

SPECIAL NEEDS TRUST FAIRNESS AND MEDICAID
IMPROVEMENT ACT

SEPTEMBER 9, 2016.—Committed to the Committee of the Whole House on the State
of the Union and ordered to be printed

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

R E P O R T

[To accompany H.R. 670]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 670) to amend title XIX of the Social Security Act to extend the Medicaid rules regarding supplemental needs trusts for Medicaid beneficiaries to trusts established by those beneficiaries, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

C O N T E N T S

	Page
Purpose and Summary	3
Background and Need for Legislation	3
Hearings	4
Committee Consideration	4
Committee Votes	4
Committee Oversight Findings	4
Statement of General Performance Goals and Objectives	4
New Budget Authority, Entitlement Authority, and Tax Expenditures	4
Earmark, Limited Tax Benefits, and Limited Tariff Benefits	5
Committee Cost Estimate	5
Congressional Budget Office Estimate	5
Federal Mandates Statement	5
Duplication of Federal Programs	5
Disclosure of Directed Rule Makings	5
Advisory Committee Statement	5
Applicability to Legislative Branch	5
Section-by-Section Analysis of the Legislation	6
Changes in Existing Law Made by the Bill, as Reported	6

The amendment is as follows:
Strike all after the enacting clause and insert the following:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) **SHORT TITLE.**—This Act may be cited as the “Special Needs Trust Fairness and Medicaid Improvement Act”.

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

- Sec. 1. Short title; table of contents.
- Sec. 2. Fairness in Medicaid supplemental needs trusts.
- Sec. 3. Medicaid coverage of tobacco cessation services for mothers of newborns.
- Sec. 4. Eliminating Federal financial participation with respect to expenditures under Medicaid for agents used for cosmetic purposes or hair growth.
- Sec. 5. Medicaid Improvement Fund.

SEC. 2. FAIRNESS IN MEDICAID SUPPLEMENTAL NEEDS TRUSTS.

(a) **IN GENERAL.**—Section 1917(d)(4)(A) of the Social Security Act (42 U.S.C. 1396p(d)(4)(A)) is amended by inserting “the individual,” after “for the benefit of such individual by”.

(b) **EFFECTIVE DATE.**—The amendment made by subsection (a) shall apply to trusts established on or after the date of the enactment of this Act.

SEC. 3. MEDICAID COVERAGE OF TOBACCO CESSATION SERVICES FOR MOTHERS OF NEWBORNS.

(a) **IN GENERAL.**—Section 1905(bb) of the Social Security Act (42 U.S.C. 1396d(bb)) is amended by adding at the end the following new paragraph:

“(4) A woman shall continue to be treated as described in this subsection as a pregnant woman through the end of the 1-year period beginning on the date of the birth of a child of the woman.”.

(b) **CONFORMING AMENDMENTS.**—

(1) Subsections (a)(2)(B) and (b)(2)(B) of section 1916 of the Social Security Act (42 U.S.C. 1396o) are each amended by inserting “(and women described in section 1905(bb) as pregnant women pursuant to paragraph (4) of such section)” after “tobacco cessation by pregnant women”.

(2) Section 1927(d)(2)(F) of the Social Security Act (42 U.S.C. 1396r–8(d)(2)(F)) is amended by inserting “(and women described in section 1905(bb) as pregnant women pursuant to paragraph (4) of such section)” after “pregnant women”.

(c) **EFFECTIVE DATE.**—

(1) **IN GENERAL.**—Subject to paragraph (2), the amendments made by this section shall apply with respect to items and services furnished on or after the date that is two years after the date of the enactment of this Act.

(2) **EXCEPTION FOR STATE LEGISLATION.**—In the case of a State plan under title XIX of the Social Security Act, which the Secretary of Health and Human Services determines requires State legislation in order for the plan to meet any requirement imposed by amendments made by this section, the plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet such an additional requirement before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the effective date specified in paragraph (1). For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of the session shall be considered to be a separate regular session of the State legislature.

(d) **REPORT.**—Not later than two years after the date of the enactment of this Act, the Inspector General of the Department of Health and Human Services shall submit to Congress a report that assesses the use of the tobacco cessation service benefit under the Medicaid program. Such report shall include an assessment of—

- (1) the extent that States are encouraging the use of such benefit, such as through promotion of beneficiary and provider awareness of such benefit; and
- (2) gaps in the delivery of such benefit.

SEC. 4. ELIMINATING FEDERAL FINANCIAL PARTICIPATION WITH RESPECT TO EXPENDITURES UNDER MEDICAID FOR AGENTS USED FOR COSMETIC PURPOSES OR HAIR GROWTH.

(a) **IN GENERAL.**—Section 1903(i)(21) of the Social Security Act (42 U.S.C. 1396b(i)(21)) is amended by inserting “section 1927(d)(2)(C) (relating to drugs when used for cosmetic purposes or hair growth), except where medically necessary, and” after “drugs described in”.

(b) **EFFECTIVE DATE.**—The amendment made by subsection (a) shall apply with respect to calendar quarters beginning on or after the date of the enactment of this Act.

SEC. 5. MEDICAID IMPROVEMENT FUND.

Section 1941(b) of the Social Security Act (42 U.S.C. 1396w–1(b)) is amended—

- (1) in paragraph (2)—

- (A) by striking “under paragraph (1)” and inserting “under this subsection”; and
- (B) by redesignating such paragraph as paragraph (3); and
- (2) by inserting after paragraph (1) the following new paragraph:
“(2) ADDITIONAL FUNDING.—In addition to any funds otherwise made available to the Fund, there shall be available to the Fund, for expenditures from the Fund—
“(A) for fiscal year 2021, \$10,000,000, to remain available until expended; and
“(B) for fiscal year 2022, \$14,000,000, to remain available until expended.”.

PURPOSE AND SUMMARY

H.R. 670, the Special Needs Trust Fairness and Medicaid Improvement Act, would extend the Medicaid special needs trust exception to allow non-elderly individuals with disabilities to establish a special needs trust on their own behalf. If enacted, special needs trusts established by a non-elderly, disabled individual would no longer be considered an asset in determining that individual’s eligibility for Medicaid. In addition, the bill would extend Medicaid coverage of tobacco cessation services to mothers of newborns for the first year of the infant’s life. To offset the cost of these policies, the bill would prohibit Federal financial participation under Medicaid for drugs used for cosmetic purposes or hair growth, except where medically necessary. The bill would also make available \$10 million in 2021, and an additional \$14 million in 2022, in the Medicaid Improvement Fund.

BACKGROUND AND NEED FOR LEGISLATION

Under Federal law, most trusts are counted as an asset in determining Medicaid eligibility for aged and disabled individuals and are subject to asset transfer rules. However, certain types of trusts are exempt and not counted as an asset for Medicaid eligibility determination. Specifically, Medicaid does not count certain special-needs trusts and pooled trusts as assets. Asset transfer rules do not apply to these trust types. This exception is commonly referred to as the “special needs trust exception.”

In order for a trust to qualify under the special needs trust exception, a trust must contain the assets of an individual under age 65 (i.e., non-elderly individual) who meets the statutory definition of disability. Such trusts must be used to provide funding for certain expenditures that supplement Medicaid benefits, subject to certain limitations. Special needs trusts allow non-elderly individuals with disabilities to maintain their eligibility for Medicaid. When the beneficiary dies, the State receives the remaining proceeds of the trust equal to any amounts paid for medical assistance provided under the State Medicaid program. Under current law, only parents, grandparents, legal guardians, or a court can establish a special needs trust on behalf of a non-elderly disabled individual. H.R. 670 would allow non-elderly individuals with disabilities to set up special needs trust for themselves without requiring them to get a court order.

The Centers for Medicare and Medicaid Services (CMS) has said that “cigarette smoking is one of the greatest drivers of adverse health outcomes and costs for state Medicaid programs.” By investing in comprehensive tobacco cessation programs, CMS notes that

States have reduced smoking rates and health care costs and have improved health outcomes. CMS's review of available literature has led the agency to conclude that "tobacco treatment is one of the most cost-effective preventive services with as much as a \$2–\$3 return on every dollar invested."

Under current law, State Medicaid programs are required to cover tobacco cessation services for pregnant women. H.R. 670 would extend tobacco cessation benefits to the mothers of newborns, helping more women make healthy choices to improve their health and the health of their child. The bill would also require the Department of Health and Human Service's Office of Inspector General to report on the use of tobacco cessation services under Medicaid.

Finally, to offset the costs of these policies, H.R. 670 would prohibit Federal financial participation for drugs used for cosmetic purposes or hair growth, except where medically necessary, with savings placed in the Medicaid Improvement Fund.

HEARINGS

The Subcommittee on Health held a hearing on H.R. 670 on September 18, 2015. The Subcommittee received testimony from:

- Michael Boyle, M.D., Vice President of Therapeutics Development, The Cystic Fibrosis Foundation;
- Tim Clontz, Senior Vice President for Health Services, Cone Health; and
- Rick Courtney, President, Special Needs Alliance.

COMMITTEE CONSIDERATION

On July 12, 13, and 14, 2016, the full Committee on Energy and Commerce met in open markup session and ordered H.R. 670, as amended, favorably reported to the House by a voice vote.

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. There were no record votes taken in connection with ordering H.R. 670 reported.

COMMITTEE OVERSIGHT FINDINGS

Pursuant to clause 3(c)(1) of rule XIII of the Rules of the House of Representatives, the Committee held a hearing and made findings that are reflected in this report.

STATEMENT OF GENERAL PERFORMANCE GOALS AND OBJECTIVES

The objective of H.R. 670 is to allow non-elderly individuals with disabilities to create a special needs trust on their own behalf and to provide for tobacco cessation benefits for mothers of newborns during the first year of the baby's life.

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. 670

would result in no new or increased budget authority, entitlement authority, or tax expenditures or revenues.

EARMARK, LIMITED TAX BENEFITS, AND LIMITED TARIFF BENEFITS

In compliance with clause 9(e), 9(f), and 9(g) of rule XXI of the Rules of the House of Representatives, the Committee finds that H.R. 670 contains no earmarks, limited tax benefits, or limited tariff benefits.

COMMITTEE COST ESTIMATE

The Committee adopts as its own the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974. At the time this report was filed, the estimate was not available.

CONGRESSIONAL BUDGET OFFICE ESTIMATE

At the time this report was filed, the cost estimate prepared by the Director of the Congressional Budget Office pursuant to section 402 of the Congressional Budget Act of 1974 was not available.

FEDERAL MANDATES STATEMENT

The Committee adopts as its own the estimate of Federal mandates prepared by the Director of the Congressional Budget Office pursuant to section 423 of the Unfunded Mandates Reform Act.

DUPLICATION OF FEDERAL PROGRAMS

No provision of H.R. 670 establishes or reauthorizes a program of the Federal Government known to be duplicative of another Federal program, a program that was included in any report from the Government Accountability Office to Congress pursuant to section 21 of Public Law 111-139, or a program related to a program identified in the most recent Catalog of Federal Domestic Assistance.

DISCLOSURE OF DIRECTED RULE MAKINGS

The Committee estimates that enacting H.R. 670 specifically directs to be completed no rule making within the meaning of 5 U.S.C. 551.

ADVISORY COMMITTEE STATEMENT

No advisory committees within the meaning of section 5(b) of the Federal Advisory Committee Act were created by this legislation.

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

Section 1. Short title; table of contents

This section provides the short title of the “Special Needs Trust Fairness and Medicaid Improvement Act” and a table of contents.

Section 2. Fairness in medicaid supplemental needs trusts

This section would, effective upon enactment, extend the special needs trust exception for non-elderly individuals with disabilities to trusts established by such individuals on their own behalf.

Section 3. Medicaid coverage of tobacco cessation services for mothers of newborns

This section would, effective two years after enactment, require States to provide Medicaid coverage of tobacco cessation services to beneficiaries who are mothers of newborns for the first year of the infant’s life. The section would also require the Inspector General of the Department of Health and Human Services to issue a report, not later than two years after enactment, that assesses the use of the existing tobacco cessation benefit for pregnant women under Medicaid.

Section 4. Eliminating federal matching for medicaid expenditures on drugs used for cosmetic purposes or hair growth

This section would prohibit Federal financial participation for drugs used for cosmetic purposes or hair growth, except where medically necessary. This policy takes effect for calendar quarters beginning on or after the date of enactment.

Section 5. Medicaid improvement fund

This section would make available, until expended, \$10 million in 2021, and an additional \$14 million in 2022, in the Medicaid Improvement Fund.

CHANGES IN EXISTING LAW MADE BY THE BILL, AS REPORTED

In compliance with clause 3(e) of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as reported, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, and existing law in which no change is proposed is shown in roman):

SOCIAL SECURITY ACT

* * * * *

TITLE XIX—GRANTS TO STATES FOR MEDICAL ASSISTANCE PROGRAMS

* * * * *

PAYMENT TO STATES

SEC. 1903. (a) From the sums appropriated therefor, the Secretary (except as otherwise provided in this section) shall pay to

each State which has a plan approved under this title, for each quarter, beginning with the quarter commencing January 1, 1966—

(1) an amount equal to the Federal medical assistance percentage (as defined in section 1905(b), subject to subsections (g) and (j) of this section and subsection 1923(f)) of the total amount expended during such quarter as medical assistance under the State plan; plus

(2)(A) an amount equal to 75 per centum of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to compensation or training of skilled professional medical personnel, and staff directly supporting such personnel, of the State agency or any other public agency; plus

(B) notwithstanding paragraph (1) or subparagraph (A), with respect to amounts expended for nursing aide training and competency evaluation programs, and competency evaluation programs, described in section 1919(e)(1) (including the costs for nurse aides to complete such competency evaluation programs), regardless of whether the programs are provided in or outside nursing facilities or of the skill of the personnel involved in such programs, an amount equal to 50 percent (or, for calendar quarters beginning on or after July 1, 1988, and before October 1, 1990, the lesser of 90 percent or the Federal medical assistance percentage plus 25 percentage points) of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to such programs; plus

(C) an amount equal to 75 percent of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to preadmission screening and resident review activities conducted by the State under section 1919(e)(7); plus

(D) for each calendar quarter during—

- (i) fiscal year 1991, an amount equal to 90 percent,
- (ii) fiscal year 1992, an amount equal to 85 percent,
- (iii) fiscal year 1993, an amount equal to 80 percent, and
- (iv) fiscal year 1994 and thereafter, an amount equal to 75 percent,

of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to State activities under section 1919(g); plus

(E) an amount equal to 75 percent of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to translation or interpretation services in connection with the enrollment of, retention of, and use of services under this title by, children of families for whom English is not the primary language; plus

(3) an amount equal to—

- (A)(i) 90 per centum of so much of the sums expended during such quarter as are attributable to the design, de-

velopment, or installation of such mechanized claims processing and information retrieval systems as the Secretary determines are likely to provide more efficient, economical, and effective administration of the plan and to be compatible with the claims processing and information retrieval systems utilized in the administration of title XVIII, including the State's share of the cost of installing such a system to be used jointly in the administration of such State's plan and the plan of any other State approved under this title,

(ii) 90 per centum of so much of the sums expended during any such quarter in the fiscal year ending June 30, 1972, or the fiscal year ending June 30, 1973, as are attributable to the design, development, or installation of cost determination systems for State-owned general hospitals (except that the total amount paid to all States under this clause for either such fiscal year shall not exceed \$150,000), and

(iii) an amount equal to the Federal medical assistance percentage (as defined in section 1905(b)) of so much of the sums expended during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to such developments or modifications of systems of the type described in clause (i) as are necessary for the efficient collection and reporting on child health measures; and

(B) 75 per centum of so much of the sums expended during such quarter as are attributable to the operation of systems (whether such systems are operated directly by the State or by another person under a contract with the State) of the type described in subparagraph (A)(i) (whether or not designed, developed, or installed with assistance under such subparagraph) which are approved by the Secretary and which include provision for prompt written notice to each individual who is furnished services covered by the plan, or to each individual in a sample group of individuals who are furnished such services, of the specific services (other than confidential services) so covered, the name of the person or persons furnishing the services, the date or dates on which the services were furnished, and the amount of the payment or payments made under the plan on account of the services; and

(C)(i) 75 per centum of the sums expended with respect to costs incurred during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to the performance of medical and utilization review by a utilization and quality control peer review organization or by an entity which meets the requirements of section 1152, as determined by the Secretary, under a contract entered into under section 1902(d); and

(ii) 75 percent of the sums expended with respect to costs incurred during such quarter (as found necessary by the Secretary for the proper and efficient administration of the State plan) as are attributable to the performance of

independent external reviews conducted under section 1932(c)(2); and

(D) 75 percent of so much of the sums expended by the State plan during a quarter in 1991, 1992, or 1993, as the Secretary determines is attributable to the statewide adoption of a drug use review program which conforms to the requirements of section 1927(g);

(E) 50 percent of the sums expended with respect to costs incurred during such quarter as are attributable to providing—

(i) services to identify and educate individuals who are likely to be eligible for medical assistance under this title and who have Sickle Cell Disease or who are carriers of the sickle cell gene, including education regarding how to identify such individuals; or

(ii) education regarding the risks of stroke and other complications, as well as the prevention of stroke and other complications, in individuals who are likely to be eligible for medical assistance under this title and who have Sickle Cell Disease; and

(F)(i) 100 percent of so much of the sums expended during such quarter as are attributable to payments to Medicaid providers described in subsection (t)(1) to encourage the adoption and use of certified EHR technology; and

(ii) 90 percent of so much of the sums expended during such quarter as are attributable to payments for reasonable administrative expenses related to the administration of payments described in clause (i) if the State meets the condition described in subsection (t)(9); plus

(H)(i) 90 percent of the sums expended during the quarter as are attributable to the design, development, or installation of such mechanized verification and information retrieval systems as the Secretary determines are necessary to implement section 1902(ee) (including a system described in paragraph (2)(B) thereof), and

(ii) 75 percent of the sums expended during the quarter as are attributable to the operation of systems to which clause (i) applies, plus

(4) an amount equal to 100 percent of the sums expended during the quarter which are attributable to the costs of the implementation and operation of the immigration status verification system described in section 1137(d); plus

(5) an amount equal to 90 per centum of the sums expended during such quarter which are attributable to the offering, arranging, and furnishing (directly or on a contract basis) of family planning services and supplies;

(6) subject to subsection (b)(3), an amount equal to—

(A) 90 per centum of the sums expended during such a quarter within the twelve-quarter period beginning with the first quarter in which a payment is made to the State pursuant to this paragraph, and

(B) 75 per centum of the sums expended during each succeeding calendar quarter, with respect to costs incurred during such quarter (as found necessary by the Secretary for the elimination of fraud in the

provision and administration of medical assistance provided under the State plan) which are attributable to the establishment and operation of (including the training of personnel employed by) a State medicaid fraud control unit (described in subsection (q)); plus

(7) subject to section 1919(g)(3)(B), an amount equal to 50 per centum of the remainder of the amounts expended during such quarter as found necessary by the Secretary for the proper and efficient administration of the State plan.

(b)(1) Notwithstanding the preceding provisions of this section, the amount determined under subsection (a)(1) for any State for any quarter beginning after December 31, 1969, shall not take into account any amounts expended as medical assistance with respect to individuals aged 65 or over and disabled individuals entitled to hospital insurance benefits under title XVIII which would not have been so expended if the individuals involved had been enrolled in the insurance program established by part B of title XVIII, other than amounts expended under provisions of the plan of such State required by section 1902(a)(34).

(2) For limitation on Federal participation for capital expenditures which are out of conformity with a comprehensive plan of a State or areawide planning agency, see section 1122.

(3) The amount of funds which the Secretary is otherwise obligated to pay a State during a quarter under subsection (a)(6) may not exceed the higher of—

(A) \$125,000, or

(B) one-quarter of 1 per centum of the sums expended by the Federal, State, and local governments during the previous quarter in carrying out the State's plan under this title.

(4) Amounts expended by a State for the use of an enrollment broker in marketing medicaid managed care organizations and other managed care entities to eligible individuals under this title shall be considered, for purposes of subsection (a)(7), to be necessary for the proper and efficient administration of the State plan but only if the following conditions are met with respect to the broker:

(A) The broker is independent of any such entity and of any health care providers (whether or not any such provider participates in the State plan under this title) that provide coverage of services in the same State in which the broker is conducting enrollment activities.

(B) No person who is an owner, employee, consultant, or has a contract with the broker either has any direct or indirect financial interest with such an entity or health care provider or has been excluded from participation in the program under this title or title XVIII or debarred by any Federal agency, or subject to a civil money penalty under this Act.

(5) Notwithstanding the preceding provisions of this section, the amount determined under subsection (a)(1) for any State shall be decreased in a quarter by the amount of any health care related taxes (described in section 1902(w)(3)(A)) that are imposed on a hospital described in subsection (w)(3)(F) in that quarter.

(c) Nothing in this title shall be construed as prohibiting or restricting, or authorizing the Secretary to prohibit or restrict, payment under subsection (a) for medical assistance for covered serv-

ices furnished to a child with a disability because such services are included in the child's individualized education program established pursuant to part B of the Individuals with Disabilities Education Act or furnished to an infant or toddler with a disability because such services are included in the child's individualized family service plan adopted pursuant to part C of such Act.

(d)(1) Prior to the beginning of each quarter, the Secretary shall estimate the amount to which a State will be entitled under subsections (a) and (b) for such quarter, such estimates to be based on (A) a report filed by the State containing its estimate of the total sum to be expended in such quarter in accordance with the provisions of such subsections, and stating the amount appropriated or made available by the State and its political subdivisions for such expenditures in such quarter, and if such amount is less than the State's proportionate share of the total sum of such estimated expenditures, the source or sources from which the difference is expected to be derived, and (B) such other investigation as the Secretary may find necessary.

(2)(A) The Secretary shall then pay to the State, in such installments as he may determine, the amount so estimated, reduced or increased to the extent of any overpayment or underpayment which the Secretary determines was made under this section to such State for any prior quarter and with respect to which adjustment has not already been made under this subsection.

(B) Expenditures for which payments were made to the State under subsection (a) shall be treated as an overpayment to the extent that the State or local agency administering such plan has been reimbursed for such expenditures by a third party pursuant to the provisions of its plan in compliance with section 1902(a)(25).

(C) For purposes of this subsection, when an overpayment is discovered, which was made by a State to a person or other entity, the State shall have a period of 1 year in which to recover or attempt to recover such overpayment before adjustment is made in the Federal payment to such State on account of such overpayment. Except as otherwise provided in subparagraph (D), the adjustment in the Federal payment shall be made at the end of the 1-year period, whether or not recovery was made.

(D)(i) In any case where the State is unable to recover a debt which represents an overpayment (or any portion thereof) made to a person or other entity on account of such debt having been discharged in bankruptcy or otherwise being uncollectable, no adjustment shall be made in the Federal payment to such State on account of such overpayment (or portion thereof).

(ii) In any case where the State is unable to recover a debt which represents an overpayment (or any portion thereof) made to a person or other entity due to fraud within 1 year of discovery because there is not a final determination of the amount of the overpayment under an administrative or judicial process (as applicable), including as a result of a judgment being under appeal, no adjustment shall be made in the Federal payment to such State on account of such overpayment (or portion thereof) before the date that is 30 days after the date on which a final judgment (including, if applicable, a final determination on an appeal) is made.

(3)(A) The pro rata share to which the United States is equitably entitled, as determined by the Secretary, of the net amount recov-

ered during any quarter by the State or any political subdivision thereof with respect to medical assistance furnished under the State plan shall be considered an overpayment to be adjusted under this subsection.

(B)(i) Subparagraph (A) and paragraph (2)(B) shall not apply to any amount recovered or paid to a State as part of the comprehensive settlement of November 1998 between manufacturers of tobacco products, as defined in section 5702(d) of the Internal Revenue Code of 1986, and State Attorneys General, or as part of any individual State settlement or judgment reached in litigation initiated or pursued by a State against one or more such manufacturers.

(ii) Except as provided in subsection (i)(19), a State may use amounts recovered or paid to the State as part of a comprehensive or individual settlement, or a judgment, described in clause (i) for any expenditures determined appropriate by the State.

(4) Upon the making of any estimate by the Secretary under this subsection, any appropriations available for payments under this section shall be deemed obligated.

(5) In any case in which the Secretary estimates that there has been an overpayment under this section to a State on the basis of a claim by such State that has been disallowed by the Secretary under section 1116(d), and such State disputes such disallowance, the amount of the Federal payment in controversy shall, at the option of the State, be retained by such State or recovered by the Secretary pending a final determination with respect to such payment amount. If such final determination is to the effect that any amount was properly disallowed, and the State chose to retain payment of the amount in controversy, the Secretary shall offset, from any subsequent payments made to such State under this title, an amount equal to the proper amount of the disallowance plus interest on such amount disallowed for the period beginning on the date such amount was disallowed and ending on the date of such final determination at a rate (determined by the Secretary) based on the average of the bond equivalent of the weekly 90-day treasury bill auction rates during such period.

(6)(A) Each State (as defined in subsection (w)(7)(D)) shall include, in the first report submitted under paragraph (1) after the end of each fiscal year, information related to—

(i) provider-related donations made to the State or units of local government during such fiscal year, and

(ii) health care related taxes collected by the State or such units during such fiscal year.

(B) Each State shall include, in the first report submitted under paragraph (1) after the end of each fiscal year, information related to the total amount of payment adjustments made, and the amount of payment adjustments made to individual providers (by provider), under section 1923(c) during such fiscal year.

(e) A State plan approved under this title may include, as a cost with respect to hospital services under the plan under this title, periodic expenditures made to reflect transitional allowances established with respect to a hospital closure or conversion under section 1884.

(f)(1)(A) Except as provided in paragraph (4), payment under the preceding provisions of this section shall not be made with respect

to any amount expended as medical assistance in a calendar quarter, in any State, for any member of a family the annual income of which exceeds the applicable income limitation determined under this paragraph.

(B)(i) Except as provided in clause (ii) of this subparagraph, the applicable income limitation with respect to any family is the amount determined, in accordance with standards prescribed by the Secretary, to be equivalent to 133⅓ percent of the highest amount which would ordinarily be paid to a family of the same size without any income or resources, in the form of money payments, under the plan of the State approved under part A of title IV of this Act.

(ii) If the Secretary finds that the operation of a uniform maximum limits payments to families of more than one size, he may adjust the amount otherwise determined under clause (i) to take account of families of different sizes.

(C) The total amount of any applicable income limitation determined under subparagraph (B) shall, if it is not a multiple of \$100 or such other amount as the Secretary may prescribe, be rounded to the next higher multiple of \$100 or such other amount, as the case may be.

(2)(A) In computing a family's income for purposes of paragraph (1), there shall be excluded any costs (whether in the form of insurance premiums or otherwise and regardless of whether such costs are reimbursed under another public program of the State or political subdivision thereof) incurred by such family for medical care or for any other type of remedial care recognized under State law or, (B) notwithstanding section 1916 at State option, an amount paid by such family, at the family's option, to the State, provided that the amount, when combined with costs incurred in prior months, is sufficient when excluded from the family's income to reduce such family's income below the applicable income limitation described in paragraph (1). The amount of State expenditures for which medical assistance is available under subsection (a)(1) will be reduced by amounts paid to the State pursuant to this subparagraph.

(3) For purposes of paragraph (1)(B), in the case of a family consisting of only one individual, the "highest amount which would ordinarily be paid" to such family under the State's plan approved under part A of title IV of this Act shall be the amount determined by the State agency (on the basis of reasonable relationship to the amounts payable under such plan to families consisting of two or more persons) to be the amount of the aid which would ordinarily be payable under such plan to a family (without any income or resources) consisting of one person if such plan provided for aid to such a family.

(4) The limitations on payment imposed by the preceding provisions of this subsection shall not apply with respect to any amount expended by a State as medical assistance for any individual described in section 1902(a)(10)(A)(i)(III), 1902(a)(10)(A)(i)(IV), 1902(a)(10)(A)(i)(V), 1902(a)(10)(A)(i)(VI), 1902(a)(10)(A)(i)(VII), 1902(a)(10)(A)(i)(VIII), 1902(a)(10)(A)(i)(IX), 1902(a)(10)(A)(ii)(IX), 1902(a)(10)(A)(ii)(X), 1902(a)(10)(A)(ii)(XIII), 1902(a)(10)(A)(ii)(XIV), or 1902(a)(10)(A)(ii)(XV), 1902(a)(10)(A)(ii)(XVI), 1902(a)(10)(A)(ii)(XVII), 1902(a)(10)(A)(ii)(XVIII),

1902(a)(10)(A)(ii)(XIX), 1902(a)(10)(A)(ii)(XX),
 1902(a)(10)(A)(ii)(XXI), 1902(a)(10)(A)(ii)(XXII), 1905(p)(1) or for
 any individual—

(A) who is receiving aid or assistance under any plan of the State approved under title I, X, XIV or XVI, or part A of title IV, or with respect to whom supplemental security income benefits are being paid under title XVI, or

(B) who is not receiving such aid or assistance, and with respect to whom such benefits are not being paid, but (i) is eligible to receive such aid or assistance, or to have such benefits paid with respect to him, or (ii) would be eligible to receive such aid or assistance, or to have such benefits paid with respect to him if he were not in a medical institution, or

(C) with respect to whom there is being paid, or who is eligible, or would be eligible if he were not in a medical institution, to have paid with respect to him, a State supplementary payment and is eligible for medical assistance equal in amount, duration, and scope to the medical assistance made available to individuals described in section 1902(a)(10)(A), or who is a PACE program eligible individual enrolled in a PACE program under section 1934, but only if the income of such individual (as determined under section 1612, but without regard to subsection (b) thereof) does not exceed 300 percent of the supplemental security income benefit rate established by section 1611(b)(1),

at the time of the provision of the medical assistance giving rise to such expenditure.

(g)(1) Subject to paragraph (3), with respect to amounts paid for the following services furnished under the State plan after June 30, 1973 (other than services furnished pursuant to a contract with a health maintenance organization as defined in section 1876 or which is a qualified health maintenance organization (as defined in section 1310(d) of the Public Health Service Act)), the Federal medical assistance percentage shall be decreased as follows: After an individual has received inpatient hospital services or services in an intermediate care facility for the mentally retarded for 60 days or inpatient mental hospital services for 90 days (whether or not such days are consecutive), during any fiscal year, the Federal medical assistance percentage with respect to amounts paid for any such care furnished thereafter to such individual shall be decreased by a per centum thereof (determined under paragraph (5)) unless the State agency responsible for the administration of the plan makes a showing satisfactory to the Secretary that, with respect to each calendar quarter for which the State submits a request for payment at the full Federal medical assistance percentage for amounts paid for inpatient hospital services or services in an intermediate care facility for the mentally retarded furnished beyond 60 days (or inpatient mental hospital services furnished beyond 90 days), such State has an effective program of medical review of the care of patients in mental hospitals and intermediate care facilities for the mentally retarded pursuant to paragraphs (26) and (31) of section 1902(a) whereby the professional management of each case is reviewed and evaluated at least annually by independent professional review teams. In determining the number of days on which an individual has received services described in this subsection,

there shall not be counted any days with respect to which such individual is entitled to have payments made (in whole or in part) on his behalf under section 1812.

(2) The Secretary shall, as part of his validation procedures under this subsection, conduct timely sample onsite surveys of private and public institutions in which recipients of medical assistance may receive care and services under a State plan approved under this title, and his findings with respect to such surveys (as well as the showings of the State agency required under this subsection) shall be made available for public inspection.

(3)(A) No reduction in the Federal medical assistance percentage of a State otherwise required to be imposed under this subsection shall take effect—

(i) if such reduction is due to the State's unsatisfactory or invalid showing made with respect to a calendar quarter beginning before January 1, 1977;

(ii) before January 1, 1978;

(iii) unless a notice of such reduction has been provided to the State at least 30 days before the date such reduction takes effect; or

(iv) due to the State's unsatisfactory or invalid showing made with respect to a calendar quarter beginning after September 30, 1977, unless notice of such reduction has been provided to the State no later than the first day of the fourth calendar quarter following the calendar quarter with respect to which such showing was made.

(B) The Secretary shall waive application of any reduction in the Federal medical assistance percentage of a State otherwise required to be imposed under paragraph (1) because a showing by the State, made under such paragraph with respect to a calendar quarter ending after January 1, 1977, and before January 1, 1978, is determined to be either unsatisfactory under such paragraph or invalid under paragraph (2), if the Secretary determines that the State's showing made under paragraph (1) with respect to any calendar quarter ending on or before December 31, 1978, is satisfactory under such paragraph and is valid under paragraph (2).

(4)(A) The Secretary may not find the showing of a State, with respect to a calendar quarter under paragraph (1), to be satisfactory if the showing is submitted to the Secretary later than the 30th day after the last day of the calendar quarter, unless the State demonstrates to the satisfaction of the Secretary good cause for not meeting such deadline.

(B) The Secretary shall find a showing of a State, with respect to a calendar quarter under paragraph (1), to be satisfactory under such paragraph with respect to the requirement that the State conduct annual onsite inspections in mental hospitals and intermediate care facilities for the mentally retarded under paragraphs (26) and (31) of section 1902(a), if the showing demonstrates that the State has conducted such an onsite inspection during the 12-month period ending on the last date of the calendar quarter—

(i) in each of not less than 98 per centum of the number of such hospitals and facilities requiring such inspection, and

(ii) in every such hospital or facility which has 200 or more beds,

and that, with respect to such hospitals and facilities not inspected within such period, the State has exercised good faith and due diligence in attempting to conduct such inspection, or if the State demonstrates to the satisfaction of the Secretary that it would have made such a showing but for failings of a technical nature only.

(5) In the case of a State's unsatisfactory or invalid showing made with respect to a type of facility or institutional services in a calendar quarter, the per centum amount of the reduction of the State's Federal medical assistance percentage for that type of services under paragraph (1) is equal to $33\frac{1}{3}$ per centum multiplied by a fraction, the denominator of which is equal to the total number of patients receiving that type of services in that quarter under the State plan in facilities or institutions for which a showing was required to be made under this subsection, and the numerator of which is equal to the number of such patients receiving such type of services in that quarter in those facilities or institutions for which a satisfactory and valid showing was not made for that calendar quarter.

(6)(A) Recertifications required under section 1902(a)(44) shall be conducted at least every 60 days in the case of inpatient hospital services.

(B) Such recertifications in the case of services in an intermediate care facility for the mentally retarded shall be conducted at least—

- (i) 60 days after the date of the initial certification,
- (ii) 180 days after the date of the initial certification,
- (iii) 12 months after the date of the initial certification,
- (iv) 18 months after the date of the initial certification,
- (v) 24 months after the date of the initial certification, and
- (vi) every 12 months thereafter.

(C) For purposes of determining compliance with the schedule established by this paragraph, a recertification shall be considered to have been done on a timely basis if it was performed not later than 10 days after the date the recertification was otherwise required and the State establishes good cause why the physician or other person making such recertification did not meet such schedule.

(i) Payment under the preceding provisions of this section shall not be made—

(1) for organ transplant procedures unless the State plan provides for written standards respecting the coverage of such procedures and unless such standards provide that—

(A) similarly situated individuals are treated alike; and

(B) any restriction, on the facilities or practitioners which may provide such procedures, is consistent with the accessibility of high quality care to individuals eligible for the procedures under the State plan; or

(2) with respect to any amount expended for an item or service (other than an emergency item or service, not including items or services furnished in an emergency room of a hospital) furnished—

(A) under the plan by any individual or entity during any period when the individual or entity is excluded from participation under title V, XVIII, or XX or under this title pursuant to section 1128, 1128A, 1156, or 1842(j)(2),

(B) at the medical direction or on the prescription of a physician, during the period when such physician is excluded from participation under title V, XVIII, or XX or under this title pursuant to section 1128, 1128A, 1156, or 1842(j)(2) and when the person furnishing such item or service knew or had reason to know of the exclusion (after a reasonable time period after reasonable notice has been furnished to the person); or

(C) by any individual or entity to whom the State has failed to suspend payments under the plan during any period when there is pending an investigation of a credible allegation of fraud against the individual or entity, as determined by the State in accordance with regulations promulgated by the Secretary for purposes of section 1862(o) and this subparagraph, unless the State determines in accordance with such regulations there is good cause not to suspend such payments; or

(3) with respect to any amount expended for inpatient hospital services furnished under the plan (other than amounts attributable to the special situation of a hospital which serves a disproportionate number of low income patients with special needs) to the extent that such amount exceeds the hospital's customary charges with respect to such services or (if such services are furnished under the plan by a public institution free of charge or at nominal charges to the public) exceeds an amount determined on the basis of those items (specified in regulations prescribed by the Secretary) included in the determination of such payment which the Secretary finds will provide fair compensation to such institution for such services; or

(4) with respect to any amount expended for care or services furnished under the plan by a hospital unless such hospital has in effect a utilization review plan which meets the requirements imposed by section 1861(k) for purposes of title XVIII; and if such hospital has in effect such a utilization review plan for purposes of title XVIII, such plan shall serve as the plan required by this subsection (with the same standards and procedures and the same review committee or group) as a condition of payment under this title; the Secretary is authorized to waive the requirements of this paragraph if the State agency demonstrates to his satisfaction that it has in operation utilization review procedures which are superior in their effectiveness to the procedures required under section 1861(k); or

(5) with respect to any amount expended for any drug product for which payment may not be made under part B of title XVIII because of section 1862(c); or

(6) with respect to any amount expended for inpatient hospital tests (other than in emergency situations) not specifically ordered by the attending physician or other responsible practitioner; or

(7) with respect to any amount expended for clinical diagnostic laboratory tests performed by a physician, independent laboratory, or hospital, to the extent such amount exceeds the amount that would be recognized under section 1833(h) for such tests performed for an individual enrolled under part B of title XVIII; or

(8) with respect to any amount expended for medical assistance (A) for nursing facility services to reimburse (or otherwise compensate) a nursing facility for payment of a civil money penalty imposed under section 1919(h) or (B) for home and community care to reimburse (or otherwise compensate) a provider of such care for payment of a civil money penalty imposed under this title or title XI or for legal expenses in defense of an exclusion or civil money penalty under this title or title XI if there is no reasonable legal ground for the provider's case; or

(10)(A) with respect to covered outpatient drugs unless there is a rebate agreement in effect under section 1927 with respect to such drugs or unless section 1927(a)(3) applies,

(B) with respect to any amount expended for an innovator multiple source drug (as defined in section 1927(k)) dispensed on or after July 1, 1991, if, under applicable State law, a less expensive multiple source drug could have been dispensed, but only to the extent that such amount exceeds the upper payment limit for such multiple source drug;

(C) with respect to covered outpatient drugs described in section 1927(a)(7), unless information respecting utilization data and coding on such drugs that is required to be submitted under such section is submitted in accordance with such section, and

(D) with respect to any amount expended for reimbursement to a pharmacy under this title for the ingredient cost of a covered outpatient drug for which the pharmacy has already received payment under this title (other than with respect to a reasonable restocking fee for such drug); or

(11) with respect to any amount expended for physicians' services furnished on or after the first day of the first quarter beginning more than 60 days after the date of establishment of the physician identifier system under section 1902(x), unless the claim for the services includes the unique physician identifier provided under such system; or

(13) with respect to any amount expended to reimburse (or otherwise compensate) a nursing facility for payment of legal expenses associated with any action initiated by the facility that is dismissed on the basis that no reasonable legal ground existed for the institution of such action; or

(14) with respect to any amount expended on administrative costs to carry out the program under section 1928; or

(15) with respect to any amount expended for a single-antigen vaccine and its administration in any case in which the administration of a combined-antigen vaccine was medically appropriate (as determined by the Secretary); or

(16) with respect to any amount expended for which funds may not be used under the Assisted Suicide Funding Restriction Act of 1997; or

(17) with respect to any amount expended for roads, bridges, stadiums, or any other item or service not covered under a State plan under this title; or

(18) with respect to any amount expended for home health care services provided by an agency or organization unless the agency or organization provides the State agency on a con-

tinuing basis a surety bond in a form specified by the Secretary under paragraph (7) of section 1861(o) and in an amount that is not less than \$50,000 or such comparable surety bond as the Secretary may permit under the last sentence of such section; or

(19) with respect to any amount expended on administrative costs to initiate or pursue litigation described in subsection (d)(3)(B);

(20) with respect to amounts expended for medical assistance provided to an individual described in subclause (XV) or (XVI) of section 1902(a)(10)(A)(ii) for a fiscal year unless the State demonstrates to the satisfaction of the Secretary that the level of State funds expended for such fiscal year for programs to enable working individuals with disabilities to work (other than for such medical assistance) is not less than the level expended for such programs during the most recent State fiscal year ending before the date of the enactment of this paragraph;

(21) with respect to amounts expended for covered outpatient drugs described in *section 1927(d)(2)(C) (relating to drugs when used for cosmetic purposes or hair growth), except where medically necessary, and section 1927(d)(2)(K) (relating to drugs when used for treatment of sexual or erectile dysfunction)*;

(22) with respect to amounts expended for medical assistance for an individual who declares under section 1137(d)(1)(A) to be a citizen or national of the United States for purposes of establishing eligibility for benefits under this title, unless the requirement of section 1902(a)(46)(B) is met;

(23) with respect to amounts expended for medical assistance for covered outpatient drugs (as defined in section 1927(k)(2)) for which the prescription was executed in written (and non-electronic) form unless the prescription was executed on a tamper-resistant pad;

(24) if a State is required to implement an asset verification program under section 1940 and fails to implement such program in accordance with such section, with respect to amounts expended by such State for medical assistance for individuals subject to asset verification under such section, unless—

(A) the State demonstrates to the Secretary's satisfaction that the State made a good faith effort to comply;

(B) not later than 60 days after the date of a finding that the State is in noncompliance, the State submits to the Secretary (and the Secretary approves) a corrective action plan to remedy such noncompliance; and

(C) not later than 12 months after the date of such submission (and approval), the State fulfills the terms of such corrective action plan;

(25) with respect to any amounts expended for medical assistance for individuals for whom the State does not report enrollee encounter data (as defined by the Secretary) to the Medicaid Statistical Information System (MSIS) in a timely manner (as determined by the Secretary);

(26) with respect to any amounts expended for medical assistance for individuals described in subclause (VIII) of subsection (a)(10)(A)(i) other than medical assistance provided through benchmark coverage described in section 1937(b)(1) or

benchmark equivalent coverage described in section 1937(b)(2);
or

(27) with respect to any amounts expended by the State on the basis of a fee schedule for items described in section 1861(n) and furnished on or after January 1, 2019, as determined in the aggregate with respect to each class of such items as defined by the Secretary, in excess of the aggregate amount, if any, that would be paid for such items within such class on a fee-for-service basis under the program under part B of title XVIII, including, as applicable, under a competitive acquisition program under section 1847 in an area of the State.

Nothing in paragraph (1) shall be construed as permitting a State to provide services under its plan under this title that are not reasonable in amount, duration, and scope to achieve their purpose. Paragraphs (1), (2), (16), (17), and (18) shall apply with respect to items or services furnished and amounts expended by or through a managed care entity (as defined in section 1932(a)(1)(B)) in the same manner as such paragraphs apply to items or services furnished and amounts expended directly by the State.

(j) Notwithstanding the preceding provisions of this section, the amount determined under subsection (a)(1) for any State for any quarter shall be adjusted in accordance with section 1914.

(k) The Secretary is authorized to provide at the request of any State (and without cost to such State) such technical and actuarial assistance as may be necessary to assist such State to contract with any medicaid managed care organization which meets the requirements of subsection (m) of this section for the purpose of providing medical care and services to individuals who are entitled to medical assistance under this title.

(m)(1)(A) The term “medicaid managed care organization” means a health maintenance organization, an eligible organization with a contract under section 1876 or a Medicare+Choice organization with a contract under part C of title XVIII, a provider sponsored organization, or any other public or private organization, which meets the requirement of section 1902(w) and—

(i) makes services it provides to individuals eligible for benefits under this title accessible to such individuals, within the area served by the organization, to the same extent as such services are made accessible to individuals (eligible for medical assistance under the State plan) not enrolled with the organization, and

(ii) has made adequate provision against the risk of insolvency, which provision is satisfactory to the State, meets the requirements of subparagraph (C)(i) (if applicable), and which assures that individuals eligible for benefits under this title are in no case held liable for debts of the organization in case of the organization’s insolvency.

An organization that is a qualified health maintenance organization (as defined in section 1310(d) of the Public Health Service Act) is deemed to meet the requirements of clauses (i) and (ii).

(B) The duties and functions of the Secretary, insofar as they involve making determinations as to whether an organization is a medicaid managed care organization within the meaning of subparagraph (A), shall be integrated with the administration of section 1312 (a) and (b) of the Public Health Service Act.

(C)(i) Subject to clause (ii), a provision meets the requirements of this subparagraph for an organization if the organization meets solvency standards established by the State for private health maintenance organizations or is licensed or certified by the State as a risk-bearing entity.

(ii) Clause (i) shall not apply to an organization if—

(I) the organization is not responsible for the provision (directly or through arrangements with providers of services) of inpatient hospital services and physicians' services;

(II) the organization is a public entity;

(III) the solvency of the organization is guaranteed by the State; or

(IV) the organization is (or is controlled by) one or more Federally-qualified health centers and meets solvency standards established by the State for such an organization.

For purposes of subclause (IV), the term "control" means the possession, whether direct or indirect, of the power to direct or cause the direction of the management and policies of the organization through membership, board representation, or an ownership interest equal to or greater than 50.1 percent.

(2)(A) Except as provided in subparagraphs (B), (C), and (G), no payment shall be made under this title to a State with respect to expenditures incurred by it for payment (determined under a prepaid capitation basis or under any other risk basis) for services provided by any entity (including a health insuring organization) which is responsible for the provision (directly or through arrangements with providers of services) of inpatient hospital services and any other service described in paragraph (2), (3), (4), (5), or (7) of section 1905(a) or for the provision of any three or more of the services described in such paragraphs unless—

(i) the Secretary has determined that the entity is a Medicaid managed care organization organization as defined in paragraph (1);

(iii) such services are provided for the benefit of individuals eligible for benefits under this title in accordance with a contract between the State and the entity under which prepaid payments to the entity are made on an actuarially sound basis and under which the Secretary must provide prior approval for contracts providing for expenditures in excess of \$1,000,000 for 1998 and, for a subsequent year, the amount established under this clause for the previous year increased by the percentage increase in the consumer price index for all urban consumers over the previous year;

(iv) such contract provides that the Secretary and the State (or any person or organization designated by either) shall have the right to audit and inspect any books and records of the entity (and of any subcontractor) that pertain (I) to the ability of the entity to bear the risk of potential financial losses, or (II) to services performed or determinations of amounts payable under the contract;

(v) such contract provides that in the entity's enrollment, reenrollment, or disenrollment of individuals who are eligible for benefits under this title and eligible to enroll, reenroll, or disenroll with the entity pursuant to the contract, the entity

will not discriminate among such individuals on the basis of their health status or requirements for health care services;

(vi) such contract (I) permits individuals who have elected under the plan to enroll with the entity for provision of such benefits to terminate such enrollment in accordance with section 1932(a)(4), and (II) provides for notification in accordance with such section of each such individual, at the time of the individual's enrollment, of such right to terminate such enrollment;

(vii) such contract provides that, in the case of medically necessary services which were provided (I) to an individual enrolled with the entity under the contract and entitled to benefits with respect to such services under the State's plan and (II) other than through the organization because the services were immediately required due to an unforeseen illness, injury, or condition, either the entity or the State provides for reimbursement with respect to those services,

(viii) such contract provides for disclosure of information in accordance with section 1124 and paragraph (4) of this subsection;

(ix) such contract provides, in the case of an entity that has entered into a contract for the provision of services with a Federally-qualified health center or a rural health clinic, that the entity shall provide payment that is not less than the level and amount of payment which the entity would make for the services if the services were furnished by a provider which is not a Federally-qualified health center or a rural health clinic;

(x) any physician incentive plan that it operates meets the requirements described in section 1876(i)(8);

(xi) such contract provides for maintenance of sufficient patient encounter data to identify the physician who delivers services to patients and for the provision of such data to the State at a frequency and level of detail to be specified by the Secretary;

(xii) such contract, and the entity complies with the applicable requirements of section 1932; and

(xiii) such contract provides that (I) covered outpatient drugs dispensed to individuals eligible for medical assistance who are enrolled with the entity shall be subject to the same rebate required by the agreement entered into under section 1927 as the State is subject to and that the State shall collect such rebates from manufacturers, (II) capitation rates paid to the entity shall be based on actual cost experience related to rebates and subject to the Federal regulations requiring actuarially sound rates, and (III) the entity shall report to the State, on such timely and periodic basis as specified by the Secretary in order to include in the information submitted by the State to a manufacturer and the Secretary under section 1927(b)(2)(A), information on the total number of units of each dosage form and strength and package size by National Drug Code of each covered outpatient drug dispensed to individuals eligible for medical assistance who are enrolled with the entity and for which the entity is responsible for coverage of such drug under this subsection (other than cov-

ered outpatient drugs that under subsection (j)(1) of section 1927 are not subject to the requirements of that section) and such other data as the Secretary determines necessary to carry out this subsection.

(B) Subparagraph (A) except with respect to clause (ix) of subparagraph (A), does not apply with respect to payments under this title to a State with respect to expenditures incurred by it for payment for services provided by an entity which—

(i)(I) received a grant of at least \$100,000 in the fiscal year ending June 30, 1976, under section 329(d)(1)(A) or 330(d)(1) of the Public Health Service Act, and for the period beginning July 1, 1976, and ending on the expiration of the period for which payments are to be made under this title has been the recipient of a grant under either such section; and

(II) provides to its enrollees, on a prepaid capitation risk basis or on any other risk basis, all of the services and benefits described in paragraphs (1), (2), (3), (4)(C), and (5) of section 1905(a) and, to the extent required by section 1902(a)(10)(D) to be provided under a State plan for medical assistance, the services and benefits described in paragraph (7) of section 1905(a); or

(ii) is a nonprofit primary health care entity located in a rural area (as defined by the Appalachian Regional Commission)—

(I) which received in the fiscal year ending June 30, 1976, at least \$100,000 (by grant, subgrant, or subcontract) under the Appalachian Regional Development Act of 1965, and

(II) for the period beginning July 1, 1976, and ending on the expiration of the period for which payments are to be made under this title either has been the recipient of a grant, subgrant, or subcontract under such Act or has provided services under a contract (initially entered into during a year in which the entity was the recipient of such a grant, subgrant, or subcontract) with a State agency under this title on a prepaid capitation risk basis or on any other risk basis; or

(iii) which has contracted with the single State agency for the provision of services (but not including inpatient hospital services) to persons eligible under this title on a prepaid risk basis prior to 1970.

(G) In the case of an entity which is receiving (and has received during the previous two years) a grant of at least \$100,000 under section 329(d)(1)(A) or 330(d)(1) of the Public Health Service Act or is receiving (and has received during the previous two years) at least \$100,000 (by grant, subgrant, or subcontract) under the Appalachian Regional Development Act of 1965, clause (i) of subparagraph (A) shall not apply.

(H) In the case of an individual who—

(i) in a month is eligible for benefits under this title and enrolled with a medicaid managed care organization with a contract under this paragraph or with a primary care case manager with a contract described in section 1905(t)(3),

(ii) in the next month (or in the next 2 months) is not eligible for such benefits, but

(iii) in the succeeding month is again eligible for such benefits, the State plan, subject to subparagraph (A)(vi), may enroll the individual for that succeeding month with the organization described in clause (i) if the organization continues to have a contract under this paragraph with the State or with the manager described in such clause if the manager continues to have a contract described in section 1905(t)(3) with the State.

(4)(A) Each medicaid managed care organization which is not a qualified health maintenance organization (as defined in section 1310(d) of the Public Health Service Act) must report to the State and, upon request, to the Secretary, the Inspector General of the Department of Health and Human Services, and the Comptroller General a description of transactions between the organization and a party in interest (as defined in section 1318(b) of such Act), including the following transactions:

(i) Any sale or exchange, or leasing of any property between the organization and such a party.

(ii) Any furnishing for consideration of goods, services (including management services), or facilities between the organization and such a party, but not including salaries paid to employees for services provided in the normal course of their employment.

(iii) Any lending of money or other extension of credit between the organization and such a party.

The State or Secretary may require that information reported respecting an organization which controls, or is controlled by, or is under common control with, another entity be in the form of a consolidated financial statement for the organization and such entity.

(B) Each organization shall make the information reported pursuant to subparagraph (A) available to its enrollees upon reasonable request.

(5)(A) If the Secretary determines that an entity with a contract under this subsection—

(i) fails substantially to provide medically necessary items and services that are required (under law or under the contract) to be provided to an individual covered under the contract, if the failure has adversely affected (or has substantial likelihood of adversely affecting) the individual;

(ii) imposes premiums on individuals enrolled under this subsection in excess of the premiums permitted under this title;

(iii) acts to discriminate among individuals in violation of the provision of paragraph (2)(A)(v), including expulsion or refusal to re-enroll an individual or engaging in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment (except as permitted by this subsection) by eligible individuals with the organization whose medical condition or history indicates a need for substantial future medical services;

(iv) misrepresents or falsifies information that is furnished—

(I) to the Secretary or the State under this subsection,

or

(II) to an individual or to any other entity under this subsection, or

(v) fails to comply with the requirements of section 1876(i)(8), the Secretary may provide, in addition to any other remedies available under law, for any of the remedies described in subparagraph (B).

(B) The remedies described in this subparagraph are—

(i) civil money penalties of not more than \$25,000 for each determination under subparagraph (A), or, with respect to a determination under clause (iii) or (iv)(I) of such subparagraph, of not more than \$100,000 for each such determination, plus, with respect to a determination under subparagraph (A)(ii), double the excess amount charged in violation of such subparagraph (and the excess amount charged shall be deducted from the penalty and returned to the individual concerned), and plus, with respect to a determination under subparagraph (A)(iii), \$15,000 for each individual not enrolled as a result of a practice described in such subparagraph, or

(ii) denial of payment to the State for medical assistance furnished under the contract under this subsection for individuals enrolled after the date the Secretary notifies the organization of a determination under subparagraph (A) and until the Secretary is satisfied that the basis for such determination has been corrected and is not likely to recur.

The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under clause (i) in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(6)(A) For purposes of this subsection and section 1902(e)(2)(A), in the case of the State of New Jersey, the term “contract” shall be deemed to include an undertaking by the State agency, in the State plan under this title, to operate a program meeting all requirements of this subsection.

(B) The undertaking described in subparagraph (A) must provide—

(i) for the establishment of a separate entity responsible for the operation of a program meeting the requirements of this subsection, which entity may be a subdivision of the State agency administering the State plan under this title;

(ii) for separate accounting for the funds used to operate such program; and

(iii) for setting the capitation rates and any other payment rates for services provided in accordance with this subsection using a methodology satisfactory to the Secretary designed to ensure that total Federal matching payments under this title for such services will be lower than the matching payments that would be made for the same services, if provided under the State plan on a fee for service basis to an actuarially equivalent population.

(C) The undertaking described in subparagraph (A) shall be subject to approval (and annual re-approval) by the Secretary in the same manner as a contract under this subsection.

(D) The undertaking described in subparagraph (A) shall not be eligible for a waiver under section 1915(b).

(o) Notwithstanding the preceding provisions of this section, no payment shall be made to a State under the preceding provisions

of this section for expenditures for medical assistance provided for an individual under its State plan approved under this title to the extent that a private insurer (as defined by the Secretary by regulation and including a group health plan (as defined in section 607(1) of the Employee Retirement Income Security Act of 1974), a service benefit plan, and a health maintenance organization) would have been obligated to provide such assistance but for a provision of its insurance contract which has the effect of limiting or excluding such obligation because the individual is eligible for or is provided medical assistance under the plan.

(p)(1) When a political subdivision of a State makes, for the State of which it is a political subdivision, or one State makes, for another State, the enforcement and collection of rights of support or payment assigned under section 1912, pursuant to a cooperative arrangement under such section (either within or outside of such State), there shall be paid to such political subdivision or such other State from amounts which would otherwise represent the Federal share of payments for medical assistance provided to the eligible individuals on whose behalf such enforcement and collection was made, an amount equal to 15 percent of any amount collected which is attributable to such rights of support or payment.

(2) Where more than one jurisdiction is involved in such enforcement or collection, the amount of the incentive payment determined under paragraph (1) shall be allocated among the jurisdictions in a manner to be prescribed by the Secretary.

(q) For the purposes of this section, the term "State medicaid fraud control unit" means a single identifiable entity of the State government which the Secretary certifies (and annually recertifies) as meeting the following requirements:

(1) The entity (A) is a unit of the office of the State Attorney General or of another department of State government which possesses statewide authority to prosecute individuals for criminal violations, (B) is in a State the constitution of which does not provide for the criminal prosecution of individuals by a statewide authority and has formal procedures, approved by the Secretary, that (i) assure its referral of suspected criminal violations relating to the program under this title to the appropriate authority or authorities in the State for prosecution and (ii) assure its assistance of, and coordination with, such authority or authorities in such prosecutions, or (C) has a formal working relationship with the office of the State Attorney General and has formal procedures (including procedures for its referral of suspected criminal violations to such office) which are approved by the Secretary and which provide effective coordination of activities between the entity and such office with respect to the detection, investigation, and prosecution of suspected criminal violations relating to the program under this title.

(2) The entity is separate and distinct from the single State agency that administers or supervises the administration of the State plan under this title.

(3) The entity's function is conducting a statewide program for the investigation and prosecution of violations of all applicable State laws regarding any and all aspects of fraud in connection with (A) any aspect of the provision of medical assist-

ance and the activities of providers of such assistance under the State plan under this title; and (B) upon the approval of the Inspector General of the relevant Federal agency, any aspect of the provision of health care services and activities of providers of such services under any Federal health care program (as defined in section 1128B(f)(1)), if the suspected fraud or violation of law in such case or investigation is primarily related to the State plan under this title.

(4)(A) The entity has—

(i) procedures for reviewing complaints of abuse or neglect of patients in health care facilities which receive payments under the State plan under this title;

(ii) at the option of the entity, procedures for reviewing complaints of abuse or neglect of patients residing in board and care facilities; and

(iii) procedures for acting upon such complaints under the criminal laws of the State or for referring such complaints to other State agencies for action.

(B) For purposes of this paragraph, the term “board and care facility” means a residential setting which receives payment (regardless of whether such payment is made under the State plan under this title) from or on behalf of two or more unrelated adults who reside in such facility, and for whom one or both of the following is provided:

(i) Nursing care services provided by, or under the supervision of, a registered nurse, licensed practical nurse, or licensed nursing assistant.

(ii) A substantial amount of personal care services that assist residents with the activities of daily living, including personal hygiene, dressing, bathing, eating, toileting, ambulation, transfer, positioning, self-medication, body care, travel to medical services, essential shopping, meal preparation, laundry, and housework.

(5) The entity provides for the collection, or referral for collection to a single State agency, of overpayments that are made under the State plan or under any Federal health care program (as so defined) to health care facilities and that are discovered by the entity in carrying out its activities. All funds collected in accordance with this paragraph shall be credited exclusively to, and available for expenditure under, the Federal health care program (including the State plan under this title) that was subject to the activity that was the basis for the collection.

(6) The entity employs such auditors, attorneys, investigators, and other necessary personnel and is organized in such a manner as is necessary to promote the effective and efficient conduct of the entity’s activities.

(7) The entity submits to the Secretary an application and annual reports containing such information as the Secretary determines, by regulation, to be necessary to determine whether the entity meets the other requirements of this subsection.

(r)(1) In order to receive payments under subsection (a) for use of automated data systems in administration of the State plan under this title, a State must, in addition to meeting the requirements of paragraph (3), have in operation mechanized claims proc-

essing and information retrieval systems that meet the requirements of this subsection and that the Secretary has found—

(A) are adequate to provide efficient, economical, and effective administration of such State plan;

(B) are compatible with the claims processing and information retrieval systems used in the administration of title XVIII, and for this purpose—

(i) have a uniform identification coding system for providers, other payees, and beneficiaries under this title or title XVIII;

(ii) provide liaison between States and carriers and intermediaries with agreements under title XVIII to facilitate timely exchange of appropriate data;

(iii) provide for exchange of data between the States and the Secretary with respect to persons sanctioned under this title or title XVIII; and

(iv) effective for claims filed on or after October 1, 2010, incorporate compatible methodologies of the National Correct Coding Initiative administered by the Secretary (or any successor initiative to promote correct coding and to control improper coding leading to inappropriate payment) and such other methodologies of that Initiative (or such other national correct coding methodologies) as the Secretary identifies in accordance with paragraph (4);

(C) are capable of providing accurate and timely data;

(D) are complying with the applicable provisions of part C of title XI;

(E) are designed to receive provider claims in standard formats to the extent specified by the Secretary; and

(F) effective for claims filed on or after January 1, 1999, provide for electronic transmission of claims data in the format specified by the Secretary and consistent with the Medicaid Statistical Information System (MSIS) (including detailed individual enrollee encounter data and other information that the Secretary may find necessary and including, for data submitted to the Secretary on or after January 1, 2010, data elements from the automated data system that the Secretary determines to be necessary for program integrity, program oversight, and administration, at such frequency as the Secretary shall determine).

(2) In order to meet the requirements of this paragraph, mechanized claims processing and information retrieval systems must meet the following requirements:

(A) The systems must be capable of developing provider, physician, and patient profiles which are sufficient to provide specific information as to the use of covered types of services and items, including prescribed drugs.

(B) The State must provide that information on probable fraud or abuse which is obtained from, or developed by, the systems, is made available to the State's medicaid fraud control unit (if any) certified under subsection (q) of this section.

(C) The systems must meet all performance standards and other requirements for initial approval developed by the Secretary.

(3) In order to meet the requirements of this paragraph, a State must have in operation an eligibility determination system which provides for data matching through the Public Assistance Reporting Information System (PARIS) facilitated by the Secretary (or any successor system), including matching with medical assistance programs operated by other States.

(4) For purposes of paragraph (1)(B)(iv), the Secretary shall do the following:

(A) Not later than September 1, 2010:

(i) Identify those methodologies of the National Correct Coding Initiative administered by the Secretary (or any successor initiative to promote correct coding and to control improper coding leading to inappropriate payment) which are compatible to claims filed under this title.

(ii) Identify those methodologies of such Initiative (or such other national correct coding methodologies) that should be incorporated into claims filed under this title with respect to items or services for which States provide medical assistance under this title and no national correct coding methodologies have been established under such Initiative with respect to title XVIII.

(iii) Notify States of—

(I) the methodologies identified under subparagraphs (A) and (B) (and of any other national correct coding methodologies identified under subparagraph (B)); and

(II) how States are to incorporate such methodologies into claims filed under this title.

(B) Not later than March 1, 2011, submit a report to Congress that includes the notice to States under clause (iii) of subparagraph (A) and an analysis supporting the identification of the methodologies made under clauses (i) and (ii) of subparagraph (A).

(s) Notwithstanding the preceding provisions of this section, no payment shall be made to a State under this section for expenditures for medical assistance under the State plan consisting of a designated health service (as defined in subsection (h)(6) of section 1877) furnished to an individual on the basis of a referral that would result in the denial of payment for the service under title XVIII if such title provided for coverage of such service to the same extent and under the same terms and conditions as under the State plan, and subsections (f) and (g)(5) of such section shall apply to a provider of such a designated health service for which payment may be made under this title in the same manner as such subsections apply to a provider of such a service for which payment may be made under such title.

(t)(1) For purposes of subsection (a)(3)(F), the payments described in this paragraph to encourage the adoption and use of certified EHR technology are payments made by the State in accordance with this subsection —

(A) to Medicaid providers described in paragraph (2)(A) not in excess of 85 percent of net average allowable costs (as defined in paragraph (3)(E)) for certified EHR technology (and support services including maintenance and training that is

for, or is necessary for the adoption and operation of, such technology) with respect to such providers; and

(B) to Medicaid providers described in paragraph (2)(B) not in excess of the maximum amount permitted under paragraph (5) for the provider involved.

(2) In this subsection and subsection (a)(3)(F), the term “Medicaid provider” means—

(A) an eligible professional (as defined in paragraph (3)(B))—

(i) who is not hospital-based and has at least 30 percent of the professional’s patient volume (as estimated in accordance with a methodology established by the Secretary) attributable to individuals who are receiving medical assistance under this title;

(ii) who is not described in clause (i), who is a pediatrician, who is not hospital-based, and who has at least 20 percent of the professional’s patient volume (as estimated in accordance with a methodology established by the Secretary) attributable to individuals who are receiving medical assistance under this title; and

(iii) who practices predominantly in a Federally qualified health center or rural health clinic and has at least 30 percent of the professional’s patient volume (as estimated in accordance with a methodology established by the Secretary) attributable to needy individuals (as defined in paragraph (3)(F)); and

(B)(i) a children’s hospital, or

(ii) an acute-care hospital that is not described in clause (i) and that has at least 10 percent of the hospital’s patient volume (as estimated in accordance with a methodology established by the Secretary) attributable to individuals who are receiving medical assistance under this title.

An eligible professional shall not qualify as a Medicaid provider under this subsection unless any right to payment under sections 1848(o) and 1853(l) with respect to the eligible professional has been waived in a manner specified by the Secretary. For purposes of calculating patient volume under subparagraph (A)(iii), insofar as it is related to uncompensated care, the Secretary may require the adjustment of such uncompensated care data so that it would be an appropriate proxy for charity care, including a downward adjustment to eliminate bad debt data from uncompensated care. In applying subparagraphs (A) and (B)(ii), the methodology established by the Secretary for patient volume shall include individuals enrolled in a Medicaid managed care plan (under section 1903(m) or section 1932).

(3) In this subsection and subsection (a)(3)(F):

(A) The term “certified EHR technology” means a qualified electronic health record (as defined in 3000(13) of the Public Health Service Act) that is certified pursuant to section 3001(c)(5) of such Act as meeting standards adopted under section 3004 of such Act that are applicable to the type of record involved (as determined by the Secretary, such as an ambulatory electronic health record for office-based physicians or an inpatient hospital electronic health record for hospitals).

(B) The term “eligible professional” means a—

(i) physician;

- (ii) dentist;
- (iii) certified nurse mid-wife;
- (iv) nurse practitioner; and
- (v) physician assistant insofar as the assistant is practicing in a rural health clinic that is led by a physician assistant or is practicing in a Federally qualified health center that is so led.

(C) The term “average allowable costs” means, with respect to certified EHR technology of Medicaid providers described in paragraph (2)(A) for—

- (i) the first year of payment with respect to such a provider, the average costs for the purchase and initial implementation or upgrade of such technology (and support services including training that is for, or is necessary for the adoption and initial operation of, such technology) for such providers, as determined by the Secretary based upon studies conducted under paragraph (4)(C); and
- (ii) a subsequent year of payment with respect to such a provider, the average costs not described in clause (i) relating to the operation, maintenance, and use of such technology for such providers, as determined by the Secretary based upon studies conducted under paragraph (4)(C).

(D) The term “hospital-based” means, with respect to an eligible professional, a professional (such as a pathologist, anesthesiologist, or emergency physician) who furnishes substantially all of the individual’s professional services in a hospital inpatient or emergency room setting and through the use of the facilities and equipment, including qualified electronic health records, of the hospital. The determination of whether an eligible professional is a hospital-based eligible professional shall be made on the basis of the site of service (as defined by the Secretary) and without regard to any employment or billing arrangement between the eligible professional and any other provider.

(E) The term “net average allowable costs” means, with respect to a Medicaid provider described in paragraph (2)(A), average allowable costs reduced by the average payment the Secretary estimates will be made to such Medicaid providers (determined on a percentage or other basis for such classes or types of providers as the Secretary may specify) from other sources (other than under this subsection, or by the Federal government or a State or local government) that is directly attributable to payment for certified EHR technology or support services described in subparagraph (C).

(F) The term “needy individual” means, with respect to a Medicaid provider, an individual—

- (i) who is receiving assistance under this title;
- (ii) who is receiving assistance under title XXI;
- (iii) who is furnished uncompensated care by the provider; or
- (iv) for whom charges are reduced by the provider on a sliding scale basis based on an individual’s ability to pay.

(4)(A) With respect to a Medicaid provider described in paragraph (2)(A), subject to subparagraph (B), in no case shall—

(i) the net average allowable costs under this subsection for the first year of payment (which may not be later than 2016), which is intended to cover the costs described in paragraph (3)(C)(i), exceed \$25,000 (or such lesser amount as the Secretary determines based on studies conducted under subparagraph (C));

(ii) the net average allowable costs under this subsection for a subsequent year of payment, which is intended to cover costs described in paragraph (3)(C)(ii), exceed \$10,000; and

(iii) payments be made for costs described in clause (ii) after 2021 or over a period of longer than 5 years.

(B) In the case of Medicaid provider described in paragraph (2)(A)(ii), the dollar amounts specified in subparagraph (A) shall be $\frac{2}{3}$ of the dollar amounts otherwise specified.

(C) For the purposes of determining average allowable costs under this subsection, the Secretary shall study the average costs to Medicaid providers described in paragraph (2)(A) of purchase and initial implementation and upgrade of certified EHR technology described in paragraph (3)(C)(i) and the average costs to such providers of operations, maintenance, and use of such technology described in paragraph (3)(C)(ii). In determining such costs for such providers, the Secretary may utilize studies of such amounts submitted by States.

(5)(A) In no case shall the payments described in paragraph (1)(B) with respect to a Medicaid provider described in paragraph (2)(B) exceed—

(i) in the aggregate the product of—

(I) the overall hospital EHR amount for the provider computed under subparagraph (B); and

(II) the Medicaid share for such provider computed under subparagraph (C);

(ii) in any year 50 percent of the product described in clause (i); and

(iii) in any 2-year period 90 percent of such product.

(B) For purposes of this paragraph, the overall hospital EHR amount, with respect to a Medicaid provider, is the sum of the applicable amounts specified in section 1886(n)(2)(A) for such provider for the first 4 payment years (as estimated by the Secretary) determined as if the Medicare share specified in clause (ii) of such section were 1. The Secretary shall establish, in consultation with the State, the overall hospital EHR amount for each such Medicaid provider eligible for payments under paragraph (1)(B). For purposes of this subparagraph in computing the amounts under section 1886(n)(2)(C) for payment years after the first payment year, the Secretary shall assume that in subsequent payment years discharges increase at the average annual rate of growth of the most recent 3 years for which discharge data are available per year.

(C) The Medicaid share computed under this subparagraph, for a Medicaid provider for a period specified by the Secretary, shall be calculated in the same manner as the Medicare share under section 1886(n)(2)(D) for such a hospital and period, except that there shall be substituted for the numerator under clause (i) of such section the amount that is equal to the number of inpatient-bed-days (as established by the Secretary) which are attributable to individ-

uals who are receiving medical assistance under this title and who are not described in section 1886(n)(2)(D)(i). In computing inpatient-bed-days under the previous sentence, the Secretary shall take into account inpatient-bed-days attributable to inpatient-bed-days that are paid for individuals enrolled in a Medicaid managed care plan (under section 1903(m) or section 1932).

(D) In no case may the payments described in paragraph (1)(B) with respect to a Medicaid provider described in paragraph (2)(B) be paid—

(i) for any year beginning after 2016 unless the provider has been provided payment under paragraph (1)(B) for the previous year; and

(ii) over a period of more than 6 years of payment.

(6) Payments described in paragraph (1) are not in accordance with this subsection unless the following requirements are met:

(A)(i) The State provides assurances satisfactory to the Secretary that amounts received under subsection (a)(3)(F) with respect to payments to a Medicaid provider are paid, subject to clause (ii), directly to such provider (or to an employer or facility to which such provider has assigned payments) without any deduction or rebate.

(ii) Amounts described in clause (i) may also be paid to an entity promoting the adoption of certified EHR technology, as designated by the State, if participation in such a payment arrangement is voluntary for the eligible professional involved and if such entity does not retain more than 5 percent of such payments for costs not related to certified EHR technology (and support services including maintenance and training) that is for, or is necessary for the operation of, such technology.

(B) A Medicaid provider described in paragraph (2)(A) is responsible for payment of the remaining 15 percent of the net average allowable cost and shall be determined to have met such responsibility to the extent that the payment to the Medicaid provider is not in excess of 85 percent of the net average allowable cost.

(C)(i) Subject to clause (ii), with respect to payments to a Medicaid provider—

(I) for the first year of payment to the Medicaid provider under this subsection, the Medicaid provider demonstrates that it is engaged in efforts to adopt, implement, or upgrade certified EHR technology; and

(II) for a year of payment, other than the first year of payment to the Medicaid provider under this subsection, the Medicaid provider demonstrates meaningful use of certified EHR technology through a means that is approved by the State and acceptable to the Secretary, and that may be based upon the methodologies applied under section 1848(o) or 1886(n).

(ii) In the case of a Medicaid provider who has completed adopting, implementing, or upgrading such technology prior to the first year of payment to the Medicaid provider under this subsection, clause (i)(I) shall not apply and clause (i)(II) shall apply to each year of payment to the Medicaid provider under this subsection, including the first year of payment.

(D) To the extent specified by the Secretary, the certified EHR technology is compatible with State or Federal administrative management systems.

For purposes of subparagraph (B), a Medicaid provider described in paragraph (2)(A) may accept payments for the costs described in such subparagraph from a State or local government. For purposes of subparagraph (C), in establishing the means described in such subparagraph, which may include clinical quality reporting to the State, the State shall ensure that populations with unique needs, such as children, are appropriately addressed.

(7) With respect to Medicaid providers described in paragraph (2)(A), the Secretary shall ensure coordination of payment with respect to such providers under sections 1848(o) and 1853(l) and under this subsection to assure no duplication of funding. Such coordination shall include, to the extent practicable, a data matching process between State Medicaid agencies and the Centers for Medicare & Medicaid Services using national provider identifiers. For such purposes, the Secretary may require the submission of such data relating to payments to such Medicaid providers as the Secretary may specify.

(8) In carrying out paragraph (6)(C), the State and Secretary shall seek, to the maximum extent practicable, to avoid duplicative requirements from Federal and State governments to demonstrate meaningful use of certified EHR technology under this title and title XVIII. In doing so, the Secretary may deem satisfaction of requirements for such meaningful use for a payment year under title XVIII to be sufficient to qualify as meaningful use under this subsection. The Secretary may also specify the reporting periods under this subsection in order to carry out this paragraph.

(9) In order to be provided Federal financial participation under subsection (a)(3)(F)(ii), a State must demonstrate to the satisfaction of the Secretary, that the State—

(A) is using the funds provided for the purposes of administering payments under this subsection, including tracking of meaningful use by Medicaid providers;

(B) is conducting adequate oversight of the program under this subsection, including routine tracking of meaningful use attestations and reporting mechanisms; and

(C) is pursuing initiatives to encourage the adoption of certified EHR technology to promote health care quality and the exchange of health care information under this title, subject to applicable laws and regulations governing such exchange.

(10) The Secretary shall periodically submit reports to the Committee on Energy and Commerce of the House of Representatives and the Committee on Finance of the Senate on status, progress, and oversight of payments described in paragraph (1), including steps taken to carry out paragraph (7). Such reports shall also describe the extent of adoption of certified EHR technology among Medicaid providers resulting from the provisions of this subsection and any improvements in health outcomes, clinical quality, or efficiency resulting from such adoption.

(u)(1)(A) Notwithstanding subsection (a)(1), if the ratio of a State's erroneous excess payments for medical assistance (as defined in subparagraph (D)) to its total expenditures for medical assistance under the State plan approved under this title exceeds

0.03, for the period consisting of the third and fourth quarters of fiscal year 1983, or for any full fiscal year thereafter, then the Secretary shall make no payment for such period or fiscal year with respect to so much of such erroneous excess payments as exceeds such allowable error rate of 0.03.

(B) The Secretary may waive, in certain limited cases, all or part of the reduction required under subparagraph (A) with respect to any State if such State is unable to reach the allowable error rate for a period or fiscal year despite a good faith effort by such State.

(C) In estimating the amount to be paid to a State under subsection (d), the Secretary shall take into consideration the limitation on Federal financial participation imposed by subparagraph (A) and shall reduce the estimate he makes under subsection (d)(1), for purposes of payment to the State under subsection (d)(3), in light of any expected erroneous excess payments for medical assistance (estimated in accordance with such criteria, including sampling procedures, as he may prescribe and subject to subsequent adjustment, if necessary, under subsection (d)(2)).

(D)(i) For purposes of this subsection, the term "erroneous excess payments for medical assistance" means the total of—

(I) payments under the State plan with respect to ineligible individuals and families, and

(II) overpayments on behalf of eligible individuals and families by reason of error in determining the amount of expenditures for medical care required of an individual or family as a condition of eligibility.

(ii) In determining the amount of erroneous excess payments for medical assistance to an ineligible individual or family under clause (i)(I), if such ineligibility is the result of an error in determining the amount of the resources of such individual or family, the amount of the erroneous excess payment shall be the smaller of (I) the amount of the payment with respect to such individual or family, or (II) the difference between the actual amount of such resources and the allowable resource level established under the State plan.

(iii) In determining the amount of erroneous excess payments for medical assistance to an individual or family under clause (i)(II), the amount of the erroneous excess payment shall be the smaller of (I) the amount of the payment on behalf of the individual or family, or (II) the difference between the actual amount incurred for medical care by the individual or family and the amount which should have been incurred in order to establish eligibility for medical assistance.

(iv) In determining the amount of erroneous excess payments, there shall not be included any error resulting from a failure of an individual to cooperate or give correct information with respect to third-party liability as required under section 1912(a)(1)(C) or 402(a)(26)(C) or with respect to payments made in violation of section 1906.

(v) In determining the amount of erroneous excess payments, there shall not be included any erroneous payments made for ambulatory prenatal care provided during a presumptive eligibility period (as defined in section 1920(b)(1)), for items and services described in subsection (a) of section 1920A provided to a child during a presumptive eligibility period under such section, for medical as-

sistance provided to an individual described in subsection (a) of section 1920B during a presumptive eligibility period under such section, or for medical assistance provided to an individual during a presumptive eligibility period resulting from a determination of presumptive eligibility made by a hospital that elects under section 1902(a)(47)(B) to be a qualified entity for such purpose.

(E) For purposes of subparagraph (D), there shall be excluded, in determining both erroneous excess payments for medical assistance and total expenditures for medical assistance—

(i) payments with respect to any individual whose eligibility therefor was determined exclusively by the Secretary under an agreement pursuant to section 1634 and such other classes of individuals as the Secretary may by regulation prescribe whose eligibility was determined in part under such an agreement; and

(ii) payments made as the result of a technical error.

(2) The State agency administering the plan approved under this title shall, at such times and in such form as the Secretary may specify, provide information on the rates of erroneous excess payments made (or expected, with respect to future periods specified by the Secretary) in connection with its administration of such plan, together with any other data he requests that are reasonably necessary for him to carry out the provisions of this subsection.

(3)(A) If a State fails to cooperate with the Secretary in providing information necessary to carry out this subsection, the Secretary, directly or through contractual or such other arrangements as he may find appropriate, shall establish the error rates for that State on the basis of the best data reasonably available to him and in accordance with such techniques for sampling and estimating as he finds appropriate.

(B) In any case in which it is necessary for the Secretary to exercise his authority under subparagraph (A) to determine a State's error rates for a fiscal year, the amount that would otherwise be payable to such State under this title for quarters in such year shall be reduced by the costs incurred by the Secretary in making (directly or otherwise) such determination.

(4) This subsection shall not apply with respect to Puerto Rico, Guam, the Virgin Islands, the Northern Mariana Islands, or American Samoa.

(v)(1) Notwithstanding the preceding provisions of this section, except as provided in paragraphs (2) and (4), no payment may be made to a State under this section for medical assistance furnished to an alien who is not lawfully admitted for permanent residence or otherwise permanently residing in the United States under color of law.

(2) Payment shall be made under this section for care and services that are furnished to an alien described in paragraph (1) only if—

(A) such care and services are necessary for the treatment of an emergency medical condition of the alien,

(B) such alien otherwise meets the eligibility requirements for medical assistance under the State plan approved under this title (other than the requirement of the receipt of aid or assistance under title IV, supplemental security income benefits under title XVI, or a State supplementary payment), and

(C) such care and services are not related to an organ transplant procedure.

(3) For purposes of this subsection, the term “emergency medical condition” means a medical condition (including emergency labor and delivery) manifesting itself by acute symptoms of sufficient severity (including severe pain) such that the absence of immediate medical attention could reasonably be expected to result in—

(A) placing the patient’s health in serious jeopardy,

(B) serious impairment to bodily functions, or

(C) serious dysfunction of any bodily organ or part.

(4)(A) A State may elect (in a plan amendment under this title) to provide medical assistance under this title, notwithstanding sections 401(a), 402(b), 403, and 421 of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996, to children and pregnant women who are lawfully residing in the United States (including battered individuals described in section 431(c) of such Act) and who are otherwise eligible for such assistance, within either or both of the following eligibility categories:

(i) PREGNANT WOMEN.—Women during pregnancy (and during the 60-day period beginning on the last day of the pregnancy).

(ii) CHILDREN.—Individuals under 21 years of age, including optional targeted low-income children described in section 1905(u)(2)(B).

(B) In the case of a State that has elected to provide medical assistance to a category of aliens under subparagraph (A), no debt shall accrue under an affidavit of support against any sponsor of such an alien on the basis of provision of assistance to such category and the cost of such assistance shall not be considered as an unreimbursed cost.

(C) As part of the State’s ongoing eligibility redetermination requirements and procedures for an individual provided medical assistance as a result of an election by the State under subparagraph (A), a State shall verify that the individual continues to lawfully reside in the United States using the documentation presented to the State by the individual on initial enrollment. If the State cannot successfully verify that the individual is lawfully residing in the United States in this manner, it shall require that the individual provide the State with further documentation or other evidence to verify that the individual is lawfully residing in the United States.

(w)(1)(A) Notwithstanding the previous provisions of this section, for purposes of determining the amount to be paid to a State (as defined in paragraph (7)(D)) under subsection (a)(1) for quarters in any fiscal year, the total amount expended during such fiscal year as medical assistance under the State plan (as determined without regard to this subsection) shall be reduced by the sum of any revenues received by the State (or by a unit of local government in the State) during the fiscal year—

(i) from provider-related donations (as defined in paragraph (2)(A)), other than—

(I) bona fide provider-related donations (as defined in paragraph (2)(B)), and

(II) donations described in paragraph (2)(C);

(ii) from health care related taxes (as defined in paragraph (3)(A)), other than broad-based health care related taxes (as defined in paragraph (3)(B));

(iii) from a broad-based health care related tax, if there is in effect a hold harmless provision (described in paragraph (4)) with respect to the tax; or

(iv) only with respect to State fiscal years (or portions thereof) occurring on or after January 1, 1992, and before October 1, 1995, from broad-based health care related taxes to the extent the amount of such taxes collected exceeds the limit established under paragraph (5).

(B) Notwithstanding the previous provisions of this section, for purposes of determining the amount to be paid to a State under subsection (a)(7) for all quarters in a Federal fiscal year (beginning with fiscal year 1993), the total amount expended during the fiscal year for administrative expenditures under the State plan (as determined without regard to this subsection) shall be reduced by the sum of any revenues received by the State (or by a unit of local government in the State) during such quarters from donations described in paragraph (2)(C), to the extent the amount of such donations exceeds 10 percent of the amounts expended under the State plan under this title during the fiscal year for purposes described in paragraphs (2), (3), (4), (6), and (7) of subsection (a).

(C)(i) Except as otherwise provided in clause (ii), subparagraph (A)(i) shall apply to donations received on or after January 1, 1992.

(ii) Subject to the limits described in clause (iii) and subparagraph (E), subparagraph (A)(i) shall not apply to donations received before the effective date specified in subparagraph (F) if such donations are received under programs in effect or as described in State plan amendments or related documents submitted to the Secretary by September 30, 1991, and applicable to State fiscal year 1992, as demonstrated by State plan amendments, written agreements, State budget documentation, or other documentary evidence in existence on that date.

(iii) In applying clause (ii) in the case of donations received in State fiscal year 1993, the maximum amount of such donations to which such clause may be applied may not exceed the total amount of such donations received in the corresponding period in State fiscal year 1992 (or not later than 5 days after the last day of the corresponding period).

(D)(i) Except as otherwise provided in clause (ii), subparagraphs (A)(ii) and (A)(iii) shall apply to taxes received on or after January 1, 1992.

(ii) Subparagraphs (A)(ii) and (A)(iii) shall not apply to impermissible taxes (as defined in clause (iii)) received before the effective date specified in subparagraph (F) to the extent the taxes (including the tax rate or base) were in effect, or the legislation or regulations imposing such taxes were enacted or adopted, as of November 22, 1991.

(iii) In this subparagraph and subparagraph (E), the term "impermissible tax" means a health care related tax for which a reduction may be made under clause (ii) or (iii) of subparagraph (A).

(E)(i) In no case may the total amount of donations and taxes permitted under the exception provided in subparagraphs (C)(ii) and (D)(ii) for the portion of State fiscal year 1992 occurring during

calendar year 1992 exceed the limit under paragraph (5) minus the total amount of broad-based health care related taxes received in the portion of that fiscal year.

(ii) In no case may the total amount of donations and taxes permitted under the exception provided in subparagraphs (C)(ii) and (D)(ii) for State fiscal year 1993 exceed the limit under paragraph (5) minus the total amount of broad-based health care related taxes received in that fiscal year.

(F) In this paragraph in the case of a State—

(i) except as provided in clause (iii), with a State fiscal year beginning on or before July 1, the effective date is October 1, 1992,

(ii) except as provided in clause (iii), with a State fiscal year that begins after July 1, the effective date is January 1, 1993, or

(iii) with a State legislature which is not scheduled to have a regular legislative session in 1992, with a State legislature which is not scheduled to have a regular legislative session in 1993, or with a provider-specific tax enacted on November 4, 1991, the effective date is July 1, 1993.

(2)(A) In this subsection (except as provided in paragraph (6)), the term “provider-related donation” means any donation or other voluntary payment (whether in cash or in kind) made (directly or indirectly) to a State or unit of local government by—

(i) a health care provider (as defined in paragraph (7)(B)),

(ii) an entity related to a health care provider (as defined in paragraph (7)(C)), or

(iii) an entity providing goods or services under the State plan for which payment is made to the State under paragraph (2), (3), (4), (6), or (7) of subsection (a).

(B) For purposes of paragraph (1)(A)(i)(I), the term “bona fide provider-related donation” means a provider-related donation that has no direct or indirect relationship (as determined by the Secretary) to payments made under this title to that provider, to providers furnishing the same class of items and services as that provider, or to any related entity, as established by the State to the satisfaction of the Secretary. The Secretary may by regulation specify types of provider-related donations described in the previous sentence that will be considered to be bona fide provider-related donations.

(C) For purposes of paragraph (1)(A)(i)(II), donations described in this subparagraph are funds expended by a hospital, clinic, or similar entity for the direct cost (including costs of training and of preparing and distributing outreach materials) of State or local agency personnel who are stationed at the hospital, clinic, or entity to determine the eligibility of individuals for medical assistance under this title and to provide outreach services to eligible or potentially eligible individuals.

(3)(A) In this subsection (except as provided in paragraph (6)), the term “health care related tax” means a tax (as defined in paragraph (7)(F)) that—

(i) is related to health care items or services, or to the provision of, the authority to provide, or payment for, such items or services, or

(ii) is not limited to such items or services but provides for treatment of individuals or entities that are providing or paying for such items or services that is different from the treatment provided to other individuals or entities.

In applying clause (i), a tax is considered to relate to health care items or services if at least 85 percent of the burden of such tax falls on health care providers.

(B) In this subsection, the term “broad-based health care related tax” means a health care related tax which is imposed with respect to a class of health care items or services (as described in paragraph (7)(A)) or with respect to providers of such items or services and which, except as provided in subparagraphs (D), (E), and (F)—

(i) is imposed at least with respect to all items or services in the class furnished by all non-Federal, nonpublic providers in the State (or, in the case of a tax imposed by a unit of local government, the area over which the unit has jurisdiction) or is imposed with respect to all non-Federal, nonpublic providers in the class; and

(ii) is imposed uniformly (in accordance with subparagraph (C)).

(C)(i) Subject to clause (ii), for purposes of subparagraph (B)(ii), a tax is considered to be imposed uniformly if—

(I) in the case of a tax consisting of a licensing fee or similar tax on a class of health care items or services (or providers of such items or services), the amount of the tax imposed is the same for every provider providing items or services within the class;

(II) in the case of a tax consisting of a licensing fee or similar tax imposed on a class of health care items or services (or providers of such services) on the basis of the number of beds (licensed or otherwise) of the provider, the amount of the tax is the same for each bed of each provider of such items or services in the class;

(III) in the case of a tax based on revenues or receipts with respect to a class of items or services (or providers of items or services) the tax is imposed at a uniform rate for all items and services (or providers of such items or services) in the class on all the gross revenues or receipts, or net operating revenues, relating to the provision of all such items or services (or all such providers) in the State (or, in the case of a tax imposed by a unit of local government within the State, in the area over which the unit has jurisdiction); or

(IV) in the case of any other tax, the State establishes to the satisfaction of the Secretary that the tax is imposed uniformly.

(ii) Subject to subparagraphs (D) and (E), a tax imposed with respect to a class of health care items and services is not considered to be imposed uniformly if the tax provides for any credits, exclusions, or deductions which have as their purpose or effect the return to providers of all or a portion of the tax paid in a manner that is inconsistent with subclauses (I) and (II) of subparagraph (E)(ii) or provides for a hold harmless provision described in paragraph (4).

(D) A tax imposed with respect to a class of health care items and services is considered to be imposed uniformly—

(i) notwithstanding that the tax is not imposed with respect to items or services (or the providers thereof) for which payment is made under a State plan under this title or title XVIII, or

(ii) in the case of a tax described in subparagraph (C)(i)(III), notwithstanding that the tax provides for exclusion (in whole or in part) of revenues or receipts from a State plan under this title or title XVIII.

(E)(i) A State may submit an application to the Secretary requesting that the Secretary treat a tax as a broad-based health care related tax, notwithstanding that the tax does not apply to all health care items or services in class (or all providers of such items and services), provides for a credit, deduction, or exclusion, is not applied uniformly, or otherwise does not meet the requirements of subparagraph (B) or (C). Permissible waivers may include exemptions for rural or sole-community providers.

(ii) The Secretary shall approve such an application if the State establishes to the satisfaction of the Secretary that—

(I) the net impact of the tax and associated expenditures under this title as proposed by the State is generally redistributive in nature, and

(II) the amount of the tax is not directly correlated to payments under this title for items or services with respect to which the tax is imposed.

The Secretary shall by regulation specify types of credits, exclusions, and deductions that will be considered to meet the requirements of this subparagraph.

(F) In no case shall a tax not qualify as a broad-based health care related tax under this paragraph because it does not apply to a hospital that is described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from taxation under section 501(a) of such Code and that does not accept payment under the State plan under this title or under title XVIII.

(4) For purposes of paragraph (1)(A)(iii), there is in effect a hold harmless provision with respect to a broad-based health care related tax imposed with respect to a class of items or services if the Secretary determines that any of the following applies:

(A) The State or other unit of government imposing the tax provides (directly or indirectly) for a payment (other than under this title) to taxpayers and the amount of such payment is positively correlated either to the amount of such tax or to the difference between the amount of the tax and the amount of payment under the State plan.

(B) All or any portion of the payment made under this title to the taxpayer varies based only upon the amount of the total tax paid.

(C)(i) The State or other unit of government imposing the tax provides (directly or indirectly) for any payment, offset, or waiver that guarantees to hold taxpayers harmless for any portion of the costs of the tax.

(ii) For purposes of clause (i), a determination of the existence of an indirect guarantee shall be made under paragraph (3)(i) of section 433.68(f) of title 42, Code of Federal Regulations, as in effect on November 1, 2006, except that for portions of fiscal years beginning on or after January 1, 2008, and be-

fore October 1, 2011, “5.5 percent” shall be substituted for “6 percent” each place it appears.

The provisions of this paragraph shall not prevent use of the tax to reimburse health care providers in a class for expenditures under this title nor preclude States from relying on such reimbursement to justify or explain the tax in the legislative process.

(5)(A) For purposes of this subsection, the limit under this subparagraph with respect to a State is an amount equal to 25 percent (or, if greater, the State base percentage, as defined in subparagraph (B)) of the non-Federal share of the total amount expended under the State plan during a State fiscal year (or portion thereof), as it would be determined pursuant to paragraph (1)(A) without regard to paragraph (1)(A)(iv).

(B)(i) In subparagraph (A), the term “State base percentage” means, with respect to a State, an amount (expressed as a percentage) equal to—

(I) the total of the amount of health care related taxes (whether or not broad-based) and the amount of provider-related donations (whether or not bona fide) projected to be collected (in accordance with clause (ii)) during State fiscal year 1992, divided by

(II) the non-Federal share of the total amount estimated to be expended under the State plan during such State fiscal year.

(ii) For purposes of clause (i)(I), in the case of a tax that is not in effect throughout State fiscal year 1992 or the rate (or base) of which is increased during such fiscal year, the Secretary shall project the amount to be collected during such fiscal year as if the tax (or increase) were in effect during the entire State fiscal year.

(C)(i) The total amount of health care related taxes under subparagraph (B)(i)(I) shall be determined by the Secretary based on only those taxes (including the tax rate or base) which were in effect, or for which legislation or regulations imposing such taxes were enacted or adopted, as of November 22, 1991.

(ii) The amount of provider-related donations under subparagraph (B)(i)(I) shall be determined by the Secretary based on programs in effect on September 30, 1991, and applicable to State fiscal year 1992, as demonstrated by State plan amendments, written agreements, State budget documentation, or other documentary evidence in existence on that date.

(iii) The amount of expenditures described in subparagraph (B)(i)(II) shall be determined by the Secretary based on the best data available as of the date of the enactment of this subsection.

(6)(A) Notwithstanding the provisions of this subsection, the Secretary may not restrict States’ use of funds where such funds are derived from State or local taxes (or funds appropriated to State university teaching hospitals) transferred from or certified by units of government within a State as the non-Federal share of expenditures under this title, regardless of whether the unit of government is also a health care provider, except as provided in section 1902(a)(2), unless the transferred funds are derived by the unit of government from donations or taxes that would not otherwise be recognized as the non-Federal share under this section.

(B) For purposes of this subsection, funds the use of which the Secretary may not restrict under subparagraph (A) shall not be

considered to be a provider-related donation or a health care related tax.

(7) For purposes of this subsection:

(A) Each of the following shall be considered a separate class of health care items and services:

- (i) Inpatient hospital services.
- (ii) Outpatient hospital services.
- (iii) Nursing facility services (other than services of intermediate care facilities for the mentally retarded).
- (iv) Services of intermediate care facilities for the mentally retarded.
- (v) Physicians' services.
- (vi) Home health care services.
- (vii) Outpatient prescription drugs.
- (viii) Services of managed care organizations (including health maintenance organizations, preferred provider organizations, and such other similar organizations as the Secretary may specify by regulation).
- (ix) Such other classification of health care items and services consistent with this subparagraph as the Secretary may establish by regulation.

(B) The term "health care provider" means an individual or person that receives payments for the provision of health care items or services.

(C) An entity is considered to be "related" to a health care provider if the entity—

- (i) is an organization, association, corporation or partnership formed by or on behalf of health care providers;
- (ii) is a person with an ownership or control interest (as defined in section 1124(a)(3)) in the provider;
- (iii) is the employee, spouse, parent, child, or sibling of the provider (or of a person described in clause (ii)); or
- (iv) has a similar, close relationship (as defined in regulations) to the provider.

(D) The term "State" means only the 50 States and the District of Columbia but does not include any State whose entire program under this title is operated under a waiver granted under section 1115.

(E) The "State fiscal year" means, with respect to a specified year, a State fiscal year ending in that specified year.

(F) The term "tax" includes any licensing fee, assessment, or other mandatory payment, but does not include payment of a criminal or civil fine or penalty (other than a fine or penalty imposed in lieu of or instead of a fee, assessment, or other mandatory payment).

(G) The term "unit of local government" means, with respect to a State, a city, county, special purpose district, or other governmental unit in the State.

(x)(1) For purposes of section 1902(a)(46)(B)(i), the requirement of this subsection is, with respect to an individual declaring to be a citizen or national of the United States, that, subject to paragraph (2), there is presented satisfactory documentary evidence of citizenship or nationality (as defined in paragraph (3)) of the individual.

(2) The requirement of paragraph (1) shall not apply to an individual declaring to be a citizen or national of the United States who is eligible for medical assistance under this title—

(A) and is entitled to or enrolled for benefits under any part of title XVIII;

(B) and is receiving—

(i) disability insurance benefits under section 223 or monthly insurance benefits under section 202 based on such individual's disability (as defined in section 223(d)); or

(ii) supplemental security income benefits under title XVI;

(C) and with respect to whom—

(i) child welfare services are made available under part B of title IV on the basis of being a child in foster care; or

(ii) adoption or foster care assistance is made available under part E of title IV;

(D) pursuant to the application of section 1902(e)(4) (and, in the case of an individual who is eligible for medical assistance on such basis, the individual shall be deemed to have provided satisfactory documentary evidence of citizenship or nationality and shall not be required to provide further documentary evidence on any date that occurs during or after the period in which the individual is eligible for medical assistance on such basis); or

(E) on such basis as the Secretary may specify under which satisfactory documentary evidence of citizenship or nationality has been previously presented.

(3)(A) For purposes of this subsection, the term “satisfactory documentary evidence of citizenship or nationality” means—

(i) any document described in subparagraph (B); or

(ii) a document described in subparagraph (C) and a document described in subparagraph (D).

(B) The following are documents described in this subparagraph:

(i) A United States passport.

(ii) Form N-550 or N-570 (Certificate of Naturalization).

(iii) Form N-560 or N-561 (Certificate of United States Citizenship).

(iv) A valid State-issued driver's license or other identity document described in section 274A(b)(1)(D) of the Immigration and Nationality Act, but only if the State issuing the license or such document requires proof of United States citizenship before issuance of such license or document or obtains a social security number from the applicant and verifies before certification that such number is valid and assigned to the applicant who is a citizen.

(v)(I) Except as provided in subclause (II), a document issued by a federally recognized Indian tribe evidencing membership or enrollment in, or affiliation with, such tribe (such as a tribal enrollment card or certificate of degree of Indian blood).

(II) With respect to those federally recognized Indian tribes located within States having an international border whose membership includes individuals who are not citizens of the United States, the Secretary shall, after consulting with such

tribes, issue regulations authorizing the presentation of such other forms of documentation (including tribal documentation, if appropriate) that the Secretary determines to be satisfactory documentary evidence of citizenship or nationality for purposes of satisfying the requirement of this subsection.

(vi) Such other document as the Secretary may specify, by regulation, that provides proof of United States citizenship or nationality and that provides a reliable means of documentation of personal identity.

(C) The following are documents described in this subparagraph:

(i) A certificate of birth in the United States.

(ii) Form FS-545 or Form DS-1350 (Certification of Birth Abroad).

(iii) Form I-197 (United States Citizen Identification Card).

(iv) Form FS-240 (Report of Birth Abroad of a Citizen of the United States).

(v) Such other document (not described in subparagraph (B)(iv)) as the Secretary may specify that provides proof of United States citizenship or nationality.

(D) The following are documents described in this subparagraph:

(i) Any identity document described in section 274A(b)(1)(D) of the Immigration and Nationality Act.

(ii) Any other documentation of personal identity of such other type as the Secretary finds, by regulation, provides a reliable means of identification.

(E) A reference in this paragraph to a form includes a reference to any successor form.

(4) In the case of an individual declaring to be a citizen or national of the United States with respect to whom a State requires the presentation of satisfactory documentary evidence of citizenship or nationality under section 1902(a)(46)(B)(i), the individual shall be provided at least the reasonable opportunity to present satisfactory documentary evidence of citizenship or nationality under this subsection as is provided under clauses (i) and (ii) of section 1137(d)(4)(A) to an individual for the submittal to the State of evidence indicating a satisfactory immigration status.

(5) Nothing in subparagraph (A) or (B) of section 1902(a)(46), the preceding paragraphs of this subsection, or the Deficit Reduction Act of 2005, including section 6036 of such Act, shall be construed as changing the requirement of section 1902(e)(4) that a child born in the United States to an alien mother for whom medical assistance for the delivery of such child is available as treatment of an emergency medical condition pursuant to subsection (v) shall be deemed eligible for medical assistance during the first year of such child's life.

(y) PAYMENTS FOR ESTABLISHMENT OF ALTERNATE NON-EMERGENCY SERVICES PROVIDERS.—

(1) PAYMENTS.—In addition to the payments otherwise provided under subsection (a), subject to paragraph (2), the Secretary shall provide for payments to States under such subsection for the establishment of alternate non-emergency service providers (as defined in section 1916A(e)(5)(B)), or networks of such providers.

(2) LIMITATION.—The total amount of payments under this subsection shall not exceed \$50,000,000 during the 4-year pe-

riod beginning with 2006. This subsection constitutes budget authority in advance of appropriations Acts and represents the obligation of the Secretary to provide for the payment of amounts provided under this subsection.

(3) PREFERENCE.—In providing for payments to States under this subsection, the Secretary shall provide preference to States that establish, or provide for, alternate non-emergency services providers or networks of such providers that—

(A) serve rural or underserved areas where beneficiaries under this title may not have regular access to providers of primary care services; or

(B) are in partnership with local community hospitals.

(4) FORM AND MANNER OF PAYMENT.—Payment to a State under this subsection shall be made only upon the filing of such application in such form and in such manner as the Secretary shall specify. Payment to a State under this subsection shall be made in the same manner as other payments under section 1903(a).

(z) MEDICAID TRANSFORMATION PAYMENTS.—

(1) IN GENERAL.—In addition to the payments provided under subsection (a), subject to paragraph (4), the Secretary shall provide for payments to States for the adoption of innovative methods to improve the effectiveness and efficiency in providing medical assistance under this title.

(2) PERMISSIBLE USES OF FUNDS.—The following are examples of innovative methods for which funds provided under this subsection may be used:

(A) Methods for reducing patient error rates through the implementation and use of electronic health records, electronic clinical decision support tools, or e-prescribing programs.

(B) Methods for improving rates of collection from estates of amounts owed under this title.

(C) Methods for reducing waste, fraud, and abuse under the program under this title, such as reducing improper payment rates as measured by annual payment error rate measurement (PERM) project rates.

(D) Implementation of a medication risk management program as part of a drug use review program under section 1927(g).

(E) Methods in reducing, in clinically appropriate ways, expenditures under this title for covered outpatient drugs, particularly in the categories of greatest drug utilization, by increasing the utilization of generic drugs through the use of education programs and other incentives to promote greater use of generic drugs.

(F) Methods for improving access to primary and specialty physician care for the uninsured using integrated university-based hospital and clinic systems.

(3) APPLICATION; TERMS AND CONDITIONS.—

(A) IN GENERAL.—No payments shall be made to a State under this subsection unless the State applies to the Secretary for such payments in a form, manner, and time specified by the Secretary.

(B) TERMS AND CONDITIONS.—Such payments are made under such terms and conditions consistent with this subsection as the Secretary prescribes.

(C) ANNUAL REPORT.—Payment to a State under this subsection is conditioned on the State submitting to the Secretary an annual report on the programs supported by such payment. Such report shall include information on—

- (i) the specific uses of such payment;
- (ii) an assessment of quality improvements and clinical outcomes under such programs; and
- (iii) estimates of cost savings resulting from such programs.

(4) FUNDING.—

(A) LIMITATION ON FUNDS.—The total amount of payments under this subsection shall be equal to, and shall not exceed—

- (i) \$75,000,000 for fiscal year 2007; and
- (ii) \$75,000,000 for fiscal year 2008.

This subsection constitutes budget authority in advance of appropriations Acts and represents the obligation of the Secretary to provide for the payment of amounts provided under this subsection.

(B) ALLOCATION OF FUNDS.—The Secretary shall specify a method for allocating the funds made available under this subsection among States. Such method shall provide preference for States that design programs that target health providers that treat significant numbers of Medicaid beneficiaries. Such method shall provide that not less than 25 percent of such funds shall be allocated among States the population of which (as determined according to data collected by the United States Census Bureau) as of July 1, 2004, was more than 105 percent of the population of the respective State (as so determined) as of April 1, 2000.

(C) FORM AND MANNER OF PAYMENT.—Payment to a State under this subsection shall be made in the same manner as other payments under section 1903(a). There is no requirement for State matching funds to receive payments under this subsection.

(5) MEDICATION RISK MANAGEMENT PROGRAM.—

(A) IN GENERAL.—For purposes of this subsection, the term “medication risk management program” means a program for targeted beneficiaries that ensures that covered outpatient drugs are appropriately used to optimize therapeutic outcomes through improved medication use and to reduce the risk of adverse events.

(B) ELEMENTS.—Such program may include the following elements:

- (i) The use of established principles and standards for drug utilization review and best practices to analyze prescription drug claims of targeted beneficiaries and identify outlier physicians.
- (ii) On an ongoing basis provide outlier physicians—
 - (I) a comprehensive pharmacy claims history for each targeted beneficiary under their care;

(II) information regarding the frequency and cost of relapses and hospitalizations of targeted beneficiaries under the physician's care; and

(III) applicable best practice guidelines and empirical references.

(iii) Monitor outlier physician's prescribing, such as failure to refill, dosage strengths, and provide incentives and information to encourage the adoption of best clinical practices.

(C) TARGETED BENEFICIARIES.—For purposes of this paragraph, the term “targeted beneficiaries” means Medicaid eligible beneficiaries who are identified as having high prescription drug costs and medical costs, such as individuals with behavioral disorders or multiple chronic diseases who are taking multiple medications.

* * * * *

DEFINITIONS

SEC. 1905. For purposes of this title—

(a) The term “medical assistance” means payment of part or all of the cost of the following care and services or the care and services themselves, or both (if provided in or after the third month before the month in which the recipient makes application for assistance or, in the case of medicare cost-sharing with respect to a qualified medicare beneficiary described in subsection (p)(1), if provided after the month in which the individual becomes such a beneficiary) for individuals, and, with respect to physicians' or dentists' services, at the option of the State, to individuals (other than individuals with respect to whom there is being paid, or who are eligible, or would be eligible if they were not in a medical institution, to have paid with respect to them a State supplementary payment and are eligible for medical assistance equal in amount, duration, and scope to the medical assistance made available to individuals described in section 1902(a)(10)(A)) not receiving aid or assistance under any plan of the State approved under title I, X, XIV, or XVI, or part A of title IV, and with respect to whom supplemental security income benefits are not being paid under title XVI, who are—

(i) under the age of 21, or, at the option of the State, under the age of 20, 19, or 18 as the State may choose,

(ii) relatives specified in section 406(b)(1) with whom a child is living if such child is (or would, if needy, be) a dependent child under part A of title IV,

(iii) 65 years of age or older,

(iv) blind, with respect to States eligible to participate in the State plan program established under title XVI,

(v) 18 years of age or older and permanently and totally disabled, with respect to States eligible to participate in the State plan program established under title XVI,

(vi) persons essential (as described in the second sentence of this subsection) to individuals receiving aid or assistance under State plans approved under title I, X, XIV, or XVI,

(vii) blind or disabled as defined in section 1614, with respect to States not eligible to participate in the State plan program established under title XVI,

- (viii) pregnant women,
 - (ix) individuals provided extended benefits under section 1925,
 - (x) individuals described in section 1902(u)(1),
 - (xi) individuals described in section 1902(z)(1),
 - (xii) employed individuals with a medically improved disability (as defined in subsection (v)),
 - (xiii) individuals described in section 1902(aa),
 - (xiv) individuals described in section 1902(a)(10)(A)(i)(VIII) or 1902(a)(10)(A)(i)(IX),
 - (xv) individuals described in section 1902(a)(10)(A)(ii)(XX),
 - (xvi) individuals described in section 1902(ii), or
 - (xvii) individuals who are eligible for home and community-based services under needs-based criteria established under paragraph (1)(A) of section 1915(i), or who are eligible for home and community-based services under paragraph (6) of such section, and who will receive home and community-based services pursuant to a State plan amendment under such subsection,
- but whose income and resources are insufficient to meet all of such cost—
- (1) inpatient hospital services (other than services in an institution for mental diseases);
 - (2)(A) outpatient hospital services, (B) consistent with State law permitting such services, rural health clinic services (as defined in subsection (1)(1)) and any other ambulatory services which are offered by a rural health clinic (as defined in subsection (1)(1)) and which are otherwise included in the plan, and (C) Federally-qualified health center services (as defined in subsection (1)(2)) and any other ambulatory services offered by a Federally-qualified health center and which are otherwise included in the plan;
 - (3) other laboratory and X-ray services;
 - (4)(A) nursing facility services (other than services in an institution for mental diseases) for individuals 21 years of age or older; (B) early and periodic screening, diagnostic, and treatment services (as defined in subsection (r)) for individuals who are eligible under the plan and are under the age of 21; (C) family planning services and supplies furnished (directly or under arrangements with others) to individuals of child-bearing age (including minors who can be considered to be sexually active) who are eligible under the State plan and who desire such services and supplies; and (D) counseling and pharmacotherapy for cessation of tobacco use by pregnant women (as defined in subsection (bb));
 - (5)(A) physicians' services furnished by a physician (as defined in section 1861(r)(1)), whether furnished in the office, the patient's home, a hospital, or a nursing facility, or elsewhere, and (B) medical and surgical services furnished by a dentist (described in section 1861(r)(2)) to the extent such services may be performed under State law either by a doctor of medicine or by a doctor of dental surgery or dental medicine and would be described in clause (A) if furnished by a physician (as defined in section 1861(r)(1));

(6) medical care, or any other type of remedial care recognized under State law, furnished by licensed practitioners within the scope of their practice as defined by State law;

(7) home health care services;

(8) private duty nursing services;

(9) clinic services furnished by or under the direction of a physician, without regard to whether the clinic itself is administered by a physician, including such services furnished outside the clinic by clinic personnel to an eligible individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address;

(10) dental services;

(11) physical therapy and related services;

(12) prescribed drugs, dentures, and prosthetic devices; and eyeglasses prescribed by a physician skilled in diseases of the eye or by an optometrist, whichever the individual may select;

(13) other diagnostic, screening, preventive, and rehabilitative services, including—

(A) any clinical preventive services that are assigned a grade of A or B by the United States Preventive Services Task Force;

(B) with respect to an adult individual, approved vaccines recommended by the Advisory Committee on Immunization Practices (an advisory committee established by the Secretary, acting through the Director of the Centers for Disease Control and Prevention) and their administration; and

(C) any medical or remedial services (provided in a facility, a home, or other setting) recommended by a physician or other licensed practitioner of the healing arts within the scope of their practice under State law, for the maximum reduction of physical or mental disability and restoration of an individual to the best possible functional level;

(14) inpatient hospital services and nursing facility services for individuals 65 years of age or over in an institution for mental diseases;

(15) services in an intermediate care facility for the mentally retarded (other than in an institution for mental diseases) for individuals who are determined, in accordance with section 1902(a)(31), to be in need of such care;

(16) effective January 1, 1973, inpatient psychiatric hospital services for individuals under age 21, as defined in subsection (h);

(17) services furnished by a nurse-midwife (as defined in section 1861(gg)) which the nurse-midwife is legally authorized to perform under State law (or the State regulatory mechanism provided by State law), whether or not the nurse-midwife is under the supervision of, or associated with, a physician or other health care provider, and without regard to whether or not the services are performed in the area of management of the care of mothers and babies throughout the maternity cycle;

(18) hospice care (as defined in subsection (o));

(19) case management services (as defined in section 1915(g)(2)) and TB-related services described in section 1902(z)(2)(F);

(20) respiratory care services (as defined in section 1902(e)(9)(C));

(21) services furnished by a certified pediatric nurse practitioner or certified family nurse practitioner (as defined by the Secretary) which the certified pediatric nurse practitioner or certified family nurse practitioner is legally authorized to perform under State law (or the State regulatory mechanism provided by State law), whether or not the certified pediatric nurse practitioner or certified family nurse practitioner is under the supervision of, or associated with, a physician or other health care provider;

(22) home and community care (to the extent allowed and as defined in section 1929) for functionally disabled elderly individuals;

(23) community supported living arrangements services (to the extent allowed and as defined in section 1930);

(24) personal care services furnished to an individual who is not an inpatient or resident of a hospital, nursing facility, intermediate care facility for the mentally retarded, or institution for mental disease that are (A) authorized for the individual by a physician in accordance with a plan of treatment or (at the option of the State) otherwise authorized for the individual in accordance with a service plan approved by the State, (B) provided by an individual who is qualified to provide such services and who is not a member of the individual's family, and (C) furnished in a home or other location;

(25) primary care case management services (as defined in subsection (t));

(26) services furnished under a PACE program under section 1934 to PACE program eligible individuals enrolled under the program under such section;

(27) subject to subsection (x), primary and secondary medical strategies and treatment and services for individuals who have Sickle Cell Disease;

(28) freestanding birth center services (as defined in subsection (1)(3)(A)) and other ambulatory services that are offered by a freestanding birth center (as defined in subsection (1)(3)(B)) and that are otherwise included in the plan; and

(29) any other medical care, and any other type of remedial care recognized under State law, specified by the Secretary, except as otherwise provided in paragraph (16), such term does not include—

(A) any such payments with respect to care or services for any individual who is an inmate of a public institution (except as a patient in a medical institution); or

(B) any such payments with respect to care or services for any individual who has not attained 65 years of age and who is a patient in an institution for mental diseases.

For purposes of clause (vi) of the preceding sentence, a person shall be considered essential to another individual if such person is the spouse of and is living with such individual, the needs of such person are taken into account in determining the amount of aid or assistance furnished to such individual (under a State plan approved under title I, X, XIV, or XVI), and such person is determined, under such a State plan, to be essential to the well-being of such

individual. The payment described in the first sentence may include expenditures for medicare cost-sharing and for premiums under part B of title XVIII for individuals who are eligible for medical assistance under the plan and (A) are receiving aid or assistance under any plan of the State approved under title I, X, XIV, or XVI, or part A of title IV, or with respect to whom supplemental security income benefits are being paid under title XVI, or (B) with respect to whom there is being paid a State supplementary payment and are eligible for medical assistance equal in amount, duration, and scope to the medical assistance made available to individuals described in section 1902(a)(10)(A), and, except in the case of individuals 65 years of age or older and disabled individuals entitled to health insurance benefits under title XVIII who are not enrolled under part B of title XVIII, other insurance premiums for medical or any other type of remedial care or the cost thereof. No service (including counseling) shall be excluded from the definition of “medical assistance” solely because it is provided as a treatment service for alcoholism or drug dependency.

(b) Subject to subsections (y), (z), and (aa) and section 1933(d), the term “Federal medical assistance percentage” for any State shall be 100 per centum less the State percentage; and the State percentage shall be that percentage which bears the same ratio to 45 per centum as the square of the per capita income of such State bears to the square of the per capita income of the continental United States (including Alaska) and Hawaii; except that (1) the Federal medical assistance percentage shall in no case be less than 50 per centum or more than 83 per centum, (2) the Federal medical assistance percentage for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa shall be 55 percent, (3) for purposes of this title and title XXI, the Federal medical assistance percentage for the District of Columbia shall be 70 percent, (4) the Federal medical assistance percentage shall be equal to the enhanced FMAP described in section 2105(b) with respect to medical assistance provided to individuals who are eligible for such assistance only on the basis of section 1902(a)(10)(A)(ii)(XVIII), and (5) in the case of a State that provides medical assistance for services and vaccines described in subparagraphs (A) and (B) of subsection (a)(13), and prohibits cost-sharing for such services and vaccines, the Federal medical assistance percentage, as determined under this subsection and subsection (y) (without regard to paragraph (1)(C) of such subsection), shall be increased by 1 percentage point with respect to medical assistance for such services and vaccines and for items and services described in subsection (a)(4)(D). The Federal medical assistance percentage for any State shall be determined and promulgated in accordance with the provisions of section 1101(a)(8)(B). Notwithstanding the first sentence of this section, the Federal medical assistance percentage shall be 100 per centum with respect to amounts expended as medical assistance for services which are received through an Indian Health Service facility whether operated by the Indian Health Service or by an Indian tribe or tribal organization (as defined in section 4 of the Indian Health Care Improvement Act). Notwithstanding the first sentence of this subsection, in the case of a State plan that meets the condition described in subsection (u)(1), with respect to expenditures (other than expendi-

tures under section 1923) described in subsection (u)(2)(A) or subsection (u)(3) for the State for a fiscal year, and that do not exceed the amount of the State's available allotment under section 2104, the Federal medical assistance percentage is equal to the enhanced FMAP described in section 2105(b).

(c) For definition of the term "nursing facility", see section 1919(a).

(d) The term "intermediate care facility for the mentally retarded" means an institution (or distinct part thereof) for the mentally retarded or persons with related conditions if—

(1) the primary purpose of such institution (or distinct part thereof) is to provide health or rehabilitative services for mentally retarded individuals and the institution meets such standards as may be prescribed by the Secretary;

(2) the mentally retarded individual with respect to whom a request for payment is made under a plan approved under this title is receiving active treatment under such a program; and

(3) in the case of a public institution, the State or political subdivision responsible for the operation of such institution has agreed that the non-Federal expenditures in any calendar quarter prior to January 1, 1975, with respect to services furnished to patients in such institution (or distinct part thereof) in the State will not, because of payments made under this title, be reduced below the average amount expended for such services in such institution in the four quarters immediately preceding the quarter in which the State in which such institution is located elected to make such services available under its plan approved under this title.

(e) In the case of any State the State plan of which (as approved under this title)—

(1) does not provide for the payment of services (other than services covered under section 1902(a)(12)) provided by an optometrist; but

(2) at a prior period did provide for the payment of services referred to in paragraph (1);

the term "physicians' services" (as used in subsection (a)(5)) shall include services of the type which an optometrist is legally authorized to perform where the State plan specifically provides that the term "physicians' services", as employed in such plan, includes services of the type which an optometrist is legally authorized to perform, and shall be reimbursed whether furnished by a physician or an optometrist.

(f) For purposes of this title, the term "nursing facility services" means services which are or were required to be given an individual who needs or needed on a daily basis nursing care (provided directly by or requiring the supervision of nursing personnel) or other rehabilitation services which as a practical matter can only be provided in a nursing facility on an inpatient basis.

(g) If the State plan includes provision of chiropractors' services, such services include only—

(1) services provided by a chiropractor (A) who is licensed as such by the State and (B) who meets uniform minimum standards promulgated by the Secretary under section 1861(r)(5); and

(2) services which consist of treatment by means of manual manipulation of the spine which the chiropractor is legally authorized to perform by the State.

(h)(1) For purposes of paragraph (16) of subsection (a), the term "inpatient psychiatric hospital services for individuals under age 21" includes only—

(A) inpatient services which are provided in an institution (or distinct part thereof) which is a psychiatric hospital as defined in section 1861(f) or in another inpatient setting that the Secretary has specified in regulations;

(B) inpatient services which, in the case of any individual (i) involve active treatment which meets such standards as may be prescribed in regulations by the Secretary, and (ii) a team, consisting of physicians and other personnel qualified to make determinations with respect to mental health conditions and the treatment thereof, has determined are necessary on an inpatient basis and can reasonably be expected to improve the condition, by reason of which such services are necessary, to the extent that eventually such services will no longer be necessary; and

(C) inpatient services which, in the case of any individual, are provided prior to (i) the date such individual attains age 21, or (ii) in the case of an individual who was receiving such services in the period immediately preceding the date on which he attained age 21, (I) the date such individual no longer requires such services, or (II) if earlier, the date such individual attains age 22;

(2) Such term does not include services provided during any calendar quarter under the State plan of any State if the total amount of the funds expended, during such quarter, by the State (and the political subdivisions thereof) from non-Federal funds for inpatient services included under paragraph (1), and for active psychiatric care and treatment provided on an outpatient basis for eligible mentally ill children, is less than the average quarterly amount of the funds expended, during the 4-quarter period ending December 31, 1971, by the State (and the political subdivisions thereof) from non-Federal funds for such services.

(i) The term "institution for mental diseases" means a hospital, nursing facility, or other institution of more than 16 beds, that is primarily engaged in providing diagnosis, treatment, or care of persons with mental diseases, including medical attention, nursing care, and related services.

(j) The term "State supplementary payment" means any cash payment made by a State on a regular basis to an individual who is receiving supplemental security income benefits under title XVI or who would but for his income be eligible to receive such benefits, as assistance based on need in supplementation of such benefits (as determined by the Commissioner of Social Security), but only to the extent that such payments are made with respect to an individual with respect to whom supplemental security income benefits are payable under title XVI, or would but for his income be payable under that title.

(k) Increased supplemental security income benefits payable pursuant to section 211 of Public Law 93-66 shall not be considered supplemental security income benefits payable under title XVI.

(1)(1) The terms “rural health clinic services” and “rural health clinic” have the meanings given such terms in section 1861(aa), except that (A) clause (ii) of section 1861(aa)(2) shall not apply to such terms, and (B) the physician arrangement required under section 1861(aa)(2)(B) shall only apply with respect to rural health clinic services and, with respect to other ambulatory care services, the physician arrangement required shall be only such as may be required under the State plan for those services.

(2)(A) The term “Federally-qualified health center services” means services of the type described in subparagraphs (A) through (C) of section 1861(aa)(1) when furnished to an individual as an patient of a Federally-qualified health center and, for this purpose, any reference to a rural health clinic or a physician described in section 1861(aa)(2)(B) is deemed a reference to a Federally-qualified health center or a physician at the center, respectively.

(B) The term “Federally-qualified health center” means an entity which—

(i) is receiving a grant under section 330 of the Public Health Service Act,

(ii)(I) is receiving funding from such a grant under a contract with the recipient of such a grant, and

(II) meets the requirements to receive a grant under section 330 of such Act,

(iii) based on the recommendation of the Health Resources and Services Administration within the Public Health Service, is determined by the Secretary to meet the requirements for receiving such a grant, including requirements of the Secretary that an entity may not be owned, controlled, or operated by another entity, or

(iv) was treated by the Secretary, for purposes of part B of title XVIII, as a comprehensive Federally funded health center as of January 1, 1990;

and includes an outpatient health program or facility operated by a tribe or tribal organization under the Indian Self-Determination Act (Public Law 93-638) or by an urban Indian organization receiving funds under title V of the Indian Health Care Improvement Act for the provision of primary health services. In applying clause (ii), the Secretary may waive any requirement referred to in such clause for up to 2 years for good cause shown.

(3)(A) The term “freestanding birth center services” means services furnished to an individual at a freestanding birth center (as defined in subparagraph (B)) at such center.

(B) The term “freestanding birth center” means a health facility—

(i) that is not a hospital;

(ii) where childbirth is planned to occur away from the pregnant woman’s residence;

(iii) that is licensed or otherwise approved by the State to provide prenatal labor and delivery or postpartum care and other ambulatory services that are included in the plan; and

(iv) that complies with such other requirements relating to the health and safety of individuals furnished services by the facility as the State shall establish.

(C) A State shall provide separate payments to providers administering prenatal labor and delivery or postpartum care in a free-

standing birth center (as defined in subparagraph (B)), such as nurse midwives and other providers of services such as birth attendants recognized under State law, as determined appropriate by the Secretary. For purposes of the preceding sentence, the term “birth attendant” means an individual who is recognized or registered by the State involved to provide health care at childbirth and who provides such care within the scope of practice under which the individual is legally authorized to perform such care under State law (or the State regulatory mechanism provided by State law), regardless of whether the individual is under the supervision of, or associated with, a physician or other health care provider. Nothing in this subparagraph shall be construed as changing State law requirements applicable to a birth attendant.

(m)(1) Subject to paragraph (2), the term “qualified family member” means an individual (other than a qualified pregnant woman or child, as defined in subsection (n)) who is a member of a family that would be receiving aid under the State plan under part A of title IV pursuant to section 407 if the State had not exercised the option under section 407(b)(2)(B)(i).

(2) No individual shall be a qualified family member for any period after September 30, 1998.

(n) The term “qualified pregnant woman or child” means—

(1) a pregnant woman who—

(A) would be eligible for aid to families with dependent children under part A of title IV (or would be eligible for such aid if coverage under the State plan under part A of title IV included aid to families with dependent children of unemployed parents pursuant to section 407) if her child had been born and was living with her in the month such aid would be paid, and such pregnancy has been medically verified;

(B) is a member of a family which would be eligible for aid under the State plan under part A of title IV pursuant to section 407 if the plan required the payment of aid pursuant to such section; or

(C) otherwise meets the income and resources requirements of a State plan under part A of title IV; and

(2) a child who has not attained the age of 19, who was born after September 30, 1983 (or such earlier date as the State may designate), and who meets the income and resources requirements of the State plan under part A of title IV.

(o)(1)(A) Subject to subparagraphs (B) and (C), the term “hospice care” means the care described in section 1861(dd)(1) furnished by a hospice program (as defined in section 1861(dd)(2)) to a terminally ill individual who has voluntarily elected (in accordance with paragraph (2)) to have payment made for hospice care instead of having payment made for certain benefits described in section 1812(d)(2)(A) and for which payment may otherwise be made under title XVIII and intermediate care facility services under the plan. For purposes of such election, hospice care may be provided to an individual while such individual is a resident of a skilled nursing facility or intermediate care facility, but the only payment made under the State plan shall be for the hospice care.

(B) For purposes of this title, with respect to the definition of hospice program under section 1861(dd)(2), the Secretary may

allow an agency or organization to make the assurance under subparagraph (A)(iii) of such section without taking into account any individual who is afflicted with acquired immune deficiency syndrome (AIDS).

(C) A voluntary election to have payment made for hospice care for a child (as defined by the State) shall not constitute a waiver of any rights of the child to be provided with, or to have payment made under this title for, services that are related to the treatment of the child's condition for which a diagnosis of terminal illness has been made.

(2) An individual's voluntary election under this subsection —

(A) shall be made in accordance with procedures that are established by the State and that are consistent with the procedures established under section 1812(d)(2);

(B) shall be for such a period or periods (which need not be the same periods described in section 1812(d)(1)) as the State may establish; and

(C) may be revoked at any time without a showing of cause and may be modified so as to change the hospice program with respect to which a previous election was made.

(3) In the case of an individual—

(A) who is residing in a nursing facility or intermediate care facility for the mentally retarded and is receiving medical assistance for services in such facility under the plan,

(B) who is entitled to benefits under part A of title XVIII and has elected, under section 1812(d), to receive hospice care under such part, and

(C) with respect to whom the hospice program under such title and the nursing facility or intermediate care facility for the mentally retarded have entered into a written agreement under which the program takes full responsibility for the professional management of the individual's hospice care and the facility agrees to provide room and board to the individual,

instead of any payment otherwise made under the plan with respect to the facility's services, the State shall provide for payment to the hospice program of an amount equal to the additional amount determined in section 1902(a)(13)(B) and, if the individual is an individual described in section 1902(a)(10)(A), shall provide for payment of any coinsurance amounts imposed under section 1813(a)(4).

(p)(1) The term "qualified medicare beneficiary" means an individual—

(A) who is entitled to hospital insurance benefits under part A of title XVIII (including an individual entitled to such benefits pursuant to an enrollment under section 1818, but not including an individual entitled to such benefits only pursuant to an enrollment under section 1818A),

(B) whose income (as determined under section 1612 for purposes of the supplemental security income program, except as provided in paragraph (2)(D)) does not exceed an income level established by the State consistent with paragraph (2), and

(C) whose resources (as determined under section 1613 for purposes of the supplemental security income program) do not exceed twice the maximum amount of resources that an individual may have and obtain benefits under that program or, ef-

fective beginning with January 1, 2010, whose resources (as so determined) do not exceed the maximum resource level applied for the year under subparagraph (D) of section 1860D-14(a)(3) (determined without regard to the life insurance policy exclusion provided under subparagraph (G) of such section) applicable to an individual or to the individual and the individual's spouse (as the case may be).

(2)(A) The income level established under paragraph (1)(B) shall be at least the percent provided under subparagraph (B) (but not more than 100 percent) of 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.

(B) Except as provided in subparagraph (C), the percent provided under this clause, with respect to eligibility for medical assistance on or after—

- (i) January 1, 1989, is 85 percent,
- (ii) January 1, 1990, is 90 percent, and
- (iii) January 1, 1991, is 100 percent.

(C) In the case of a State which has elected treatment under section 1902(f) and which, as of January 1, 1987, used an income standard for individuals age 65 or older which was more restrictive than the income standard established under the supplemental security income program under title XVI, the percent provided under subparagraph (B), with respect to eligibility for medical assistance on or after—

- (i) January 1, 1989, is 80 percent,
- (ii) January 1, 1990, is 85 percent,
- (iii) January 1, 1991, is 95 percent, and
- (iv) January 1, 1992, is 100 percent.

(D)(i) In determining under this subsection the income of an individual who is entitled to monthly insurance benefits under title II for a transition month (as defined in clause (ii)) in a year, such income shall not include any amounts attributable to an increase in the level of monthly insurance benefits payable under such title which have occurred pursuant to section 215(i) for benefits payable for months beginning with December of the previous year.

(ii) For purposes of clause (i), the term “transition month” means each month in a year through the month following the month in which the annual revision of the official poverty line, referred to in subparagraph (A), is published.

(3) The term “medicare cost-sharing” means (subject to section 1902(n)(2)) the following costs incurred with respect to a qualified medicare beneficiary, without regard to whether the costs incurred were for items and services for which medical assistance is otherwise available under the plan:

- (A)(i) premiums under section 1818 or 1818A, and
- (ii) premiums under section 1839,
- (B) Coinsurance under title XVIII (including coinsurance described in section 1813).
- (C) Deductibles established under title XVIII (including those described in section 1813 and section 1833(b)).
- (D) The difference between the amount that is paid under section 1833(a) and the amount that would be paid under such

section if any reference to “80 percent” therein were deemed a reference to “100 percent”.

Such term also may include, at the option of a State, premiums for enrollment of a qualified medicare beneficiary with an eligible organization under section 1876.

(4) Notwithstanding any other provision of this title, in the case of a State (other than the 50 States and the District of Columbia)—

(A) the requirement stated in section 1902(a)(10)(E) shall be optional, and

(B) for purposes of paragraph (2), the State may substitute for the percent provided under subparagraph (B) of such paragraph or 1902(a)(10)(E)(iii) any percent.

In the case of any State which is providing medical assistance to its residents under a waiver granted under section 1115, the Secretary shall require the State to meet the requirement of section 1902(a)(10)(E) in the same manner as the State would be required to meet such requirement if the State had in effect a plan approved under this title.

(5)(A) The Secretary shall develop and distribute to States a simplified application form for use by individuals (including both qualified medicare beneficiaries and specified low-income medicare beneficiaries) in applying for medical assistance for medicare cost-sharing under this title in the States which elect to use such form. Such form shall be easily readable by applicants and uniform nationally. The Secretary shall provide for the translation of such application form into at least the 10 languages (other than English) that are most often used by individuals applying for hospital insurance benefits under section 226 or 226A and shall make the translated forms available to the States and to the Commissioner of Social Security.

(B) In developing such form, the Secretary shall consult with beneficiary groups and the States.

(6) For provisions relating to outreach efforts to increase awareness of the availability of medicare cost-sharing, see section 1144.

(q) The term “qualified severely impaired individual” means an individual under age 65—

(1) who for the month preceding the first month to which this subsection applies to such individual—

(A) received (i) a payment of supplemental security income benefits under section 1611(b) on the basis of blindness or disability, (ii) a supplementary payment under section 1616 of this Act or under section 212 of Public Law 93-66 on such basis, (iii) a payment of monthly benefits under section 1619(a), or (iv) a supplementary payment under section 1616(c)(3), and

(B) was eligible for medical assistance under the State plan approved under this title; and

(2) with respect to whom the Commissioner of Social Security determines that—

(A) the individual continues to be blind or continues to have the disabling physical or mental impairment on the basis of which he was found to be under a disability and, except for his earnings, continues to meet all non-disability-related requirements for eligibility for benefits under title XVI,

(B) the income of such individual would not, except for his earnings, be equal to or in excess of the amount which would cause him to be ineligible for payments under section 1611(b) (if he were otherwise eligible for such payments),

(C) the lack of eligibility for benefits under this title would seriously inhibit his ability to continue or obtain employment, and

(D) the individual's earnings are not sufficient to allow him to provide for himself a reasonable equivalent of the benefits under title XVI (including any federally administered State supplementary payments), this title, and publicly funded attendant care services (including personal care assistance) that would be available to him in the absence of such earnings.

In the case of an individual who is eligible for medical assistance pursuant to section 1619(b) in June, 1987, the individual shall be a qualified severely impaired individual for so long as such individual meets the requirements of paragraph (2).

(r) The term "early and periodic screening, diagnostic, and treatment services" means the following items and services:

(1) Screening services—

(A) which are provided—

(i) at intervals which meet reasonable standards of medical and dental practice, as determined by the State after consultation with recognized medical and dental organizations involved in child health care and, with respect to immunizations under subparagraph (B)(iii), in accordance with the schedule referred to in section 1928(c)(2)(B)(i) for pediatric vaccines, and

(ii) at such other intervals, indicated as medically necessary, to determine the existence of certain physical or mental illnesses or conditions; and

(B) which shall at a minimum include—

(i) a comprehensive health and developmental history (including assessment of both physical and mental health development),

(ii) a comprehensive unclothed physical exam,

(iii) appropriate immunizations (according to the schedule referred to in section 1928(c)(2)(B)(i) for pediatric vaccines) according to age and health history,

(iv) laboratory tests (including lead blood level assessment appropriate for age and risk factors), and

(v) health education (including anticipatory guidance).

(2) Vision services—

(A) which are provided—

(i) at intervals which meet reasonable standards of medical practice, as determined by the State after consultation with recognized medical organizations involved in child health care, and

(ii) at such other intervals, indicated as medically necessary, to determine the existence of a suspected illness or condition; and

(B) which shall at a minimum include diagnosis and treatment for defects in vision, including eyeglasses.

(3) Dental services—

(A) which are provided—

(i) at intervals which meet reasonable standards of dental practice, as determined by the State after consultation with recognized dental organizations involved in child health care, and

(ii) at such other intervals, indicated as medically necessary, to determine the existence of a suspected illness or condition; and

(B) which shall at a minimum include relief of pain and infections, restoration of teeth, and maintenance of dental health.

(4) Hearing services—

(A) which are provided—

(i) at intervals which meet reasonable standards of medical practice, as determined by the State after consultation with recognized medical organizations involved in child health care, and

(ii) at such other intervals, indicated as medically necessary, to determine the existence of a suspected illness or condition; and

(B) which shall at a minimum include diagnosis and treatment for defects in hearing, including hearing aids.

(5) Such other necessary health care, diagnostic services, treatment, and other measures described in section 1905(a) to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services, whether or not such services are covered under the State plan.

Nothing in this title shall be construed as limiting providers of early and periodic screening, diagnostic, and treatment services to providers who are qualified to provide all of the items and services described in the previous sentence or as preventing a provider that is qualified under the plan to furnish one or more (but not all) of such items or services from being qualified to provide such items and services as part of early and periodic screening, diagnostic, and treatment services. The Secretary shall, not later than July 1, 1990, and every 12 months thereafter, develop and set annual participation goals for each State for participation of individuals who are covered under the State plan under this title in early and periodic screening, diagnostic, and treatment services.

(s) The term “qualified disabled and working individual” means an individual—

(1) who is entitled to enroll for hospital insurance benefits under part A of title XVIII under section 1818A (as added by 6012 of the Omnibus Budget Reconciliation Act of 1989);

(2) whose income (as determined under section 1612 for purposes of the supplemental security income program) does not exceed 200 percent of 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;

(3) whose resources (as determined under section 1613 for purposes of the supplemental security income program) do not exceed twice the maximum amount of resources that an individual or a couple (in the case of an individual with a spouse) may have and obtain benefits for supplemental security income benefits under title XVI; and

(4) who is not otherwise eligible for medical assistance under this title.

(t)(1) The term “primary care case management services” means case-management related services (including locating, coordinating, and monitoring of health care services) provided by a primary care case manager under a primary care case management contract.

(2) The term “primary care case manager” means any of the following that provides services of the type described in paragraph (1) under a contract referred to in such paragraph:

(A) A physician, a physician group practice, or an entity employing or having other arrangements with physicians to provide such services.

(B) At State option—

(i) a nurse practitioner (as described in section 1905(a)(21));

(ii) a certified nurse-midwife (as defined in section 1861(gg)); or

(iii) a physician assistant (as defined in section 1861(aa)(5)).

(3) The term “primary care case management contract” means a contract between a primary care case manager and a State under which the manager undertakes to locate, coordinate, and monitor covered primary care (and such other covered services as may be specified under the contract) to all individuals enrolled with the manager, and which—

(A) provides for reasonable and adequate hours of operation, including 24-hour availability of information, referral, and treatment with respect to medical emergencies;

(B) restricts enrollment to individuals residing sufficiently near a service delivery site of the manager to be able to reach that site within a reasonable time using available and affordable modes of transportation;

(C) provides for arrangements with, or referrals to, sufficient numbers of physicians and other appropriate health care professionals to ensure that services under the contract can be furnished to enrollees promptly and without compromise to quality of care;

(D) prohibits discrimination on the basis of health status or requirements for health care services in enrollment, disenrollment, or reenrollment of individuals eligible for medical assistance under this title;

(E) provides for a right for an enrollee to terminate enrollment in accordance with section 1932(a)(4); and

(F) complies with the other applicable provisions of section 1932.

(4) For purposes of this subsection, the term “primary care” includes all health care services customarily provided in accordance with State licensure and certification laws and regulations, and all laboratory services customarily provided by or through, a general

practitioner, family medicine physician, internal medicine physician, obstetrician/gynecologist, or pediatrician.

(u)(1) The conditions described in this paragraph for a State plan are as follows:

(A) The State is complying with the requirement of section 2105(d)(1).

(B) The plan provides for such reporting of information about expenditures and payments attributable to the operation of this subsection as the Secretary deems necessary in order to carry out the fourth sentence of subsection (b).

(2)(A) For purposes of subsection (b), the expenditures described in this subparagraph are expenditures for medical assistance for optional targeted low-income children described in subparagraph (B).

(B) For purposes of this paragraph, the term “optional targeted low-income child” means a targeted low-income child as defined in section 2110(b)(1) (determined without regard to that portion of subparagraph (C) of such section concerning eligibility for medical assistance under this title) who would not qualify for medical assistance under the State plan under this title as in effect on March 31, 1997 (but taking into account the expansion of age of eligibility effected through the operation of section 1902(l)(1)(D)). Such term excludes any child eligible for medical assistance only by reason of section 1902(a)(10)(A)(ii)(XIX).

(3) For purposes of subsection (b), the expenditures described in this paragraph are expenditures for medical assistance for children who are born before October 1, 1983, and who would be described in section 1902(l)(1)(D) if they had been born on or after such date, and who are not eligible for such assistance under the State plan under this title based on such State plan as in effect as of March 31, 1997.

(4) The limitations on payment under subsections (f) and (g) of section 1108 shall not apply to Federal payments made under section 1903(a)(1) based on an enhanced FMAP described in section 2105(b).

(v)(1) The term “employed individual with a medically improved disability” means an individual who—

(A) is at least 16, but less than 65, years of age;

(B) is employed (as defined in paragraph (2));

(C) ceases to be eligible for medical assistance under section 1902(a)(10)(A)(ii)(XV) because the individual, by reason of medical improvement, is determined at the time of a regularly scheduled continuing disability review to no longer be eligible for benefits under section 223(d) or 1614(a)(3); and

(D) continues to have a severe medically determinable impairment, as determined under regulations of the Secretary.

(2) For purposes of paragraph (1), an individual is considered to be “employed” if the individual—

(A) is earning at least the applicable minimum wage requirement under section 6 of the Fair Labor Standards Act (29 U.S.C. 206) and working at least 40 hours per month; or

(B) is engaged in a work effort that meets substantial and reasonable threshold criteria for hours of work, wages, or other measures, as defined by the State and approved by the Secretary.’

(w)(1) For purposes of this title, the term “independent foster care adolescent” means an individual—

(A) who is under 21 years of age;

(B) who, on the individual’s 18th birthday, was in foster care under the responsibility of a State; and

(C) whose assets, resources, and income do not exceed such levels (if any) as the State may establish consistent with paragraph (2).

(2) The levels established by a State under paragraph (1)(C) may not be less than the corresponding levels applied by the State under section 1931(b).

(3) A State may limit the eligibility of independent foster care adolescents under section 1902(a)(10)(A)(ii)(XVII) to those individuals with respect to whom foster care maintenance payments or independent living services were furnished under a program funded under part E of title IV before the date the individuals attained 18 years of age.

(x) For purposes of subsection (a)(27), the strategies, treatment, and services described in that subsection include the following:

(1) Chronic blood transfusion (with deferoxamine chelation) to prevent stroke in individuals with Sickle Cell Disease who have been identified as being at high risk for stroke.

(2) Genetic counseling and testing for individuals with Sickle Cell Disease or the sickle cell trait to allow health care professionals to treat such individuals and to prevent symptoms of Sickle Cell Disease.

(3) Other treatment and services to prevent individuals who have Sickle Cell Disease and who have had a stroke from having another stroke.

(y) INCREASED FMAP FOR MEDICAL ASSISTANCE FOR NEWLY ELIGIBLE MANDATORY INDIVIDUALS.—

(1) AMOUNT OF INCREASE.—Notwithstanding subsection (b), the Federal medical assistance percentage for a State that is one of the 50 States or the District of Columbia, with respect to amounts expended by such State for medical assistance for newly eligible individuals described in subclause (VIII) of section 1902(a)(10)(A)(i), shall be equal to—

(A) 100 percent for calendar quarters in 2014, 2015, and 2016;

(B) 95 percent for calendar quarters in 2017;

(C) 94 percent for calendar quarters in 2018;

(D) 93 percent for calendar quarters in 2019; and

(E) 90 percent for calendar quarters in 2020 and each year thereafter.

(2) DEFINITIONS.—In this subsection:

(A) NEWLY ELIGIBLE.—The term “newly eligible” means, with respect to an individual described in subclause (VIII) of section 1902(a)(10)(A)(i), an individual who is not under 19 years of age (or such higher age as the State may have elected) and who, as of December 1, 2009, is not eligible under the State plan or under a waiver of the plan for full benefits or for benchmark coverage described in subparagraph (A), (B), or (C) of section 1937(b)(1) or benchmark equivalent coverage described in section 1937(b)(2) that has an aggregate actuarial value that is at least actuari-

ally equivalent to benchmark coverage described in subparagraph (A), (B), or (C) of section 1937(b)(1), or is eligible but not enrolled (or is on a waiting list) for such benefits or coverage through a waiver under the plan that has a capped or limited enrollment that is full.

(B) FULL BENEFITS.—The term “full benefits” means, with respect to an individual, medical assistance for all services covered under the State plan under this title that is not less in amount, duration, or scope, or is determined by the Secretary to be substantially equivalent, to the medical assistance available for an individual described in section 1902(a)(10)(A)(i).

(z) EQUITABLE SUPPORT FOR CERTAIN STATES.—

(1)(A) During the period that begins on January 1, 2014, and ends on December 31, 2015, notwithstanding subsection (b), the Federal medical assistance percentage otherwise determined under subsection (b) with respect to a fiscal year occurring during that period shall be increased by 2.2 percentage points for any State described in subparagraph (B) for amounts expended for medical assistance for individuals who are not newly eligible (as defined in subsection (y)(2)) individuals described in subclause (VIII) of section 1902(a)(10)(A)(i).

(B) For purposes of subparagraph (A), a State described in this subparagraph is a State that—

(i) is an expansion State described in paragraph (3);

(ii) the Secretary determines will not receive any payments under this title on the basis of an increased Federal medical assistance percentage under subsection (y) for expenditures for medical assistance for newly eligible individuals (as so defined); and

(iii) has not been approved by the Secretary to divert a portion of the DSH allotment for a State to the costs of providing medical assistance or other health benefits coverage under a waiver that is in effect on July 2009.

(2)(A) For calendar quarters in 2014 and each year thereafter, the Federal medical assistance percentage otherwise determined under subsection (b) for an expansion State described in paragraph (3) with respect to medical assistance for individuals described in section 1902(a)(10)(A)(i)(VIII) who are non-pregnant childless adults with respect to whom the State may require enrollment in benchmark coverage under section 1937 shall be equal to the percent specified in subparagraph (B)(i) for such year.

(B)(i) The percent specified in this subparagraph for a State for a year is equal to the Federal medical assistance percentage (as defined in the first sentence of subsection (b)) for the State increased by a number of percentage points equal to the transition percentage (specified in clause (ii) for the year) of the number of percentage points by which—

(I) such Federal medical assistance percentage for the State, is less than

(II) the percent specified in subsection (y)(1) for the year.

(ii) The transition percentage specified in this clause for—

(I) 2014 is 50 percent;

(II) 2015 is 60 percent;

- (III) 2016 is 70 percent;
- (IV) 2017 is 80 percent;
- (V) 2018 is 90 percent; and
- (VI) 2019 and each subsequent year is 100 percent.

(3) A State is an expansion State if, on the date of the enactment of the Patient Protection and Affordable Care Act, the State offers health benefits coverage statewide to parents and nonpregnant, childless adults whose income is at least 100 percent of the poverty line, that includes inpatient hospital services, is not dependent on access to employer coverage, employer contribution, or employment and is not limited to premium assistance, hospital-only benefits, a high deductible health plan, or alternative benefits under a demonstration program authorized under section 1938. A State that offers health benefits coverage to only parents or only nonpregnant childless adults described in the preceding sentence shall not be considered to be an expansion State.

(aa)(1) Notwithstanding subsection (b), beginning January 1, 2011, the Federal medical assistance percentage for a fiscal year for a disaster-recovery FMAP adjustment State shall be equal to the following:

(A) In the case of the first fiscal year (or part of a fiscal year) for which this subsection applies to the State, the State's regular FMAP shall be increased by 50 percent of the number of percentage points by which the State's regular FMAP for such fiscal year is less than the Federal medical assistance percentage determined for the State for the preceding fiscal year after the application of only subsection (a) of section 5001 of Public Law 111-5 (if applicable to the preceding fiscal year) and without regard to this subsection, subsections (y) and (z), and subsections (b) and (c) of section 5001 of Public Law 111-5.

(B) In the case of the second or any succeeding fiscal year for which this subsection applies to the State, the State's regular FMAP for such fiscal year shall be increased by 25 percent (or 50 percent in the case of fiscal year 2013) of the number of percentage points by which the State's regular FMAP for such fiscal year is less than the Federal medical assistance percentage received by the State during the preceding fiscal year.

(2) In this subsection, the term "disaster-recovery FMAP adjustment State" means a State that is one of the 50 States or the District of Columbia, for which, at any time during the preceding 7 fiscal years, the President has declared a major disaster under section 401 of the Robert T. Stafford Disaster Relief and Emergency Assistance Act and determined as a result of such disaster that every county or parish in the State warrant individual and public assistance or public assistance from the Federal Government under such Act and for which—

(A) in the case of the first fiscal year (or part of a fiscal year) for which this subsection applies to the State, the State's regular FMAP for the fiscal year is less than the Federal medical assistance percentage determined for the State for the preceding fiscal year after the application of only subsection (a) of section 5001 of Public Law 111-5 (if applicable to the preceding fiscal year) and without regard to this subsection, sub-

sections (y) and (z), and subsections (b) and (c) of section 5001 of Public Law 111–5, by at least 3 percentage points; and

(B) in the case of the second or any succeeding fiscal year for which this subsection applies to the State, the State’s regular FMAP for the fiscal year is less than the Federal medical assistance percentage determined for the State for the preceding fiscal year under this subsection by at least 3 percentage points.

(3) In this subsection, the term “regular FMAP” means, for each fiscal year for which this subsection applies to a State, the Federal medical assistance percentage that would otherwise apply to the State for the fiscal year, as determined under subsection (b) and without regard to this subsection, subsections (y) and (z), and section 10202 of the Patient Protection and Affordable Care Act.

(4) The Federal medical assistance percentage determined for a disaster-recovery FMAP adjustment State under paragraph (1) shall apply for purposes of this title (other than with respect to disproportionate share hospital payments described in section 1923 and payments under this title that are based on the enhanced FMAP described in 2105(b)) and shall not apply with respect to payments under title IV (other than under part E of title IV) or payments under title XXI.

(bb)(1) For purposes of this title, the term “counseling and pharmacotherapy for cessation of tobacco use by pregnant women” means diagnostic, therapy, and counseling services and pharmacotherapy (including the coverage of prescription and non-prescription tobacco cessation agents approved by the Food and Drug Administration) for cessation of tobacco use by pregnant women who use tobacco products or who are being treated for tobacco use that is furnished—

(A) by or under the supervision of a physician; or

(B) by any other health care professional who—

(i) is legally authorized to furnish such services under State law (or the State regulatory mechanism provided by State law) of the State in which the services are furnished; and

(ii) is authorized to receive payment for other services under this title or is designated by the Secretary for this purpose.

(2) Subject to paragraph (3), such term is limited to—

(A) services recommended with respect to pregnant women in “Treating Tobacco Use and Dependence: 2008 Update: A Clinical Practice Guideline”, published by the Public Health Service in May 2008, or any subsequent modification of such Guideline; and

(B) such other services that the Secretary recognizes to be effective for cessation of tobacco use by pregnant women.

(3) Such term shall not include coverage for drugs or biologicals that are not otherwise covered under this title.

(4) *A woman shall continue to be treated as described in this subsection as a pregnant woman through the end of the 1-year period beginning on the date of the birth of a child of the woman.*

(cc) REQUIREMENT FOR CERTAIN STATES.—Notwithstanding subsections (y), (z), and (aa), in the case of a State that requires political subdivisions within the State to contribute toward the non-

Federal share of expenditures required under the State plan under section 1902(a)(2), the State shall not be eligible for an increase in its Federal medical assistance percentage under such subsections if it requires that political subdivisions pay a greater percentage of the non-Federal share of such expenditures, or a greater percentage of the non-Federal share of payments under section 1923, than the respective percentages that would have been required by the State under the State plan under this title, State law, or both, as in effect on December 31, 2009, and without regard to any such increase. Voluntary contributions by a political subdivision to the non-Federal share of expenditures under the State plan under this title or to the non-Federal share of payments under section 1923, shall not be considered to be required contributions for purposes of this subsection. The treatment of voluntary contributions, and the treatment of contributions required by a State under the State plan under this title, or State law, as provided by this subsection, shall also apply to the increases in the Federal medical assistance percentage under section 5001 of the American Recovery and Reinvestment Act of 2009.

(dd) INCREASED FMAP FOR ADDITIONAL EXPENDITURES FOR PRIMARY CARE SERVICES.—Notwithstanding subsection (b), with respect to the portion of the amounts expended for medical assistance for services described in section 1902(a)(13)(C) furnished on or after January 1, 2013, and before January 1, 2015, that is attributable to the amount by which the minimum payment rate required under such section (or, by application, section 1932(f)) exceeds the payment rate applicable to such services under the State plan as of July 1, 2009, the Federal medical assistance percentage for a State that is one of the 50 States or the District of Columbia shall be equal to 100 percent. The preceding sentence does not prohibit the payment of Federal financial participation based on the Federal medical assistance percentage for amounts in excess of those specified in such sentence.

* * * * *

USE OF ENROLLMENT FEES, PREMIUMS, DEDUCTIONS, COST SHARING, AND SIMILAR CHARGES

SEC. 1916. (a) Subject to subsections (g), (i), and (j), the State plan shall provide that in the case of individuals described in subparagraph (A) or (E)(i) of section 1902(a)(10) who are eligible under the plan—

(1) no enrollment fee, premium, or similar charge will be imposed under the plan (except for a premium imposed under subsection (c));

(2) no deduction, cost sharing or similar charge will be imposed under the plan with respect to—

(A) services furnished to individuals under 18 years of age (and, at the option of the State, individuals under 21, 20, or 19 years of age, or any reasonable category of individuals 18 years of age or over),

(B) services furnished to pregnant women, if such services relate to the pregnancy or to any other medical condition which may complicate the pregnancy, and counseling and pharmacotherapy for cessation of tobacco use by preg-

nant women (as defined in section 1905(bb)) and covered outpatient drugs (as defined in subsection (k)(2) of section 1927 and including nonprescription drugs described in subsection (d)(2) of such section) that are prescribed for purposes of promoting, and when used to promote, tobacco cessation by pregnant women (*and women described in section 1905(bb) as pregnant women pursuant to paragraph (4) of such section*) in accordance with the Guideline referred to in section 1905(bb)(2)(A) (or, at the option of the State, any services furnished to pregnant women),

(C) services furnished to any individual who is an inpatient in a hospital, nursing facility, intermediate care facility for the mentally retarded, or other medical institution, if such individual is required, as a condition of receiving services in such institution under the State plan, to spend for costs of medical care all but a minimal amount of his income required for personal needs,

(D) emergency services (as defined by the Secretary), family planning services and supplies described in section 1905(a)(4)(C), or

(E) services furnished to an individual who is receiving hospice care (as defined in section 1905(o)); and

(3) any deduction, cost sharing, or similar charge imposed under the plan with respect to other such individuals or other care and services will be nominal in amount (as determined by the Secretary in regulations which shall, if the definition of “nominal” under the regulations in effect on July 1, 1982 is changed, take into account the level of cash assistance provided in such State and such other criteria as the Secretary determines to be appropriate); except that a deduction, cost-sharing, or similar charge of up to twice the nominal amount established for outpatient services may be imposed by a State under a waiver granted by the Secretary for services received at a hospital emergency room if the services are not emergency services (referred to in paragraph (2)(D)) and the State has established to the satisfaction of the Secretary that individuals eligible for services under the plan have actually available and accessible to them alternative sources of nonemergency, outpatient services.

(b) The State plan shall provide that in the case of individuals other than those described in subparagraph (A) or (E) of section 1902(a)(10) who are eligible under the plan—

(1) there may be imposed an enrollment fee, premium, or similar charge, which (as determined in accordance with standards prescribed by the Secretary) is related to the individual's income,

(2) no deduction, cost sharing, or similar charge will be imposed under the plan with respect to—

(A) services furnished to individuals under 18 years of age (and, at the option of the State, individuals under 21, 20, or 19 years of age, or any reasonable category of individuals 18 years of age or over),

(B) services furnished to pregnant women, if such services relate to the pregnancy or to any other medical condition which may complicate the pregnancy, and counseling

and pharmacotherapy for cessation of tobacco use by pregnant women (as defined in section 1905(bb)) and covered outpatient drugs (as defined in subsection (k)(2) of section 1927 and including nonprescription drugs described in subsection (d)(2) of such section) that are prescribed for purposes of promoting, and when used to promote, tobacco cessation by pregnant women (*and women described in section 1905(bb) as pregnant women pursuant to paragraph (4) of such section*) in accordance with the Guideline referred to in section 1905(bb)(2)(A) (or, at the option of the State, any services furnished to pregnant women),

(C) services furnished to any individual who is an inpatient in a hospital, nursing facility, intermediate care facility for the mentally retarded, or other medical institution, if such individual is required, as a condition of receiving services in such institution under the State plan, to spend for costs of medical care all but a minimal amount of his income required for personal needs,

(D) emergency services (as defined by the Secretary), family planning services and supplies described in section 1905(a)(4)(C), or

(E) services furnished to an individual who is receiving hospice care (as defined in section 1905(o)); and

(3) any deduction, cost sharing, or similar charge imposed under the plan with respect to other such individuals or other care and services will be nominal in amount (as determined by the Secretary in regulations which shall, if the definition of "nominal" under the regulations in effect on July 1, 1982 is changed, take into account the level of cash assistance provided in such State and such other criteria as the Secretary determines to be appropriate); except that a deduction, cost-sharing, or similar charge of up to twice the nominal amount established for outpatient services may be imposed by a State under a waiver granted by the Secretary for services received at a hospital emergency room if the services are not emergency services (referred to in paragraph (2)(D)) and the State has established to the satisfaction of the Secretary that individuals eligible for services under the plan have actually available and accessible to them alternative sources of nonemergency, outpatient services.

(c)(1) The State plan of a State may at the option of the State provide for imposing a monthly premium (in an amount that does not exceed the limit established under paragraph (2)) with respect to an individual described in subparagraph (A) or (B) of section 1902(l)(1) who is receiving medical assistance on the basis of section 1902(a)(10)(A)(ii)(IX) and whose family income (as determined in accordance with the methodology specified in section 1902(l)(3)) equals or exceeds 150 percent of the income official poverty line (as defined by the Office of Management and Budget, and revised annually in accordance with section 673(2) of the Omnibus Budget Reconciliation Act of 1981) applicable to a family of the size involved.

(2) In no case may the amount of any premium imposed under paragraph (1) exceed 10 percent of the amount by which the family

income (less expenses for the care of a dependent child) of an individual exceeds 150 percent of the line described in paragraph (1).

(3) A State shall not require prepayment of a premium imposed pursuant to paragraph (1) and shall not terminate eligibility of an individual for medical assistance under this title on the basis of failure to pay any such premium until such failure continues for a period of not less than 60 days. The State may waive payment of any such premium in any case where the State determines that requiring such payment would create an undue hardship.

(4) A State may permit State or local funds available under other programs to be used for payment of a premium imposed under paragraph (1). Payment of a premium with such funds shall not be counted as income to the individual with respect to whom such payment is made.

(d) With respect to a qualified disabled and working individual described in section 1905(s) whose income (as determined under paragraph (3) of that section) exceeds 150 percent of the official poverty line referred to in that paragraph, the State plan of a State may provide for the charging of a premium (expressed as a percentage of the medicare cost-sharing described in section 1905(p)(3)(A)(i) provided with respect to the individual) according to a sliding scale under which such percentage increases from 0 percent to 100 percent, in reasonable increments (as determined by the Secretary), as the individual's income increases from 150 percent of such poverty line to 200 percent of such poverty line.

(e) The State plan shall require that no provider participating under the State plan may deny care or services to an individual eligible for such care or services under the plan on account of such individual's inability to pay a deduction, cost sharing, or similar charge. The requirements of this subsection shall not extinguish the liability of the individual to whom the care or services were furnished for payment of the deduction, cost sharing, or similar charge.

(f) No deduction, cost sharing, or similar charge may be imposed under any waiver authority of the Secretary, except as provided in subsections (a)(3) and (b)(3) and section 1916A, unless such waiver is for a demonstration project which the Secretary finds after public notice and opportunity for comment—

(1) will test a unique and previously untested use of copayments,

(2) is limited to a period of not more than two years,

(3) will provide benefits to recipients of medical assistance which can reasonably be expected to be equivalent to the risks to the recipients,

(4) is based on a reasonable hypothesis which the demonstration is designed to test in a methodologically sound manner, including the use of control groups of similar recipients of medical assistance in the area, and

(5) is voluntary, or makes provision for assumption of liability for preventable damage to the health of recipients of medical assistance resulting from involuntary participation.

(g) With respect to individuals provided medical assistance only under subclause (XV) or (XVI) of section 1902(a)(10)(A)(ii)—

(1) a State may (in a uniform manner for individuals described in either such subclause)—

(A) require such individuals to pay premiums or other cost-sharing charges set on a sliding scale based on income that the State may determine; and

(B) require payment of 100 percent of such premiums for such year in the case of such an individual who has income for a year that exceeds 250 percent of the income official poverty line (referred to in subsection (c)(1)) applicable to a family of the size involved, except that in the case of such an individual who has income for a year that does not exceed 450 percent of such poverty line, such requirement may only apply to the extent such premiums do not exceed 7.5 percent of such income; and

(2) such State shall require payment of 100 percent of such premiums for a year by such an individual whose adjusted gross income (as defined in section 62 of the Internal Revenue Code of 1986) for such year exceeds \$75,000, except that a State may choose to subsidize such premiums by using State funds which may not be federally matched under this title.

In the case of any calendar year beginning after 2000, the dollar amount specified in paragraph (2) shall be increased in accordance with the provisions of section 215(i)(2)(A)(ii).

(h) In applying this section and subsections (c) and (e) of section 1916A, with respect to cost sharing that is “nominal” in amount, the Secretary shall increase such “nominal” amounts for each year (beginning with 2006) by the annual percentage increase in the medical care component of the consumer price index for all urban consumers (U.S. city average) as rounded up in an appropriate manner.

(i)(1) With respect to disabled children provided medical assistance under section 1902(a)(10)(A)(ii)(XIX), subject to paragraph (2), a State may (in a uniform manner for such children) require the families of such children to pay monthly premiums set on a sliding scale based on family income.

(2) A premium requirement imposed under paragraph (1) may only apply to the extent that—

(A) in the case of a disabled child described in that paragraph whose family income—

(i) does not exceed 200 percent of the poverty line, the aggregate amount of such premium and any premium that the parent is required to pay for family coverage under section 1902(cc)(2)(A)(i) and other cost-sharing charges do not exceed 5 percent of the family’s income; and

(ii) exceeds 200, but does not exceed 300, percent of the poverty line, the aggregate amount of such premium and any premium that the parent is required to pay for family coverage under section 1902(cc)(2)(A)(i) and other cost-sharing charges do not exceed 7.5 percent of the family’s income; and

(B) the requirement is imposed consistent with section 1902(cc)(2)(A)(ii)(I).

(3) A State shall not require prepayment of a premium imposed pursuant to paragraph (1) and shall not terminate eligibility of a child under section 1902(a)(10)(A)(ii)(XIX) for medical assistance under this title on the basis of failure to pay any such premium until such failure continues for a period of at least 60 days from

the date on which the premium became past due. The State may waive payment of any such premium in any case where the State determines that requiring such payment would create an undue hardship.

(j) NO PREMIUMS OR COST SHARING FOR INDIANS FURNISHED ITEMS OR SERVICES DIRECTLY BY INDIAN HEALTH PROGRAMS OR THROUGH REFERRAL UNDER CONTRACT HEALTH SERVICES.—

(1) NO COST SHARING FOR ITEMS OR SERVICES FURNISHED TO INDIANS THROUGH INDIAN HEALTH PROGRAMS.—

(A) IN GENERAL.—No enrollment fee, premium, or similar charge, and no deduction, copayment, cost sharing, or similar charge shall be imposed against an Indian who is furnished an item or service directly by the Indian Health Service, an Indian Tribe, Tribal Organization, or Urban Indian Organization or through referral under contract health services for which payment may be made under this title.

(B) NO REDUCTION IN AMOUNT OF PAYMENT TO INDIAN HEALTH PROVIDERS.—Payment due under this title to the Indian Health Service, an Indian Tribe, Tribal Organization, or Urban Indian Organization, or a health care provider through referral under contract health services for the furnishing of an item or service to an Indian who is eligible for assistance under such title, may not be reduced by the amount of any enrollment fee, premium, or similar charge, or any deduction, copayment, cost sharing, or similar charge that would be due from the Indian but for the operation of subparagraph (A).

(2) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed as restricting the application of any other limitations on the imposition of premiums or cost sharing that may apply to an individual receiving medical assistance under this title who is an Indian.

* * * * *

LIENS, ADJUSTMENTS AND RECOVERIES, AND TRANSFERS OF ASSETS

SEC. 1917. (a)(1) No lien may be imposed against the property of any individual prior to his death on account of medical assistance paid or to be paid on his behalf under the State plan, except—

(A) pursuant to the judgment of a court on account of benefits incorrectly paid on behalf of such individual, or

(B) in the case of the real property of an individual—

(i) who is an inpatient in a nursing facility, intermediate care facility for the mentally retarded, or other medical institution, if such individual is required, as a condition of receiving services in such institution under the State plan, to spend for costs of medical care all but a minimal amount of his income required for personal needs, and

(ii) with respect to whom the State determines, after notice and opportunity for a hearing (in accordance with procedures established by the State), that he cannot reasonably be expected to be discharged from the medical institution and to return home,

except as provided in paragraph (2).

(2) No lien may be imposed under paragraph (1)(B) on such individual's home if—

(A) the spouse of such individual,

(B) such individual's child who is under age 21, or (with respect to States eligible to participate in the State program established under title XVI) is blind or permanently and totally disabled, or (with respect to States which are not eligible to participate in such program) is blind or disabled as defined in section 1614, or

(C) a sibling of such individual (who has an equity interest in such home and who was residing in such individual's home for a period of at least one year immediately before the date of the individual's admission to the medical institution),
is lawfully residing in such home.

(3) Any lien imposed with respect to an individual pursuant to paragraph (1)(B) shall dissolve upon that individual's discharge from the medical institution and return home.

(b)(1) No adjustment or recovery of any medical assistance correctly paid on behalf of an individual under the State plan may be made, except that the State shall seek adjustment or recovery of any medical assistance correctly paid on behalf of an individual under the State plan in the case of the following individuals:

(A) In the case of an individual described in subsection (a)(1)(B), the State shall seek adjustment or recovery from the individual's estate or upon sale of the property subject to a lien imposed on account of medical assistance paid on behalf of the individual.

(B) In the case of an individual who was 55 years of age or older when the individual received such medical assistance, the State shall seek adjustment or recovery from the individual's estate, but only for medical assistance consisting of—

(i) nursing facility services, home and community-based services, and related hospital and prescription drug services, or

(ii) at the option of the State, any items or services under the State plan (but not including medical assistance for medicare cost-sharing or for benefits described in section 1902(a)(10)(E)).

(C)(i) In the case of an individual who has received (or is entitled to receive) benefits under a long-term care insurance policy in connection with which assets or resources are disregarded in the manner described in clause (ii), except as provided in such clause, the State shall seek adjustment or recovery from the individual's estate on account of medical assistance paid on behalf of the individual for nursing facility and other long-term care services.

(ii) Clause (i) shall not apply in the case of an individual who received medical assistance under a State plan of a State which had a State plan amendment approved as of May 14, 1993, and which satisfies clause (iv), or which has a State plan amendment that provides for a qualified State long-term care insurance partnership (as defined in clause (iii)) which provided for the disregard of any assets or resources—

(I) to the extent that payments are made under a long-term care insurance policy; or

(II) because an individual has received (or is entitled to receive) benefits under a long-term care insurance policy.

(iii) For purposes of this paragraph, the term “qualified State long-term care insurance partnership” means an approved State plan amendment under this title that provides for the disregard of any assets or resources in an amount equal to the insurance benefit payments that are made to or on behalf of an individual who is a beneficiary under a long-term care insurance policy if the following requirements are met:

(I) The policy covers an insured who was a resident of such State when coverage first became effective under the policy.

(II) The policy is a qualified long-term care insurance policy (as defined in section 7702B(b) of the Internal Revenue Code of 1986) issued not earlier than the effective date of the State plan amendment.

(III) The policy meets the model regulations and the requirements of the model Act specified in paragraph (5).

(IV) If the policy is sold to an individual who—

(aa) has not attained age 61 as of the date of purchase, the policy provides compound annual inflation protection;

(bb) has attained age 61 but has not attained age 76 as of such date, the policy provides some level of inflation protection; and

(cc) has attained age 76 as of such date, the policy may (but is not required to) provide some level of inflation protection.

(V) The State Medicaid agency under section 1902(a)(5) provides information and technical assistance to the State insurance department on the insurance department’s role of assuring that any individual who sells a long-term care insurance policy under the partnership receives training and demonstrates evidence of an understanding of such policies and how they relate to other public and private coverage of long-term care.

(VI) The issuer of the policy provides regular reports to the Secretary, in accordance with regulations of the Secretary, that include notification regarding when benefits provided under the policy have been paid and the amount of such benefits paid, notification regarding when the policy otherwise terminates, and such other information as the Secretary determines may be appropriate to the administration of such partnerships.

(VII) The State does not impose any requirement affecting the terms or benefits of such a policy unless the State imposes such requirement on long-term care insurance policies without regard to whether the policy is covered under the partnership or is offered in connection with such a partnership.

In the case of a long-term care insurance policy which is exchanged for another such policy, subclause (I) shall be applied based on the coverage of the first such policy that was exchanged. For purposes of this clause and paragraph (5), the

term “long-term care insurance policy” includes a certificate issued under a group insurance contract.

(iv) With respect to a State which had a State plan amendment approved as of May 14, 1993, such a State satisfies this clause for purposes of clause (ii) if the Secretary determines that the State plan amendment provides for consumer protection standards which are no less stringent than the consumer protection standards which applied under such State plan amendment as of December 31, 2005.

(v) The regulations of the Secretary required under clause (iii)(VI) shall be promulgated after consultation with the National Association of Insurance Commissioners, issuers of long-term care insurance policies, States with experience with long-term care insurance partnership plans, other States, and representatives of consumers of long-term care insurance policies, and shall specify the type and format of the data and information to be reported and the frequency with which such reports are to be made. The Secretary, as appropriate, shall provide copies of the reports provided in accordance with that clause to the State involved.

(vi) The Secretary, in consultation with other appropriate Federal agencies, issuers of long-term care insurance, the National Association of Insurance Commissioners, State insurance commissioners, States with experience with long-term care insurance partnership plans, other States, and representatives of consumers of long-term care insurance policies, shall develop recommendations for Congress to authorize and fund a uniform minimum data set to be reported electronically by all issuers of long-term care insurance policies under qualified State long-term care insurance partnerships to a secure, centralized electronic query and report-generating mechanism that the State, the Secretary, and other Federal agencies can access.

(2) Any adjustment or recovery under paragraph (1) may be made only after the death of the individual’s surviving spouse, if any, and only at a time—

(A) when he has no surviving child who is under age 21, or (with respect to States eligible to participate in the State program established under title XVI) is blind or permanently and totally disabled, or (with respect to States which are not eligible to participate in such program) is blind or disabled as defined in section 1614; and

(B) in the case of a lien on an individual’s home under subsection (a)(1)(B), when—

(i) no sibling of the individual (who was residing in the individual’s home for a period of at least one year immediately before the date of the individual’s admission to the medical institution), and

(ii) no son or daughter of the individual (who was residing in the individual’s home for a period of at least two years immediately before the date of the individual’s admission to the medical institution, and who establishes to the satisfaction of the State that he or she provided care to such individual which permitted such individual to reside at home rather than in an institution),

is lawfully residing in such home who has lawfully resided in such home on a continuous basis since the date of the individual's admission to the medical institution.

(3)(A) The State agency shall establish procedures (in accordance with standards specified by the Secretary) under which the agency shall waive the application of this subsection (other than paragraph (1)(C)) if such application would work an undue hardship as determined on the basis of criteria established by the Secretary.

(B) The standards specified by the Secretary under subparagraph (A) shall require that the procedures established by the State agency under subparagraph (A) exempt income, resources, and property that are exempt from the application of this subsection as of April 1, 2003, under manual instructions issued to carry out this subsection (as in effect on such date) because of the Federal responsibility for Indian Tribes and Alaska Native Villages. Nothing in this subparagraph shall be construed as preventing the Secretary from providing additional estate recovery exemptions under this title for Indians.

(4) For purposes of this subsection, the term "estate", with respect to a deceased individual—

(A) shall include all real and personal property and other assets included within the individual's estate, as defined for purposes of State probate law; and

(B) may include, at the option of the State (and shall include, in the case of an individual to whom paragraph (1)(C)(i) applies), any other real and personal property and other assets in which the individual had any legal title or interest at the time of death (to the extent of such interest), including such assets conveyed to a survivor, heir, or assign of the deceased individual through joint tenancy, tenancy in common, survivorship, life estate, living trust, or other arrangement.

(5)(A) For purposes of clause (iii)(III), the model regulations and the requirements of the model Act specified in this paragraph are:

(i) In the case of the model regulation, the following requirements:

(I) Section 6A (relating to guaranteed renewal or noncancellability), other than paragraph (5) thereof, and the requirements of section 6B of the model Act relating to such section 6A.

(II) Section 6B (relating to prohibitions on limitations and exclusions) other than paragraph (7) thereof.

(III) Section 6C (relating to extension of benefits).

(IV) Section 6D (relating to continuation or conversion of coverage).

(V) Section 6E (relating to discontinuance and replacement of policies).

(VI) Section 7 (relating to unintentional lapse).

(VII) Section 8 (relating to disclosure), other than sections 8F, 8G, 8H, and 8I thereof.

(VIII) Section 9 (relating to required disclosure of rating practices to consumer).

(IX) Section 11 (relating to prohibitions against post-claims underwriting).

(X) Section 12 (relating to minimum standards).

- (XI) Section 14 (relating to application forms and replacement coverage).
- (XII) Section 15 (relating to reporting requirements).
- (XIII) Section 22 (relating to filing requirements for marketing).
- (XIV) Section 23 (relating to standards for marketing), including inaccurate completion of medical histories, other than paragraphs (1), (6), and (9) of section 23C.
- (XV) Section 24 (relating to suitability).
- (XVI) Section 25 (relating to prohibition against pre-existing conditions and probationary periods in replacement policies or certificates).
- (XVII) The provisions of section 26 relating to contingent nonforfeiture benefits, if the policyholder declines the offer of a nonforfeiture provision described in paragraph (4).
- (XVIII) Section 29 (relating to standard format outline of coverage).
- (XIX) Section 30 (relating to requirement to deliver shopper's guide).
- (ii) In the case of the model Act, the following:
 - (I) Section 6C (relating to preexisting conditions).
 - (II) Section 6D (relating to prior hospitalization).
 - (III) The provisions of section 8 relating to contingent nonforfeiture benefits.
 - (IV) Section 6F (relating to right to return).
 - (V) Section 6G (relating to outline of coverage).
 - (VI) Section 6H (relating to requirements for certificates under group plans).
 - (VII) Section 6J (relating to policy summary).
 - (VIII) Section 6K (relating to monthly reports on accelerated death benefits).
 - (IX) Section 7 (relating to incontestability period).
- (B) For purposes of this paragraph and paragraph (1)(C)—
 - (i) the terms “model regulation” and “model Act” mean the long-term care insurance model regulation, and the long-term care insurance model Act, respectively, promulgated by the National Association of Insurance Commissioners (as adopted as of October 2000);
 - (ii) any provision of the model regulation or model Act listed under subparagraph (A) shall be treated as including any other provision of such regulation or Act necessary to implement the provision; and
 - (iii) with respect to a long-term care insurance policy issued in a State, the policy shall be deemed to meet applicable requirements of the model regulation or the model Act if the State plan amendment under paragraph (1)(C)(iii) provides that the State insurance commissioner for the State certifies (in a manner satisfactory to the Secretary) that the policy meets such requirements.
- (C) Not later than 12 months after the National Association of Insurance Commissioners issues a revision, update, or other modification of a model regulation or model Act provision specified in subparagraph (A), or of any provision of such regulation or Act that is substantively related to a provision specified in such subparagraph, the Secretary shall review the changes made to the provi-

sion, determine whether incorporating such changes into the corresponding provision specified in such subparagraph would improve qualified State long-term care insurance partnerships, and if so, shall incorporate the changes into such provision.

(c)(1)(A) In order to meet the requirements of this subsection for purposes of section 1902(a)(18), the State plan must provide that if an institutionalized individual or the spouse of such an individual (or, at the option of a State, a noninstitutionalized individual or the spouse of such an individual) disposes of assets for less than fair market value on or after the look-back date specified in subparagraph (B)(i), the individual is ineligible for medical assistance for services described in subparagraph (C)(i) (or, in the case of a noninstitutionalized individual, for the services described in subparagraph (C)(ii)) during the period beginning on the date specified in subparagraph (D) and equal to the number of months specified in subparagraph (E).

(B)(i) The look-back date specified in this subparagraph is a date that is 36 months (or, in the case of payments from a trust or portions of a trust that are treated as assets disposed of by the individual pursuant to paragraph (3)(A)(iii) or (3)(B)(ii) of subsection (d) or in the case of any other disposal of assets made on or after the date of the enactment of the Deficit Reduction Act of 2005, 60 months) before the date specified in clause (ii).

(ii) The date specified in this clause, with respect to—

(I) an institutionalized individual is the first date as of which the individual both is an institutionalized individual and has applied for medical assistance under the State plan, or

(II) a noninstitutionalized individual is the date on which the individual applies for medical assistance under the State plan or, if later, the date on which the individual disposes of assets for less than fair market value.

(C)(i) The services described in this subparagraph with respect to an institutionalized individual are the following:

(I) Nursing facility services.

(II) A level of care in any institution equivalent to that of nursing facility services.

(III) Home or community-based services furnished under a waiver granted under subsection (c) or (d) of section 1915.

(ii) The services described in this subparagraph with respect to a noninstitutionalized individual are services (not including any services described in clause (i)) that are described in paragraph (7), (22), or (24) of section 1905(a), and, at the option of a State, other long-term care services for which medical assistance is otherwise available under the State plan to individuals requiring long-term care.

(D)(i) In the case of a transfer of asset made before the date of the enactment of the Deficit Reduction Act of 2005, the date specified in this subparagraph is the first day of the first month during or after which assets have been transferred for less than fair market value and which does not occur in any other periods of ineligibility under this subsection.

(ii) In the case of a transfer of asset made on or after the date of the enactment of the Deficit Reduction Act of 2005, the date specified in this subparagraph is the first day of a month during or after which assets have been transferred for less than fair mar-

ket value, or the date on which the individual is eligible for medical assistance under the State plan and would otherwise be receiving institutional level care described in subparagraph (C) based on an approved application for such care but for the application of the penalty period, whichever is later, and which does not occur during any other period of ineligibility under this subsection.

(E)(i) With respect to an institutionalized individual, the number of months of ineligibility under this subparagraph for an individual shall be equal to—

(I) the total, cumulative uncompensated value of all assets transferred by the individual (or individual's spouse) on or after the look-back date specified in subparagraph (B)(i), divided by

(II) the average monthly cost to a private patient of nursing facility services in the State (or, at the option of the State, in the community in which the individual is institutionalized) at the time of application.

(ii) With respect to a noninstitutionalized individual, the number of months of ineligibility under this subparagraph for an individual shall not be greater than a number equal to—

(I) the total, cumulative uncompensated value of all assets transferred by the individual (or individual's spouse) on or after the look-back date specified in subparagraph (B)(i), divided by

(II) the average monthly cost to a private patient of nursing facility services in the State (or, at the option of the State, in the community in which the individual is institutionalized) at the time of application.

(iii) The number of months of ineligibility otherwise determined under clause (i) or (ii) with respect to the disposal of an asset shall be reduced—

(I) in the case of periods of ineligibility determined under clause (i), by the number of months of ineligibility applicable to the individual under clause (ii) as a result of such disposal, and

(II) in the case of periods of ineligibility determined under clause (ii), by the number of months of ineligibility applicable to the individual under clause (i) as a result of such disposal.

(iv) A State shall not round down, or otherwise disregard any fractional period of ineligibility determined under clause (i) or (ii) with respect to the disposal of assets.

(F) For purposes of this paragraph, the purchase of an annuity shall be treated as the disposal of an asset for less than fair market value unless—

(i) the State is named as the remainder beneficiary in the first position for at least the total amount of medical assistance paid on behalf of the institutionalized individual under this title; or

(ii) the State is named as such a beneficiary in the second position after the community spouse or minor or disabled child and is named in the first position if such spouse or a representative of such child disposes of any such remainder for less than fair market value.

(G) For purposes of this paragraph with respect to a transfer of assets, the term “assets” includes an annuity purchased by or on

behalf of an annuitant who has applied for medical assistance with respect to nursing facility services or other long-term care services under this title unless—

(i) the annuity is—

(I) an annuity described in subsection (b) or (q) of section 408 of the Internal Revenue Code of 1986; or

(II) purchased with proceeds from—

(aa) an account or trust described in subsection (a), (c), or (p) of section 408 of such Code;

(bb) a simplified employee pension (within the meaning of section 408(k) of such Code); or

(cc) a Roth IRA described in section 408A of such Code; or

(ii) the annuity—

(I) is irrevocable and nonassignable;

(II) is actuarially sound (as determined in accordance with actuarial publications of the Office of the Chief Actuary of the Social Security Administration); and

(III) provides for payments in equal amounts during the term of the annuity, with no deferral and no balloon payments made.

(H) Notwithstanding the preceding provisions of this paragraph, in the case of an individual (or individual's spouse) who makes multiple fractional transfers of assets in more than 1 month for less than fair market value on or after the applicable look-back date specified in subparagraph (B), a State may determine the period of ineligibility applicable to such individual under this paragraph by—

(i) treating the total, cumulative uncompensated value of all assets transferred by the individual (or individual's spouse) during all months on or after the look-back date specified in subparagraph (B) as 1 transfer for purposes of clause (i) or (ii) (as the case may be) of subparagraph (E); and

(ii) beginning such period on the earliest date which would apply under subparagraph (D) to any of such transfers.

(I) For purposes of this paragraph with respect to a transfer of assets, the term “assets” includes funds used to purchase a promissory note, loan, or mortgage unless such note, loan, or mortgage—

(i) has a repayment term that is actuarially sound (as determined in accordance with actuarial publications of the Office of the Chief Actuary of the Social Security Administration);

(ii) provides for payments to be made in equal amounts during the term of the loan, with no deferral and no balloon payments made; and

(iii) prohibits the cancellation of the balance upon the death of the lender.

In the case of a promissory note, loan, or mortgage that does not satisfy the requirements of clauses (i) through (iii), the value of such note, loan, or mortgage shall be the outstanding balance due as of the date of the individual's application for medical assistance for services described in subparagraph (C).

(J) For purposes of this paragraph with respect to a transfer of assets, the term “assets” includes the purchase of a life estate interest in another individual's home unless the purchaser resides in

the home for a period of at least 1 year after the date of the purchase.

(2) An individual shall not be ineligible for medical assistance by reason of paragraph (1) to the extent that—

(A) the assets transferred were a home and title to the home was transferred to—

(i) the spouse of such individual;

(ii) a child of such individual who (I) is under age 21, or (II) (with respect to States eligible to participate in the State program established under title XVI) is blind or permanently and totally disabled, or (with respect to States which are not eligible to participate in such program) is blind or disabled as defined in section 1614;

(iii) a sibling of such individual who has an equity interest in such home and who was residing in such individual's home for a period of at least one year immediately before the date the individual becomes an institutionalized individual; or

(iv) a son or daughter of such individual (other than a child described in clause (ii)) who was residing in such individual's home for a period of at least two years immediately before the date the individual becomes an institutionalized individual, and who (as determined by the State) provided care to such individual which permitted such individual to reside at home rather than in such an institution or facility;

(B) the assets—

(i) were transferred to the individual's spouse or to another for the sole benefit of the individual's spouse,

(ii) were transferred from the individual's spouse to another for the sole benefit of the individual's spouse,

(iii) were transferred to, or to a trust (including a trust described in subsection (d)(4)) established solely for the benefit of, the individual's child described in subparagraph (A)(ii)(II), or

(iv) were transferred to a trust (including a trust described in subsection (d)(4)) established solely for the benefit of an individual under 65 years of age who is disabled (as defined in section 1614(a)(3));

(C) a satisfactory showing is made to the State (in accordance with regulations promulgated by the Secretary) that (i) the individual intended to dispose of the assets either at fair market value, or for other valuable consideration, (ii) the assets were transferred exclusively for a purpose other than to qualify for medical assistance, or (iii) all assets transferred for less than fair market value have been returned to the individual; or

(D) the State determines, under procedures established by the State (in accordance with standards specified by the Secretary), that the denial of eligibility would work an undue hardship as determined on the basis of criteria established by the Secretary.

The procedures established under subparagraph (D) shall permit the facility in which the institutionalized individual is residing to file an undue hardship waiver application on behalf

of the individual with the consent of the individual or the personal representative of the individual. While an application for an undue hardship waiver is pending under subparagraph (D) in the case of an individual who is a resident of a nursing facility, if the application meets such criteria as the Secretary specifies, the State may provide for payments for nursing facility services in order to hold the bed for the individual at the facility, but not in excess of payments for 30 days.

(3) For purposes of this subsection, in the case of an asset held by an individual in common with another person or persons in a joint tenancy, tenancy in common, or similar arrangement, the asset (or the affected portion of such asset) shall be considered to be transferred by such individual when any action is taken, either by such individual or by any other person, that reduces or eliminates such individual's ownership or control of such asset.

(4) A State (including a State which has elected treatment under section 1902(f)) may not provide for any period of ineligibility for an individual due to transfer of resources for less than fair market value except in accordance with this subsection. In the case of a transfer by the spouse of an individual which results in a period of ineligibility for medical assistance under a State plan for such individual, a State shall, using a reasonable methodology (as specified by the Secretary), apportion such period of ineligibility (or any portion of such period) among the individual and the individual's spouse if the spouse otherwise becomes eligible for medical assistance under the State plan.

(5) In this subsection, the term "resources" has the meaning given such term in section 1613, without regard to the exclusion described in subsection (a)(1) thereof.

(d)(1) For purposes of determining an individual's eligibility for, or amount of, benefits under a State plan under this title, subject to paragraph (4), the rules specified in paragraph (3) shall apply to a trust established by such individual.

(2)(A) For purposes of this subsection, an individual shall be considered to have established a trust if assets of the individual were used to form all or part of the corpus of the trust and if any of the following individuals established such trust other than by will:

(i) The individual.

(ii) The individual's spouse.

(iii) A person, including a court or administrative body, with legal authority to act in place of or on behalf of the individual or the individual's spouse.

(iv) A person, including any court or administrative body, acting at the direction or upon the request of the individual or the individual's spouse.

(B) In the case of a trust the corpus of which includes assets of an individual (as determined under subparagraph (A)) and assets of any other person or persons, the provisions of this subsection shall apply to the portion of the trust attributable to the assets of the individual.

(C) Subject to paragraph (4), this subsection shall apply without regard to—

(i) the purposes for which a trust is established,

(ii) whether the trustees have or exercise any discretion under the trust,

(iii) any restrictions on when or whether distributions may be made from the trust, or

(iv) any restrictions on the use of distributions from the trust.

(3)(A) In the case of a revocable trust—

(i) the corpus of the trust shall be considered resources available to the individual,

(ii) payments from the trust to or for the benefit of the individual shall be considered income of the individual, and

(iii) any other payments from the trust shall be considered assets disposed of by the individual for purposes of subsection (c).

(B) In the case of an irrevocable trust—

(i) if there are any circumstances under which payment from the trust could be made to or for the benefit of the individual, the portion of the corpus from which, or the income on the corpus from which, payment to the individual could be made shall be considered resources available to the individual, and payments from that portion of the corpus or income—

(I) to or for the benefit of the individual, shall be considered income of the individual, and

(II) for any other purpose, shall be considered a transfer of assets by the individual subject to subsection (c); and

(ii) any portion of the trust from which, or any income on the corpus from which, no payment could under any circumstances be made to the individual shall be considered, as of the date of establishment of the trust (or, if later, the date on which payment to the individual was foreclosed) to be assets disposed by the individual for purposes of subsection (c), and the value of the trust shall be determined for purposes of such subsection by including the amount of any payments made from such portion of the trust after such date.

(4) This subsection shall not apply to any of the following trusts:

(A) A trust containing the assets of an individual under age 65 who is disabled (as defined in section 1614(a)(3)) and which is established for the benefit of such individual by *the individual*, a parent, grandparent, legal guardian of the individual, or a court if the State will receive all amounts remaining in the trust upon the death of such individual up to an amount equal to the total medical assistance paid on behalf of the individual under a State plan under this title.

(B) A trust established in a State for the benefit of an individual if—

(i) the trust is composed only of pension, Social Security, and other income to the individual (and accumulated income in the trust),

(ii) the State will receive all amounts remaining in the trust upon the death of such individual up to an amount equal to the total medical assistance paid on behalf of the individual under a State plan under this title, and

(iii) the State makes medical assistance available to individuals described in section 1902(a)(10)(A)(ii)(V), but does not make such assistance available to individuals for nursing facility services under section 1902(a)(10)(C).

(C) A trust containing the assets of an individual who is disabled (as defined in section 1614(a)(3)) that meets the following conditions:

(i) The trust is established and managed by a nonprofit association.

(ii) A separate account is maintained for each beneficiary of the trust, but, for purposes of investment and management of funds, the trust pools these accounts.

(iii) Accounts in the trust are established solely for the benefit of individuals who are disabled (as defined in section 1614(a)(3)) by the parent, grandparent, or legal guardian of such individuals, by such individuals, or by a court.

(iv) To the extent that amounts remaining in the beneficiary's account upon the death of the beneficiary are not retained by the trust, the trust pays to the State from such remaining amounts in the account an amount equal to the total amount of medical assistance paid on behalf of the beneficiary under the State plan under this title.

(5) The State agency shall establish procedures (in accordance with standards specified by the Secretary) under which the agency waives the application of this subsection with respect to an individual if the individual establishes that such application would work an undue hardship on the individual as determined on the basis of criteria established by the Secretary.

(6) The term "trust" includes any legal instrument or device that is similar to a trust but includes an annuity only to such extent and in such manner as the Secretary specifies.

(e)(1) In order to meet the requirements of this section for purposes of section 1902(a)(18), a State shall require, as a condition for the provision of medical assistance for services described in subsection (c)(1)(C)(i) (relating to long-term care services) for an individual, the application of the individual for such assistance (including any recertification of eligibility for such assistance) shall disclose a description of any interest the individual or community spouse has in an annuity (or similar financial instrument, as may be specified by the Secretary), regardless of whether the annuity is irrevocable or is treated as an asset. Such application or recertification form shall include a statement that under paragraph (2) the State becomes a remainder beneficiary under such an annuity or similar financial instrument by virtue of the provision of such medical assistance.

(2)(A) In the case of disclosure concerning an annuity under subsection (c)(1)(F), the State shall notify the issuer of the annuity of the right of the State under such subsection as a preferred remainder beneficiary in the annuity for medical assistance furnished to the individual. Nothing in this paragraph shall be construed as preventing such an issuer from notifying persons with any other remainder interest of the State's remainder interest under such subsection.

(B) In the case of such an issuer receiving notice under subparagraph (A), the State may require the issuer to notify the State when there is a change in the amount of income or principal being withdrawn from the amount that was being withdrawn at the time of the most recent disclosure described in paragraph (1). A State shall take such information into account in determining the

amount of the State's obligations for medical assistance or in the individual's eligibility for such assistance.

(3) The Secretary may provide guidance to States on categories of transactions that may be treated as a transfer of asset for less than fair market value.

(4) Nothing in this subsection shall be construed as preventing a State from denying eligibility for medical assistance for an individual based on the income or resources derived from an annuity described in paragraph (1).

(f)(1)(A) Notwithstanding any other provision of this title, subject to subparagraphs (B) and (C) of this paragraph and paragraph (2), in determining eligibility of an individual for medical assistance with respect to nursing facility services or other long-term care services, the individual shall not be eligible for such assistance if the individual's equity interest in the individual's home exceeds \$500,000.

(B) A State may elect, without regard to the requirements of section 1902(a)(1) (relating to statewideness) and section 1902(a)(10)(B) (relating to comparability), to apply subparagraph (A) by substituting for "\$500,000", an amount that exceeds such amount, but does not exceed \$750,000.

(C) The dollar amounts specified in this paragraph shall be increased, beginning with 2011, from year to year based on the percentage increase in the consumer price index for all urban consumers (all items; United States city average), rounded to the nearest \$1,000.

(2) Paragraph (1) shall not apply with respect to an individual if—

(A) the spouse of such individual, or

(B) such individual's child who is under age 21, or (with respect to States eligible to participate in the State program established under title XVI) is blind or permanently and totally disabled, or (with respect to States which are not eligible to participate in such program) is blind or disabled as defined in section 1614,

is lawfully residing in the individual's home.

(3) Nothing in this subsection shall be construed as preventing an individual from using a reverse mortgage or home equity loan to reduce the individual's total equity interest in the home.

(4) The Secretary shall establish a process whereby paragraph (1) is waived in the case of a demonstrated hardship.

(g) TREATMENT OF ENTRANCE FEES OF INDIVIDUALS RESIDING IN CONTINUING CARE RETIREMENT COMMUNITIES.—

(1) IN GENERAL.—For purposes of determining an individual's eligibility for, or amount of, benefits under a State plan under this title, the rules specified in paragraph (2) shall apply to individuals residing in continuing care retirement communities or life care communities that collect an entrance fee on admission from such individuals.

(2) TREATMENT OF ENTRANCE FEE.—For purposes of this subsection, an individual's entrance fee in a continuing care retirement community or life care community shall be considered a resource available to the individual to the extent that—

(A) the individual has the ability to use the entrance fee, or the contract provides that the entrance fee may be used,

to pay for care should other resources or income of the individual be insufficient to pay for such care;

(B) the individual is eligible for a refund of any remaining entrance fee when the individual dies or terminates the continuing care retirement community or life care community contract and leaves the community; and

(C) the entrance fee does not confer an ownership interest in the continuing care retirement community or life care community.

(h) In this section, the following definitions shall apply:

(1) The term “assets”, with respect to an individual, includes all income and resources of the individual and of the individual’s spouse, including any income or resources which the individual or such individual’s spouse is entitled to but does not receive because of action—

(A) by the individual or such individual’s spouse,

(B) by a person, including a court or administrative body, with legal authority to act in place of or on behalf of the individual or such individual’s spouse, or

(C) by any person, including any court or administrative body, acting at the direction or upon the request of the individual or such individual’s spouse.

(2) The term “income” has the meaning given such term in section 1612.

(3) The term “institutionalized individual” means an individual who is an inpatient in a nursing facility, who is an inpatient in a medical institution and with respect to whom payment is made based on a level of care provided in a nursing facility, or who is described in section 1902(a)(10)(A)(ii)(VI).

(4) The term “noninstitutionalized individual” means an individual receiving any of the services specified in subsection (c)(1)(C)(ii).

(5) The term “resources” has the meaning given such term in section 1613, without regard (in the case of an institutionalized individual) to the exclusion described in subsection (a)(1) of such section.

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PAYMENT FOR COVERED OUTPATIENT DRUGS

SEC. 1927. (a) REQUIREMENT FOR REBATE AGREEMENT.—

(1) IN GENERAL.—In order for payment to be available under section 1903(a) or under part B of title XVIII for covered outpatient drugs of a manufacturer, the manufacturer must have entered into and have in effect a rebate agreement described in subsection (b) with the Secretary, on behalf of States (except that, the Secretary may authorize a State to enter directly into agreements with a manufacturer), and must meet the requirements of paragraph (5) (with respect to drugs purchased by a covered entity on or after the first day of the first month that begins after the date of the enactment of title VI of the Veterans Health Care Act of 1992) and paragraph (6). Any agreement between a State and a manufacturer prior to April 1, 1991, shall be deemed to have been entered into on January 1, 1991, and payment to such manufacturer shall be retro-

actively calculated as if the agreement between the manufacturer and the State had been entered into on January 1, 1991. If a manufacturer has not entered into such an agreement before March 1, 1991, such an agreement, subsequently entered into, shall become effective as of the date on which the agreement is entered into or, at State option, on any date thereafter on or before the first day of the calendar quarter that begins more than 60 days after the date the agreement is entered into.

(2) EFFECTIVE DATE.—Paragraph (1) shall first apply to drugs dispensed under this title on or after January 1, 1991.

(3) AUTHORIZING PAYMENT FOR DRUGS NOT COVERED UNDER REBATE AGREEMENTS.—Paragraph (1), and section 1903(i)(10)(A), shall not apply to the dispensing of a single source drug or innovator multiple source drug if (A)(i) the State has made a determination that the availability of the drug is essential to the health of beneficiaries under the State plan for medical assistance; (ii) such drug has been given a rating of 1-A by the Food and Drug Administration; and (iii)(I) the physician has obtained approval for use of the drug in advance of its dispensing in accordance with a prior authorization program described in subsection (d), or (II) the Secretary has reviewed and approved the State's determination under subparagraph (A); or (B) the Secretary determines that in the first calendar quarter of 1991, there were extenuating circumstances.

(4) EFFECT ON EXISTING AGREEMENTS.—In the case of a rebate agreement in effect between a State and a manufacturer on the date of the enactment of this section, such agreement, for the initial agreement period specified therein, shall be considered to be a rebate agreement in compliance with this section with respect to that State, if the State agrees to report to the Secretary any rebates paid pursuant to the agreement and such agreement provides for a minimum aggregate rebate of 10 percent of the State's total expenditures under the State plan for coverage of the manufacturer's drugs under this title. If, after the initial agreement period, the State establishes to the satisfaction of the Secretary that an agreement in effect on the date of the enactment of this section provides for rebates that are at least as large as the rebates otherwise required under this section, and the State agrees to report any rebates under the agreement to the Secretary, the agreement shall be considered to be a rebate agreement in compliance with the section for the renewal periods of such agreement.

(5) LIMITATION ON PRICES OF DRUGS PURCHASED BY COVERED ENTITIES.—

(A) AGREEMENT WITH SECRETARY.—A manufacturer meets the requirements of this paragraph if the manufacturer has entered into an agreement with the Secretary that meets the requirements of section 340B of the Public Health Service Act with respect to covered outpatient drugs purchased by a covered entity on or after the first day of the first month that begins after the date of the enactment of this paragraph.

(B) COVERED ENTITY DEFINED.—In this subsection, the term “covered entity” means an entity described in section 340B(a)(4) of the Public Health Service Act.

(C) ESTABLISHMENT OF ALTERNATIVE MECHANISM TO ENSURE AGAINST DUPLICATE DISCOUNTS OR REBATES.—If the Secretary does not establish a mechanism under section 340B(a)(5)(A) of the Public Health Service Act within 12 months of the date of the enactment of such section, the following requirements shall apply:

(i) ENTITIES.—Each covered entity shall inform the single State agency under section 1902(a)(5) when it is seeking reimbursement from the State plan for medical assistance described in section 1905(a)(12) with respect to a unit of any covered outpatient drug which is subject to an agreement under section 340B(a) of such Act.

(ii) STATE AGENCY.—Each such single State agency shall provide a means by which a covered entity shall indicate on any drug reimbursement claims form (or format, where electronic claims management is used) that a unit of the drug that is the subject of the form is subject to an agreement under section 340B of such Act, and not submit to any manufacturer a claim for a rebate payment under subsection (b) with respect to such a drug.

(D) EFFECT OF SUBSEQUENT AMENDMENTS.—In determining whether an agreement under subparagraph (A) meets the requirements of section 340B of the Public Health Service Act, the Secretary shall not take into account any amendments to such section that are enacted after the enactment of title VI of the Veterans Health Care Act of 1992.

(E) DETERMINATION OF COMPLIANCE.—A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 340B of the Public Health Service Act (as in effect immediately after the enactment of this paragraph, and would have entered into an agreement under such section (as such section was in effect at such time), but for a legislative change in such section after the date of the enactment of this paragraph.

(6) REQUIREMENTS RELATING TO MASTER AGREEMENTS FOR DRUGS PROCURED BY DEPARTMENT OF VETERANS AFFAIRS AND CERTAIN OTHER FEDERAL AGENCIES.—

(A) IN GENERAL.—A manufacturer meets the requirements of this paragraph if the manufacturer complies with the provisions of section 8126 of title 38, United States Code, including the requirement of entering into a master agreement with the Secretary of Veterans Affairs under such section.

(B) EFFECT OF SUBSEQUENT AMENDMENTS.—In determining whether a master agreement described in subparagraph (A) meets the requirements of section 8126 of title 38, United States Code, the Secretary shall not

take into account any amendments to such section that are enacted after the enactment of title VI of the Veterans Health Care Act of 1992.

(C) DETERMINATION OF COMPLIANCE.—A manufacturer is deemed to meet the requirements of this paragraph if the manufacturer establishes to the satisfaction of the Secretary that the manufacturer would comply (and has offered to comply) with the provisions of section 8126 of title 38, United States Code (as in effect immediately after the enactment of this paragraph) and would have entered into an agreement under such section (as such section was in effect at such time), but for a legislative change in such section after the date of the enactment of this paragraph.

(7) REQUIREMENT FOR SUBMISSION OF UTILIZATION DATA FOR CERTAIN PHYSICIAN ADMINISTERED DRUGS.—

(A) SINGLE SOURCE DRUGS.—In order for payment to be available under section 1903(a) for a covered outpatient drug that is a single source drug that is physician administered under this title (as determined by the Secretary), and that is administered on or after January 1, 2006, the State shall provide for the collection and submission of such utilization data and coding (such as J-codes and National Drug Code numbers) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates under this section for drugs administered for which payment is made under this title.

(B) MULTIPLE SOURCE DRUGS.—

(i) IDENTIFICATION OF MOST FREQUENTLY PHYSICIAN ADMINISTERED MULTIPLE SOURCE DRUGS.—Not later than January 1, 2007, the Secretary shall publish a list of the 20 physician administered multiple source drugs that the Secretary determines have the highest dollar volume of physician administered drugs dispensed under this title. The Secretary may modify such list from year to year to reflect changes in such volume.

(ii) REQUIREMENT.—In order for payment to be available under section 1903(a) for a covered outpatient drug that is a multiple source drug that is physician administered (as determined by the Secretary), that is on the list published under clause (i), and that is administered on or after January 1, 2008, the State shall provide for the submission of such utilization data and coding (such as J-codes and National Drug Code numbers) for each such drug as the Secretary may specify as necessary to identify the manufacturer of the drug in order to secure rebates under this section.

(C) USE OF NDC CODES.—Not later than January 1, 2007, the information shall be submitted under subparagraphs (A) and (B)(ii) using National Drug Code codes unless the Secretary specifies that an alternative coding system should be used.

(D) **HARDSHIP WAIVER.**—The Secretary may delay the application of subparagraph (A) or (B)(ii), or both, in the case of a State to prevent hardship to States which require additional time to implement the reporting system required under the respective subparagraph.

(b) **TERMS OF REBATE AGREEMENT.**—

(1) **PERIODIC REBATES.**—

(A) **IN GENERAL.**—A rebate agreement under this subsection shall require the manufacturer to provide, to each State plan approved under this title, a rebate for a rebate period in an amount specified in subsection (c) for covered outpatient drugs of the manufacturer dispensed after December 31, 1990, for which payment was made under the State plan for such period, including such drugs dispensed to individuals enrolled with a medicaid managed care organization if the organization is responsible for coverage of such drugs. Such rebate shall be paid by the manufacturer not later than 30 days after the date of receipt of the information described in paragraph (2) for the period involved.

(B) **OFFSET AGAINST MEDICAL ASSISTANCE.**—Amounts received by a State under this section (or under an agreement authorized by the Secretary under subsection (a)(1) or an agreement described in subsection (a)(4)) in any quarter shall be considered to be a reduction in the amount expended under the State plan in the quarter for medical assistance for purposes of section 1903(a)(1).

(C) **SPECIAL RULE FOR INCREASED MINIMUM REBATE PERCENTAGE.**—

(i) **IN GENERAL.**—In addition to the amounts applied as a reduction under subparagraph (B), for rebate periods beginning on or after January 1, 2010, during a fiscal year, the Secretary shall reduce payments to a State under section 1903(a) in the manner specified in clause (ii), in an amount equal to the product of—

(I) 100 percent minus the Federal medical assistance percentage applicable to the rebate period for the State; and

(II) the amounts received by the State under such subparagraph that are attributable (as estimated by the Secretary based on utilization and other data) to the increase in the minimum rebate percentage effected by the amendments made by subsections (a)(1), (b), and (d) of section 2501 of the Patient Protection and Affordable Care Act, taking into account the additional drugs included under the amendments made by subsection (c) of section 2501 of such Act.

The Secretary shall adjust such payment reduction for a calendar quarter to the extent the Secretary determines, based upon subsequent utilization and other data, that the reduction for such quarter was greater or less than the amount of payment reduction that should have been made.

(ii) **MANNER OF PAYMENT REDUCTION.**—The amount of the payment reduction under clause (i) for a State

for a quarter shall be deemed an overpayment to the State under this title to be disallowed against the State's regular quarterly draw for all Medicaid spending under section 1903(d)(2). Such a disallowance is not subject to a reconsideration under section 1116(d).

(2) STATE PROVISION OF INFORMATION.—

(A) STATE RESPONSIBILITY.—Each State agency under this title shall report to each manufacturer not later than 60 days after the end of each rebate period and in a form consistent with a standard reporting format established by the Secretary, information on the total number of units of each dosage form and strength and package size of each covered outpatient drug dispensed after December 31, 1990, for which payment was made under the plan during the period, including such information reported by each medicare managed care organization, and shall promptly transmit a copy of such report to the Secretary.

(B) AUDITS.—A manufacturer may audit the information provided (or required to be provided) under subparagraph (A). Adjustments to rebates shall be made to the extent that information indicates that utilization was greater or less than the amount previously specified.

(3) MANUFACTURER PROVISION OF PRICE INFORMATION.—

(A) IN GENERAL.—Each manufacturer with an agreement in effect under this section shall report to the Secretary—

(i) not later than 30 days after the last day of each rebate period under the agreement—

(I) on the average manufacturer price (as defined in subsection (k)(1)) for covered outpatient drugs for the rebate period under the agreement (including for all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act); and

(II) for single source drugs and innovator multiple source drugs (including all such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), on the manufacturer's best price (as defined in subsection (c)(1)(C)) for such drugs for the rebate period under the agreement;

(ii) not later than 30 days after the date of entering into an agreement under this section on the average manufacturer price (as defined in subsection (k)(1)) as of October 1, 1990 for each of the manufacturer's covered outpatient drugs (including for such drugs that are sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act); and

(iii) for calendar quarters beginning on or after January 1, 2004, in conjunction with reporting required under clause (i) and by National Drug Code (including package size)—

(I) the manufacturer's average sales price (as defined in section 1847A(c)) and the total number of units specified under section 1847A(b)(2)(A);

(II) if required to make payment under section 1847A, 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 1847A(c)(2)(B);

for a drug or biological described in subparagraph (C), (D), (E), or (G) of section 1842(o)(1) or section 1881(b)(13)(A)(ii), and, for calendar quarters beginning on or after January 1, 2007 and only with respect to the information described in subclause (III), for covered outpatient drugs.

(iv) not later than 30 days after the last day of each month of a rebate period under the agreement, on the manufacturer's total number of units that are used to calculate the monthly average manufacturer price for each covered outpatient drug;

Information reported under this subparagraph is subject to audit by the Inspector General of the Department of Health and Human Services. Beginning July 1, 2006, the Secretary shall provide on a monthly basis to States under subparagraph (D)(iv) the most recently reported average manufacturer prices for single source drugs and for multiple source drugs and shall, on at least a quarterly basis, update the information posted on the website under subparagraph (D)(v) (relating to the weighted average of the most recently reported monthly average manufacturer prices).

(B) VERIFICATION SURVEYS OF AVERAGE MANUFACTURER PRICE AND MANUFACTURER'S AVERAGE SALES PRICE.—The Secretary may survey wholesalers and manufacturers that directly distribute their covered outpatient drugs, when necessary, to verify manufacturer prices and manufacturer's average sales prices (including wholesale acquisition cost) if required to make payment reported under subparagraph (A). The Secretary may impose a civil monetary penalty in an amount not to exceed \$100,000 on a wholesaler, manufacturer, or direct seller, if the wholesaler, manufacturer, or direct seller of a covered outpatient drug refuses a request for information about charges or prices by the Secretary in connection with a survey under this subparagraph or knowingly provides false information. The provisions of section 1128A (other than subsections (a) (with respect to amounts of penalties or additional assessments) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(C) PENALTIES.—

(i) FAILURE TO PROVIDE TIMELY INFORMATION.—In the case of a manufacturer with an agreement under this section that fails to provide information required under subparagraph (A) on a timely basis, the amount of the penalty shall be increased by \$10,000 for each day in which such information has not been provided

and such amount shall be paid to the Treasury, and, if such information is not reported within 90 days of the deadline imposed, the agreement shall be suspended for services furnished after the end of such 90-day period and until the date such information is reported (but in no case shall such suspension be for a period of less than 30 days).

(ii) FALSE INFORMATION.—Any manufacturer with an agreement under this section that knowingly provides false information is subject to a civil money penalty in an amount not to exceed \$100,000 for each item of false information. Such civil money penalties are in addition to other penalties as may be prescribed by law. The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil money penalty under this subparagraph in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(D) CONFIDENTIALITY OF INFORMATION.—Notwithstanding any other provision of law, information disclosed by manufacturers or wholesalers under this paragraph or under an agreement with the Secretary of Veterans Affairs described in subsection (a)(6)(A)(ii) (other than the wholesale acquisition cost for purposes of carrying out section 1847A) is confidential and shall not be disclosed by the Secretary or the Secretary of Veterans Affairs or a State agency (or contractor therewith) in a form which discloses the identity of a specific manufacturer or wholesaler, prices charged for drugs by such manufacturer or wholesaler, except—

(i) as the Secretary determines to be necessary to carry out this section, to carry out section 1847A (including the determination and implementation of the payment amount), or to carry out section 1847B,

(ii) to permit the Comptroller General to review the information provided,

(iii) to permit the Director of the Congressional Budget Office to review the information provided,

(iv) to States to carry out this title, and

(v) to the Secretary to disclose (through a website accessible to the public) the weighted average of the most recently reported monthly average manufacturer prices and the average retail survey price determined for each multiple source drug in accordance with subsection (f).

The previous sentence shall also apply to information disclosed under section 1860D–2(d)(2) or 1860D–4(c)(2)(E) and drug pricing data reported under the first sentence of section 1860D–31(i)(1).

(4) LENGTH OF AGREEMENT.—

(A) IN GENERAL.—A rebate agreement shall be effective for an initial period of not less than 1 year and shall be automatically renewed for a period of not less than one year unless terminated under subparagraph (B).

(B) TERMINATION.—

(i) BY THE SECRETARY.—The Secretary may provide for termination of a rebate agreement for violation of the requirements of the agreement or other good cause shown. Such termination shall not be effective earlier than 60 days after the date of notice of such termination. The Secretary shall provide, upon request, a manufacturer with a hearing concerning such a termination, but such hearing shall not delay the effective date of the termination.

(ii) BY A MANUFACTURER.—A manufacturer may terminate a rebate agreement under this section for any reason. Any such termination shall not be effective until the calendar quarter beginning at least 60 days after the date the manufacturer provides notice to the Secretary.

(iii) EFFECTIVENESS OF TERMINATION.—Any termination under this subparagraph shall not affect rebates due under the agreement before the effective date of its termination.

(iv) NOTICE TO STATES.—In the case of a termination under this subparagraph, the Secretary shall provide notice of such termination to the States within not less than 30 days before the effective date of such termination.

(v) APPLICATION TO TERMINATIONS OF OTHER AGREEMENTS.—The provisions of this subparagraph shall apply to the terminations of agreements described in section 340B(a)(1) of the Public Health Service Act and master agreements described in section 8126(a) of title 38, United States Code.

(C) DELAY BEFORE REENTRY.—In the case of any rebate agreement with a manufacturer under this section which is terminated, another such agreement with the manufacturer (or a successor manufacturer) may not be entered into until a period of 1 calendar quarter has elapsed since the date of the termination, unless the Secretary finds good cause for an earlier reinstatement of such an agreement.

(c) DETERMINATION OF AMOUNT OF REBATE.—

(1) BASIC REBATE FOR SINGLE SOURCE DRUGS AND INNOVATOR MULTIPLE SOURCE DRUGS.—

(A) IN GENERAL.—Except as provided in paragraph (2), the amount of the rebate specified in this subsection for a rebate period (as defined in subsection (k)(8)) with respect to each dosage form and strength of a single source drug or an innovator multiple source drug shall be equal to the product of—

(i) the total number of units of each dosage form and strength paid for under the State plan in the rebate period (as reported by the State); and

(ii) subject to subparagraph (B)(ii), the greater of—

(I) the difference between the average manufacturer price and the best price (as defined in subparagraph (C)) for the dosage form and strength of the drug, or

(II) the minimum rebate percentage (specified in subparagraph (B)(i)) of such average manufacturer price,
of or the rebate period.

(B) RANGE OF REBATES REQUIRED.—

(i) MINIMUM REBATE PERCENTAGE.—For purposes of subparagraph (A)(ii)(II), the “minimum rebate percentage” for rebate periods beginning—

(I) after December 31, 1990, and before October 1, 1992, is 12.5 percent;

(II) after September 30, 1992, and before January 1, 1994, is 15.7 percent;

(III) after December 31, 1993, and before January 1, 1995, is 15.4 percent;

(IV) after December 31, 1994, and before January 1, 1996, is 15.2 percent;

(V) after December 31, 1995, and before January 1, 2010 is 15.1 percent; and

(VI) except as provided in clause (iii), after December 31, 2009, 23.1 percent.

(ii) TEMPORARY LIMITATION ON MAXIMUM REBATE AMOUNT.—In no case shall the amount applied under subparagraph (A)(ii) for a rebate period beginning—

(I) before January 1, 1992, exceed 25 percent of the average manufacturer price; or

(II) after December 31, 1991, and before January 1, 1993, exceed 50 percent of the average manufacturer price.

(iii) MINIMUM REBATE PERCENTAGE FOR CERTAIN DRUGS.—

(I) IN GENERAL.—In the case of a single source drug or an innovator multiple source drug described in subclause (II), the minimum rebate percentage for rebate periods specified in clause (i)(VI) is 17.1 percent.

(II) DRUG DESCRIBED.—For purposes of subclause (I), a single source drug or an innovator multiple source drug described in this subclause is any of the following drugs:

(aa) A clotting factor for which a separate furnishing payment is made under section 1842(o)(5) and which is included on a list of such factors specified and updated regularly by the Secretary.

(bb) A drug approved by the Food and Drug Administration exclusively for pediatric indications.

(C) BEST PRICE DEFINED.—For purposes of this section—

(i) IN GENERAL.—The term “best price” means, with respect to a single source drug or innovator multiple source drug of a manufacturer (including the lowest price available to any entity for any such drug of a manufacturer that is sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act), the lowest price avail-

able from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity within the United States, excluding—

(I) any prices charged on or after October 1, 1992, to the Indian Health Service, the Department of Veterans Affairs, a State home receiving funds under section 1741 of title 38, United States Code, the Department of Defense, the Public Health Service, or a covered entity described in subsection (a)(5)(B) (including inpatient prices charged to hospitals described in section 340B(a)(4)(L) of the Public Health Service Act);

(II) any prices charged under the Federal Supply Schedule of the General Services Administration;

(III) any prices used under a State pharmaceutical assistance program;

(IV) any depot prices and single award contract prices, as defined by the Secretary, of any agency of the Federal Government;

(V) the prices negotiated from drug manufacturers for covered discount card drugs under an endorsed discount card program under section 1860D-31; and

(VI) any prices charged which are negotiated by a prescription drug plan under part D of title XVIII, by an MA-PD plan under part C of such title with respect to covered part D drugs or by a qualified retiree prescription drug plan (as defined in section 1860D-22(a)(2)) with respect to such drugs on behalf of individuals entitled to benefits under part A or enrolled under part B of such title, or any discounts provided by manufacturers under the Medicare coverage gap discount program under section 1860D-14A.

(ii) SPECIAL RULES.—The term “best price”—

(I) shall be inclusive of cash discounts, free goods that are contingent on any purchase requirement, volume discounts, and rebates (other than rebates under this section);

(II) shall be determined without regard to special packaging, labeling, or identifiers on the dosage form or product or package;

(III) shall not take into account prices that are merely nominal in amount; and

(IV) in the case of a manufacturer that approves, allows, or otherwise permits any other drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, shall be inclusive of the lowest price for such authorized drug available from the manufacturer during the rebate period to any manufacturer, wholesaler, retailer, provider, health maintenance organization, nonprofit entity, or governmental entity

within the United States, excluding those prices described in subclauses (I) through (IV) of clause (i).

(iii) APPLICATION OF AUDITING AND RECORDKEEPING REQUIREMENTS.—With respect to a covered entity described in section 340B(a)(4)(L) of the Public Health Service Act, any drug purchased for inpatient use shall be subject to the auditing and recordkeeping requirements described in section 340B(a)(5)(C) of the Public Health Service Act.

(D) LIMITATION ON SALES AT A NOMINAL PRICE.—

(i) IN GENERAL.—For purposes of subparagraph (C)(ii)(III) and subsection (b)(3)(A)(iii)(III), only sales by a manufacturer of covered outpatient drugs at nominal prices to the following shall be considered to be sales at a nominal price or merely nominal in amount:

(I) A covered entity described in section 340B(a)(4) of the Public Health Service Act.

(II) An intermediate care facility for the mentally retarded.

(III) A State-owned or operated nursing facility.

(IV) An entity that—

(aa) is described in section 501(c)(3) of the Internal Revenue Code of 1986 and exempt from tax under section 501(a) of such Act or is State-owned or operated; and

(bb) would be a covered entity described in section 340B(a)(4) of the Public Health Service Act insofar as the entity provides the same type of services to the same type of populations as a covered entity described in such section provides, but does not receive funding under a provision of law referred to in such section;

(V) A public or nonprofit entity, or an entity based at an institution of higher learning whose primary purpose is to provide health care services to students of that institution, that provides a service or services described under section 1001(a) of the Public Health Service Act, 42 U.S.C. 300.

(VI) Any other facility or entity that the Secretary determines is a safety net provider to which sales of such drugs at a nominal price would be appropriate based on the factors described in clause (ii).

(ii) FACTORS.—The factors described in this clause with respect to a facility or entity are the following:

(I) The type of facility or entity.

(II) The services provided by the facility or entity.

(III) The patient population served by the facility or entity.

(IV) The number of other facilities or entities eligible to purchase at nominal prices in the same service area.

(iii) NONAPPLICATION.—Clause (i) shall not apply with respect to sales by a manufacturer at a nominal price of covered outpatient drugs pursuant to a master agreement under section 8126 of title 38, United States Code.

(iv) RULE OF CONSTRUCTION.—Nothing in this subparagraph shall be construed to alter any existing statutory or regulatory prohibition on services with respect to an entity described in clause (i)(IV), including the prohibition set forth in section 1008 of the Public Health Service Act.

(2) ADDITIONAL REBATE FOR SINGLE SOURCE AND INNOVATOR MULTIPLE SOURCE DRUGS.—

(A) IN GENERAL.—The amount of the rebate specified in this subsection for a rebate period, with respect to each dosage form and strength of a single source drug or an innovator multiple source drug, shall be increased by an amount equal to the product of—

(i) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period; and

(ii) the amount (if any) by which—

(I) the average manufacturer price for the dosage form and strength of the drug for the period, exceeds

(II) the average manufacturer price for such dosage form and strength for the calendar quarter beginning July 1, 1990 (without regard to whether or not the drug has been sold or transferred to an entity, including a division or subsidiary of the manufacturer, after the first day of such quarter), increased by the percentage by which the consumer price index for all urban consumers (United States city average) for the month before the month in which the rebate period begins exceeds such index for September 1990.

(B) TREATMENT OF SUBSEQUENTLY APPROVED DRUGS.—In the case of a covered outpatient drug approved by the Food and Drug Administration after October 1, 1990, clause (ii)(II) of subparagraph (A) shall be applied by substituting “the first full calendar quarter after the day on which the drug was first marketed” for “the calendar quarter beginning July 1, 1990” and “the month prior to the first month of the first full calendar quarter after the day on which the drug was first marketed” for “September 1990”.

(C) TREATMENT OF NEW FORMULATIONS.—In the case of a drug that is a line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form, the rebate obligation with respect to such drug under this section shall be the amount computed under this section for such new drug or, if greater, the product of—

(i) the average manufacturer price of the line extension of a single source drug or an innovator multiple source drug that is an oral solid dosage form;

(ii) the highest additional rebate (calculated as a percentage of average manufacturer price) under this section for any strength of the original single source drug or innovator multiple source drug; and

(iii) the total number of units of each dosage form and strength of the line extension product paid for under the State plan in the rebate period (as reported by the State).

In this subparagraph, the term “line extension” means, with respect to a drug, a new formulation of the drug, such as an extended release formulation.

(D) MAXIMUM REBATE AMOUNT.—In no case shall the sum of the amounts applied under paragraph (1)(A)(ii) and this paragraph with respect to each dosage form and strength of a single source drug or an innovator multiple source drug for a rebate period beginning after December 31, 2009, exceed 100 percent of the average manufacturer price of the drug.

(3) REBATE FOR OTHER DRUGS.—

(A) IN GENERAL.—Except as provided in subparagraph (C), the amount of the rebate paid to a State for a rebate period with respect to each dosage form and strength of covered outpatient drugs (other than single source drugs and innovator multiple source drugs) shall be equal to the product of—

(i) the applicable percentage (as described in subparagraph (B)) of the average manufacturer price for the dosage form and strength for the rebate period, and

(ii) the total number of units of such dosage form and strength dispensed after December 31, 1990, for which payment was made under the State plan for the rebate period.

(B) APPLICABLE PERCENTAGE DEFINED.—For purposes of subparagraph (A)(i), the “applicable percentage” for rebate periods beginning—

(i) before January 1, 1994, is 10 percent,

(ii) after December 31, 1993, and before January 1, 2010, is 11 percent; and

(iii) after December 31, 2009, is 13 percent.

(C) ADDITIONAL REBATE.—

(i) IN GENERAL.—The amount of the rebate specified in this paragraph for a rebate period, with respect to each dosage form and strength of a covered outpatient drug other than a single source drug or an innovator multiple source drug of a manufacturer, shall be increased in the manner that the rebate for a dosage form and strength of a single source drug or an innovator multiple source drug is increased under subparagraphs (A) and (D) of paragraph (2), except as provided in clause (ii).

(ii) SPECIAL RULES FOR APPLICATION OF PROVISION.—In applying subparagraphs (A) and (D) of paragraph (2) under clause (i)—

(I) the reference in subparagraph (A)(i) of such paragraph to “1990” shall be deemed a reference to “2014”;

(II) subject to clause (iii), the reference in subparagraph (A)(ii) of such paragraph to “the calendar quarter beginning July 1, 1990” shall be deemed a reference to “the calendar quarter beginning July 1, 2014”; and

(III) subject to clause (iii), the reference in subparagraph (A)(ii) of such paragraph to “September 1990” shall be deemed a reference to “September 2014”;

(IV) the references in subparagraph (D) of such paragraph to “paragraph (1)(A)(ii)”, “this paragraph”, and “December 31, 2009” shall be deemed references to “subparagraph (A)”, “this subparagraph”, and “December 31, 2014”, respectively; and

(V) any reference in such paragraph to a “single source drug or an innovator multiple source drug” shall be deemed to be a reference to a drug to which clause (i) applies.

(iii) SPECIAL RULE FOR CERTAIN NONINNOVATOR MULTIPLE SOURCE DRUGS.—In applying paragraph (2)(A)(ii)(II) under clause (i) with respect to a covered outpatient drug that is first marketed as a drug other than a single source drug or an innovator multiple source drug after April 1, 2013, such paragraph shall be applied—

(I) by substituting “the applicable quarter” for “the calendar quarter beginning July 1, 1990”; and

(II) by substituting “the last month in such applicable quarter” for “September 1990”.

(iv) APPLICABLE QUARTER DEFINED.—In this subsection, the term “applicable quarter” means, with respect to a drug described in clause (iii), the fifth full calendar quarter after which the drug is marketed as a drug other than a single source drug or an innovator multiple source drug.

(d) LIMITATIONS ON COVERAGE OF DRUGS.—

(1) PERMISSIBLE RESTRICTIONS.—(A) A State may subject to prior authorization any covered outpatient drug. Any such prior authorization program shall comply with the requirements of paragraph (5).

(B) A State may exclude or otherwise restrict coverage of a covered outpatient drug if—

(i) the prescribed use is not for a medically accepted indication (as defined in subsection (k)(6));

(ii) the drug is contained in the list referred to in paragraph (2);

- (iii) the drug is subject to such restrictions pursuant to an agreement between a manufacturer and a State authorized by the Secretary under subsection (a)(1) or in effect pursuant to subsection (a)(4); or
 - (iv) the State has excluded coverage of the drug from its formulary established in accordance with paragraph (4).
- (2) LIST OF DRUGS SUBJECT TO RESTRICTION.—The following drugs or classes of drugs, or their medical uses, may be excluded from coverage or otherwise restricted:
- (A) Agents when used for anorexia, weight loss, or weight gain.
 - (B) Agents when used to promote fertility.
 - (C) Agents when used for cosmetic purposes or hair growth.
 - (D) Agents when used for the symptomatic relief of cough and colds.
 - (E) Prescription vitamins and mineral products, except prenatal vitamins and fluoride preparations.
 - (F) Nonprescription drugs, except, in the case of pregnant women (*and women described in section 1905(bb) as pregnant women pursuant to paragraph (4) of such section*) when recommended in accordance with the Guideline referred to in section 1905(bb)(2)(A), agents approved by the Food and Drug Administration under the over-the-counter monograph process for purposes of promoting, and when used to promote, tobacco cessation.
 - (G) Covered outpatient drugs which the manufacturer seeks to require as a condition of sale that associated tests or monitoring services be purchased exclusively from the manufacturer or its designee.
 - (H) Agents when used for the treatment of sexual or erectile dysfunction, unless such agents are used to treat a condition, other than sexual or erectile dysfunction, for which the agents have been approved by the Food and Drug Administration.
- (3) UPDATE OF DRUG LISTINGS.—The Secretary shall, by regulation, periodically update the list of drugs or classes of drugs described in paragraph (2) or their medical uses, which the Secretary has determined, based on data collected by surveillance and utilization review programs of State medical assistance programs, to be subject to clinical abuse or inappropriate use.
- (4) REQUIREMENTS FOR FORMULARIES.—A State may establish a formulary if the formulary meets the following requirements:
- (A) The formulary is developed by a committee consisting of physicians, pharmacists, and other appropriate individuals appointed by the Governor of the State (or, at the option of the State, the State's drug use review board established under subsection (g)(3)).
 - (B) Except as provided in subparagraph (C), the formulary includes the covered outpatient drugs of any manufacturer which has entered into and complies with an agreement under subsection (a) (other than any drug ex-

cluded from coverage or otherwise restricted under paragraph (2)).

(C) A covered outpatient drug may be excluded with respect to the treatment of a specific disease or condition for an identified population (if any) only if, based on the drug's labeling (or, in the case of a drug the prescribed use of which is not approved under the Federal Food, Drug, and Cosmetic Act but is a medically accepted indication, based on information from the appropriate compendia described in subsection (k)(6)), the excluded drug does not have a significant, clinically meaningful therapeutic advantage in terms of safety, effectiveness, or clinical outcome of such treatment for such population over other drugs included in the formulary and there is a written explanation (available to the public) of the basis for the exclusion.

(D) The State plan permits coverage of a drug excluded from the formulary (other than any drug excluded from coverage or otherwise restricted under paragraph (2)) pursuant to a prior authorization program that is consistent with paragraph (5).

(E) The formulary meets such other requirements as the Secretary may impose in order to achieve program savings consistent with protecting the health of program beneficiaries.

A prior authorization program established by a State under paragraph (5) is not a formulary subject to the requirements of this paragraph.

(5) REQUIREMENTS OF PRIOR AUTHORIZATION PROGRAMS.—A State plan under this title may require, as a condition of coverage or payment for a covered outpatient drug for which Federal financial participation is available in accordance with this section, with respect to drugs dispensed on or after July 1, 1991, the approval of the drug before its dispensing for any medically accepted indication (as defined in subsection (k)(6)) only if the system providing for such approval—

(A) provides response by telephone or other telecommunication device within 24 hours of a request for prior authorization; and

(B) except with respect to the drugs on the list referred to in paragraph (2), provides for the dispensing of at least 72-hour supply of a covered outpatient prescription drug in an emergency situation (as defined by the Secretary).

(6) OTHER PERMISSIBLE RESTRICTIONS.—A State may impose limitations, with respect to all such drugs in a therapeutic class, on the minimum or maximum quantities per prescription or on the number of refills, if such limitations are necessary to discourage waste, and may address instances of fraud or abuse by individuals in any manner authorized under this Act.

(7) NON-EXCLUDABLE DRUGS.—The following drugs or classes of drugs, or their medical uses, shall not be excluded from coverage:

(A) Agents when used to promote smoking cessation, including agents approved by the Food and Drug Administration under the over-the-counter monograph process for

purposes of promoting, and when used to promote, tobacco cessation.

(B) Barbiturates.

(C) Benzodiazepines.

(e) TREATMENT OF PHARMACY REIMBURSEMENT LIMITS.—

(1) IN GENERAL.—During the period beginning on January 1, 1991, and ending on December 31, 1994—

(A) a State may not reduce the payment limits established by regulation under this title or any limitation described in paragraph (3) with respect to the ingredient cost of a covered outpatient drug or the dispensing fee for such a drug below the limits in effect as of January 1, 1991, and

(B) except as provided in paragraph (2), the Secretary may not modify by regulation the formula established under sections 447.331 through 447.334 of title 42, Code of Federal Regulations, in effect on November 5, 1990, to reduce the limits described in subparagraph (A).

(2) SPECIAL RULE.—If a State is not in compliance with the regulations described in paragraph (1)(B), paragraph (1)(A) shall not apply to such State until such State is in compliance with such regulations.

(3) EFFECT ON STATE MAXIMUM ALLOWABLE COST LIMITATIONS.—This section shall not supersede or affect provisions in effect prior to January 1, 1991, or after December 31, 1994, relating to any maximum allowable cost limitation established by a State for payment by the State for covered outpatient drugs, and rebates shall be made under this section without regard to whether or not payment by the State for such drugs is subject to such a limitation or the amount of such a limitation.

(4) ESTABLISHMENT OF UPPER PAYMENT LIMITS.—Subject to paragraph (5), the Secretary shall establish a Federal upper reimbursement limit for each multiple source drug for which the FDA has rated three or more products therapeutically and pharmaceutically equivalent, regardless of whether all such additional formulations are rated as such and shall use only such formulations when determining any such upper limit.

(5) USE OF AMP IN UPPER PAYMENT LIMITS.—The Secretary shall calculate the Federal upper reimbursement limit established under paragraph (4) as no less than 175 percent of the weighted average (determined on the basis of utilization) of the most recently reported monthly average manufacturer prices for pharmaceutically and therapeutically equivalent multiple source drug products that are available for purchase by retail community pharmacies on a nationwide basis. The Secretary shall implement a smoothing process for average manufacturer prices. Such process shall be similar to the smoothing process used in determining the average sales price of a drug or biological under section 1847A.

(f) SURVEY OF RETAIL PRICES; STATE PAYMENT AND UTILIZATION RATES; AND PERFORMANCE RANKINGS.—

(1) SURVEY OF RETAIL PRICES.—

(A) USE OF VENDOR.—The Secretary may contract services for—

(i) with respect to a retail community pharmacy, the determination on a monthly basis of retail survey

prices for covered outpatient drugs that represent a nationwide average of consumer purchase prices for such drugs, net of all discounts and rebates (to the extent any information with respect to such discounts and rebates is available); and

(ii) the notification of the Secretary when a drug product that is therapeutically and pharmaceutically equivalent and bioequivalent becomes generally available.

(B) SECRETARY RESPONSE TO NOTIFICATION OF AVAILABILITY OF MULTIPLE SOURCE PRODUCTS.—If contractor notifies the Secretary under subparagraph (A)(ii) that a drug product described in such subparagraph has become generally available, the Secretary shall make a determination, within 7 days after receiving such notification, as to whether the product is now described in subsection (e)(4).

(C) USE OF COMPETITIVE BIDDING.—In contracting for such services, the Secretary shall competitively bid for an outside vendor that has a demonstrated history in—

(i) surveying and determining, on a representative nationwide basis, retail prices for ingredient costs of prescription drugs;

(ii) working with retail community pharmacies, commercial payers, and States in obtaining and disseminating such price information; and

(iii) collecting and reporting such price information on at least a monthly basis.

In contracting for such services, the Secretary may waive such provisions of the Federal Acquisition Regulation as are necessary for the efficient implementation of this subsection, other than provisions relating to confidentiality of information and such other provisions as the Secretary determines appropriate.

(D) ADDITIONAL PROVISIONS.—A contract with a vendor under this paragraph shall include such terms and conditions as the Secretary shall specify, including the following:

(i) The vendor must monitor the marketplace and report to the Secretary each time there is a new covered outpatient drug generally available.

(ii) The vendor must update the Secretary no less often than monthly on the retail survey prices for covered outpatient drugs.

(iii) The contract shall be effective for a term of 2 years.

(E) AVAILABILITY OF INFORMATION TO STATES.—Information on retail survey prices obtained under this paragraph, including applicable information on single source drugs, shall be provided to States on at least a monthly basis. The Secretary shall devise and implement a means for providing access to each State agency designated under section 1902(a)(5) with responsibility for the administration or supervision of the administration of the State plan under this title of the retail survey price determined under this paragraph.

(2) ANNUAL STATE REPORT.—Each State shall annually report to the Secretary information on—

(A) the payment rates under the State plan under this title for covered outpatient drugs;

(B) the dispensing fees paid under such plan for such drugs; and

(C) utilization rates for noninnovator multiple source drugs under such plan.

(3) ANNUAL STATE PERFORMANCE RANKINGS.—

(A) COMPARATIVE ANALYSIS.—The Secretary annually shall compare, for the 50 most widely prescribed drugs identified by the Secretary, the national retail sales price data (collected under paragraph (1)) for such drugs with data on prices under this title for each such drug for each State.

(B) AVAILABILITY OF INFORMATION.—The Secretary shall submit to Congress and the States full information regarding the annual rankings made under subparagraph (A).

(4) APPROPRIATION.—Out of any funds in the Treasury not otherwise appropriated, there is appropriated to the Secretary of Health and Human Services \$5,000,000 for each of fiscal years 2006 through 2010 to carry out this subsection.

(g) DRUG USE REVIEW.—

(1) IN GENERAL.—

(A) In order to meet the requirement of section 1903(i)(10)(B), a State shall provide, by not later than January 1, 1993, for a drug use review program described in paragraph (2) for covered outpatient drugs in order to assure that prescriptions (i) are appropriate, (ii) are medically necessary, and (iii) are not likely to result in adverse medical results. The program shall be designed to educate physicians and pharmacists to identify and reduce the frequency of patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists, and patients, or associated with specific drugs or groups of drugs, as well as potential and actual severe adverse reactions to drugs including education on therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse.

(B) The program shall assess data on drug use against predetermined standards, consistent with the following:

(i) compendia which shall consist of the following:

(I) American Hospital Formulary Service Drug Information;

(II) United States Pharmacopeia-Drug Information (or its successor publications); and

(III) the DRUGDEX Information System; and

(ii) the peer-reviewed medical literature.

(C) The Secretary, under the procedures established in section 1903, shall pay to each State an amount equal to 75 per centum of so much of the sums expended by the

State plan during calendar years 1991 through 1993 as the Secretary determines is attributable to the statewide adoption of a drug use review program which conforms to the requirements of this subsection.

(D) States shall not be required to perform additional drug use reviews with respect to drugs dispensed to residents of nursing facilities which are in compliance with the drug regimen review procedures prescribed by the Secretary for such facilities in regulations implementing section 1919, currently at section 483.60 of title 42, Code of Federal Regulations.

(2) DESCRIPTION OF PROGRAM.—Each drug use review program shall meet the following requirements for covered outpatient drugs:

(A) PROSPECTIVE DRUG REVIEW.—(i) The State plan shall provide for a review of drug therapy before each prescription is filled or delivered to an individual receiving benefits under this title, typically at the point-of-sale or point of distribution. The review shall include screening for potential drug therapy problems due to therapeutic duplication, drug-disease contraindications, drug-drug interactions (including serious interactions with nonprescription or over-the-counter drugs), incorrect drug dosage or duration of drug treatment, drug-allergy interactions, and clinical abuse/misuse. Each State shall use the compendia and literature referred to in paragraph (1)(B) as its source of standards for such review.

(ii) As part of the State's prospective drug use review program under this subparagraph applicable State law shall establish standards for counseling of individuals receiving benefits under this title by pharmacists which includes at least the following:

(I) The pharmacist must offer to discuss with each individual receiving benefits under this title or caregiver of such individual (in person, whenever practicable, or through access to a telephone service which is toll-free for long-distance calls) who presents a prescription, matters which in the exercise of the pharmacist's professional judgment (consistent with State law respecting the provision of such information), the pharmacist deems significant including the following:

(aa) The name and description of the medication.

(bb) The route, dosage form, dosage, route of administration, and duration of drug therapy.

(cc) Special directions and precautions for preparation, administration and use by the patient.

(dd) Common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur.

(ee) Techniques for self-monitoring drug therapy.

(ff) Proper storage.

(gg) Prescription refill information.

(hh) Action to be taken in the event of a missed dose.

(II) A reasonable effort must be made by the pharmacist to obtain, record, and maintain at least the following information regarding individuals receiving benefits under this title:

(aa) Name, address, telephone number, date of birth (or age) and gender.

(bb) Individual history where significant, including disease state or states, known allergies and drug reactions, and a comprehensive list of medications and relevant devices.

(cc) Pharmacist comments relevant to the individual's drug therapy.

Nothing in this clause shall be construed as requiring a pharmacist to provide consultation when an individual receiving benefits under this title or caregiver of such individual refuses such consultation, or to require verification of the offer to provide consultation or a refusal of such offer.

(B) RETROSPECTIVE DRUG USE REVIEW.—The program shall provide, through its mechanized drug claims processing and information retrieval systems (approved by the Secretary under section 1903(r)) or otherwise, for the ongoing periodic examination of claims data and other records in order to identify patterns of fraud, abuse, gross overuse, or inappropriate or medically unnecessary care, among physicians, pharmacists and individuals receiving benefits under this title, or associated with specific drugs or groups of drugs.

(C) APPLICATION OF STANDARDS.—The program shall, on an ongoing basis, assess data on drug use against explicit predetermined standards (using the compendia and literature referred to in subsection (1)(B) as the source of standards for such assessment) including but not limited to monitoring for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, and clinical abuse/misuse and, as necessary, introduce remedial strategies, in order to improve the quality of care and to conserve program funds or personal expenditures.

(D) EDUCATIONAL PROGRAM.—The program shall, through its State drug use review board established under paragraph (3), either directly or through contracts with accredited health care educational institutions, State medical societies or State pharmacists associations/societies or other organizations as specified by the State, and using data provided by the State drug use review board on common drug therapy problems, provide for active and ongoing educational outreach programs (including the activities described in paragraph (3)(C)(iii) of this subsection) to educate practitioners on common drug therapy problems with the aim of improving prescribing or dispensing practices.

(3) STATE DRUG USE REVIEW BOARD.—

(A) ESTABLISHMENT.—Each State shall provide for the establishment of a drug use review board (hereinafter referred to as the “DUR Board”) either directly or through a contract with a private organization.

(B) MEMBERSHIP.—The membership of the DUR Board shall include health care professionals who have recognized knowledge and expertise in one or more of the following:

- (i) The clinically appropriate prescribing of covered outpatient drugs.
- (ii) The clinically appropriate dispensing and monitoring of covered outpatient drugs.
- (iii) Drug use review, evaluation, and intervention.
- (iv) Medical quality assurance.

The membership of the DUR Board shall be made up of at least $\frac{1}{3}$ but no more than 51 percent licensed and actively practicing physicians and at least $\frac{1}{3}$ licensed and actively practicing pharmacists.

(C) ACTIVITIES.—The activities of the DUR Board shall include but not be limited to the following:

- (i) Retrospective DUR as defined in section (2)(B).
- (ii) Application of standards as defined in section (2)(C).
- (iii) Ongoing interventions for physicians and pharmacists, targeted toward therapy problems or individuals identified in the course of retrospective drug use reviews performed under this subsection. Intervention programs shall include, in appropriate instances, at least:

(I) information dissemination sufficient to ensure the ready availability to physicians and pharmacists in the State of information concerning its duties, powers, and basis for its standards;

(II) written, oral, or electronic reminders containing patient-specific or drug-specific (or both) information and suggested changes in prescribing or dispensing practices, communicated in a manner designed to ensure the privacy of patient-related information;

(III) use of face-to-face discussions between health care professionals who are experts in rational drug therapy and selected prescribers and pharmacists who have been targeted for educational intervention, including discussion of optimal prescribing, dispensing, or pharmacy care practices, and follow-up face-to-face discussions; and

(IV) intensified review or monitoring of selected prescribers or dispensers.

The Board shall re-evaluate interventions after an appropriate period of time to determine if the intervention improved the quality of drug therapy, to evaluate the success of the interventions and make modifications as necessary.

(D) ANNUAL REPORT.—Each State shall require the DUR Board to prepare a report on an annual basis. The State shall submit a report on an annual basis to the Secretary which shall include a description of the activities of the Board, including the nature and scope of the prospective and retrospective drug use review programs, a summary of the interventions used, an assessment of the impact of these educational interventions on quality of care, and an estimate of the cost savings generated as a result of such program. The Secretary shall utilize such report in evaluating the effectiveness of each State's drug use review program.

(h) ELECTRONIC CLAIMS MANAGEMENT.—

(1) IN GENERAL.—In accordance with chapter 35 of title 44, United States Code (relating to coordination of Federal information policy), the Secretary shall encourage each State agency to establish, as its principal means of processing claims for covered outpatient drugs under this title, a point-of-sale electronic claims management system, for the purpose of performing on-line, real time eligibility verifications, claims data capture, adjudication of claims, and assisting pharmacists (and other authorized persons) in applying for and receiving payment.

(2) ENCOURAGEMENT.—In order to carry out paragraph (1)—

(A) for calendar quarters during fiscal years 1991 and 1992, expenditures under the State plan attributable to development of a system described in paragraph (1) shall receive Federal financial participation under section 1903(a)(3)(A)(i) (at a matching rate of 90 percent) if the State acquires, through applicable competitive procurement process in the State, the most cost-effective telecommunications network and automatic data processing services and equipment; and

(B) the Secretary may permit, in the procurement described in subparagraph (A) in the application of part 433 of title 42, Code of Federal Regulations, and parts 95, 205, and 307 of title 45, Code of Federal Regulations, the substitution of the State's request for proposal in competitive procurement for advance planning and implementation documents otherwise required.

(i) ANNUAL REPORT.—

(1) IN GENERAL.—Not later than May 1 of each year the Secretary shall transmit to the Committee on Finance of the Senate, the Committee on Energy and Commerce of the House of Representatives, and the Committees on Aging of the Senate and the House of Representatives a report on the operation of this section in the preceding fiscal year.

(2) DETAILS.—Each report shall include information on—

(A) ingredient costs paid under this title for single source drugs, multiple source drugs, and nonprescription covered outpatient drugs;

(B) the total value of rebates received and number of manufacturers providing such rebates;

- (C) how the size of such rebates compare with the size or rebates offered to other purchasers of covered outpatient drugs;
 - (D) the effect of inflation on the value of rebates required under this section;
 - (E) trends in prices paid under this title for covered outpatient drugs; and
 - (F) Federal and State administrative costs associated with compliance with the provisions of this title.
- (j) EXEMPTION OF ORGANIZED HEALTH CARE SETTINGS.—
- (1) Covered outpatient drugs are not subject to the requirements of this section if such drugs are—
 - (A) dispensed by health maintenance organizations, including Medicaid managed care organizations that contract under section 1903(m); and
 - (B) subject to discounts under section 340B of the Public Health Service Act.
 - (2) The State plan shall provide that a hospital (providing medical assistance under such plan) that dispenses covered outpatient drugs using drug formulary systems, and bills the plan no more than the hospital's purchasing costs for covered outpatient drugs (as determined under the State plan) shall not be subject to the requirements of this section.
 - (3) Nothing in this subsection shall be construed as providing that amounts for covered outpatient drugs paid by the institutions described in this subsection should not be taken into account for purposes of determining the best price as described in subsection (c).
- (k) DEFINITIONS.—In the section—
- (1) AVERAGE MANUFACTURER PRICE.—
 - (A) IN GENERAL.—Subject to subparagraph (B), the term “average manufacturer price” means, with respect to a covered outpatient drug of a manufacturer for a rebate period, the average price paid to the manufacturer for the drug in the United States by—
 - (i) wholesalers for drugs distributed to retail community pharmacies; and
 - (ii) retail community pharmacies that purchase drugs directly from the manufacturer.
 - (B) EXCLUSION OF CUSTOMARY PROMPT PAY DISCOUNTS AND OTHER PAYMENTS.—
 - (i) IN GENERAL.—The average manufacturer price for a covered outpatient drug shall exclude—
 - (I) customary prompt pay discounts extended to wholesalers;
 - (II) bona fide service fees paid by manufacturers to wholesalers or retail community pharmacies, including (but not limited to) distribution service fees, inventory management fees, product stocking allowances, and fees associated with administrative services agreements and patient care programs (such as medication compliance programs and patient education programs);
 - (III) reimbursement by manufacturers for recalled, damaged, expired, or otherwise unsalable

returned goods, including (but not limited to) reimbursement for the cost of the goods and any reimbursement of costs associated with return goods handling and processing, reverse logistics, and drug destruction;

(IV) payments received from, and rebates or discounts provided to, pharmacy benefit managers, managed care organizations, health maintenance organizations, insurers, hospitals, clinics, mail order pharmacies, long term care providers, manufacturers, or any other entity that does not conduct business as a wholesaler or a retail community pharmacy, unless the drug is an inhalation, infusion, instilled, implanted, or injectable drug that is not generally dispensed through a retail community pharmacy; and

(V) discounts provided by manufacturers under section 1860D-14A.

(ii) INCLUSION OF OTHER DISCOUNTS AND PAYMENTS.—Notwithstanding clause (i), any other discounts, rebates, payments, or other financial transactions that are received by, paid by, or passed through to, retail community pharmacies shall be included in the average manufacturer price for a covered outpatient drug.

(C) INCLUSION OF SECTION 505(c) DRUGS.—In the case of a manufacturer that approves, allows, or otherwise permits any drug of the manufacturer to be sold under a new drug application approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act, such term shall be inclusive of the average price paid for such drug by wholesalers for drugs distributed to retail community pharmacies.

(2) COVERED OUTPATIENT DRUG.—Subject to the exceptions in paragraph (3), the term “covered outpatient drug” means—

(A) of those drugs which are treated as prescribed drugs for purposes of section 1905(a)(12), a drug which may be dispensed only upon prescription (except as provided in paragraph (5)), and—

(i) which is approved for safety and effectiveness as a prescription drug under section 505 or 507 of the Federal Food, Drug, and Cosmetic Act or which is approved under section 505(j) of such Act;

(ii)(I) which was commercially used or sold in the United States before the date of the enactment of the Drug Amendments of 1962 or which is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) which has not been the subject of a final determination by the Secretary that it is a “new drug” (within the meaning of section 201(p) of the Federal Food, Drug, and Cosmetic Act) or an action brought by the Secretary under section 301, 302(a), or 304(a) of such Act to enforce section 502(f) or 505(a) of such Act; or

(iii)(I) which is described in section 107(c)(3) of the Drug Amendments of 1962 and for which the Secretary has determined there is a compelling justification for its medical need, or is identical, similar, or related (within the meaning of section 310.6(b)(1) of title 21 of the Code of Federal Regulations) to such a drug, and (II) for which the Secretary has not issued a notice of an opportunity for a hearing under section 505(e) of the Federal Food, Drug, and Cosmetic Act on a proposed order of the Secretary to withdraw approval of an application for such drug under such section because the Secretary has determined that the drug is less than effective for some or all conditions of use prescribed, recommended, or suggested in its labeling; and

(B) a biological product, other than a vaccine which—

(i) may only be dispensed upon prescription,

(ii) is licensed under section 351 of the Public Health Service Act, and

(iii) is produced at an establishment licensed under such section to produce such product; and

(C) insulin certified under section 506 of the Federal Food, Drug, and Cosmetic Act.

(3) **LIMITING DEFINITION.**—The term “covered outpatient drug” does not include any drug, biological product, or insulin provided as part of, or as incident to and in the same setting as, any of the following (and for which payment may be made under this title as part of payment for the following and not as direct reimbursement for the drug):

(A) Inpatient hospital services.

(B) Hospice services.

(C) Dental services, except that drugs for which the State plan authorizes direct reimbursement to the dispensing dentist are covered outpatient drugs.

(D) Physicians’ services.

(E) Outpatient hospital services.

(F) Nursing facility services and services provided by an intermediate care facility for the mentally retarded.

(G) Other laboratory and x-ray services.

(H) Renal dialysis.

Such term also does not include any such drug or product for which a National Drug Code number is not required by the Food and Drug Administration or a drug or biological used for a medical indication which is not a medically accepted indication. Any drug, biological product, or insulin excluded from the definition of such term as a result of this paragraph shall be treated as a covered outpatient drug for purposes of determining the best price (as defined in subsection (c)(1)(C)) for such drug, biological product, or insulin.

(4) **NONPRESCRIPTION DRUGS.**—If a State plan for medical assistance under this title includes coverage of prescribed drugs as described in section 1905(a)(12) and permits coverage of drugs which may be sold without a prescription (commonly referred to as “over-the-counter” drugs), if they are prescribed by a physician (or other person authorized to prescribe under

State law), such a drug shall be regarded as a covered outpatient drug.

(5) MANUFACTURER.—The term “manufacturer” means any entity which is engaged in—

(A) the production, preparation, propagation, compounding, conversion, or processing of prescription drug products, either directly or indirectly by extraction from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and chemical synthesis, or

(B) in the packaging, repackaging, labeling, relabeling, or distribution of prescription drug products.

Such term does not include a wholesale distributor of drugs or a retail pharmacy licensed under State law.

(6) MEDICALLY ACCEPTED INDICATION.—The term “medically accepted indication” means any use for a covered outpatient drug which is approved under the Federal Food, Drug, and Cosmetic Act, or the use of which is supported by one or more citations included or approved for inclusion in any of the compendia described in subsection (g)(1)(B)(i).

(7) MULTIPLE SOURCE DRUG; INNOVATOR MULTIPLE SOURCE DRUG; NONINNOVATOR MULTIPLE SOURCE DRUG; SINGLE SOURCE DRUG.—

(A) DEFINED.—

(i) MULTIPLE SOURCE DRUG.—The term “multiple source drug” means, with respect to a rebate period, a covered outpatient drug (not including any drug described in paragraph (5)) for which there at least 1 other drug product which—

(I) is 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 (B), is pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C) and as determined by the Food and Drug Administration, and

(III) is sold or marketed in the United States during the period.

(ii) INNOVATOR MULTIPLE SOURCE DRUG.—The term “innovator multiple source drug” means a multiple source drug that was originally marketed under an original new drug application approved by the Food and Drug Administration.

(iii) NONINNOVATOR MULTIPLE SOURCE DRUG.—The term “noninnovator multiple source drug” means a multiple source drug that is not an innovator multiple source drug.

(iv) SINGLE SOURCE DRUG.—The term “single source drug” means a covered outpatient drug 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.

(B) EXCEPTION.—Subparagraph (A)(i)(II) shall not apply if the Food and Drug Administration changes by regulation the requirement that, for purposes of the publication described in subparagraph (A)(i)(I), in order for drug products to be rated as therapeutically equivalent, they must be pharmaceutically equivalent and bioequivalent, as defined in subparagraph (C).

(C) DEFINITIONS.—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.

(8) REBATE PERIOD.—The term “rebate period” means, with respect to an agreement under subsection (a), a calendar quarter or other period specified by the Secretary with respect to the payment of rebates under such agreement.

(9) STATE AGENCY.—The term “State agency” means the agency designated under section 1902(a)(5) to administer or supervise the administration of the State plan for medical assistance.

(10) RETAIL COMMUNITY PHARMACY.—The term “retail community pharmacy” means an independent pharmacy, a chain pharmacy, a supermarket pharmacy, or a mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medications to the general public at retail prices. Such term does not include a pharmacy that dispenses prescription medications to patients primarily through the mail, nursing home pharmacies, long-term care facility pharmacies, hospital pharmacies, clinics, charitable or not-for-profit pharmacies, government pharmacies, or pharmacy benefit managers.

(11) WHOLESALE.—The term “wholesaler” means a drug wholesaler that is engaged in wholesale distribution of prescription drugs to retail community pharmacies, including (but not limited to) manufacturers, repackers, distributors, own-label distributors, private-label distributors, jobbers, brokers, warehouses (including manufacturer’s and distributor’s warehouses, chain drug warehouses, and wholesale drug warehouses) independent wholesale drug traders, and retail community pharmacies that conduct wholesale distributions.

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MEDICAID IMPROVEMENT FUND

SEC. 1941. (a) ESTABLISHMENT.—The Secretary shall establish under this title a Medicaid Improvement Fund (in this section referred to as the “Fund”) which shall be available to the Secretary to improve the management of the Medicaid program by the Centers for Medicare & Medicaid Services, including oversight of contracts and contractors and evaluation of demonstration projects.

Payments made for activities under this subsection shall be in addition to payments that would otherwise be made for such activities.

(b) FUNDING.—

(1) IN GENERAL.—There shall be available to the Fund, for expenditures from the Fund—

(A) for fiscal year 2014, \$10,000,000; and

(B) for each of fiscal years 2015 through 2018, \$0.

(2) ADDITIONAL FUNDING.—*In addition to any funds otherwise made available to the Fund, there shall be available to the Fund, for expenditures from the Fund—*

(A) for fiscal year 2021, \$10,000,000, to remain available until expended; and

(B) for fiscal year 2022, \$14,000,000, to remain available until expended.

[(2)] (3) FUNDING LIMITATION.—Amounts in the Fund shall be available in advance of appropriations but only if the total amount obligated from the Fund does not exceed the amount available to the Fund [under paragraph (1)] *under this subsection*. The Secretary may obligate funds from the Fund only if the Secretary determines (and the Chief Actuary of the Centers for Medicare & Medicaid Services and the appropriate budget officer certify) that there are available in the Fund sufficient amounts to cover all such obligations incurred consistent with the previous sentence.

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