels, states can contribute funds into seniors' accounts. States can save administrative expenses by contributing money to seniors' accounts instead of operating their own state drug assistance programs. Employers can add money to the drug expenditure accounts up to \$5,000. Employers can also offer their own drug value card/drug benefit for their retirees and the retirees will also receive the federal government account contribution. The funds in the accounts will rollover from

year to year.

This section also provides for an appropriate transition and eventual discontinuance of this program at the time that prescription drug benefits become available under Part D.

Section 106. Disclosure of return information for purposes of carrying out Medicare catastrophic prescription drug program

Section 106 permits the Secretary of the Treasury, upon written request from the Secretary of the Department of Health and Human Services (HHS) to disclose to officers and employees of HHS specific information with respect to a specified taxpayer for a specific tax year. The information that could be disclosed is taxpayer identity information and the adjusted gross income for the taxpayer or, if less, the income threshold limit specified under the new Part D (\$200,000 in 2006). A specified taxpayer would be either: (1) an individual who had adjusted gross income for the year in question in excess of the income threshold specified in the new Part D (\$60,000); or, (2) an individual who elected to use more recent income information as permitted under Part D. Individuals filing joint returns would each be treated separately with each person considered to have an adjusted gross income equal to one-half of the total.

Return information disclosed could be used by officers and employees of HHS only for administering the prescription drug benefit. They could disclose the annual out-of-pocket threshold applicable to an individual to the entity offering the individual prescription drug coverage. The sponsor could use such information only for the purposes of administering the benefit.

Section 107. State pharmaceutical assistance transition commission

Section 107 establishes a State Pharmaceutical Assistance Transition Commission to develop a proposal for dealing with the transitional issues facing state programs and participants due to implementation of the new Part D prescription drug program. The Commission, to be established on the first day of the third month following enactment, would include: (1) a representative of each governor from each state with a program that the Secretary identifies as having a benefit package comparable to or more generous than the new Part D; (2) representatives from other states that have pharmaceutical assistance programs, as appointed by the Secretary; (3) representatives (not exceeding the total under #1 and #2) of organizations that represent interests of participants, appointed by the Secretary; (4) representatives of Medicare Advantage organizations; and, (5) the Secretary or the Secretary's designee and other members specified by the Secretary. The Commission sion would develop the proposal in accordance with specified principles, namely: (1) protection of the interests of program participants in the least disruptive manner; (2) protection of the financial and flexibility interests of states so they are not financially worse off; and, (3) principles of Medicare modernization outlined in Title II of the Act.

The Commission would report to the President and Congress by January 1, 2005. The report would contain specific proposals including specific legislative or administrative recommendations, if any. The Commission would terminate 30 days later.

Finally, the Committee notes that Medicare Quality Improvement Organizations (QIOs) may offer assistance to Medicare Advantage plans under part C, providers, practitioners and Prescription Drug Plan Sponsors under part D, Enhanced Fee For Service Plans under Part E and the Prescription Drug Card Program. QIOs are currently required to offer assistance with clinical improvement under Parts A and B in hospitals, physicians' offices, nursing homes and home health agencies and to all M+C organizations. The Committee believes that expanding the QIOs' work to include the new entities and benefits created in this legislation will help improve the quality of care for all Medicare beneficiaries across the entire continuum of the care.

TITLE II—MEDICARE ENHANCED FEE-FOR-SERVICE AND MEDICARE ADVANTAGE PROGRAMS; MEDICARE COMPETITION

Section 200. Medicare modernization and revitalization

Section 200 provides for the establishment of the Medicare enhanced fee-for-service (EFFS) program, the Medicare Advantage program, and competitive bidding among enhanced fee-for-service plans and Medicare Advantage plans.

Subtitle A—Medicare Enhanced Fee-for-Service Program

Section 201. Establishment of enhanced fee-for-service (EFFS) program under Medicare

Section 201 establishes an enhanced fee-for-service program under a new Part E of title XVIII of the Social Security Act, as follows:

Section 1860E-1. Offering of enhanced fee-for-service plans throughout the United States

New section 1860E–1 establishes a new "Part E" of the Medicare program called the Enhanced Fee-for-Service ("EFFS") program beginning January 1, 2006. The program will allow enhanced fee-for-service plans (preferred provider organizations (PPOs) or private fee-for-service plans) to offer benefits to Medicare beneficiaries on a regional basis. The Medicare Benefits Administrator (MBA) will establish a minimum of 10 regions throughout the country.

Section 1860E-2. Offering of enhanced fee-for-service (EFFS) plans

New section 1860E–2 establishes plan requirements for EFFS plans. No EFFS plan may be offered in a region unless it meets all the requirements of EFFS plans established under Part E. A plan offered within an EFFS region must be offered to all EFFS-eligible individuals in the region. Benefits must be uniform for all enrollees in a plan, must include all statutory Part A and Part B benefits under Medicare, and must have a single deductible and a catastrophic limit on out-of-pocket expenditures for benefits under Parts A and B. Plans must also provide drug coverage for beneficiaries enrolled in Part D of Medicare. Drug coverage offered under an EFFS plan must comply with the rules outlined in Title I.

Section 1860E-3. Submission of bids; beneficiary savings; payment of plans

New section 1860E-3 states that beginning in 2006, enhancedfee-for-service (EFFS) organizations will submit to the MBA a monthly bid amount for each EFFS plan offered in a region. The bid amount cannot vary among eligible individuals for an EFFS plan in an EFFS region. In addition to submitting the full bid amount, the organization will also submit the proportions of such bid amount attributable to (1) the provision of statutory non-drug (Part A and Part B) benefits, (2) the provision of statutory drug (Part D) benefits, and, (3) the provision of non-statutory (supplemental) benefits, along with the actuarial basis for the bid and the proportions. The MBA will have the authority to negotiate regarding the monthly bid amounts, in a similar fashion as the Director of the Office of Personnel Management (OPM) has with respect to the Federal Employees Health Benefits Program (FEHBP). The Administrator may enter into contracts with up to three EFFS plans in each region.

Plan bids for statutory non-drug benefits within a region will be compared to a benchmark for such benefits. The benchmark amount will be the weighted average of the Medicare Advantage payment rates in the region. Beneficiaries who enroll in plans with bids below the benchmark will receive a rebate of 75 percent of the difference between the benchmark and the bid. The remaining 25 percent will be savings for the Medicare program. In calculating the rebate, both the benchmark and the bid will be risk adjusted to reflect the health and demographic characteristics of each plan's enrollees. The rebate can be credited to the premium for prescription drugs or supplemental benefits, returned to the beneficiary in the form of cash rebates, or provided to the beneficiary through other means approved by the MBA.

Payment to plans for non-drug benefits will be as follows: (A) Plans with bids below the benchmark will receive payment of their risk-adjusted bid amount, plus the rebate amount described above (75 percent of the difference between the benchmark and the bid). (B) Plans with bids at or above the benchmark will receive the risk-adjusted benchmark amount as payment. Plans will be paid for statutory drug benefits in the manner outlined in Title I.

Section 1860E-4. Premiums; organizational and financial requirements; establishment of standards; contracts with EFFS organizations

New section 1860E–4 defines the EFFS monthly basic beneficiary premium, the EFFS monthly prescription drug premium, and the EFFS monthly supplemental premium. All premiums are required to be uniform among plan enrollees, and beneficiary premiums for non-drug, drug, and supplemental benefits can be consolidated into a single premium.

Subtitle B-Medicare Advantage Program

CHAPTER 1—IMPLEMENTATION OF PROGRAM

Section 211. Implementation of Medicare advantage program

Section 211 renames the current Medicare+Choice program to "Medicare Advantage".

Section 212. Medicare advantage improvements

Section 212 adds a fourth payment option for Medicare Advantage plans: 100 percent of local fee-for-service costs for 2004, excluding direct graduate medical education and including adjustments for costs that would have occurred had beneficiaries not received care from a Veterans Administration (VA) or Department of Defense (DOD) facility. It also funds the blend payment amount for 2004 by eliminating the budget neutrality requirement. The section changes the minimum percentage increase for 2004 and subsequent years to the greater of 2 percent or the Medicare Advantage national growth percentage.

CHAPTER 2—IMPLEMENTATION OF COMPETITION PROGRAM

Section 221. Competition program beginning in 2006

Section 221 states that beginning in 2006, Medicare Advantage plans will be required to submit bids to provide services to Medicare beneficiaries. In addition to submitting the full bid amount, the organization will also submit the proportions of such bid amount attributable to (1) the provision of statutory non-drug (Part A and Part B) benefits, (2) the provision of statutory drug (Part D) benefits, and (3) the provision of non-statutory (supplemental) benefits, along with the actuarial basis for the bid and the proportions. The MBA will have the authority to negotiate regarding the monthly bid amounts, in a similar fashion as the Director of the Office of Personnel Management (OPM) has with respect to the Federal Employees Health Benefits Program (FEHBP). The Administrator may reject a plan if it is designed to discourage enrollment by certain Medicare beneficiaries.

Plan bids for statutory non-drug benefits within a region will be compared to a benchmark for such benefits. The benchmark amount will be the Medicare Advantage payment rate. Beneficiaries who enroll in plans with bids below the benchmark will receive a rebate of 75 percent of the difference between the benchmark and the bid. The remaining 25 percent will be savings for the Medicare program. In calculating the rebate, both the benchmark and the bid will be risk adjusted to reflect the health and demographic characteristics of each plan's enrollees. The rebate can be credited to the premium for prescription drugs or supplemental benefits, returned to the beneficiary in the form of cash rebates, or provided to the beneficiary through other means approved by the MRA

Payment to plans for non-drug benefits will be as follows: (A) Plans with bids below the benchmark will receive payment of their risk-adjusted bid amount, plus the rebate amount described above (75 percent of the difference between the benchmark and the bid).

(B) Plans with bids at or above the benchmark will receive the risk-adjusted benchmark amount as payment. Plans will be paid for statutory drug benefits in the manner outlined in Title I.

CHAPTER 3—ADDITIONAL REFORMS

Section 231. Making permanent change in Medicare advantage reporting deadlines and annual, coordinated election period

Section 231 creates a permanent change in the reporting deadline for Medicare Advantage plans on their payment rates. The new deadline will now be the second Tuesday in September instead of July 1. This section also creates a permanent change in the election period to occur in November, which is consistent with the 3-year change that was made in the Bioterrorism bill. Finally, the section creates a permanent change to the annual announcement of Medicare Advantage payment rates by requiring the Secretary to make the payment rates for Medicare Advantage plans available by the second Monday in May. This is also consistent with the 2-year change that was included in the Bioterrorism bill.

Section 232. Avoiding duplicative State regulation

Section 232 ensures that Medicare Advantage plans are not subject to state laws that do not pertain to solvency and licensing. This provision will take effect on the date of enactment of this Act.

Section 233. Specialized Medicare advantage plans for special needs beneficiaries

Section 233 ensures that Medicare Advantage plans that target special needs beneficiaries are treated in the same manner as regular Medicare Advantage plans. This section will make the current special needs demonstration program permanent (i.e., Evercare).

Section 234. Medicare MSAs

Section 234 exempts Medical Savings Accounts (MSA) plans from reporting quality and encounter data to the Trustees. It also makes the MSA program permanent in law and eliminates the cap of people eligible to enroll.

Section 235. Extension of reasonable cost contracts

Section 235 allows the continuation of reasonable cost contracts indefinitely, with the following exception: After January 1, 2008, a reasonable cost contract may not be extended or renewed in an area that is served by 2 or more Medicare Advantage plans or 2 or more enhanced fee-for-service plans, each of which meets certain minimum enrollment requirements in that area.

Subtitle C—Application of FEHBP-Style Competitive Reforms

Section 241. Application of FEHBP-style competitive reform beginning in 2010

Section 241 states that beginning in 2010, any EFFS region that has EFFS enrollment equal to at least the national Medicare private plan enrollment rate or 20 percent and is served by 2 or more EFFS plans, meeting certain minimum enrollment requirements, will be deemed a competitive EFFS region. For such competitive re-

gions, the benchmark amount against which plan bids will be compared will be based on a weighted average of plan bids and the regional costs of the traditional fee-for-service program. The competi-

tive benchmark will be phased in over a 5-year period.

Beginning in 2010, an area will be considered a competitive Medicare Advantage area if the Administrator finds that the area has Medicare Advantage enrollment equal to at least the national Medicare private plan enrollment rate or 20 percent and that at least 2 Medicare Advantage plans, meeting certain minimum enrollment requirements, will be offered in the area by different Medicare Advantage organizations. The competitive area must be a metropolitan statistical area or other similar-sized area in which the Administrator finds there are a substantial number of Medicare Advantage enrollees. For such competitive areas, the benchmark amount against which plan bids will be compared will be based on a weighted average of plan bids and the costs of the traditional fee-for-service program in the area. The competitive benchmark will be phased in over a 5-year period.

Enrollees in the traditional Medicare program who reside in a competitive EFFS region or a competitive Medicare Advantage area may have their Part B premiums adjusted either up or down, subject to a 5-year phase in. If an enrollee resides in a competitive area and the fee-for-service cost in the region or area is lower than the competitive benchmark amount, then beneficiaries are entitled to 75 percent of the difference between the fee-for-service amount and the benchmark, phased in over 5 years. If the fee-for-service cost is greater than the competitive benchmark, the beneficiary premium is adjusted to make up the difference between the bid and the benchmark, and any such adjustment is phased in over 5 years.

TITLE III—COMBATTING WASTE, FRAUD, AND ABUSE

Section 301. Medicare secondary payor (MSP) provisions

Section 301 modifies the conditions under which Medicare becomes the secondary payer for medical services. Effective immediately (as if enacted with Balanced Budget Refinement Act (BBRA) of 1984), the Secretary can make payments for an item or service another payer has not made or cannot reasonably be expected to make payment. The Secretary makes payment on condition that the appropriate Trust Fund is reimbursed if and when the plans make payment. Reimbursement to the Trust Fund must be made if it is shown that the primary plan has or had a responsibility to make payment.

This section also authorizes the US to bring an action against any or all entities that are or were required or responsible to make payment. The US may collect double damages, and may recover from any entity that has received payment or profit from a primary

plan's payment.

Section 302. Competitive acquisition of certain items and services

Section 302 directs the Secretary to establish competitive acquisition areas throughout the United States for certain Part B items and services beginning in 2004. This policy, phased in over a 3-year period, specifies that certain durable medical equipment and off-the-shelf orthotics will be subject to competitive bidding practices.

The Secretary will have the discretion to choose the appropriate codes for competitive bidding. Exemptions may be made for areas that are not competitive due to low-population density (rural areas) or for items and services for which competitive bidding will not likely result in significant savings. This policy limits beneficiaries' co-payments to 20% of the contract price and ensures that multiple suppliers in each geographic area will be maintained. Additionally, quality and customer service standards will be created for the items and services subject to competition. The provision also directs the Secretary to conduct a demonstration project of competitive bidding for clinical diagnostic laboratories and submit to Congress an initial report on the project.

Section 303. Competitive acquisition of covered outpatient drugs and biologicals

Section 303(a) requires the Secretary to establish the practice expense relative value for the physician fee schedule in CY2005 using the survey data provided by entities and organizations if consistent with the Secretary's criteria for acceptable survey data. If submitted prior to December 31, 2004, increases in expenditures resulting from this provision would be exempt from the budget-neutrality requirement. The Secretary would not be prevented from adjusting the practice expense relative values in subsequent years. Also, the Secretary would be required to adjust the non-physician work pool methodology so that practice expense relative values for these services are not disproportionately reduced as a result of the above changes.

This section is in response to certain physician specialty groups, including medical oncologists, who have asserted that they are inadequately compensated under the physician fee schedule, as a result of inaccurate survey data and methodological flaws in the formula. They have further asserted that they depended on the current overpayment for drugs to make up for these inadequate and

flawed Medicare reimbursements.

Section 303(b) will provide physicians with two options for acquiring the drugs they will administer to Medicare patients. They can either elect to continue to purchase drugs and bill Medicare directly, or obtain their drugs through new Medicare contractors, who will in turn bill Medicare for the drugs provided. In the first instance, Medicare's reimbursement will be based on new Average Sales Prices ("ASP"), as defined in the section, and which manufacturers will be required to report directly to the government. ASP will be the average of all prices at which a manufacturer sells the drug or biologic, including any rebates, chargebacks or other discounts that would lower the final price to the purchaser, excluding only those sales already excluded from the calculation of the Medicaid Best Price and sales at nominal prices.

In the second instance, Medicare's reimbursements to contractors will be based on an average of the winning bids of contractors selected through a competitive bidding process. The Secretary would be required to establish a competitive acquisition program to acquire and pay for covered outpatient drugs. The competitive acquisition areas for oncology products need not be identical to those specified for other categories. Under this program, at least 2 contractors would be established in each competitive acquisition area

(which would be defined as an appropriate geographic region) throughout the United States. Each year, a physician would be required to select a contractor who would deliver covered drugs and biologicals to the physician. There would be 2 categories of drugs under this program: the oncology category (including drugs determined by the Secretary as primarily billed by oncologists or are otherwise used to treat cancer), which would be implemented beginning in 2005 and the non-oncology category that would be im-

plemented beginning in 2006.

In this case, covered drugs means certain drugs currently covered under section 1842(o) of the Social Security Act (SSA) which are not covered as part of the competitive acquisition for durable medical equipment. Blood clotting factors, separately billable drugs furnished as treatment for end-stage renal disease (ESRD), and radiopharmaceuticals would not be considered covered drugs under the competitive acquisition program. Nothing in the section would affect the carrier invoice pricing method used to pay for radiopharmaceuticals. The Secretary would also be able to exclude other drugs and biologicals or classes of drugs and biologicals that are not appropriate for competitive bidding or would not produce sav-

The Secretary would be required to establish an annual selection process for a contractor in each area for each of the 2 categories of drugs. In order to be considered, the contractor must have the capacity to supply covered outpatient drugs within the applicable category and meet quality, service, financial performance and solvency standards established by the Secretary. Specifically the entity would be required to have arrangements to ship covered drugs at least 5 days of the week and on an emergency basis, and procedures for the prompt response and resolution of physician and beneficiary complaints and inquiries. The Secretary would not be able to contract with an entity that has had its license for distributing drugs (including controlled substances) suspended or revoked by the Federal or state government or that has been excluded from program participation. As part of the terms of the contract, the Secretary may specify that contractors be required to adopt rigorous safeguards to deter the use of counterfeit or otherwise adulterated products. Contracts would be able to be terminated by either the Secretary or the entity with appropriate advance notice.

The Secretary would be able to limit the number of qualified entities in each category and area, but not below 2. The Secretary would be required to base selection on bid prices for covered drugs, bid prices for distribution of those drugs, ability to insure product integrity, customer service, past experience with drug distribution, and other factors. The bid prices in an area would be effective for that area throughout the 2-year contract period. The Secretary would not be able to accept a contract for an area if its aggregate average bid prices exceed 120% of the Average Sales Prices for those products. Under the program, the Secretary would be required to compute an area average of the submitted bid prices. The reimbursement rate for contractors may vary, according to the terms of the contract entered into, based upon changes in prices that materially affect the prices paid by the contractor for these products. Such price changes may result from, among other things, the entry or exit of a generic or other competitor product in the

market. Contractors shall submit bids based upon Healthcare Common Procedure Code (HCPCs) code classifications. The Secretary shall then either develop or adopt a methodology to cross-walk, on a nation-wide basis, pricing information derived from National Drug Code (NDC) codes into HCPCs codes. Beneficiary liability would be limited to 20% of the payment basis for the covered drug or biological.

The contractor supplying the physician in the area would submit the claim for the drug and would collect the cost-sharing amount from the beneficiary after administration of the drug. Both program payment and beneficiary cost sharing amounts would only be made to the contractor upon administration of the drug and would be based on the average bid of prices for the drug or biological in the area. The Secretary would be required to establish a process for recovery of payments billed at the time of dispensing for drugs that were not actually administered.

The appropriate contractor, as selected by the physician, would supply covered drugs directly to the physician, except under the circumstances when a beneficiary is presently able to receive a drug at home. The contractor would not be able to deliver drugs to a physician without first receiving a prescription as well as other necessary information specified by the Secretary, although a physician would not be required to submit a prescription for each individual treatment. The Secretary would establish requirements in order for a physician to administer drugs or biologicals, which may be needed in emergency situations, and allow the physician to be compensated accordingly. These drugs would be those that would be immediately required, not reasonably foreseen as immediately required, and not able to be delivered by the contractor in a timely manner. No applicable State requirements relating to the licensing of pharmacies would be waived. The current payment methodology for radiopharmaceuticals, including the carriers' use of invoice pricing methodology, would not be affected by this provision.

Section 304. Demonstration project for use of recovery audit contractors

Section 304 directs the Secretary to implement a demonstration project using recovery audit contractors under the Medicare Integrity Program to identify underpayments and overpayments and recoup overpayments made by the Medicare program.

TITLE IV—RURAL HEALTH CARE IMPROVEMENTS

Section 401. Enhanced disproportionate share hospital (DSH) treatment for rural hospitals and urban hospitals with fewer than 100 beds

Section 401 ensures that starting for discharges on or after October 1, 2003, the DSH adjustment that rural and small urban hospitals would receive would be based on a blend of their current DSH adjustment and the current DSH adjustment for large urban hospitals. However, the new DSH adjustment would not exceed 10% for any hospital that was not classified as a rural referral center.

Section 402. Immediate establishment of uniform standardized amount in rural and small urban areas

Section 402 sets the average standardized amount for rural and small urban hospitals so that it would be equal to that of the amount paid to the hospitals in large urban areas for discharges occurring in the fiscal year beginning on October 1, 2003.

Section 403. Establishment of essential rural hospital classification

Section 403 establishes an "Essential Rural Hospital" for the purposes of hospital classification. An essential rural hospital is defined as a hospital that is located in a rural area, has more than 25 licensed acute care inpatient beds, has applied to the Secretary for such a classification, and with respect to which the Secretary has determined that the closure of the hospital would significantly diminish the ability of Medicare beneficiaries to obtain essential health care services. In order to receive this classification, the following criteria must be met: (1) a high percentage of beneficiaries residing in the area of the hospital receive care at that facility. For hospitals with more than 200 licensed beds, a high percentage of beneficiaries must receive specialized surgical care inpatient care, and almost all physicians described in this section must have privileges at the hospital and provide their inpatient services primarily at the hospital. (2) If the hospital were to close, there would be a significant amount of time needed for residents to reach emergency treatment, resulting in harm to beneficiaries. There would be an inability in the community to stabilize emergency cases for transfers to another acute care setting and any other nearby hospital lacks the physical and clinical capacity to take over the hospital's

In making this determination, the Secretary may also consider the following: (1) free-standing ambulatory surgery centers, office based oncology care, and imaging center services are insufficient in the hospital's area to handle the outpatient care of the hospital; (2) beneficiaries in nearby areas would be adversely affected if the hospital were to close as the hospital provides specialized knowledge and services to a network of smaller hospitals and critical access hospitals; (3) Medicare beneficiaries would have difficulty in accessing care if the hospital were to close as the hospital provides significant subsidies to support ambulatory care in local clinics, including mental health clinics and to support post acute care; and, (4) the hospital has a commitment to provide graduate medical education in a rural area.

For hospital inpatient and outpatient services, the hospital shall be reimbursed at 102% of reasonable costs and may not be treated as a sole community hospital, Medicare dependent hospital, or a rural referral center.

Section 404. More frequent update in weights used in hospital market basket

Section 404 directs the Secretary to revise the MBI cost weights to reflect the most current data available and to establish a schedule for revising the cost weights, including the labor share, with the most current data available more often than once every 5 years. The Secretary is required to submit a report to Congress by

October 1, 2004 on the reasons for and the options considered in establishing such a schedule.

Section 405. Improvements to critical access hospital program

Section 405 stabilizes Critical Access Hospitals (CAHs) through the following: (1) provides an increase in reimbursement by paying 102 percent of reasonable costs; (2) covers costs for emergency room services for physicians, physician assistance, nurse practitioners, and clinical nurse specialists who are on-call, (3) does not penalize CAH-based ambulance services that are first responders for incidents over 35 miles; (4) reinstates Periodic Interim Payments (PIP)—Medicare makes payments every 2 weeks that are based on estimated annual costs and settles any discrepancies at the end of the year; (5) streamlines the billing process through which physicians who provide services at CAHs are reimbursed; (6) provides an increased (up to five) in the number of acute beds to account for seasonal variance; and, (7) 5-year Extension for rural hospital grant fund—authorizes \$25 million through 2008.

Section 406. Redistribution of unused resident positions

Section 406 provides that starting on July 1, 2004, hospitals can apply to receive unfilled resident positions. Applications will be accepted through December 31, 2005. The Secretary will consider the need for an increase by specialty and location, first distributing an increase to programs or hospitals located in rural or small urban areas on a first-come-first-served basis, based on a demonstration that the hospital will fill the positions made available under this clause. No hospital can receive more than an increase of 25 fulltime equivalent positions during this redistribution process. Hospitals will be reimbursed for direct graduate medical education costs for the new positions they receive at 100% of the adjusted national average per resident amount. Those hospitals that have unfilled positions (they have not reached their cap on the number of residents for which Medicare will pay direct graduate medical education costs) and have not met their cap over the past 3 cost reporting periods will have their cap adjusted. Starting January 1, 2004, their cap will be reduced by 75% of the difference between the cap and the highest number of filled positions over the past 3 cost reporting periods. In other words, their cap will be adjusted to reflect the highest number of filled positions over the past 3 cost reporting periods, plus 25% of the remaining unfilled positions.

Section 407. Two-year extension of hold harmless provisions for small rural hospitals and sole community hospitals under prospective payment system for hospital outpatient department services

Section 407 provides financial stability to small, rural hospitals that are unintentionally harmed by the prospective payment system (PPS). In addition, the Secretary will conduct a study to determine if, under the PPS for outpatient department services, costs incurred by rural providers exceed costs incurred by urban providers. Pursuant to the findings of this study, the Secretary has the flexibility to adjust reimbursement rates as of January 1, 2005.

Section 408. Exclusion of certain rural health clinic and federally qualified health center services from the prospective payment system for skilled nursing facilities

Section 408 exempts certain rural health clinic and federally qualified health center services from the prospective payment system effective January 1, 2004.

Section 409. Recognition of attending nurse practitioners as attending physicians to serve hospice patients

Section 409 recognizes nurse practitioners as attending physicians to care for hospice patients. In addition, this provision prohibits nurse practitioners from certifying the need for hospice care.

Section 410. Improvement in payments to retain emergency capacity for ambulance services in rural areas

Under section 410, the Secretary shall provide an increase in the base rate of the fee schedule for mileage for an ambulance trip originating in a rural area. A qualified rural area is defined in this section as a rural area with a population density of Medicare beneficiaries residing in the area that is the lowest quartile of all rural county populations. This provision becomes effective January 1, 2004.

Section 411. Providing safe harbor for certain collaborative efforts that benefit medically underserved populations

Section 411 creates a safe harbor for certain health center arrangements that contribute to the ability of such centers to maintain or increase the availability, or enhance the quality, of services provided to medically underserved populations served by the health center. Coverage under the safe harbor is limited to agreements between a health center receiving grant money under section 330 of the Public Health Service Act and any individual or entity providing goods, items, services, donations, or loans to the health center. The safe harbor provides that the agreement to provide such goods, items, services, donations, or loans will not be considered unlawful remuneration under the anti-kickback statute if the agreement satisfies the standards established by the Secretary. The Secretary is required to publish an interim final rule, which would be effective immediately, within 180 days of enactment to establish these standards.

Section 412. GAO study of geographic differences in payments for physicians' services

Section 412 requires the Comptroller General to conduct a study of differences in payment amounts under the physician fee schedule for physicians' services furnished in different geographical areas. This study will include an assessment of the validity of the geographic adjustment factors used for each component of the fee schedule, an evaluation of the measures used for such adjustment (including the frequency of revisions), and an evaluation of the methods used to determine professional liability costs used in computing the malpractice component. Within 1 year of enactment, the Comptroller General will submit to Congress a report detailing the results of this study with recommendations regarding the use of more current data in computing geographic cost of practice indices

and the use of data directly representative of physicians' costs (rather than proxy measures of such costs).

Section 413. Treatment of missing cost reporting periods for sole community hospitals

Section 413 provides protection for Sole Community Hospitals. In no case shall a Sole Community Hospital be denied treatment or payment because data are unavailable for any cost reporting period due to changes in ownership, changes in fiscal intermediaries, or other extraordinary circumstances. This provision is effective January 1, 2004.

Section 414. Extension of telemedicine demonstration project

Section 414 extends the telemedicine demonstration project authorized by the Balanced Budget Act of 1997 for an additional four years.

Section 415. Two-year increase for home health services furnished in a rural area

Section 415 extends the 5% additional payment for home health services furnished in rural areas through the end of calendar year 2005.

TITLE V—PROVISIONS RELATING TO PART A

Subtitle A—Inpatient Hospital Services

Section 501. Revision of acute care hospital payment updates

Section 501 provides that for FY2004 through FY2006, hospitals would receive an update of Market Based Index (MBI) minus 0.4 percentage points. For FY2007, hospitals will receive a full market basket update.

Section 502. Recognition of new medical technologies under inpatient hospital PPS

Section 502 requires the Secretary to add new diagnosis codes in April 1 of each year that would not affect Medicare's payment or Diagnosis Related Group (DRG) classification until the following fiscal year. The Secretary will not be able to deny a service or technology treatment as a new technology if the service (or technology) has been in use for a period of time shorter than the 2-to-3 year period after the implementation of a billing code that permits identification of a sample of specific discharges where the service had been used. When establishing whether DRG payments are inadequate, the Secretary would be required to apply a threshold that is 75% of the national standardized amount for all hospitals or one standard deviation for the DRG involved. The Secretary is required to provide additional clarification in regulation on the criteria used to determine whether a new service represents a substantial improvement on existing treatment and is required to deem that a technology provides substantial improvement on an existing treatment if the technology meets certain requirements. The Secretary is also required to obtain public input regarding whether a new service or technology represents an advance in medical technology that substantially improves the diagnosis or treatment of beneficiaries. Further, before establishing an add-on payment for new technology, the Secretary is directed to demonstrate a preference for assigning an eligible technology into a DRG, taking into account similar clinical or anatomical characteristics and the relative cost of the technology. The Secretary would assign an eligible technology into a DRG where the average cost of care most closely approximates the cost of the new technology. Add-on payments for new technology must be calculated based on the marginal rate associated with outlier cases. This section is effective October 1, 2005. The Secretary is also directed to automatically reconsider a new technology application that was denied in FY 2004 as a FY 2005 application under these new provisions. If the application is granted, the maximum time period permitted for the new technology classification will be extended by 12 months.

Section 503. Increase in Federal rate for hospitals in Puerto Rico

Section 503 provides that hospitals in Puerto Rico would receive Medicare payments based on a 50/50 split between federal and local amounts before October 1, 2003. From FY2004 through FY2007, an increasing amount of the payment rate would be based on the federal rate—55% federal and 45% local in FY2004, 60% federal and 40% local in FY2005, 65% federal and 35% local in FY2006, 70% federal and 30% local in FY2007, and 75% federal and 25% local for FY2007 and subsequent fiscal years.

Section 504. Wage index adjustment reclassification reform

Section 504 directs the Comptroller General to conduct a study on the improvements that can be made in the measurement of regional differences in hospital wages reflected in the hospital wage index. This study must examine (1) the use of metropolitan statistical areas for purposes of computing and applying the wage index and (2) the portions of the hospital cost reports relating to wages, including methods for improving the accuracy of the age data and for reducing inequities resulting from differences among hospitals in the reporting of wage data. The Comptroller General is directed to consult with the Office of Management and Budget and submit a report to Congress by May 1, 2004. This report must include recommendations on changes in the definition of labor market areas used for purposes of the area wage index and improvements in methods for the collection of wage data.

Section 505. MedPAC report on specialty hospitals

Section 505 requires the Medicare Payment Advisory Group (MedPAC) to conduct a study of specialty hospitals compared with other similar general acute care hospitals that examines (1) self-referrals, (2) quality of care furnished, (3) the impact of specialty hospitals on such general acute care hospitals, and (4) differences in the scope of services, Medicaid utilization, and uncompensated care.

Subtitle B—Other Provisions

Section 511. Payment for covered skilled nursing facility services

Section 511 provides for the adjustment to resource utilization groups (RUG) for AIDS residents. Starting October 1, 2003, the per

diem payment amount for a Skilled Nursing Facilities (SNF) resident with AIDS will be increased by 128%. The 128% increase will not apply on or after such date as the Secretary certifies that there is an appropriate change to the SNF case mix adjustment to cover the increased costs associated with caring for residents with AIDS.

Section 512. Coverage of hospice consultation services

Section 512 provides that beginning January 1, 2004, consultation services for individuals who are terminally ill, including (1) an evaluation of the individual's need for pain and symptom management, (2) counseling the individual with respect to end-of-life issues and care options, and (3) advising the individual regarding advanced care planning, will be covered by the Medicare program when provided by a physician who is the medical director or an employee of a hospice program. Persons entitled to these services are individuals who had not elected the hospice benefit or had not previously received consultation services. The hospice program will be paid an amount equivalent to the amount established for an office or other outpatient visit for evaluation and management associated with presenting problems of moderate severity under the physician fee schedule (excluding practice expense).

TITLE VI—PROVISIONS RELATING TO PART B

Subtitle A—Physicians' Services

Section 601. Revision of updates for physicians' services

Section 601 modifies the calculation of the updates for the physician fee schedule in 2004 and 2005. The 2004 and 2005 update to the conversion factor is set at not less than 1.5 percent. Beginning in 2003, it permanently changes the current gross domestic product (GDP) component of the sustainable growth rate formula to a 10-year rolling average of GDP. This section is effective upon enactment. The Committee also intends to work towards developing fundamental, systemic reforms to the SGR formula so that annual updates to the conversion factor more accurately mirror increases in the costs of furnishing health care services to Medicare beneficiaries.

Section 602. Studies on access to physicians' services

Section 602, the Comptroller General is directed to study Medicare beneficiary access to physician services. The study will (1) assess beneficiaries' use of physician services, (2) examine changes in beneficiaries' use of services over time, and (3) examine the extent to which physicians are not accepting new Medicare beneficiaries as patients. Within 1 year of enactment, the Comptroller General will submit to Congress a report regarding this study focusing on whether Medicare claims data indicate potential access problems in certain geographic areas and whether access to physician services may have improved, remained constant, or deteriorated over time.

The provision also directs the Secretary to request that the Institute of Medicine of the National Academy of Sciences conduct a study on the adequacy of the supply of physicians (including specialists) in the United States and the factors that affect such supply. Within 2 years of enactment, the Secretary must submit to

Congress a report on the results of this study, including any rec-

ommendations for legislation.

Finally, the provision requires the Comptroller General of the United States to conduct a study to examine the adequacy of reimbursements for inhalation therapy under Medicare and report the results to Congress by May 1, 2004.

Section 603. MedPAC report on payment for physicians' services

Section 603 requires the Medicare Payment Advisory Commission to submit a report to Congress within 1 year of enactment on the effect of refinements to the practice expense component of payments for physicians' services in the case of services for which there are no physician work relative value units. The study should examine this issue as it relates to each physician specialty—specifically (1) the effect of such refinements on payment for physicians' services, (2) the interaction of the practice expense component with other components of and adjustments to payment for physicians' services, (3) the appropriateness of the amount of compensation by reason of such refinements, (4) the effect of such refinements on access to care, and (5) the effect of such refinements on physician

participation under the Medicare program.

The Medicare Payment Advisory Commission is also required to complete a report on the extent to which increases in the volume of physicians' services under part B of the Medicare program. The study shall include: (1) an analysis of recent and historic growth in the components that the Secretary includes under the Sustainable Growth Rate (section 1848 (f) of the Social Security Act; (2) examination of the relative growth of volume in physicians' services between Medicare beneficiaries and other populations; (3) an analysis of the degree to which new technology has affected the volume of physicians' services; (4) an examination of the impact on volume of demographic changes; (5) an examination of shifts in the site of service of services that influence the number and intensity of services furnished in physicians' offices and the extent that reimbursement changes may have affected such shifts; and, (6) an evaluation of the extent to which the Centers for Medicare and Medicaid Services takes into account the impact of law and regulation on the sustainable growth rate. This section is effective upon enactment.

Section 604. Inclusion of podiatrists and dentists under private contracting authority

Section 604 allows podiatrists and dentists to privately contract for Medicare services pursuant to the same current law requirements that effect physicians.

Section 605. Establishment of floor on work geographic adjustment

Section 605 establishes a floor on the work component of this part of the physician fee schedule of no less than 1 for services furnished on or after January 1, 2004 through December 31, 2005. Based on the report required by the section the Secretary may not apply this provision if he or she determines that there is no sound economic rationale for its implementation.

Section 605 also requires the Comptroller General of the United States to evaluate whether there is sound economic rationale for a 1.0 floor for the physician work component. The study must also detail whether such adjustments in payment affect physician retention and recruitment. The report must be submitted to Congress no later than September 1, 2004. This provision is effective upon enactment.

On the issue of cardiac rehabilitation, the Committee believes that direct physician supervision, which has been required for Medicare coverage of cardiac rehabilitation since the 1980s, is the correct level of supervision for cardiac rehabilitation services that are currently covered by Medicare, i.e., those services furnished to patients who (1) have a documented diagnosis of acute myocardial infarction within the preceding 12 months; (2) have had coronary bypass surgery; or, (3) have stable angina pectoris.

Cardiac rehabilitation includes medical evaluation, prescribed exercise, cardiac risk factor modification, education, counseling, and behavioral interventions. The Committee notes that there is no specific Medicare benefit category for cardiac rehabilitation programs; rather they are covered as services furnished incident to a physician's professional service and have been covered by Medicare as an "incident to" services ince the 1980s. To be covered by Medicare, "incident to" services must be "reasonable and necessary" and pro-

vided under a physician's direct supervision.

The Committee emphasizes that section 35–25 of the Medicare Coverage Issues Manual defines direct supervision for cardiac rehabilitation as requiring a physician to be "in the exercise program area and immediately available and accessible for an emergency at all times the exercise program is conducted. It does not require that a physician be physically present in the exercise room itself."

Subtitle B—Preventive Services

Section 611. Coverage of an initial preventive physical examination

Section 611 provides that on or after January 1, 2004, Medicare will cover an initial preventive physical examination, but only for individuals whose coverage period begins on or after such date (and within 6 months of the date the individual's coverage period first begins). An initial preventive physical examination is defined as physician services consisting of a physical examination that promotes health and disease detection, as well as items and services that the Secretary may specify in regulation.

The Committee also encourages the United States Preventive Health Task Force ("USPHTF") to examine aortic aneurysm screening using ultrasound. Aortic aneurysms are a leading cause of death in the United States, and many in the medical community believe that most, if not all, of the approximately 15,000 known deaths each year would be prevented with appropriate screening.

Section 612. Coverage of cholesterol and blood lipid screening

Section 612 extends Medicare coverage to cholesterol and other blood lipid screening tests, starting January 1, 2005. The Secretary will establish standards regarding the frequency and type of cholesterol and other blood lipid screening tests, except that the frequency cannot be more often than once every 2 years.

Section 613. Waiver of deductible for colorectal cancer screening tests

Section 613 would waive the Part B deductible for colorectal cancer screening tests beginning January 1, 2004.

Section 614. Improved payment for certain mammography services

Section 614 excludes both screening and diagnostic mammography from the hospital outpatient prospective payment system on or after January 1, 2004. In addition, this section directs the Secretary to determine a new reimbursement rate for diagnostic mammography performed on or after January 1, 2004 based on the most current cost data available.

Section 615. Medicare coverage of diabetes laboratory diagnostic tests

Section 615 provides a new benefit under Medicare by covering diabetes screening tests for the purpose of early detection of diabetes.

Subtitle C—Other Services

Section 621. Hospital outpatient department (HOPD) payment reform

Section 621 stabilizes payments for non-pass-through drugs through the use of transitional payment floors for 2004–2006. Single Source: 83%, 77%, and 71%. Multi-source: 81.5%, 75%, and 68%. Generics will be 46% for all years. In addition, radiopharmaceuticals are classified as drugs and not diagnostic tests in the hospital outpatient setting.

This section also provides enhanced treatment for brachytherapy devices. It creates separate payment Ambulatory Payment Classifications (APC) for brachytherapy devices and pays these devices on a cost basis rather than a charge basis from January 1, 2004 through January 1, 2007. The General Accounting Office (GAO) is directed to study this payment policy and report back to Congress in regards to its appropriateness. This section also: (1) Requires the Secretary to pay new FDA-approved drugs at 95% of Average Wholesale Price (AWP) until a temporary HCPCS code is assigned; (2) lowers the threshold for separate APCs for drugs and biologics to \$50 per administration; (3) excludes separate drug APCs from outlier payments; (4) addresses the issue of "functional equivalence" and the application thereof prospectively; and, (5) directs the Secretary to conduct a study on the costs incurred by hospitals in acquiring covered outpatient drugs. The study shall explore: (1) whether or not it should be repeated; (b) whether or not the study produced useful data; (c) whether the study produces data that is appropriate for use in making adjustments to payments; and, (d) whether separate estimates can be made of overhead costs, including handling and administering costs for drugs.

Further, this section revises Medicare payments for certain medical technologies delivered in the Hospital Outpatient Department. The Committee is concerned that current payment policies could impede patient access to innovative medical technologies and has designed this section to address this concern.

The products covered by the transitional provision include all radiopharmaceuticals, though new radiopharmaceuticals also are eligible for pass-through treatment under section 1833(t)(6)(A)(iv). In addition, the section 1927(k)(2) definition of covered drugs should be read to include all biological products licensed under section 351 of the Public Health Service Act, including vaccines. All such biological products are sole source drugs. Products approved under a biologics license application shall be deemed to meet the requirement in clause (iii) of section 1927(k)(2)(B) that they be produced at an establishment licensed under such section to produce such product. Finally, any products whose pass-through status expires during the transitional period would be covered by the transitional provision.

It is the Committee's intent that the Secretary would be prohibited from publishing regulations on (including the HOPD-PPS payment rate rules) and subsequently applying a functional equivalence standard to a drug or biological for transitional pass-through payments under HOPD-PPS. This provision does not affect the Secretary (or his contractors) from making payment determinations

in other settings as allowed for under current law.

This prohibition would apply to the application of the functional equivalence standard on or after the date of enactment, unless such application was being made to a drug or biological prior to enactment. Any such application of functional equivalence prior to enactment would be allowed to continue, but only for the limited purpose of determining eligibility for additional pass-through payments.

With respect to orphan products used to treat patients with rare disorders, the Committee applauds CMS for excluding certain therapies from the HOPD prospective payment system ("PPS") in order to protect patient access to them. The Committee expects that CMS will continue to exclude these therapies and to ensure adequate payment for them. In addition, the Committee encourages CMS to exclude other orphan products that meet the agency's criteria. Moreover, the Committee expects that any product with orphan designation under the Food Drug and Cosmetic Act no longer eligible, or soon to become ineligible, for transitional pass-through payments under section 1833(t)(6) will have ample opportunity to request exclusion from the HOPD-PPS as an orphan product and will receive adequate notice of the Secretary's proposed reimbursement treatment for the coming year. For each request for exclusion that is denied, CMS should fully address the reasons for denial as part of the annual rulemaking process. In addition, CMS shall include on its website—and cross reference in each proposed and final HOPD-PPS rule—a simple, easy to complete application for exclusion from the HOPD-PPS for manufacturers of orphan products and other interested parties. The application shall be accompanied by clear instructions regarding how to complete and submit it in a timely fashion.

Next, the section directs the Secretary to conduct a study on the costs incurred by hospitals in acquiring covered outpatient drugs that cost \$50 or more per administration and for which payment is made under section 1833(t) and to submit a report to Congress on the study no later than January 1, 2006. In conducting the survey, the Secretary shall collect data from a statistically valid sample of hospitals in both rural and urban areas. The Secretary also

shall collect data on pharmacy service and overhead costs, including the unique storage, handling, and administration costs of individual products. The purpose of this study is to gather information on hospital acquisition, pharmacy service, handling, and administration costs for covered drugs. As noted, the Committee is concerned that any shortfalls in hospital reimbursement could threaten patient access to certain medicines.

Finally, in regards to the hospital outpatient setting, the Committee instructs the Secretary to compile and clarify the procedures and policies for billing for blood and blood costs, including the handling of the blood deductible.

Section 622. Payment for ambulance services

Section 622 provides for the phase-in of a transitional fee schedule through the use of payment floors. By January 1, 2004, the Secretary is required to develop nine regional fee schedules corresponding to the nine Census Divisions. These fee schedules are to be based on the same methodology and data used to construct the national fee schedule. The regional conversion factor in each regional fee schedule will be adjusted in the same way the national conversion factor is adjusted—the relative value units will be used with each regional conversion factor to create a regional base payment rate for each level of service. In addition, the same payment adjustments will apply in the regional fee schedules, including the rural mileage adjustments. Payments under the appropriate regional fee schedule will be blended with the payment amount under the national fee schedule within the existing fee schedule transition. This blend replaces the national fee schedule amount in the current transition. In 2004, the blended rate will be based on 20% of the payment under the national fee schedule and 80% of the payment under the appropriate regional fee schedule. In 2005, the blended rate will be based on 40% of the national fee schedule amount and 60% of the regional fee schedule amount. In 2006, the blended rate will be based on 60% of the national fee schedule amount and 40% of the regional fee schedule amount. In 2007 through 2009, the blended rate will be based on 80% of the national fee schedule and 20% of the regional fee schedule amount. Beginning in 2010, payment for ambulance services will be based entirely on the national fee schedule.

This section also increases mileage payments for ground ambulance trips above 50 miles. Such payments will be increased by at least one-quarter of the payment per mile otherwise established under the fee schedule for trips on or after January 1, 2004 through December 31, 2009.

Section 623. Renal dialysis services

Section 623 provides a 1.6% increase in the composite payment rate for services furnished in 2004.

Section 624. One-year moratorium on therapy caps; provisions relating to reports

Section 624 places a 1-year moratorium on the payment limits established per beneficiary for all outpatient therapy services provided by non-hospital providers through 2005.

The Secretary is urged to submit overdue reports to Congress by December 31, 2003 so that Congress can review any alternative policies to the per beneficiary therapy caps as soon as possible. The Secretary is directed to request that the Institute of Medicine of the National Academy of Sciences identify conditions or diseases that should justify conducting an assessment of the need to waive the therapy caps. By July 1, 2004, the Secretary must submit to Congress a preliminary report on the conditions and diseases identified. By September 1, 2004, the Secretary must submit a final report. And, by October 1, 2004, the Secretary is required to submit to Congress a recommendation of criteria under which a waiver of the therapy cap would apply.

The Comptroller General is directed to study access to physical therapist services in States that authorize such services without a physician referral and in States that require such a referral, examining the use of and referral patterns for patients age 50 and older, including patients who are Medicare beneficiaries, and the delivery of physical therapists' services within facilities of the DOD. In addition, the Comptroller General is directed to analyze the potential impact on Medicare beneficiaries and on Medicare expenditures of eliminating the need for a physician referral. The report will be

submitted to Congress within 1 year of enactment.

Section 625. Adjustment to payments for services furnished in ambulatory surgical centers

Section 625 adjusts payments to ambulatory surgical centers for 2004–2008 at a rate of Consumer Price Index (CPI) minus 2%.

Section 626. Payment for certain shoes and inserts under the fee schedule for orthotics and prosthetics

Section 626 provides that effective January 1, 2004, certain custom molded shoes, extra depth shoes and inserts will be paid under the fee schedule for orthotics and prosthetics. The Committee does not intend these products to be subject to the competitive bidding requirements of section 302.

Section 627. Waiver of part B late enrollment penalty for certain military retirees; special enrollment period

Section 627 provides that military retirees who failed to enroll in Medicare Part B in a timely manner will have the premium penalty waived if they demonstrate to the Secretary before December 31, 2004 that they are covered beneficiaries under TRICARE. This section applies to premiums for months beginning with January 2003.

This section provides for a special enrollment period during which individuals may enroll under Part B of Medicare. This period will begin as soon as possible after enactment and end on December 31, 2004.

Section 628. Part B deductible

Section 628 would index the Part B deductible to increases in Part B costs beginning in 2004.

Section 629. Demonstration project for coverage of self-injected biologics for rheumatoid arthritis

Section 629 authorizes a demonstration project to measure patient access to care and outcomes, as well as any cost savings to the Medicare program attributable to reduced physician's services delivered in the hospital outpatient setting for the administration of biologics. The duration of the project shall be two years, conducted in 3 states, and requires a report to be submitted to Congress by January 1, 2006.

TITLE VII—PROVISIONS RELATING TO PARTS A AND B

Subtitle A—Home Health Services

Section 701. Update in home health services

Section 701 establishes the home health market basket percent increase for 2004 through 2006 at MBI minus 0.4 percentage points.

Section 702. MedPAC study on Medicare margins of home health agencies

Section 702 directs MedPAC to conduct a study examining whether systematic differences in payment margins for home health agencies are related to differences in case mix. MedPAC must submit a report on this study to Congress within 2 years of enactment.

Section 703. Demonstration project to clarify the definition of homebound

Section 703 authorizes a demonstration project to analyze Medicare beneficiaries that are "homebound." The duration of the demonstration shall be for 2 years, conducted in 3 states, limits the number of participants to 15,000 total, and requires the Secretary to report back to Congress no later than one year after the completion of the project.

Subtitle B—Direct Graduate Medical Education

Section 711. Extension of update limitation on high cost programs

Medicare pays hospitals for its share of direct graduate medical education (DGME) costs in approved programs using a count of the hospital's number of full-time equivalent residents and a hospital-specific historic cost per resident, updated for inflation. BBRA changed Medicare's methodology for calculating DGME payments to teaching hospitals to incorporate a national average amount based on FY1997 hospital specific per resident amounts. Starting in FY2001, hospitals received no less than 70% of a geographically adjusted national average amount. The Benefits Improvements and Protection Act (BIPA) increased this floor to 85% of the locality adjusted, updated, and weighted national per resident amount (PRA) starting for cost report periods beginning during FY2002. Hospitals with per resident amounts above 140% of the geographically adjusted national average amount had payments frozen at current levels for FY2001 and FY2002, and in FY2003–FY2005 would receive an update equal to the Consumer Price Index (CPI) increase

minus 2 percentage points. Currently, hospitals with per resident amounts between 85% and 140% of the geographically adjusted national average would continue to receive payments based on their hospital-specific per resident amounts updated for inflation.

Subtitle C—Chronic Care Improvement

Section 721. Voluntary chronic care improvement under traditional fee-for-service

Section 721 amends Title XVIII of the Social Security Act to create a new section 1808 entitled "Chronic Care Improvement." This new section requires the Secretary to establish a process for providing chronic care improvement programs in regions throughout the country for beneficiaries in the traditional fee-for-service program. This new section requires the secretary to award at least 2 winning contracts in each chronic care improvement region.

In addition, under this new section, each contractor will identify Medicare beneficiaries in the region to whom it will offer services under its program. The Secretary will then contact the beneficiaries identified as a prospective participant to describe the program. It will then notify beneficiaries that the contractor(s) offering a program may contact them directly, notify beneficiaries that program participation is voluntary, and describe the method by which the beneficiary can select a single program in which to participate. Medicare beneficiaries may only participate in one program, even if multiple programs are offered by multiple contractors in a region.

For each beneficiary who elects to participate in a program, the contractor will develop an individualized, goal oriented chronic care improvement plans. Each plan will include a single point of contact to coordinate care along with education for the beneficiary, coordination of health services, collaboration with physicians and other providers, use of monitoring technologies, and the provision of information about hospice care. Contractors are required to guide participants in managing their health, use decision support tools such as evidence-based practice guidelines, and develop a clinical information database to track and monitor each participant.

The Secretary may determine the terms and conditions of contracts. The use of subcontractors is permitted. In entering into contracts, the Secretary shall establish payment rates to ensure that there will be no net aggregate increase in Medicare payments over any period of 3 years or longer. Contractors will be required to provide reports to the Secretary describing the quality of care and efficacy of the program in terms of process measures, such as reductions in rehospitalizations, beneficiary and provider satisfaction, health outcomes, and financial outcomes. The Secretary is allowed to phase-in this program throughout the country.

Section 722. Chronic care improvement under Medicare advantage and enhanced fee-for-service programs

Section 722 requires each Medicare Advantage and EFFS organization, with respect to each plan that if offers, to have in effect a chronic care improvement program designed to manage the needs of enrollees with multiple or severe chronic conditions. Each program must have a method for identifying enrollees with multiple or sufficiently severe chronic conditions.

For each enrollee identified, the program shall develop, with the enrollee's consent, an individualized, goal-oriented chronic care improvement plan. Each plan will include a single point of contact to coordinate care along with education for the beneficiary, coordination of health services, collaboration with physicians and other providers, use of monitoring technologies, and the provision of information about hospice care. Organizations are required to guide participants in managing their health, use decision support tools such as evidence-based practice guidelines, and develop a clinical information database to track and monitor each participant.

Organizations will be required to provide reports to the Secretary describing the quality of care and efficacy of the program with such information as the Secretary may require.

Section 723. Institute of Medicine report

Section 723 requires the Secretary to contract with the Institute of Medicine to conduct a study of the barriers to effective integrated chronic care improvement for Medicare beneficiaries with multiple or severe chronic conditions.

The study must examine the statutory and regulatory barriers to coordinating care across settings for Medicare beneficiaries. Specifically, the study must identify clinical, financial or administrative requirements in the Medicare program that present barriers to effective, seamless transitions across care settings; policies that impede the establishment of administrative and clinical information systems; and, state level requirements that may present barriers to better care for Medicare beneficiaries. This report must be submitted to the Secretary and Congress within 18 months of the date of enactment of this Act.

Section 724. MedPAC report

Section 724 requires the Medicare Payment Advisory Commission (MedPAC) to conduct an evaluation of the status of implementation of chronic care improvement programs in the traditional feefor-service Medicare program. The report must be submitted not later than 2 years after the date of implementation of such chronic care improvement programs.

Subtitle D—Other Provisions

Section 731. Modifications to Medicare payment advisory commission (MedPAC)

Section 731 requires MedPAC to review payment policies under Parts A and B, including the factors affecting expenditures for "the efficient provision of" services in different sectors. Before making any recommendations, the Commission will examine the budget impact of their recommendations either directly or through consultation with experts. MedPAC will conduct a study and submit a report to Congress by June 1, 2003 on the need for current data and data sources to determine the solvency and financial circumstances of hospitals and other Medicare providers. They will also submit a report to Congress by June 1, 2004 on the investments and capital financing of hospitals participating under the Medicare program and related foundations.

Section 732. Demonstration project for medical adult day care services

Section 732 requires the Secretary to establish a demonstration project for home health agencies to directly, or under arrangements with a medical adult day care facility, provide medical adult day care services as a substitute for certain home health services that

would otherwise be provided at home.

The payment amount for the episode of care, including the medical adult day care service, under the demonstration project will be at a rate of 95% of the amount that would otherwise apply for such home health services. Home health agencies or medical adult day care facilities may not separately charge a beneficiary for medical adult day care services furnished under the plan of care. The demonstration project will not result in additional expenditures from the Trust Funds-aggregate payments under the home health PPS will be reduced to reflect any increases in amounts expended as a result of the demonstration project.

The project will be conducted in up to 5 sites in states chosen by the Secretary that license or certify providers of medical adult day care services. The demonstration will be conducted for a period of 3 years with up to 15,000 beneficiaries participating in the project on a voluntary basis. The Secretary will give preference to home health agencies that are currently licensed or certified to provide medical adult day care services and have provided such services to Medicare beneficiaries for a continuous 2–year period prior to the project. The Secretary may waive requirements under title XVIII of the Social Security Act except for requirement that the beneficiary be homebound in order to be eligible for home health care.

The Secretary will conduct an evaluation of the clinical and costeffectiveness of the demonstration project. A report to Congress will be submitted within 30 months of project initiation and will include a comparative analysis of the patient outcomes and cost of care between settings of care and recommendations on program extension,

expansion, or termination.

Home health agency is defined as it is in previous statute. Medicare adult day care facility means a facility that has been licensed or certified by a state to provide medical adult day care services for a continuous 2–year period, is engaged in providing skilled nursing services and other therapeutic services directly or under agreement with a home health agency, and meets standards established by the Secretary to ensure quality of care and patient safety. Medical adult day care services are defined as home health services provided in a medical adult day care facility, a program of supervised activities furnished in a group setting in a facility that is designed to promote the physical and mental health of the individuals, and any other services specified by the Secretary. Medicare beneficiary under this section means an individual enrolled in either Part A, Part B, or both.

Section 733. Improvements in national and local coverage determination process to respond to changes in technology

Section 733(a) would require the Secretary to establish the general guidelines used in making national coverage determinations under Medicare, including the way in which evidence is considered by the Secretary regarding whether a procedure or device is rea-

sonable or necessary. The provision would establish a time frame for decisions regarding national coverage determinations of six months after a request when a technology assessment is not required and 12 months when a technology assessment is required and in which a clinical trial is not requested. Following the six- or 12-month period, the Secretary would be required to make a draft of the proposed decision available in the HHS website or by other means; to provide a 30-day public comment period; to make a final decision on the request with 60 days following the conclusion of the public comment period; and make the clinical evidence and data used in making the decision available to the public. In instances where a request for a national coverage determination is not reviewed by the Medicare Coverage Advisory Committee, the Secretary would be required to consult with appropriate outside clinical experts. The Secretary would also be required to develop a plan to evaluate new local coverage determinations to decide which local decisions should be adopted nationally and to decide to what extent greater consistency can be achieved among local coverage decisions, to require the Medicare contractors within an area to consult on new local coverage policies, and to disseminate information on local coverage determinations among Medicare contractors to reduce duplication of effort. The provision would be effective for determinations as of January 1, 2004.

Subsection (b) would provide for the coverage of the routine costs of care for Medicare beneficiaries participating in clinical trials that are conducted in accordance with an investigational device exemption approved under section 530(g) of the Federal Food, Drug, and Cosmetic Act. The provision would be effective for clinical trials begun before, on, or after the date of enactment and to items and services furnished on or after enactment.

Subsection (c) would require that the Secretary implement revised procedures for the issuance of temporary national HCPCS codes. The provision would further require the Secretary to use data reflecting prices and costs of products in the United States in setting payment rates. The provision would be effective not later than one year after enactment.

Section 734. Treatment of certain physician pathology services

Section 734 makes permanent the requirement for the payment of the technical component of certain physician pathology services to the laboratory for inpatient hospital services.

Section 735. Medicare pancreatic islet cell transplant demonstration project

Section 735 authorizes a demonstration project to analyze the appropriateness of pancreatic islet cell transplantation and related items and services in the case of Medicare beneficiaries who have Type I (juvenile) diabetes and have end stage renal disease. The duration of the project shall be for five years and requires the Secretary to submit a report to Congress within 120 of completion of the project.

Section 736. Demonstration project for consumer-directed chronic outpatient services

Section 736 authorizes the Secretary to conduct three demonstration projects to evaluate methods that improve the quality of care provided to Medicare beneficiaries with chronic conditions and that reduce expenditures to the Medicare program. The project shall be initiated no later than two tears after enactment, and requires the Secretary to submit a report to Congress within two years of completion of the project.

TITLE VIII—MEDICARE BENEFITS ADMINISTRATION

Section 801. Establishment of Medicare Benefits Administration

Section 801 establishes a new agency, the Medicare Benefits Administration (MBA), will be created within the Department of Health and Human Services.

The Administrator of this agency will be appointed for a term of 5 years by the President, with Senate confirmation, and will report directly to the Secretary. The Administrator will have the authority to develop and implement new rules and regulations pertaining to the Administration and delegate responsibilities to officers and employees of the Administration. A Deputy Administrator will also be appointed by the President, with Senate confirmation, for a term of 5 years. The position of Chief Actuary will also be established. The Chief Actuary will be appointed by and report directly to the Administrator. The Secretary will be responsible for coordination between the Administrator for the MBA and the Administrator for the Centers for Medicare & Medicaid Services (CMS) in carrying out the Part C and Part D programs.

The Administrator will negotiate, enter into, and enforce contracts with PDP sponsors under Part D and Medicare Advantage plans under Part C, including those offering qualified prescription drug coverage. In carrying out duties related to the prescription drug benefit, the Administrator will not be allowed to require a particular formulary or pricing structure for the reimbursement of drugs or interfere with the competitive nature of the PDPs and their sponsors. The Administrator will also carry out demonstration projects under Parts C and D, implement the prescription drug discount card program, and submit annual reports to Congress and the President. With the approval of the Secretary, the MBA will employ officers and employees that are necessary to administer Parts C and D. For functions of CMS that are transferred to MBA, new staff will be employed at numbers not to exceed the number of full time employees that previously handled those functions at CMS. The Secretary and the CMS and MBA Administrator will determine an appropriate transition of responsibility for Part C, which will include the transfer of relevant data and information.

This office will coordinate functions relating to outreach and education of Medicare beneficiaries. It will disseminate benefit information to beneficiaries via the Internet, mail, and phone, and disseminate information on appeals rights to beneficiaries.

An advisory board will be established to advise, consult with, and make recommendations to the Administrator of the MBA regarding the administration of Parts C and D. The Board will submit to Congress and the Administrator reports on Parts C and D issues

they deem appropriate. Each report will include legislative or administrative changes to improve the administration of the benefits under Parts C and D. Topics may include fostering competition, education and enrollment, implementation of risk-adjustment, disease management programs, and rural access. The Board will be independent and will not be required to seek comment or approval of reports from an officer or agency prior to submission to Congress. The Board will consist of 7 members; 3 appointed by the President; 2 appointed by the Speaker of the House with advice from the chairmen and minority ranking members of the Committees on Ways and Means and on Energy and Commerce; and 2 appointed by the President pro tempore of the Senate taking advice from the chairman and ranking minority member of the Senate Finance Committee. The members will be chosen based on their integrity, impartiality, and good judgment and will have education or experience related to health care benefits management. No federal employee will serve on the Board. In general, appointees will serve for a term of 3 years; however, the initial appointees will serve from 1 to 3 years. The Chair of the Board will be elected by the members and will also serve for 3 years. The Board will also have a Director appointed by the Chair. The Board will meet at least three times each year.

The funding necessary to carry out this section will be appropriated in part from the Hospital Insurance Trust Fund and from the Supplementary Medical Insurance Trust Fund. The Administrator and Deputy will not be appointed until January 1, 2004. Until the appointment of an Administrator, the Secretary will handle the responsibilities of such a position. The Administrator will serve as a member of the Board of Trustees of the Medicare Trust Funds.

TITLE IX—REGULATORY REDUCTION AND CONTRACTING REFORM

Subtitle A—Regulatory Reform

Section 901. Construction; definition of supplier

Section 901 defines a "supplier" as a physician, practitioner, facility or other nonprovider entity that furnishes Medicare items or services unless otherwise indicated, and "Secretary" as the Secretary of Health and Human Services.

This section reflects the bipartisan regulatory relief provisions

agreed to by the Committee over the past three years.

None of the provisions would be construed to (1) compromise existing remedies for addressing Medicare fraud or abuse with respect to criminal prosecution, civil enforcement, or administrative remedies, including those established by the False Claims Act or (2) prevent HHS from its ongoing efforts to eliminate waste, fraud, and abuse in Medicare. Also, consolidation of Medicare's administrative contracting provided for in this bill would not consolidate the Federal Hospital Insurance Trust Fund which pays for Part A services and the Federal Supplementary Medical Insurance Trust Fund which pays for Part B services. The Committee notes that this administrative consolidation does not reflect any position on that issue.

Section 902. Issuance of regulations

Section 902(a) requires the Secretary, in consultation with the Director of the Office of Management and Budget, to establish and publish a regular timeline for the publication of final regulations based on the previous publication of a proposed regulation or an interim final regulation. The timeline may vary by regulation due to complexity, number and scope of comments received and other factors, but would not be longer than 3 years unless there are exceptional circumstances. If the Secretary intends to vary a regulation's timeline, a notice of the different timeline would be required to be published in the Federal Register. This notice would include a brief explanation of the justification for such variation. If the timeline established for an interim final regulation expires without promulgation of a final regulation (including the public comment period), the interim final regulation would not remain in effect unless the Secretary publishes a notice of continuation that includes an explanation for not complying with the deadlines. This provision applies to the regular timelines and any subsequent 1-year extension to the timeline. If a notice of continuation is published, the regular timeline or the timeline as previously extended would be extended for 1 additional year. The Secretary would be required to submit a report to Congress that describes and explains the instances where the final regulation was not published within the applicable timeline. The Secretary would be required to provide for a transition period for previously published interim final regulations.

Subsection (b) provides that a provision in a final regulation that is not a logical outgrowth of the proposed regulation (including an interim final regulation) would be treated as a proposed regulation and would not take effect without a separate public comment period followed by its publication as a final regulation. This provision would apply to final regulations published on or after enactment.

Section 903. Compliance with changes in regulations and policies

Section 903(a) states that a substantive change in a regulatory or a subregulatory issuance would not be applied retroactively to items or services, unless the Secretary determines that retroactive application (1) would be necessary to comply with statutory requirements; or (2) would be beneficial to the public interest. This provision would also apply to substantive changes issued on or after enactment.

In subsection (b), a substantive change would not become effective before 30 days after the date the change is issued or published. The Secretary would be able to waive the 30-day period to comply with statutory requirements or if such waiver is in the public interest. If an earlier date is established, the Secretary would be required to include a brief explanation of such finding in the issuance or publication of the substantive change. No compliance action against a provider or supplier for goods and services furnished before the effective date of the substantive change would be permitted. This provision would apply to compliance actions undertaken on or after enactment.

Subsection (c) provides that if (1) a provider or supplier follows written guidance (which may be transmitted electronically) provided by the Secretary or a Medicare contractor when furnishing an item or service and submitting a claim; (2) the Secretary finds

that the circumstances relating to the furnished items and services have been accurately presented in writing to the contractor; and, (3) the guidance is inaccurate, then the provider or supplier who reasonably relied on the guidance would not be subject to any sanction or penalty, including repayment. This provision would not be construed to prevent recoupment or repayment (without additional penalty) if the overpayment was solely the result of a clerical or technical operational error. This provision would be effective upon enactment, but would not apply to sanctions where notice was provided on or before enactment.

Section 904. Reports and studies relating to regulatory reform

Section 904 requires the GAO to conduct a study to determine the appropriateness and feasibility of providing the authority to the Secretary to issue legally binding advisory opinions on the interpretation and application of Medicare regulations. The study would examine the appropriate time frame for issuing the opinions as well as the need for additional staff and funding. GAO would submit the study to Congress no later than one year after enactment.

The Secretary would be required to report to Congress on the administration of the Medicare program and inconsistencies among existing Medicare statutory or regulatory provisions. The report would include (1) information from beneficiaries, providers, suppliers, Medicare Beneficiary and Provider Ombudsmen (established in Section 303 of this legislation), and Medicare contractors; (2) descriptions of efforts to reduce inconsistencies; and, (3) recommendations from the Secretary for appropriate legislation or administrative actions. The report would be due no later than 2 years after enactment and every 2 years thereafter.

Subtitle B—Contracting Reform

Section 911. Increased flexibility in Medicare administration

Subsection (a) of section 911 adds a new section 1874A to Title XVIII of the Social Security Act that would permit the Secretary to enter into contracts with any eligible entity to serve as a Medicare administrative contractor. These contractors would perform or secure the performance (through subcontracting) of some or all of the following tasks: determine payment amounts; make payments; educate and assist beneficiaries; provide consultative services; communicate with providers and suppliers; educate and offer technical assistance to providers; and perform additional functions as necessary. An entity eligible to enter into a contract with respect to the performance of a particular function would (1) have demonstrated capability to carry out such function; (2) comply with conflict of interest standards that are generally applicable to Federal acquisition and procurement; (3) have sufficient assets to financially support the performance of such functions; and, (4) meet other requirements imposed by the Secretary. The claims processing jurisdiction of a Medicare administrative contractor would be determined by the scope of the contract awarded to the entity. Specifically, the Medicare administrative contractor that would perform a particular function is the entity that has the contract to perform that function for any given beneficiary, any given provider or supplier.

The Federal Acquisition Regulations (FAR) would apply to Medicare administration contracts except to the extent inconsistent with a specific Medicare requirement. The Secretary would be required to use competitive procedures when entering into a Medicare administrative contract and would take into account performance quality, price, and other factors. The Secretary would be able to renew a contract for up to 5 years without regard to statutory requirements concerning competitive contracting if the entity has met or exceeded specified performance standards. The Secretary would be able to transfer functions among contractors consistent with these provisions. The Secretary would be required to (1) ensure that performance quality is considered in such transfers and (2) provide notice of such transfer (in the Federal Register or otherwise) that describes the transferred functions and the affected providers and suppliers and also includes contractor contact information.

The Secretary would be required to (1) provide incentives for the Medicare administrative contractors to provide efficient, high-quality services; and, (2) develop performance standards with respect to each of the payment, provider service, and beneficiary service functions required of the contractors. In developing the performance standards, the Secretary would be able to consult with providers and suppliers, organizations representing Medicare beneficiaries, and Medicare contractors. The Secretary would be required to contract only with those entities that (1) perform efficiently and effectively; (2) meet standards for financial responsibility, legal authority and service quality among other pertinent matters; (3) agree to furnish timely and necessary data; and (4) maintain and provide access to necessary records. The performance requirements would be (1) set forth in the contract between the Secretary and the appropriate Medicare contractor; (2) used to evaluate contractor performance; and, (3) consistent with the contract's written statement of work. A Medicare administrative contract would contain provisions deemed necessary by the Secretary and may provide for advances of Medicare funds for the purposes of making payments to providers and suppliers. In developing contract performance requirements for Medicare administrative contractors, the Secretary would be required to consider the existing timeliness standards for reconsiderations, applications for exemption, initial determinations

and fair hearing decisions.

The existing MSP provision would apply: the Secretary would not be able to require contractors to match their data with Medicare data for the purposes of identifying beneficiaries with other insurance coverage. The Secretary would assure that the activities of the Medicare administrative contractors do not duplicate the Medicare Integrity Program (MIP) functions except with respect to the prior authorization of durable medical equipment. An entity with a MIP contract would not be treated as a Medicare administrative con-

tractor, solely by reason of the MIP contract.

A Medicare administrative contractor and any of its employees certifying or disbursing payments may be required to give surety bond to the United States in an amount established by the Secretary. The contractor's employee who certifies payments will be liable for erroneous payments in the absence of reckless disregard or intent to defraud the United States. The contractor's employee

who disburses payments would not be liable for erroneous payments in the absence, if such payments are based upon an authorization from the certifying employee and the authorization meets the internal control standards established by GAO. The contractor would not be liable for payments made by certifying or disbursing officers unless grossly negligent when supervising or selecting these officers.

The Secretary would be able to indemnify a Medicare administrative contractor, subcontractor, or employee who is made a party to any judicial or administrative proceeding arising from the claims administration process to an appropriate extent as determined by the Secretary and specified in the contract. Indemnification in this case may include payment of judgments, certain settlements, awards and costs (including reasonable legal expenses). Settlement proposals would not be negotiated or compromised without prior written approval by the Secretary. The Secretary would not be able to provide any indemnification if the liability arises directly from conduct that is determined in the judicial proceeding or by the Secretary to be criminal in nature, fraudulent, or grossly negligent; if such indemnification is provided before this determination, the contractor would reimburse the Secretary for the costs. The provisions would not change common law immunity available to the Medicare contractor or other party or permit the payment of costs not otherwise allowable, reasonable or allocable under FAR.

Subsection (b) would establish that the existing administrative activities of fiscal intermediaries would be conducted through contracts with Medicare administrative contractors set forth previously. The provider nomination process and contracting specifications would be repealed. Certain performance standards with respect to the processing of clean claims would be retained. Certain annual reporting requirements concerning the contractor's overpayment recovery efforts would be retained.

Subsection (c) establishes that carriers will be used to administer certain Medicare benefits as well as the contracting requirements and certain performance standards for those activities, conforming

to section 1842 of the Social Security Act.

This subsection would establish that the existing administrative activities of carriers would be conducted through contracts with Medicare administrative contractors set forth previously. Certain instructions including those pertaining to nursing facilities payments, claims assignment, physician participation, overpayment recoveries and billing by suppliers would be retained. Certain performance standards with respect to the processing of clean claims would be retained. Contracting specifications and other conforming changes would be established. The Secretary, not the contractor, would be responsible for taking necessary actions to assure that reasonable payments are made, for those made on both a cost and charge basis. The Secretary, not the contractor, would be responsible for maintaining a toll-free telephone number for beneficiaries to obtain information on participating suppliers. The requirements for carrier fair hearings would be eliminated to conform to existing law. Certain annual reporting requirements concerning the contractor's overpayment recovery efforts would be retained.

Subsection (d) states that except as otherwise provided in this section, all the provisions would become effective October 1, 2005.

The Secretary would be authorized to take necessary actions prior to that date in order to implement these amendments on a timely basis, to transition from the contracts established under sections 1816 and 1842 of the Act to those established under the new section 1874A created by this legislation. The transition would be consistent with the requirement that the administrative contracts be competitively bid by October 1, 2010. The MIP contracts awarded on a competitive basis would continue to apply and would not be affected by the provisions in this section. Any reference to a contract in the existing MIP contracting exceptions would be deemed to include a contract under the new 1874A that continues such MIP activities.

Subsection (e) states that after this section becomes effective, any reference to fiscal intermediary or carrier would be considered a reference to the appropriate Medicare administrative contractor.

Subsection (f) would require the Secretary to submit an implementation plan to Congress and GAO no later than October 1, 2004. GAO would evaluate the plan and include appropriate recommendations no later than 6 months after the plan is received. No later than October 1, 2008, the Secretary would be required to submit a status report to Congress including (1) the number of contracts that have been competitively bid; (2) the distribution of functions among contracts and contractors; (3) a timeline for complete transition to full competition; and, (4) a detailed description of changes to contractor oversight and management.

Section 912. Requirements for information security for Medicare administrative contractors

Section 912 requires Medicare administrative contractors that determine and make payments to implement a contractor-wide information security program that meets the requirements imposed on Federal agencies to ensure the security, integrity, confidentiality, authenticity, and availability of operational data and systems supporting operations. An annual audit of the information security at each Medicare administrative contractor: (1) would be performed by an independent entity that meets the independence reguirements specified by the Office of Inspector General (OIG) in HHS; and (2) would test the effectiveness of information security control techniques for an appropriate subset of the contractor's systems. An audit of new contractors (those that have not been fiscal intermediaries or carriers) would be required prior to the start of their performing Medicare payment functions. An audit of existing contractors (those that are now fiscal intermediaries and carriers) would be required to be completed within 1 year from enactment. The results of the audits would be reported promptly to the OIG which will submit a report annually to Congress. These provisions would be equally applicable to fiscal intermediaries and carriers as to Medicare administrative contractors.

Subtitle C—Education and Outreach

Section 921. Provider education and technical assistance

Section 921(a) adds a new section 1889 to Title XVIII of the Social Security Act entitled "Provider Education and Technical Assistance." This new section would require the Secretary (1) to coordi-

nate the educational activities provided through the Medicare administrative and MIP contractors; and, (2) to submit an evaluation to Congress, no later than October 1, 2004, on actions taken to co-

ordinate the funding of provider education.

Subsection (b) requires the Secretary to develop and implement a methodology to measure the specific claims payment error rates at each Medicare administrative contractor. This methodology would apply to existing fiscal intermediaries and carriers in the same manner as it applies to Medicare administrative contractors. No later than October 1, 2004, GAO would submit to Congress and to the Secretary a report on the adequacy of the methodology, including recommendations as appropriate. No later than October 1, 2004, the Secretary would be required to report to Congress on (1) the use of the claims error rate methodology in assessing the effectiveness of contractors' provider education and outreach programs; and, (2) whether such methodology should be used as a basis of

contractors' performance bonuses.

Under subsection (c), by October 1, 2004, the Secretary would be required to develop a communication strategy with beneficiaries, providers and suppliers. Each Medicare administrative contractor would be required to (1) provide general written responses (which may be through electronic transmission) in a clear, concise and accurate manner to written inquiries from beneficiaries, providers and suppliers within 45 business days; (2) provide a toll-free telephone number where these interested parties may obtain billing, coding, claims, coverage and other appropriate Medicare information; (3) maintain a system for identifying which employee provided both the written and oral information; and, (4) monitor the accuracy, consistency, and timeliness of the information provided. The Secretary would be required to establish and make public the standards used to monitor the accuracy, consistency, and timeliness of information provided in response to written and telephone inquiries. The standards would be developed in consultation with provider, supplier, and beneficiary organizations and would be consistent with the contractors' performance requirements. The Secretary would be able to directly monitor the quality of the information so provided. These provisions would also apply to existing fiscal intermediaries and carriers.

Subsection (d) would authorize \$25 million in Medicare appropriations in FY2005 and FY2006 and such funds as necessary in subsequent years to increase provider education and training and to improve the accuracy and quality of contractor responses. Starting on October 1, 2004, the contractors' training activities would be tailored to the special needs of small providers and suppliers. This provision defines a small provider as an institution with fewer than 25 full-time equivalents employees (FTEs) and a small supplier as one with fewer than 10 FTEs.

Subsection (e) provides that by October 1, 2004, the Secretary and each contractor would be required to maintain an Internet site that provides answers to frequently asked questions in an easily accessible format as well as other materials published by the contractor.

Subsection (f) prohibits a Medicare contractor to use attendance records at educational programs or information gathered during these programs to select or track candidates for audit or prepayment review. Nothing in the proposed legislation would require Medicare administrative contractors to disclose information that would compromise pending law enforcement activities or reveal findings of law enforcement-related audits.

Section 922. Small provider technical assistance demonstration program

Section 922 requires the Secretary to establish a demonstration program and contract with qualified entities to offer technical assistance, when requested and on a voluntary basis, to small providers or suppliers. Small providers and suppliers would be those institutional providers with less than 25 FTEs or suppliers with less than 10 FTEs. Technical assistance would include direct, inperson examination of billing systems and internal controls by qualified entities such as peer review organizations or other entities. In awarding these contracts, the Secretary would be required to consider any prior investigations of the entity's work by the OIG in HHS or GAO. Participating providers and suppliers would be required to pay an amount estimated and disclosed in advance that would equal 25% of the cost of the technical assistance they received. Absent indications of fraud, errors found in the review would not be subject to recovery if the problem is corrected within 30 days of the on-site visit and remains corrected for an appropriate period. However, this protection would only apply to claims filed as part of the demonstration project, would last only for the duration of the project and only as long as the provider or supplier was participating in the project. GAO, in consultation with the OIG, would be required to evaluate and recommend continuation of the demonstration project no later than 2 years after its implementation. The evaluation would include a determination of whether claims error rates were reduced for providers and suppliers who participated in the program. The demonstration project would be authorized at \$1 million in FY2005 and \$6 million in FY2006 of appropriations from the Medicare Trust Funds.

Section 923. Medicare Provider Ombudsman; Medicare Beneficiary Ombudsman

Section 923 would require the Secretary, one year after enactment, to appoint a Medicare Provider Ombudsman within HHS to (1) resolve unclear guidance and provide confidential assistance to providers and suppliers regarding complaints or questions about the Medicare program including peer review and administrative requirements; and, (2) recommend changes to improve program administration. The ombudsman would not advocate any increases in payments or expanded coverage, but would identify issues and problems in current payment and coverage policies.

Additionally under this section, the Secretary would be required to appoint a Medicare Beneficiary Ombudsman within HHS from individuals with health care expertise, advocacy, and education of Medicare beneficiaries. The ombudsman would (1) receive complaints, grievances, and requests for information from Medicare beneficiaries; (2) provide assistance with respect to those complaints, grievances and requests, including assistance to beneficiaries who appeal claims determinations or those affected by the decisions of Medicare Advantage organizations to leave Medicare;

and, (3) submit an annual report to Congress and the Secretary describing activities and recommending changes to improve program administration. The ombudsman would not advocate any increases in payments or expanded coverage, but would identify issues and problems in current payment and coverage policies. To the extent possible, the Beneficiary Ombudsman would work with the Health Insurance Counseling Programs, authorized under section 4360 of Omnibus Reconciliation Act of 1990, to facilitate the provision of information to Medicare beneficiaries regarding Medicare Advantage plans and any changes related to those plans. Nothing in this section would preclude further collaboration between the Medicare Beneficiary Ombudsman and these programs.

The section also establishes a toll-free number (1–800–MEDI-CARE) that will transfer individuals with questions or seeking help to the appropriate entities. The transfer would occur with no charge. This toll-free number would be the general information and assistance number listed on the annual notice provided to beneficiaries. GAO would be required to (1) monitor the adequacy, accuracy, and consistency of the information provided to Medicare beneficiaries through the toll-free 1–800 MEDICARE number; and, (2) to examine the education and training of those providing the information through the toll-free number. GAO would be required to submit a report to Congress no later than 1 year from enactment.

Section 924. Beneficiary outreach demonstration program

Section 924 would require the Secretary to establish a 3-year demonstration project where Medicare specialists who are HHS employees are placed in at least six SSA offices to advise and assist Medicare beneficiaries. The SSA offices would be those with a high-volume of visits by Medicare beneficiaries; at least two of which would be in rural areas. In the rural SSA offices, the Secretary would provide for the Medicare specialists to travel among local offices on a scheduled basis. The Secretary would be required to (1) evaluate the project with respect to beneficiary utilization, beneficiary satisfaction, and cost-effectiveness; and, (2) recommend whether the demonstration should be established on a permanent basis.

Section 925. Inclusion of additional information in notices to beneficiaries about skilled nursing facility benefits

Section 925 would require the Secretary to provide in Medicare beneficiary notices (sec. 1806(a) of the SSA title XVIII) information on the number of days of coverage of nursing home services remaining well in advance of the end of the 100 days of care. This shall apply to notices provided more than 6 months after the date of enactment of this Act. Beneficiaries currently utilizing skilled nursing facilities (SNFs) are sometimes unaware that their Medicare coverage is ending and they must secure other means of payment for their nursing home care.

Section 926. Information on Medicare-certified skilled nursing facilities in hospital discharge plans

Section 926 requires the Secretary to provide public information that enables hospital discharger planners, Medicare beneficiaries, and the public to identify skilled nursing facilities that are participating in the Medicare program. This shall apply to discharge plans made no more than 6 months after the date the Secretary provides for the availability of information under this section. Some hospitals discharge patients, who would otherwise be eligible for the Medicare SNF benefit, to facilities that are not Medicare-certified without informing the beneficiary that they would not receive Medicare coverage for their care or that other Medicare-certified facilities may be available.

Subtitle D—Appeals and Recovery

Section 931. Transfer of responsibility for Medicare appeals

Medicare beneficiaries and, in certain circumstances, providers and suppliers of health care services may appeal claims that are denied or payments that are reduced. Section 1869 of the Act, which covers the Medicare claims appeals process, was amended by the Medicare Medicaid and SCHIP Benefits Improvement and Protection Act of 2000 (BIPA) in its entirety, but the BIPA provisions are not yet effective. Generally, parties who have been denied coverage of an item or service have the right to appeal that decision through a series of administrative appeals and then to a federal district court if the amounts of disputed claims in question meet certain thresholds at each step of the appeals process. A hearing by an Administrative Law Judge (ALJ) in the SSA and a review by the Department Appeals Board (DAB) are components of the administrative appeals process.

Section 931 states that by October 1, 2004, the Commissioner of SSA and the Secretary would develop and transmit a plan to Congress and GAO describing the transfer of functions of the ALJs who are responsible for hearing Medicare and Medicare related cases from SSA to HHS. GAO would evaluate the plan and submit a report to Congress no later than October 1, 2005. The Secretary would (1) assure the independence of the ALJs performing the ALJ function from the Centers of Medicare and Medicaid Services (CMS) and its contractors; and, (2) locate the ALJs with an appropriate geographic distribution to ensure access. Subject to appropriations, the Secretary would be permitted to hire ALJs and support staff with priority given to ALJs with experience in handling Medicare appeals. Amounts previously paid to SSA for the ALJs performing the ALJ functions would be payable to the Secretary for the transferred functions. The Secretary would be permitted to enter into arrangements with SSA to share office space, support staff, and other resources with appropriate reimbursement from the Medicare trust funds. Increased appropriations would be permitted to increase the number of ALJs and support staff; improve education and training for ALJs and their staff; and increase DAB staff.

Section 932. Process for expedited access to review

Section 932 makes modification to the current practice for expedited access to review. Section 521 of BIPA (which is not yet implemented) amends section 1869 to establish deadlines for filing appeals and for making decisions in the Medicare appeals process. Generally, an initial determination is to be completed no later than 45 days from the date a claim for benefits is received; an individual

dissatisfied with an initial determination is entitled to a redetermination by a carrier or fiscal intermediary if requested within 120 days of the determination date. The redetermination is to be completed no later than 30 days from the request date. The Secretary may reopen or revise any initial determination or reconsidered de-

termination under guidelines established by regulation.

An individual dissatisfied with the redetermination is entitled to reconsideration by a qualified independent contractor (QIC) if the request is initiated within 180 days of the notice of the adverse redetermination. With certain exceptions, a QIC reconsideration decision is to be completed within 30 days from the date a timely request has been filed. After a QIC's reconsideration, if the remaining contested amount is greater than \$100, an individual is entitled to a hearing by an administrative law judge and then a review by the DAB. Both the ALJ hearing and the DAB review are to be completed within 90 days of a timely filed request for such an action.

If the dispute is not satisfactorily resolved and the contested amounts are greater than \$1,000, the individual is entitled to judicial review of the decision. Under certain circumstances, a beneficiary is entitled to an expedited determination with accelerated deadlines. BIPA also provides for an expedited hearing under section 1869, where the moving party alleges that no material issues of fact are in dispute; the Secretary makes an expedited determination as to whether any such facts are in dispute and, if not, renders

a decision expeditiously.

The Secretary would establish an appeals process for a provider, supplier, or beneficiary which permits access to judicial review when a review panel determines that no entity in the administrative appeals process has authority to decide the question of law or regulation in controversy and where material facts are not in dispute. The appellant would be able to make such request only once with respect to a question of law or regulation for a specific dispute. If the appellant requests this determination and submits appropriate supporting documentation, the review panel would make this determination in writing no later than 60 days after receiving the request. A review panel would consist of a panel of three members who are ALJs, members of the DAB, or qualified individuals associated with a QIC or other independent entity designated by the Secretary to make these determinations. The determination by the review panel would be considered a final decision and not subject to review by the Secretary. Given such a determination or a failure to make the determination within the 60-day deadline, the appellant would be able to request judicial review before a civil court. The filing deadline for this civil action would be within 60 days of the determination or within 60 days of the end of the deadline to make such determination. The venue for judicial review would be the U.S. District Court where the appellant is located, or where the greatest number of appellants are located, or in the district court for the District of Columbia. The amount in controversy would be subject to annual interest beginning on the first day of the first month beginning after the 60-day deadline for filing. Interest would be equal to the rate of interest on obligations issued for purchase by the Medicare trust funds effective for the month that the civil action is authorized to commence. The interest payments would not be deemed to be Medicare reimbursement.

Under this section, an agency or institution's appeal concerning program participation under section 1866 would have access to expedited judicial review under section 1869 provisions. This provision would not be construed to affect remedies applied to assure quality of care in skilled nursing facilities (under section 1819)

while such appeals are pending.

Finally, the Secretary would develop and implement a process under 1866(h) to expedite provider agreement determinations including those instances where participation is terminated or other sanctions (including denials of new admissions or the immediate appointment of temporary management) against skilled nursing facilities have been imposed. Priority would be given to termination of provider agreements. Increased appropriations from the Medicare trust funds in FY2003 subsequently would be authorized in order to (1) reduce the average time for administrative determinations on provider participation appeals by 50%; (2) increase the number of ALJs and their staff as well as appellate level staff at the DAB; and (3) educate such judges and their staff on long-term care issues.

Section 933. Revisions to Medicare appeals process

Section 933 provides that starting no later than October 1, 2004, a provider or supplier would not be able to introduce evidence that was not presented at reconsideration conducted by the QIC unless a good cause precluded its introduction at or before that reconsideration.

In addition, medical records of the individual involved in the appeal would be included as part of the applicable information used

by QICs in their reconsideration process.

The section also would establish that a written notice of an initial determination associated with a claims denial be provided. The notice would include: (1) the reason for the denial and, upon request, the policy, manual or regulation used to make the decision; (2) the procedures for obtaining additional information concerning the determination; and (3) the notification of appeal rights and associated instructions.

The section would amend the existing requirement that a reconsideration decision be written and would establish that the decision be provided in printed form and written in a manner that could be understood by the beneficiary; the notice would include; as appropriate, a summary of the clinical or scientific evidence used to make the decision; upon request, the policy manual or regulation used to make the decision; and a detailed explanation of the decision to the extent appropriate. The requirement that the reconsideration decision include a notice of appeal rights and relevant instructions would also be established.

Comparable requirements would be extended to ALJ decisions. These decisions would have to be written in an understandable manner and include the specific reasons for the decision, an appropriate summary of the evidence, the procedures for obtaining additional information about the decision, and a notification of appeal rights and instructions.

The current requirements that a QIC prepare documentation and an explanation of the issues for an appeal to an ALJ would be modified: a QIC would be required to submit the information required in an appeal of a Medicare contractor's decision to the ALJ.

The Committee votes that BIPA established QIC reconsiderations as part of Medicare's administrative review process. A QIC is an entity or organization that is independent of any organization under contract with the Secretary, that makes initial determinations and that meets the established requirements for sufficient training and expertise in medical science and legal matters to make such reconsiderations. QIC reviews include consideration of the facts and circumstances by a panel of physicians or appropriate health professionals. No physician or health care professional employed by a QIC may review determinations regarding services provided to a patient, if directly responsible for furnishing the services to that patient. Review of home health care services is also prohibited by physicians and other professionals who have a significant direct or indirect financial interest in the agency or institution providing the care. This prohibition extends to physicians and professionals who have family members with such significant financial interests.

To qualify as a QIC, an entity would be required to have sufficient medical, legal and other expertise, including knowledge of the Medicare program as well as sufficient professional qualifications, independence and staffing to make reconsideration decisions. A QIC would be required to assure that reviewers meet qualification and compensation requirements. If a reconsideration request indicates that the treatment was furnished or a physician provided the item or service, each reviewing professional should be a physician.

Entities and their professional reviewers would have to meet independence requirements and may not (1) be a related party; (2) have a material familial, financial, or professional relationship with a related party; or (3) have a conflict of interest with respect to a related party. QIC's compensation would not be contingent on any decision by the QIC or by any reviewing professional. A reviewer's compensation would not be contingent on any decision rendered by the reviewer. In this context, a related party to a Medicare case involving an individual beneficiary would be (1) the Secretary, the Medicare administrative contractor involved, any fiduciary, officer, director or employee of HHS or such Medicare contractor; (2) the individual or authorized representative; (3) the health professional, institution or entity that provides or manufactures the item or service involved in the case; and, (4) any other party with substantial interest in the case, as defined by regulation. An individual affiliated with a fiscal intermediary, carrier or other contractor would be able to act as a QIC reviewer if (1) the individual is not involved with the provision of the item or service of the case; (2) the individual is not an employee of the Medicare contractor and does not provide services exclusively or primarily to or on behalf of the contractor; and, (3) the fact of the relationship is disclosed to the Secretary and the Medicare beneficiary or authorized representative who do not object. An individual with staff privileges at the institution where treatment occurs would be able to serve as a reviewer if the affiliation is disclosed without objection.

Each reviewing professional would be required to be (1) an allopathic or osteopathic physician or health care professional who is appropriately credentialed or licensed in one or more states to deliver health care services and has medical expertise in the field of practice appropriate for the case; or, (2) a health care professional who is legally authorized in one or more states (in accordance with state law or according to the appropriate state regulatory mechanism) to furnish the health care items or service and has medical expertise in the field of practice appropriate for the case. A sufficient number of qualified independent contractors (but not fewer than four) shall be available to conduct appeals consistent with the timeframes under this section.

Section 934. Prepayment review

Section 934 permits Medicare administrative contractors to conduct random prepayment reviews in order to develop contractorwide or program-wide claims payment error rates or under additional circumstances as established by regulations that are developed in consultation with providers and suppliers. Medicare administrative contractors would be permitted to conduct random prepayment reviews in accordance with a standard protocol developed by the Secretary. The Secretary would not be able to initiate a nonrandom prepayment review based on the initial identification by a provider or supplier of an improper billing practice unless there is a likelihood of sustained or high level of payment error. The Secretary would be required to issue regulations relating to the termination of such non-random prepayment reviews that could incorporate differences in the circumstances that triggered such a review that may affect its duration. No provision would prevent the denial of payment for claims actually reviewed under random prepayment review. These provisions would be applied to fiscal intermediaries and carriers. The provisions would be effective no later than 1 year from enactment. The Secretary would be required to issue regulations before that deadline; the random prepayment review protocols would apply to reviews after a date specified by the Secretary (but no later than 1 year from enactment.)

Section 935. Recovery of overpayments

Section 935 provides that interest accrues on underpayments or overpayments starting within 30 days of the date of the final determination of the accurate payment amount.

Subject to certain qualifications, in circumstances where refund of an overpayment within 30 days would constitute a hardship, providers and suppliers on request would be allowed to repay the overpayment amount (by offset or otherwise) over a period of at least 6 months and up to 3 years when their obligation exceeds a 10% threshold of their annual payments from Medicare. The Secretary would be able to establish a repayment period of up to 5 years in cases of extreme hardship. Interest would accrue on the balance through the repayment period. The Secretary would be required to establish a process under which newly participating providers and suppliers could qualify for a repayment plan under this hardship provision. Previous overpayment amounts already included in an ongoing repayment plan would not be included in the calculation of the hardship threshold. The Secretary would be allowed to seek immediate collection if payments are not made as scheduled. Exceptions to this provision would be permitted in cases where bankruptcy may be declared, where Medicare participation

may be discontinued, or where fraud or abuse against Medicare is indicated. This provision would not affect the application of existing no-fault provisions which preclude recovery under circumstances where incorrect payment has been made to an individual who is without fault or where the recovery would decrease

payments to another person who is without fault.

Upon enactment, the Secretary would not be able to initiate any recovery action if the provider or supplier has sought a reconsideration of the Medicare overpayment by a QIC until the date of the reconsideration decision. If QIC's are not yet in place, the recovery would not be initiated until the date of a redetermination decision by a fiscal intermediary or a carrier. If monies have been offset or repaid, the Secretary would return those amounts plus applicable interest if the original overpayment determination is reversed. If such an overpayment determination is upheld, interest would accrue beginning on the date of the original overpayment notice; the interest amount would be the rate otherwise applicable for Medicare overpayments.

Not later than 1 year after enactment, a Medicare contractor would not be able to use extrapolation to determine overpayment amounts for statistically valid random samples initiated after the date of enactment, unless, as determined by the Secretary, a sustained or high level of payment error exists or a documented educational intervention did not correct the payment error. Where providers and suppliers have previously been overpaid, Medicare contractors would be able to require periodic production of records or supporting documentation for a limited sample of submitted claims

to ensure that a previous practice has been discontinued.

The Secretary would be able to use a consent settlement to resolve a projected overpayment. Before entering into any consent settlements after the date of enactment, the Secretary would be required to communicate to a provider or supplier that based on a preliminary evaluation of a medical records review, an overpayment may exist; the nature of the identified problems; and the necessary steps to address the problem. The Secretary would provide 45 days where additional information may be submitted concerning the claims for which the medical records have been reviewed. After considering the additional information, the Secretary would provide notice and explanation of any remaining overpayment determination and would offer the opportunity for a statistically valid random sample (which would not waive appeal rights) or a consent settlement (based on a smaller sample with a waiver of appeal rights) to resolve the overpayment amounts.

Not later than 1 year after enactment, the Secretary would be required to establish, in consultation with health care associations, a process where classes of providers and suppliers are notified that their Medicare contractor has identified specific billing codes that

may be over-utilized.

For audits initiated after enactment, Medicare contractors would be required to provide a written notice (which may be in electronic form) of the intent to conduct a post-payment audit to those selected as audit candidates. Medicare contractors would be required to provide those who have been audited a full review and understandable explanation of the findings that: (1) permits the development of an appropriate corrective action plan; (2) provides informa-

tion on appeal rights as well as consent settlements (which are at the discretion of the Secretary); and, (3) provides for an opportunity to supply additional information to the contractor. Medicare contractors would be required to take into account the information provided, on a timely basis. The provisions requiring notice of audit and findings would not apply if pending law enforcement activities would be compromised or findings of law enforcement-related audits would be revealed.

Not later than 1 year after enactment, the Secretary would be required to establish a standard methodology for Medicare contractors to use in selecting a claims sample for a review of abnormal billing patterns. These provisions would apply to Medicare administrative contractors including fiscal intermediaries and carriers as well as those eligible entities with MIP contracts.

Section 936. Provider enrollment process; right of appeal

Section 936 would require the Secretary to (1) establish by regulation an enrollment process for providers and suppliers which would include deadlines for actions on enrollment applications within 6 months of enactment; (2) monitor the performance of Medicare administrative contractors in meeting the deadlines; and, (3) consult with providers and suppliers in making changes to the enrollment forms made on or after January 1, 2004.

Providers and suppliers whose application to enroll or reenroll has been denied and who are dissatisfied with the determination would be entitled to a hearing and judicial review of the determination under the procedures that currently apply to providers. This provision would apply to denials, after a date specified by the Secretary, which could not be later than 1 year from enactment.

Section 937. Process for correction of minor errors and omissions without pursuing appeals process

Section 937 would require the Secretary to develop, in consultation with appropriate Medicare contractors and health care associations, a process where minor claims errors and omissions can be corrected and resubmitted without appealing the claims denial.

Section 938. Prior determination process for certain items and services; advance beneficiary notices

Medicare law prohibits payment for items and services that are not medically reasonable and necessary for the diagnosis or treatment of an illness or an injury. Under certain circumstances, however, Medicare will pay for non-covered services that have been provided if both the beneficiary and the provider of the services did not know and could not have reasonably been expected to know that Medicare payment would not be made for these services.

A provider may be held liable for providing uncovered services, if, for example, specific requirements are published by the Medicare contractor or the provider has received a denial or reduction of payment on the same or similar service. In cases where the provider believes that the service may not be covered as reasonable and necessary, the provider may limit his liability by providing an acceptable advance notice of Medicare's possible denial of payment to the patient. The notice must be given in writing, in advance of providing the service; include the patient's name, date and descrip-

tion of service as well as reasons why the service would not be covered; and must be signed and dated by the patient to indicate that the beneficiary will assume financial liability for the service if

Medicare payment is denied or reduced.

The Secretary would be required to establish a process through regulation where physicians and beneficiaries can establish whether Medicare covers certain items and services before such services are provided. An eligible requestor would be either a physician, but only with respect to eligible items and services for which the physician may be paid directly or a Medicare beneficiary who receives an advance beneficiary notice (ABN) from the physician who may be paid directly for the service in question.

The Secretary would establish by regulation reasonable limits on the categories of eligible items and services for which a prior determination may be requested. The Secretary would be able to require that the request be accompanied by a description of the item or service and other supporting documentation including a copy of the ABN if the beneficiary is requesting the prior determination.

The contractor would be required to provide the eligible requester with a written notice stating whether the item or service is covered or not covered or whether the information is not sufficient to make a decision. This notice would be subject to existing deadlines applying to initial determinations and would include a brief explanation of the basis for the decision and the right to redetermination. If a physician's request for a prior determination was unsuccessful, the beneficiary would be informed of that decision. These prior determinations would be binding on the Medicare contractor, absent fraud or misrepresentation of facts. If unsuccessful, the requestor would have the right to request a redetermination. Contractors' prior determinations (and redeterminations) would not be subject to further administrative or judicial review. However, an individual would retain existing rights to administrative or judicial review after receiving the service or receiving a determination that a service would not be covered. No prior determinations would be rendered after services are rendered or items are provided.

The Secretary would be required to (1) establish the process to allow for the processing of such requests beginning 18 months after enactment; (2) collect data on the advance determinations; and, (3) establish a beneficiary and provider outreach and education program. GAO would be required to report on the use of the advance beneficiary notice and prior determination process no later than 18

months of its implementation.

Subtitle V—Miscellaneous Provisions

Section 941. Policy development regarding evaluation and management (E&M) documentation guidelines

Section 941 would not permit the Secretary to implement any new documentation guidelines on or after enactment for evaluation and management (E&M) physician services unless the guidelines (1) are developed in collaboration with practicing physicians (both generalists and specialists) after assessment by the physician community; (2) are based on a plan with deadlines for improving use of E&M codes; (3) are developed after completion of the pilot projects to test modifications to the codes; (4) are found to meet the

desired objectives; and, (5) are preceded by establishment of appropriate outreach and education of the physician community. The Secretary would make changes to existing E&M guidelines to reduce paperwork burdens on physicians.

The Secretary would also be required to modify E&M guidelines to (1) identify clinically relevant documentation: (2) decrease non-clinically pertinent documentation; (3) increase the reviewers' accu-

racy; and, (4) educate the physicians and the reviewers.

The provisions would establish different pilot projects in specified settings that would be (1) conducted on a voluntary basis in consultation with practicing physicians (both generalists and specialists); (2) be of sufficient length to educate physicians and contractors on E&M guidelines; and, (3) allow for an assessment of E&M guidelines and their use. A range of different projects would be established and include at least one project that (1) uses a physician peer review method; (2) uses an alternative method based on faceto-face encounter time with the patient; (3) is in a rural area; (4) is outside a rural area; and, (5) involves physicians billing in a teaching setting and non-teaching setting. The projects would examine the effect of modified E&M guidelines on different types of physician practices in terms of the cost of compliance. Data collected under these projects would not be the basis for overpayment demands or post-payment audits. This protection would apply to claims filed as part of the project, would last the duration of the project, and would last for as long as the provider participated in the project. The Secretary, in consultation with practicing physicians including those in groups practices as well as generalists and specialists, would be required to evaluate the development of alternative E&M documentation systems with respect to administrative simplification requirements and report results of the study to Congress by October 1, 2005. The Medicare Payment Advisory Commission would conduct an analysis of the results of this study and submit a report to Congress.

Finally, under this section, the Secretary would be required to conduct a study of the appropriate coding of extended office visits where no diagnosis is made and submit a report with recommenda-

tions to Congress no later than October 1, 2005.

Section 942. Improvement in oversight of technology and coverage

Section 942 requires the Secretary to establish a Council for Technology and Innovation within CMS. The council would be composed of senior CMS staff with an executive coordinator, who is designated or appointed by the Secretary and reports to the CMS administrator. The chairperson would serve as a single point of contact for outside groups and entities regarding Medicare coverage, coding, and payment processes. The Council would coordinate Medicare's coverage, coding, and payment processes as well as information exchange with other entities with respect to new technologies and procedures, including drug therapies.

This section would also require the Secretary to establish procedures (by regulation) for determining the basis and amount of payments for new or substantially revised clinical diagnostic laboratory tests assigned a Health Care Procedure Coding System (HCPCS) code on or after January 1, 2005. A code would be consid-

ered as substantially revised if there is a substantive change to the definition of a test or procedure to which the HCPCS code applies.

The Secretary, as part of this procedure, would be required to (1) provide a list (on an Internet site or other appropriate venue) of tests for which payments are being established in that year; (2) publish a notice of a meeting in the Federal Register on the day the list becomes available; (3) hold the public meeting no earlier than 30 days after the notice to receive public comments and recommendations; and, (4) take into account the comments, recommendations and accompanying data in both proposed and final payment determinations. The Secretary would set forth the criteria for making these determinations; make public the available data considered in making such determinations; and could convene other public meetings as necessary.

This section also requires GAO to conduct a study analyzing which external data can be collected by CMS for use in computing Medicare's inpatient hospital payments. The study may include an evaluation of the feasibility and appropriateness of using quarterly samples or special surveys among other methods. The study would include an analysis of whether other agencies, such as the Bureau of Labor Statistics in the Department of Commerce (sic), are best suited to collect this information. The report would be submitted to

Congress no later than October 1, 2004.

If the National Committee on Vital and Health Statistics (NCVHS) has not made a recommendation to the Secretary before the date of enactment with respect to the adoption of the International Classification of Diseases, 10th Revision, Procedure Coding System (ICD–10–PCS) and the International Classification of Diseases, 10th Revision, Clinical Modification (ICD–10–CM), the Secretary may adopt ICD–10–PCS and ICD–10–CM as a standard for hospital inpatient services only on or after enactment of this Act.

Section 943. Treatment of hospitals for certain services under Medicare secondary payor (MSP) provisions

Section 943 states that the Secretary would not require a hospital or a critical access hospital to ask questions or obtain information relating to the Medicare secondary payor provisions in the case of reference laboratory services if the same requirements are not imposed upon those provided by an independent laboratory. Reference laboratory services would be those clinical laboratory diagnostic tests and interpretations of the same that are furnished without a face-to-face encounter between the beneficiary and the hospital where the hospital submits a claim for the services.

Section 944. EMTALA improvements

Section 944 requires that emergency room services provided to screen and stabilize a Medicare beneficiary furnished after January 1, 2004, would be evaluated as reasonable and necessary on the basis of the patient's presenting symptoms or complaint available to the treating physician or practitioner at the time the services were ordered and not the patient's principal diagnosis. The Secretary would not be able to consider the frequency with which the item or service was provided to the patient before or after the time of admission or visit. The Secretary would be required to establish

a procedure to notify hospitals and physicians when an Emergency Medical Treatment and Active Labor Act (EMTALA) investigation is closed. Except in the case where a delay would jeopardize the health and safety of individuals, the Secretary would be required to request a PRO review before making a compliance determination that would terminate a hospital's Medicare participation because of EMTALA violation. The period of 5 business days would apply to such a PRO review. The Secretary would be required to provide a copy of the report to the hospital or physician, consistent with existing confidentiality requirements. This provision would apply to terminations initiated on or after enactment.

Section 945. Emergency Medical Treatment and Active Labor Act (EMTALA) technical advisory group

Section 945 requires the Secretary to establish a 19-member technical advisory group under specified requirements to review issues related to EMTALA. The advisory group would be comprised of: the CMS administrator; the OIG; four hospital representatives who have EMTALA experience (including one person from a public hospital and at least two of whom have not experienced EMTALA violations), seven practicing physicians with EMTALA experience; two patient representatives; two regional CMS staff involved in EMTALA investigations; one representative from a state survey organization and one representative from a PRO. The Secretary would (1) consider qualified individuals who are nominated by organizations representing providers and patients in selecting the task force; and, (2) establish the advisory group without regard to any limits on the number of such group that may be established (within HHS or otherwise).

The advisory group would be required to (1) elect a member as chairperson; (2) schedule its first meeting at the direction of the Secretary and meet at least twice a year subsequently; and, (3) terminate 30 months after the date of its first meeting. The advisory group would review EMTALA regulations; provide advice and recommendations to the Secretary; solicit public comments from interested parties; and disseminate information on the application of the EMTALA regulations.

Section 946. Authorizing use of arrangements to provide core hospice services in certain circumstances

Section 946 allows hospice programs to enter into arrangements with another certified hospice program to provide services if the services are highly specialized services of a registered nurse. The services that could be provided under these arrangements would be limited to extraordinary or non-routine circumstances, such as unanticipated periods of staffing shortages. The originating hospice program would continue to be responsible for billing and maintaining quality of care.

Section 947. Application of OSHA bloodborne pathogens standard to certain hospitals

Section 947 would require public hospitals that are not otherwise subject to the Occupational Safety and Health Act of 1970, to comply with the Bloodborne Pathogens standard under section 1910.1030 of Title 29 of the Code of Federal Regulations by July 1, 2004. A hospital that fails to comply with the requirement would be subject to a civil monetary penalty, but would not be terminated from participating in Medicare.

Section 948. BIPA-related technical amendments and corrections

Section 948 would incorporate section 1114 of the Act which relates to the appointment of advisory councils and other advisory groups into section 1862 of the Act which relates to exclusions from Medicare coverage. Other terms established by BIPA would be changed-from "policy" to "determinations."

Section 949. Conforming authority to waive a program exclusion

Section 949 permits the Administrator of a federal health program to request a waiver of a program exclusion if the exclusion of a sole community physician or source of specialized services in a community would impose a hardship. This conforming change would extend the same waiver authority currently in Medicare and Medicaid to federal health programs. In addition, waivers could be requested for Medicare, Medicaid, and federal health programs with respect to all exclusions except those related to patient abuse or neglect.

Section 950. Treatment of certain dental claims

Section 950 states that starting 60 days after enactment, a group health plan providing supplemental or secondary coverage to Medicare beneficiaries would not be able to require dentists to obtain documentation from Medicare that categorically excluded dental services are not covered prior to paying the claim.

Section 951. Furnishing hospitals with information to compute dsh formula

Section 951 requires the Secretary to furnish the appropriate information to subsection (d) hospitals so that that they may accurately calculate their disproportionate patient percentage. This is effective one year after the date of enactment.

Section 952. Revisions to reassignment provisions

Section 952 would amend the Social Security Act to allow physicians providing Medicare covered services to reassign Medicare payment to entities with which they have an independent contractor arrangement (such as a medical group, a physician practice management organization, or a staffing company) so long as there is a contractual arrangement between the physician and the entity under which the entity submits the bill for such service. As a result, the Secretary could enroll these entities in the Medicare program. The Secretary may also provide for other enrollment qualifications to assure program integrity.

This provision will streamline Medicare enrollment while also enhancing HHS' program integrity efforts. By permitting entities that retain independent contractors to enroll with the Medicare program, HHS will be able to monitor the claims submitted by the entities that retain independent contractors as well as those entities that employ physicians. The Secretary may develop enrollment qualifications to assure program integrity. The Committee supports appropriate program integrity efforts for any entities billing the

Medicare program including entities with employees as well as independent contractors. The changes made by this provision shall apply to Medicare payments made on or after date of enactment. This provision is effective upon enactment.

Section 953. Other provisions

Subsection (a) of section 953 states that no later than 6 months from enactment, GAO would be required to report to Congress on the appropriateness of the updates in the conversion factor including the appropriateness of the sustainable growth rate (SGR) formula for 2002 and subsequent years. The report would examine the stability and predictability of the updates and rate as well as the alternatives for use of the SGR in the updates. No later than 12 months from enactment, GAO would be required to report to Congress on all aspects of physician compensation for Medicare services. The report would review alternative physician payment structures, and provide recommendations to make the current system more stable and less complex.

Subsection (b) requires the Secretary would to provide, in an annual report that will be publicly available, a list of Medicare's national coverage determinations made in the previous year and include information on how to learn more about such determinations.

Subsection (c) directs the GAO to submit to Congress a report on the implications if there were flexibility in the application of the Medicare Conditions of Participation (COP) for home health agencies with respect to groups or types of patients who are not Medicare beneficiaries. This report shall be submitted to Congress no later than 6 months after enactment of this Act.

Subsection (d) requires the HHS OIG to submit a report to Congress that examines (1) the extent to which hospitals provide notice to Medicare beneficiaries in accordance with application requirement before they use their 60 lifetime reserve days and (2) the appropriateness and feasibility of hospitals providing a notice to such beneficiaries before they completely exhaust their lifetime reserve days. The OIG shall submit this report no later than one year after enactment of this Act.

TITLE X—MEDICAID

Section 1001. Medicaid disproportionate share hospital (DSH) payments

Section 1001 would increase DSH allotments for FY2004 by setting those amounts at the specified levels in 1923(f)(2) for FY2003. It also would add a special one-time 6 percent increase to that amount. Allotments for FY2005 and thereafter would be equal to the allotment for the previous year as calculated by the amendment, increased by 1.9 percent unless the Secretary determines that the allotment under this provision will equal (or no longer exceed) the allotment for that state that would have been in effect under prior law. For those states, beginning in the first fiscal year that their allotment would equal or no longer exceed the prior law levels, their allotment would be equal to the allotment for the previous year increased by the percentage change in the Consumer Price Index for Urban areas CPI–U for the previous year.

Section 1002. Clarification of inclusion of inpatient drug prices charged to certain public hospitals in the best price exemptions for the Medicaid drug rebate program

Section 1002 would exempt the prices paid by 340B institutions for inpatient drugs from the calculation of Medicaid Best Price.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

A document depicting the changes in existing law made by the bill, as ordered reported, pursuant to clause 3(e) of rule XIII of the Rules of the House of Representatives was requested from the Office of the House Legislative Counsel, but was not prepared as of the date of the filing of this report.

DISSENTING VIEWS

It is particularly disappointing that at a time when the public is calling for a bipartisan meaningful prescription drug benefit under Medicare, our Republican colleagues have taken a sharp partisan ideological turn toward a policy that not only fails to meet the needs of our Nation's seniors and those with disabilities for prescription drugs, but also takes a dangerous step toward dismantling all of Medicare as we know it.

Let us be clear. This bill is not the Senate bill—this is the

gravest threat to Medicare since it was enacted in 1965.

In the last Congress, the Republican drug plan barely passed the House by a vote of 221–208. The criticisms of that bill were defined in our Dissenting Views on H.R. 4988. The most glaring problem of the plan was reliance on private insurers to provide a drug-only benefit, despite being told that insurers would not enter the market. For the first time, seniors and individuals with disabilities would not be permitted to get a benefit through Medicare but would have to enter the private insurance market to do so. Even those who wanted to remain in traditional Medicare would have to join a private insurance company or forgo a critically important benefit, prescription medicines. The plan had no backup method for providing drugs if insurers, in fact, chose not to participate in various parts of the country. Until this point, seniors and individuals with disabilities have had the choice to remain in traditional Medicare for their coverage or join a private plan—the Republican plan would take that choice away.

In addition, there was no requirement for a uniform standard premium or standard benefit. Even worse, the Republican plan had a huge gap in coverage. That gap, often referred to as a "doughnut hole," meant that seniors had to pay 100 percent of the costs of their drugs from \$2,000 to \$4,800.

This year's version of drug benefits actually got worse. The only "coverage" under this bill, H.R. 2473, is for Republicans in Congress and the White House. The plan is still based upon a reliance on private insurance companies and continues to ignore the need for a backup plan of any sort. As President Bush's Medicare Administrator Tom Scully has said, these drug-only plans "don't exist in nature and won't work in practice." Instead, the bill would bribe these private insurance plans to come serve seniors rather than just provide a guaranteed federal fall-back plan.

Seniors would be forced to go outside of Medicare to look for a private drug insurance policy, which could enter and exit the market from year-to-year. Seniors and individuals with disabilities would be subject to the full force of insurance market volatility with no protections to guarantee stability of coverage, benefits or costs. Once again, there is no premium specified in law, and premiums could vary wildly throughout the country. In Nevada, where drug-only insurance plans were tried, the monthly premiums were \$85 in 2001. Similarly, insurers would be allowed to vary benefits and the drugs covered, making choices for seniors confusing at best, or incomprehensible at worst. The gap in coverage also

grew—it is now from \$2,000 to \$4,900.

Middle income seniors earning between \$60,000 and \$200,000 would have to pay much more out-of-pocket for their catastrophic drug coverage—the first time we have ever related income to benefits in Medicare, a dangerous precedent for a social insurance policy in which all Americans participate. Given that wealthier beneficiaries have already paid more through the payroll taxes during their working years, this double taxation of Medicare benefits should be rejected. In addition, this is not really a true means-test. Under a normal means-test, you pay more to get the same benefit. Under this policy, you pay more to get less. And this misguided policy will require the Internal Revenue Service (IRS) and the Department of Health and Human Services (HHS) to share sensitive income data on beneficiaries for the first time. HHS would then have to give information to the plan to indicate the level of the benefit for each beneficiary, a de facto disclosure of income. It appears that beneficiaries who refuse to authorize the sharing of this information might be excluded from the drug coverage.

Also, it is not at all clear that the IRS, HHS, or private insurance companies have the capacity to administer such a program. Levels of coverage would vary by individual within each plan, and individuals could petition the Secretary for a change of status. This would require significant expansion of existing bureaucracy. Private insurance companies who obtain this information would have an easier time cherry picking beneficiaries—selecting out the healthiest, less costly, participants. The more high income beneficiaries a plan can attract, the less benefits they must pay out. In addition, since there is a correlation between income and health, with lower-income seniors and individuals with disabilities tending to have poorer health status, HMOs, and PPOs would have access to handy information with which to avoid lower income (and thus

more costly) Medicare beneficiaries.

Another attempt to provide health insurance companies the information needed to select out the healthiest beneficiaries for enrollment in private plans comes in the provisions allowing "discount cards" to be run by health insurance plans—HMOs, PPOs, and others. Between 2004 and 2006, private insurance companies can offer "drug discount cards" to beneficiaries, using this mechanism to gain valuable information about prescription drug use, health status, and illnesses of individual beneficiaries. When the drug benefit is slated to begin in 2006, these private insurance companies will have a host of critical information allowing them to target their marketing and enrollment material to only those individuals whose private information indicates they are low-cost, healthy, and not likely to pose a financial risk to the insurance company's profit margin. An amendment offered to address this violation of privacy and gift to private insurers was defeated on party lines.

Republican Members of the Committee on Energy and Commerce and the President of the United States are fond of saying that Medicare beneficiaries should get the same choices as Members of Congress do with respect to prescription drug coverage. Unfortunately, on this point the rhetoric does not match the reality of this bill. Members of Congress get health insurance through the Federal Employees Health Benefits Plan like all federal employees, yet there is not a single plan option in FEHBP as bad as the one they

are promoting for seniors in Medicare.

While Republicans purport to protect those on the lower-ends of the income scale, even those provisions fall far short. Help for even the poorest seniors—those with incomes below \$8,980—is contingent on meeting an assets test. This means that they will not get the extra help they need if they have even modest savings (\$4,000 or more). Data suggest that more than one-third of otherwise eligible low-income beneficiaries would be excluded as a result of this hidden hatchet.

Moreover, the legislation would do nothing to stem the rising prices of medicines for the elderly and individuals with disabilities. It specifically includes language prohibiting the new Medicare Benefits Administrator, the overseer of private insurance plans, from taking actions to assist beneficiaries by reducing prices. The entire construct of the bill, fragmenting 40 million Medicare beneficiaries into small clusters in private insurance plans, will ensure that seniors will never be able to use their market clout. An amendment was offered in Committee that would have granted the power for the Medicare program to negotiate on behalf of the elderly and individuals with disabilities, but it was defeated.

In spite of the new 28 percent employer subsidy for retiree coverage in this bill, the Republican Medicare bill will still cause employers to drop retiree prescription drug coverage. According to Congressional Budget Office estimates, 32 percent of employers who are currently providing retiree prescription drug benefits will drop that coverage if this bill becomes law as written. We should be using this opportunity to reinforce the better coverage that is

out there, not erode it.

The Democratic Members of the Committee offered amendments to address the major flaws in the prescription drug title of the Republican legislation: improved coverage by filing in the gap, protecting against exorbitant premiums, defining the benefit, eliminating means-testing, and providing coverage as generous as that received by Members of Congress; improved stability through a guaranteed Medicare plan and two-year contracts for private plans; eliminating the penalty for those with employer-sponsored coverage; and addressing rising prices of prescription drugs. All of these were defeated by overwhelmingly partisan votes.

But if this were not bad enough, the Republican bill is a stalking horse to fulfill the Republicans' lifelong dream to privatize Medicare and turn a program that promises seniors an entitlement to their health care needs into a program that promises nothing more than financial support in buying health insurance. Medicare Part B has always been a shared program with the Government paying 75 percent and the beneficiary paying 25 percent. This new Republican proposal would fix the Government contribution and leave it to the beneficiary to pay the rest. This type of program, which goes under the names of premium-support, vouchers, or defined pay-

ment, is no program at all. It is an open invitation to begin the gradual destruction of Medicare, as the Government payment to seniors can be reduced year-to-year, while the seniors' payment will be increased. (If anyone should doubt this, one need only look at H. Con. Res. 95, the Budget Resolution for FY 2004, which passed the House this year and would have required our Committee to reduce health care spending by over \$100 billion in jut the coming fiscal year.)

The concept of replacing Medicare with vouchers is not new to the Republican Party; the Republican-appointed members of the Medicare Commission all supported Chairman Thomas's plan to voucherize Medicare as well. This year Representative Terry (R–NE) offered an amendment in Committee to immediately replace the existing Medicare program with a premium support/voucher program; however, he withdrew his amendment and Democrats were not allowed to show their antipathy toward such a program with a recorded vote.

The privatization policy, which can be found in Title II of the bill, would require Medicare, beginning in 2010, to "compete" with private plans. If Medicare costs more than the private plans, seniors would be forced to pay the difference. This would likely force seniors to choose between leaving their doctors and a system they know and understand, or paying increasing amounts to stay in the traditional Medicare system. Seniors' health care costs could vary

wildly across the country, and even from county to county.

Medicare is not more costly than private plans. To the contrary, every analysis from the Congressional Budget Office (CBO) and the General Accounting Office has determined that Medicare is far more cost-effective than private plans. The experience with HMOs under the Medicare+Choice program begun in 1997 has proven this point, and this bill acknowledges the fact by increasing private plan payments in 2006 to at least the fee-for-service rate in Medicare—in some instances payments to these plans will exceed what Medicare would have paid for a senior in the traditional program. With these additional payments, plans could offer supplemental benefits to lure seniors into them, thus fulfilling President Bush's original desire for seniors to get their benefits (including drugs) through private plans, not traditional fee-for-service Medicare. By establishing private drug-only plans that will not work, increasing payments to HMO's, and allowing only the private plans to offer extra benefits, and raising the premiums for fee-for-service Medicare, seniors may have no choice but to join HMOs if they want an affordable drug benefit.

And if that is not enough, analysts expect the private plans to cherry-pick the healthiest seniors, leaving the fee-for-service Medicare program with those who have the greatest medical needs, and thus pricing traditional Medicare higher and higher. An analysis by the Chief Actuary of the Health Care Financing Administration of a similar premium support system proposed by Congressman Thomas during the Medicare Commission found that premiums for those who remained in the traditional Medicare program would increase by 47 percent. While economists may believe that the reimbursement rates could be altered by "risk-adjustment," as was required in the 1997 law, the Government has never been able to im-

plement the requirement, and in fact private insurance plans have

fought such a system vigorously.

The end result will be that Medicare as we know it will "wither on the vine." The main argument for this risky plan is that it would save money and help the solvency of Medicare. We now know, however, that there are no significant cost savings from this radical experiment. According to CBO, this whole program is expected to save at best \$1.6 billion over the next ten years, or less than one-half of one-tenth of one percent of Medicare spending over the same period. In spite of proclamations that this new private system is "reform" and will "save Medicare," it does not even add one year to the solvency of the Medicare Trust Fund. In other words, this whole provision is an ideological experiment in which our Nation's seniors are the guinea pigs, with no real cost savings or improvement in Medicare's outlook.

The Republican antipathy toward traditional Medicare is not matched by how our Nation's seniors view the same program. In a poll released by the Kaiser Family Foundation/Harvard School of Public Health on the very day our Committee considered this privatization scheme, 77 percent of all citizens aged 65 and over had a favorable opinion of Medicare. Those seniors also preferred Medicare over private health plans by 63 percent to 19 percent. While our Republican colleagues at the markup used terms like "antiquated" to describe Medicare, the Nation's seniors continue to view Medicare favorably. While our Republican colleagues suggest that what our Nation's seniors want is a choice of private insurers, what our seniors really want is their choice of doctors, which is what Medicare offers.

So what is our alternative? It is a straightforward, simple, honest, and affordable new voluntary drug benefit in Medicare. We propose a new Part D in Medicare, just like outpatient benefits under Part B. To be specific, our alternative—all of which is defined in law—will provide a benefit as follows:

- \$25 monthly premium;
- \$100 deductible;
- 80 percent coverage by Medicare of all drug costs up to \$2,000;
- 100 percent coverage by Medicare of all drug costs over to \$2,000;
- No premiums or cost sharing for those whose incomes are under 150 percent of poverty; and,

• Sliding scale of assistance for those whose incomes are between 150 and 175 percent of poverty.

Our legislation granted the Secretary of Health and Human Services the power to negotiate better prices on behalf of Medicare's 40 million beneficiaries. And, as introduced (H.R. 1199), it closed loopholes in the "Hatch-Waxman" generic drug laws preventing drug companies from keeping less expensive alternatives from consumers. (This was not included in the Dingell Substitute as it was not germane to the Chairman's Amendment.)

We offer our alternative during the Committee markup, and it was defeated by a party line vote of 25–27. When denied the right to offer this alternative during the consideration of the Republican

prescription drug bill last year, we offered it as a motion to recommit, and it was narrowly defeated by a vote of 204–223.

Does our alternative cost more money than the Republican bill? Of course it does since, unlike the Republican bill, it provides a comprehensive, affordable benefit for seniors. A preliminary estimate by CBO last year suggested a cost of over \$900 billion compared to the cost of the Republican bill of \$400 billion over 10 years. Can we afford the more expensive version? Of course we can.

Our Republican colleagues have chosen to place their priorities on tax cuts that primarily benefit the very richest in our country. Ironically, on the same day that our Republican colleagues voted down our alternative, they went to the House Floor to pass a permanent extension of the abolition of the estate tax. After defeating a substitute that would have protected all estates below \$3 million for individuals and \$6 million for couples, they voted to abolish the estate tax for those above that income level—approximately 200,000 of the richest families in the country. By abolishing the estate taxes for the richest few, the Joint Committee on Taxation estimates that it will cost the Federal Government \$800 billion in the next decade.

The list of tax cuts appears endless. Earlier this year, House Republicans passed a \$750 billion tax bill, that was subsequently reduced with a sunset provision at the insistence of the Senate, to \$300 billion. Similarly, a Senate bill to provide a child tax credit to families below \$26,000 in income, and costing just \$3.5 billion (with additional paid-for child tax credit provisions raising the cost of about \$10 billion) was amended by House Republicans to provide tax cuts for a total of \$83 billion. The additional tax cuts passed just this year by House Republicans compared to their Senate colleagues would pay for the difference in the cost of our Democratic alternative. And this does not count the tax cuts of the last Congress that are likely to cost another \$2 trillion over the next ten years.

It is ironic that after depleting the U.S. Treasury of more than \$8 trillion through tax cuts for the wealthiest one percent of American (a \$5.6 trillion surplus converted to a \$3 to \$4 trillion deficit in little over two years), Republicans have the audacity to argue that we cannot afford a decent, dependable prescription medicine benefit under Medicare that will benefit the 100 million seniors and individuals with disabilities projected to soon join the program as the baby boomers are

as the baby boomers age.

We also must spend a few words on the recurring abusive processes in the House of Representatives which have sped this bill to the Floor. On Friday, June 13, 2003, during the late afternoon and one day after Members had left Washington for their Districts, Democrats for the first time received a draft of the Republican Medicare bill. On Tuesday, June 17, 2003, we received a revised version in the morning, and began the markup in the afternoon with opening statements only. We are told we would be permitted just two days to amend the bill in Committee. While the Chairman conducted a fair markup under the circumstances, permitting all amendments to be offered, the condensed time frame, which has become a regular feature in today's House of Representatives, did not allow for reasonable consideration of the bill. Despite our calls

several weeks ago to have public hearings on the bill, as well as a markup in the Health Subcommittee, we were forced to consider these changes without the benefit of public input. We, unfortunately, expect similar limitations in consideration on the House Floor. When our future colleagues and the public look back upon this bill and ask how the Committee could have reported such an assault on the Nation's seniors, they must look to these procedures as a partial answer.

The following is a more detailed analysis of this flawed legislation as well as our alternative:

TITLE I—PRESCRIPTION DRUGS

1. Risky, untested framework for prescription drug benefits

- No alternative but private insurance plans. The Republican plan, H.R. 2473, forces Medicare into private insurance plans in order to get prescription drugs. There is no option under the Republican bill for a senior to have Medicare provide coverage for their drugs like it provides coverage for doctor visits, hospital care, or other health services today. The bill vests private insurance companies with the power to determine what benefits get offered and for how much. This is dramatically different from Medicare today, where senior citizens and individuals with disabilities are guaranteed affordable health care.
- Flawed private-market model. The Republican plan relies on a model that is largely untested. The State of Nevada experimented with private drug-only insurance plans for low-income elderly and found that even with state subsidies, the \$85 premium was not affordable for seniors. Drugs commonly used by seniors were excluded from plan formularies. Multiple benefit offerings were confusing to beneficiaries. Relying on a private insurance system will increase the costs to the beneficiary and the Government due to the additional expenses related to product development, marketing, administration, and profit, not to mention the "bribe" or subsidy it will take to get them to participate. Developing a new private insurance product market will be difficult in sparsely populated rural areas, where the need is greatest, risk pools are smaller, and costs often higher. Rather than use Medicare beneficiaries as guinea pigs, we should build on the Medicare model that we know works.

2. Inadequate benefit

• Pay more and get less. For most seniors in the Republican plan, the more you spend, the less coverage you get; about half of all seniors will fall into the "coverage gap" where they must pay premiums but receive no benefits. The design of the Committee bill forces the elderly to pay a higher percentage of costs as their needs increase. Once the initial \$250 deductible is met, beneficiaries have to pay 20 percent of the cost until there has been \$2,000 in drug spending. But then the beneficiary has to pay 100 percent after \$2,000 in drug spending. Beneficiaries are forced to pay all of their drug costs for spending between \$2,000 and \$4,900, while continuing to pay premiums. (Note: The Republican \$3,500 out-of-pocket cap translates into \$4,900 in total drug spending.)

• Coverage Stops Mid-Year. nearly 50 percent of Medicare beneficiaries will get no drug coverage for part of the year under the Republican bill—and 60 percent of those never spend enough to get out of the gap. Beneficiaries with average spending (\$263/month) will run out of coverage in August. Beneficiaries with above average spending (\$5,000/year or \$416/month) will run out of coverage in May. This falls far short of what seniors get today in Medicare and short of what we get as Members of Congress under our health plan.

3. No guaranteed drug benefit—no predictable costs

• No guaranteed premium. Insurers determine what premium beneficiaries will pay. While Republicans claim that the premium will be \$35, which is 40 percent higher than the premium in the Democratic plan, there is nothing in the legislation to support that claim. In fact, there are no limits or guidelines regarding the setting of the premium. This is a dramatic change from Medicare today where Part B premiums are set in statute as a percentage of program costs. Under the Republican proposal, premiums will vary by plan and place.

• No standard benefit. The benefits outlined in the Republican bill are merely suggestions. Private plans can vary the deductible and co-insurance as well as the premium in both the "standard coverage" option and in the "alternative coverage" option. In fact, there is not even a requirement in the Republican legislation that any plan offer the "standard" benefit package. This is an invitation for plans to design benefits that "cherry pick" low-cost, healthy en-

rollees.

It is also a recipe for beneficiary confusion. This model represents a retreat from the Medigap reforms of the early 1990s that standardized benefits, thus ensuring that plans compete on price and quality and not prey on consumer confusion. Finally, there is nothing in the bill that would ensure beneficiaries can depend on the plans remaining in their area or providing the same benefits from year-to-year. This invites the annual chaos that Congress has witnessed with the Medicare+Choice program in recent years.

• Not a real entitlement. The prescription drug benefit outlined in the bill is not a true Medicare entitlement. Under Medicare today, beneficiaries are entitled to a set of benefits defined in law, regardless of where they live or what it costs to deliver the benefits. For example, beneficiaries in Milwaukee and Miami pay a \$100 deductible for Part B and 20 percent co-insurance for Part B services. Beneficiaries in Bakersfield and Boston are guaranteed the same coverage for hospital care and home health services.

Under the Republic plan, there is no such entitlement.

• Limits access to specific drugs and pharmacies. Under the bill, private drug-only plans can refuse to cover needed medications. The private plans decide what specific drugs are on their formulary and whether to provide any coverage for non-formulary drugs. Plans are allowed to change the formulary during the year with "adequate" notice. Because the Republican plan uses the Medicare+Choice enrollment procedures, beneficiaries will be locked into the private plan for the entire year—even if the plan drops a needed drug or local pharmacy.

• Encourages Erosion of Employer-Sponsored Coverage. The bill strictly limits the dollars that count toward the out-of-pocket cap by specifying that only costs which are paid by the individual and are not reimbursed by another person count toward the out-of-pocket limit. In other words, if a beneficiary receives any assistance—other than low-income assistance—with his or her drug costs, those costs do not count toward the \$3,500 limit. The definition of "true" out-of-pocket costs puts employers, unions, and others who provide retiree coverage in a bind. Employers would be forced to drop or cap coverage for retirees to supplement the Medicare drug benefit, because each dollar spent would not be counted toward catastrophic coverage. Retirees would lose a valuable benefit that many employers provide today. Seniors also could not purchase Medigap insurance to fill the gap, unless they were willing to forgo catastrophic drug coverage under the bill.

4. Inadequate investment for prescription drugs

• H.R. 2347 covers less than 20 percent of seniors' drug costs over the next ten years. This is the exact opposite of the coverage seniors receive in Medicare Part B today where Medicare covers 80 percent of the cost of services. An actuarial comparison by the Congressional Research Service between the Democratic and Republican proposals found that the Republican bill has an actuarial value of only \$1,900 and the Democratic bill has a value of \$2,800, closer to the value of the FEHBP drug benefit at \$2,700. Congress needs to act to make senior citizens a priority on the agenda. If seniors are a real priority, there is no excuse not to provide a comprehensive prescription drug benefit that meets the needs of seniors.

The Democratic alternative would have provided an affordable comprehensive benefit for seniors under Medicare. By rejecting the Dingell substitute, the Committee missed its opportunity to provide an affordable, comprehensive prescription drug benefit under Medicare. We urge the House to take a different position and pass a

more comprehensive alternative.

Our plan is an entitlement that will guarantee all beneficiaries the option to purchase affordable, dependable, comprehensive prescription drug coverage at a uniform price. The program will be administered and managed through pharmacy contractors, much like carriers and fiscal intermediaries do for the rest of Medicare today. Starting in 2006, under our plan, beneficiaries would pay a \$25 monthly premium, \$100 annual deductible and not more than 20 percent co-insurance until they spend \$2,000. After \$2,000, the government would pay 100 percent of the drug costs.

Low-income beneficiaries receive additional assistance under our proposal. Those with incomes up to 150 percent of poverty (\$13,470 for one person) will pay nothing. Those with incomes between 150–175 percent of poverty (\$13,470–\$15,715 for a single person) will not pay any cost-sharing but will pay premiums on a sliding scale. The Democratic substitute also substantially reduces the soaring

The Democratic substitute also substantially reduces the soaring costs that seniors currently pay for prescription drugs. Under our plan, the Secretary would leverage the collective bargaining power of 40 million beneficiaries to negotiate with manufacturers for lower drug prices. Secretary Thompson recently demonstrated the

effectiveness of similar bargaining power when he negotiated an 80 percent discount off the list price of the antibiotic Cipro during the anthrax scare in 2001. Pharmacy contractors would also negotiate additional savings. The savings from these negotiations are required to be directly passed on to beneficiaries through lower prices. Pharmacy contractors will be held accountable for achieving promised discounts for beneficiaries.

The Democratic substitute guarantees senior citizens and those with disabilities the choices that matter—choice of drugs and choice of pharmacy. Under our plan, Medicare would pay toward the cost of every prescription drug. The Democratic substitute also assures access to pharmacies by prohibiting pharmacy contractors from refusing to contract with a pharmacy that agreed to meet its

standards. These are the choices people want and need.

Most importantly, unlike the Republican plan, our plan will never force seniors into an HMO or similar private plan in order to get a prescription drug benefit. It preserves seniors ability to remain in traditional Medicare for all of their health care needs, including prescription drugs benefits.

TITLE II—PRIVATIZATION OF MEDICARE

The Republican bill begins a risky ideological privatization program that would end Medicare as we know it. The centerpiece of the House Republican Rx bill is its privatization of Medicare through private insurance plans that are supposed to provide benefits to seniors through a model called "premium support." Premium support breaks the fundamental promise of Medicare. Medicare will no longer be a shared responsibility with seniors. Instead, the government will only pay a fixed amount and the senior will have to pay the rest. The message to seniors is that even though they worked hard all their lives and paid into Medicare, they will no longer be guaranteed quality health care. Instead, they'll get a fixed payment—a Medicare voucher—and have to fend for themselves in a market where they may not be able to find a plan that meets their needs at a price they can afford.

Under premium support, the Federal Government pays only a share of the premium costs of plans that participate in Medicare. There is no guarantee that this fixed share will be adequate to meet seniors' needs. Because the Federal share of premiums is calculated regionally, not nationally, for the first time in the history of Medicare, seniors will pay different premiums for the exact same fee-for-service benefit. In some instances the fee-for-service premiums could vary locally as well. Seniors in one area might have to pay more to enroll in fee-for-service than seniors in another area. We are all familiar with the problems created by the geographic inequalities in Medicare+Choice payment rates. Just imagine what would happen if we were dealing with different payments for individual seniors instead of different payments for HMOs.

Seniors will have no way of knowing from year to year what kind of coverage this set premium will buy. The benefits they received will depend on which plans decide to participate each year, the type of benefits these plans decide to offer, and how much these plans decide to charge for their premiums. The consequences of premium support are profound. If HMOs, PPOs, or other private

plans artificially depress prices by reducing services, then their average premiums drop—not because of greater efficiencies, but because seniors are denied coverage for the health care they need.

If only the healthiest seniors join HMOs, leaving the sickest beneficiaries in Medicare, then the premiums of HMOs will drop. Right now, Medicare premium are 25 percent of Medicare costs. They do not go up or down based on what HMOs or PPOs charge in a given market. Under premium support, when HMO premiums drop, the Federal share of the premiums paid by seniors in Medicare will drop too—leaving older and sicker seniors to cover an increasing share of their Medicare premiums costs. As a result, the Federal share of all premium—including fee-for-service—will drop dramatically. In 1999, the Chief Actuary for the HCFA found fee-for-service premiums would increase 47 percent under the Medicare Commission's premium support model. Quality coverage will be priced out of the reach of those who need it most—while HMOs receive ever-larger subsidies for providing health care coverage to the healthy.

In an extensive analysis of the impact of premium support on Medicare, Marilyn Moon of the Urban Institute found that moving to a premium support model would increase the Medicare out-of-pocket costs by 2025 for a typical senior who remains in fee-for-service by \$1,657 a year in inflation-adjusted terms. Under a premium support model, this same senior in 2025 would pay 39.4 percent of his or her income for Medicare—as compared to 28.6 percent if we retain the current structure.

Premium support also encourages cherry-picking by private plans. If plans receive a fixed Federal allotment for premium support—regardless of the level of care provided—then HMOs have every incentive to use marketing tricks to try to enroll only the healthiest seniors, who use the lowest amount of health care services. Studies by the GAO confirm that managed care plans in Medicare tend to attract healthier seniors, leaving Medicare to provide care for those who need it most.

Starving the free-for-service program not only harms beneficiaries—it hurts the institutions that serve those patients. HMOs are under no obligation to serve their communities through graduate medical education funding or support for sole providers in rural communities. When we cut the fee-for-service program, we deprive many of our Nation's health care providers of the funds they need to survive.

HMOs reap the rewards of premium support—while seniors who remain in Medicare are left with its aftermath. The premiums that Medicare must charge to maintain a proper level of service for the seniors who remain in fee-for-service will necessarily increase. But the Federal share of that contribution will not keep pace, because it is tied only to a fixed payment of the average premium for all plans.

As a result, seniors who remain in Medicare will see their share of their premium payments rise ever more sharply compared to those in private plans. Seniors and people with disabilities may no longer be able to stay in traditional Medicare because it would become too expensive. Their "choice" of plan would be limited to the lowest-cost HMO or PPO in their community. Sicker seniors in

these areas would have to pay more to preserve their "choice" of

doctors and hospitals.

The result will be an ever-dwindling number of seniors in fee-forservice Medicare. According to an analysis done for the Kaiser Family Foundation, a premium support model would result in the percentage of seniors enrolled in fee-for-service Medicare dropping

from 84 percent to just 47 percent over ten years.

Moreover, forcing seniors into private insurance plans will ultimately force them into the poor house. Social Security checks do not increase enough each year to meet the profit demands of private insurance companies. Millions of seniors solely on their Social Security checks, and receive very modest increases from year-to-year. In 2003, senior's Social Security checks increased only 1.4 percent.

Private plans, on the other hands, have no limits on what they can charge. Premium increases for private health insurance—even the Federal Employees Plans—have been skyrocketing, increasing

at rates much higher than with Social Security.

Once privatization is complete, it will not take long before seniors are unable to afford their Medicare private plan premiums. Cumulatively, from 1999 to 2003 seniors saw a 15.9 percent increase in Social Security benefits; and had they been enrolled in FEHBP for example, they would have seen a 69 percent increase in premium costs, not to mention a reduction in benefits.

The only "choice" seniors will have under the Republican privatization scheme is whether or not they can continue to afford Medicare at all. The House Republican privatization scheme is a bad

deal for America's seniors.

Democrats offered an amendment to strike the privatization provisions and an amendment to protect seniors and individuals with disabilities from premium increases in fee-for-service. Both were defeated on partisan votes. We also offered an amendment to protect seniors in private insurance plans from facing higher costsharing than that charged in fee-for-service and an amendment to ensure beneficiaries in traditional Medicare had access to catastrophic coverage like those in private plans, which were likewise defeated.

OTHER PROVISIONS OF H.R. 2473

Title VIII of H.R. 2473 creates a separate "Medicare Benefits Administration" to oversee the Medicare Advantage program, the Enhanced Fee For Service program, and the new Part D prescription drug benefit. This entirely duplicative entity would administer the pieces of the Medicare program that are run by private, risk-bearing insurance companies, managed care plans, and PPOs. The only conceivable purpose of creating such an Administrator would be to prepare for phase-out of the traditional Medicare fee-for-service program, administered by the Center for Medicare and Medicaid Services, and a transfer of the Medicare program to the private sector.

While the Medicare program has always relied on private sector providers, there is a difference between the current structure and the one envisioned under the Committee bill. Since Medicare was enacted, private sector entities have delivered benefits to seniors and processed the program's claims. The Medicare program itself, however, has always assumed the ultimate responsibility—and the ultimate financial risk-of caring for our Nation's seniors and people with disabilities. The private sector entities overseen by the Medicare Benefits Administration will not only deliver and manage the program's benefits and process the program's claims, but will assume financial risk as well—meaning their profits are on the line if seniors cost more than they expect, giving strong incentives to reduce care and deny access to needed medicines or increase costs to beneficiaries.

The Medicare program was originally created because the private sector did not offer affordable and reliable health insurance to the elderly and those with disabilities. We see little evidence that the elderly and those with disabilities have become more attractive populations to insure, and we have serious doubts about the wis-

dom of the approach established in H.R. 2473.

We would be remiss if we did not comment on the other provisions in the legislation affecting provider payments. The legislation provides some assistance with physician reimbursement rates; however, the fix in the bill appears to be crafted for budgetary rather than policy reasons. Democrats offered an amendment in Committee that would have further increased physician payments according to MedPACs recommendation for the next two years. This amendment was defeated.

While not in this Committee's purview, we do not support the cuts to hospital payments included in the legislation either and believe the assistance for rural providers is paltry, falling short of what was provided under the legislation passed out of the Senate Finance Committee. A Democratic amendment to improve the por-

tions of the rural package in this Committee's jurisdiction, including physician and home health payments, was defeated.

We maintain our belief that, like those in last year's bill, the provisions pertaining to Medicaid disproportionate share hospital payments are also inadequate. In the Balanced Budget Act of 1997, Congress established limits on payments to the states for Disproportionate Share Hospitals (DSH). In the case of many states, there was a precipitous decline in dollars available over the five-year period. Institutions that are critical to providing services to low-income Medicaid beneficiaries and uninsured persons have already absorbed reductions in funding. Public hospitals, children's hospitals, and private hospitals serving large numbers of Medicaid and uninsured people cannot weather additional reductions that are slated to take effect.

Three years ago, this Committee recognized that this decline in available dollars had to be stopped. We passed legislation that stopped the decline at the level established for FY 2000, and applied inflationary factors for the next two fiscal years and beyond. Unfortunately, the final legislation ended up with only a two-year fix, and an intention to resolve the problem before the original precipitous decline otherwise scheduled for FY 2003 could occur. Members on both sides of the aisle in this Committee have worked to rectify this problem, thus it was particularly disappointing to see the failure to fully restore DSH funding in the amendment approved by the Committee. We believe that a true solution to the

DSH funding crisis should fully address the cuts and restore funding. We also believe we should address the issue of "low-DSH" states to enable them to provide adequate funding to their facilities that serve as a critical safety net for poor and uninsured individuals.

In sum, the Committee's product provided an inadequate, privatized drug benefit, provided for unfair and ultimately damaging private plan competition with traditional fee-for-service Medicare, and missed opportunities to address provider needs. This is the result of ideological experimentation, coupled with a secretive and irresponsible process. We oppose it.

JOHN D. DINGELL. SHERROD BROWN. RICK BOUCHER. Lois Capps. MIKE DOYLE. Frank Pallone, Jr. ALBERT R. WYNN. ANNA G. ESHOO. HILDA L. SOLIS. HENRY A. WAXMAN. KAREN McCarthy. TED STRICKLAND. ELIOT L. ENGEL. ED MARKEY. GENE GREEN. PETER DEUTSCH. BART STUPAK. TOM ALLEN. EDOLPHUS TOWNS. JAN SCHAKOWSKY. Bobby L. Rush. BART GORDON. DIANA DEGETTE.

ADDITIONAL VIEWS

We have been working for several months on an alternative method of delivering a prescription drug program to Medicare beneficiaries. We have been guided by the following principles:

First. The benefit from the government should extend assistance to those who need help purchasing prescription drugs. The majority of Medicare beneficiaries have some type of prescription drug coverage through Medigap insurance, Medicaid, employer provided retiree health benefits, veterans benefits, or other coverage. Approximately 27% of beneficiaries have no coverage to help with the purchase of prescription drugs. These beneficiaries are also more likely to be between 100% and 175% of the federal poverty level. A Medicare prescription drug benefit should not displace existing coverage and should be focused on that percentage that has no coverage whatsoever.

Second. The government should encourage employers and families and others to help seniors with the purchase of expensive prescription drugs. The Congressional Budget Office has estimated that seniors will spend \$1.8 Trillion in the next decade for prescription drugs. The House Budget Resolution assumes \$400 Billion for the provision of a drug benefit under Medicare. In order to fill this gap, families, employers and others should be encouraged to step forward.

Third. The government's assistance to beneficiaries should be a defined contribution. Good fiscal management of the federal treasury requires that this benefit be manageable and known. Medicare faces dire circumstances in the future if Congress does not address its structure as the Baby Boomers approach retirement. It currently consumes 12% of the federal budget. That is expected to grow as the Baby Boomers age into the Medicare program. Medicare is expected to be 30% to 35% of the federal budget in 2030 without any additional benefits. Congress must face this reality as it seeks to add a prescription drug benefit.

Fourth. All beneficiaries should have some access to a prescription drug benefit under Medicare. It should be universal. While that does not mean it should be identical for all beneficiaries, it should be available through the Medicare program to all beneficiaries.

Fifth. It should serve as a bridge to bring Medicare into the 21st Century. The benefit structure under Medicare has not changed in nearly 40 years. It does not match the type of delivery mechanisms in the private sector that have been modernized and keep current with new technologies. Medicare needs to improve how it delivers health care benefits to seniors.

Working from these principles, we have fashioned a delivery of a prescription drug benefit. The benefit would be focused on a drug discount, or value, card. This drug value card has been proposed by President Bush. The drug value card would be available to all seniors. Any qualified entity by the Centers for Medicare and Medicaid Services (CMS) could offer a prescription drug value card to Medicare beneficiaries: pharmacy benefit managers, employers, pharmacists associations, insurers, and non-profit entities, such as AARP. Card issuers would negotiate with pharmaceutical manufacturers for discounts on drugs utilizing mechanisms that are common in the private sector. It is anticipated that these negotiations would result in savings from 15% to 35% on prescription drug costs for beneficiaries. Cards must be issued on at least a Statewide basis, to insure access for beneficiaries living in rural areas. Employers could limit their discount cards to their retiree populations. Seniors would pay an annual \$30 fee for the card and would be able to choose a card during an annual open season. We believe there would be competition among card issuers to provide services to beneficiaries that would result in attractive offers being made to

Recognizing that some beneficiaries will still need help in paying drug bills, the government would add funds to the drug cards through a prescription drug account for seniors related to the income level of the senior. Under our proposal, beneficiaries under 100% of the Federal poverty level (FPL) would have the government pay their costs, either by the Federal government or through Medicaid. Even low-income seniors would be required to contribute very modest co-pays for prescriptions to ensure that everyone has a personal stake in their health care. For seniors from 100% to 125% of the FPL, the federal government would provide \$1500 in annual assistance; from 126% to 175% of FPL, \$1100; from 176% to 250%, \$600; from 251% to 350%, \$300; and 351% and above \$100.

Non-government contributions could be added to the accounts. The beneficiary, family members, and employers could add resources to the account and take an above the line tax deduction. We have proposed that beneficiaries and family members combined be able to contribute up to \$5,000 and that employers be able to contribute an additional \$5,000 per beneficiary. Non-profits and State pharmaceutical assistance programs could also contribute to a beneficiary's drug spending account. All funding in the account rolls over from year to year. This is very family-friendly.

These accounts could be used for prescription drug purchases. The funds could also be utilized to pay premiums to an enhanced Medicare health insurance product, should the beneficiary decide to move into that delivery system. The funds would also rollover to a

spouse upon the death of a beneficiary.

We would also create a catastrophic insurance program for prescription drugs offered by the private sector. It would provide \$10,000 stop loss coverage to seniors. Seniors who choose a drug value card would be required to enroll in the catastophic insurance coverage. The federal government would provide subsidies to low income individuals to assist with the premiums. The government would share the costs with others.

We think this approach accesses the best management techniques available in the private sector which provides excellent drug coverage. This also provides assistance to those beneficiaries who

need it the most, low and moderate income seniors with no drug coverage currently. It also protects all seniors who choose this option from very expensive drug costs should they become gravely ill.

This is a private sector option but with some government help. Since the contributions by the government are known, a defined contribution model, this makes government outlays predictable and manageable. It does not expose the government to unlimited and unknown risk of a benefit program.

This option, to us, works best for the beneficiary and best for the government. We are disappointed that the Committee did not consider this approach as the base bill.

Nonetheless, we are very pleased that the Committee adopted on a voice vote, an amendment offered by Congressman Burr that encompasses some of our ideas. Under the Burr amendment, a prescription drug benefit will be offered in years 2004 and 2005 using a drug value card. This is two years earlier than a benefit will be delivered in the base bill. We think having drug value cards available soon to seniors will be of enormous benefit in helping seniors manage prescription drug costs. The government will also provide some limited assistance to seniors related to their income to help in buying drugs. The federal contributions would be placed in individual drug accounts. In addition, these cards will continue to be available at the discretion of the Secretary beyond 2005 in those areas where 2 plans are not available. This has become the "fallback" provision of the Committee bill. This ensures that seniors still have access to a prescription drug benefit under Medicare if their area of the country does not yet have competitive drug insurance products.

While we believe there is a better way to provide prescription drug coverage to seniors, we supported the Committee bill on the motion to report and look forward to working with our colleagues to continue to make improvements to Medicare for this nation's 40

million beneficiaries.

RICHARD BURR. JOE BARTON. CHARLIE NORWOOD. JOHN SHADEGG. STEVE BUYER.

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