SOCIAL SECURITY ACT

[Chapter 531 of the 74th Congress, approved August 14, 1935, 49 Stat. 620.]

[As Amended Through P.L. 119–21, Enacted July 4, 2025]

[Currency: This publication is a compilation of the text of title XI of Chapter 531 of the 74th Congress. It was last amended by the public law listed in the As Amended Through note above and below at the bottom of each page of the pdf version and reflects current law through the date of the enactment of the public law listed at https://www.govinfo.gov/app/collection/comps/]

[Note: While this publication does not represent an official version of any Federal statute, substantial efforts have been made to ensure the accuracy of its contents. The official version of Federal law is found in the United States Statutes at Large and in the United States Code. The legal effect to be given to the Statutes at Large and the United States Code is established by statute (1 U.S.C. 112, 204).]

TITLE XI—GENERAL PROVISIONS, PEER REVIEW, AND ADMINISTRATIVE SIMPLIFICATION

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PART A—GENERAL PROVISIONS

[1] This table of contents does not appear in the law.

PART A—GENERAL PROVISIONS

DEFINITIONS

SEC. 1101. [42 U.S.C. 1301] (a) When used in this Act—

(1) The term "State", except where otherwise provided, includes the District of Columbia and the Commonwealth of Puerto Rico, and when used in titles IV, V, VII, XI, XIX, and XXI includes the Virgin Islands and Guam. Such term when used in titles III, IX, and XII also includes the Virgin Islands. Such term when used in title V and in part B of this title also includes American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands. Such term when used in titles XIX and XXI also includes the Northern Mariana

Islands and American Samoa. In the case of Puerto Rico, the Virgin Islands, and Guam, titles I, X, and XIV, and title XVI (as in effect without regard to the amendment made by section 301 of the Social Security Amendments of 1972) shall continue to apply, and the term "State" when used in such titles (but not in title XVI as in effect pursuant to such amendment after December 31, 1973) includes Puerto Rico, the Virgin Islands, and Guam. Such term when used in title XX also includes the Virgin Islands, Guam, American Samoa, and the Northern Mariana Islands. Such term when used in title IV also includes American Samoa.

(2) The term "United States" when used in a geographical sense means, except where otherwise provided, the States.

(3) The term "person" means an individual, a trust or estate, a partnership, or a corporation.

(4) The term "corporation" includes associations, joint-stock companies, and insurance companies.

(5) The term "shareholder" includes a member in an association, joint-stock company, or insurance company.

(6) The term "Secretary", except when the context otherwise requires, means the Secretary of Health and Human Services.

(7) The terms "physician" and "medical care" and "hospitalization" include osteopathic practitioners or the services of osteopathic practitioners and hospitals within the scope of their practice as defined by State law.

(8)(A) The "Federal percentage" for any State (other than Puerto Rico, the Virgin Islands, and Guam) shall be 100 per centum less the State percentage; and the State percentage shall be that percentage which bears the same ratio to 50 per centum as the square of the per capita income of such State bears to the square of the per capita income of the United States; except that the Federal percentage shall in no case be less than 50 per centum or more than 65 per centum.

(B) The Federal percentage for each State (other than Puerto Rico, the Virgin Islands, and Guam) shall be promulgated by the Secretary between October 1 and November 30 of each year, on the basis of the average per capita income of each State and of the United States for the three most recent calendar years for which satisfactory data are available from the Department of Commerce. Such promulgation shall be conclusive for each of the four quarters in the period beginning October 1 next succeeding such promulgation: *Provided*, That the Secretary shall promulgate such percentages as soon as possible after the enactment of the Social Security Amendments of 1958, which promulgation shall be conclusive for each of the eleven quarters in the period beginning October 1, 1958, and ending with the close of June 30, 1961.

(C) The term "United States" means (but only for purposes of subparagraphs (A) and (B) of this paragraph) the fifty States and the District of Columbia.

(D) Promulgations made before satisfactory data are available from the Department of Commerce for a full year on the per capita income of Alaska shall prescribe a Federal percent-

age for Alaska of 50 per centum and, for purposes of such promulgations, Alaska shall not be included as part of the "United States". Promulgations made thereafter but before per capita income data for Alaska for a full three-year period are available from the Department of Commerce shall be based on satisfactory data available therefrom for Alaska for such one full year or, when such data are available for a two-year period, for such two years.

(9) The term "shared health facility" means any arrangement whereby—

(A) two or more health care practitioners practice their professions at a common physical location;

(B) such practitioners share (i) common waiting areas, examining rooms, treatment rooms, or other space, (ii) the services of supporting staff, or (iii) equipment;

(C) such practitioners have a person (who may himself be a practitioner)—

(i) who is in charge of, controls, manages, or supervises substantial aspects of the arrangement or operation for the delivery of health or medical services at such common physical location, other than the direct furnishing of professional health care services by the practitioners to their patients; or

(ii) who makes available to such practitioners the services of supporting staff who are not employees of such practitioners;

and who is compensated in whole or in part, for the use of such common physical location or support services pertaining thereto, on a basis related to amounts charged or collected for the services rendered or ordered at such location or on any basis clearly unrelated to the value of the services provided by the person; and

(D) at least one of such practitioners received payments on a fee-for-service basis under titles XVIII and XIX in an amount exceeding $5,000 for any one month during the preceding 12 months or in an aggregate amount exceeding $40,000 during the preceding 12 months;

except that such term does not include a provider of services (as defined in section 1861(u) of this Act), a health maintenance organization (as defined in section 1301(a) of the Public Health Service Act), a hospital cooperative shared services organization meeting the requirements of section 501(e) of the Internal Revenue Code of 1954, or any public entity.

(10) The term "Administration" means the Social Security Administration, except where the context requires otherwise.

(b) The terms "includes" and "including" when used in a definition contained in this Act shall not be deemed to exclude other things otherwise within the meaning of the term defined.

(c) Whenever under this Act or any Act of Congress, or under the law of any State, an employer is required or permitted to deduct any amount from the remuneration of an employee and to pay the amount deducted to the United States, a State, or any political subdivision thereof, then for the purposes of this Act the amount

so deducted shall be considered to have been paid to the employee at the time of such deduction.

(d) Nothing in this Act shall be construed as authorizing any Federal official, agent, or representative, in carrying out any of the provisions of this Act, to take charge of any child over the objection of either of the parents of such child, or of the person standing in loco parentis to such child.

RULES AND REGULATIONS

SEC. 1102. [42 U.S.C. 1302] (a) The Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services, respectively, shall make and publish such rules and regulations, not inconsistent with this Act, as may be necessary to the efficient administration of the functions with which each is charged under this Act.

(b)(1) Whenever the Secretary publishes a general notice of proposed rulemaking for any rule or regulation proposed under title XVIII, title XIX, or part B of this title that may have a significant impact on the operations of a substantial number of small rural hospitals, the Secretary shall prepare and make available for public comment an initial regulatory impact analysis. Such analysis shall describe the impact of the proposed rule or regulation on such hospitals and shall set forth, with respect to small rural hospitals, the matters required under section 603 of title 5, United States Code, to be set forth with respect to small entities. The initial regulatory impact analysis (or a summary) shall be published in the Federal Register at the time of the publication of general notice of proposed rulemaking for the rule or regulation.

(2) Whenever the Secretary promulgates a final version of a rule or regulation with respect to which an initial regulatory impact analysis is required by paragraph (1), the Secretary shall prepare a final regulatory impact analysis with respect to the final version of such rule or regulation. Such analysis shall set forth, with respect to small rural hospitals, the matters required under section 604 of title 5, United States Code, to be set forth with respect to small entities. The Secretary shall make copies of the final regulatory impact analysis available to the public and shall publish, in the Federal Register at the time of publication of the final version of the rule or regulation, a statement describing how a member of the public may obtain a copy of such analysis.

(3) If a regulatory flexibility analysis is required by chapter 6 of title 5, United States Code, for a rule or regulation to which this subsection applies, such analysis shall specifically address the impact of the rule or regulation on small rural hospitals.

SEPARABILITY

SEC. 1103. [42 U.S.C. 1303] If any provision of this Act, or the application thereof to any person or circumstance, is held invalid, the remainder of the Act and the application of such provision to other persons or circumstances shall not be affected thereby.

RESERVATION OF POWER

SEC. 1104. [42 U.S.C. 1304] The right to alter, amend, or repeal any provision of this Act is hereby reserved to the Congress.

SHORT TITLE

SEC. 1105. [42 U.S.C. 1305] This Act may be cited as the "Social Security Act".

DISCLOSURE OF INFORMATION IN POSSESSION OF AGENCY

SEC. 1106. [42 U.S.C. 1306] (a)(1) No disclosure of any return or portion of a return (including information returns and other written statements) filed with the Commissioner of Internal Revenue under title VIII of the Social Security Act or under subchapter E of chapter 1 or subchapter A of chapter 9 of the Internal Revenue Code, or under regulations made under authority thereof, which has been transmitted to the head of the applicable agency by the Commissioner of Internal Revenue, or of any file, record, report, or other paper, or any information, obtained at any time by the head of the applicable agency or by any officer or employee of the applicable agency in the course of discharging the duties of the head of the applicable agency under this Act, and no disclosure of any such file, record, report, or other paper, or information, obtained at any time by any person from the head of the applicable agency or from any officer or employee of the applicable agency, shall be made except as the head of the applicable agency may by regulations prescribe and except as otherwise provided by Federal law. Any person who shall violate any provision of this section shall be deemed guilty of a felony and, upon conviction thereof, shall be punished by a fine not exceeding $10,000 for each occurrence of a violation, or by imprisonment not exceeding 5 years, or both.

(2) For purposes of this subsection and subsection (b), the term "applicable agency" means—

(A) the Social Security Administration, with respect to matter transmitted to or obtained by such Administration or matter disclosed by such Administration, or

(B) the applicable agency, with respect to matter transmitted to or obtained by such Department or matter disclosed by such Department.

(b) Requests for information, disclosure of which is authorized by regulations prescribed pursuant to subsection (a) of this section, and requests for services, may, subject to such limitations as may be prescribed by the head of the applicable agency to avoid undue interference with his functions under this Act, be complied with if the agency, person, or organization making the request agrees to pay for the information or services requested in such amount, if any (not exceeding the cost of furnishing the information or services), as may be determined by the head of the applicable agency. Payments for information or services furnished pursuant to this section shall be made in advance or by way of reimbursement, as may be requested by the head of the applicable agency, and shall be deposited in the Treasury as a special deposit to be used to reimburse the appropriations (including authorizations to make ex-

penditures from the Federal Old-Age and Survivors Insurance Trust Fund, the Federal Disability Insurance Trust Fund, the Federal Hospital Insurance Trust Fund, and the Federal Supplementary Medical Insurance Trust Fund) for the unit or units of the applicable agency which furnished the information or services. Notwithstanding the preceding provisions of this subsection, requests for information made pursuant to the provisions of part D of title IV of this Act for the purpose of using Federal records for locating parents shall be complied with and the cost incurred in providing such information shall be paid for as provided in such part D of title IV.

(c) Notwithstanding sections 552 and 552a of title 5, United States Code, or any other provision of law, whenever the Commissioner of Social Security or the Secretary determines that a request for information is made in order to assist a party in interest (as defined in section 3 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1002)) with respect to the administration of an employee benefit plan (as so defined), or is made for any other purpose not directly related to the administration of the program or programs under this Act to which such information relates, such Commissioner or Secretary may require the requester to pay the full cost, as determined by the such Commissioner or Secretary, of providing such information.

(d) Notwithstanding any other provision of this section, in any case in which—

(1) information regarding whether an individual is shown on the records of the Commissioner of Social Security as being alive or deceased is requested from the Commissioner for purposes of epidemiological or similar research which the Commissioner in consultation with the Secretary of Health and Human Services finds may reasonably be expected to contribute to a national health interest, and

(2) the requester agrees to reimburse the Commissioner for providing such information and to comply with limitations on safeguarding and rerelease or redisclosure of such information as may be specified by the Commissioner,

the Commissioner shall comply with such request, except to the extent that compliance with such request would constitute a violation of the terms of any contract entered into under section 205(r).

(e) Notwithstanding any other provision of this section the Secretary shall make available to each State agency operating a program under title XIX and shall, subject to the limitations contained in subsection (e)[2], make available for public inspection in readily accessible form and fashion, the following official reports (not including, however, references to any internal tolerance rules and practices that may be contained therein, internal working papers or other informal memoranda) dealing with the operation of the health programs established by titles XVIII and XIX—

(1) individual contractor performance reviews and other formal evaluations of the performance of carriers, intermediaries, and State agencies, including the reports of follow-up reviews;

[2] As in original. Probably should be "subsection (f)".

(2) comparative evaluations of the performance of such contractors, including comparisons of either overall performance or of any particular aspect of contractor operation; and

(3) program validation survey reports and other formal evaluations of the performance of providers of services, including the reports of follow-up reviews, except that such reports shall not identify individual patients, individual health care practitioners, or other individuals.

(f) No report described in subsection (e) shall be made public by the Secretary or the State title XIX agency until the contractor or provider of services whose performance is being evaluated has had a reasonable opportunity (not exceeding 60 days) to review such report and to offer comments pertinent parts of which may be incorporated in the public report; nor shall the Secretary be required to include in any such report information with respect to any deficiency (or improper practice or procedures) which is known by the Secretary to have been fully corrected, within 60 days of the date such deficiency was first brought to the attention of such contractor or provider of services, as the case may be.

(g)[3] Notwithstanding any other provision of this section, the Commissioner of Social Security shall enter into an agreement with the Secretary of the Treasury under which—

(1) if the Secretary provides the Commissioner with the information described in section 6103(k)(15) of the Internal Revenue Code of 1986 with respect to any individual, the Commissioner shall indicate to the Secretary as to whether such individual receives disability insurance benefits under section 223 or supplemental security income benefits under title XVI (including State supplementary payments of the type referred to in section 1616(a) or payments of the type described in section 212(a) of Public Law 93-66);

(2) appropriate safeguards are included to assure that the indication described in paragraph (1) will be used solely for the purpose of determining if tax receivables involving such individual are not eligible for collection pursuant to a qualified tax collection contract by reason of section 6306(d)(3)(E) of the Internal Revenue Code of 1986; and

(3) the Secretary shall pay the Commissioner of Social Security the full costs (including systems and administrative costs) of providing the indication described in paragraph (1).

PENALTY FOR FRAUD

SEC. 1107. [42 U.S.C. 1307] (a) Whoever, with the intent to defraud any person, shall make or cause to be made any false representation concerning the requirements of this Act, of chapter 2, 21, or 23 of the Internal Revenue Code of 1954, or of any provision of subtitle F of such Code which corresponds (within the meaning of section 7852(b) of such Code) to a provision contained in subchapter E of chapter 9 of the Internal Revenue Code of 1939, or of any rules or regulations issued thereunder, knowing such represen-

[3] Section 283(a) of division N and section 102(a) of division FF of Public Law 116–260 both add an identical subsection (g) to the end of section 1106; however, these amendments were carried out one time.

tations to be false, shall be deemed guilty of a misdemeanor, and, upon conviction thereof, shall be punished by a fine not exceeding $1,000, or by imprisonment not exceeding one year, or both.

(b) Whoever, with the intent to elicit information as to the social security account number, date of birth, employment, wages, or benefits of any individual (1) falsely represents to the Commissioner of Social Security or the Secretary that he is such individual, or the wife, husband, widow, widower, divorced wife, divorced husband, surviving divorced wife, surviving divorced husband, surviving divorced mother, surviving divorced father, child, or parent of such individual, or the duly authorized agent of such individual, or of the wife, husband, widow, widower, divorced wife, divorced husband, surviving divorced wife, surviving divorced husband, surviving divorced mother, surviving divorced father, child, or parent of such individual, or (2) falsely represents to any person that he is an employee or agent of the United States, shall be deemed guilty of a felony and, upon conviction thereof, shall be punished by a fine not exceeding $10,000 for each recurrence of a violation or by imprisonment not exceeding 5 years or both.

SEC. 1108. [42 U.S.C. 1308] ADDITIONAL GRANTS TO PUERTO RICO, THE VIRGIN ISLANDS, GUAM, AND AMERICAN SAMOA; LIMITATION ON TOTAL PAYMENTS.

(a) LIMITATION ON TOTAL PAYMENTS TO EACH TERRITORY.—

(1) IN GENERAL.—Notwithstanding any other provision of this Act (except for paragraph (2) of this subsection), the total amount certified by the Secretary of Health and Human Services under titles I, X, XIV, and XVI, under parts A and E of title IV, and under subsection (b) of this section, for payment to any territory for a fiscal year shall not exceed the ceiling amount for the territory for the fiscal year.

(2) CERTAIN PAYMENTS DISREGARDED.—Paragraph (1) of this subsection shall be applied without regard to any payment made under section 403(a)(2), 403(a)(4), 403(a)(5), 406, 413(f), or 474(a)(6).

(b) ENTITLEMENT TO MATCHING GRANT.—

(1) IN GENERAL.—Each territory shall be entitled to receive from the Secretary for each fiscal year a grant in an amount equal to 75 percent of the amount (if any) by which—

(A) the total expenditures of the territory during the fiscal year under the territory programs funded under parts A and E of title IV, including any amount paid to the State under part A of title IV that is transferred in accordance with section 404(d) and expended under the program to which transferred; exceeds

(B) the sum of—

(i) the amount of the family assistance grant payable to the territory without regard to section 409; and

(ii) the total amount expended by the territory during fiscal year 1995 pursuant to parts A and F of title IV (as so in effect), other than for child care.

(2) APPROPRIATION.—Out of any money in the Treasury of the United States not otherwise appropriated, there are appropriated for each of fiscal years 2017 and 2018, such sums as are necessary for grants under this paragraph.

(c) DEFINITIONS.—As used in this section:

(1) TERRITORY.—The term "territory" means Puerto Rico, the Virgin Islands, Guam, and American Samoa.

(2) CEILING AMOUNT.—The term "ceiling amount" means, with respect to a territory and a fiscal year, the mandatory ceiling amount with respect to the territory, reduced for the fiscal year in accordance with subsection (e), and reduced by the amount of any penalty imposed on the territory under any provision of law specified in subsection (a) during the fiscal year.

(3) FAMILY ASSISTANCE GRANT.—The term "family assistance grant" has the meaning given such term by section 403(a)(1)(B).

(4) MANDATORY CEILING AMOUNT.—The term "mandatory ceiling amount" means—

(A) $107,255,000 with respect to Puerto Rico;

(B) $4,686,000 with respect to Guam;

(C) $3,554,000 with respect to the Virgin Islands; and

(D) $1,000,000 with respect to American Samoa.

(5) TOTAL AMOUNT EXPENDED BY THE TERRITORY.—The term "total amount expended by the territory"—

(A) does not include expenditures during the fiscal year from amounts made available by the Federal Government; and

(B) when used with respect to fiscal year 1995, also does not include—

(i) expenditures during fiscal year 1995 under subsection (g) or (i) of section 402 (as in effect on September 30, 1995); or

(ii) any expenditures during fiscal year 1995 for which the territory (but for section 1108, as in effect on September 30, 1995) would have received reimbursement from the Federal Government.

(d) AUTHORITY TO TRANSFER FUNDS TO CERTAIN PROGRAMS.—A territory to which an amount is paid under subsection (b) of this section may use the amount in accordance with section 404(d).

[(e) Repealed by section 5512(c) of Public Law 105–33 (111 Stat. 619)]

(f) Subject to subsections (g) and (h) and section 1935(e)(1)(B), the total amount certified by the Secretary under title XIX with respect to a fiscal year for payment to—

(1) Puerto Rico shall not exceed (A) $116,500,000 for fiscal year 1994 and (B) for each succeeding fiscal year the amount provided in this paragraph for the preceding fiscal year increased by the percentage increase in the medical care component of the consumer price index for all urban consumers (as published by the Bureau of Labor Statistics) for the twelve-month period ending in March preceding the beginning of the fiscal year, rounded to the nearest $100,000;

(2) the Virgin Islands shall not exceed (A) $3,837,500 for fiscal year 1994, and (B) for each succeeding fiscal year the amount provided in this paragraph for the preceding fiscal year increased by the percentage increase referred to in paragraph (1)(B), rounded to the nearest $10,000;

(3) Guam shall not exceed (A) $3,685,000 for fiscal year 1994, and (B) for each succeeding fiscal year the amount provided in this paragraph for the preceding fiscal year increased by the percentage increase referred to in paragraph (1)(B), rounded to the nearest $10,000;

(4) Northern Mariana Islands shall not exceed (A) $1,110,000 for fiscal year 1994, and (B) for each succeeding fiscal year the amount provided in this paragraph for the preceding fiscal year increased by the percentage increase referred to in paragraph (1)(B), rounded to the nearest $10,000; and

(5) American Samoa shall not exceed (A) $2,140,000 for fiscal year 1994, and (B) for each succeeding fiscal year the amount provided in this paragraph for the preceding fiscal year increased by the percentage increase referred to in paragraph (1)(B), rounded to the nearest $10,000.

(g) MEDICAID PAYMENTS TO TERRITORIES FOR FISCAL YEAR 1998 AND THEREAFTER.—

(1) FISCAL YEAR 1998.—With respect to fiscal year 1998, the amounts otherwise determined for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa under subsection (f) for such fiscal year shall be increased by the following amounts:

(A) For Puerto Rico, $30,000,000.

(B) For the Virgin Islands, $750,000.

(C) For Guam, $750,000.

(D) For the Northern Mariana Islands, $500,000.

(E) For American Samoa, $500,000.

(2) FISCAL YEAR 1999 AND THEREAFTER.—Notwithstanding subsection (f) and subject to section 1323(a)(2) of the Patient Protection and Affordable Care Act and paragraphs (3), (5), and (14), with respect to fiscal year 1999 and any fiscal year thereafter, the total amount certified by the Secretary under title XIX for payment to—

(A) Puerto Rico shall not exceed—

(i) except as provided in clause (ii) or (iii), the sum of the amount provided in this subsection for the preceding fiscal year increased by the percentage increase in the medical care component of the Consumer Price Index for all urban consumers (as published by the Bureau of Labor Statistics) for the 12-month period ending in March preceding the beginning of the fiscal year, rounded to the nearest $100,000;

(ii) for each of fiscal years 2020 through 2021, the amount specified in paragraph (6) for each such fiscal year; and

(iii) for fiscal year 2023 and each subsequent fiscal year, the amount specified in paragraph (11) for such fiscal year;

(B) the Virgin Islands shall not exceed—

(i) except as provided in clause (ii), the sum of the amount provided in this subsection for the preceding fiscal year increased by the percentage increase referred to in subparagraph (A), rounded to the nearest $10,000;

(ii) for fiscal year 2020, $128,712,500; and
(iii) for fiscal year 2021, $127,937,500;

(C) Guam shall not exceed—

(i) except as provided in clause (ii), the sum of the amount provided in this subsection for the preceding fiscal year increased by the percentage increase referred to in subparagraph (A), rounded to the nearest $10,000;
(ii) for fiscal year 2020, $130,875,000; and
(iii) for fiscal year 2021, $129,712,500;

(D) the Northern Mariana Islands shall not exceed—

(i) except as provided in clause (ii), the sum of the amount provided in this subsection for the preceding fiscal year increased by the percentage increase referred to in subparagraph (A), rounded to the nearest $10,000;
(ii) for fiscal year 2020, $63,100,000; and
(iii) for fiscal year 2021, $62,325,000; and

(E) American Samoa shall not exceed—

(i) except as provided in clause (ii), the sum of the amount provided in this subsection for the preceding fiscal year increased by the percentage increase referred to in subparagraph (A), rounded to the nearest $10,000;
(ii) for fiscal year 2020, $86,325,000; and
(iii) for fiscal year 2021, $85,550,000.

For fiscal year 2022 (and, in the case of a territory other than Puerto Rico, for each subsequent fiscal year), the total amount certified for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa under subsection (f) and this subsection for the fiscal year shall be determined as if the preceding subparagraphs were applied to each of fiscal years 2020 through 2021 without regard to clause (ii) of each such subparagraph.

(3) FISCAL YEARS 2006 AND 2007 FOR CERTAIN INSULAR AREAS.—The amounts otherwise determined under this subsection for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa for fiscal year 2006 and fiscal year 2007 shall be increased by the following amounts:

(A) For Puerto Rico, $12,000,000 for fiscal year 2006 and $12,000,000 for fiscal year 2007.

(B) For the Virgin Islands, $2,500,000 for fiscal year 2006 and $5,000,000 for fiscal year 2007.

(C) For Guam, $2,500,000 for fiscal year 2006 and $5,000,000 for fiscal year 2007.

(D) For the Northern Mariana Islands, $1,000,000 for fiscal year 2006 and $2,000,000 for fiscal year 2007.

(E) For American Samoa, $2,000,000 for fiscal year 2006 and $4,000,000 for fiscal year 2007.

Such amounts shall not be taken into account in applying paragraph (2) for fiscal year 2007 but shall be taken into account in applying such paragraph for fiscal year 2008 and subsequent fiscal years.

(4) EXCLUSION OF CERTAIN EXPENDITURES FROM PAYMENT LIMITS.—

(A) IN GENERAL.—With respect to fiscal years beginning with fiscal year 2009, if Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, or American Samoa qualify for a payment under subparagraph (A)(i), (B), or (F) of section 1903(a)(3) for a calendar quarter of such fiscal year, and with respect to fiscal years beginning with fiscal year 2017, if Puerto Rico qualifies for a payment under section 1903(a)(6) for a calendar quarter (beginning on or after July 1, 2017) of such fiscal year, and with respect to fiscal years beginning with fiscal year 2018, if the Virgin Islands qualifies for a payment under section 1903(a)(6) for a calendar quarter (beginning on or after January 1, 2018) of such fiscal year, the payment shall not be taken into account in applying subsection (f) (as increased in accordance with paragraphs (1), (2), (3), and (4) of this subsection) to such commonwealth or territory for such fiscal year.

(B) ADDITIONAL EXEMPTION.—Payments under section 1903 for medical assistance consisting of routine patient costs (as defined in section 1905(gg)(1)) shall not be taken into account in applying subsection (f).

(5) ADDITIONAL INCREASE.—(A) Subject to subparagraphs (B), (C), (D), (E), and (F), the Secretary shall increase the amounts otherwise determined under this subsection for Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa (after the application of subsection (f) and the preceding paragraphs of this subsection) for the period beginning July 1, 2011, and ending on September 30, 2019, by such amounts that the total additional payments under title XIX to such territories equals $6,300,000,000 for such period. The Secretary shall increase such amounts in proportion to the amounts applicable to such territories under this subsection and subsection (f) on the date of enactment of this paragraph.

(B) The amount of the increase otherwise provided under subparagraph (A) for Puerto Rico shall be further increased by $295,900,000.

(C) Subject to subparagraphs (D) and (F), for the period beginning January 1, 2018, and ending September 30, 2019—

(i) the amount of the increase otherwise provided under subparagraphs (A) and (B) for Puerto Rico shall be further increased by $3,600,000,000; and

(ii) the amount of the increase otherwise provided under subparagraph (A) for the Virgin Islands shall be further increased by $106,931,000.

(D) For the period described in subparagraph (C), the amount of the increase otherwise provided under subparagraph (A)—

(i) for Puerto Rico shall be further increased by $1,200,000,000 if the Secretary certifies that Puerto Rico has taken reasonable and appropriate steps during such

period, in accordance with a timeline established by the Secretary, to—

(I) implement methods, satisfactory to the Secretary, for the collection and reporting of reliable data to the Transformed Medicaid Statistical Information System (T–MSIS) (or a successor system); and

(II) demonstrate progress in establishing a State medicaid fraud control unit described in section 1903(q); and

(ii) for the Virgin Islands shall be further increased by $35,644,000 if the Secretary certifies that the Virgin Islands has taken reasonable and appropriate steps during such period, in accordance with a timeline established by the Secretary, to meet the conditions for certification specified in subclauses (I) and (II) of clause (i).

(E)[4] Subject to subparagraph (F), for the period beginning January 1, 2019, and ending September 30, 2019, the amount of the increase otherwise provided under subparagraph (A) for the Northern Mariana Islands shall be further increased by $36,000,000.

(F) Notwithstanding any other provision of title XIX—

(i)[4] during the period in which the additional funds provided under subparagraphs (C), (D), and (E) are available for Puerto Rico, the Virgin Islands, and the Northern Mariana Islands, respectively, with respect to payments from such additional funds for amounts expended by Puerto Rico, the Virgin Islands, and the Northern Mariana Islands under such title, the Secretary shall increase the Federal medical assistance percentage or other rate that would otherwise apply to such payments to 100 percent; and

(ii)[4] for the period beginning January 1, 2019, and ending September 30, 2019, with respect to payments to Guam and American Samoa from the additional funds provided under subparagraph (A), the Secretary shall increase the Federal medical assistance percentage or other rate that would otherwise apply to such payments to 100 percent.

(G)[4] Not later than September 30, 2019, Guam and American Samoa shall each submit a plan to the Secretary outlining the steps each such territory shall take to collect and report reliable data to the Transformed Medicaid Statistical Information System (T–MSIS) (or a successor system).

(6) APPLICATION TO PUERTO RICO FOR FISCAL YEARS 2020 THROUGH 2021.—

(A) IN GENERAL.—Subject to subparagraph (B), the amount specified in this paragraph is—

(i) for fiscal year 2020, $2,716,188,000; and

(ii) for fiscal year 2021, $2,809,063,000.

(B) ADDITIONAL INCREASE FOR PUERTO RICO.—

[4] Margins are so in law.

(i) IN GENERAL.—For each of fiscal years 2020 through 2021, the amount specified in this paragraph for the fiscal year shall be equal to the amount specified for such fiscal year under subparagraph (A) increased by $200,000,000 if the Secretary certifies that, with respect to such fiscal year, Puerto Rico's State plan under title XIX (or a waiver of such plan) establishes a reimbursement floor, implemented through a directed payment arrangement plan, for physician services that are covered under the Medicare part B fee schedule in the Puerto Rico locality established under section 1848(b) that is not less than 70 percent of the payment that would apply to such services if they were furnished under part B of title XVIII during such fiscal year.

(ii) APPLICATION TO MANAGED CARE.—In certifying whether Puerto Rico has established a reimbursement floor under a directed payment arrangement plan that satisfies the requirements of clause (i)—

(I) for fiscal year 2020, the Secretary shall apply such requirements to payments for physician services under a managed care contract entered into or renewed after the date of enactment of this paragraph and disregard payments for physician services under any managed care contract that was entered into prior to such date; and

(II) for each of fiscal years 2020 through 2021—

(aa) the Secretary shall disregard payments made under sub-capitated arrangements for services such as primary care case management; and

(bb) if the reimbursement floor for physician services applicable under a managed care contract satisfies the requirements of clause (i) for the fiscal year in which the contract is entered into or renewed, such reimbursement floor shall be deemed to satisfy such requirements for the subsequent fiscal year.

(7) PUERTO RICO PROGRAM INTEGRITY REQUIREMENTS.—

(A) IN GENERAL.—

(i) PROGRAM INTEGRITY LEAD.—Not later than 6 months after the date of enactment of this paragraph, the agency responsible for the administration of Puerto Rico's Medicaid program under title XIX shall designate an officer (other than the director of such agency) to serve as the Program Integrity Lead for such program.

(ii) PERM REQUIREMENT.—Not later than 18 months after the date of enactment of this paragraph, Puerto Rico shall publish a plan, developed by Puerto Rico in coordination with the Administrator of the Centers for Medicare & Medicaid Services and approved by the Administrator, for how Puerto Rico will

develop measures to satisfy the payment error rate measurement (PERM) requirements under subpart Q of part 431 of title 42, Code of Federal Regulations (or any successor regulation).

(iii) CONTRACTING REFORM REPORTING.—Not later than 12 months after the date of enactment of this paragraph, Puerto Rico shall publish a contracting reform plan to combat fraudulent, wasteful, or abusive contracts under Puerto Rico's Medicaid program under title XIX that includes—

(I) metrics for evaluating the success of the plan; and

(II) a schedule for publicly releasing status reports on the plan.

(iv) MEQC.—Not later than 18 months after the date of enactment of this paragraph, Puerto Rico shall publish a plan, developed by Puerto Rico in coordination with the Administrator of the Centers for Medicare & Medicaid Services and approved by the Administrator, for how Puerto Rico will comply with the Medicaid eligibility quality control (MEQC) requirements of subpart P of part 431 of title 42, Code of Federal Regulations (or any successor regulation).

(v) CONTRACTING AND PROCUREMENT OVERSIGHT LEAD REQUIREMENT.—

(I) IN GENERAL.—Not later than 6 months after the date of the enactment of this clause, the agency responsible for the administration of Puerto Rico's Medicaid program under title XIX shall designate an officer (other than the director of such agency) to serve as the Contracting and Procurement Oversight Lead to carry out the duties specified in subclause (II).

(II) DUTIES.—Not later than 60 days after the end of each fiscal quarter (beginning with the first fiscal quarter beginning on or after the date that is 1 year after the date of the enactment of this clause), the officer designated pursuant to subclause (I) shall, with respect to each contract described in clause (iii) with an annual value exceeding $150,000 entered into during such quarter, certify to the Secretary either—

(aa) that such contract has met the procurement standards identified under any of sections 75.327, 75.328, and 75.329 of title 45, Code of Federal Regulations (or successor regulations); or

(bb) that extenuating circumstances (including a lack of multiple entities competing for such contract) prevented the compliance of such contract with such standards.

(III) PUBLICATION.—The officer designated pursuant to subclause (I) shall make public each certification containing extenuating circumstances

described in subclause (II)(bb) not later than 30 days after such certification is made, including a description of, and justification of, such extenuating circumstances.

(IV) REVIEW OF COMPLIANCE.—Not later than 2 years after the date of the enactment of this clause, the Inspector General of the Department of Health and Human Services shall submit to Congress a report on the compliance of Puerto Rico with the provisions of this clause.

(B) FMAP REDUCTION FOR FAILURE TO MEET ADDITIONAL REQUIREMENTS.—

(i) IN GENERAL.—For each fiscal quarter during the period beginning on January 1, 2020, and ending on September 30, 2021:

(I) For every clause under subparagraph (A) with respect to which Puerto Rico does not fully satisfy the requirements described in the clause (including requirements imposed under the terms of a plan described in the clause) in the fiscal quarter, the Federal medical assistance percentage applicable to Puerto Rico under section 1905(ff) shall be reduced by the number of percentage points determined for the clause and fiscal quarter under subclause (II).

(II) The number of percentage points determined under this subclause with respect to a clause under subparagraph (A) and a fiscal quarter shall be the number of percentage points (not to exceed 2.5 percentage points) equal to—

(aa) 0.25 percentage points; multiplied by

(bb) the total number of consecutive fiscal quarters for which Puerto Rico has not fully satisfied the requirements described in such clause.

(ii) EXCEPTION FOR EXTENUATING CIRCUMSTANCES OR REASONABLE PROGRESS.—For purposes of clause (i), Puerto Rico shall be deemed to have fully satisfied the requirements of a clause under subparagraph (A) (including requirements imposed under the terms of a plan described in the clause) for a fiscal quarter if—

(I) the Secretary approves an application from Puerto Rico describing extenuating circumstances that prevented Puerto Rico from fully satisfying the requirements of the clause; or

(II) in the case of a requirement imposed under the terms of a plan described in a clause under subparagraph (A), Puerto Rico has made objectively reasonable progress towards satisfying such terms and has submitted a timely request for an exception to the imposition of a penalty to the Secretary.

(8) PROGRAM INTEGRITY LEAD REQUIREMENT FOR THE VIRGIN ISLANDS, GUAM, THE NORTHERN MARIANA ISLANDS, AND AMERICAN SAMOA.—

(A) PROGRAM INTEGRITY LEAD REQUIREMENT.—Not later than October 1, 2020, the agency responsible for the administration of the Medicaid program under title XIX of each territory specified in subparagraph (C) shall designate an officer (other than the director of such agency) to serve as the Program Integrity Lead for such program.

(B) FMAP REDUCTION.—For each fiscal quarter during fiscal year 2021, if the territory fails to satisfy the requirement of subparagraph (A) for the fiscal quarter, the Federal medical assistance percentage applicable to the territory under section 1905(ff) for such fiscal quarter shall be reduced by the number of percentage points (not to exceed 5 percentage points) equal to—

(i) 0.25 percentage points; multiplied by

(ii) the total number of fiscal quarters during the fiscal year in which the territory failed to satisfy such requirement.

(C) SCOPE.—This paragraph shall apply to the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa.

(9) ANNUAL REPORT.—

(A) IN GENERAL.—Not later than the date that is 30 days after the end of each fiscal year (beginning with fiscal year 2020 and ending with fiscal year 2021) and for fiscal year 2023 and each subsequent fiscal year (or, in the case of Puerto Rico, and for fiscal year 2023 and each subsequent fiscal year before fiscal year 2028), in the case that a specified territory receives a Medicaid cap increase, or an increase in the Federal medical assistance percentage for such territory under section 1905(ff), for such fiscal year, such territory shall submit to the Chair and Ranking Member of the Committee on Energy and Commerce of the House of Representatives and the Chair and Ranking Member of the Committee on Finance of the Senate a report, employing the most up-to-date information available, that describes how such territory has used such Medicaid cap increase, or such increase in the Federal medical assistance percentage, as applicable, to increase access to health care under the State Medicaid plan of such territory under title XIX (or a waiver of such plan). Such report may include—

(i) the extent to which such territory has, with respect to such plan (or waiver)—

(I) increased payments to health care providers;

(II) increased covered benefits;

(III) expanded health care provider networks; or

(IV) improved in any other manner the carrying out of such plan (or waiver); and

(ii) any other information as determined necessary by such territory.

(B) DEFINITIONS.—In this paragraph:

(i) MEDICAID CAP INCREASE.—The term "Medicaid cap increase" means, with respect to a specified territory and fiscal year, any increase in the amounts otherwise determined under this subsection for such territory for such fiscal year by reason of the amendments made by section 202 of division N of the Further Consolidated Appropriations Act, 2020 or by reason of the amendments made by section 5101 of the Health Extenders, Improving Access to Medicare, Medicaid, and CHIP, and Strengthening Public Health Act of 2022.

(ii) SPECIFIED TERRITORY.—The term "specified territory" means Puerto Rico, the Virgin Islands, Guam, the Northern Mariana Islands, and American Samoa.

(10) ADDITIONAL INCREASE FOR PUERTO RICO FOR FISCAL YEAR 2022.—

(A) IN GENERAL.—Notwithstanding the preceding provisions of this subsection, the total amount certified for Puerto Rico for fiscal year 2022 under this subsection shall be increased by $200,000,000 if the Secretary certifies that, with respect to such fiscal year, Puerto Rico's State plan under title XIX (or a waiver of such plan) establishes a reimbursement floor, implemented through a directed payment arrangement plan, for physician services that are covered under the Medicare part B fee schedule in the Puerto Rico locality established under section 1848(b) that is not less than 70 percent of the payment that would apply to such services if they were furnished under part B of title XVIII during such fiscal year.

(B) APPLICATION TO MANAGED CARE.—In certifying whether Puerto Rico has established a reimbursement floor under a directed payment arrangement plan that satisfies the requirements of subparagraph (A) for fiscal year 2022, the Secretary shall—

(i) disregard payments made under sub-capitated arrangements for services such as primary care case management; and

(ii) if the reimbursement floor for physician services applicable under a managed care contract satisfies the requirements of subparagraph (A) for the fiscal year in which the contract is entered into or renewed, such reimbursement floor shall be deemed to satisfy such requirements for the subsequent fiscal year.

(11) ALLOTMENT AMOUNTS FOR PUERTO RICO FOR FISCAL YEAR 2023 AND SUBSEQUENT FISCAL YEARS.—For purposes of paragraph (2)(A)(iii), subject to paragraphs (12) and (13), the amounts specified in this paragraph are the following:

(A) For fiscal year 2023, $3,275,000,000.

(B) For fiscal year 2024, $3,325,000,000.

(C) For fiscal year 2025, $3,475,000,000.

(D) For fiscal year 2026, $3,645,000,000.

(E) For fiscal year 2027, $3,825,000,000.

(F) For fiscal year 2028, the sum of the amount that would have been provided under this subsection for Puerto Rico for such fiscal year in accordance with clause (i) of paragraph (2)(A) (without regard to clause (iii) of such paragraph) had the amount provided under this subsection for Puerto Rico for each of fiscal years 2020 through 2027 been equal to the following:

(i) For fiscal year 2020, the sum of the amount provided under this subsection for Puerto Rico for fiscal year 2019, increased by the percentage increase in the medical care component of the Consumer Price Index for all urban consumers (as published by the Bureau of Labor Statistics) for the 12-month period ending in March preceding the beginning of the fiscal year, rounded to the nearest $100,000.

(ii) For each of fiscal years 2021 through 2027, the sum of the amount provided under this subparagraph for the preceding fiscal year, increased in accordance with the percentage increase described in clause (i), rounded to the nearest $100,000.

(G) For fiscal year 2029 and each subsequent fiscal year, the sum of the amount specified in this paragraph for the preceding fiscal year, increased by the percentage increase in the medical care component of the Consumer Price Index for all urban consumers (as published by the Bureau of Labor Statistics) for the 12-month period ending in March preceding the beginning of the fiscal year, rounded to the nearest $100,000.

In determining the amount specified under subparagraph (F) for fiscal year 2028 or under subparagraph (G) for fiscal year 2029 or a subsequent fiscal year, the Secretary may in no way take into account the amount that was provided under this subsection for Puerto Rico for fiscal year 2022 that was based on the Centers for Medicare & Medicaid Services' interpretation of the flush language following paragraph (2)(E) (as described in the letters sent by the Centers for Medicare & Medicaid Services to the Director of the Medicaid Program for Puerto Rico dated September 24, 2021, and November 18, 2021, respectively).

(12) ADDITIONAL INCREASE FOR PUERTO RICO.—

(A) IN GENERAL.—For fiscal year 2023 and each subsequent fiscal year through fiscal year 2027, the amount specified in paragraph (11) for the fiscal year shall be equal to the amount specified for such fiscal year under such paragraph increased by $300,000,000 if the Secretary certifies that, with respect to such fiscal year, Puerto Rico's State plan under title XIX (or waiver of such plan) establishes a reimbursement floor, implemented through a directed payment arrangement plan, for physician services that are covered under the Medicare part B fee schedule in the Puerto Rico locality established under section 1848(b) that is not less than 75 percent of the payment

that would apply to such services if they were furnished under part B of title XVIII during such fiscal year.

(B) APPLICATION TO MANAGED CARE.—In certifying whether Puerto Rico has established a reimbursement floor under a directed payment arrangement plan that satisfies the requirements of subparagraph (A)—

(i) for fiscal year 2023, the Secretary shall apply such requirements to payments for physician services under a managed care contract entered into or renewed after the date of enactment of this paragraph and disregard payments for physician services under any managed care contract that was entered into prior to such date; and

(ii) for each subsequent fiscal year through fiscal year 2027—

(I) the Secretary shall disregard payments made under subcapitated arrangements for services such as primary care case management; and

(II) if the reimbursement floor for physician services applicable under a managed care contract satisfies the requirements of subparagraph (A) for the fiscal year in which the contract is entered into or renewed, such reimbursement floor shall be deemed to satisfy such requirements for the subsequent fiscal year.

(C) NONAPPLICATION OF INCREASE IN DETERMINING ALLOTMENTS FOR SUBSEQUENT FISCAL YEARS.—An increase under this paragraph for a fiscal year may not be taken into account in calculating the amount specified under paragraph (11) for the succeeding fiscal year.

(13) FURTHER INCREASE FOR PUERTO RICO.—

(A) IN GENERAL.—For each of fiscal years 2023 through 2027, the amount specified in paragraph (11) for the fiscal year shall be equal to the amount specified for such fiscal year under such paragraph (increased, if applicable, in accordance with paragraph (12)) and further increased—

(i) in the case of each of fiscal years 2023 through 2025, by $75,000,000 if the Secretary determines that Puerto Rico fully satisfies the requirements described in paragraph (7)(A)(i) for such fiscal year; and

(ii) in the case of each of fiscal years 2026 and 2027, by $75,000,000 if the Secretary determines that Puerto Rico fully satisfies the requirements described in—

(I) paragraph (7)(A)(i) for such fiscal year; and

(II) paragraph (7)(A)(v) for such fiscal year.

(B) NONAPPLICATION OF INCREASE IN DETERMINING ALLOTMENTS FOR SUBSEQUENT FISCAL YEARS.—An increase under this paragraph for a fiscal year may not be taken into account in calculating the amount specified under paragraph (11) for the succeeding fiscal year.

(14) ADDITIONAL INCREASE FOR THE NORTHERN MARIANA ISLANDS.—

(A) IN GENERAL.—The Secretary shall increase the total amount otherwise determined under this subsection for the Northern Mariana Islands for the period beginning on October 1, 2022, and ending on September 30, 2024, by $27,100,000.

(B) SPECIAL RULES.—The increase described in subparagraph (A)—

(i) shall apply to the total amount certified by the Secretary under title XIX for payment to the Northern Mariana Islands for services attributable to fiscal year 2023 or 2024, notwithstanding that payments for any such services are made by the Northern Mariana Islands in fiscal year 2025; and

(ii) shall be in addition to the amount calculated under paragraph (2) for the Northern Mariana Islands for fiscal years 2023 and 2024 and shall not be taken into account in calculating an amount under paragraph (2) for the Northern Mariana Islands for fiscal year 2025 or a subsequent fiscal year.

(h) EXCLUSION OF MEDICAL ASSISTANCE EXPENDITURES FOR CITIZENS OF FREELY ASSOCIATED STATES.—Expenditures for medical assistance provided to an individual described in section 431(b)(8) of the Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (8 U.S.C. 1641(b)(8)) shall not be taken into account for purposes of applying payment limits under subsections (f) and (g).

(i) DATA SYSTEMS IMPROVEMENT PAYMENTS.—

(1) IN GENERAL.—Subject to paragraphs (2) and (3), the Secretary shall pay to each eligible territory an amount equal to 100 percent of the qualifying data system improvement expenditures incurred by such territory on or after October 1, 2023.

(2) TREATMENT AS MEDICAID PAYMENTS.—

(A) IN GENERAL.—Payments to eligible territories made under this paragraph shall be considered to have been made under, and are subject to the requirements of, section 1903.

(B) NONDUPLICATION.—No payment shall be made under title XIX (other than as provided under paragraph (1)), title XXI, or any other provision of law with respect to an expenditure for which payment is made under such paragraph.

(3) ALLOTMENTS.—The Secretary shall specify an allotment for each eligible territory for payments made under paragraph (1) in a manner such that—

(A) the total amount of payments made under such paragraph for all eligible territories does not exceed $20,000,000; and

(B) each eligible territory receives an equitable allotment of such payments.

(4) NO EFFECT ON TERRITORIAL CAPS.—A payment to an eligible territory under this subsection shall not be taken into account for purposes of applying the payment limits under subsections (f) and (g).

(5) DEFINITIONS.—In this subsection:

(A) ELIGIBLE TERRITORY.—The term "eligible territory" means American Samoa, Guam, the Northern Mariana Islands, and the Virgin Islands.

(B) QUALIFYING DATA SYSTEM IMPROVEMENT EXPENDITURE.—The term "qualifying data system improvement expenditure" means an expenditure by an eligible territory to improve, update, or enhance a data system that is used by the territory to carry out an administrative activity for which Federal financial participation is available under section 1903(a).

AMOUNTS DISREGARDED NOT TO BE TAKEN INTO ACCOUNT IN DETERMINING ELIGIBILITY OF OTHER INDIVIDUALS

SEC. 1109. [42 U.S.C. 1309] Any amount which is disregarded (or set aside for future needs) in determining the eligibility of and amount of the aid or assistance for any individual under a State plan approved under title I, X, XIV, XVI, or XIX, shall not be taken into consideration in determining the eligibility of and amount of aid or assistance for any other individual under a State plan approved under any other of such titles.

COOPERATIVE RESEARCH OR DEMONSTRATION PROJECTS

SEC. 1110. [42 U.S.C. 1310] (a)(1) There are hereby authorized to be appropriated for the fiscal year ending June 30, 1957, $5,000,000 and for each fiscal year thereafter such sums as the Congress may determine for (A) making grants to States and public and other organizations and agencies for paying part of the cost of research or demonstration projects such as those relating to the prevention and reduction of dependency, or which will aid in effecting coordination of planning between private and public welfare agencies or which will help improve the administration and effectiveness of programs carried on or assisted under the Social Security Act and programs related thereto, and (B) making contracts or jointly financed cooperative arrangements with States and public and other organizations and agencies for the conduct of research or demonstration projects relating to such matters.

(2) No contract or jointly financed cooperative arrangement shall be entered into, and no grant shall be made, under paragraph (1), until the Secretary (or the Commissioner, with respect to any jointly financed cooperative agreement or grant concerning titles II or XVI) obtains the advice and recommendations of specialists who are competent to evaluate the proposed projects as to soundness of their design, the possibilities of securing productive results, the adequacy of resources to conduct the proposed research or demonstrations, and their relationship to other similar research or demonstrations already completed or in process.

(3) Grants and payments under contracts or cooperative arrangements under paragraph (1) may be made either in advance or by way of reimbursement, as may be determined by the Secretary (or the Commissioner, with respect to any jointly financed cooperative agreement or grant concerning title II or XVI); and shall be made in such installments and on such conditions as the Secretary

(or the Commissioner, as applicable) finds necessary to carry out the purposes of this subsection.

(b)(1) The Commissioner is authorized to waive any of the requirements, conditions, or limitations of title XVI (or to waive them only for specified purposes, or to impose additional requirements, conditions, or limitations) to such extent and for such period as the Commissioner finds necessary to carry out one or more experimental, pilot, or demonstration projects which, in the Commissioner's judgment, are likely to assist in promoting the objectives or facilitate the administration of such title. Any costs for benefits under or administration of any such project (including planning for the project and the review and evaluation of the project and its results), in excess of those that would have been incurred without regard to the project, shall be met by the Commissioner from amounts available to the Commissioner for this purpose from appropriations made to carry out such title. The costs of any such project which is carried out in coordination with one or more related projects under other titles of this Act shall be allocated among the appropriations available for such projects and any Trust Funds involved, in a manner determined by the Commissioner with respect to the old-age, survivors, and disability insurance programs under title II and the supplemental security income program under title XVI, and by the Secretary with respect to other titles of this Act, taking into consideration the programs (or types of benefit) to which the project (or part of a project) is most closely related or which the project (or part of a project) is intended to benefit. If, in order to carry out a project under this subsection, the Commissioner requests a State to make supplementary payments (or the Commissioner makes them pursuant to an agreement under section 1616) to individuals who are not eligible therefor, or in amounts or under circumstances in which the State does not make such payments, the Commissioner shall reimburse such State for the non-Federal share of such payments from amounts appropriated to carry out title XVI. If, in order to carry out a project under this subsection, the Secretary requests a State to provide medical assistance under its plan approved under title XIX to individuals who are not eligible therefor, or in amounts or under circumstances in which the State does not provide such medical assistance, the Secretary shall reimburse such State for the non-Federal share of such assistance from amounts appropriated to carry out title XVI, which shall be provided by the Commissioner to the Secretary for this purpose.

(2) With respect to the participation of recipients of supplemental security income benefits in experimental, pilot, or demonstration projects under this subsection—

(A) the Commissioner is not authorized to carry out any project that would result in a substantial reduction in any individual's total income and resources as a result of his or her participation in the project;

(B) the Commissioner may not require any individual to participate in a project; and the Commissioner shall assure (i) that the voluntary participation of individuals in any project is obtained through informed written consent which satisfies the requirements for informed consent established by the Commis-

sioner for use in any experimental, pilot, or demonstration project in which human subjects are at risk, and (ii) that any individual's voluntary agreement to participate in any project may be revoked by such individual at any time;

(C) the Commissioner shall, to the extent feasible and appropriate, include recipients who are under age 18 as well as adult recipients; and

(D) the Commissioner shall include in the projects carried out under this section such experimental, pilot, or demonstration projects as may be necessary to ascertain the feasibility of treating alcoholics and drug addicts to prevent the onset of irreversible medical conditions which may result in permanent disability, including programs in residential care treatment centers.

(c)(1) In addition to the amount otherwise appropriated in any other law to carry out subsection (a) for fiscal year 2004, up to $8,500,000 is authorized and appropriated and shall be used by the Commissioner of Social Security under this subsection for purposes of conducting a statistically valid survey to determine how payments made to individuals, organizations, and State or local government agencies that are representative payees for benefits paid under title II or XVI are being managed and used on behalf of the beneficiaries for whom such benefits are paid.

(2) Not later than 18 months after the date of enactment of this subsection, the Commissioner of Social Security shall submit a report on the survey conducted in accordance with paragraph (1) to the Committee on Ways and Means of the House of Representatives and the Committee on Finance of the Senate.

PUBLIC ASSISTANCE PAYMENTS TO LEGAL REPRESENTATIVES

SEC. 1111. [42 U.S.C. 1311] For purposes of titles I, X, XIV, and XVI, and part A of title IV, payments on behalf of an individual, made to another person who has been judicially appointed, under the law of the State in which such individual resides, as legal representative of such individual for the purpose of receiving and managing such payments (whether or not he is such individual's legal representative for other purposes), shall be regarded as money payments to such individual.

MEDICAL CARE GUIDES AND REPORTS FOR PUBLIC ASSISTANCE AND MEDICAL ASSISTANCE

SEC. 1112. [42 U.S.C. 1312] In order to assist the States to extend the scope and content, and improve the quality, of medical care and medical services for which payments are made to or on behalf of needy and low-income individuals under this Act and in order to promote better public understanding about medical care and medical assistance for needy and low-income individuals, the Secretary shall develop and revise from time to time guides or recommended standards as to the level, content, and quality of medical care and medical services for the use of the States in evaluating and improving their public assistance medical care programs and their programs of medical assistance; shall secure periodic reports from the States on items included in, and the quantity of,

medical care and medical services for which expenditures under such programs are made; and shall from time to time publish data secured from these reports and other information necessary to carry out the purposes of this section.

ASSISTANCE FOR UNITED STATES CITIZENS RETURNED FROM FOREIGN COUNTRIES

SEC. 1113. [42 U.S.C. 1313] (a)(1) The Secretary is authorized to provide temporary assistance to citizens of the United States and to dependents of citizens of the United States, if they (A) are identified by the Department of State as having returned, or been brought, from a foreign country to the United States because of the destitution of the citizen of the United States or the illness of such citizen or any of his dependents or because of war, threat of war, invasion, or similar crisis, and (B) are without available resources.

(2) Except in such cases or classes of cases as are set forth in regulations of the Secretary, provision shall be made for reimbursement to the United States by the recipients of the temporary assistance to cover the cost thereof.

(3) The Secretary may provide assistance under paragraph (1) directly or through utilization of the services and facilities of appropriate public or private agencies and organizations, in accordance with agreements providing for payment, in advance or by way of reimbursement, as may be determined by the Secretary, of the cost thereof. Such cost shall be determined by such statistical, sampling, or other method as may be provided in the agreement.

(b) The Secretary is authorized to develop plans and make arrangements for provision of temporary assistance within the United States to individuals specified in subsection (a)(1). Such plans shall be developed and such arrangements shall be made after consultation with the Secretary of State, the Attorney General, and the Secretary of Defense. To the extent feasible, assistance provided under subsection (a) shall be provided in accordance with the plans developed pursuant to this subsection, as modified from time to time by the Secretary.

(c) For purposes of this section, the term "temporary assistance" means money payments, medical care, temporary billeting, transportation, and other goods and services necessary for the health or welfare of individuals (including guidance, counseling, and other welfare services) furnished to them within the United States upon their arrival in the United States and for such period after their arrival, not exceeding ninety days, as may be provided in regulations of the Secretary; except that assistance under this section may be furnished beyond such ninety-day period in the case of any citizen or dependent upon a finding by the Secretary that the circumstances involved necessitate or justify the furnishing of assistance beyond such period in that particular case.

(d) The total amount of temporary assistance provided under this section shall not exceed $1,000,000 during any fiscal year beginning after September 30, 2009, except that, in the case of fiscal years 2021 and 2022, the total amount of such assistance provided during each such fiscal year shall not exceed $10,000,000.

(e)(1) The Secretary may accept on behalf of the United States gifts, in cash or in kind, for use in carrying out the program established under this section. Gifts in the form of cash shall be credited to the appropriation account from which this program is funded, in addition to amounts otherwise appropriated, and shall remain available until expended.

(2) Gifts accepted under paragraph (1) shall be available for obligation or other use by the United States only to the extent and in the amounts provided in appropriation Acts.

APPOINTMENT OF ADVISORY COUNCIL AND OTHER ADVISORY GROUPS

SEC. 1114. [42 U.S.C. 1314] (a) The Secretary shall, during 1964, appoint an Advisory Council on Public Welfare for the purpose of reviewing the administration of the public assistance and child welfare services programs for which funds are appropriated pursuant to this Act and making recommendations for improvement of such administration, and reviewing the status of and making recommendations with respect to the public assistance programs for which funds are so appropriated, especially in relation to the old-age, survivors, and disability insurance program, with respect to the fiscal capacities of the States and the Federal Government, and with respect to any other matters bearing on the amount and proportion of the Federal and State shares in the public assistance and child welfare services programs.

(b) The Council shall be appointed by the Secretary without regard to the provisions of title 5, United States Code, governing appointments in the competitive service and shall consist of twelve persons who shall, to the extent possible, be representatives of employers and employees in equal numbers, representatives of State or Federal agencies concerned with the administration or financing of the public assistance and child welfare services programs, representatives of nonprofit private organizations concerned with social welfare programs, other persons with special knowledge, experience, or qualifications with respect to such programs, and members of the public.

(c) The Council is authorized to engage such technical assistance as may be required to carry out its functions, and the Secretary shall, in addition, make available to the Council such secretarial, clerical, and other assistance and such pertinent data prepared by the Department of Health and Human Services as it may require to carry out such functions.

(d) The Council shall make a report of its findings and recommendations (including recommendations for changes in the provisions of the Social Security Act) to the Secretary, such report to be submitted not later than July 1, 1966, after which date such Council shall cease to exist.

(e) The Secretary shall also from time to time thereafter appoint an Advisory Council on Public Welfare, with the same functions and constituted in the same manner as prescribed for the Advisory Council in the preceding subsections of this section. Each Council so appointed shall report its findings and recommendations, as prescribed in subsection (d), not later than July 1 of the

second year after the year in which it is appointed, after which date such Council shall cease to exist.

(f) The Secretary may also appoint, without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, such advisory committees as he may deem advisable to advise and consult with him in carrying out any of his functions under this Act. The Secretary shall report to the Congress annually on the number of such committees and on the membership and activities of each such committee.

(g) Members of the Council or of any advisory committee appointed under this section who are not regular full-time employees of the United States shall, while serving on business of the Council or any such committee, be entitled to receive compensation at rates fixed by the Secretary, but not exceeding $75 per day, including travel time; and while so serving away from their homes or regular places of business, they may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of title 5, United States Code, for persons in Government service employed intermittently.

(h)(1) Any member of the Council or any advisory committee appointed under this Act, who is not a regular full-time employee of the United States, is hereby exempted, with respect to such appointment, from the operation of sections 203, 205, and 209 of title 18, United States Code, except as otherwise specified in paragraph (2) of this subsection.

(2) The exemption granted by paragraph (1) shall not extend—

(A) to the receipt or payment of salary in connection with the appointee's Government service from any source other than the employer of the appointee at the time of his appointment, or

(B) during the period of such appointment, to the prosecution or participation in the prosecution, by any person so appointed, of any claim against the Government involving any matter with which such person, during such period, is or was directly connected by reason of such appointment.

NATIONAL ADVISORY COMMITTEE ON THE SEX TRAFFICKING OF CHIILDREN AND YOUTH IN THE UNITED STATES

SEC. 1114A. [42 U.S.C. 1314b] (a) OFFICIAL DESIGNATION.—This section relates to the National Advisory Committee on the Sex Trafficking of Children and Youth in the United States (in this section referred to as the "Committee").

(b) AUTHORITY.—Not later than 2 years after the date of enactment of this section, the Secretary shall establish and appoint all members of the Committee.

(c) MEMBERSHIP.—

(1) COMPOSITION.—The Committee shall be composed of not more than 21 members whose diverse experience and background enable them to provide balanced points of view with regard to carrying out the duties of the Committee.

(2) SELECTION.—The Secretary, in consultation with the Attorney General and National Governors Association, shall appoint the members to the Committee. At least 1 Committee member shall be a former sex trafficking victim. 2 Committee

members shall be a Governor of a State, 1 of whom shall be a member of the Democratic Party and 1 of whom shall be a member of the Republican Party.

(3) PERIOD OF APPOINTMENT; VACANCIES.—Members shall be appointed for the life of the Committee. A vacancy in the Committee shall be filled in the manner in which the original appointment was made and shall not affect the powers or duties of the Committee.

(4) COMPENSATION.—Committee members shall serve without compensation or per diem in lieu of subsistence.

(d) DUTIES.—

(1) NATIONAL RESPONSE.—The Committee shall advise the Secretary and the Attorney General on practical and general policies concerning improvements to the Nation's response to the sex trafficking of children and youth in the United States.

(2) POLICIES FOR COOPERATION.—The Committee shall advise the Secretary and the Attorney General on practical and general policies concerning the cooperation of Federal, State, local, and tribal governments, child welfare agencies, social service providers, physical health and mental health providers, victim service providers, State or local courts with responsibility for conducting or supervising proceedings relating to child welfare or social services for children and their families, Federal, State, and local police, juvenile detention centers, and runaway and homeless youth programs, schools, the gaming and entertainment industry, and businesses and organizations that provide services to youth, on responding to sex trafficking, including the development and implementation of—

(A) successful interventions with children and youth who are exposed to conditions that make them vulnerable to, or victims of, sex trafficking; and

(B) recommendations for administrative or legislative changes necessary to use programs, properties, or other resources owned, operated, or funded by the Federal Government to provide safe housing for children and youth who are sex trafficking victims and provide support to entities that provide housing or other assistance to the victims.

(3) BEST PRACTICES AND RECOMMENDATIONS FOR STATES.—

(A) IN GENERAL.—Within 2 years after the establishment of the Committee, the Committee shall develop 2 tiers (referred to in this subparagraph as "Tier I" and "Tier II") of recommended best practices for States to follow in combating the sex trafficking of children and youth. Tier I shall provide States that have not yet substantively addressed the sex trafficking of children and youth with an idea of where to begin and what steps to take. Tier II shall provide States that are already working to address the sex trafficking of children and youth with examples of policies that are already being used effectively by other States to address sex trafficking.

(B) DEVELOPMENT.—The best practices shall be based on multidisciplinary research and promising, evidence-based models and programs as reflected in State efforts to

meet the requirements of sections 101 and 102 of the Preventing Sex Trafficking and Strengthening Families Act.

(C) CONTENT.—The best practices shall be user-friendly, incorporate the most up-to-date technology, and include the following:

(i) Sample training materials, protocols, and screening tools that, to the extent possible, accommodate for regional differences among the States, to prepare individuals who administer social services to identify and serve children and youth who are sex trafficking victims or at-risk of sex trafficking.

(ii) Multidisciplinary strategies to identify victims, manage cases, and improve services for all children and youth who are at risk of sex trafficking, or are sex trafficking victims, in the United States.

(iii) Sample protocols and recommendations based on current States' efforts, accounting for regional differences between States that provide for effective, cross-system collaboration between Federal, State, local, and tribal governments, child welfare agencies, social service providers, physical health and mental health providers, victim service providers, State or local courts with responsibility for conducting or supervising proceedings relating to child welfare or social services for children and their families, the gaming and entertainment industry, Federal, State, and local police, juvenile detention centers and runaway and homeless youth programs, housing resources that are appropriate for housing child and youth victims of trafficking, schools, and businesses and organizations that provide services to children and youth. These protocols and recommendations should include strategies to identify victims and collect, document, and share data across systems and agencies, and should be designed to help agencies better understand the type of sex trafficking involved, the scope of the problem, the needs of the population to be served, ways to address the demand for trafficked children and youth and increase prosecutions of traffickers and purchasers of children and youth, and the degree of victim interaction with multiple systems.

(iv) Developing the criteria and guidelines necessary for establishing safe residential placements for foster children who have been sex trafficked as well as victims of trafficking identified through interaction with law enforcement.

(v) Developing training guidelines for caregivers that serve children and youth being cared for outside the home.

(D) INFORMING STATES OF BEST PRACTICES.—The Committee, in coordination with the National Governors Association, Secretary and Attorney General, shall ensure that State Governors and child welfare agencies are notified and informed on a quarterly basis of the best practices and

recommendations for States, and notified 6 months in advance that the Committee will be evaluating the extent to which States adopt the Committee's recommendations.

(E) REPORT ON STATE IMPLEMENTATION.—Within 3 years after the establishment of the Committee, the Committee shall submit to the Secretary and the Attorney General, as part of its final report as well as for online and publicly available publication, a description of what each State has done to implement the recommendations of the Committee.

(e) REPORTS.—

(1) IN GENERAL.—The Committee shall submit an interim and a final report on the work of the Committee to—

(A) the Secretary;

(B) the Attorney General;

(C) the Committee on Finance of the Senate; and

(D) the Committee on Ways and Means of the House of Representatives.

(2) REPORTING DATES.—The interim report shall be submitted not later than 3 years after the establishment of the Committee. The final report shall be submitted not later than 4 years after the establishment of the Committee.

(f) ADMINISTRATION.—

(1) AGENCY SUPPORT.—The Secretary shall direct the head of the Administration for Children and Families of the Department of Health and Human Services to provide all necessary support for the Committee.

(2) MEETINGS.—

(A) IN GENERAL.—The Committee will meet at the call of the Secretary at least twice each year to carry out this section, and more often as otherwise required.

(B) ACCOMMODATION FOR COMMITTEE MEMBERS UNABLE TO ATTEND IN PERSON.—The Secretary shall create a process through which Committee members who are unable to travel to a Committee meeting in person may participate remotely through the use of video conference, teleconference, online, or other means.

(3) SUBCOMMITTEES.—The Committee may establish subcommittees or working groups, as necessary and consistent with the mission of the Committee. The subcommittees or working groups shall have no authority to make decisions on behalf of the Committee, nor shall they report directly to any official or entity listed in subsection (d).

(4) RECORDKEEPING.—The records of the Committee and any subcommittees and working groups shall be maintained in accordance with appropriate Department of Health and Human Services policies and procedures and shall be available for public inspection and copying, subject to the Freedom of Information Act (5 U.S.C. 552).

(g) TERMINATION.—The Committee shall terminate 5 years after the date of its establishment, but the Secretary shall continue to operate and update, as necessary, an Internet website displaying the State best practices, recommendations, and evaluation of State-by-State implementation of the Secretary's recommendations.

(h) DEFINITION.—For the purpose of this section, the term "sex trafficking" includes the definition set forth in section 103(10) of the Trafficking Victims Protection Act of 2000 (22 U.S.C. 7102(10)) and "severe form of trafficking in persons" described in section 103(9)(A) of such Act.

DEMONSTRATION PROJECTS

SEC. 1115. [42 U.S.C. 1315] (a) In the case of any experimental, pilot, or demonstration project which, in the judgment of the Secretary, is likely to assist in promoting the objectives of title I, X, XIV, XVI, or XIX, or part A or D of title IV, in a State or States—

(1) the Secretary may waive compliance with any of the requirements of section 2, 402, 454, 1002, 1402, 1602, or 1902, as the case may be, to the extent and for the period he finds necessary to enable such State or States to carry out such project, and

(2)(A) costs of such project which would not otherwise be included as expenditures under section 3, 455, 1003, 1403, 1603, or 1903, as the case may be, and which are not included as part of the costs of projects under section 1110, shall, to the extent and for the period prescribed by the Secretary, be regarded as expenditures under the State plan or plans approved under such title, or for administration of such State plan or plans, as may be appropriate, or

(B) costs of such project which would not otherwise be a permissible use of funds under part A of title IV and which are not included as part of the costs of projects under section 1110, shall to the extent and for the period prescribed by the Secretary, be regarded as a permissible use of funds under such part.

In addition, not to exceed $4,000,000 of the aggregate amount appropriated for payments to States under such titles for any fiscal year beginning after June 30, 1967, shall be available, under such terms and conditions as the Secretary may establish, for payments to States to cover so much of the cost of such projects as is not covered by payments under such titles and is not included as part of the cost of projects for purposes of section 1110.

(b)(1) In the case of any experimental, pilot, or demonstration project undertaken under subsection (a) to assist in promoting the objectives of part D of title IV, the project—

(A) must be designed to improve the financial well-being of children or otherwise improve the operation of the child support program;

(B) may not permit modifications in the child support program which would have the effect of disadvantaging children in need of support; and

(C) must not result in increased cost to the Federal Government under part A of such title.

(2) An Indian tribe or tribal organization operating a program under section 455(f) shall be considered a State for purposes of authority to conduct an experimental, pilot, or demonstration project under subsection (a) to assist in promoting the objectives of part D

of title IV and receiving payments under the second sentence of that subsection. The Secretary may waive compliance with any requirements of section 455(f) or regulations promulgated under that section to the extent and for the period the Secretary finds necessary for an Indian tribe or tribal organization to carry out such project. Costs of the project which would not otherwise be included as expenditures of a program operating under section 455(f) and which are not included as part of the costs of projects under section 1110, shall, to the extent and for the period prescribed by the Secretary, be regarded as expenditures under a tribal plan or plans approved under such section, or for the administration of such tribal plan or plans, as may be appropriate. An Indian tribe or tribal organization applying for or receiving start-up program development funding pursuant to section 309.16 of title 45, Code of Federal Regulations, shall not be considered to be an Indian tribe or tribal organization operating a program under section 455(f) for purposes of this paragraph.

(c)(1)(A) The Secretary shall enter into agreements with up to 8 States submitting applications under this subsection for the purpose of conducting demonstration projects in such States to test and evaluate the use, with respect to individuals who received aid under part A of title IV in the preceding month (on the basis of the unemployment of the parent who is the principal earner), of a number greater than 100 for the number of hours per month that such individuals may work and still be considered to be unemployed for purposes of section 407. If any State submits an application under this subsection for the purpose of conducting a demonstration project to test and evaluate the total elimination of the 100-hour rule, the Secretary shall approve at least one such application.

(B) If any State with an agreement under this subsection so requests, the demonstration project conducted pursuant to such agreement may test and evaluate the complete elimination of the 100-hour rule and of any other durational standard that might be applied in defining unemployment for purposes of determining eligibility under section 407.

(2) Notwithstanding section 402(a)(1), a demonstration project conducted under this subsection may be conducted in one or more political subdivisions of the State.

(3) An agreement under this subsection shall be entered into between the Secretary and the State agency designated under section 402(a)(3). Such agreement shall provide for the payment of aid under the applicable State plan under part A of title IV as though section 407 had been modified to reflect the definition of unemployment used in the demonstration project but shall also provide that such project shall otherwise be carried out in accordance with all of the requirements and conditions of section 407 (and, except as provided in paragraph (2), any related requirements and conditions under part A of title IV).

(4) A demonstration project under this subsection may be commenced any time after September 30, 1990, and shall be conducted for such period of time as the agreement with the Secretary may provide; except that, in no event may a demonstration project under this section be conducted after September 30, 1995.

(5)(A) Any State with an agreement under this subsection shall evaluate the comparative cost and employment effects of the use of the definition of unemployment in its demonstration project under this section by use of experimental and control groups comprised of a random sample of individuals receiving aid under section 407 and shall furnish the Secretary with such information as the Secretary determines to be necessary to evaluate the results of the project conducted by the State.

(B) The Secretary shall report the results of the demonstration projects conducted under this subsection to the Congress not later than 6 months after all such projects are completed.

(d)(1) An application or renewal of any experimental, pilot, or demonstration project undertaken under subsection (a) to promote the objectives of title XIX or XXI in a State that would result in an impact on eligibility, enrollment, benefits, cost-sharing, or financing with respect to a State program under title XIX or XXI (in this subsection referred to as a "demonstration project") shall be considered by the Secretary in accordance with the regulations required to be promulgated under paragraph (2).

(2) Not later than 180 days after the date of enactment of this subsection, the Secretary shall promulgate regulations relating to applications for, and renewals of, a demonstration project that provide for—

(A) a process for public notice and comment at the State level, including public hearings, sufficient to ensure a meaningful level of public input;

(B) requirements relating to—

(i) the goals of the program to be implemented or renewed under the demonstration project;

(ii) the expected State and Federal costs and coverage projections of the demonstration project; and

(iii) the specific plans of the State to ensure that the demonstration project will be in compliance with title XIX or XXI;

(C) a process for providing public notice and comment after the application is received by the Secretary, that is sufficient to ensure a meaningful level of public input;

(D) a process for the submission to the Secretary of periodic reports by the State concerning the implementation of the demonstration project; and

(E) a process for the periodic evaluation by the Secretary of the demonstration project.

(3) The Secretary shall annually report to Congress concerning actions taken by the Secretary with respect to applications for demonstration projects under this section.

(e)(1) The provisions of this subsection shall apply to the extension of any State-wide comprehensive demonstration project (in this subsection referred to as "waiver project") for which a waiver of compliance with requirements of title XIX is granted under subsection (a).

(2) During the 6-month period ending 1 year before the date the waiver under subsection (a) with respect to a waiver project would otherwise expire, the chief executive officer of the State which is operating the project may submit to the Secretary a writ-

ten request for an extension, of up to 3 years (5 years, in the case of a waiver described in section 1915(h)(2)), of the project.

(3) If the Secretary fails to respond to the request within 6 months after the date it is submitted, the request is deemed to have been granted.

(4) If such a request is granted, the deadline for submittal of a final report under the waiver project is deemed to have been extended until the date that is 1 year after the date the waiver project would otherwise have expired.

(5) The Secretary shall release an evaluation of each such project not later than 1 year after the date of receipt of the final report.

(6) Subject to paragraphs (4) and (7), the extension of a waiver project under this subsection shall be on the same terms and conditions (including applicable terms and conditions relating to quality and access of services, budget neutrality, data and reporting requirements, and special population protections) that applied to the project before its extension under this subsection.

(7) If an original condition of approval of a waiver project was that Federal expenditures under the project not exceed the Federal expenditures that would otherwise have been made, the Secretary shall take such steps as may be necessary to ensure that, in the extension of the project under this subsection, such condition continues to be met. In applying the previous sentence, the Secretary shall take into account the Secretary's best estimate of rates of change in expenditures at the time of the extension.

(f) An application by the chief executive officer of a State for an extension of a waiver project the State is operating under an extension under subsection (e) (in this subsection referred to as the "waiver project") shall be submitted and approved or disapproved in accordance with the following:

(1) The application for an extension of the waiver project shall be submitted to the Secretary at least 120 days prior to the expiration of the current period of the waiver project.

(2) Not later than 45 days after the date such application is received by the Secretary, the Secretary shall notify the State if the Secretary intends to review the terms and conditions of the waiver project. A failure to provide such notification shall be deemed to be an approval of the application.

(3) Not later than 45 days after the date a notification is made in accordance with paragraph (2), the Secretary shall inform the State of proposed changes in the terms and conditions of the waiver project. A failure to provide such information shall be deemed to be an approval of the application.

(4) During the 30-day period that begins on the date information described in paragraph (3) is provided to a State, the Secretary shall negotiate revised terms and conditions of the waiver project with the State.

(5)(A) Not later than 120 days after the date an application for an extension of the waiver project is submitted to the Secretary (or such later date agreed to by the chief executive officer of the State), the Secretary shall—

(i) approve the application subject to such modifications in the terms and conditions—

(I) as have been agreed to by the Secretary and the State; or

(II) in the absence of such agreement, as are determined by the Secretary to be reasonable, consistent with the overall objectives of the waiver project, and not in violation of applicable law; or

(ii) disapprove the application.

(B) A failure by the Secretary to approve or disapprove an application submitted under this subsection in accordance with the requirements of subparagraph (A) shall be deemed to be an approval of the application subject to such modifications in the terms and conditions as have been agreed to (if any) by the Secretary and the State.

(6) An approval of an application for an extension of a waiver project under this subsection shall be for a period not to exceed 3 years (5 years, in the case of a waiver described in section 1915(h)(2)).

(7) An extension of a waiver project under this subsection shall be subject to the final reporting and evaluation requirements of paragraphs (4) and (5) of subsection (e) (taking into account the extension under this subsection with respect to any timing requirements imposed under those paragraphs).

(g) REQUIREMENT OF BUDGET NEUTRALITY FOR MEDICAID DEMONSTRATION PROJECTS.—

(1) IN GENERAL.—Beginning January 1 2027, the Secretary may not approve an application for (or renewal or amendment of) an experimental, pilot, or demonstration project undertaken under subsection (a) to promote the objectives of title XIX in a State (in this subsection referred to as a "Medicaid demonstration project") unless the Chief Actuary for the Centers for Medicare & Medicaid Services certifies that such project, or, in the case of a renewal, the duration of the preceding waiver, is not expected to result in an increase in the amount of Federal expenditures compared to the amount that such expenditures would otherwise be in the absence of such project. For purposes of this subsection, expenditures for the coverage of populations and services that the State could have otherwise provided through its Medicaid State plan or other authority under title XIX, including expenditures that could be made under such authority but for the provision of such services at a different site of service than authorized under such State plan or other authority, shall be considered expenditures in the absence of such a project.

(2) TREATMENT OF SAVINGS.—In the event that expenditures with respect to a State under a Medicaid demonstration project are, during an approval period for such project, less than the amount of such expenditures that would have otherwise been made in the absence of such project, the Secretary shall specify the methodology to be used with respect to the subsequent approval period for such project for purposes of taking the difference between such expenditures into account.

CENTER FOR MEDICARE AND MEDICAID INNOVATION

SEC. 1115A. [42 U.S.C. 1315a] (a) CENTER FOR MEDICARE AND MEDICAID INNOVATION ESTABLISHED.—

(1) IN GENERAL.—There is created within the Centers for Medicare & Medicaid Services a Center for Medicare and Medicaid Innovation (in this section referred to as the "CMI") to carry out the duties described in this section. The purpose of the CMI is to test innovative payment and service delivery models to reduce program expenditures under the applicable titles while preserving or enhancing the quality of care furnished to individuals under such titles. In selecting such models, the Secretary shall give preference to models that also improve the coordination, quality, and efficiency of health care services furnished to applicable individuals defined in paragraph (4)(A).

(2) DEADLINE.—The Secretary shall ensure that the CMI is carrying out the duties described in this section by not later than January 1, 2011.

(3) CONSULTATION.—In carrying out the duties under this section, the CMI shall consult representatives of relevant Federal agencies, and clinical and analytical experts with expertise in medicine and health care management. The CMI shall use open door forums or other mechanisms to seek input from interested parties.

(4) DEFINITIONS.—In this section:

(A) APPLICABLE INDIVIDUAL.—The term "applicable individual" means—

(i) an individual who is entitled to, or enrolled for, benefits under part A of title XVIII or enrolled for benefits under part B of such title;

(ii) an individual who is eligible for medical assistance under title XIX, under a State plan or waiver; or

(iii) an individual who meets the criteria of both clauses (i) and (ii).

(B) APPLICABLE TITLE.—The term "applicable title" means title XVIII, title XIX, or both.

(5) TESTING WITHIN CERTAIN GEOGRAPHIC AREAS.—For purposes of testing payment and service delivery models under this section, the Secretary may elect to limit testing of a model to certain geographic areas.

(b) TESTING OF MODELS (PHASE I).—

(1) IN GENERAL.—The CMI shall test payment and service delivery models in accordance with selection criteria under paragraph (2) to determine the effect of applying such models under the applicable title (as defined in subsection (a)(4)(B)) on program expenditures under such titles and the quality of care received by individuals receiving benefits under such title.

(2) SELECTION OF MODELS TO BE TESTED.—

(A) IN GENERAL.—The Secretary shall select models to be tested from models where the Secretary determines that there is evidence that the model addresses a defined population for which there are deficits in care leading to poor clinical outcomes or potentially avoidable expendi-

tures. The Secretary shall focus on models expected to reduce program costs under the applicable title while preserving or enhancing the quality of care received by individuals receiving benefits under such title. The models selected under this subparagraph may include, but are not limited to, the models described in subparagraph (B).

(B) OPPORTUNITIES.—The models described in this subparagraph are the following models:

(i) Promoting broad payment and practice reform in primary care, including patient-centered medical home models for high-need applicable individuals, medical homes that address women's unique health care needs, and models that transition primary care practices away from fee-for-service based reimbursement and toward comprehensive payment or salary-based payment.

(ii) Contracting directly with groups of providers of services and suppliers to promote innovative care delivery models, such as through risk-based comprehensive payment or salary-based payment.

(iii) Utilizing geriatric assessments and comprehensive care plans to coordinate the care (including through interdisciplinary teams) of applicable individuals with multiple chronic conditions and at least one of the following:

(I) An inability to perform 2 or more activities of daily living.

(II) Cognitive impairment, including dementia.

(iv) Promote care coordination between providers of services and suppliers that transition health care providers away from fee-for-service based reimbursement and toward salary-based payment.

(v) Supporting care coordination for chronically-ill applicable individuals at high risk of hospitalization through a health information technology-enabled provider network that includes care coordinators, a chronic disease registry, and home tele-health technology.

(vi) Varying payment to physicians who order advanced diagnostic imaging services (as defined in section 1834(e)(1)(B)) according to the physician's adherence to appropriateness criteria for the ordering of such services, as determined in consultation with physician specialty groups and other relevant stakeholders.

(vii) Utilizing medication therapy management services, such as those described in section 935 of the Public Health Service Act.

(viii) Establishing community-based health teams to support small-practice medical homes by assisting the primary care practitioner in chronic care management, including patient self-management, activities.

(ix) Assisting applicable individuals in making informed health care choices by paying providers of serv-

ices and suppliers for using patient decision-support tools, including tools that meet the standards developed and identified under section 936(c)(2)(A) of the Public Health Service Act, that improve applicable individual and caregiver understanding of medical treatment options.

(x) Allowing States to test and evaluate fully integrating care for dual eligible individuals in the State, including the management and oversight of all funds under the applicable titles with respect to such individuals.

(xi) Allowing States to test and evaluate systems of all-payer payment reform for the medical care of residents of the State, including dual eligible individuals.

(xii) Aligning nationally recognized, evidence-based guidelines of cancer care with payment incentives under title XVIII in the areas of treatment planning and follow-up care planning for applicable individuals described in clause (i) or (iii) of subsection (a)(4)(A) with cancer, including the identification of gaps in applicable quality measures.

(xiii) Improving post-acute care through continuing care hospitals that offer inpatient rehabilitation, long-term care hospitals, and home health or skilled nursing care during an inpatient stay and the 30 days immediately following discharge.

(xiv) Funding home health providers who offer chronic care management services to applicable individuals in cooperation with interdisciplinary teams.

(xv) Promoting improved quality and reduced cost by developing a collaborative of high-quality, low-cost health care institutions that is responsible for—

(I) developing, documenting, and disseminating best practices and proven care methods;

(II) implementing such best practices and proven care methods within such institutions to demonstrate further improvements in quality and efficiency; and

(III) providing assistance to other health care institutions on how best to employ such best practices and proven care methods to improve health care quality and lower costs.

(xvi) Facilitate inpatient care, including intensive care, of hospitalized applicable individuals at their local hospital through the use of electronic monitoring by specialists, including intensivists and critical care specialists, based at integrated health systems.

(xvii) Promoting greater efficiencies and timely access to outpatient services (such as outpatient physical therapy services) through models that do not require a physician or other health professional to refer the service or be involved in establishing the plan of care for the service, when such service is furnished by a

health professional who has the authority to furnish the service under existing State law.

(xviii) Establishing comprehensive payments to Healthcare Innovation Zones, consisting of groups of providers that include a teaching hospital, physicians, and other clinical entities, that, through their structure, operations, and joint-activity deliver a full spectrum of integrated and comprehensive health care services to applicable individuals while also incorporating innovative methods for the clinical training of future health care professionals.

(xix) Utilizing, in particular in entities located in medically underserved areas and facilities of the Indian Health Service (whether operated by such Service or by an Indian tribe or tribal organization (as those terms are defined in section 4 of the Indian Health Care Improvement Act)), telehealth services—

(I) in treating behavioral health issues (such as post-traumatic stress disorder) and stroke; and

(II) to improve the capacity of non-medical providers and non-specialized medical providers to provide health services for patients with chronic complex conditions.

(xx) Utilizing a diverse network of providers of services and suppliers to improve care coordination for applicable individuals described in subsection (a)(4)(A)(i) with 2 or more chronic conditions and a history of prior-year hospitalization through interventions developed under the Medicare Coordinated Care Demonstration Project under section 4016 of the Balanced Budget Act of 1997 (42 U.S.C. 1395b–1 note).

(xxi) Focusing primarily on physicians' services (as defined in section 1848(j)(3)) furnished by physicians who are not primary care practitioners.

(xxii) Focusing on practices of 15 or fewer professionals.

(xxiii) Focusing on risk-based models for small physician practices which may involve two-sided risk and prospective patient assignment, and which examine risk-adjusted decreases in mortality rates, hospital readmissions rates, and other relevant and appropriate clinical measures.

(xxiv) Focusing primarily on title XIX, working in conjunction with the Center for Medicaid and CHIP Services.

(xxv) Providing, for the adoption and use of certified EHR technology (as defined in section 1848(o)(4)) to improve the quality and coordination of care through the electronic documentation and exchange of health information, incentive payments to behavioral health providers (such as psychiatric hospitals (as defined in section 1861(f)), community mental health centers (as defined in section 1861(ff)(3)(B)), hospitals that participate in a State plan under title

XIX or a waiver of such plan, treatment facilities that participate in such a State plan or such a waiver, mental health or substance use disorder providers that participate in such a State plan or such a waiver, clinical psychologists (as defined in section 1861(ii)), nurse practitioners (as defined in section 1861(aa)(5)) with respect to the provision of psychiatric services, and clinical social workers (as defined in section 1861(hh)(1))).

(xxvi) Supporting ways to familiarize individuals with the availability of coverage under part B of title XVIII for qualified psychologist services (as defined in section 1861(ii)).

(xxvii) Exploring ways to avoid unnecessary hospitalizations or emergency department visits for mental and behavioral health services (such as for treating depression) through use of a 24-hour, 7-day a week help line that may inform individuals about the availability of treatment options, including the availability of qualified psychologist services (as defined in section 1861(ii)).

(C) ADDITIONAL FACTORS FOR CONSIDERATION.—In selecting models for testing under subparagraph (A), the CMI may consider the following additional factors:

(i) Whether the model includes a regular process for monitoring and updating patient care plans in a manner that is consistent with the needs and preferences of applicable individuals.

(ii) Whether the model places the applicable individual, including family members and other informal caregivers of the applicable individual, at the center of the care team of the applicable individual.

(iii) Whether the model provides for in-person contact with applicable individuals.

(iv) Whether the model utilizes technology, such as electronic health records and patient-based remote monitoring systems, to coordinate care over time and across settings.

(v) Whether the model provides for the maintenance of a close relationship between care coordinators, primary care practitioners, specialist physicians, community-based organizations, and other providers of services and suppliers.

(vi) Whether the model relies on a team-based approach to interventions, such as comprehensive care assessments, care planning, and self-management coaching.

(vii) Whether, under the model, providers of services and suppliers are able to share information with patients, caregivers, and other providers of services and suppliers on a real time basis.

(viii) Whether the model demonstrates effective linkage with other public sector payers, private sector payers, or statewide payment models.

(3) BUDGET NEUTRALITY.—

(A) INITIAL PERIOD.—The Secretary shall not require, as a condition for testing a model under paragraph (1), that the design of such model ensure that such model is budget neutral initially with respect to expenditures under the applicable title.

(B) TERMINATION OR MODIFICATION.—The Secretary shall terminate or modify the design and implementation of a model unless the Secretary determines (and the Chief Actuary of the Centers for Medicare & Medicaid Services, with respect to program spending under the applicable title, certifies), after testing has begun, that the model is expected to—

(i) improve the quality of care (as determined by the Administrator of the Centers for Medicare & Medicaid Services) without increasing spending under the applicable title;

(ii) reduce spending under the applicable title without reducing the quality of care; or

(iii) improve the quality of care and reduce spending.

Such termination may occur at any time after such testing has begun and before completion of the testing.

(4) EVALUATION.—

(A) IN GENERAL.—The Secretary shall conduct an evaluation of each model tested under this subsection. Such evaluation shall include an analysis of—

(i) the quality of care furnished under the model, including the measurement of patient-level outcomes and patient-centeredness criteria determined appropriate by the Secretary; and

(ii) the changes in spending under the applicable titles by reason of the model.

(B) INFORMATION.—The Secretary shall make the results of each evaluation under this paragraph available to the public in a timely fashion and may establish requirements for States and other entities participating in the testing of models under this section to collect and report information that the Secretary determines is necessary to monitor and evaluate such models.

(C) MEASURE SELECTION.—To the extent feasible, the Secretary shall select measures under this paragraph that reflect national priorities for quality improvement and patient-centered care consistent with the measures described in 1890(b)(7)(B).

(c) EXPANSION OF MODELS (PHASE II).—Taking into account the evaluation under subsection (b)(4), the Secretary may, through rulemaking, expand (including implementation on a nationwide basis) the duration and the scope of a model that is being tested under subsection (b) or a demonstration project under section 1866C, to the extent determined appropriate by the Secretary, if—

(1) the Secretary determines that such expansion is expected to—

(A) reduce spending under applicable title without reducing the quality of care; or

(B) improve the quality of patient care without increasing spending;

(2) the Chief Actuary of the Centers for Medicare & Medicaid Services certifies that such expansion would reduce (or would not result in any increase in) net program spending under applicable titles; and

(3) the Secretary determines that such expansion would not deny or limit the coverage or provision of benefits under the applicable title for applicable individuals.

In determining which models or demonstration projects to expand under the preceding sentence, the Secretary shall focus on models and demonstration projects that improve the quality of patient care and reduce spending.

(d) IMPLEMENTATION.—

(1) WAIVER AUTHORITY.—The Secretary may waive such requirements of titles XI and XVIII and of sections 1902(a)(1), 1902(a)(13), 1903(m)(2)(A)(iii), and 1934 (other than subsections (b)(1)(A) and (c)(5) of such section) as may be necessary solely for purposes of carrying out this section with respect to testing models described in subsection (b).

(2) LIMITATIONS ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of—

(A) the selection of models for testing or expansion under this section;

(B) the selection of organizations, sites, or participants to test those models selected;

(C) the elements, parameters, scope, and duration of such models for testing or dissemination;

(D) determinations regarding budget neutrality under subsection (b)(3);

(E) the termination or modification of the design and implementation of a model under subsection (b)(3)(B); and

(F) determinations about expansion of the duration and scope of a model under subsection (c), including the determination that a model is not expected to meet criteria described in paragraph (1) or (2) of such subsection.

(3) ADMINISTRATION.—Chapter 35 of title 44, United States Code, shall not apply to the testing and evaluation of models or expansion of such models under this section.

(e) APPLICATION TO CHIP.—The Center may carry out activities under this section with respect to title XXI in the same manner as provided under this section with respect to the program under the applicable titles.

(f) FUNDING.—

(1) IN GENERAL.—There are appropriated, from amounts in the Treasury not otherwise appropriated—

(A) $5,000,000 for the design, implementation, and evaluation of models under subsection (b) for fiscal year 2010;

(B) $10,000,000,000 for the activities initiated under this section for the period of fiscal years 2011 through 2019; and

(C) the amount described in subparagraph (B) for the activities initiated under this section for each subsequent 10-year fiscal period (beginning with the 10-year fiscal period beginning with fiscal year 2020).

Amounts appropriated under the preceding sentence shall remain available until expended.

(2) USE OF CERTAIN FUNDS.—Out of amounts appropriated under subparagraphs (B) and (C) of paragraph (1), not less than $25,000,000 shall be made available each such fiscal year to design, implement, and evaluate models under subsection (b).

(g) REPORT TO CONGRESS.—Beginning in 2012, and not less than once every other year thereafter, the Secretary shall submit to Congress a report on activities under this section. Each such report shall describe the models tested under subsection (b), including the number of individuals described in subsection (a)(4)(A)(i) and of individuals described in subsection (a)(4)(A)(ii) participating in such models and payments made under applicable titles for services on behalf of such individuals, any models chosen for expansion under subsection (c), and the results from evaluations under subsection (b)(4). In addition, each such report shall provide such recommendations as the Secretary determines are appropriate for legislative action to facilitate the development and expansion of successful payment models.

ADMINISTRATIVE AND JUDICIAL REVIEW OF CERTAIN ADMINISTRATIVE DETERMINATIONS

SEC. 1116. [42 U.S.C. 1316] (a)(1) Whenever a State plan is submitted to the Secretary by a State for approval under title I, X, XIV, XVI, or XIX, he shall, not later than 90 days after the date the plan is submitted to him, make a determination as to whether it conforms to the requirements for approval under such title. The 90- day period provided herein may be extended by written agreement of the Secretary and the affected State.

(2) Any State dissatisfied with a determination of the Secretary under paragraph (1) with respect to any plan may, within 60 days after it has been notified of such determination, file a petition with the Secretary for reconsideration of the issue of whether such plan conforms to the requirements for approval under such title. Within 30 days after receipt of such a petition, the Secretary shall notify the State of the time and place at which a hearing will be held for the purpose of reconsidering such issue. Such hearing shall be held not less than 20 days nor more than 60 days after the date notice of such hearing is furnished to such State, unless the Secretary and such State agree in writing to holding the hearing at another time. The Secretary shall affirm, modify, or reverse his original determination within 60 days of the conclusion of the hearing.

(3) Any State which is dissatisfied with a final determination made by the Secretary on such a reconsideration or a final deter-

mination of the Secretary under section 4, 1004, 1404, 1604, or 1904 may, within 60 days after it has been notified of such determination, file with the United States court of appeals for the circuit in which such State is located a petition for review of such determination. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary. The Secretary thereupon shall file in the court the record of the proceedings on which he based his determination as provided in section 2112 of title 28, United States Code.

(4) The findings of fact by the Secretary, if supported by substantial evidence, shall be conclusive; but the court, for good cause shown, may remand the case to the Secretary to take further evidence, and the Secretary may thereupon make new or modified findings of fact and may modify his previous action, and shall certify to the court the transcript and record of the further proceedings. Such new or modified findings of fact shall likewise be conclusive if supported by substantial evidence.

(5) The court shall have jurisdiction to affirm the action of the Secretary or to set it aside, in whole or in part. The judgment of the court shall be subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28, United States Code.

(b) For the purposes of subsection (a), any amendment of a State plan approved under title I, X, XIV, XVI, or XIX, may, at the option of the State, be treated as the submission of a new State plan.

(c) Action pursuant to an initial determination of the Secretary described in subsection (a) shall not be stayed pending reconsideration, but in the event that the Secretary subsequently determines that his initial determination was incorrect he shall certify restitution forthwith in a lump sum of any funds incorrectly withheld or otherwise denied.

(d) Whenever the Secretary determines that any item or class of items on account of which Federal financial participation is claimed under title I, X, XIV, XVI, or part A of title IV, shall be disallowed for such participation, the State shall be entitled to and upon request shall receive a reconsideration of the disallowance.

(e)(1) Whenever the Secretary determines that any item or class of items on account of which Federal financial participation is claimed under title XIX shall be disallowed for such participation, the State shall be entitled to and upon request shall receive a reconsideration of the disallowance, provided that such request is made during the 60-day period that begins on the date the State receives notice of the disallowance.

(2)(A) A State may appeal a disallowance of a claim for federal financial participation under title XIX by the Secretary, or an unfavorable reconsideration of a disallowance, during the 60-day period that begins on the date the State receives notice of the disallowance or of the unfavorable reconsideration, in whole or in part, to the Departmental Appeals Board, established in the Department of Health and Human Services (in this paragraph referred to as the "Board"), by filing a notice of appeal with the Board.

(B) The Board shall consider a State's appeal of a disallowance of such a claim (or of an unfavorable reconsideration of a disallow-

ance) on the basis of such documentation as the State may submit and as the Board may require to support the final decision of the Board. In deciding whether to uphold a disallowance of such a claim or any portion thereof, the Board shall be bound by all applicable laws and regulations and shall conduct a thorough review of the issues, taking into account all relevant evidence. The Board's decision of an appeal under subparagraph (A) shall be the final decision of the Secretary and shall be subject to reconsideration by the Board only upon motion of either party filed during the 60-day period that begins on the date of the Board's decision or to judicial review in accordance with subparagraph (C).

(C) A State may obtain judicial review of a decision of the Board by filing an action in any United States District Court located within the appealing State (or, if several States jointly appeal the disallowance of claims for Federal financial participation under section 1903, in any United States District Court that is located within any State that is a party to the appeal) or the United States District Court for the District of Columbia. Such an action may only be filed—

(i) if no motion for reconsideration was filed within the 60-day period specified in subparagraph (B), during such 60-day period; or

(ii) if such a motion was filed within such period, during the 60-day period that begins on the date of the Board's decision on such motion.

APPOINTMENT OF THE ADMINISTRATOR AND CHIEF ACTUARY OF THE CENTERS FOR MEDICARE & MEDICAID SERVICES

SEC. 1117. [42 U.S.C. 1317] (a) The Administrator of the Centers for Medicare & Medicaid Services shall be appointed by the President by and with the advice and consent of the Senate.

(b)(1) There is established in the Centers for Medicare & Medicaid Services the position of Chief Actuary. The Chief Actuary shall be appointed by, and in direct line of authority to, the Administrator of such Centers. The Chief Actuary shall be appointed from among individuals who have demonstrated, by their education and experience, superior expertise in the actuarial sciences. The Chief Actuary shall exercise such duties as are appropriate for the office of the Chief Actuary and in accordance with professional standards of actuarial independence. The Chief Actuary may be removed only for cause.

(2) The Chief Actuary shall be compensated at the highest rate of basic pay for the Senior Executive Service under section 5382(b) of title 5, United States Code.

(3) In the office of the Chief Actuary there shall be an actuary whose duties relate exclusively to the programs under parts C and D of title XVIII and related provisions of such title.

ALTERNATIVE FEDERAL PAYMENT WITH RESPECT TO PUBLIC ASSISTANCE EXPENDITURES

SEC. 1118. [42 U.S.C. 1318] In the case of any State which has in effect a plan approved under title XIX for any calendar quarter, the total of the payments to which such State is entitled

for such quarter, and for each succeeding quarter in the same fiscal year (which for purposes of this section means the 4 calendar quarters ending with September 30), under paragraphs (1) and (2) of sections 3(a), 1003(a), 1403(a), and 1603(a) shall, at the option of the State, be determined by application of the Federal medical assistance percentage (as defined in section 1905), instead of the percentages provided under each such section, to the expenditures under its State plans approved under titles I, X, XIV, and XVI, which would be included in determining the amounts of the Federal payments to which such State is entitled under such sections, but without regard to any maximum on the dollar amounts per recipient which may be counted under such sections. For purposes of the preceding sentence, the term "Federal medical assistance percentage" shall, in the case of Puerto Rico, the Virgin Islands, and Guam, mean 75 per centum.

FEDERAL PARTICIPATION IN PAYMENTS FOR REPAIRS TO HOME OWNED BY RECIPIENT OF AID OR ASSISTANCE

SEC. 1119. [42 U.S.C. 1319] In the case of an expenditure for repairing the home owned by an individual who is receiving aid or assistance, other than medical assistance to the aged, under a State plan approved under title I, X, XIV, or XVI, if—

(1) the State agency or local agency administering the plan approved under such title has made a finding (prior to making such expenditure) that (A) such home is so defective that continued occupancy is unwarranted, (B) unless repairs are made to such home, rental quarters will be necessary for such individual, and (C) the cost of rental quarters to take care of the needs of such individual (including his spouse living with him in such home and any other individual whose needs were taken into account in determining the need of such individual) would exceed (over such time as the Secretary may specify) the cost of repairs needed to make such home habitable together with other costs attributable to continued occupancy of such home, and

(2) no such expenditures were made for repairing such home pursuant to any prior finding under this section, the amount paid to any such State for any quarter under section 3(a), 1003(a), 1403(a), or 1603(a) shall be increased by 50 per centum of such expenditures, except that the excess above $500 expended with respect to any one home shall not be included in determining such expenditures.

APPROVAL OF CERTAIN PROJECTS

SEC. 1120. [42 U.S.C. 1320] No payment shall be made under this Act with respect to any experimental, pilot, demonstration, or other project all or any part of which is wholly financed with Federal funds made available under this Act (without any State, local, or other non-Federal financial participation) unless such project shall have been personally approved by the Secretary or Under Secretary of Health and Human Services.

UNIFORM REPORTING SYSTEMS FOR HEALTH SERVICES FACILITIES AND ORGANIZATIONS

SEC. 1121. [42 U.S.C. 1320a] (a) For the purposes of reporting the cost of services provided by, of planning, and of measuring and comparing the efficiency of and effective use of services in, hospitals, skilled nursing facilities, intermediate care facilities, home health agencies, health maintenance organizations, and other types of health services facilities and organizations to which payment may be made under this Act, the Secretary shall establish by regulation, for each such type of health services facility or organization, a uniform system for the reporting by a facility or organization of that type of the following information:

(1) The aggregate cost of operation and the aggregate volume of services.

(2) The costs and volume of services for various functional accounts and subaccounts.

(3) Rates, by category of patient and class of purchaser.

(4) Capital assets, as defined by the Secretary, including (as appropriate) capital funds, debt service, lease agreements used in lieu of capital funds, and the value of land, facilities, and equipment.

(5) Discharge and bill data.

The uniform reporting system for a type of health services facility or organization shall provide for appropriate variation in the application of the system to different classes of facilities or organizations within that type and shall be established, to the extent practicable, consistent with the cooperative system for producing comparable and uniform health information and statistics described in section 306(e)(1) of the Public Health Service Act. In reporting under such a system, hospitals shall employ such chart of accounts, definitions, principles, and statistics as the Secretary may prescribe in order to reach a uniform reconciliation of financial and statistical data for specified uniform reports to be provided to the Secretary.

(b) The Secretary shall—

(1) monitor the operation of the systems established under subsection (a);

(2) assist with and support demonstrations and evaluations of the effectiveness and cost of the operation of such systems and encourage State adoption of such systems; and

(3) periodically revise such systems to improve their effectiveness and diminish their cost.

(c) The Secretary shall provide information obtained through use of the uniform reporting systems described in subsection (a) in a useful manner and format to appropriate agencies and organizations, including health systems agencies (designated under section 1515 of the Public Health Service Act) and State health planning and development agencies (designated under section 1521 of such Act), as may be necessary to carry out such agencies' and organizations' functions.

LIMITATION ON FEDERAL PARTICIPATION FOR CAPITAL EXPENDITURES

SEC. 1122. [42 U.S.C. 1320a–1] (a) The purpose of this section is to assure that Federal funds appropriated under titles XVIII and

XIX are not used to support unnecessary capital expenditures made by or on behalf of health care facilities which are reimbursed under any of such titles and that, to the extent possible, reimbursement under such titles shall support planning activities with respect to health services and facilities in the various States.

(b) The Secretary, after consultation with the Governor (or other chief executive officer) and with appropriate local public officials, shall make an agreement with any State which is able and willing to do so under which a designated planning agency (which shall be an agency described in clause (ii) of subsection (d)(1)(B) that has a governing body or advisory board at least half of whose members represent consumer interests) will—

(1) make, and submit to the Secretary together with such supporting materials as he may find necessary, findings and recommendations with respect to capital expenditures proposed by or on behalf of any health care facility in such State within the field of its responsibilities,

(2) receive from other agencies described in clause (ii) of subsection (d)(1)(B), and submit to the Secretary together with such supporting material as he may find necessary, the findings and recommendations of such other agencies with respect to capital expenditures proposed by or on behalf of health care facilities in such State within the fields of their respective responsibilities, and

(3) establish and maintain procedures pursuant to which a person proposing any such capital expenditure may appeal a recommendation by the designated agency and will be granted an opportunity for a fair hearing by such agency or person other than the designated agency as the Governor (or other chief executive officer) may designate to hold such hearings,

whenever and to the extent that the findings of such designated agency or any such other agency indicate that any such expenditure is not consistent with the standards, criteria, or plans developed pursuant to the Public Health Service Act to meet the need for adequate health care facilities in the area covered by the plan or plans so developed.

(c) The Secretary shall pay any such State from the general fund in the Treasury, in advance or by way of reimbursement as may be provided in the agreement with it (and may make adjustments in such payments on account of overpayments or underpayments previously made), for the reasonable cost of performing the functions specified in subsection (b).

(d)(1) Except as provided in paragraph (2), if the Secretary determines that—

(A) neither the planning agency designated in the agreement described in subsection (b) nor an agency described in clause (ii) of subparagraph (B) of this paragraph had been given notice of any proposed capital expenditure (in accordance with such procedure or in such detail as may be required by such agency) at least 60 days prior to obligation for such expenditure; or

(B)(i) the planning agency so designated or an agency so described had received such timely notice of the intention to make such capital expenditure and had, within a reasonable

period after receiving such notice and prior to obligation for such expenditure, notified the person proposing such expenditure that the expenditure would not be in conformity with the standards, criteria, or plans developed by such agency or any other agency described in clause (ii) for adequate health care facilities in such State or in the area for which such other agency has responsibility, and

(ii) the planning agency so designated had, prior to submitting to the Secretary the findings referred to in subsection (b)—

(I) consulted with, and taken into consideration the findings and recommendations of, the State planning agencies established pursuant to sections 314(a) and 604(a) of the Public Health Service Act (to the extent that either such agency is not the agency so designated) as well as the public or nonprofit private agency or organization responsible for the comprehensive regional, metropolitan area, or other local area plan or plans referred to in section 314(b) of the Public Health Service Act and covering the area in which the health care facility proposing such capital expenditure is located (where such agency is not the agency designated in the agreement), or, if there is no such agency, such other public or nonprofit private agency or organization (if any) as performs, as determined in accordance with criteria included in regulations, similar functions, and

(II) granted to the person proposing such capital expenditure an opportunity for a fair hearing with respect to such findings;

then, for such period as he finds necessary in any case to effectuate the purpose of this section, he shall, in determining the Federal payments to be made under titles XVIII and XIX with respect to services furnished in the health care facility for which such capital expenditure is made, not include any amount which is attributable to depreciation, interest on borrowed funds, a return on equity capital (in the case of proprietary facilities), or other expenses related to such capital expenditure. With respect to any organization which is reimbursed on a per capita or a fixed fee or negotiated rate basis, in determining the Federal payments to be made under titles XVIII and XIX, the Secretary shall exclude an amount which in his judgment is a reasonable equivalent to the amount which would otherwise be excluded under this subsection if payment were to be made on other than a per capita or a fixed fee or negotiated rate basis.

(2) If the Secretary, after submitting the matters involved to the advisory council established or designated under subsection (i), determines that an exclusion of expenses related to any capital expenditure of any health care facility would discourage the operation or expansion of such facility which has demonstrated to his satisfaction proof of capability to provide comprehensive health care services (including institutional services) efficiently, effectively, and economically, or would otherwise be inconsistent with the effective organization and delivery of health services or the effective administration of title XVIII or XIX, he shall not exclude such expenses pursuant to paragraph (1).

(e) Where a person obtains under lease or comparable arrangement any facility or part thereof, or equipment for a facility, which would have been subject to an exclusion under subsection (d) if the person had acquired it by purchase, the Secretary shall (1) in computing such person's rental expense in determining the Federal payments to be made under titles XVIII and XIX with respect to services furnished in such facility, deduct the amount which in his judgment is a reasonable equivalent of the amount that would have been excluded if the person had acquired such facility or such equipment by purchase, and (2) in computing such person's return on equity capital deduct any amount deposited under the terms of the lease or comparable arrangement.

(f) Any person dissatisfied with a determination by the Secretary under this section may within six months following notification of such determination request the Secretary to reconsider such determination. A determination by the Secretary under this section shall not be subject to administrative or judicial review.

(g) For the purposes of this section, a "capital expenditure" is an expenditure which, under generally accepted accounting principles, is not properly chargeable as an expense of operation and maintenance and which (1) exceeds $600,000 (or such lesser amount as the State may establish), (2) changes the bed capacity of the facility with respect to which such expenditure is made, or (3) substantially changes the services of the facility with respect to which such expenditure is made. For purposes of clause (1) of the preceding sentence, the cost of the studies, surveys, designs, plans, working drawings, specifications, and other activities essential to the acquisition, improvement, expansion, or replacement of the plant and equipment with respect to which such expenditure is made shall be included in determining whether such expenditure exceeds the dollar amount specified in clause (1).

(h) The provisions of this section shall not apply to a religious nonmedical health care institution (as defined in section 1861(ss)(1)).

(i)(1) The Secretary shall establish a national advisory council, or designate an appropriate existing national advisory council, to advise and assist him in the preparation of general regulations to carry out the purposes of this section and on policy matters arising in the administration of this section, including the coordination of activities under this section with those under other parts of this Act or under other Federal or federally assisted health programs.

(2) The Secretary shall make appropriate provision for consultation between and coordination of the work of the advisory council established or designated under paragraph (1) and the Federal Hospital Council, the National Advisory Health Council, the Health Insurance Benefits Advisory Council, and other appropriate national advisory councils with respect to matters bearing on the purposes and administration of this section and the coordination of activities under this section with related Federal health programs.

(3) If an advisory council is established by the Secretary under paragraph (1), it shall be composed of members who are not otherwise in the regular full-time employ of the United States, and who shall be appointed by the Secretary without regard to the civil service laws from among leaders in the fields of the fundamental

sciences, the medical sciences, and the organization, delivery, and financing of health care, and persons who are State or local officials or are active in community affairs or public or civic affairs or who are representative of minority groups. Members of such advisory council, while attending meetings of the council or otherwise serving on business of the council, shall be entitled to receive compensation at rates fixed by the Secretary, but not exceeding the maximum rate specified at the time of such service for grade GS-18 in section 5332 of title 5, United States Code, including traveltime, and while away from their homes or regular places of business they may also be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5703 of such title 5 for persons in the Government service employed intermittently.

(j) A capital expenditure made by or on behalf of a health care facility shall not be subject to review pursuant to this section if 75 percent of the patients who can reasonably be expected to use the service with respect to which the capital expenditure is made will be individuals enrolled in an eligible organization as defined in section 1876(b), and if the Secretary determines that such capital expenditure is for services and facilities which are needed by such organization in order to operate efficiently and economically and which are not otherwise readily accessible to such organization because—

(1) the facilities do not provide common services at the same site (as usually provided by the organization),

(2) the facilities are not available under a contract of reasonable duration,

(3) full and equal medical staff privileges in the facilities are not available,

(4) arrangements with such facilities are not administratively feasible, or

(5) the purchase of such services is more costly than if the organization provided the services directly.

SEC. 1123. [42 U.S.C. 1320a–2] EFFECT OF FAILURE TO CARRY OUT STATE PLAN.

In an action brought to enforce a provision of the Social Security Act, such provision is not to be deemed unenforceable because of its inclusion in a section of the Act requiring a State plan or specifying the required contents of a State plan. This section is not intended to limit or expand the grounds for determining the availability of private actions to enforce State plan requirements other than by overturning any such grounds applied in Suter v. Artist M., 112 S. Ct. 1360 (1992), but not applied in prior Supreme Court decisions respecting such enforceability; provided, however, that this section is not intended to alter the holding in Suter v. Artist M., that section 471(a)(15) of the Act is not enforceable in a private right of action.

REVIEWS OF CHILD AND FAMILY SERVICES PROGRAMS, AND OF FOSTER CARE AND ADOPTION ASSISTANCE PROGRAMS, FOR CONFORMITY WITH STATE PLAN REQUIREMENTS

SEC. 1123A. [42 U.S.C. 1320a–2a] (a) IN GENERAL.—The Secretary, in consultation with the State agencies administering the

State programs under parts B and E of title IV, shall promulgate regulations for the review of such programs to determine whether such programs are in substantial conformity with—

(1) State plan requirements under such parts B and E,

(2) implementing regulations promulgated by the Secretary, and

(3) the relevant approved State plans.

(b) ELEMENTS OF REVIEW SYSTEM.—The regulations referred to in subsection (a) shall—

(1) specify the timetable for conformity reviews of State programs, including—

(A) an initial review of each State program;

(B) a timely review of a State program following a review in which such program was found not to be in substantial conformity; and

(C) less frequent reviews of State programs which have been found to be in substantial conformity, but such regulations shall permit the Secretary to reinstate more frequent reviews based on information which indicates that a State program may not be in conformity;

(2) specify the requirements subject to review (which shall include determining whether the State program is in conformity with the requirement of section 471(a)(27)), and the criteria to be used to measure conformity with such requirements and to determine whether there is a substantial failure to so conform;

(3) specify the method to be used to determine the amount of any Federal matching funds to be withheld (subject to paragraph (4)) due to the State program's failure to so conform, which ensures that—

(A) such funds will not be withheld with respect to a program, unless it is determined that the program fails substantially to so conform;

(B) such funds will not be withheld for a failure to so conform resulting from the State's reliance upon and correct use of formal written statements of Federal law or policy provided to the State by the Secretary; and

(C) the amount of such funds withheld is related to the extent of the failure to so conform; and

(4) require the Secretary, with respect to any State program found to have failed substantially to so conform—

(A) to afford the State an opportunity to adopt and implement a corrective action plan, approved by the Secretary, designed to end the failure to so conform;

(B) to make technical assistance available to the State to the extent feasible to enable the State to develop and implement such a corrective action plan;

(C) to suspend the withholding of any Federal matching funds under this section while such a corrective action plan is in effect; and

(D) to rescind any such withholding if the failure to so conform is ended by successful completion of such a corrective action plan.

(c) PROVISIONS FOR ADMINISTRATIVE AND JUDICIAL REVIEW.—The regulations referred to in subsection (a) shall—

(1) require the Secretary, not later than 10 days after a final determination that a program of the State is not in conformity, to notify the State of—

(A) the basis for the determination; and

(B) the amount of the Federal matching funds (if any) to be withheld from the State;

(2) afford the State an opportunity to appeal the determination to the Departmental Appeals Board within 60 days after receipt of the notice described in paragraph (1), (or, if later after failure to continue or to complete a corrective action plan); and

(3) afford the State an opportunity to obtain judicial review of an adverse decision of the Board, within 60 days after the State receives notice of the decision of the Board, by appeal to the district court of the United States for the judicial district in which the principal or headquarters office of the agency responsible for administering the program is located.

DISCLOSURE OF OWNERSHIP AND RELATED INFORMATION

SEC. 1124. [42 U.S.C. 1320a–3] (a)(1) The Secretary shall by regulation or by contract provision provide that each disclosing entity (as defined in paragraph (2)) shall—

(A) as a condition of the disclosing entity's participation in, or certification or recertification under, any of the programs established by titles V, XVIII, and XIX, or

(B) as a condition for the approval or renewal of a contract or agreement between the disclosing entity and the Secretary or the appropriate State agency under any of the programs established under titles V, XVIII, and XIX,

supply the Secretary or the appropriate State agency with full and complete information as to the identity of each person with an ownership or control interest (as defined in paragraph (3)) in the entity or in any subcontractor (as defined by the Secretary in regulations) in which the entity directly or indirectly has a 5 per centum or more ownership interest and supply the Secretary with the[5] both the employer identification number (assigned pursuant to section 6109 of the Internal Revenue Code of 1986) and social security account number (assigned under section 205(c)(2)(B)) of the disclosing entity, each person with an ownership or control interest (as defined in subsection (a)(3)), and any subcontractor in which the entity directly or indirectly has a 5 percent or more ownership interest..[6]

(2) As used in this section, the term "disclosing entity" means an entity which is—

(A) a provider of services (as defined in section 1861(u), other than a fund), an independent clinical laboratory, a renal disease facility, a managed care entity, as defined in section

[5] So in original. The word "the" probably should be deleted.

[6] So in original. The amendment made by section 4313(a) of P.L. 105–33 (111 Stat. 388) inserted before the period at the end of subsection (a)(1) "and supply" through "ownership interest." There probably should have been closing quotes before the period at the end.

1932(a)(1)(B), or a health maintenance organization (as defined in section 1301(a) of the Public Health Service Act;

(B) an entity (other than an individual practitioner or group of practitioners) that furnishes, or arranges for the furnishing of, items or services with respect to which payment may be claimed by the entity under any plan or program established pursuant to title V or under a State plan approved under title XIX; or

(C) a carrier or other agency or organization that is acting as a fiscal intermediary or agent with respect to one or more providers of services (for purposes of part A or part B of title XVIII, or both, or for purposes of a State plan approved under title XIX) pursuant to (i) an agreement under section 1816, (ii) a contract under section 1842, or (iii) an agreement with a single State agency administering or supervising the administration of a State plan approved under title XIX.

(3) As used in this section, the term "person with an ownership or control interest" means, with respect to an entity, a person who—

(A)(i) has directly or indirectly (as determined by the Secretary in regulations) an ownership interest of 5 per centum or more in the entity; or

(ii) is the owner of a whole or part interest in any mortgage, deed of trust, note, or other obligation secured (in whole or in part) by the entity or any of the property or assets thereof, which whole or part interest is equal to or exceeds 5 per centum of the total property and assets of the entity; or

(B) is an officer or director of the entity, if the entity is organized as a corporation; or

(C) is a partner in the entity, if the entity is organized as a partnership.

(b) To the extent determined to be feasible under regulations of the Secretary, a disclosing entity shall also include in the information supplied under subsection (a)(1), with respect to each person with an ownership or control interest in the entity, the name of any other disclosing entity with respect to which the person is a person with an ownership or control interest.

(c) REQUIRED DISCLOSURE OF OWNERSHIP AND ADDITIONAL DISCLOSABLE PARTIES INFORMATION.—

(1) DISCLOSURE.—A facility shall have the information described in paragraph (2) available—

(A) during the period beginning on the date of the enactment of this subsection and ending on the date such information is made available to the public under section 6101(b) of the Patient Protection and Affordable Care Act for submission to the Secretary, the Inspector General of the Department of Health and Human Services, the State in which the facility is located, and the State long-term care ombudsman in the case where the Secretary, the Inspector General, the State, or the State long-term care ombudsman requests such information; and

(B) beginning on the effective date of the final regulations promulgated under paragraph (3)(A), for reporting such information in accordance with such final regulations.

Nothing in subparagraph (A) shall be construed as authorizing a facility to dispose of or delete information described in such subparagraph after the effective date of the final regulations promulgated under paragraph (3)(A).

(2) INFORMATION DESCRIBED.—

(A) IN GENERAL.—The following information is described in this paragraph:

(i) The information described in subsections (a) and (b), subject to subparagraph (C).

(ii) The identity of and information on—

(I) each member of the governing body of the facility, including the name, title, and period of service of each such member;

(II) each person or entity who is an officer, director, member, partner, trustee, or managing employee of the facility, including the name, title, and period of service of each such person or entity; and

(III) each person or entity who is an additional disclosable party of the facility.

(iii) The organizational structure of each additional disclosable party of the facility and a description of the relationship of each such additional disclosable party to the facility and to one another.

(B) SPECIAL RULE WHERE INFORMATION IS ALREADY REPORTED OR SUBMITTED.—To the extent that information reported by a facility to the Internal Revenue Service on Form 990, information submitted by a facility to the Securities and Exchange Commission, or information otherwise submitted to the Secretary or any other Federal agency contains the information described in clauses (i), (ii), or (iii) of subparagraph (A), the facility may provide such Form or such information submitted to meet the requirements of paragraph (1).

(C) SPECIAL RULE.—In applying subparagraph (A)(i)—

(i) with respect to subsections (a) and (b), "ownership or control interest" shall include direct or indirect interests, including such interests in intermediate entities; and

(ii) subsection (a)(3)(A)(ii) shall include the owner of a whole or part interest in any mortgage, deed of trust, note, or other obligation secured, in whole or in part, by the entity or any of the property or assets thereof, if the interest is equal to or exceeds 5 percent of the total property or assets of the entirety.

(3) REPORTING.—

(A) IN GENERAL.—Not later than the date that is 2 years after the date of the enactment of this subsection, the Secretary shall promulgate final regulations requiring, effective on the date that is 90 days after the date on which such final regulations are published in the Federal Register, a facility to report the information described in paragraph (2) to the Secretary in a standardized format, and such other regulations as are necessary to carry out

this subsection. Such final regulations shall ensure that the facility certifies, as a condition of participation and payment under the program under title XVIII or XIX, that the information reported by the facility in accordance with such final regulations is, to the best of the facility's knowledge, accurate and current.

(B) GUIDANCE.—The Secretary shall provide guidance and technical assistance to States on how to adopt the standardized format under subparagraph (A).

(4) NO EFFECT ON EXISTING REPORTING REQUIREMENTS.—Nothing in this subsection shall reduce, diminish, or alter any reporting requirement for a facility that is in effect as of the date of the enactment of this subsection.

(5) DEFINITIONS.—In this subsection:

(A) ADDITIONAL DISCLOSABLE PARTY.—The term "additional disclosable party" means, with respect to a facility, any person or entity who—

(i) exercises operational, financial, or managerial control over the facility or a part thereof, or provides policies or procedures for any of the operations of the facility, or provides financial or cash management services to the facility;

(ii) leases or subleases real property to the facility, or owns a whole or part interest equal to or exceeding 5 percent of the total value of such real property; or

(iii) provides management or administrative services, management or clinical consulting services, or accounting or financial services to the facility.

(B) FACILITY.—The term "facility" means a disclosing entity which is—

(i) a skilled nursing facility (as defined in section 1819(a)); or

(ii) a nursing facility (as defined in section 1919(a)).

(C) MANAGING EMPLOYEE.—The term "managing employee" means, with respect to a facility, an individual (including a general manager, business manager, administrator, director, or consultant) who directly or indirectly manages, advises, or supervises any element of the practices, finances, or operations of the facility.

(D) ORGANIZATIONAL STRUCTURE.—The term "organizational structure" means, in the case of—

(i) a corporation, the officers, directors, and shareholders of the corporation who have an ownership interest in the corporation which is equal to or exceeds 5 percent;

(ii) a limited liability company, the members and managers of the limited liability company (including, as applicable, what percentage each member and manager has of the ownership interest in the limited liability company);

(iii) a general partnership, the partners of the general partnership;

(iv) a limited partnership, the general partners and any limited partners of the limited partnership who have an ownership interest in the limited partnership which is equal to or exceeds 10 percent;

(v) a trust, the trustees of the trust;

(vi) an individual, contact information for the individual; and

(vii) any other person or entity, such information as the Secretary determines appropriate.

DISCLOSURE REQUIREMENTS FOR OTHER PROVIDERS UNDER PART B OF MEDICARE

SEC. 1124A. [42 U.S.C. 1320a–3a] (a) DISCLOSURE REQUIRED TO RECEIVE PAYMENT.—No payment may be made under part B of title XVIII for items or services furnished by any disclosing part B provider unless such provider has provided the Secretary with full and complete information—

(1) on the identity of each person with an ownership or control interest in the provider or in any subcontractor (as defined by the Secretary in regulations) in which the provider directly or indirectly has a 5 percent or more ownership interest;

(2) with respect to any person identified under paragraph (1) or any managing employee of the provider—

(A) on the identity of any other entities providing items or services for which payment may be made under title XVIII with respect to which such person or managing employee is a person with an ownership or control interest at the time such information is supplied or at any time during the 3-year period ending on the date such information is supplied, and

(B) as to whether any penalties, assessments, or exclusions have been assessed against such person or managing employee under section 1128, 1128A, or 1128B; and

(3) including the employer identification number (assigned pursuant to section 6109 of the Internal Revenue Code of 1986) and social security account number (assigned under section 205(c)(2)(B)) of the disclosing part B provider and any person, managing employee, or other entity identified or described under paragraph (1) or (2).

(b) UPDATES TO INFORMATION SUPPLIED.—A disclosing part B provider shall notify the Secretary of any changes or updates to the information supplied under subsection (a) not later than 180 days after such changes or updates take effect.

(c) VERIFICATION.—

(1) TRANSMITTAL BY HHS.—The Secretary shall transmit—

(A) to the Commissioner of Social Security information concerning each social security account number (assigned under section 205(c)(2)(B)), and

(B) to the Secretary of the Treasury information concerning each employer identification number (assigned pursuant to section 6109 of the Internal Revenue Code of 1986),

supplied to the Secretary pursuant to subsection (a)(3) or section 1124(c)[7] to the extent necessary for verification of such information in accordance with paragraph (2).

(2) VERIFICATION.—The Commissioner of Social Security and the Secretary of the Treasury shall verify the accuracy of, or correct, the information supplied by the Secretary to such official pursuant to paragraph (1), and shall report such verifications or corrections to the Secretary.

(3) FEES FOR VERIFICATION.—The Secretary shall reimburse the Commissioner and Secretary of the Treasury, at a rate negotiated between the Secretary and such official, for the costs incurred by such official in performing the verification and correction services described in this subsection.

(d) DEFINITIONS.—For purposes of this section—

(1) the term "disclosing part B provider" means any entity receiving payment on an assignment-related basis (or, for purposes of subsection (a)(3), any entity receiving payment) for furnishing items or services for which payment may be made under part B of title XVIII, except that such term does not include an entity described in section 1124(a)(2);

(2) the term "managing employee" means, with respect to a provider, a person described in section 1126(b); and

(3) the term "person with an ownership or control interest" means, with respect to a provider—

(A) a person described in section 1124(a)(3), or

(B) a person who has one of the 5 largest direct or indirect ownership or control interests in the provider.

ISSUANCE OF SUBPENAS BY COMPTROLLER GENERAL

SEC. 1125. [42 U.S.C. 1320a–4] (a) For the purpose of any audit, investigation, examination, analysis, review, evaluation, or other function authorized by law with respect to any program authorized under this Act, the Comptroller General of the United States shall have power to sign and issue subpenas to any person requiring the production of any pertinent books, records, documents, or other information. Subpenas so issued by the Comptroller General shall be served by anyone authorized by him (1) by delivering a copy thereof to the person named therein, or (2) by registered mail or by certified mail addressed to such person at his last dwelling place or principal place of business. A verified return by the person so serving the subpena setting forth the manner of service, or, in the case of service by registered mail or by certified mail, the return post office receipt therefor signed by the person so served, shall be proof of service.

(b) In case of contumacy by, or refusal to obey a subpena issued pursuant to subsection (a) of this section and duly served upon, any person, any district court of the United States for the judicial district in which such person charged with contumacy or refusal to obey is found or resides or transacts business, upon application by the Comptroller General, shall have jurisdiction to issue an order requiring such person to produce the books, records, documents, or other information sought by the subpena; and any failure

[7] So in original. Probably should be "1124A(c)".

to obey such order of the court may be punished by the court as a contempt thereof. In proceedings brought under this subsection, the Comptroller General shall be represented by attorneys employed in the General Accounting Office or by counsel whom he may employ without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and the provisions of chapter 51 and subchapters III and VI of chapter 53 of such title, relating to classification and General Schedule pay rates.

(c) No personal medical record in the possession of the General Accounting Office shall be subject to subpena or discovery proceedings in a civil action.

DISCLOSURE BY INSTITUTIONS, ORGANIZATIONS, AND AGENCIES OF OWNERS AND CERTAIN OTHER INDIVIDUALS WHO HAVE BEEN CONVICTED OF CERTAIN OFFENSES

SEC. 1126. [42 U.S.C. 1320a–5] (a) As a condition of participation in or certification or recertification under the programs established by titles XVIII, and XIX, any hospital, nursing facility, or other entity (other than an individual practitioner or group of practitioners) shall be required to disclose to the Secretary or to the appropriate State agency the name of any person that is a person described in subparagraphs (A) and (B) of section 1128(b)(8). The Secretary or the appropriate State agency shall promptly notify the Inspector General in the Department of Health and Human Services of the receipt from any entity of any application or request for such participation, certification, or recertification which discloses the name of any such person, and shall notify the Inspector General of the action taken with respect to such application or request.

(b) For the purposes of this section, the term "managing employee" means, with respect to an entity, an individual, including a general manager, business manager, administrator, and director, who exercises operational or managerial control over the entity, or who directly or indirectly conducts the day-to-day operations of the entity.

ADJUSTMENTS IN SSI BENEFITS ON ACCOUNT OF RETROACTIVE BENEFITS UNDER TITLE II

SEC. 1127. [42 U.S.C. 1320a6] (a) Notwithstanding any other provision of this Act, in any case where an individual—

(1) is entitled to benefits under title II that were not paid in the months in which they were regularly due; and

(2) is an individual or eligible spouse eligible for supplemental security income benefits for one or more months in which the benefits referred to in clause (1) were regularly due,

then any benefits under title II that were regularly due in such month or months, or supplemental security income benefits for such month or months, which are due but have not been paid to such individual or eligible spouse shall be reduced by an amount equal to so much of the supplemental security income benefits, whether or not paid retroactively, as would not have been paid or would not be paid with respect to such individual or spouse if he had received such benefits under title II in the month or months

in which they were regularly due. A benefit under title II shall not be reduced pursuant to the preceding sentence to the extent that any amount of such benefit would not otherwise be available for payment in full of the maximum fee which may be recovered from such benefit by an attorney pursuant to subsection (a)(4) or (b) of section 206.

(b) For purposes of this section, the term "supplemental security income benefits" means benefits paid or payable by the Commissioner of Social Security under title XVI, including State supplementary payments under an agreement pursuant to section 1616(a) or an administration agreement under section 212(b) of Public Law 93–66.

(c) From the amount of the reduction made under subsection (a), the Commissioner of Social Security shall reimburse the State on behalf of which supplementary payments were made for the amount (if any) by which such State's expenditures on account of such supplementary payments for the month or months involved exceeded the expenditures which the State would have made (for such month or months) if the individual had received the benefits under title II at the times they were regularly due. An amount equal to the portion of such reduction remaining after reimbursement of the State under the preceding sentence shall be covered into the general fund of the Treasury.

INTERAGENCY COORDINATION TO IMPROVE PROGRAM ADMINISTRATION

SEC. 1127A. [42 U.S.C. 1320a–6a] (a) COORDINATION AGREEMENT.—Notwithstanding any other provision of law, including section 207 of this Act, the Commissioner of Social Security (referred to in this section as 'the Commissioner') and the Director of the Office of Personnel Management (referred to in this section as 'the Director') shall enter into an agreement under which a system is established to carry out the following procedure:

(1) The Director shall notify the Commissioner when any individual is determined to be entitled to a monthly disability annuity payment pursuant to subchapter V of chapter 84 of subpart G of part III of title 5, United States Code, and shall certify that such individual has provided the authorization described in subsection (f).

(2) If the Commissioner determines that an individual described in paragraph (1) is also entitled to past-due benefits under section 223, the Commissioner shall notify the Director of such fact.

(3) Not later than 30 days after receiving a notification described in paragraph (2) with respect to an individual, the Director shall provide the Commissioner with the total amount of any disability annuity overpayments made to such individual, as well as any other information (in such form and manner as the Commissioner shall require) that the Commissioner determines is necessary to carry out this section.

(4) If the Director provides the Commissioner with the information described in paragraph (3) in a timely manner, the Commissioner may withhold past-due benefits under section 223 to which such individual is entitled and may pay the

amount described in paragraph (3) to the Office of Personnel Management for any disability annuity overpayments made to such individual.

(5) The Director shall credit any amount received under paragraph (4) with respect to an individual toward any disability annuity overpayment owed by such individual.

(b) LIMITATIONS.—

(1)[8] PRIORITY OF OTHER REDUCTIONS.—Benefits shall only be withheld under this section after any other reduction applicable under this Act, including sections 206(a)(4), 224, and 1127(a).

(2) TIMELY NOTIFICATION REQUIRED.—The Commissioner may not withhold benefits under this section if the Director does not provide the notice described in subsection (a)(3) within the time period described in such subsection.

(c) DELAYED PAYMENT OF PAST-DUE BENEFITS.—If the Commissioner is required to make a notification described in subsection (a)(2) with respect to an individual, the Commissioner shall not make any payment of past-due benefits under section 223 to such individual until after the period described in subsection (a)(3).

(d) REVIEW.—Notwithstanding section 205 or any other provision of law, any determination regarding the withholding of past-due benefits under this section shall only be subject to adjudication and review by the Director under section 8461 of title 5, United States Code.

(e) DISABILITY ANNUITY OVERPAYMENT DEFINED.—For purposes of this section, the term "disability annuity overpayment" means the amount of the reduction under section 8452(a)(2) of title 5, United States Code, applicable to a monthly annuity payment made to an individual pursuant to subchapter V of chapter 84 of subpart G of part III of such title due to the individual's concurrent entitlement to a disability insurance benefit under section 223 during such month.

(f) AUTHORIZATION TO WITHHOLD BENEFITS.—The authorization described in this subsection, with respect to an individual, is written authorization provided by the individual to the Director which authorizes the Commissioner to withhold past-due benefits under section 223 to which such individual is entitled in order to pay the amount withheld to the Office of Personnel Management for any disability overpayments made to such individual.

(g) EXPENSES.—The Director shall pay to the Social Security Administration an amount equal to the amount estimated by the Commissioner as the total cost incurred by the Social Security Administration in carrying out this section for each calendar quarter.

EXCLUSION OF CERTAIN INDIVIDUALS AND ENTITIES FROM PARTICIPATION IN MEDICARE AND STATE HEALTH CARE PROGRAMS

SEC. 1128. [42 U.S.C. 1320a–7] (a) MANDATORY EXCLUSION.—The Secretary shall exclude the following individuals and entities from participation in any Federal health care program (as defined in section 1128B(f)):

(1) CONVICTION OF PROGRAM-RELATED CRIMES.—Any individual or entity that has been convicted of a criminal offense

[8] Margins for paragraphs (1) and (2) of subsection (b) are so in law.

related to the delivery of an item or service under title XVIII or under any State health care program.

(2) CONVICTION RELATING TO PATIENT ABUSE.—Any individual or entity that has been convicted, under Federal or State law, of a criminal offense relating to neglect or abuse of patients in connection with the delivery of a health care item or service.

(3) FELONY CONVICTION RELATING TO HEALTH CARE FRAUD.—Any individual or entity that has been convicted for an offense which occurred after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, under Federal or State law, in connection with the delivery of a health care item or service or with respect to any act or omission in a health care program (other than those specifically described in paragraph (1)) operated by or financed in whole or in part by any Federal, State, or local government agency, of a criminal offense consisting of a felony relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct.

(4) FELONY CONVICTION RELATING TO CONTROLLED SUBSTANCE.—Any individual or entity that has been convicted for an offense which occurred after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, under Federal or State law, of a criminal offense consisting of a felony relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.

(b) PERMISSIVE EXCLUSION.—The Secretary may exclude the following individuals and entities from participation in any Federal health care program (as defined in section 1128B(f)):

(1) CONVICTION RELATING TO FRAUD.—Any individual or entity that has been convicted for an offense which occurred after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, under Federal or State law—

(A) of a criminal offense consisting of a misdemeanor relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct—

(i) in connection with the delivery of a health care item or service, or

(ii) with respect to any act or omission in a health care program (other than those specifically described in subsection (a)(1)) operated by or financed in whole or in part by any Federal, State, or local government agency; or

(B) of a criminal offense relating to fraud, theft, embezzlement, breach of fiduciary responsibility, or other financial misconduct with respect to any act or omission in a program (other than a health care program) operated by or financed in whole or in part by any Federal, State, or local government agency.

(2) CONVICTION RELATING TO OBSTRUCTION OF AN INVESTIGATION OR AUDIT.—Any individual or entity that has been convicted, under Federal or State law, in connection with the

interference with or obstruction of any investigation or audit related to—

(i) any offense described in paragraph (1) or in subsection (a); or

(ii) the use of funds received, directly or indirectly, from any Federal health care program (as defined in section 1128B(f)).

(3) MISDEMEANOR CONVICTION RELATING TO CONTROLLED SUBSTANCE.—Any individual or entity that has been convicted, under Federal or State law, of a criminal offense consisting of a misdemeanor relating to the unlawful manufacture, distribution, prescription, or dispensing of a controlled substance.

(4) LICENSE REVOCATION OR SUSPENSION.—Any individual or entity—

(A) whose license to provide health care has been revoked or suspended by any State licensing authority, or who otherwise lost such a license or the right to apply for or renew such a license, for reasons bearing on the individual's or entity's professional competence, professional performance, or financial integrity, or

(B) who surrendered such a license while a formal disciplinary proceeding was pending before such an authority and the proceeding concerned the individual's or entity's professional competence, professional performance, or financial integrity.

(5) EXCLUSION OR SUSPENSION UNDER FEDERAL OR STATE HEALTH CARE PROGRAM.—Any individual or entity which has been suspended or excluded from participation, or otherwise sanctioned, under—

(A) any Federal program, including programs of the Department of Defense or the Department of Veterans Affairs, involving the provision of health care, or

(B) a State health care program,

for reasons bearing on the individual's or entity's professional competence, professional performance, or financial integrity.

(6) CLAIMS FOR EXCESSIVE CHARGES OR UNNECESSARY SERVICES AND FAILURE OF CERTAIN ORGANIZATIONS TO FURNISH MEDICALLY NECESSARY SERVICES.—Any individual or entity that the Secretary determines—

(A) has submitted or caused to be submitted bills or requests for payment (where such bills or requests are based on charges or cost) under title XVIII or a State health care program containing charges (or, in applicable cases, requests for payment of costs) for items or services furnished substantially in excess of such individual's or entity's usual charges (or, in applicable cases, substantially in excess of such individual's or entity's costs) for such items or services, unless the Secretary finds there is good cause for such bills or requests containing such charges or costs;

(B) has furnished or caused to be furnished items or services to patients (whether or not eligible for benefits under title XVIII or under a State health care program)

substantially in excess of the needs of such patients or of a quality which fails to meet professionally recognized standards of health care;

(C) is—

(i) a health maintenance organization (as defined in section 1903(m)) providing items and services under a State plan approved under title XIX, or

(ii) an entity furnishing services under a waiver approved under section 1915(b)(1),

and has failed substantially to provide medically necessary items and services that are required (under law or the contract with the State under title XIX) to be provided to individuals covered under that plan or waiver, if the failure has adversely affected (or has a substantial likelihood of adversely affecting) these individuals; or

(D) is an entity providing items and services as an eligible organization under a risk-sharing contract under section 1876 and has failed substantially to provide medically necessary items and services that are required (under law or such contract) to be provided to individuals covered under the risk-sharing contract, if the failure has adversely affected (or has a substantial likelihood of adversely affecting) these individuals.

(7) FRAUD, KICKBACKS, AND OTHER PROHIBITED ACTIVITIES.—Any individual or entity that the Secretary determines has committed an act which is described in section 1128A, 1128B, or 1129.

(8) ENTITIES CONTROLLED BY A SANCTIONED INDIVIDUAL.—Any entity with respect to which the Secretary determines that a person—

(A)(i) who has a direct or indirect ownership or control interest of 5 percent or more in the entity or with an ownership or control interest (as defined in section 1124(a)(3)) in that entity,[9]

(ii) who is an officer, director, agent, or managing employee (as defined in section 1126(b)) of that entity; or

(iii) who was described in clause (i) but is no longer so described because of a transfer of ownership or control interest, in anticipation of (or following) a conviction, assessment, or exclusion described in subparagraph (B) against the person, to an immediate family member (as defined in subsection (j)(1)) or a member of the household of the person (as defined in subsection (j)(2)) who continues to maintain an interest described in such clause—

is a person—

(B)(i) who has been convicted of any offense described in subsection (a) or in paragraph (1), (2), or (3) of this subsection;

(ii) against whom a civil monetary penalty has been assessed under section 1128A or 1129; or

[9] So in original.

(iii) who has been excluded from participation under a program under title XVIII or under a State health care program.

(9) FAILURE TO DISCLOSE REQUIRED INFORMATION.—Any entity that did not fully and accurately make any disclosure required by section 1124, section 1124A, or section 1126.

(10) FAILURE TO SUPPLY REQUESTED INFORMATION ON SUBCONTRACTORS AND SUPPLIERS.—Any disclosing entity (as defined in section 1124(a)(2)) that fails to supply (within such period as may be specified by the Secretary in regulations) upon request specifically addressed to the entity by the Secretary or by the State agency administering or supervising the administration of a State health care program—

(A) full and complete information as to the ownership of a subcontractor (as defined by the Secretary in regulations) with whom the entity has had, during the previous 12 months, business transactions in an aggregate amount in excess of $25,000, or

(B) full and complete information as to any significant business transactions (as defined by the Secretary in regulations), occurring during the five-year period ending on the date of such request, between the entity and any wholly owned supplier or between the entity and any subcontractor.

(11) FAILURE TO SUPPLY PAYMENT INFORMATION.—Any individual or entity furnishing, ordering, referring for furnishing, or certifying the need for items or services for which payment may be made under title XVIII or a State health care program that fails to provide such information as the Secretary or the appropriate State agency finds necessary to determine whether such payments are or were due and the amounts thereof, or has refused to permit such examination of its records by or on behalf of the Secretary or that agency as may be necessary to verify such information.

(12) FAILURE TO GRANT IMMEDIATE ACCESS.—Any individual or entity that fails to grant immediate access, upon reasonable request (as defined by the Secretary in regulations) to any of the following:

(A) To the Secretary, or to the agency used by the Secretary, for the purpose specified in the first sentence of section 1864(a) (relating to compliance with conditions of participation or payment).

(B) To the Secretary or the State agency, to perform the reviews and surveys required under State plans under paragraphs (26), (31), and (33) of section 1902(a) and under section 1903(g).

(C) To the Inspector General of the Department of Health and Human Services, for the purpose of reviewing records, documents, and other data necessary to the performance of the statutory functions of the Inspector General.

(D) To a State medicaid fraud control unit (as defined in section 1903(q)), for the purpose of conducting activities described in that section.

(13) FAILURE TO TAKE CORRECTIVE ACTION.—Any hospital that fails to comply substantially with a corrective action required under section 1886(f)(2)(B).

(14) DEFAULT ON HEALTH EDUCATION LOAN OR SCHOLARSHIP OBLIGATIONS.—Any individual who the Secretary determines is in default on repayments of scholarship obligations or loans in connection with health professions education made or secured, in whole or in part, by the Secretary and with respect to whom the Secretary has taken all reasonable steps available to the Secretary to secure repayment of such obligations or loans, except that (A) the Secretary shall not exclude pursuant to this paragraph a physician who is the sole community physician or sole source of essential specialized services in a community if a State requests that the physician not be excluded, and (B) the Secretary shall take into account, in determining whether to exclude any other physician pursuant to this paragraph, access of beneficiaries to physician services for which payment may be made under title XVIII or XIX.

(15) INDIVIDUALS CONTROLLING A SANCTIONED ENTITY.—(A) Any individual—

(i) who has a direct or indirect ownership or control interest in a sanctioned entity and who knows or should know (as defined in section 1128A(i)(6))[10] of the action constituting the basis for the conviction or exclusion described in subparagraph (B); or

(ii) who is an officer or managing employee (as defined in section 1126(b)) of such an entity.

(B) For purposes of subparagraph (A), the term "sanctioned entity" means an entity—

(i) that has been convicted of any offense described in subsection (a) or in paragraph (1), (2), or (3) of this subsection; or

(ii) that has been excluded from participation under a program under title XVIII or under a State health care program.

(16) MAKING FALSE STATEMENTS OR MISREPRESENTATION OF MATERIAL FACTS.—Any individual or entity that knowingly makes or causes to be made any false statement, omission, or misrepresentation of a material fact in any application, agreement, bid, or contract to participate or enroll as a provider of services or supplier under a Federal health care program (as defined in section 1128B(f)), including Medicare Advantage organizations under part C of title XVIII, prescription drug plan sponsors under part D of title XVIII, medicaid managed care organizations under title XIX, and entities that apply to participate as providers of services or suppliers in such managed care organizations and such plans.

(17) KNOWINGLY MISCLASSIFYING COVERED OUTPATIENT DRUGS.—Any manufacturer or officer, director, agent, or managing employee of such manufacturer that knowingly misclassifies a covered outpatient drug under an agreement under section 1927, knowingly fails to correct such

[10] So in original. Probably should be "1128A(i)(7))".

misclassification, or knowingly provides false information related to drug pricing, drug product information, or data related to drug pricing or drug product information.

(c) NOTICE, EFFECTIVE DATE, AND PERIOD OF EXCLUSION.—(1) An exclusion under this section or under section 1128A shall be effective at such time and upon such reasonable notice to the public and to the individual or entity excluded as may be specified in regulations consistent with paragraph (2).

(2)(A) Except as provided in subparagraph (B), such an exclusion shall be effective with respect to services furnished to an individual on or after the effective date of the exclusion.

(B) Unless the Secretary determines that the health and safety of individuals receiving services warrants the exclusion taking effect earlier, an exclusion shall not apply to payments made under title XVIII or under a State health care program for—

(i) inpatient institutional services furnished to an individual who was admitted to such institution before the date of the exclusion, or

(ii) home health services and hospice care furnished to an individual under a plan of care established before the date of the exclusion,

until the passage of 30 days after the effective date of the exclusion.

(3)(A) The Secretary shall specify, in the notice of exclusion under paragraph (1) and the written notice under section 1128A, the minimum period (or, in the case of an exclusion of an individual under subsection (b)(12) or in the case described in subparagraph (G), the period) of the exclusion.

(B) Subject to subparagraph (G), in the case of an exclusion under subsection (a), the minimum period of exclusion shall be not less than five years, except that, upon the request of the administrator of a Federal health care program (as defined in section 1128B(f)) who determines that the exclusion would impose a hardship on beneficiaries (as defined in section 1128A(i)(5)) of that program, the Secretary may, after consulting with the Inspector General of the Department of Health and Human Services, waive the exclusion under subsection (a)(1), (a)(3), or (a)(4) with respect to that program in the case of an individual or entity that is the sole community physician or sole source of essential specialized services in a community. The Secretary's decision whether to waive the exclusion shall not be reviewable.

(C) In the case of an exclusion of an individual under subsection (b)(12), the period of the exclusion shall be equal to the sum of—

(i) the length of the period in which the individual failed to grant the immediate access described in that subsection, and

(ii) an additional period, not to exceed 90 days, set by the Secretary.

(D) Subject to subparagraph (G), in the case of an exclusion of an individual or entity under paragraph (1), (2), or (3) of subsection (b), the period of the exclusion shall be 3 years, unless the Secretary determines in accordance with published regulations that a shorter period is appropriate because of mitigating circumstances

or that a longer period is appropriate because of aggravating circumstances.

(E) In the case of an exclusion of an individual or entity under subsection (b)(4) or (b)(5), the period of the exclusion shall not be less than the period during which the individual's or entity's license to provide health care is revoked, suspended, or surrendered, or the individual or the entity is excluded or suspended from a Federal or State health care program.

(F) In the case of an exclusion of an individual or entity under subsection (b)(6)(B), the period of the exclusion shall be not less than 1 year.

(G) In the case of an exclusion of an individual under subsection (a) based on a conviction occurring on or after the date of the enactment of this subparagraph, if the individual has (before, on, or after such date) been convicted—

(i) on one previous occasion of one or more offenses for which an exclusion may be effected under such subsection, the period of the exclusion shall be not less than 10 years, or

(ii) on 2 or more previous occasions of one or more offenses for which an exclusion may be effected under such subsection, the period of the exclusion shall be permanent.

(d) NOTICE TO STATE AGENCIES AND EXCLUSION UNDER STATE HEALTH CARE PROGRAMS.—(1) Subject to paragraph (3), the Secretary shall exercise the authority under this section and section 1128A in a manner that results in an individual's or entity's exclusion from all the programs under title XVIII and all the State health care programs in which the individual or entity may otherwise participate.

(2) The Secretary shall promptly notify each appropriate State agency administering or supervising the administration of each State health care program (and, in the case of an exclusion effected pursuant to subsection (a) and to which section 304(a)(5) of the Controlled Substances Act may apply, the Attorney General)—

(A) of the fact and circumstances of each exclusion effected against an individual or entity under this section or section 1128A, and

(B) of the period (described in paragraph (3)) for which the State agency is directed to exclude the individual or entity from participation in the State health care program.

(3)(A) Except as provided in subparagraph (B), the period of the exclusion under a State health care program under paragraph (2) shall be the same as any period of exclusion under title XVIII.

(B)(i) The Secretary may waive an individual's or entity's exclusion under a State health care program under paragraph (2) if the Secretary receives and approves a request for the waiver with respect to the individual or entity from the State agency administering or supervising the administration of the program.

(ii) A State health care program may provide for a period of exclusion which is longer than the period of exclusion under title XVIII.

(e) NOTICE TO STATE LICENSING AGENCIES.—The Secretary shall—

(1) promptly notify the appropriate State or local agency or authority having responsibility for the licensing or certification

of an individual or entity excluded (or directed to be excluded) from participation under this section or section 1128A, of the fact and circumstances of the exclusion,

(2) request that appropriate investigations be made and sanctions invoked in accordance with applicable State law and policy, and

(3) request that the State or local agency or authority keep the Secretary and the Inspector General of the Department of Health and Human Services fully and currently informed with respect to any actions taken in response to the request.

(f) NOTICE, HEARING, AND JUDICIAL REVIEW.—(1) Subject to paragraph (2), any individual or entity that is excluded (or directed to be excluded) from participation under this section is entitled to reasonable notice and opportunity for a hearing thereon by the Secretary to the same extent as is provided in section 205(b), and to judicial review of the Secretary's final decision after such hearing as is provided in section 205(g), except that, in so applying such sections and section 205(l), any reference therein to the Commissioner of Social Security or the Social Security Administration shall be considered a reference to the Secretary or the Department of Health and Human Services, respectively.

(2) Unless the Secretary determines that the health or safety of individuals receiving services warrants the exclusion taking effect earlier, any individual or entity that is the subject of an adverse determination under subsection (b)(7) shall be entitled to a hearing by an administrative law judge (as provided under section 205(b)) on the determination under subsection (b)(7) before any exclusion based upon the determination takes effect.

(3) The provisions of section 205(h) shall apply with respect to this section and sections 1128A, 1129, and 1156 to the same extent as it is applicable with respect to title II, except that, in so applying such section and section 205(l), any reference therein to the Commissioner of Social Security shall be considered a reference to the Secretary.

(4)[11] The provisions of subsections (d) and (e) of section 205 shall apply with respect to this section to the same extent as they are applicable with respect to title II. The Secretary may delegate the authority granted by section 205(d) (as made applicable to this section) to the Inspector General of the Department of Health and Human Services for purposes of any investigation under this section.

(g) APPLICATION FOR TERMINATION OF EXCLUSION.—(1) An individual or entity excluded (or directed to be excluded) from participation under this section or section 1128A may apply to the Secretary, in the manner specified by the Secretary in regulations and at the end of the minimum period of exclusion provided under subsection (c)(3) and at such other times as the Secretary may provide, for termination of the exclusion effected under this section or section 1128A.

(2) The Secretary may terminate the exclusion if the Secretary determines, on the basis of the conduct of the applicant which oc-

[11] Margin so in law.

curred after the date of the notice of exclusion or which was unknown to the Secretary at the time of the exclusion, that—

(A) there is no basis under subsection (a) or (b) or section 1128A(a) for a continuation of the exclusion, and

(B) there are reasonable assurances that the types of actions which formed the basis for the original exclusion have not recurred and will not recur.

(3) The Secretary shall promptly notify each appropriate State agency administering or supervising the administration of each State health care program (and, in the case of an exclusion effected pursuant to subsection (a) and to which section 304(a)(5) of the Controlled Substances Act may apply, the Attorney General) of the fact and circumstances of each termination of exclusion made under this subsection.

(h) DEFINITION OF STATE HEALTH CARE PROGRAM.—For purposes of this section and sections 1128A and 1128B, the term "State health care program" means—

(1) a State plan approved under title XIX,

(2) any program receiving funds under title V or from an allotment to a State under such title,

(3) any program receiving funds under subtitle 1 of title XX or from an allotment to a State under such subtitle, or

(4) a State child health plan approved under title XXI.

(i) CONVICTED DEFINED.—For purposes of subsections (a) and (b), an individual or entity is considered to have been "convicted" of a criminal offense—

(1) when a judgment of conviction has been entered against the individual or entity by a Federal, State, or local court, regardless of whether there is an appeal pending or whether the judgment of conviction or other record relating to criminal conduct has been expunged;

(2) when there has been a finding of guilt against the individual or entity by a Federal, State, or local court;

(3) when a plea of guilty or nolo contendere by the individual or entity has been accepted by a Federal, State, or local court; or

(4) when the individual or entity has entered into participation in a first offender, deferred adjudication, or other arrangement or program where judgment of conviction has been withheld.

(j) DEFINITION OF IMMEDIATE FAMILY MEMBER AND MEMBER OF HOUSEHOLD.—For purposes of subsection (b)(8)(A)(iii):

(1) The term "immediate family member" means, with respect to a person—

(A) the husband or wife of the person;

(B) the natural or adoptive parent, child, or sibling of the person;

(C) the stepparent, stepchild, stepbrother, or stepsister of the person;

(D) the father-, mother-, daughter-, son-, brother-, or sister-in-law of the person;

(E) the grandparent or grandchild of the person; and

(F) the spouse of a grandparent or grandchild of the person.

(2) The term "member of the household" means, with respect to any person, any individual sharing a common abode as part of a single family unit with the person, including domestic employees and others who live together as a family unit, but not including a roomer or boarder.

CIVIL MONETARY PENALTIES

SEC. 1128A. [42 U.S.C. 1320a–7a] (a) Any person (including an organization, agency, or other entity, but excluding a beneficiary, as defined in subsection (i)(5)) that—

(1) knowingly presents or causes to be presented to an officer, employee, or agent of the United States, or of any department or agency thereof, or of any State agency (as defined in subsection (i)(1)), a claim (as defined in subsection (i)(2)) that the Secretary determines—

(A) is for a medical or other item or service that the person knows or should know was not provided as claimed, including any person who engages in a pattern or practice of presenting or causing to be presented a claim for an item or service that is based on a code that the person knows or should know will result in a greater payment to the person than the code the person knows or should know is applicable to the item or service actually provided,

(B) is for a medical or other item or service and the person knows or should know the claim is false or fraudulent,

(C) is presented for a physician's service (or an item or service incident to a physician's service) by a person who knows or should know that the individual who furnished (or supervised the furnishing of) the service—

(i) was not licensed as a physician,

(ii) was licensed as a physician, but such license had been obtained through a misrepresentation of material fact (including cheating on an examination required for licensing), or

(iii) represented to the patient at the time the service was furnished that the physician was certified in a medical specialty by a medical specialty board when the individual was not so certified,

(D) is for a medical or other item or service furnished during a period in which the person was excluded from the program under which the claim was made pursuant to a determination by the Secretary under this section or under section 1128, 1156, 1160(b) (as in effect on September 2, 1982), 1862(d) (as in effect on the date of the enactment of the Medicare and Medicaid Patient and Program Protection Act of 1987), or 1866(b) or as a result of the application of the provisions of section 1842(j)(2), or

(E) is for a pattern of medical or other items or services that a person knows or should know are not medically necessary;

(2) knowingly presents or causes to be presented to any person a request for payment which is in violation of the terms

of (A) an assignment under section 1842(b)(3)(B)(ii), or (B) an agreement with a State agency (or other requirement of a State plan under title XIX) not to charge a person for an item or service in excess of the amount permitted to be charged, or (C) an agreement to be a participating physician or supplier under section 1842(h)(1), or (D) an agreement pursuant to section 1866(a)(1)(G);

(3) knowingly gives or causes to be given to any person, with respect to coverage under title XVIII of inpatient hospital services subject to the provisions of section 1886, information that he knows or should know is false or misleading, and that could reasonably be expected to influence the decision when to discharge such person or another individual from the hospital;

(4) in the case of a person who is not an organization, agency, or other entity, is excluded from participating in a program under title XVIII or a State health care program in accordance with this subsection or under section 1128 and who, at the time of a violation of this subsection—

(A) retains a direct or indirect ownership or control interest in an entity that is participating in a program under title XVIII or a State health care program, and who knows or should know of the action constituting the basis for the exclusion; or

(B) is an officer or managing employee (as defined in section 1126(b)) of such an entity;

(5) offers to or transfers remuneration to any individual eligible for benefits under title XVIII of this Act, or under a State health care program (as defined in section 1128(h)) that such person knows or should know is likely to influence such individual to order or receive from a particular provider, practitioner, or supplier any item or service for which payment may be made, in whole or in part, under title XVIII, or a State health care program (as so defined);

(6) arranges or contracts (by employment or otherwise) with an individual or entity that the person knows or should know is excluded from participation in a Federal health care program (as defined in section 1128B(f)), for the provision of items or services for which payment may be made under such a program;

(7) commits an act described in paragraph (1) or (2) of section 1128B(b);

(8) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim for payment for items and services furnished under a Federal health care program; or

(9) fails to grant timely access, upon reasonable request (as defined by the Secretary in regulations), to the Inspector General of the Department of Health and Human Services, for the purpose of audits, investigations, evaluations, or other statutory functions of the Inspector General of the Department of Health and Human Services;

(8)[12] orders or prescribes a medical or other item or service during a period in which the person was excluded from a Federal health care program (as so defined), in the case where the person knows or should know that a claim for such medical or other item or service will be made under such a program;

(9)[12] knowingly makes or causes to be made any false statement, omission, or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider of services or a supplier under a Federal health care program (as so defined), including Medicare Advantage organizations under part C of title XVIII, prescription drug plan sponsors under part D of title XVIII, medicaid managed care organizations under title XIX, and entities that apply to participate as providers of services or suppliers in such managed care organizations and such plans;

(10) knows of an overpayment (as defined in paragraph (4) of section 1128J(d)) and does not report and return the overpayment in accordance with such section;

shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than $20,000 for each item or service (or, in cases under paragraph (3), $30,000 for each individual with respect to whom false or misleading information was given; in cases under paragraph (4), $20,000 for each day the prohibited relationship occurs; in cases under paragraph (7), $100,000 for each such act; or in cases under paragraph (9), $100,000 for each false statement or misrepresentation of a material fact). In addition, such a person shall be subject to an assessment of not more than 3 times the amount claimed for each such item or service in lieu of damages sustained by the United States or a State agency because of such claim (or, in cases under paragraph (7), damages of not more than 3 times the total amount of remuneration offered, paid, solicited, or received, without regard to whether a portion of such remuneration was offered, paid, solicited, or received for a lawful purpose; or in cases under paragraph (9), an assessment of not more than 3 times the total amount claimed for each item or service for which payment was made based upon the application containing the false statement or misrepresentation of a material fact). In addition the Secretary may make a determination in the same proceeding to exclude the person from participation in the Federal health care programs (as defined in section 1128B(f)(1)) and to direct the appropriate State agency to exclude the person from participation in any State health care program.

(b)(1) If a hospital or a critical access hospital knowingly makes a payment, directly or indirectly, to a physician as an inducement to reduce or limit medically necessary services provided with respect to individuals who—

(A) are entitled to benefits under part A or part B of title XVIII or to medical assistance under a State plan approved under title XIX, and

(B) are under the direct care of the physician,

[12] So in law. See amendments made by sections 6402(d) and 6408(a) of Public Law 111–148.

the hospital or a critical access hospital shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than $5,000 for each such individual with respect to whom the payment is made.

(2) Any physician who knowingly accepts receipt of a payment described in paragraph (1) shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty of not more than $5,000 for each individual described in such paragraph with respect to whom the payment is made.

(3)(A) Any physician who executes a document described in subparagraph (B) with respect to an individual knowing that all of the requirements referred to in such subparagraph are not met with respect to the individual shall be subject to a civil monetary penalty of not more than the greater of—

(i) $10,000, or

(ii) three times the amount of the payments under title XVIII for home health services which are made pursuant to such certification.

(B) A document described in this subparagraph is any document that certifies, for purposes of title XVIII, that an individual meets the requirements of section 1814(a)(2)(C) or 1835(a)(2)(A) in the case of home health services furnished to the individual.

(c)(1) The Secretary may initiate a proceeding to determine whether to impose a civil money penalty, assessment, or exclusion under subsection (a) or (b) only as authorized by the Attorney General pursuant to procedures agreed upon by them. The Secretary may not initiate an action under this section with respect to any claim, request for payment, or other occurrence described in this section later than six years after the date the claim was presented, the request for payment was made, or the occurrence took place. The Secretary may initiate an action under this section by serving notice of the action in any manner authorized by Rule 4 of the Federal Rules of Civil Procedure.

(2) The Secretary shall not make a determination adverse to any person under subsection (a) or (b) until the person has been given written notice and an opportunity for the determination to be made on the record after a hearing at which the person is entitled to be represented by counsel, to present witnesses, and to cross-examine witnesses against the person.

(3) In a proceeding under subsection (a) or (b) which—

(A) is against a person who has been convicted (whether upon a verdict after trial or upon a plea of guilty or nolo contendere) of a Federal crime charging fraud or false statements, and

(B) involves the same transaction as in the criminal action, the person is estopped from denying the essential elements of the criminal offense.

(4) The official conducting a hearing under this section may sanction a person, including any party or attorney, for failing to comply with an order or procedure, failing to defend an action, or other misconduct as would interfere with the speedy, orderly, or fair conduct of the hearing. Such sanction shall reasonably relate to the severity and nature of the failure or misconduct. Such sanction may include—

(A) in the case of refusal to provide or permit discovery, drawing negative factual inferences or treating such refusal as an admission by deeming the matter, or certain facts, to be established,

(B) prohibiting a party from introducing certain evidence or otherwise supporting a particular claim or defense,

(C) striking pleadings, in whole or in part,

(D) staying the proceedings,

(E) dismissal of the action,

(F) entering a default judgment,

(G) ordering the party or attorney to pay attorneys' fees and other costs caused by the failure or misconduct, and

(H) refusing to consider any motion or other action which is not filed in a timely manner.

(d) In determining the amount or scope of any penalty, assessment, or exclusion imposed pursuant to subsection (a) or (b), the Secretary shall take into account—

(1) the nature of claims and the circumstances under which they were presented,

(2) the degree of culpability, history of prior offenses, and financial condition of the person presenting the claims, and

(3) such other matters as justice may require.

(e) Any person adversely affected by a determination of the Secretary under this section may obtain a review of such determination in the United States Court of Appeals for the circuit in which the person resides, or in which the claim or specified claim was presented, by filing in such court (within sixty days following the date the person is notified of the Secretary's determination) a written petition requesting that the determination be modified or set aside. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary, and thereupon the Secretary shall file in the Court the record in the proceeding as provided in section 2112 of title 28, United States Code. Upon such filing, the court shall have jurisdiction of the proceeding and of the question determined therein, and shall have the power to make and enter upon the pleadings, testimony, and proceedings set forth in such record a decree affirming, modifying, remanding for further consideration, or setting aside, in whole or in part, the determination of the Secretary and enforcing the same to the extent that such order is affirmed or modified. No objection that has not been urged before the Secretary shall be considered by the court, unless the failure or neglect to urge such objection shall be excused because of extraordinary circumstances. The findings of the Secretary with respect to questions of fact, if supported by substantial evidence on the record considered as a whole, shall be conclusive. If any party shall apply to the court for leave to adduce additional evidence and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the hearing before the Secretary, the court may order such additional evidence to be taken before the Secretary and to be made a part of the record. The Secretary may modify his findings as to the facts, or make new findings, by reason of additional evidence so taken and filed, and he shall file with the court such modified or new findings, which findings with respect to

questions of fact, if supported by substantial evidence on the record considered as a whole, shall be conclusive, and his recommendations, if any, for the modification or setting aside of his original order. Upon the filing of the record with it, the jurisdiction of the court shall be exclusive and its judgment and decree shall be final, except that the same shall be subject to review by the Supreme Court of the United States, as provided in section 1254 of title 28, United States Code.

(f) Civil money penalties and assessments imposed under this section may be compromised by the Secretary and may be recovered in a civil action in the name of the United States brought in United States district court for the district where the claim or specified claim (as defined in subsection (r)) was presented, or where the claimant (or, with respect to a person described in subsection (o), the person) resides, as determined by the Secretary. Amounts recovered under this section shall be paid to the Secretary and disposed of as follows:

(1)(A) In the case of amounts recovered arising out of a claim under title XIX, there shall be paid to the State agency an amount bearing the same proportion to the total amount recovered as the State's share of the amount paid by the State agency for such claim bears to the total amount paid for such claim.

(B) In the case of amounts recovered arising out of a claim under an allotment to a State under title V, there shall be paid to the State agency an amount equal to three-sevenths of the amount recovered.

(2) Such portion of the amounts recovered as is determined to have been paid out of the trust funds under sections 1817 and 1841 shall be repaid to such trust funds.

(3) With respect to amounts recovered arising out of a claim under a Federal health care program (as defined in section 1128B(f)), the portion of such amounts as is determined to have been paid by the program shall be repaid to the program, and the portion of such amounts attributable to the amounts recovered under this section by reason of the amendments made by the Health Insurance Portability and Accountability Act of 1996 (as estimated by the Secretary) shall be deposited into the Federal Hospital Insurance Trust Fund pursuant to section 1817(k)(2)(C).

(4) The remainder of the amounts recovered shall be deposited as miscellaneous receipts of the Treasury of the United States.

The amount of such penalty or assessment, when finally determined, or the amount agreed upon in compromise, may be deducted from any sum then or later owing by the United States or a State agency (or, in the case of a penalty or assessment under subsection (o), by a specified State agency (as defined in subsection (q)(6)), to the person against whom the penalty or assessment has been assessed.

(g) A determination by the Secretary to impose a penalty, assessment, or exclusion under subsection (a) or (b) shall be final upon the expiration of the sixty-day period referred to in subsection (e). Matters that were raised or that could have been raised in a

hearing before the Secretary or in an appeal pursuant to subsection (e) may not be raised as a defense to a civil action by the United States to collect a penalty, assessment, or exclusion assessed under this section.

(h) Whenever the Secretary's determination to impose a penalty, assessment, or exclusion under subsection (a) or (b) becomes final, he shall notify the appropriate State or local medical or professional organization, the appropriate State agency or agencies administering or supervising the administration of State health care programs (as defined in section 1128(h)), and the appropriate utilization and quality control peer review organization, and the appropriate State or local licensing agency or organization (including the agency specified in section 1864(a) and 1902(a)(33)) that such a penalty, assessment, or exclusion has become final and the reasons therefor.

(i) For the purposes of this section:

(1) The term "State agency" means the agency established or designated to administer or supervise the administration of the State plan under title XIX of this Act or designated to administer the State's program under title V or subtitle 1 of title XX of this Act.

(2) The term "claim" means an application for payments for items and services under a Federal health care program (as defined in section 1128B(f)).

(3) The term "item or service" includes (A) any particular item, device, medical supply, or service claimed to have been provided to a patient and listed in an itemized claim for payment, and (B) in the case of a claim based on costs, any entry in the cost report, books of account or other documents supporting such claim.

(4) The term "agency of the United States" includes any contractor acting as a fiscal intermediary, carrier, or fiscal agent or any other claims processing agent for a Federal health care program (as so defined).

(5) The term "beneficiary" means an individual who is eligible to receive items or services for which payment may be made under a Federal health care program (as so defined) but does not include a provider, supplier, or practitioner.

(6) The term "remuneration" includes the waiver of coinsurance and deductible amounts (or any part thereof), and transfers of items or services for free or for other than fair market value. The term "remuneration" does not include—

(A) the waiver of coinsurance and deductible amounts by a person, if—

(i) the waiver is not offered as part of any advertisement or solicitation;

(ii) the person does not routinely waive coinsurance or deductible amounts; and

(iii) the person—

(I) waives the coinsurance and deductible amounts after determining in good faith that the individual is in financial need; or

(II) fails to collect coinsurance or deductible amounts after making reasonable collection efforts;

(B) subject to subsection (n), any permissible practice described in any subparagraph of section 1128B(b)(3) or in regulations issued by the Secretary;

(C) differentials in coinsurance and deductible amounts as part of a benefit plan design as long as the differentials have been disclosed in writing to all beneficiaries, third party payers, and providers, to whom claims are presented and as long as the differentials meet the standards as defined in regulations promulgated by the Secretary not later than 180 days after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996;

(D) incentives given to individuals to promote the delivery of preventive care as determined by the Secretary in regulations so promulgated;

(E) a reduction in the copayment amount for covered OPD services under section 1833(t)(5)(B);

(F) any other remuneration which promotes access to care and poses a low risk of harm to patients and Federal health care programs (as defined in section 1128B(f) and designated by the Secretary under regulations);

(G) the offer or transfer of items or services for free or less than fair market value by a person, if—

(i) the items or services consist of coupons, rebates, or other rewards from a retailer;

(ii) the items or services are offered or transferred on equal terms available to the general public, regardless of health insurance status; and

(iii) the offer or transfer of the items or services is not tied to the provision of other items or services reimbursed in whole or in part by the program under title XVIII or a State health care program (as defined in section 1128(h));

(H) the offer or transfer of items or services for free or less than fair market value by a person, if—

(i) the items or services are not offered as part of any advertisement or solicitation;

(ii) the items or services are not tied to the provision of other services reimbursed in whole or in part by the program under title XVIII or a State health care program (as so defined);

(iii) there is a reasonable connection between the items or services and the medical care of the individual; and

(iv) the person provides the items or services after determining in good faith that the individual is in financial need;

(I) effective on a date specified by the Secretary (but not earlier than January 1, 2011), the waiver by a PDP sponsor of a prescription drug plan under part D of title XVIII or an MA organization offering an MA–PD plan

under part C of such title of any copayment for the first fill of a covered part D drug (as defined in section 1860D–2(e)) that is a generic drug for individuals enrolled in the prescription drug plan or MA–PD plan, respectively; or

(J) the provision of telehealth technologies (as defined by the Secretary) on or after January 1, 2019, by a provider of services or a renal dialysis facility (as such terms are defined for purposes of title XVIII) to an individual with end stage renal disease who is receiving home dialysis for which payment is being made under part B of such title, if—

(i) the telehealth technologies are not offered as part of any advertisement or solicitation;

(ii) the telehealth technologies are provided for the purpose of furnishing telehealth services related to the individual's end stage renal disease; and

(iii) the provision of the telehealth technologies meets any other requirements set forth in regulations promulgated by the Secretary.

(7) The term "should know" means that a person, with respect to information—

(A) acts in deliberate ignorance of the truth or falsity of the information; or

(B) acts in reckless disregard of the truth or falsity of the information,

and no proof of specific intent to defraud is required.

(j)(1) The provisions of subsections (d) and (e) of section 205 shall apply with respect to this section to the same extent as they are applicable with respect to title II. The Secretary may delegate the authority granted by section 205(d) (as made applicable to this section) to the Inspector General of the Department of Health and Human Services for purposes of any investigation under this section.

(2) The Secretary may delegate authority granted under this section and under section 1128 to the Inspector General of the Department of Health and Human Services.

(k) Whenever the Secretary has reason to believe that any person has engaged, is engaging, or is about to engage in any activity which makes the person subject to a civil monetary penalty under this section, the Secretary may bring an action in an appropriate district court of the United States (or, if applicable, a United States court of any territory) to enjoin such activity, or to enjoin the person from concealing, removing, encumbering, or disposing of assets which may be required in order to pay a civil monetary penalty if any such penalty were to be imposed or to seek other appropriate relief.

(l) A principal is liable for penalties, assessments, and an exclusion under this section for the actions of the principal's agent acting within the scope of the agency.

(m)(1) For purposes of this section, with respect to a Federal health care program not contained in this Act, references to the Secretary in this section shall be deemed to be references to the Secretary or Administrator of the department or agency with jurisdiction over such program and references to the Inspector General

of the Department of Health and Human Services in this section shall be deemed to be references to the Inspector General of the applicable department or agency.

(2)(A) The Secretary and Administrator of the departments and agencies referred to in paragraph (1) may include in any action pursuant to this section, claims within the jurisdiction of other Federal departments or agencies as long as the following conditions are satisfied:

(i) The case involves primarily claims submitted to the Federal health care programs of the department or agency initiating the action.

(ii) The Secretary or Administrator of the department or agency initiating the action gives notice and an opportunity to participate in the investigation to the Inspector General of the department or agency with primary jurisdiction over the Federal health care programs to which the claims were submitted.

(B) If the conditions specified in subparagraph (A) are fulfilled, the Inspector General of the department or agency initiating the action is authorized to exercise all powers granted under chapter 4 of title 5, United States Code, with respect to the claims submitted to the other departments or agencies to the same manner and extent as provided in that Act with respect to claims submitted to such departments or agencies.

(n)(1) Subparagraph (B) of subsection (i)(6) shall not apply to a practice described in paragraph (2) unless—

(A) the Secretary, through the Inspector General of the Department of Health and Human Services, promulgates a rule authorizing such a practice as an exception to remuneration; and

(B) the remuneration is offered or transferred by a person under such rule during the 2-year period beginning on the date the rule is first promulgated.

(2) A practice described in this paragraph is a practice under which a health care provider or facility pays, in whole or in part, premiums for medicare supplemental policies for individuals entitled to benefits under part A of title XVIII pursuant to section 226A.

(o) Any person (including an organization, agency, or other entity, but excluding a program beneficiary, as defined in subsection (q)(4)) that, with respect to a grant, contract, or other agreement for which the Secretary provides funding—

(1) knowingly presents or causes to be presented a specified claim (as defined in subsection (r)) under such grant, contract, or other agreement that the person knows or should know is false or fraudulent;

(2) knowingly makes, uses, or causes to be made or used any false statement, omission, or misrepresentation of a material fact in any application, proposal, bid, progress report, or other document that is required to be submitted in order to directly or indirectly receive or retain funds provided in whole or in part by such Secretary pursuant to such grant, contract, or other agreement;

(3) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent specified claim under such grant, contract, or other agreement;

(4) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation (as defined in subsection (s)) to pay or transmit funds or property to such Secretary with respect to such grant, contract, or other agreement, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit funds or property to such Secretary with respect to such grant, contract, or other agreement; or

(5) fails to grant timely access, upon reasonable request (as defined by such Secretary in regulations), to the Inspector General of the Department, for the purpose of audits, investigations, evaluations, or other statutory functions of such Inspector General in matters involving such grants, contracts, or other agreements;

shall be subject, in addition to any other penalties that may be prescribed by law, to a civil money penalty in cases under paragraph (1), of not more than $10,000 for each specified claim; in cases under paragraph (2), not more than $50,000 for each false statement, omission, or misrepresentation of a material fact; in cases under paragraph (3), not more than $50,000 for each false record or statement; in cases under paragraph (4), not more than $50,000 for each false record or statement or $10,000 for each day that the person knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay; or in cases under paragraph (5), not more than $15,000 for each day of the failure described in such paragraph. In addition, in cases under paragraphs (1) and (3), such a person shall be subject to an assessment of not more than 3 times the amount claimed in the specified claim described in such paragraph in lieu of damages sustained by the United States or a specified State agency because of such specified claim, and in cases under paragraphs (2) and (4), such a person shall be subject to an assessment of not more than 3 times the total amount of the funds described in paragraph (2) or (4), respectively (or, in the case of an obligation to transmit property to the Secretary described in paragraph (4), of the value of the property described in such paragraph) in lieu of damages sustained by the United States or a specified State agency because of such case. In addition, the Secretary may make a determination in the same proceeding to exclude the person from participation in the Federal health care programs (as defined in section 1128B(f)(1)) and to direct the appropriate State agency to exclude the person from participation in any State health care program.

(p) The provisions of subsections (c), (d), (g), and (h) shall apply to a civil money penalty or assessment under subsection (o) in the same manner as such provisions apply to a penalty, assessment, or proceeding under subsection (a). In applying subsection (d), each reference to a claim under such subsection shall be treated as including a reference to a specified claim (as defined in subsection (r)).

(q) For purposes of this subsection and subsections (o) and (p):

(1) The term "Department" means the Department of Health and Human Services.

(2) The term "material" means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property.

(3) The term "other agreement" includes a cooperative agreement, scholarship, fellowship, loan, subsidy, payment for a specified use, donation agreement, award, or subaward (regardless of whether one or more of the persons entering into the agreement is a contractor or subcontractor).

(4) The term "program beneficiary" means, in the case of a grant, contract, or other agreement designed to accomplish the objective of awarding or otherwise furnishing benefits or assistance to individuals and for which the Secretary provides funding, an individual who applies for, or who receives, such benefits or assistance from such grant, contract, or other agreement. Such term does not include, with respect to such grant, contract, or other agreement, an officer, employee, or agent of a person or entity that receives such grant or that enters into such contract or other agreement.

(5) The term "recipient" includes a subrecipient or subcontractor.

(6) The term "specified State agency" means an agency of a State government established or designated to administer or supervise the administration of a grant, contract, or other agreement funded in whole or in part by the Secretary.

(r) For purposes of this section, the term "specified claim" means any application, request, or demand under a grant, contract, or other agreement for money or property, whether or not the United States or a specified State agency has title to the money or property, that is not a claim (as defined in subsection (i)(2)) and that—

(1) is presented or caused to be presented to an officer, employee, or agent of the Department or agency thereof, or of any specified State agency; or

(2) is made to a contractor, grantee, or any other recipient if the money or property is to be spent or used on the Department's behalf or to advance a Department program or interest, and if the Department—

(A) provides or has provided any portion of the money or property requested or demanded; or

(B) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded.

(s) For purposes of subsection (o), the term "obligation" means an established duty, whether or not fixed, arising from an express or implied contractual, grantor-grantee, or licensor-licensee relationship, for a fee-based or similar relationship, from statute or regulation, or from the retention of any overpayment.

CRIMINAL PENALTIES FOR ACTS INVOLVING FEDERAL HEALTH CARE PROGRAMS

SEC. 1128B. [42 U.S.C. 1320a–7b] (a) Whoever—

(1) knowingly and willfully makes or causes to be made any false statement or representation of a material fact in any application for any benefit or payment under a Federal health care program (as defined in subsection (f)),

(2) at any time knowingly and willfully makes or causes to be made any false statement or representation of a material fact for use in determining rights to such benefit or payment,

(3) having knowledge of the occurrence of any event affecting (A) his initial or continued right to any such benefit or payment, or (B) the initial or continued right to any such benefit or payment of any other individual in whose behalf he has applied for or is receiving such benefit or payment, conceals or fails to disclose such event with an intent fraudulently to secure such benefit or payment either in a greater amount or quantity than is due or when no such benefit or payment is authorized,

(4) having made application to receive any such benefit or payment for the use and benefit of another and having received it, knowingly and willfully converts such benefit or payment or any part thereof to a use other than for the use and benefit of such other person,

(5) presents or causes to be presented a claim for a physician's service for which payment may be made under a Federal health care program and knows that the individual who furnished the service was not licensed as a physician, or

(6) for a fee knowingly and willfully counsels or assists an individual to dispose of assets (including by any transfer in trust) in order for the individual to become eligible for medical assistance under a State plan under title XIX, if disposing of the assets results in the imposition of a period of ineligibility for such assistance under section 1917(c),

shall (i) in the case of such a statement, representation, concealment, failure, conversion, or provision of counsel or assistance by any other person in connection with the furnishing (by that person) of items or services for which payment is or may be made under the program, be guilty of a felony and upon conviction thereof fined not more than $100,000 or imprisoned for not more than 10 years or both, or (ii) in the case of such a statement, representation, concealment, failure, conversion, or provision of counsel or assistance by any other person, be guilty of a misdemeanor and upon conviction thereof fined not more than $20,000 or imprisoned for not more than one year, or both. In addition, in any case where an individual who is otherwise eligible for assistance under a Federal health care program is convicted of an offense under the preceding provisions of this subsection, the administrator of such program may at its option (notwithstanding any other provision of such program) limit, restrict, or suspend the eligibility of that individual for such period (not exceeding one year) as it deems appropriate; but the imposition of a limitation, restriction, or suspension with respect to the eligibility of any individual under this sentence shall not affect the eligibility of any other person for assistance under the plan, regardless of the relationship between that individual and such other person.

(b)(1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—

(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—

(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

(3) Paragraphs (1) and (2) shall not apply to—

(A) a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program;

(B) any amount paid by an employer to an employee (who has a bona fide employment relationship with such employer) for employment in the provision of covered items or services;

(C) any amount paid by a vendor of goods or services to a person authorized to act as a purchasing agent for a group of individuals or entities who are furnishing services reimbursed under a Federal health care program if—

(i) the person has a written contract, with each such individual or entity, which specifies the amount to be paid the person, which amount may be a fixed amount or a fixed percentage of the value of the purchases made by each such individual or entity under the contract, and

(ii) in the case of an entity that is a provider of services (as defined in section 1861(u)), the person discloses (in such form and manner as the Secretary requires) to the entity and, upon request, to the Secretary the amount received from each such vendor with respect to purchases made by or on behalf of the entity;

(D) a waiver of any coinsurance under part B of title XVIII by a Federally qualified health care center with respect to an individual who qualifies for subsidized services under a provision of the Public Health Service Act;

(E) any payment practice specified by the Secretary in regulations promulgated pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987 or in regulations under section 1860D–3(e)(6) [13];

(F) any remuneration between an organization and an individual or entity providing items or services, or a combination thereof, pursuant to a written agreement between the organization and the individual or entity if the organization is an eligible organization under section 1876 or if the written agreement, through a risk-sharing arrangement, places the individual or entity at substantial financial risk for the cost or utilization of the items or services, or a combination thereof, which the individual or entity is obligated to provide;

(G) the waiver or reduction by pharmacies (including pharmacies of the Indian Health Service, Indian tribes, tribal organizations, and urban Indian organizations) of any cost-sharing imposed under part D of title XVIII, if the conditions described in clauses (i) through (iii) of section 1128A(i)(6)(A) are met with respect to the waiver or reduction (except that, in the case of such a waiver or reduction on behalf of a subsidy eligible individual (as defined in section 1860D–14(a)(3)), section 1128A(i)(6)(A) shall be applied without regard to clauses (ii) and (iii) of that section);

(H) any remuneration between a federally qualified health center (or an entity controlled by such a health center) and an MA organization pursuant to a written agreement described in section 1853(a)(4);

(I) any remuneration between a health center entity described under clause (i) or (ii) of section 1905(l)(2)(B) and any individual or entity providing goods, items, services, donations, loans, or a combination thereof, to such health center entity pursuant to a contract, lease, grant, loan, or other agreement, if such agreement contributes to the ability of the health center entity to maintain or increase the availability, or enhance the quality, of services provided to a medically underserved population served by the health center entity;

(J) [14] a discount in the price of an applicable drug (as defined in paragraph (2) of section 1860D–14A(g)) of a manufacturer that is furnished to an applicable beneficiary (as defined in paragraph (1) of such section) under the Medicare coverage gap discount program under section 1860D–14A;

(K) [14] an incentive payment made to a Medicare fee-for-service beneficiary by an ACO under an ACO Beneficiary Incentive Program established under subsection (m)

[13] The amendment to insert "or in regulations under section 1860D–3(e)(6)" after "1987" in section 1128B(b)(3)(C) made by section 101(e)(8)(A) of P.L. 108–173 (117 Stat. 2152) was executed to suparagraph (E) in order to reflect the probable intent of the Congress. The reference in the matter added by such public law probably should be "section 1860D–4(e)(6)".

[14] Margin so in law.

of section 1899, if the payment is made in accordance with the requirements of such subsection and meets such other conditions as the Secretary may establish; and

(L) a bona fide mental health or behavioral health improvement or maintenance program, if—

(i) such program—

(I) consists of counseling, mental health services, a suicide prevention program, or a substance use disorder prevention and treatment program;

(II) is made available to a physician or other clinician for the primary purpose of preventing suicide, improving mental health and resiliency, or providing training in appropriate strategies to promote the mental health and resiliency of such physician or other clinician;

(III) is set out in a written policy, approved in advance of the operation of the program by the governing body of the entity providing such program (and which shall be updated accordingly in advance to substantial changes to the operation of such program), that includes—

(aa) a description of the content and duration of the program;

(bb) a description of the evidence-based support for the design of the program;

(cc) the estimated cost of the program;

(dd) the personnel (including the qualifications of such personnel) implementing the program; and

(ee) the method by which such entity will evaluate the use and success of the program;

(IV) is offered by an entity described in clause (ii) with a formal medical staff to all physicians and other clinicians who practice in the geographic area served by such entity, including physicians who hold bona fide appointments to the medical staff of such entity or otherwise have clinical privileges at such entity;

(V) is offered to all such physicians and clinicians on the same terms and conditions and without regard to the volume or value of referrals or other business generated by a physician or clinician for such entity;

(VI) is evidence-based and conducted by a qualified health professional; and

(VII) meets such other requirements the Secretary may impose by regulation as needed to protect against program or patient abuse;

(ii) such entity is—

(I) a hospital;

(II) an ambulatory surgical center;

(III) a community health center;

(IV) a rural emergency hospital;

(V) a skilled nursing facility; or

(VI) any similar entity, as determined by the Secretary; and

(iii) neither the provision of such program, nor the value of such program, are contingent upon the number or value of referrals made by a physician or other clinician to such entity or the amount or value of other business generated by such physician for the entity.

(4)[14] Whoever without lawful authority knowingly and willfully purchases, sells or distributes, or arranges for the purchase, sale, or distribution of a beneficiary identification number or unique health identifier for a health care provider under title XVIII, title XIX, or title XXI shall be imprisoned for not more than 10 years or fined not more than $500,000 ($1,000,000 in the case of a corporation), or both.

(c) Whoever knowingly and willfully makes or causes to be made, or induces or seeks to induce the making of, any false statement or representation of a material fact with respect to the conditions or operation of any institution, facility, or entity in order that such institution, facility, or entity may qualify (either upon initial certification or upon recertification) as a hospital, critical access hospital, skilled nursing facility, nursing facility, intermediate care facility for the mentally retarded, or other entity (including an eligible organization under section 1876(b)) for which certification is required under title XVIII or a State health care program (as defined in section 1128(h)), or with respect to information required to be provided under section 1124A, shall be guilty of a felony and upon conviction thereof shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

(d) Whoever knowingly and willfully—

(1) charges, for any service provided to a patient under a State plan approved under title XIX, money or other consideration at a rate in excess of the rates established by the State (or, in the case of services provided to an individual enrolled with a medicaid managed care organization under title XIX under a contract under section 1903(m) or under a contractual, referral, or other arrangement under such contract, at a rate in excess of the rate permitted under such contract), or

(2) charges, solicits, accepts, or receives, in addition to any amount otherwise required to be paid under a State plan approved under title XIX, any gift, money, donation, or other consideration (other than a charitable, religious, or philanthropic contribution from an organization or from a person unrelated to the patient)—

(A) as a precondition of admitting a patient to a hospital, nursing facility, or intermediate care facility for the mentally retarded, or

(B) as a requirement for the patient's continued stay in such a facility,

when the cost of the services provided therein to the patient is paid for (in whole or in part) under the State plan,

shall be guilty of a felony and upon conviction thereof shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

(e) Whoever accepts assignments described in section 1842(b)(3)(B)(ii) or agrees to be a participating physician or supplier under section 1842(h)(1) and knowingly, willfully, and repeat-

edly violates the term of such assignments or agreement, shall be guilty of a misdemeanor and upon conviction thereof shall be fined not more than $4,000 or imprisoned for not more than six months, or both.

(f) For purposes of this section, the term "Federal health care program" means—

(1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the health insurance program under chapter 89 of title 5, United States Code); or

(2) any State health care program, as defined in section 1128(h).

(g) In addition to the penalties provided for in this section or section 1128A, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of title 31, United States Code.

(h) With respect to violations of this section, a person need not have actual knowledge of this section or specific intent to commit a violation of this section.

FRAUD AND ABUSE CONTROL PROGRAM

SEC. 1128C. [42 U.S.C. 1320a–7c] (a) ESTABLISHMENT OF PROGRAM.—

(1) IN GENERAL.—Not later than January 1, 1997, the Secretary, acting through the Office of the Inspector General of the Department of Health and Human Services, and the Attorney General shall establish a program—

(A) to coordinate Federal, State, and local law enforcement programs to control fraud and abuse with respect to health plans,

(B) to conduct investigations, audits, evaluations, and inspections relating to the delivery of and payment for health care in the United States,

(C) to facilitate the enforcement of the provisions of sections 1128, 1128A, and 1128B and other statutes applicable to health care fraud and abuse, and

(D) to provide for the modification and establishment of safe harbors and to issue advisory opinions and special fraud alerts pursuant to section 1128D.

(2) COORDINATION WITH HEALTH PLANS.—In carrying out the program established under paragraph (1), the Secretary and the Attorney General shall consult with, and arrange for the sharing of data with representatives of health plans.

(3) GUIDELINES.—

(A) IN GENERAL.—The Secretary and the Attorney General shall issue guidelines to carry out the program under paragraph (1). The provisions of sections 553, 556, and 557 of title 5, United States Code, shall not apply in the issuance of such guidelines.

(B) INFORMATION GUIDELINES.—

(i) IN GENERAL.—Such guidelines shall include guidelines relating to the furnishing of information by health plans, providers, and others to enable the Secretary and the Attorney General to carry out the program (including coordination with health plans under paragraph (2)).

(ii) CONFIDENTIALITY.—Such guidelines shall include procedures to assure that such information is provided and utilized in a manner that appropriately protects the confidentiality of the information and the privacy of individuals receiving health care services and items.

(iii) QUALIFIED IMMUNITY FOR PROVIDING INFORMATION.—The provisions of section 1157(a) (relating to limitation on liability) shall apply to a person providing information to the Secretary or the Attorney General in conjunction with their performance of duties under this section.

(4) ENSURING ACCESS TO DOCUMENTATION.—The Inspector General of the Department of Health and Human Services is authorized to exercise such authority described in paragraphs (3) through (9) of section 406(a) of title 5, United States Code, as necessary with respect to the activities under the fraud and abuse control program established under this subsection.

(5) AUTHORITY OF INSPECTOR GENERAL.—Nothing in this Act shall be construed to diminish the authority of any Inspector General, including such authority as provided in chapter 4 of title 5, United States Code.

(6) PUBLIC-PRIVATE PARTNERSHIP FOR WASTE, FRAUD, AND ABUSE DETECTION.—

(A) IN GENERAL.—Under the program described in paragraph (1), there is established a public-private partnership (in this paragraph referred to as the "partnership") of health plans, Federal and State agencies, law enforcement agencies, health care anti-fraud organizations, and any other entity determined appropriate by the Secretary (in this paragraph referred to as "partners") for purposes of detecting and preventing health care waste, fraud, and abuse.

(B) CONTRACT WITH TRUSTED THIRD PARTY.—In carrying out the partnership, the Secretary shall enter into a contract with a trusted third party for purposes of carrying out the duties of the partnership described in subparagraph (C).

(C) DUTIES OF PARTNERSHIP.—The partnership shall—

(i) provide technical and operational support to facilitate data sharing between partners in the partnership;

(ii) analyze data so shared to identify fraudulent and aberrant billing patterns;

(iii) conduct aggregate analyses of health care data so shared across Federal, State, and private health plans for purposes of detecting fraud, waste, and abuse schemes;

(iv) identify outlier trends and potential vulnerabilities of partners in the partnership with respect to such schemes;

(v) refer specific cases of potential unlawful conduct to appropriate governmental entities;

(vi) convene, not less than annually, meetings with partners in the partnership for purposes of providing updates on the partnership's work and facilitating information sharing between the partners;

(vii) enter into data sharing and data use agreements with partners in the partnership in such a manner so as to ensure the partnership has access to data necessary to identify waste, fraud, and abuse while maintaining the confidentiality and integrity of such data;

(viii) provide partners in the partnership with plan-specific, confidential feedback on any aberrant billing patterns or potential fraud identified by the partnership with respect to such partner;

(ix) establish a process by which entities described in subparagraph (A) may enter the partnership and requirements such entities must meet to enter the partnership;

(x) provide appropriate training, outreach, and education to partners based on the results of data analyses described in clauses (ii) and (iii); and

(xi) perform such other duties as the Secretary determines appropriate.

(D) SUBSTANCE USE DISORDER TREATMENT ANALYSIS.—Not later than 2 years after the date of the enactment of the Consolidated Appropriations Act, 2021, the trusted third party with a contract in effect under subparagraph (B) shall perform an analysis of aberrant or fraudulent billing patterns and trends with respect to providers and suppliers of substance use disorder treatments from data shared with the partnership.

(E) EXECUTIVE BOARD.—

(i) EXECUTIVE BOARD COMPOSITION.—

(I) IN GENERAL.—There shall be an executive board of the partnership comprised of representatives of the Federal Government and representatives of the private sector selected by the Secretary.

(II) CHAIRS.—The executive board shall be co-chaired by one Federal Government official and one representative from the private sector.

(ii) MEETINGS.—The executive board of the partnership shall meet at least once per year.

(iii) EXECUTIVE BOARD DUTIES.—The duties of the executive board shall include the following:

(I) Providing strategic direction for the partnership, including membership criteria and a mission statement.

(II) Communicating with the leadership of the Department of Health and Human Services and the Department of Justice and the various private health sector associations.

(F) REPORTS.—Not later than January 1, 2023, and every 2 years thereafter, the Secretary shall submit to Congress and make available on the public website of the Centers for Medicare & Medicaid Services a report containing—

(i) a review of activities conducted by the partnership over the 2-year period ending on the date of the submission of such report, including any progress to any objectives established by the partnership;

(ii) any savings voluntarily reported by health plans participating in the partnership attributable to the partnership during such period;

(iii) any savings to the Federal Government attributable to the partnership during such period;

(iv) any other outcomes attributable to the partnership, as determined by the Secretary, during such period; and

(v) a strategic plan for the 2-year period beginning on the day after the date of the submission of such report, including a description of any emerging fraud and abuse schemes, trends, or practices that the partnership intends to study during such period.

(G) FUNDING.—The partnership shall be funded by amounts otherwise made available to the Secretary for carrying out the program described in paragraph (1).

(H) TRANSITIONAL PROVISIONS.—To the extent consistent with this subsection, all functions, personnel, assets, liabilities, and administrative actions applicable on the date before the date of the enactment of this paragraph to the National Fraud Prevention Partnership established on September 17, 2012, by charter of the Secretary shall be transferred to the partnership established under subparagraph (A) as of the date of the enactment of this paragraph.

(I) NONAPPLICABILITY OF FACA.—The provisions of the Federal Advisory Committee Act shall not apply to the partnership established by subparagraph (A).

(J) IMPLEMENTATION.—Notwithstanding any other provision of law, the Secretary may implement the partnership established by subparagraph (A) by program instruction or otherwise.

(K) DEFINITION.—For purposes of this paragraph, the term "trusted third party" means an entity that—

(i) demonstrates the capability to carry out the duties of the partnership described in subparagraph (C);

(ii) complies with such conflict of interest standards determined appropriate by the Secretary; and

(iii) meets such other requirements as the Secretary may prescribe.

(b) ADDITIONAL USE OF FUNDS BY INSPECTOR GENERAL.—

(1) REIMBURSEMENTS FOR INVESTIGATIONS.—The Inspector General of the Department of Health and Human Services is authorized to receive and retain for current use reimbursement for the costs of conducting investigations and audits and for monitoring compliance plans when such costs are ordered by a court, voluntarily agreed to by the payor, or otherwise.

(2) CREDITING.—Funds received by the Inspector General under paragraph (1) as reimbursement for costs of conducting investigations shall be deposited to the credit of the appropriation from which initially paid, or to appropriations for similar purposes currently available at the time of deposit, and shall remain available for obligation for 1 year from the date of the deposit of such funds.

(c) HEALTH PLAN DEFINED.—For purposes of this section, the term "health plan" means a plan or program that provides health benefits, whether directly, through insurance, or otherwise, and includes—

(1) a policy of health insurance;

(2) a contract of a service benefit organization; and

(3) a membership agreement with a health maintenance organization or other prepaid health plan.

GUIDANCE REGARDING APPLICATION OF HEALTH CARE FRAUD AND ABUSE SANCTIONS

SEC. 1128D. [42 U.S.C. 1320a–7d] (a) SOLICITATION AND PUBLICATION OF MODIFICATIONS TO EXISTING SAFE HARBORS AND NEW SAFE HARBORS.—

(1) IN GENERAL.—

(A) SOLICITATION OF PROPOSALS FOR SAFE HARBORS.—Not later than January 1, 1997, and not less than annually thereafter, the Secretary shall publish a notice in the Federal Register soliciting proposals, which will be accepted during a 60-day period, for—

(i) modifications to existing safe harbors issued pursuant to section 14(a) of the Medicare and Medicaid Patient and Program Protection Act of 1987 (42 U.S.C. 1320a–7b note);

(ii) additional safe harbors specifying payment practices that shall not be treated as a criminal offense under section 1128B(b) and shall not serve as the basis for an exclusion under section 1128(b)(7);

(iii) advisory opinions to be issued pursuant to subsection (b); and

(iv) special fraud alerts to be issued pursuant to subsection (c).

(B) PUBLICATION OF PROPOSED MODIFICATIONS AND PROPOSED ADDITIONAL SAFE HARBORS.—After considering the proposals described in clauses (i) and (ii) of subparagraph (A), the Secretary, in consultation with the Attorney General, shall publish in the Federal Register proposed modifications to existing safe harbors and proposed additional safe harbors, if appropriate, with a 60-day comment period. After considering any public comments received

during this period, the Secretary shall issue final rules modifying the existing safe harbors and establishing new safe harbors, as appropriate.

(C) REPORT.—The Inspector General of the Department of Health and Human Services (in this section referred to as the "Inspector General") shall, in an annual report to Congress or as part of the year-end semiannual report required by section 405 of title 5, United States Code, describe the proposals received under clauses (i) and (ii) of subparagraph (A) and explain which proposals were included in the publication described in subparagraph (B), which proposals were not included in that publication, and the reasons for the rejection of the proposals that were not included.

(2) CRITERIA FOR MODIFYING AND ESTABLISHING SAFE HARBORS.—In modifying and establishing safe harbors under paragraph (1)(B), the Secretary may consider the extent to which providing a safe harbor for the specified payment practice may result in any of the following:

(A) An increase or decrease in access to health care services.

(B) An increase or decrease in the quality of health care services.

(C) An increase or decrease in patient freedom of choice among health care providers.

(D) An increase or decrease in competition among health care providers.

(E) An increase or decrease in the ability of health care facilities to provide services in medically underserved areas or to medically underserved populations.

(F) An increase or decrease in the cost to Federal health care programs (as defined in section 1128B(f)).

(G) An increase or decrease in the potential overutilization of health care services.

(H) The existence or nonexistence of any potential financial benefit to a health care professional or provider which may vary based on their decisions of—

(i) whether to order a health care item or service; or

(ii) whether to arrange for a referral of health care items or services to a particular practitioner or provider.

(I) Any other factors the Secretary deems appropriate in the interest of preventing fraud and abuse in Federal health care programs (as so defined).

(3) CONSIDERATION OF SAFE HARBOR FOR CERTAIN CONTINGENCY MANAGEMENT INTERVENTIONS.—

(A) IN GENERAL.—Not later than one year after the date of the enactment of this paragraph, the Inspector General shall conduct a review on whether to establish a safe harbor described in paragraph (1)(A)(ii) for evidence-based contingency management incentives and the parameters for such a safe harbor. In conducting the review under the previous sentence, the Inspector General shall

consider the extent to which providing such a safe harbor for evidence-based contingency management incentives may result in any of the factors described in paragraph (2).

(B) REPORT.—Not later than two years after the date of the enactment of this paragraph, the Secretary and the Inspector General shall submit to Congress recommendations, including based on the review conducted under subparagraph (A), for improving access to evidence-based contingency management interventions while ensuring quality of care, ensuring fidelity to evidence-based practices, and including strong program integrity safeguards that prevent increased waste, fraud, and abuse and prevent medically unnecessary or inappropriate items or services reimbursed in whole or in part by a Federal health care program.

(b) ADVISORY OPINIONS.—

(1) ISSUANCE OF ADVISORY OPINIONS.—The Secretary, in consultation with the Attorney General, shall issue written advisory opinions as provided in this subsection.

(2) MATTERS SUBJECT TO ADVISORY OPINIONS.—The Secretary shall issue advisory opinions as to the following matters:

(A) What constitutes prohibited remuneration within the meaning of section 1128B(b) or section 1128A(i)(6).

(B) Whether an arrangement or proposed arrangement satisfies the criteria set forth in section 1128B(b)(3) for activities which do not result in prohibited remuneration.

(C) Whether an arrangement or proposed arrangement satisfies the criteria which the Secretary has established, or shall establish by regulation for activities which do not result in prohibited remuneration.

(D) What constitutes an inducement to reduce or limit services to individuals entitled to benefits under title XVIII or title XIX within the meaning of section 1128A(b).

(E) Whether any activity or proposed activity constitutes grounds for the imposition of a sanction under section 1128, 1128A, or 1128B.

(3) MATTERS NOT SUBJECT TO ADVISORY OPINIONS.—Such advisory opinions shall not address the following matters:

(A) Whether the fair market value shall be, or was paid or received for any goods, services or property.

(B) Whether an individual is a bona fide employee within the requirements of section 3121(d)(2) of the Internal Revenue Code of 1986.

(4) EFFECT OF ADVISORY OPINIONS.—

(A) BINDING AS TO SECRETARY AND PARTIES INVOLVED.—Each advisory opinion issued by the Secretary shall be binding as to the Secretary and the party or parties requesting the opinion.

(B) FAILURE TO SEEK OPINION.—The failure of a party to seek an advisory opinion may not be introduced into evidence to prove that the party intended to violate the provisions of sections [15] 1128, 1128A, or 1128B.

(5) REGULATIONS.—

[15] So in original. Probably should be "section".

(A) IN GENERAL.—Not later than 180 days after the date of the enactment of this section, the Secretary shall issue regulations to carry out this section. Such regulations shall provide for—

(i) the procedure to be followed by a party applying for an advisory opinion;

(ii) the procedure to be followed by the Secretary in responding to a request for an advisory opinion;

(iii) the interval in which the Secretary shall respond;

(iv) the reasonable fee to be charged to the party requesting an advisory opinion; and

(v) the manner in which advisory opinions will be made available to the public.

(B) SPECIFIC CONTENTS.—Under the regulations promulgated pursuant to subparagraph (A)—

(i) the Secretary shall be required to issue to a party requesting an advisory opinion by not later than 60 days after the request is received; and

(ii) the fee charged to the party requesting an advisory opinion shall be equal to the costs incurred by the Secretary in responding to the request.

(6) APPLICATION OF SUBSECTION.—This subsection shall apply to requests for advisory opinions made on or after the date which is 6 months after the date of enactment of this section.

(c) SPECIAL FRAUD ALERTS.—

(1) IN GENERAL.—

(A) REQUEST FOR SPECIAL FRAUD ALERTS.—Any person may present, at any time, a request to the Inspector General for a notice which informs the public of practices which the Inspector General considers to be suspect or of particular concern under the Medicare program under title XVIII or a State health care program, as defined in section 1128(h) (in this subsection referred to as a "special fraud alert").

(B) ISSUANCE AND PUBLICATION OF SPECIAL FRAUD ALERTS.—Upon receipt of a request described in subparagraph (A), the Inspector General shall investigate the subject matter of the request to determine whether a special fraud alert should be issued. If appropriate, the Inspector General shall issue a special fraud alert in response to the request. All special fraud alerts issued pursuant to this subparagraph shall be published in the Federal Register.

(2) CRITERIA FOR SPECIAL FRAUD ALERTS.—In determining whether to issue a special fraud alert upon a request described in paragraph (1), the Inspector General may consider—

(A) whether and to what extent the practices that would be identified in the special fraud alert may result in any of the consequences described in subsection (a)(2); and

(B) the volume and frequency of the conduct that would be identified in the special fraud alert.

HEALTH CARE FRAUD AND ABUSE DATA COLLECTION PROGRAM

SEC. 1128E. [42 U.S.C. 1320a–7e] (a) IN GENERAL.—The Secretary shall maintain a national health care fraud and abuse data collection program under this section for the reporting of certain final adverse actions (not including settlements in which no findings of liability have been made) against health care providers, suppliers, or practitioners as required by subsection (b), with access as set forth in subsection (d), and shall furnish the information collected under this section to the National Practitioner Data Bank established pursuant to the Health Care Quality Improvement Act of 1986 (42 U.S.C. 11101 et seq.).

(b) REPORTING OF INFORMATION.—

(1) IN GENERAL.—Each Government agency and health plan shall report any final adverse action (not including settlements in which no findings of liability have been made) taken against a health care provider, supplier, or practitioner.

(2) INFORMATION TO BE REPORTED.—The information to be reported under paragraph (1) includes:

(A) The name and TIN (as defined in section 7701(a)(41) of the Internal Revenue Code of 1986) of any health care provider, supplier, or practitioner who is the subject of a final adverse action.

(B) The name (if known) of any health care entity with which a health care provider, supplier, or practitioner, who is the subject of a final adverse action, is affiliated or associated.

(C) The nature of the final adverse action and whether such action is on appeal.

(D) A description of the acts or omissions and injuries upon which the final adverse action was based, and such other information as the Secretary determines by regulation is required for appropriate interpretation of information reported under this section.

(3) CONFIDENTIALITY.—In determining what information is required, the Secretary shall include procedures to assure that the privacy of individuals receiving health care services is appropriately protected.

(4) TIMING AND FORM OF REPORTING.—The information required to be reported under this subsection shall be reported regularly (but not less often than monthly) and in such form and manner as the Secretary prescribes. Such information shall first be required to be reported on a date specified by the Secretary.

(5) TO WHOM REPORTED.—The information required to be reported under this subsection shall be reported to the Secretary.

(6) SANCTIONS FOR FAILURE TO REPORT.—

(A) HEALTH PLANS.—Any health plan that fails to report information on an adverse action required to be reported under this subsection shall be subject to a civil money penalty of not more than $25,000 for each such adverse action not reported. Such penalty shall be imposed and collected in the same manner as civil money penalties

under subsection (a) of section 1128A are imposed and collected under that section.

(B) GOVERNMENTAL AGENCIES.—The Secretary shall provide for a publication of a public report that identifies those Government agencies that have failed to report information on adverse actions as required to be reported under this subsection.

(c) DISCLOSURE AND CORRECTION OF INFORMATION.—

(1) DISCLOSURE.—With respect to the information about final adverse actions (not including settlements in which no findings of liability have been made) reported to the Secretary under this section with respect to a health care provider, supplier, or practitioner, the Secretary shall, by regulation, provide for—

(A) disclosure of the information, upon request, to the health care provider, supplier, or licensed practitioner, and

(B) procedures in the case of disputed accuracy of the information.

(2) CORRECTIONS.—Each Government agency and health plan shall report corrections of information already reported about any final adverse action taken against a health care provider, supplier, or practitioner, in such form and manner that the Secretary prescribes by regulation.

(d) ACCESS TO REPORTED INFORMATION.—

(1) AVAILABILITY.—The information collected under this section shall be available from the National Practitioner Data Bank to the agencies, authorities, and officials which are provided under section 1921(b) information reported under section 1921(a).

(2) FEES FOR DISCLOSURE.—The Secretary may establish or approve reasonable fees for the disclosure of information under this section. The amount of such a fee may not exceed the costs of processing the requests for disclosure and of providing such information. Such fees shall be available to the Secretary to cover such costs.

(e) PROTECTION FROM LIABILITY FOR REPORTING.—No person or entity, including the agency designated by the Secretary in subsection (b)(5) shall be held liable in any civil action with respect to any report made as required by this section, without knowledge of the falsity of the information contained in the report.

(f) APPROPRIATE COORDINATION.—In implementing this section, the Secretary shall provide for the maximum appropriate coordination with part B of the Health Care Quality Improvement Act of 1986 (42 U.S.C. 11131 et seq.) and section 1921.

(g) DEFINITIONS AND SPECIAL RULES.—For purposes of this section:

(1) FINAL ADVERSE ACTION.—

(A) IN GENERAL.—The term "final adverse action" includes:

(i) Civil judgments against a health care provider, supplier, or practitioner in Federal or State court related to the delivery of a health care item or service.

(ii) Federal or State criminal convictions related to the delivery of a health care item or service.

(iii) Actions by Federal agencies responsible for the licensing and certification of health care providers, suppliers, and licensed health care practitioners, including—

(I) formal or official actions, such as revocation or suspension of a license (and the length of any such suspension), reprimand, censure or probation,

(II) any dismissal or closure of the proceedings by reason of the provider, supplier, or practitioner surrendering their license or leaving the State or jurisdiction [16]

(III) any other loss of license or the right to apply for, or renew, a license of the provider, supplier, or practitioner, whether by operation of law, voluntary surrender, non-renewability, or otherwise, or

(IV) any other negative action or finding by such Federal agency that is publicly available information.

(iv) Exclusion from participation in a Federal health care program (as defined in section 1128B(f)).

(v) Any other adjudicated actions or decisions that the Secretary shall establish by regulation.

(B) EXCEPTION.—The term does not include any action with respect to a malpractice claim.

(2) PRACTITIONER.—The terms "licensed health care practitioner", "licensed practitioner", and "practitioner" mean, with respect to a State, an individual who is licensed or otherwise authorized by the State to provide health care services (or any individual who, without authority holds himself or herself out to be so licensed or authorized).

(3) GOVERNMENT AGENCY.—The term "Government agency" shall include:

(A) The Department of Justice.

(B) The Department of Health and Human Services.

(C) Any other Federal agency that either administers or provides payment for the delivery of health care services, including, but not limited to the Department of Defense and the Department of Veterans Affairs.

(D) Federal agencies responsible for the licensing and certification of health care providers and licensed health care practitioners.

(4) HEALTH PLAN.—The term "health plan" has the meaning given such term by section 1128C(c).

(5) DETERMINATION OF CONVICTION.—For purposes of paragraph (1), the existence of a conviction shall be determined under paragraphs (1) through (4) of section 1128(i).

[16] So in law. There is no punctuation.

COORDINATION OF MEDICARE AND MEDICAID SURETY BOND PROVISIONS

SEC. 1128F. [42 U.S.C. 1320a–7f] In the case of a home health agency that is subject to a surety bond requirement under title XVIII and title XIX, the surety bond provided to satisfy the requirement under one such title shall satisfy the requirement under the other such title so long as the bond applies to guarantee return of overpayments under both such titles.

SEC. 1128G. [42 U.S.C. 1320a–7h] TRANSPARENCY REPORTS AND REPORTING OF PHYSICIAN OWNERSHIP OR INVESTMENT INTERESTS.

(a) TRANSPARENCY REPORTS.—

(1) PAYMENTS OR OTHER TRANSFERS OF VALUE.—

(A) IN GENERAL.—On March 31, 2013, and on the 90th day of each calendar year beginning thereafter, any applicable manufacturer that provides a payment or other transfer of value to a covered recipient (or to an entity or individual at the request of or designated on behalf of a covered recipient), shall submit to the Secretary, in such electronic form as the Secretary shall require, the following information with respect to the preceding calendar year:

(i) The name of the covered recipient.

(ii) The business address of the covered recipient and, in the case of a covered recipient who is a physician, the specialty and National Provider Identifier of the covered recipient.

(iii) The amount of the payment or other transfer of value.

(iv) The dates on which the payment or other transfer of value was provided to the covered recipient.

(v) A description of the form of the payment or other transfer of value, indicated (as appropriate for all that apply) as—

(I) cash or a cash equivalent;

(II) in-kind items or services;

(III) stock, a stock option, or any other ownership interest, dividend, profit, or other return on investment; or

(IV) any other form of payment or other transfer of value (as defined by the Secretary).

(vi) A description of the nature of the payment or other transfer of value, indicated (as appropriate for all that apply) as—

(I) consulting fees;

(II) compensation for services other than consulting;

(III) honoraria;

(IV) gift;

(V) entertainment;

(VI) food;

(VII) travel (including the specified destinations);

(VIII) education;
(IX) research;
(X) charitable contribution;
(XI) royalty or license;
(XII) current or prospective ownership or investment interest;
(XIII) direct compensation for serving as faculty or as a speaker for a medical education program;
(XIV) grant; or
(XV) any other nature of the payment or other transfer of value (as defined by the Secretary).

(vii) If the payment or other transfer of value is related to marketing, education, or research specific to a covered drug, device, biological, or medical supply, the name of that covered drug, device, biological, or medical supply.

(viii) Any other categories of information regarding the payment or other transfer of value the Secretary determines appropriate.

(B) SPECIAL RULE FOR CERTAIN PAYMENTS OR OTHER TRANSFERS OF VALUE.—In the case where an applicable manufacturer provides a payment or other transfer of value to an entity or individual at the request of or designated on behalf of a covered recipient, the applicable manufacturer shall disclose that payment or other transfer of value under the name of the covered recipient.

(2) PHYSICIAN OWNERSHIP.—In addition to the requirement under paragraph (1)(A), on March 31, 2013, and on the 90th day of each calendar year beginning thereafter, any applicable manufacturer or applicable group purchasing organization shall submit to the Secretary, in such electronic form as the Secretary shall require, the following information regarding any ownership or investment interest (other than an ownership or investment interest in a publicly traded security and mutual fund, as described in section 1877(c)) held by a physician (or an immediate family member of such physician (as defined for purposes of section 1877(a))) in the applicable manufacturer or applicable group purchasing organization during the preceding year:

(A) The dollar amount invested by each physician holding such an ownership or investment interest.

(B) The value and terms of each such ownership or investment interest.

(C) Any payment or other transfer of value provided to a physician holding such an ownership or investment interest (or to an entity or individual at the request of or designated on behalf of a physician holding such an ownership or investment interest), including the information described in clauses (i) through (viii) of paragraph (1)(A), except that in applying such clauses, "physician" shall be substituted for "covered recipient" each place it appears.

(D) Any other information regarding the ownership or investment interest the Secretary determines appropriate.

(b) PENALTIES FOR NONCOMPLIANCE.—

(1) FAILURE TO REPORT.—

(A) IN GENERAL.—Subject to subparagraph (B) except as provided in paragraph (2), any applicable manufacturer or applicable group purchasing organization that fails to submit information required under subsection (a) in a timely manner in accordance with rules or regulations promulgated to carry out such subsection, shall be subject to a civil money penalty of not less than $1,000, but not more than $10,000, for each payment or other transfer of value or ownership or investment interest not reported as required under such subsection. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.

(B) LIMITATION.—The total amount of civil money penalties imposed under subparagraph (A) with respect to each annual submission of information under subsection (a) by an applicable manufacturer or applicable group purchasing organization shall not exceed $150,000.

(2) KNOWING FAILURE TO REPORT.—

(A) IN GENERAL.—Subject to subparagraph (B), any applicable manufacturer or applicable group purchasing organization that knowingly fails to submit information required under subsection (a) in a timely manner in accordance with rules or regulations promulgated to carry out such subsection, shall be subject to a civil money penalty of not less than $10,000, but not more than $100,000, for each payment or other transfer of value or ownership or investment interest not reported as required under such subsection. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A are imposed and collected under that section.

(B) LIMITATION.—The total amount of civil money penalties imposed under subparagraph (A) with respect to each annual submission of information under subsection (a) by an applicable manufacturer or applicable group purchasing organization shall not exceed $1,000,000.

(3) USE OF FUNDS.—Funds collected by the Secretary as a result of the imposition of a civil money penalty under this subsection shall be used to carry out this section.

(c) PROCEDURES FOR SUBMISSION OF INFORMATION AND PUBLIC AVAILABILITY.—

(1) IN GENERAL.—

(A) ESTABLISHMENT.—Not later than October 1, 2011, the Secretary shall establish procedures—

(i) for applicable manufacturers and applicable group purchasing organizations to submit information to the Secretary under subsection (a); and

(ii) for the Secretary to make such information submitted available to the public.

(B) DEFINITION OF TERMS.—The procedures established under subparagraph (A) shall provide for the defini-

tion of terms (other than those terms defined in subsection (e)), as appropriate, for purposes of this section.

(C) PUBLIC AVAILABILITY.—Except as provided in subparagraph (E), the procedures established under subparagraph (A)(ii) shall ensure that, not later than September 30, 2013, and on June 30 of each calendar year beginning thereafter, the information submitted under subsection (a) with respect to the preceding calendar year is made available through an Internet website that—

(i) is searchable and is in a format that is clear and understandable;

(ii) contains information that is presented by the name of the applicable manufacturer or applicable group purchasing organization, the name of the covered recipient, the business address of the covered recipient, the specialty of the covered recipient, the value of the payment or other transfer of value, the date on which the payment or other transfer of value was provided to the covered recipient, the form of the payment or other transfer of value, indicated (as appropriate) under subsection (a)(1)(A)(v), the nature of the payment or other transfer of value, indicated (as appropriate) under subsection (a)(1)(A)(vi), and the name of the covered drug, device, biological, or medical supply, as applicable;

(iii) contains information that is able to be easily aggregated and downloaded;

(iv) contains a description of any enforcement actions taken to carry out this section, including any penalties imposed under subsection (b), during the preceding year;

(v) contains background information on industry-physician relationships;

(vi) in the case of information submitted with respect to a payment or other transfer of value described in subparagraph (E)(i), lists such information separately from the other information submitted under subsection (a) and designates such separately listed information as funding for clinical research;

(vii) contains any other information the Secretary determines would be helpful to the average consumer;

(viii) in the case of information made available under this subparagraph prior to January 1, 2022, does not contain the National Provider Identifier of the covered recipient, and

(ix) subject to subparagraph (D), provides the applicable manufacturer, applicable group purchasing organization, or covered recipient an opportunity to review and submit corrections to the information submitted with respect to the applicable manufacturer, applicable group purchasing organization, or covered recipient, respectively, for a period of not less than 45 days prior to such information being made available to the public.

(D) CLARIFICATION OF TIME PERIOD FOR REVIEW AND CORRECTIONS.—In no case may the 45-day period for review and submission of corrections to information under subparagraph (C)(ix) prevent such information from being made available to the public in accordance with the dates described in the matter preceding clause (i) in subparagraph (C).

(E) DELAYED PUBLICATION FOR PAYMENTS MADE PURSUANT TO PRODUCT RESEARCH OR DEVELOPMENT AGREEMENTS AND CLINICAL INVESTIGATIONS.—

(i) IN GENERAL.—In the case of information submitted under subsection (a) with respect to a payment or other transfer of value made to a covered recipient by an applicable manufacturer pursuant to a product research or development agreement for services furnished in connection with research on a potential new medical technology or a new application of an existing medical technology or the development of a new drug, device, biological, or medical supply, or by an applicable manufacturer in connection with a clinical investigation regarding a new drug, device, biological, or medical supply, the procedures established under subparagraph (A)(ii) shall provide that such information is made available to the public on the first date described in the matter preceding clause (i) in subparagraph (C) after the earlier of the following:

(I) The date of the approval or clearance of the covered drug, device, biological, or medical supply by the Food and Drug Administration.

(II) Four calendar years after the date such payment or other transfer of value was made.

(ii) CONFIDENTIALITY OF INFORMATION PRIOR TO PUBLICATION.—Information described in clause (i) shall be considered confidential and shall not be subject to disclosure under section 552 of title 5, United States Code, or any other similar Federal, State, or local law, until on or after the date on which the information is made available to the public under such clause.

(2) CONSULTATION.—In establishing the procedures under paragraph (1), the Secretary shall consult with the Inspector General of the Department of Health and Human Services, affected industry, consumers, consumer advocates, and other interested parties in order to ensure that the information made available to the public under such paragraph is presented in the appropriate overall context.

(d) ANNUAL REPORTS AND RELATION TO STATE LAWS.—

(1) ANNUAL REPORT TO CONGRESS.—Not later than April 1 of each year beginning with 2013, the Secretary shall submit to Congress a report that includes the following:

(A) The information submitted under subsection (a) during the preceding year, aggregated for each applicable manufacturer and applicable group purchasing organization that submitted such information during such year (ex-

cept, in the case of information submitted with respect to a payment or other transfer of value described in subsection (c)(1)(E)(i), such information shall be included in the first report submitted to Congress after the date on which such information is made available to the public under such subsection).

(B) A description of any enforcement actions taken to carry out this section, including any penalties imposed under subsection (b), during the preceding year.

(2) ANNUAL REPORTS TO STATES.—Not later than September 30, 2013 and on June 30 of each calendar year thereafter, the Secretary shall submit to States a report that includes a summary of the information submitted under subsection (a) during the preceding year with respect to covered recipients in the State (except, in the case of information submitted with respect to a payment or other transfer of value described in subsection (c)(1)(E)(i), such information shall be included in the first report submitted to States after the date on which such information is made available to the public under such subsection).

(3) RELATION TO STATE LAWS.—

(A) IN GENERAL.—In the case of a payment or other transfer of value provided by an applicable manufacturer that is received by a covered recipient (as defined in subsection (e)) on or after January 1, 2012, subject to subparagraph (B), the provisions of this section shall preempt any statute or regulation of a State or of a political subdivision of a State that requires an applicable manufacturer (as so defined) to disclose or report, in any format, the type of information (as described in subsection (a)) regarding such payment or other transfer of value.

(B) NO PREEMPTION OF ADDITIONAL REQUIREMENTS.—Subparagraph (A) shall not preempt any statute or regulation of a State or of a political subdivision of a State that requires the disclosure or reporting of information—

(i) not of the type required to be disclosed or reported under this section;

(ii) described in subsection (e)(10)(B), except in the case of information described in clause (i) of such subsection;

(iii) by any person or entity other than an applicable manufacturer (as so defined) or a covered recipient (as defined in subsection (e)); or

(iv) to a Federal, State, or local governmental agency for public health surveillance, investigation, or other public health purposes or health oversight purposes.

(C) Nothing in subparagraph (A) shall be construed to limit the discovery or admissibility of information described in such subparagraph in a criminal, civil, or administrative proceeding.

(4) CONSULTATION.—The Secretary shall consult with the Inspector General of the Department of Health and Human Services on the implementation of this section.

(e) DEFINITIONS.—In this section:

(1) APPLICABLE GROUP PURCHASING ORGANIZATION.—The term "applicable group purchasing organization" means a group purchasing organization (as defined by the Secretary) that purchases, arranges for, or negotiates the purchase of a covered drug, device, biological, or medical supply which is operating in the United States, or in a territory, possession, or commonwealth of the United States.

(2) APPLICABLE MANUFACTURER.—The term "applicable manufacturer" means a manufacturer of a covered drug, device, biological, or medical supply which is operating in the United States, or in a territory, possession, or commonwealth of the United States.

(3) CLINICAL INVESTIGATION.—The term "clinical investigation" means any experiment involving 1 or more human subjects, or materials derived from human subjects, in which a drug or device is administered, dispensed, or used.

(4) COVERED DEVICE.—The term "covered device" means any device for which payment is available under title XVIII or a State plan under title XIX or XXI (or a waiver of such a plan).

(5) COVERED DRUG, DEVICE, BIOLOGICAL, OR MEDICAL SUPPLY.—The term "covered drug, device, biological, or medical supply" means any drug, biological product, device, or medical supply for which payment is available under title XVIII or a State plan under title XIX or XXI (or a waiver of such a plan).

(6) COVERED RECIPIENT.—

(A) IN GENERAL.—Except as provided in subparagraph (B), the term "covered recipient" means the following:

(i) A physician.

(ii) A teaching hospital.

(iii) A physician assistant, nurse practitioner, or clinical nurse specialist (as such terms are defined in section 1861(aa)(5)).

(iv) A certified registered nurse anesthetist (as defined in section 1861(bb)(2)).

(v) A certified nurse-midwife (as defined in section 1861(gg)(2)).

(B) EXCLUSION.—Such term does not include a physician, physician assistant, nurse practitioner, clinical nurse specialist, certified nurse anesthetist, or certified nurse-midwife who is an employee of the applicable manufacturer that is required to submit information under subsection (a).

(7) EMPLOYEE.—The term "employee" has the meaning given such term in section 1877(h)(2).

(8) KNOWINGLY.—The term "knowingly" has the meaning given such term in section 3729(b) of title 31, United States Code.

(9) MANUFACTURER OF A COVERED DRUG, DEVICE, BIOLOGICAL, OR MEDICAL SUPPLY.—The term "manufacturer of a covered drug, device, biological, or medical supply" means any entity which is engaged in the production, preparation, propagation, compounding, or conversion of a covered drug, device, bio-

logical, or medical supply (or any entity under common ownership with such entity which provides assistance or support to such entity with respect to the production, preparation, propagation, compounding, conversion, marketing, promotion, sale, or distribution of a covered drug, device, biological, or medical supply).

(10) PAYMENT OR OTHER TRANSFER OF VALUE.—

(A) IN GENERAL.—The term "payment or other transfer of value" means a transfer of anything of value. Such term does not include a transfer of anything of value that is made indirectly to a covered recipient through a third party in connection with an activity or service in the case where the applicable manufacturer is unaware of the identity of the covered recipient.

(B) EXCLUSIONS.—An applicable manufacturer shall not be required to submit information under subsection (a) with respect to the following:

(i) A transfer of anything the value of which is less than $10, unless the aggregate amount transferred to, requested by, or designated on behalf of the covered recipient by the applicable manufacturer during the calendar year exceeds $100. For calendar years after 2012, the dollar amounts specified in the preceding sentence shall be increased by the same percentage as the percentage increase in the consumer price index for all urban consumers (all items; U.S. city average) for the 12-month period ending with June of the previous year.

(ii) Product samples that are not intended to be sold and are intended for patient use.

(iii) Educational materials that directly benefit patients or are intended for patient use.

(iv) The loan of a covered device for a short-term trial period, not to exceed 90 days, to permit evaluation of the covered device by the covered recipient.

(v) Items or services provided under a contractual warranty, including the replacement of a covered device, where the terms of the warranty are set forth in the purchase or lease agreement for the covered device.

(vi) A transfer of anything of value to a covered recipient when the covered recipient is a patient and not acting in the professional capacity of a covered recipient.

(vii) Discounts (including rebates).

(viii) In-kind items used for the provision of charity care.

(ix) A dividend or other profit distribution from, or ownership or investment interest in, a publicly traded security and mutual fund (as described in section 1877(c)).

(x) In the case of an applicable manufacturer who offers a self-insured plan, payments for the provision of health care to employees under the plan.

(xi) In the case of a covered recipient who is a licensed non-medical professional, a transfer of anything of value to the covered recipient if the transfer is payment solely for the non-medical professional services of such licensed non-medical professional.

(xii) In the case of a covered recipient who is a physician, a transfer of anything of value to the covered recipient if the transfer is payment solely for the services of the covered recipient with respect to a civil or criminal action or an administrative proceeding.

(11) PHYSICIAN.—The term "physician" has the meaning given that term in section 1861(r).

SEC. 1128H. [42 U.S.C. 1320a–7i] REPORTING OF INFORMATION RELATING TO DRUG SAMPLES.

(a) IN GENERAL.—Not later than April 1 of each year (beginning with 2012), each manufacturer and authorized distributor of record of an applicable drug shall submit to the Secretary (in a form and manner specified by the Secretary) the following information with respect to the preceding year:

(1) In the case of a manufacturer or authorized distributor of record which makes distributions by mail or common carrier under subsection (d)(2) of section 503 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 353), the identity and quantity of drug samples requested and the identity and quantity of drug samples distributed under such subsection during that year, aggregated by—

(A) the name, address, professional designation, and signature of the practitioner making the request under subparagraph (A)(i) of such subsection, or of any individual who makes or signs for the request on behalf of the practitioner; and

(B) any other category of information determined appropriate by the Secretary.

(2) In the case of a manufacturer or authorized distributor of record which makes distributions by means other than mail or common carrier under subsection (d)(3) of such section 503, the identity and quantity of drug samples requested and the identity and quantity of drug samples distributed under such subsection during that year, aggregated by—

(A) the name, address, professional designation, and signature of the practitioner making the request under subparagraph (A)(i) of such subsection, or of any individual who makes or signs for the request on behalf of the practitioner; and

(B) any other category of information determined appropriate by the Secretary.

(b) DEFINITIONS.—In this section:

(1) APPLICABLE DRUG.—The term "applicable drug" means a drug—

(A) which is subject to subsection (b) of such section 503; and

(B) for which payment is available under title XVIII or a State plan under title XIX or XXI (or a waiver of such a plan).

(2) AUTHORIZED DISTRIBUTOR OF RECORD.—The term "authorized distributor of record" has the meaning given that term in subsection (e)(3)(A) of such section.

(3) MANUFACTURER.—The term "manufacturer" has the meaning given that term for purposes of subsection (d) of such section.

SEC. 1128I. [42 U.S.C. 1320a–7j] ACCOUNTABILITY REQUIREMENTS FOR FACILITIES.

(a) DEFINITION OF FACILITY.—In this section, the term "facility" means—

(1) a skilled nursing facility (as defined in section 1819(a)); or

(2) a nursing facility (as defined in section 1919(a)).

(b) EFFECTIVE COMPLIANCE AND ETHICS PROGRAMS.—

(1) REQUIREMENT.—On or after the date that is 36 months after the date of the enactment of this section, a facility shall, with respect to the entity that operates the facility (in this subparagraph referred to as the "operating organization" or "organization"), have in operation a compliance and ethics program that is effective in preventing and detecting criminal, civil, and administrative violations under this Act and in promoting quality of care consistent with regulations developed under paragraph (2).

(2) DEVELOPMENT OF REGULATIONS.—

(A) IN GENERAL.—Not later than the date that is 2 years after such date of the enactment, the Secretary, working jointly with the Inspector General of the Department of Health and Human Services, shall promulgate regulations for an effective compliance and ethics program for operating organizations, which may include a model compliance program.

(B) DESIGN OF REGULATIONS.—Such regulations with respect to specific elements or formality of a program shall, in the case of an organization that operates 5 or more facilities, vary with the size of the organization, such that larger organizations should have a more formal program and include established written policies defining the standards and procedures to be followed by its employees. Such requirements may specifically apply to the corporate level management of multi unit nursing home chains.

(C) EVALUATION.—Not later than 3 years after the date of the promulgation of regulations under this paragraph, the Secretary shall complete an evaluation of the compliance and ethics programs required to be established under this subsection. Such evaluation shall determine if such programs led to changes in deficiency citations, changes in quality performance, or changes in other metrics of patient quality of care. The Secretary shall submit to Congress a report on such evaluation and shall include in such report such recommendations regarding changes in the requirements for such programs as the Secretary determines appropriate.

(3) REQUIREMENTS FOR COMPLIANCE AND ETHICS PROGRAMS.—In this subsection, the term "compliance and ethics

program" means, with respect to a facility, a program of the operating organization that—

(A) has been reasonably designed, implemented, and enforced so that it generally will be effective in preventing and detecting criminal, civil, and administrative violations under this Act and in promoting quality of care; and

(B) includes at least the required components specified in paragraph (4).

(4) REQUIRED COMPONENTS OF PROGRAM.—The required components of a compliance and ethics program of an operating organization are the following:

(A) The organization must have established compliance standards and procedures to be followed by its employees and other agents that are reasonably capable of reducing the prospect of criminal, civil, and administrative violations under this Act.

(B) Specific individuals within high-level personnel of the organization must have been assigned overall responsibility to oversee compliance with such standards and procedures and have sufficient resources and authority to assure such compliance.

(C) The organization must have used due care not to delegate substantial discretionary authority to individuals whom the organization knew, or should have known through the exercise of due diligence, had a propensity to engage in criminal, civil, and administrative violations under this Act.

(D) The organization must have taken steps to communicate effectively its standards and procedures to all employees and other agents, such as by requiring participation in training programs or by disseminating publications that explain in a practical manner what is required.

(E) The organization must have taken reasonable steps to achieve compliance with its standards, such as by utilizing monitoring and auditing systems reasonably designed to detect criminal, civil, and administrative violations under this Act by its employees and other agents and by having in place and publicizing a reporting system whereby employees and other agents could report violations by others within the organization without fear of retribution.

(F) The standards must have been consistently enforced through appropriate disciplinary mechanisms, including, as appropriate, discipline of individuals responsible for the failure to detect an offense.

(G) After an offense has been detected, the organization must have taken all reasonable steps to respond appropriately to the offense and to prevent further similar offenses, including any necessary modification to its program to prevent and detect criminal, civil, and administrative violations under this Act.

(H) The organization must periodically undertake reassessment of its compliance program to identify changes

necessary to reflect changes within the organization and its facilities.

(c) QUALITY ASSURANCE AND PERFORMANCE IMPROVEMENT PROGRAM.—

(1) IN GENERAL.—Not later than December 31, 2011, the Secretary shall establish and implement a quality assurance and performance improvement program (in this subparagraph referred to as the "QAPI program") for facilities, including multi unit chains of facilities. Under the QAPI program, the Secretary shall establish standards relating to quality assurance and performance improvement with respect to facilities and provide technical assistance to facilities on the development of best practices in order to meet such standards. Not later than 1 year after the date on which the regulations are promulgated under paragraph (2), a facility must submit to the Secretary a plan for the facility to meet such standards and implement such best practices, including how to coordinate the implementation of such plan with quality assessment and assurance activities conducted under sections 1819(b)(1)(B) and 1919(b)(1)(B), as applicable.

(2) REGULATIONS.—The Secretary shall promulgate regulations to carry out this subsection.

(f) STANDARDIZED COMPLAINT FORM.—

(1) DEVELOPMENT BY THE SECRETARY.—The Secretary shall develop a standardized complaint form for use by a resident (or a person acting on the resident's behalf) in filing a complaint with a State survey and certification agency and a State long-term care ombudsman program with respect to a facility.

(2) COMPLAINT FORMS AND RESOLUTION PROCESSES.—

(A) COMPLAINT FORMS.—The State must make the standardized complaint form developed under paragraph (1) available upon request to—

(i) a resident of a facility; and

(ii) any person acting on the resident's behalf.

(B) COMPLAINT RESOLUTION PROCESS.—The State must establish a complaint resolution process in order to ensure that the legal representative of a resident of a facility or other responsible party is not denied access to such resident or otherwise retaliated against if they have complained about the quality of care provided by the facility or other issues relating to the facility. Such complaint resolution process shall include—

(i) procedures to assure accurate tracking of complaints received, including notification to the complainant that a complaint has been received;

(ii) procedures to determine the likely severity of a complaint and for the investigation of the complaint; and

(iii) deadlines for responding to a complaint and for notifying the complainant of the outcome of the investigation.

(3) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed as preventing a resident of a facility (or a person acting on the resident's behalf) from submitting a com-

plaint in a manner or format other than by using the standardized complaint form developed under paragraph (1) (including submitting a complaint orally).

(g) SUBMISSION OF STAFFING INFORMATION BASED ON PAYROLL DATA IN A UNIFORM FORMAT.—Beginning not later than 2 years after the date of the enactment of this subsection, and after consulting with State long-term care ombudsman programs, consumer advocacy groups, provider stakeholder groups, employees and their representatives, and other parties the Secretary deems appropriate, the Secretary shall require a facility to electronically submit to the Secretary direct care staffing information (including information with respect to agency and contract staff) based on payroll and other verifiable and auditable data in a uniform format (according to specifications established by the Secretary in consultation with such programs, groups, and parties). Such specifications shall require that the information submitted under the preceding sentence—

(1) specify the category of work a certified employee performs (such as whether the employee is a registered nurse, licensed practical nurse, licensed vocational nurse, certified nursing assistant, therapist, or other medical personnel);

(2) include resident census data and information on resident case mix;

(3) include a regular reporting schedule; and

(4) include information on employee turnover and tenure and on the hours of care provided by each category of certified employees referenced in paragraph (1) per resident per day.

Nothing in this subsection shall be construed as preventing the Secretary from requiring submission of such information with respect to specific categories, such as nursing staff, before other categories of certified employees. Information under this subsection with respect to agency and contract staff shall be kept separate from information on employee staffing.

(h) NOTIFICATION OF FACILITY CLOSURE.—

(1) IN GENERAL.—Any individual who is the administrator of a facility must—

(A) submit to the Secretary, the State long-term care ombudsman, residents of the facility, and the legal representatives of such residents or other responsible parties, written notification of an impending closure—

(i) subject to clause (ii), not later than the date that is 60 days prior to the date of such closure; and

(ii) in the case of a facility where the Secretary terminates the facility's participation under this title, not later than the date that the Secretary determines appropriate;

(B) ensure that the facility does not admit any new residents on or after the date on which such written notification is submitted; and

(C) include in the notice a plan for the transfer and adequate relocation of the residents of the facility by a specified date prior to closure that has been approved by the State, including assurances that the residents will be transferred to the most appropriate facility or other setting

in terms of quality, services, and location, taking into consideration the needs, choice, and best interests of each resident.

(2) RELOCATION.—

(A) IN GENERAL.—The State shall ensure that, before a facility closes, all residents of the facility have been successfully relocated to another facility or an alternative home and community-based setting.

(B) CONTINUATION OF PAYMENTS UNTIL RESIDENTS RELOCATED.—The Secretary may, as the Secretary determines appropriate, continue to make payments under this title with respect to residents of a facility that has submitted a notification under paragraph (1) during the period beginning on the date such notification is submitted and ending on the date on which the resident is successfully relocated.

(3) SANCTIONS.—Any individual who is the administrator of a facility that fails to comply with the requirements of paragraph (1)—

(A) shall be subject to a civil monetary penalty of up to $100,000;

(B) may be subject to exclusion from participation in any Federal health care program (as defined in section 1128B(f)); and

(C) shall be subject to any other penalties that may be prescribed by law.

(4) PROCEDURE.—The provisions of section 1128A (other than subsections (a) and (b) and the second sentence of subsection (f)) shall apply to a civil money penalty or exclusion under paragraph (3) in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

SEC. 1128J. [42 U.S.C. 1320a–7k] MEDICARE AND MEDICAID PROGRAM INTEGRITY PROVISIONS.

(a) DATA MATCHING.—

(1) INTEGRATED DATA REPOSITORY.—

(A) INCLUSION OF CERTAIN DATA.—

(i) IN GENERAL.—The Integrated Data Repository of the Centers for Medicare & Medicaid Services shall include, at a minimum, claims and payment data from the following:

(I) The programs under titles XVIII and XIX (including parts A, B, C, and D of title XVIII).

(II) The program under title XXI.

(III) Health-related programs administered by the Secretary of Veterans Affairs.

(IV) Health-related programs administered by the Secretary of Defense.

(V) The program of old-age, survivors, and disability insurance benefits established under title II.

(VI) The Indian Health Service and the Contract Health Service program.

(ii) PRIORITY FOR INCLUSION OF CERTAIN DATA.—Inclusion of the data described in subclause (I) of such

clause in the Integrated Data Repository shall be a priority. Data described in subclauses (II) through (VI) of such clause shall be included in the Integrated Data Repository as appropriate.

(B) DATA SHARING AND MATCHING.—

(i) IN GENERAL.—The Secretary shall enter into agreements with the individuals described in clause (ii) under which such individuals share and match data in the system of records of the respective agencies of such individuals with data in the system of records of the Department of Health and Human Services for the purpose of identifying potential fraud, waste, and abuse under the programs under titles XVIII and XIX.

(ii) INDIVIDUALS DESCRIBED.—The following individuals are described in this clause:

(I) The Commissioner of Social Security.

(II) The Secretary of Veterans Affairs.

(III) The Secretary of Defense.

(IV) The Director of the Indian Health Service.

(iii) DEFINITION OF SYSTEM OF RECORDS.—For purposes of this paragraph, the term "system of records" has the meaning given such term in section 552a(a)(5) of title 5, United States Code.

(2) ACCESS TO CLAIMS AND PAYMENT DATABASES.—For purposes of conducting law enforcement and oversight activities and to the extent consistent with applicable information, privacy, security, and disclosure laws, including the regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 and section 552a of title 5, United States Code, and subject to any information systems security requirements under such laws or otherwise required by the Secretary, the Inspector General of the Department of Health and Human Services and the Attorney General shall have access to claims and payment data of the Department of Health and Human Services and its contractors related to titles XVIII, XIX, and XXI.

(b) OIG AUTHORITY TO OBTAIN INFORMATION.—

(1) IN GENERAL.—Notwithstanding and in addition to any other provision of law, the Inspector General of the Department of Health and Human Services may, for purposes of protecting the integrity of the programs under titles XVIII and XIX, obtain information from any individual (including a beneficiary provided all applicable privacy protections are followed) or entity that—

(A) is a provider of medical or other items or services, supplier, grant recipient, contractor, or subcontractor; or

(B) directly or indirectly provides, orders, manufactures, distributes, arranges for, prescribes, supplies, or receives medical or other items or services payable by any Federal health care program (as defined in section 1128B(f)) regardless of how the item or service is paid for, or to whom such payment is made.

(2) INCLUSION OF CERTAIN INFORMATION.—Information which the Inspector General may obtain under paragraph (1) includes any supporting documentation necessary to validate claims for payment or payments under title XVIII or XIX, including a prescribing physician's medical records for an individual who is prescribed an item or service which is covered under part B of title XVIII, a covered part D drug (as defined in section 1860D–2(e)) for which payment is made under an MA–PD plan under part C of such title, or a prescription drug plan under part D of such title, and any records necessary for evaluation of the economy, efficiency, and effectiveness of the programs under titles XVIII and XIX.

(c) ADMINISTRATIVE REMEDY FOR KNOWING PARTICIPATION BY BENEFICIARY IN HEALTH CARE FRAUD SCHEME.—

(1) IN GENERAL.—In addition to any other applicable remedies, if an applicable individual has knowingly participated in a Federal health care fraud offense or a conspiracy to commit a Federal health care fraud offense, the Secretary shall impose an appropriate administrative penalty commensurate with the offense or conspiracy.

(2) APPLICABLE INDIVIDUAL.—For purposes of paragraph (1), the term "applicable individual" means an individual—

(A) entitled to, or enrolled for, benefits under part A of title XVIII or enrolled under part B of such title;

(B) eligible for medical assistance under a State plan under title XIX or under a waiver of such plan; or

(C) eligible for child health assistance under a child health plan under title XXI.

(d) REPORTING AND RETURNING OF OVERPAYMENTS.—

(1) IN GENERAL.—If a person has received an overpayment, the person shall—

(A) report and return the overpayment to the Secretary, the State, an intermediary, a carrier, or a contractor, as appropriate, at the correct address; and

(B) notify the Secretary, State, intermediary, carrier, or contractor to whom the overpayment was returned in writing of the reason for the overpayment.

(2) DEADLINE FOR REPORTING AND RETURNING OVERPAYMENTS.—An overpayment must be reported and returned under paragraph (1) by the later of—

(A) the date which is 60 days after the date on which the overpayment was identified; or

(B) the date any corresponding cost report is due, if applicable.

(3) ENFORCEMENT.—Any overpayment retained by a person after the deadline for reporting and returning the overpayment under paragraph (2) is an obligation (as defined in section 3729(b)(3) of title 31, United States Code) for purposes of section 3729 of such title.

(4) DEFINITIONS.—In this subsection:

(A) KNOWING AND KNOWINGLY.—The terms "knowing" and "knowingly" have the meaning given those terms in section 3729(b) of title 31, United States Code.

(B) OVERPAYMENT.—The term "'overpayment'" [17] means any funds that a person receives or retains under title XVIII or XIX to which the person, after applicable reconciliation, is not entitled under such title.

(C) PERSON.—

(i) IN GENERAL.—The term "person" means a provider of services, supplier, medicaid managed care organization (as defined in section 1903(m)(1)(A)), Medicare Advantage organization (as defined in section 1859(a)(1)), or PDP sponsor (as defined in section 1860D–41(a)(13)).

(ii) EXCLUSION.—Such term does not include a beneficiary.

(e) INCLUSION OF NATIONAL PROVIDER IDENTIFIER ON ALL APPLICATIONS AND CLAIMS.—The Secretary shall promulgate a regulation that requires, not later than January 1, 2011, all providers of medical or other items or services and suppliers under the programs under titles XVIII and XIX that qualify for a national provider identifier to include their national provider identifier on all applications to enroll in such programs and on all claims for payment submitted under such programs.

SEC. 1128K. [42 U.S.C. 1320a–7n] DISCLOSURE OF PREDICTIVE MODELING AND OTHER ANALYTICS TECHNOLOGIES TO IDENTIFY AND PREVENT WASTE, FRAUD, AND ABUSE.

(a) REFERENCE TO PREDICTIVE MODELING TECHNOLOGIES REQUIREMENTS.—For provisions relating to the use of predictive modeling and other analytics technologies to identify and prevent waste, fraud, and abuse with respect to the Medicare program under title XVIII, the Medicaid program under title XIX, and the Children's Health Insurance Program under title XXI, see section 4241 of the Small Business Jobs Act of 2010 (42 U.S.C. 1320a–7m).

(b) LIMITING DISCLOSURE OF PREDICTIVE MODELING TECHNOLOGIES.—In implementing such provisions under such section 4241 with respect to covered algorithms (as defined in subsection (c)), the following shall apply:

(1) NONAPPLICATION OF FOIA.—The covered algorithms used or developed for purposes of such section 4241 (including by the Secretary or a State (or an entity operating under a contract with a State)) shall be exempt from disclosure under section 552(b)(3) of title 5, United States Code.

(2) LIMITATION WITH RESPECT TO USE AND DISCLOSURE OF INFORMATION BY STATE AGENCIES.—

(A) IN GENERAL.—A State agency may not use or disclose covered algorithms used or developed for purposes of such section 4241 except for purposes of administering the State plan (or a waiver of the plan) under the Medicaid program under title XIX or the State child health plan (or a waiver of the plan) under the Children's Health Insurance Program under title XXI, including by enabling an entity operating under a contract with a State to assist the State to identify or prevent waste, fraud, and abuse with respect to such programs.

[17] So in law.

(B) INFORMATION SECURITY.—A State agency shall have in effect data security and control policies that the Secretary finds adequate to ensure the security of covered algorithms used or developed for purposes of such section 4241 and to ensure that access to such information is restricted to authorized persons for purposes of authorized uses and disclosures described in subparagraph (A).

(C) PROCEDURAL REQUIREMENTS.—State agencies to which information is disclosed pursuant to such section 4241 shall adhere to uniform procedures established by the Secretary.

(c) COVERED ALGORITHM DEFINED.—In this section, the term "covered algorithm"—

(1) means a predictive modeling or other analytics technology, as used for purposes of section 4241(a) of the Small Business Jobs Act of 2010 (42 U.S.C. 1320a–7m(a)) to identify and prevent waste, fraud, and abuse with respect to the Medicare program under title XVIII, the Medicaid program under title XIX, and the Children's Health Insurance Program under title XXI; and

(2) includes the mathematical expressions utilized in the application of such technology and the means by which such technology is developed.

SEC. 1129. [42 U.S.C. 1320a–8] CIVIL MONETARY PENALTIES AND ASSESSMENTS FOR TITLES II, VIII AND XVI.

(a)(1) Any person (including an organization, agency, or other entity) who—

(A) makes, or causes to be made, a statement or representation of a material fact, for use in determining any initial or continuing right to or the amount of monthly insurance benefits under title II or benefits or payments under title VIII or XVI, that the person knows or should know is false or misleading,

(B) makes such a statement or representation for such use with knowing disregard for the truth, or

(C) omits from a statement or representation for such use, or otherwise withholds disclosure of, a fact which the person knows or should know is material to the determination of any initial or continuing right to or the amount of monthly insurance benefits under title II or benefits or payments under title VIII or XVI, if the person knows, or should know, that the statement or representation with such omission is false or misleading or that the withholding of such disclosure is misleading,

shall be subject to, in addition to any other penalties that may be prescribed by law, a civil money penalty of not more than $5,000 for each such statement or representation or each receipt of such benefits or payments while withholding disclosure of such fact, except that in the case of such a person who receives a fee or other income for services performed in connection with any such determination (including a claimant representative, translator, or current or former employee of the Social Security Administration) or who is a physician or other health care provider who submits, or causes the submission of, medical or other evidence in connection

with any such determination, the amount of such penalty shall be not more than $7,500. Such person also shall be subject to an assessment, in lieu of damages sustained by the United States because of such statement or representation or because of such withholding of disclosure of a material fact, of not more than twice the amount of benefits or payments paid as a result of such a statement or representation or such a withholding of disclosure. In addition, the Commissioner of Social Security may make a determination in the same proceeding to recommend that the Secretary exclude, as provided in section 1128, such a person who is a medical provider or physician from participation in the programs under title XVIII.

(2) For purposes of this section, a material fact is one which the Commissioner of Social Security may consider in evaluating whether an applicant is entitled to benefits under title II or title VIII, or eligible for benefits or payments under title XVI.

(3) Any person (including an organization, agency, or other entity) who, having received, while acting in the capacity of a representative payee pursuant to section 205(j), 807, or 1631(a)(2), a payment under title II, VIII, or XVI for the use and benefit of another individual, converts such payment, or any part thereof, to a use that such person knows or should know is other than for the use and benefit of such other individual shall be subject to, in addition to any other penalties that may be prescribed by law, a civil money penalty of not more than $5,000 for each such conversion. Such person shall also be subject to an assessment, in lieu of damages sustained by the United States resulting from the conversion, of not more than twice the amount of any payments so converted.

(b)(1) The Commissioner of Social Security may initiate a proceeding to determine whether to impose a civil money penalty or assessment, or whether to recommend exclusion under subsection (a) only as authorized by the Attorney General pursuant to procedures agreed upon by the Commissioner of Social Security and the Attorney General. The Commissioner of Social Security may not initiate an action under this section with respect to any violation described in subsection (a) later than 6 years after the date the violation was committed. The Commissioner of Social Security may initiate an action under this section by serving notice of the action in any manner authorized by Rule 4 of the Federal Rules of Civil Procedure.

(2) The Commissioner of Social Security shall not make a determination adverse to any person under this section until the person has been given written notice and an opportunity for the determination to be made on the record after a hearing at which the person is entitled to be represented by counsel, to present witnesses, and to cross-examine witnesses against the person.

(3) In a proceeding under this section which—

(A) is against a person who has been convicted (whether upon a verdict after trial or upon a plea of guilty or nolo contendere) of a Federal or State crime; and

(B) involves the same transaction as in the criminal action;

the person is estopped from denying the essential elements of the criminal offense.

(4) The official conducting a hearing under this section may sanction a person, including any party or attorney, for failing to comply with an order or procedure, for failing to defend an action, or for such other misconduct as would interfere with the speedy, orderly, or fair conduct of the hearing. Such sanction shall reasonably relate to the severity and nature of the failure or misconduct. Such sanction may include—

(A) in the case of refusal to provide or permit discovery, drawing negative factual inference or treating such refusal as an admission by deeming the matter, or certain facts, to be established;

(B) prohibiting a party from introducing certain evidence or otherwise supporting a particular claim or defense;

(C) striking pleadings, in whole or in part;

(D) staying the proceedings;

(E) dismissal of the action;

(F) entering a default judgment;

(G) ordering the party or attorney to pay attorney's fees and other costs caused by the failure or misconduct; and

(H) refusing to consider any motion or other action which is not filed in a timely manner.

(c) In determining pursuant to subsection (a) the amount or scope of any penalty or assessment, or whether to recommend and exclusion, the Commissioner of Social Security shall take into account—

(1) the nature of the statements, representations, or actions referred to in subsection (a) and the circumstances under which they occurred;

(2) the degree of culpability, history of prior offenses, and financial condition of the person committing the offense; and

(3) such other matters as justice may require.

(d)(1) Any person adversely affected by a determination of the Commissioner of Social Security under this section may obtain a review of such determination in the United States Court of Appeals for the circuit in which the person resides, or in which the statement or representation referred to in subsection (a) was made, by filing in such court (within 60 days following the date the person is notified of the Secretary's determination) a written petition requesting that the determination be modified or set aside. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Commissioner of Social Security, and thereupon the Commissioner of Social Security shall file in the court the record in the proceeding as provided in section 2112 of title 28, United States Code. Upon such filing, the court shall have jurisdiction of the proceeding and of the question determined therein, and shall have the power to make and enter upon the pleadings, testimony, and proceedings set forth in such record a decree affirming, modifying, remanding for further consideration, or setting aside, in whole or in part, the determination of the Commissioner of Social Security and enforcing the same to the extent that such order is affirmed or modified. No objection that has not been urged before the Commissioner of Social Security shall be considered by the court, unless the failure to neglect to urge such objection shall be excused because of extraordinary circumstances.

(2) The findings of the Commissioner of Social Security with respect to questions of fact, if supported by substantial evidence on the record considered as a whole, shall be conclusive in the review described in paragraph (1). If any party shall apply to the court for leave to adduce additional evidence and shall show to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the hearing before the Commissioner of Social Security, the court may order such additional evidence to be taken before the Commissioner of Social Security and to be made a part of the record. The Commissioner of Social Security may modify such findings as to the facts, or make new findings, by reason of additional evidence so taken and filed, and the Secretary shall file with the court such modified or new findings, which findings with respect to questions of fact, if supported by substantial evidence on the record considered as a whole shall be conclusive, and the Secretary's recommendations, if any, for the modification or setting aside of the Secretary's original order.

(3) Upon the filing of the record and the Secretary's original or modified order with the court, the jurisdiction of the court shall be exclusive and its judgment and decree shall be final, except that the same shall be subject to review by the Supreme Court of the United States, as provided in section 1254 of title 28, United States Code.

(e)(1) Civil money penalties and assessments imposed under this section may be compromised by the Commissioner of Social Security and may be recovered—

(A) in a civil action in the name of the United States brought in United States district court for the district where the violation occurred, or where the person resides, as determined by the Commissioner of Social Security;

(B) by means of reduction in tax refunds to which the person is entitled, based on notice to the Secretary of the Treasury as permitted under section 3720A of title 31, United States Code;

(C)(i) by decrease of any payment of monthly insurance benefits under title II, notwithstanding section 207,

(ii)[18] by decrease of any payment under title VIII to which the person is entitled, or

(iii) by decrease of any payment under title XVI for which the person is eligible, notwithstanding section 207, as made applicable to title XVI by reason of section 1631(d)(1);

(D) by authorities provided under the Debt Collection Act of 1982, as amended, to the extent applicable to debts arising under the Social Security Act;

(E) by deduction of the amount of such penalty or assessment, when finally determined, or the amount agreed upon in comprise, from any sum then or later owing by the United States to the person against whom the penalty or assessment has been assessed; or

(F) by any combination of the foregoing.

[18] Margin so in law.

(2) Amounts recovered under this section shall be recovered by the Commissioner of Social Security and shall be disposed of as follows:

(A) In the case of amounts recovered arising out of a determination relating to title II, the amounts shall be transferred to the Managing Trustee of the Federal Old-Age and Survivors Insurance Trust Fund or the Federal Disability Insurance Trust Fund, as determined appropriate by the Secretary, and such amounts shall be deposited by the Managing Trustee into such Trust Fund.

(B) In the case of any other amounts recovered under this section, the amounts shall be deposited by the Commissioner of Social Security into the general fund of the Treasury as miscellaneous receipts.

(f) A determination pursuant to subsection (a) by the Commissioner of Social Security to impose a penalty or assessment, or to recommend an exclusion shall be final upon the expiration of the 60-day period referred to in subsection (d). Matters that were raised or that could have been raised in a hearing before the Commissioner of Social Security or in an appeal pursuant to subsection (d) may not be raised as a defense to a civil action by the United States to collect a penalty or assessment imposed under this section.

(g) Whenever the Commissioner's determination to impose a penalty or assessment under this section with respect to a medical provider or physician becomes final, the Commissioner shall notify the Secretary of the final determination and the reasons therefor, and the Secretary shall then notify the entities described in section 1128A(h) of such final determination.

(h) Whenever the Commissioner of Social Security has reason to believe that any person has engaged, is engaging, or is about to engage in any activity which makes the person subject to a civil monetary penalty under this section, the Commissioner of Social Security may bring action in an appropriate district court of the United States (or, if applicable, a United States court of any territory) to enjoin such activity, or to enjoin the person from concealing, removing, encumbering, or disposing of assets which may be required in order to pay a civil monetary penalty and assessment if any such penalty were to be imposed or to seek other appropriate relief.

(i)(1) The provisions of subsections (d) and (e) of section 205 shall apply with respect to this section to the same extent as they are applicable with respect to title II. The Commissioner of Social Security may delegate the authority granted by section 205(d) (as made applicable to this section) to the Inspector General for purposes of any investigation under this section.

(2) The Commissioner of Social Security may delegate authority granted under this section to the Inspector General.

(j) For purposes of this section, the term "State agency", shall have the same meaning as in section 1128A(i)(1).

(k) A principal is liable for penalties and assessments under subsection(a), and for an exclusion under section 1128 based on a recommendation under subsection (a), for the actions of the principal's agent acting within the scope of the agency.

(l) As soon as the Inspector General, Social Security Administration, has reason to believe that fraud was involved in the application of an individual for monthly insurance benefits under title II or for benefits under title VIII or XVI, the Inspector General shall make available to the Commissioner of Social Security information identifying the individual, unless a United States attorney, or equivalent State prosecutor, with jurisdiction over potential or actual related criminal cases, certifies, in writing, that there is a substantial risk that making the information so available in a particular investigation or redetermining the eligibility of the individual for such benefits would jeopardize the criminal prosecution of any person who is a subject of the investigation from which the information is derived.

SEC. 1129A. [42 U.S.C. 1320a–8a] ADMINISTRATIVE PROCEDURE FOR IMPOSING PENALTIES FOR FALSE OR MISLEADING STATEMENTS.

(a) IN GENERAL.—Any person who—

(1) makes, or causes to be made, a statement or representation of a material fact, for use in determining any initial or continuing right to or the amount of monthly insurance benefits under title II or benefits or payments under title XVI that the person knows or should know is false or misleading,

(2) makes such a statement or representation for such use with knowing disregard for the truth, or

(3) omits from a statement or representation for such use, or otherwise withholds disclosure of, a fact which the person knows or should know is material to the determination of any initial or continuing right to or the amount of monthly insurance benefits under title II or benefits or payments under title XVI, if the person knows, or should know, that the statement or representation with such omission is false or misleading or that the withholding of such disclosure is misleading,

shall be subject to, in addition to any other penalties that may be prescribed by law, a penalty described in subsection (b) to be imposed by the Commissioner of Social Security.

(b) PENALTY.—The penalty described in this subsection is—

(1) nonpayment of benefits under title II that would otherwise be payable to the person; and

(2) ineligibility for cash benefits under title XVI,

for each month that begins during the applicable period described in subsection (c).

(c) DURATION OF PENALTY.—The duration of the applicable period, with respect to a determination by the Commissioner under subsection (a) that a person has engaged in conduct described in subsection (a), shall be—

(1) six consecutive months, in the case of the first such determination with respect to the person;

(2) twelve consecutive months, in the case of the second such determination with respect to the person; and

(3) twenty-four consecutive months, in the case of the third or subsequent such determination with respect to the person.

(d) EFFECT ON OTHER ASSISTANCE.—A person subject to a period of nonpayment of benefits under title II or ineligibility for title XVI benefits by reason of this section nevertheless shall be consid-

ered to be eligible for and receiving such benefits, to the extent that the person would be receiving or eligible for such benefits but for the imposition of the penalty, for purposes of—

(1) determination of the eligibility of the person for benefits under titles XVIII and XIX; and

(2) determination of the eligibility or amount of benefits payable under title II or XVI to another person.

(e)[19] DEFINITION.—In this section, the term "benefits under VIII or title XVI" includes State supplementary payments made by the Commissioner pursuant to an agreement under section 810A or 1616(a) of this Act or section 212(b) of Public Law 93–66, as the case may be.

(f) CONSULTATIONS.—The Commissioner of Social Security shall consult with the Inspector General of the Social Security Administration regarding initiating actions under this section.

ATTEMPTS TO INTERFERE WITH ADMINISTRATION OF SOCIAL SECURITY ACT

SEC. 1129B. [42 U.S.C. 1320a–8b] Whoever corruptly or by force or threats of force (including any threatening letter or communication) attempts to intimidate or impede any officer, employee, or contractor of the Social Security Administration (including any State employee of a disability determination service or any other individual designated by the Commissioner of Social Security) acting in an official capacity to carry out a duty under this Act, or in any other way corruptly or by force or threats of force (including any threatening letter or communication) obstructs or impedes, or attempts to obstruct or impede, the due administration of this Act, shall be fined not more than $5,000, imprisoned not more than 3 years, or both, except that if the offense is committed only by threats of force, the person shall be fined not more than $3,000, imprisoned not more than 1 year, or both. In this subsection, the term "threats of force" means threats of harm to the officer or employee of the United States or to a contractor of the Social Security Administration, or to a member of the family of such an officer or employee or contractor.

DEMONSTRATION PROJECTS

SEC. 1130. [42 U.S.C. 1320a–9] (a) AUTHORITY TO APPROVE DEMONSTRATION PROJECTS.—

(1) IN GENERAL.—The Secretary may authorize States to conduct demonstration projects pursuant to this section which the Secretary finds are likely to promote the objectives of part B or E of title IV.

(2) LIMITATION.—During fiscal years 2012 through 2014, the Secretary may authorize demonstration projects described in paragraph (1), with not more than 10 demonstration projects to be authorized in each fiscal year.

[19] The amendment by section 518(b)(2)(C) of the Departments of Labor, Health and Human Services, and Education, and Related Agencies Appropriations Act, 2001 (114 Stat. 2763A–74), as enacted into law by section 1(a)(1) of Public Law 106–554, to insert "1010A or" before "1382(e)(a)" could not be executed because the text indicating where to make the insertion does not appear.

(3) CONDITIONS FOR STATE ELIGIBILITY.—For purposes of a new demonstration project under this section that is initially approved in any of fiscal years 2012 through 2014, a State shall be authorized to conduct such demonstration project only if the State satisfies the following conditions:

(A) IDENTIFY 1 OR MORE GOALS.—

(i) IN GENERAL.—The State shall demonstrate that the demonstration project is designed to accomplish 1 or more of the following goals:

(I) Increase permanency for all infants, children, and youth by reducing the time in foster placements when possible and promoting a successful transition to adulthood for older youth.

(II) Increase positive outcomes for infants, children, youth, and families in their homes and communities, including tribal communities, and improve the safety and well-being of infants, children, and youth.

(III) Prevent child abuse and neglect and the re-entry of infants, children, and youth into foster care.

(ii) LONG-TERM THERAPEUTIC FAMILY TREATMENT CENTERS; ADDRESSING DOMESTIC VIOLENCE.—With respect to a demonstration project that is designed to accomplish 1 or more of the goals described in clause (i), the State may elect to establish a program—

(I) to permit foster care maintenance payments to be made under part E of title IV to a long-term therapeutic family treatment center (as described in paragraph (8)(B)) on behalf of a child residing in the center; or

(II) to identify and address domestic violence that endangers children and results in the placement of children in foster care.

(B) DEMONSTRATE READINESS.—The State shall demonstrate through a narrative description the State's capacity to effectively use the authority to conduct a demonstration project under this section by identifying changes the State has made or plans to make in policies, procedures, or other elements of the State's child welfare program that will enable the State to successfully achieve the goal or goals of the project.

(C) DEMONSTRATE IMPLEMENTED OR PLANNED CHILD WELFARE PROGRAM IMPROVEMENT POLICIES.—

(i) IN GENERAL.—The State shall demonstrate that the State has implemented, or plans to implement within 3 years of the date on which the State submits its application to conduct the demonstration project or 2 years after the date on which the Secretary approves such demonstration project (whichever is later), at least 2 of the child welfare program improvement policies described in paragraph (7).

(ii) PREVIOUS IMPLEMENTATION.—For purposes of the requirement described in clause (i), at least 1 of

the child welfare program improvement policies to be implemented by the State shall be a policy that the State has not previously implemented as of the date on which the State submits an application to conduct the demonstration project.

(iii) IMPLEMENTATION REVIEW.—The Secretary may terminate the authority of a State to conduct a demonstration project under this section if, after the 3-year period following approval of the demonstration project, the State has not made significant progress in implementing the child welfare program improvement policies proposed by the State under clause (i).

(4) LIMITATION ON ELIGIBILITY.—The Secretary may not authorize a State to conduct a demonstration project under this section if the State fails to provide health insurance coverage to any child with special needs (as determined under section 473(c)) for whom there is in effect an adoption assistance agreement between a State and an adoptive parent or parents.

(5) REQUIREMENT TO CONSIDER EFFECT OF PROJECT ON TERMS AND CONDITIONS OF CERTAIN COURT ORDERS.—In considering an application to conduct a demonstration project under this section that has been submitted by a State in which there is in effect a court order determining that the State's child welfare program has failed to comply with the provisions of part B or E of title IV, or with the Constitution of the United States, the Secretary shall take into consideration the effect of approving the proposed project on the terms and conditions of the court order related to the failure to comply and the ability of the State to implement a corrective action plan approved under section 1123A.

(6) INAPPLICABILITY OF RANDOM ASSIGNMENT FOR CONTROL GROUPS AS A FACTOR FOR APPROVAL OF DEMONSTRATION PROJECTS.—For purposes of evaluating an application to conduct a demonstration project under this section, the Secretary shall not take into consideration whether such project requires random assignment of children and families to groups served under the project and to control groups.

(7) CHILD WELFARE PROGRAM IMPROVEMENT POLICIES.—For purposes of paragraph (3)(C), the child welfare program improvement policies described in this paragraph are the following:

(A) The establishment of a bill of rights for infants, children, and youth in foster care that is widely shared and clearly outlines protections for infants, children, and youth, such as assuring frequent visits with parents, siblings, and caseworkers, access to attorneys, and participation in age-appropriate extracurricular activities, and procedures for ensuring the protections are provided.

(B) The development and implementation of a plan for meeting the health and mental health needs of infants, children, and youth in foster care that includes ensuring that the provision of health and mental health care is child-specific, comprehensive, appropriate, and consistent (through means such as ensuring the infant, child, or

youth has a medical home, regular wellness medical visits, and addressing the issue of trauma, when appropriate).

(C) The inclusion in the State plan under section 471 of an amendment implementing the option under subsection (a)(28) of that section to enter into kinship guardianship assistance agreements.

(D) The election under the State plan under section 471 to define a "child" for purposes of the provision of foster care maintenance payments, adoption assistance payments, and kinship guardianship assistance payments, so as to include individuals described in each of subclauses (I), (II), and (III) of section 475(8)(B)(i) who have not attained age 21.

(E) The development and implementation of a plan that ensures congregate care is used appropriately and reduces the placement of children and youth in such care.

(F) Of those infants, children, and youth in out-of-home placements, substantially increasing the number of cases of siblings who are in the same foster care, kinship guardianship, or adoptive placement, above the number of such cases in fiscal year 2008.

(G) The development and implementation of a plan to improve the recruitment and retention of high quality foster family homes trained to help assist infants, children, and youth swiftly secure permanent families. Supports for foster families under such a plan may include increasing maintenance payments to more adequately meet the needs of infants, children, and youth in foster care and expanding training, respite care, and other support services for foster parents.

(H) The establishment of procedures designed to assist youth as they prepare for their transition out of foster care, such as arranging for participation in age-appropriate extra-curricular activities, providing appropriate access to cell phones, computers, and opportunities to obtain a driver's license, providing notification of all sibling placements if siblings are in care and sibling location if siblings are out of care, and providing counseling and financial support for post-secondary education.

(I) The inclusion in the State plan under section 471 of a description of State procedures for—

(i) ensuring that youth in foster care who have attained age 16 are engaged in discussions, including during the development of the transition plans required under paragraphs (1)(D) and (5)(H) of section 475, that explore whether the youth wishes to reconnect with the youth's biological family, including parents, grandparents, and siblings, and, if so, what skills and strategies the youth will need to successfully and safely reconnect with those family members;

(ii) providing appropriate guidance and services to youth whom affirm an intent to reconnect with biological family members on how to successfully and safely manage such reconnections; and

(iii) making, when appropriate, efforts to include biological family members in such reconnection efforts.

(J) The establishment of one or more of the following programs designed to prevent infants, children, and youth from entering foster care or to provide permanency for infants, children, and youth in foster care:

(i) An intensive family finding program.

(ii) A kinship navigator program.

(iii) A family counseling program, such as a family group decision-making program, and which may include in-home peer support for families.

(iv) A comprehensive family-based substance abuse treatment program.

(v) A program under which special efforts are made to identify and address domestic violence that endangers infants, children, and youth and puts them at risk of entering foster care.

(vi) A mentoring program.

(8) DEFINITIONS.—In this subsection—

(A) the term "youth" means, with respect to a State, an individual who has attained age 12 but has not attained the age at which an individual is no longer considered to be a child under the State plans under parts B and E of title IV, and

(B) the term "long-term therapeutic family treatment center" means a State licensed or certified program that enables parents and their children to live together in a safe environment for a period of not less than 6 months and provides, on-site or by referral, substance abuse treatment services, children's early intervention services, family counseling, legal services, medical care, mental health services, nursery and preschool, parenting skills training, pediatric care, prenatal care, sexual abuse therapy, relapse prevention, transportation, and job or vocational training or classes leading to a secondary school diploma or a certificate of general equivalence.

(b) WAIVER AUTHORITY.—The Secretary may waive compliance with any requirement of part B or E of title IV which (if applied) would prevent a State from carrying out a demonstration project under this section or prevent the State from effectively achieving the purpose of such a project, except that the Secretary may not waive—

(1) any provision of section 422(b)(8), or section 479; or

(2) any provision of such part E, to the extent that the waiver would impair the entitlement of any qualified child or family to benefits under a State plan approved under such part E.

(c) TREATMENT AS PROGRAM EXPENDITURES.—For purposes of parts B and E of title IV, the Secretary shall consider the expenditures of any State to conduct a demonstration project under this section to be expenditures under subpart 1 or 2 of such part B, or under such part E, as the State may elect.

(d) DURATION OF DEMONSTRATION.—

(1) IN GENERAL.—Subject to paragraph (2), a demonstration project under this section may be conducted for not more than 5 years, unless in the judgment of the Secretary, the demonstration project should be allowed to continue.

(2) TERMINATION OF AUTHORITY.—In no event shall a demonstration project under this section be conducted after September 30, 2019.

(e) APPLICATION.—Any State seeking to conduct a demonstration project under this section shall submit to the Secretary an application, in such form as the Secretary may require, which includes—

(1) a description of the proposed project, the geographic area in which the proposed project would be conducted, the children or families who would be served by the proposed project, and the services which would be provided by the proposed project;

(2) a statement of the period during which the proposed project would be conducted;

(3) a discussion of the benefits that are expected from the proposed project (compared to a continuation of activities under the approved plan or plans of the State);

(4) an estimate of the costs or savings of the proposed project;

(5) a statement of program requirements for which waivers would be needed to permit the proposed project to be conducted;

(6) a description of the proposed evaluation design;

(7) an accounting of any additional Federal, State, and local investments made, as well as any private investments made in coordination with the State, during the 2 fiscal years preceding the application to provide the services described in paragraph (1), and an assurance that the State will provide an accounting of that same spending for each year of an approved demonstration project; and

(8) such additional information as the Secretary may require.

(f) EVALUATIONS.—Each State authorized to conduct a demonstration project under this section shall obtain an evaluation by an independent contractor of the effectiveness of the project, using an evaluation design approved by the Secretary which provides for—

(1) comparison of methods of service delivery under the project, and such methods under a State plan or plans, with respect to efficiency, economy, and any other appropriate measures of program management;

(2) comparison of outcomes for children and families (and groups of children and families) under the project, and such outcomes under a State plan or plans, for purposes of assessing the effectiveness of the project in achieving program goals; and

(3) any other information that the Secretary may require.

(g) REPORTS.—

(1) STATE REPORTS; PUBLIC AVAILABILITY.—Each State authorized to conduct a demonstration project under this section shall—

(A) submit periodic reports to the Secretary on the specific programs, activities, and strategies used to improve outcomes for infants, children, youth, and families and the results achieved for infants, children, and youth during the conduct of the demonstration project, including with respect to those infants, children, and youth who are prevented from entering foster care, infants, children, and youth in foster care, and infants, children, and youth who move from foster care to permanent families; and

(B) post a copy of each such report on the website for the State child welfare program concurrent with the submission of the report to the Secretary.

(2) REPORTS TO CONGRESS.—The Secretary shall submit to the Committee on Ways and Means of the House of Representatives and the Committee on Finance of the Senate—

(A) periodic reports based on the State reports submitted under paragraph (1); and

(B) a report based on the results of the State evaluations required under subsection (f) that includes an analysis of the results of such evaluations and such recommendations for administrative or legislative changes as the Secretary determines appropriate.

(h) COST NEUTRALITY.—The Secretary may not authorize a State to conduct a demonstration project under this section unless the Secretary determines that the total amount of Federal funds that will be expended under (or by reason of) the project over its approved term (or such portion thereof or other period as the Secretary may find appropriate) will not exceed the amount of such funds that would be expended by the State under the State plans approved under parts B and E of title IV if the project were not conducted.

(i) INDIAN TRIBES OPERATING IV–E PROGRAMS CONSIDERED STATES.—An Indian tribe, tribal organization, or tribal consortium that has elected to operate a program under part E of title IV in accordance with section 479B shall be considered a State for purposes of this section.

EFFECT OF FAILURE TO CARRY OUT STATE PLAN

SEC. 1130A. [42 U.S.C. 1320a–10] In an action brought to enforce a provision of the Social Security Act, such provision is not to be deemed unenforceable because of its inclusion in a section of the Act requiring a State plan or specifying the required contents of a State plan. This section is not intended to limit or expand the grounds for determining the availability of private actions to enforce State plan requirements other than by overturning any such grounds applied in Suter v. Artist M., 112 S. Ct. 1360 (1992), but not applied in prior Supreme Court decisions respecting such enforceability*: Provided, however,* That this section is not intended to alter the holding in Suter v. Artist M. that section 471(a)(15) of the Act is not enforceable in a private right of action.

NOTIFICATION OF SOCIAL SECURITY CLAIMANT WITH RESPECT TO DEFERRED VESTED BENEFITS

SEC. 1131. [42 U.S.C. 1320b–1] (a) Whenever—

(1) the Commissioner of Social Security makes a finding of fact and a decision as to—

(A) the entitlement of any individual to monthly benefits under section 202, 223, or 228, or

(B) the entitlement of any individual to a lump-sum death payment payable under section 202(i) on account of the death of any person to whom such individual is related by blood, marriage, or adoption, or

(2) the Commissioner of Social Security makes a finding of fact and a decision as to the entitlement under section 226 of any individual to hospital insurance benefits under part A of title XVIII, or

(3) the Commissioner of Social Security is requested to do so—

(A) by any individual with respect to whom the Commissioner of Social Security holds information obtained under section 6057 of the Internal Revenue Code of 1954, or

(B) in the case of the death of the individual referred to in subparagraph (A), by the individual who would be entitled to payment under section 204(d) of this Act,

the Commissioner of Social Security shall transmit to the individual referred to in paragraph (1) or (2) or the individual making the request under paragraph (3) any information, as reported by the employer, regarding any deferred vested benefit transmitted to the Commissioner of Social Security pursuant to such section 6057 with respect to the individual referred to in paragraph (1), (2), or (3)(A) or the person on whose wages and self-employment income entitlement (or claim of entitlement) is based.

(b)(1) For purposes of section 201(g)(1), expenses incurred in the administration of subsection (a) shall be deemed to be expenses incurred for the administration of title II.

(2) There are hereby authorized to be appropriated to the Federal Old-Age and Survivors Insurance Trust Fund for each fiscal year (commencing with the fiscal year ending June 30, 1974) such sums as the Commissioner of Social Security deems necessary on account of additional administrative expenses resulting from the enactment of the provisions of subsection (a).

PERIOD WITHIN WHICH CERTAIN CLAIMS MUST BE FILED

SEC. 1132. [42 U.S.C. 1320b–2] (a) Notwithstanding any other provision of this Act (but subject to subsection (b)), any claim by a State for payment with respect to an expenditure made during any calendar quarter by the State—

(1) in carrying out a State plan approved under title I, IV, X, XIV, XVI, XIX, or XX of this Act, or

(2) under any other provision of this Act which provides (on an entitlement basis) for Federal financial participation in expenditures made under State plans or programs,

shall be filed (in such form and manner as the Secretary shall by regulations prescribe) within the two-year period which begins on the first day of the calendar quarter immediately following such calendar quarter; and payment shall not be made under this Act on account of any such expenditure if claim therefor is not made within such two-year period; except that this subsection shall not be applied so as to deny payment with respect to any expenditure involving court-ordered retroactive payments or audit exceptions, or adjustments to prior year costs.

(b) The Secretary shall waive the requirement imposed under subsection (a) with respect to the filing of any claim if he determines (in accordance with regulations) that there was good cause for the failure by the State to file such claim within the period prescribed under subsection (a). Any such waiver shall be only for such additional period of time as may be necessary to provide the State with a reasonable opportunity to file such claim. A failure to file a claim within such time period which is attributable to neglect or administrative inadequacies shall be deemed not to be for good cause.

APPLICANTS OR RECIPIENTS UNDER PUBLIC ASSISTANCE PROGRAMS NOT TO BE REQUIRED TO MAKE ELECTION RESPECTING CERTAIN VETERANS' BENEFITS

SEC. 1133. [42 U.S.C. 1320b–3] (a) Notwithstanding any other provision of law (but subject to subsection (b)), no individual who is an applicant for or recipient of aid or assistance under a State plan approved under title I, X, XIV, or XVI, or of benefits under the Supplemental Security Income program established by title XVI shall—

(1) be required, as a condition of eligibility for (or of continuing to receive) such aid, assistance, or benefits, to make an election under section 306 of the Veterans' and Survivors' Pension Improvement Act of 1978 with respect to pension paid by the Secretary of Veterans Affairs, or

(2) by reason of failure or refusal to make such an election, be denied (or suffer a reduction in the amount of) such aid, assistance, or benefits.

(b) The provisions of subsection (a) shall be applicable only with respect to an individual, who is an applicant for or recipient of aid, assistance, or benefits described in subsection (a), during a period with respect to which there is in effect—

(1) in case such individual is an applicant for or recipient of aid or assistance under a State plan referred to in subsection (a), in the State having such plan, or

(2) in case such individual is an applicant for or recipient of benefits under the Supplemental Security Income program established by title XVI, in the State in which the individual applies for or receives such benefits,

a State plan for medical assistance, approved under title XIX, under which medical assistance is available to such individual only for periods for which such individual is a recipient of aid, assistance, or benefits described in subsection (a).

NONPROFIT HOSPITAL PHILANTHROPY

SEC. 1134. [42 U.S.C. 1320b–4] For purposes of determining, under titles XVIII and XIX of this Act, the reasonable costs of services provided by nonprofit hospitals or critical access hospitals, the following items shall not be deducted from the operating costs of such hospitals or critical access hospitals:

(1) A grant, gift, or endowment, or income therefrom, which is to or for such a hospital and which has not been designated by the donor for paying any specific operating costs.

(2) A grant or similar payment which is to such a hospital, which was made by a governmental entity, and which is not available under the terms of the grant or payment for use as operating funds.

(3) Those types of donor designated [20] grants and gifts (including grants and similar payments which are made by a governmental entity), and income therefrom, which the Secretary determines, in the best interests of needed health care, should be encouraged.

(4) The proceeds from the sale or mortgage of any real estate or other capital asset of such a hospital, which real estate or asset the hospital acquired through gift or grant, if such proceeds are not available for use as operating funds under the terms of the gift or grant.

Paragraph (4) shall not apply to the recovery of the appropriate share of depreciation when gains or losses are realized from the disposal of depreciable assets.

AUTHORITY TO WAIVE REQUIREMENTS DURING NATIONAL EMERGENCIES

SEC. 1135. [42 U.S.C. 1320b–5] (a) PURPOSE.—The purpose of this section is to enable the Secretary to ensure to the maximum extent feasible, in any emergency area and during an emergency period (as defined in subsection (g)(1))—

(1) that sufficient health care items and services are available to meet the needs of individuals in such area enrolled in the programs under titles XVIII, XIX, and XXI; and

(2) that health care providers (as defined in subsection (g)(2)) that furnish such items and services in good faith, but that are unable to comply with one or more requirements described in subsection (b), may be reimbursed for such items and services and exempted from sanctions for such noncompliance, absent any determination of fraud or abuse.

(b) SECRETARIAL AUTHORITY.—To the extent necessary to accomplish the purpose specified in subsection (a), the Secretary is authorized, subject to the provisions of this section, to temporarily waive or modify the application of, with respect to health care items and services furnished by a health care provider (or classes of health care providers) in any emergency area (or portion of such an area) during any portion of an emergency period, the requirements of titles XVIII, XIX, or XXI, or any regulation thereunder (and the requirements of this title other than this section, and reg-

[20] As in original. Probably should be "donor-designated".

ulations thereunder, insofar as they relate to such titles), pertaining to—

(1)(A) conditions of participation or other certification requirements for an individual health care provider or types of providers,

(B) program participation and similar requirements for an individual health care provider or types of providers, and

(C) pre-approval requirements;

(2) requirements that physicians and other health care professionals be licensed in the State in which they provide such services, if they have equivalent licensing in another State and are not affirmatively excluded from practice in that State or in any State a part of which is included in the emergency area;

(3) actions under section 1867 (relating to examination and treatment for emergency medical conditions and women in labor) for—

(A) a transfer of an individual who has not been stabilized in violation of subsection (c) of such section if the transfer is necessitated by the circumstances of the declared emergency in the emergency area during the emergency period; or

(B) the direction or relocation of an individual to receive medical screening in an alternative location—

(i) pursuant to an appropriate State emergency preparedness plan; or

(ii) in the case of a public health emergency described in subsection (g)(1)(B) that involves a pandemic infectious disease, pursuant to a State pandemic preparedness plan or a plan referred to in clause (i), whichever is applicable in the State;

(4) sanctions under section 1877(g) (relating to limitations on physician referral);

(5) deadlines and timetables for performance of required activities, except that such deadlines and timetables may only be modified, not waived;

(6) limitations on payments under section 1851(i) for health care items and services furnished to individuals enrolled in a Medicare+Choice plan by health care professionals or facilities not included under such plan;

(7) sanctions and penalties that arise from noncompliance with the following requirements (as promulgated under the authority of section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note)—

(A) section 164.510 of title 45, Code of Federal Regulations, relating to—

(i) requirements to obtain a patient's agreement to speak with family members or friends; and

(ii) the requirement to honor a request to opt out of the facility directory;

(B) section 164.520 of such title, relating to the requirement to distribute a notice; or

(C) section 164.522 of such title, relating to—

(i) the patient's right to request privacy restrictions; and

(ii) the patient's right to request confidential communications;

(8) in the case of a telehealth service (as defined in paragraph (4)(F) of section 1834(m)) furnished in any emergency area (or portion of such an area) during any portion of any emergency period, the requirements of section 1834(m); and

(9) any requirement under section 1861(s)(7) or section 1834(l) that an ambulance service include the transport of an individual to the extent necessary to allow payment for ground ambulance services furnished in response to a 911 call (or the equivalent in areas without a 911 call system) in cases in which an individual would have been transported to a destination permitted under Medicare regulations (as described in section 410.40 to title 42, Code of Federal Regulations (or successor regulations)) but such transport did not occur as a result of community-wide emergency medical service (EMS) protocols due to the public health emergency described in subsection (g)(1)(B).

Insofar as the Secretary exercises authority under paragraph (6) with respect to individuals enrolled in a Medicare+Choice plan, to the extent possible given the circumstances, the Secretary shall reconcile payments made on behalf of such enrollees to ensure that the enrollees do not pay more than would be required had they received services from providers within the network of the plan and may reconcile payments to the organization offering the plan to ensure that such organization pays for services for which payment is included in the capitation payment it receives under part C of title XVIII. A waiver or modification provided for under paragraph (3) or (7) shall only be in effect if such actions are taken in a manner that does not discriminate among individuals on the basis of their source of payment or of their ability to pay, and, except in the case of a waiver or modification to which the fifth sentence of this subsection applies, shall be limited to a 72-hour period beginning upon implementation of a hospital disaster protocol. A waiver or modification under such paragraph (7) shall be withdrawn after such period and the provider shall comply with the requirements under such paragraph for any patient still under the care of the provider. If a public health emergency described in subsection (g)(1)(B) involves a pandemic infectious disease (such as pandemic influenza), the duration of a waiver or modification under paragraph (3) shall be determined in accordance with subsection (e) as such subsection applies to public health emergencies. Ground ambulance services for which payment is made pursuant to paragraph (9) shall be paid at the base rate that would have been paid under the fee schedule established under 1834(l) (excluding any mileage payment) if the individual had been so transported and, with respect to ambulance services furnished by a critical access hospital or an entity described in paragraph (8) of such section, at the amount that otherwise would be paid under such paragraph.

(c) AUTHORITY FOR RETROACTIVE WAIVER.—A waiver or modification of requirements pursuant to this section may, at the Secretary's discretion, be made retroactive to the beginning of the

emergency period or any subsequent date in such period specified by the Secretary.

(d) CERTIFICATION TO CONGRESS.—The Secretary shall provide a certification and advance written notice to the Congress at least two days before exercising the authority under this section with respect to an emergency area. Such a certification and notice shall include—

(1) a description of—

(A) the specific provisions that will be waived or modified;

(B) the health care providers to whom the waiver or modification will apply;

(C) the geographic area in which the waiver or modification will apply; and

(D) the period of time for which the waiver or modification will be in effect; and

(2) a certification that the waiver or modification is necessary to carry out the purpose specified in subsection (a).

(e) DURATION OF WAIVER.—

(1) IN GENERAL.—A waiver or modification of requirements pursuant to this section terminates upon—

(A) the termination of the applicable declaration of emergency or disaster described in subsection (g)(1)(A);

(B) the termination of the applicable declaration of public health emergency described in subsection (g)(1)(B); or

(C) subject to paragraph (2), the termination of a period of 60 days from the date the waiver or modification is first published (or, if applicable, the date of extension of the waiver or modification under paragraph (2)).

(2) EXTENSION OF 60-DAY PERIODS.—The Secretary may, by notice, provide for an extension of a 60-day period described in paragraph (1)(C) (or an additional period provided under this paragraph) for additional period or periods (not to exceed, except as subsequently provided under this paragraph, 60 days each), but any such extension shall not affect or prevent the termination of a waiver or modification under subparagraph (A) or (B) of paragraph (1).

(f) REPORT TO CONGRESS.—Within one year after the end of the emergency period in an emergency area in which the Secretary exercised the authority provided under this section, the Secretary shall report to the Congress regarding the approaches used to accomplish the purposes described in subsection (a), including an evaluation of such approaches and recommendations for improved approaches should the need for such emergency authority arise in the future.

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

(1) EMERGENCY AREA; EMERGENCY PERIOD.—

(A) IN GENERAL.—Subject to subparagraph (B), an "emergency area" is a geographical area in which, and an "emergency period" is the period during which, there exists—

(i) an emergency or disaster declared by the President pursuant to the National Emergencies Act or the

Robert T. Stafford Disaster Relief and Emergency Assistance Act; and

(ii) a public health emergency declared by the Secretary pursuant to section 319 of the Public Health Service Act.

(B) EXCEPTION.—For purposes of paragraphs (8) and (9) of subsection (b), an "emergency area" is a geographical area in which, and an "emergency period" is the period during which, there exists—

(i) the public health emergency declared by the Secretary pursuant to section 319 of the Public Health Service Act on January 31, 2020, entitled "Determination that a Public Health Emergency Exists Nationwide as the Result of the 2019 Novel Coronavirus"; and

(ii) any renewal of such declaration pursuant to such section 319.

(2) HEALTH CARE PROVIDER.—The term "health care provider" means any entity that furnishes health care items or services, and includes a hospital or other provider of services, a physician or other health care practitioner or professional, a health care facility, or a supplier of health care items or services.

EXCLUSION OF REPRESENTATIVES AND HEALTH CARE PROVIDERS CONVICTED OF VIOLATIONS FROM PARTICIPATION IN SOCIAL SECURITY PROGRAMS

SEC. 1136. [42 U.S.C. 1320b–6] (a) IN GENERAL.—The Commissioner of Social Security shall exclude from participation in the social security programs any representative or health care provider—

(1) who is convicted of a violation of section 208 or 1632 of this Act;

(2) who is convicted of any violation under title 18, United States Code, relating to an initial application for or continuing entitlement to, or amount of, benefits under title II of this Act, or an initial application for or continuing eligibility for, or amount of, benefits under title XVI of this Act; or

(3) who the Commissioner determines has committed an offense described in section 1129(a)(1) of this Act.

(b) NOTICE, EFFECTIVE DATE, AND PERIOD OF EXCLUSION.—(1) An exclusion under this section shall be effective at such time, for such period, and upon such reasonable notice to the public and to the individual excluded as may be specified in regulations consistent with paragraph (2).

(2) Such an exclusion shall be effective with respect to services furnished to any individual on or after the effective date of the exclusion. Nothing in this section may be construed to preclude, in determining disability under title II or title XVI, consideration of any medical evidence derived from services provided by a health care provider before the effective date of the exclusion of the health care provider under this section.

(3)(A) The Commissioner shall specify, in the notice of exclusion under paragraph (1), the period of the exclusion.

(B) Subject to subparagraph (C), in the case of an exclusion under subsection (a), the minimum period of exclusion shall be 5 years, except that the Commissioner may waive the exclusion in the case of an individual who is the sole source of essential services in a community. The Commissioner's decision whether to waive the exclusion shall not be reviewable.

(C) In the case of an exclusion of an individual under subsection (a) based on a conviction or a determination described in subsection (a)(3) occurring on or after the date of the enactment of this section, if the individual has (before, on, or after such date of the enactment) been convicted, or if such a determination has been made with respect to the individual—

(i) on one previous occasion of one or more offenses for which an exclusion may be effected under such subsection, the period of the exclusion shall be not less than 10 years; or

(ii) on two or more previous occasions of one or more offenses for which an exclusion may be effected under such subsection, the period of the exclusion shall be permanent.

(c) NOTICE TO STATE AGENCIES.—The Commissioner shall promptly notify each appropriate State agency employed for the purpose of making disability determinations under section 221 or 1633(a)—

(1) of the fact and circumstances of each exclusion effected against an individual under this section; and

(2) of the period (described in subsection (b)(3)) for which the State agency is directed to exclude the individual from participation in the activities of the State agency in the course of its employment.

(d) NOTICE TO STATE LICENSING AGENCIES.—The Commissioner shall—

(1) promptly notify the appropriate State or local agency or authority having responsibility for the licensing or certification of an individual excluded from participation under this section of the fact and circumstances of the exclusion;

(2) request that appropriate investigations be made and sanctions invoked in accordance with applicable State law and policy; and

(3) request that the State or local agency or authority keep the Commissioner and the Inspector General of the Social Security Administration fully and currently informed with respect to any actions taken in response to the request.

(e) NOTICE, HEARING, AND JUDICIAL REVIEW.—(1) Any individual who is excluded (or directed to be excluded) from participation under this section is entitled to reasonable notice and opportunity for a hearing thereon by the Commissioner to the same extent as is provided in section 205(b), and to judicial review of the Commissioner's final decision after such hearing as is provided in section 205(g).

(2) The provisions of section 205(h) shall apply with respect to this section to the same extent as it is applicable with respect to title II.

(f) APPLICATION FOR TERMINATION OF EXCLUSION.—(1) An individual excluded from participation under this section may apply to the Commissioner, in the manner specified by the Commissioner in regulations and at the end of the minimum period of exclusion provided under subsection (b)(3) and at such other times as the Commissioner may provide, for termination of the exclusion effected under this section.

(2) The Commissioner may terminate the exclusion if the Commissioner determines, on the basis of the conduct of the applicant which occurred after the date of the notice of exclusion or which was unknown to the Commissioner at the time of the exclusion, that—

(A) there is no basis under subsection (a) for a continuation of the exclusion; and

(B) there are reasonable assurances that the types of actions which formed the basis for the original exclusion have not recurred and will not recur.

(3) The Commissioner shall promptly notify each State agency employed for the purpose of making disability determinations under section 221 or 1633(a) of the fact and circumstances of each termination of exclusion made under this subsection.

(g) AVAILABILITY OF RECORDS OF EXCLUDED REPRESENTATIVES AND HEALTH CARE PROVIDERS.—Nothing in this section shall be construed to have the effect of limiting access by any applicant or beneficiary under title II or XVI, any State agency acting under section 221 or 1633(a), or the Commissioner to records maintained by any representative or health care provider in connection with services provided to the applicant or beneficiary prior to the exclusion of such representative or health care provider under this section.

(h) REPORTING REQUIREMENT.—Any representative or health care provider participating in, or seeking to participate in, a social security program shall inform the Commissioner, in such form and manner as the Commissioner shall prescribe by regulation, whether such representative or health care provider has been convicted of a violation described in subsection (a).

(i) DELEGATION OF AUTHORITY.—The Commissioner may delegate authority granted by this section to the Inspector General.

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

(1) EXCLUDE.—The term "exclude" from participation means—

(A) in connection with a representative, to prohibit from engaging in representation of an applicant for, or recipient of, benefits, as a representative payee under section 205(j) or section 1631(a)(2)(A)(ii), or otherwise as a representative, in any hearing or other proceeding relating to entitlement to benefits; and

(B) in connection with a health care provider, to prohibit from providing items or services to an applicant for, or recipient of, benefits for the purpose of assisting such applicant or recipient in demonstrating disability.

(2) SOCIAL SECURITY PROGRAM.—The term "social security programs" means the program providing for monthly insurance benefits under title II, and the program providing for monthly supplemental security income benefits to individuals under

title XVI (including State supplementary payments made by the Commissioner pursuant to an agreement under section 1616(a) of this Act or section 212(b) of Public Law 93–66).

(3) CONVICTED.—An individual is considered to have been "convicted" of a violation—

(A) when a judgment of conviction has been entered against the individual by a Federal, State, or local court, except if the judgment of conviction has been set aside or expunged;

(B) when there has been a finding of guilt against the individual by a Federal, State, or local court;

(C) when a plea of guilty or nolo contendere by the individual has been accepted by a Federal, State, or local court; or

(D) when the individual has entered into participation in a first offender, deferred adjudication, or other arrangement or program where judgment of conviction has been withheld.

INCOME AND ELIGIBILITY VERIFICATION SYSTEM

SEC. 1137. [42 U.S.C. 1320b–7] (a) In order to meet the requirements of this section, a State must have in effect an income and eligibility verification system which meets the requirements of subsection (d) and under which—

(1) the State shall require, as a condition of eligibility for benefits under any program listed in subsection (b), that each applicant for or recipient of benefits under that program furnish to the State his social security account number (or numbers, if he has more than one such number), and the State shall utilize such account numbers in the administration of that program so as to enable the association of the records pertaining to the applicant or recipient with his account number;

(2) wage information from agencies administering State unemployment compensation laws available pursuant to section 3304(a)(16) of the Internal Revenue Code of 1954, wage information reported pursuant to paragraph (3) of this subsection, and wage, income, and other information from the Social Security Administration and the Internal Revenue Service available pursuant to section 6103(l)(7) of such Code, shall be requested and utilized to the extent that such information may be useful in verifying eligibility for, and the amount of, benefits available under any program listed in subsection (b), as determined by the Secretary of Health and Human Services (or, in the case of the unemployment compensation program, by the Secretary of Labor, or, in the case of the supplemental nutrition assistance program, by the Secretary of Agriculture);

(3) employers (as defined in section 453A(a)(2)(B)) (including State and local governmental entities and labor organizations (as defined in section 453A(a)(2)(B)(ii)))[21] in such State

[21] Section 401(p) of the Foster Care Independence Act of 1999 (P.L. 106–169) amended this paragraph "by striking '453A(a)(2)(B)(iii))' and inserting '453A(a)(2)(B)(ii)))'". Section 405(b)(1) of the Ticket to Work and Work Incentives Improvement Act of 1999 (P.L. 106–170) attempted to amend this paragraph "by striking '(as defined in section 453A(a)(2)(B)(iii))'".

are required, effective September 30, 1988, to make quarterly wage reports to a State agency (which may be the agency administering the State's unemployment compensation law) except that the Secretary of Labor (in consultation with the Secretary of Health and Human Services and the Secretary of Agriculture) may waive the provisions of this paragraph if he determines that the State has in effect an alternative system which is as effective and timely for purposes of providing employment related income and eligibility data for the purposes described in paragraph (2), and except that no report shall be filed with respect to an employee of a State or local agency performing intelligence or counterintelligence functions, if the head of such agency has determined that filing such a report could endanger the safety of the employee or compromise an ongoing investigation or intelligence mission, and except that in the case of wage reports with respect to domestic service employment, a State may permit employers (as so defined) that make returns with respect to such employment on a calendar year basis pursuant to section 3510 of the Internal Revenue Code of 1986 to make such reports on an annual basis;

(4) the State agencies administering the programs listed in subsection (b) adhere to standardized formats and procedures established by the Secretary of Health and Human Services (in consultation with the Secretary of Agriculture) under which—

(A) the agencies will exchange with each other information in their possession which may be of use in establishing or verifying eligibility or benefit amounts under any other such program;

(B) such information shall be made available to assist in the child support program under part D of title IV of this Act, and to assist the Secretary of Health and Human Services in establishing or verifying eligibility or benefit amounts under titles II and XVI of this Act, but subject to the safeguards and restrictions established by the Secretary of the Treasury with respect to information released pursuant to section 6103(l) of the Internal Revenue Code of 1954; and

(C) the use of such information shall be targeted to those uses which are most likely to be productive in identifying and preventing ineligibility and incorrect payments, and no State shall be required to use such information to verify the eligibility of all recipients;

(5) adequate safeguards are in effect so as to assure that—

(A) the information exchanged by the State agencies is made available only to the extent necessary to assist in the valid administrative needs of the program receiving such information, and the information released pursuant to section 6103(l) of the Internal Revenue Code of 1954 is only exchanged with agencies authorized to receive such information under such section 6103(l); and

(B) the information is adequately protected against unauthorized disclosure for other purposes, as provided in regulations established by the Secretary of Health and Human Services, or, in the case of the unemployment com-

pensation program, the Secretary of Labor, or, in the case of the supplemental nutrition assistance program, the Secretary of Agriculture, or in the case of information released pursuant to section 6103(l) of the Internal Revenue Code of 1954, the Secretary of the Treasury;

(6) all applicants for and recipients of benefits under any such program shall be notified at the time of application, and periodically thereafter, that information available through the system will be requested and utilized; and

(7) accounting systems are utilized which assure that programs providing data receive appropriate reimbursement from the programs utilizing the data for the costs incurred in providing the data.

(b) The programs which must participate in the income and eligibility verification system are—

(1) any State program funded under part A of title IV of this Act;

(2) the medicaid program under title XIX of this Act;

(3) the unemployment compensation program under section 3304 of the Internal Revenue Code of 1954;

(4) the supplemental nutrition assistance program established under the Food and Nutrition Act of 2008 (7 U.S.C. 2011 et seq.); and

(5) any State program under a plan approved under title I, X, XIV, or XVI of this Act.

(c)(1) In order to protect applicants for and recipients of benefits under the programs identified in subsection (b), or under the supplemental security income program under title XVI, from the improper use of information obtained from the Secretary of the Treasury under section 6103(l)(7)(B) of the Internal Revenue Code of 1954, no Federal, State, or local agency receiving such information may terminate, deny, suspend, or reduce any benefits of an individual until such agency has taken appropriate steps to independently verify information relating to—

(A) the amount of the asset or income involved,

(B) whether such individual actually has (or had) access to such asset or income for his own use, and

(C) the period or periods when the individual actually had such asset or income.

(2) Such individual shall be informed by the agency of the findings made by the agency on the basis of such verified information, and shall be given an opportunity to contest such findings, in the same manner as applies to other information and findings relating to eligibility factors under the program.

(d) The requirements of this subsection, with respect to an income and eligibility verification system of a State, are as follows:

(1)(A) The State shall require, as a condition of an individual's eligibility for benefits under a program listed in subsection (b), a declaration in writing, under penalty of perjury—

(i) by the individual,

(ii) in the case in which eligibility for program benefits is determined on a family or household basis, by any adult member of such individual's family or household (as applicable), or

(iii) in the case of an individual born into a family or household receiving benefits under such program, by any adult member or such family or household no later than the next redetermination of eligibility of such family or household following the birth of such individual,

stating whether the individual is a citizen or national of the United States, and, if that individual is not a citizen or national of the United States, that the individual is in a satisfactory immigration status.

(B) In this subsection, in the case of the program described in subsection (b)(4)—

(i) any reference to the State shall be considered a reference to the State agency, and

(ii) any reference to an individual's eligibility for benefits under the program shall be considered a reference to the individual's eligibility to participate in the program as a member of a household, and

(iii) the term "satisfactory immigration status" means an immigration status which does not make the individual ineligible for benefits under the applicable program.

(2) If such an individual is not a citizen or national of the United States, there must be presented either—

(A) alien registration documentation or other proof of immigration registration from the Immigration and Naturalization Service that contains the individual's alien admission number or alien file number (or numbers if the individual has more than one number), or

(B) such other documents as the State determines constitutes reasonable evidence indicating a satisfactory immigration status.

(3) If the documentation described in paragraph (2)(A) is presented, the State shall utilize the individual's alien file or alien admission number to verify with the Immigration and Naturalization Service the individual's immigration status through an automated or other system (designated by the Service for use with States) that—

(A) utilizes the individual's name, file number, admission number, or other means permitting efficient verification, and

(B) protects the individual's privacy to the maximum degree possible.

(4) In the case of such an individual who is not a citizen or national of the United States, if, at the time of application for benefits, the statement described in paragraph (1) is submitted but the documentation required under paragraph (2) is not presented or if the documentation required under paragraph (2)(A) is presented but such documentation is not verified under paragraph (3)—

(A) the State—

(i) shall provide a reasonable opportunity to submit to the State evidence indicating a satisfactory immigration status, and

(ii) may not delay, deny, reduce, or terminate the individual's eligibility for benefits under the program

on the basis of the individual's immigration status until such a reasonable opportunity has been provided; and

(B) if there are submitted documents which the State determines constitutes reasonable evidence indicating such status—

(i) the State shall transmit to the Immigration and Naturalization Service either photostatic or other similar copies of such documents, or information from such documents, as specified by the Immigration and Naturalization Service, for official verification,

(ii) pending such verification, the State may not delay, deny, reduce, or terminate the individual's eligibility for benefits under the program on the basis of the individual's immigration status, and

(iii) the State shall not be liable for the consequences of any action, delay, or failure of the Service to conduct such verification.

(5) If the State determines, after complying with the requirements of paragraph (4), that such an individual is not in a satisfactory immigration status under the applicable program—

(A) the State shall deny or terminate the individual's eligibility for benefits under the program, and

(B) the applicable fair hearing process shall be made available with respect to the individual.

(e) Each Federal agency responsible for administration of a program described in subsection (b) shall not take any compliance, disallowance, penalty, or other regulatory action against a State with respect to any error in the State's determination to make an individual eligible for benefits based on citizenship or immigration status—

(1) if the State has provided such eligibility based on a verification of satisfactory immigration status by the Immigration and Naturalization Service,

(2) because the State, under subsection (d)(4)(A)(ii), was required to provide a reasonable opportunity to submit documentation,

(3) because the State, under subsection (d)(4)(B)(ii), was required to wait for the response of the Immigration and Naturalization Service to the State's request for official verification of the immigration status of the individual, or

(4) because of a fair hearing process described in subsection (d)(5)(B).

(f) Subsections (a)(1) and (d) shall not apply with respect to aliens seeking medical assistance for the treatment of an emergency medical condition under section 1903(v)(2).

HOSPITAL PROTOCOLS FOR ORGAN PROCUREMENT AND STANDARDS FOR ORGAN PROCUREMENT AGENCIES

SEC. 1138. [42 U.S.C. 1320b–8] (a)(1) The Secretary shall provide that a hospital or critical access hospital meeting the require-

ments of title XVIII or XIX may participate in the program established under such title only if—

(A) the hospital or critical access hospital establishes written protocols for the identification of potential organ donors that—

(i) assure that families of potential organ donors are made aware of the option of organ or tissue donation and their option to decline,

(ii) encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of such families, and

(iii) require that such hospital's designated organ procurement agency (as defined in paragraph (3)(B)) is notified of potential organ donors;

(B) in the case of a hospital in which organ transplants are performed, the hospital is a member of, and abides by the rules and requirements of, the Organ Procurement and Transplantation Network established pursuant to section 372 of the Public Health Service Act (in this section referred to as the "Network"); and

(C) the hospital or critical access hospital has an agreement (as defined in paragraph (3)(A)) only with such hospital's designated organ procurement agency.

(2)(A) The Secretary shall grant a waiver of the requirements under subparagraphs (A)(iii) and (C) of paragraph (1) to a hospital or critical access hospital desiring to enter into an agreement with an organ procurement agency other than such hospital's designated organ procurement agency if the Secretary determines that—

(i) the waiver is expected to increase organ donation; and

(ii) the waiver will assure equitable treatment of patients referred for transplants within the service area served by such hospital's designated organ procurement agency and within the service area served by the organ procurement agency with which the hospital seeks to enter into an agreement under the waiver.

(B) In making a determination under subparagraph (A), the Secretary may consider factors that would include, but not be limited to—

(i) cost effectiveness;

(ii) improvements in quality;

(iii) whether there has been any change in a hospital's designated organ procurement agency due to a change made on or after December 28, 1992, in the definitions for metropolitan statistical areas (as established by the Office of Management and Budget); and

(iv) the length and continuity of a hospital's relationship with an organ procurement agency other than the hospital's designated organ procurement agency;

except that nothing in this subparagraph shall be construed to permit the Secretary to grant a waiver that does not meet the requirements of subparagraph (A).

(C) Any hospital or critical access hospital seeking a waiver under subparagraph (A) shall submit an application to the Secretary containing such information as the Secretary determines appropriate.

(D) The Secretary shall—

(i) publish a public notice of any waiver application received from a hospital or critical access hospital under this paragraph within 30 days of receiving such application; and

(ii) prior to making a final determination on such application under subparagraph (A), offer interested parties the opportunity to submit written comments to the Secretary during the 60-day period beginning on the date such notice is published.

(3) For purposes of this subsection—

(A) the term "agreement" means an agreement described in seciton 371(b)(3)(A) of the Public Health Service Act;

(B) the term "designated organ procurement agency" means, with respect to a hospital or critical access hospital, the organ procurement agency designated pursuant to subsection (b) for the service area in which such hospital is located; and

(C) the term "organ" means a human kidney, liver, heart, lung, pancreas, and any other human organ or tissue specified by the Secretary for purposes of this subsection.

(b)(1) The Secretary shall provide that payment may be made under title XVIII or XIX with respect to organ procurement costs attributable to payments made to an organ procurement agency only if the agency—

(A)(i) is a qualified organ procurement organization (as described in section 371(b) of the Public Health Service Act) that is operating under a grant made under section 371(a) of such Act, or (ii) has been certified or recertified by the Secretary within the previous 2 years (4 years if the Secretary determines appropriate for an organization on the basis of its past practices) as meeting the standards to be a qualified organ procurement organization (as so described);

(B) meets the requirements that are applicable under such title for organ procurement agencies;

(C) meets performance-related standards prescribed by the Secretary;

(D) is a member of, and abides by the rules and requirements of, the Network;

(E) allocates organs, within its service area and nationally, in accordance with medical criteria and the policies of the Network; and

(F) is designated by the Secretary as an organ procurement organization payments to which may be treated as organ procurement costs for purposes of reimbursement under such title.

(2) The Secretary may not designate more than one organ procurement organization for each service area (described in section 371(b)(1)(E) of the Public Health Service Act) under paragraph (1)(F).

SEC. 1139. [42 U.S.C. 1320b–9] IMPROVED ACCESS TO, AND DELIVERY OF, HEALTH CARE FOR INDIANS UNDER TITLES XIX AND XXI.

(a) AGREEMENTS WITH STATES FOR MEDICAID AND CHIP OUTREACH ON OR NEAR RESERVATIONS TO INCREASE THE ENROLLMENT OF INDIANS IN THOSE PROGRAMS.—

(1) IN GENERAL.—In order to improve the access of Indians residing on or near a reservation to obtain benefits under the Medicaid and State children's health insurance programs established under titles XIX and XXI, the Secretary shall encourage the State to take steps to provide for enrollment on or near the reservation. Such steps may include outreach efforts such as the outstationing of eligibility workers, entering into agreements with the Indian Health Service, Indian Tribes, Tribal Organizations, and Urban Indian Organizations to provide outreach, education regarding eligibility and benefits, enrollment, and translation services when such services are appropriate.

(2) CONSTRUCTION.—Nothing in paragraph (1) shall be construed as affecting arrangements entered into between States and the Indian Health Service, Indian Tribes, Tribal Organizations, or Urban Indian Organizations for such Service, Tribes, or Organizations to conduct administrative activities under such titles.

(b) REQUIREMENT TO FACILITATE COOPERATION.—The Secretary, acting through the Centers for Medicare & Medicaid Services, shall take such steps as are necessary to facilitate cooperation with, and agreements between, States and the Indian Health Service, Indian Tribes, Tribal Organizations, or Urban Indian Organizations with respect to the provision of health care items and services to Indians under the programs established under title XIX or XXI.

(c) DEFINITION OF INDIAN; INDIAN TRIBE; INDIAN HEALTH PROGRAM; TRIBAL ORGANIZATION; URBAN INDIAN ORGANIZATION.—For purposes of this section, title XIX, and title XXI, the terms "Indian", "Indian Tribe", "Indian Health Program", "Tribal Organization", and "Urban Indian Organization" have the meanings given those terms in section 4 of the Indian Health Care Improvement Act.

SEC. 1139A. [42 U.S.C. 1320b–9a] CHILD HEALTH QUALITY MEASURES.

(a) DEVELOPMENT OF AN INITIAL CORE SET OF HEALTH CARE QUALITY MEASURES FOR CHILDREN ENROLLED IN MEDICAID OR CHIP.—

(1) IN GENERAL.—Not later than January 1, 2010, the Secretary shall identify and publish for general comment an initial, recommended core set of child health quality measures for use by State programs administered under titles XIX and XXI, health insurance issuers and managed care entities that enter into contracts with such programs, and providers of items and services under such programs.

(2) IDENTIFICATION OF INITIAL CORE MEASURES.—In consultation with the individuals and entities described in subsection (b)(3), the Secretary shall identify existing quality of care measures for children that are in use under public and privately sponsored health care coverage arrangements, or that are part of reporting systems that measure both the presence and duration of health insurance coverage over time.

(3) RECOMMENDATIONS AND DISSEMINATION.—Based on such existing and identified measures, the Secretary shall publish an initial core set of child health quality measures that includes (but is not limited to) the following:

(A) The duration of children's health insurance coverage over a 12-month time period.

(B) The availability and effectiveness of a full range of—

(i) preventive services, treatments, and services for acute conditions, including services to promote healthy birth, prevent and treat premature birth, and detect the presence or risk of physical or mental conditions that could adversely affect growth and development; and

(ii) treatments to correct or ameliorate the effects of physical and mental conditions, including chronic conditions and, with respect to dental care, conditions requiring the restoration of teeth, relief of pain and infection, and maintenance of dental health, in infants, young children, school-age children, and adolescents.

(C) The availability of care in a range of ambulatory and inpatient health care settings in which such care is furnished.

(D) The types of measures that, taken together, can be used to estimate the overall national quality of health care for children, including children with special needs, and to perform comparative analyses of pediatric health care quality and racial, ethnic, and socioeconomic disparities in child health and health care for children.

(4) ENCOURAGE VOLUNTARY AND STANDARDIZED REPORTING AND MANDATORY REPORTING.—

(A) VOLUNTARY REPORTING.—Not later than 2 years after the date of enactment of the Children's Health Insurance Program Reauthorization Act of 2009, the Secretary, in consultation with States, shall develop a standardized format for reporting information and procedures and approaches that encourage States to use the initial core measurement set to voluntarily report information regarding the quality of pediatric health care under titles XIX and XXI.

(B) MANDATORY REPORTING.—Beginning with the annual State report on fiscal year 2024 required under subsection (c)(1), the Secretary shall require States to use the initial core measurement set and any updates or changes to that set to report information regarding the quality of pediatric health care under titles XIX and XXI using the standardized format for reporting information and procedures developed under subparagraph (A).

(5) ADOPTION OF BEST PRACTICES IN IMPLEMENTING QUALITY PROGRAMS.—The Secretary shall disseminate information to States regarding best practices among States with respect to measuring and reporting on the quality of health care for children, and shall facilitate the adoption of such best practices. In developing best practices approaches, the Secretary shall give particular attention to State measurement techniques that ensure the timeliness and accuracy of provider reporting, encourage provider reporting compliance, encourage successful qual-

ity improvement strategies, and improve efficiency in data collection using health information technology.

(6) REPORTS TO CONGRESS.—Not later than January 1, 2011, and every 3 years thereafter, the Secretary shall report to Congress on—

(A) the status of the Secretary's efforts to improve—

(i) quality related to the duration and stability of health insurance coverage for children under titles XIX and XXI;

(ii) the quality of children's health care under such titles, including preventive health services, dental care, health care for acute conditions, chronic health care, and health services to ameliorate the effects of physical and mental conditions and to aid in growth and development of infants, young children, school-age children, and adolescents with special health care needs; and

(iii) the quality of children's health care under such titles across the domains of quality, including clinical quality, health care safety, family experience with health care, health care in the most integrated setting, and elimination of racial, ethnic, and socioeconomic disparities in health and health care;

(B) the status of voluntary reporting by States under titles XIX and XXI, utilizing the initial core quality measurement set and, beginning with the report required on January 1, 2025, and for each annual report thereafter, the status of mandatory reporting by States under titles XIX and XXI, utilizing the initial core quality measurement set and any updates or changes to that set; and

(C) any recommendations for legislative changes needed to improve the quality of care provided to children under titles XIX and XXI, including recommendations for quality reporting by States.

(7) TECHNICAL ASSISTANCE.—The Secretary shall provide technical assistance to States to assist them in adopting and utilizing core child health quality measures in administering the State plans under titles XIX and XXI.

(8) DEFINITION OF CORE SET.—In this section, the term "core set" means a group of valid, reliable, and evidence-based quality measures that, taken together—

(A) provide information regarding the quality of health coverage and health care for children;

(B) address the needs of children throughout the developmental age span; and

(C) allow purchasers, families, and health care providers to understand the quality of care in relation to the preventive needs of children, treatments aimed at managing and resolving acute conditions, and diagnostic and treatment services whose purpose is to correct or ameliorate physical, mental, or developmental conditions that could, if untreated or poorly treated, become chronic.

(b) ADVANCING AND IMPROVING PEDIATRIC QUALITY MEASURES.—

(1) ESTABLISHMENT OF PEDIATRIC QUALITY MEASURES PROGRAM.—Not later than January 1, 2011, the Secretary shall establish a pediatric quality measures program to—

(A) improve and strengthen the initial core child health care quality measures established by the Secretary under subsection (a);

(B) expand on existing pediatric quality measures used by public and private health care purchasers and advance the development of such new and emerging quality measures; and

(C) increase the portfolio of evidence-based, consensus pediatric quality measures available to public and private purchasers of children's health care services, providers, and consumers.

(2) EVIDENCE-BASED MEASURES.—The measures developed under the pediatric quality measures program shall, at a minimum, be—

(A) evidence-based and, where appropriate, risk adjusted;

(B) designed to identify and eliminate racial and ethnic disparities in child health and the provision of health care;

(C) designed to ensure that the data required for such measures is collected and reported in a standard format that permits comparison of quality and data at a State, plan, and provider level;

(D) periodically updated; and

(E) responsive to the child health needs, services, and domains of health care quality described in clauses (i), (ii), and (iii) of subsection (a)(6)(A).

(3) PROCESS FOR PEDIATRIC QUALITY MEASURES PROGRAM.—In identifying gaps in existing pediatric quality measures and establishing priorities for development and advancement of such measures, the Secretary shall consult with—

(A) States;

(B) pediatricians, children's hospitals, and other primary and specialized pediatric health care professionals (including members of the allied health professions) who specialize in the care and treatment of children, particularly children with special physical, mental, and developmental health care needs;

(C) dental professionals, including pediatric dental professionals;

(D) health care providers that furnish primary health care to children and families who live in urban and rural medically underserved communities or who are members of distinct population sub-groups at heightened risk for poor health outcomes;

(E) national organizations representing children, including children with disabilities and children with chronic conditions;

(F) national organizations representing consumers and purchasers of children's health care;

(G) national organizations and individuals with expertise in pediatric health quality measurement; and

(H) voluntary consensus standards setting organizations and other organizations involved in the advancement of evidence-based measures of health care.

(4) DEVELOPING, VALIDATING, AND TESTING A PORTFOLIO OF PEDIATRIC QUALITY MEASURES.—As part of the program to advance pediatric quality measures, the Secretary shall—

(A) award grants and contracts for the development, testing, and validation of new, emerging, and innovative evidence-based measures for children's health care services across the domains of quality described in clauses (i), (ii), and (iii) of subsection (a)(6)(A); and

(B) award grants and contracts for—

(i) the development of consensus on evidence-based measures for children's health care services;

(ii) the dissemination of such measures to public and private purchasers of health care for children; and

(iii) the updating of such measures as necessary.

(5) REVISING, STRENGTHENING, AND IMPROVING INITIAL CORE MEASURES.—Beginning no later than January 1, 2013, and annually thereafter, the Secretary shall publish recommended changes to the core measures described in subsection (a) that shall reflect the testing, validation, and consensus process for the development of pediatric quality measures described in subsection paragraphs (1) through (4).

(6) DEFINITION OF PEDIATRIC QUALITY MEASURE.—In this subsection, the term "pediatric quality measure" means a measurement of clinical care that is capable of being examined through the collection and analysis of relevant information, that is developed in order to assess 1 or more aspects of pediatric health care quality in various institutional and ambulatory health care settings, including the structure of the clinical care system, the process of care, the outcome of care, or patient experiences in care.

(7) CONSTRUCTION.—Nothing in this section shall be construed as supporting the restriction of coverage, under title XIX or XXI or otherwise, to only those services that are evidence-based.

(c) ANNUAL STATE REPORTS REGARDING STATE-SPECIFIC QUALITY OF CARE MEASURES APPLIED UNDER MEDICAID OR CHIP.—

(1) ANNUAL STATE REPORTS.—Each State with a State plan approved under title XIX or a State child health plan approved under title XXI shall annually report to the Secretary on the—

(A) State-specific child health quality measures applied by the States under such plans, including measures described in subparagraphs (A) and (B) of subsection (a)(6) and, beginning with the annual report on fiscal year 2024, all of the core measures described in subsection (a) and any updates or changes to those measures; and

(B) State-specific information on the quality of health care furnished to children under such plans, including information collected through external quality reviews of managed care organizations under section 1932 of the So-

cial Security Act (42 U.S.C. 1396u–4) and benchmark plans under sections 1937 and 2103 of such Act (42 U.S.C. 1396u–7, 1397cc).

(2) PUBLICATION.—Not later than September 30, 2010, and annually thereafter, the Secretary shall collect, analyze, and make publicly available the information reported by States under paragraph (1).

(d) DEMONSTRATION PROJECTS FOR IMPROVING THE QUALITY OF CHILDREN'S HEALTH CARE AND THE USE OF HEALTH INFORMATION TECHNOLOGY.—

(1) IN GENERAL.—During the period of fiscal years 2009 through 2013, the Secretary shall award not more than 10 grants to States and child health providers to conduct demonstration projects to evaluate promising ideas for improving the quality of children's health care provided under title XIX or XXI, including projects to—

(A) experiment with, and evaluate the use of, new measures of the quality of children's health care under such titles (including testing the validity and suitability for reporting of such measures);

(B) promote the use of health information technology in care delivery for children under such titles;

(C) evaluate provider-based models which improve the delivery of children's health care services under such titles, including care management for children with chronic conditions and the use of evidence-based approaches to improve the effectiveness, safety, and efficiency of health care services for children; or

(D) demonstrate the impact of the model electronic health record format for children developed and disseminated under subsection (f) on improving pediatric health, including the effects of chronic childhood health conditions, and pediatric health care quality as well as reducing health care costs.

(2) REQUIREMENTS.—In awarding grants under this subsection, the Secretary shall ensure that—

(A) only 1 demonstration project funded under a grant awarded under this subsection shall be conducted in a State; and

(B) demonstration projects funded under grants awarded under this subsection shall be conducted evenly between States with large urban areas and States with large rural areas.

(3) AUTHORITY FOR MULTISTATE PROJECTS.—A demonstration project conducted with a grant awarded under this subsection may be conducted on a multistate basis, as needed.

(4) FUNDING.—$20,000,000 of the amount appropriated under subsection (i) for a fiscal year shall be used to carry out this subsection.

(e) CHILDHOOD OBESITY DEMONSTRATION PROJECT.—

(1) AUTHORITY TO CONDUCT DEMONSTRATION.—The Secretary, in consultation with the Administrator of the Centers for Medicare & Medicaid Services, shall conduct a demonstration project to develop a comprehensive and systematic model

for reducing childhood obesity by awarding grants to eligible entities to carry out such project. Such model shall—

(A) identify, through self-assessment, behavioral risk factors for obesity among children;

(B) identify, through self-assessment, needed clinical preventive and screening benefits among those children identified as target individuals on the basis of such risk factors;

(C) provide ongoing support to such target individuals and their families to reduce risk factors and promote the appropriate use of preventive and screening benefits; and

(D) be designed to improve health outcomes, satisfaction, quality of life, and appropriate use of items and services for which medical assistance is available under title XIX or child health assistance is available under title XXI among such target individuals.

(2) ELIGIBILITY ENTITIES.—For purposes of this subsection, an eligible entity is any of the following:

(A) A city, county, or Indian tribe.

(B) A local or tribal educational agency.

(C) An accredited university, college, or community college.

(D) A Federally-qualified health center.

(E) A local health department.

(F) A health care provider.

(G) A community-based organization.

(H) Any other entity determined appropriate by the Secretary, including a consortia or partnership of entities described in any of subparagraphs (A) through (G).

(3) USE OF FUNDS.—An eligible entity awarded a grant under this subsection shall use the funds made available under the grant to—

(A) carry out community-based activities related to reducing childhood obesity, including by—

(i) forming partnerships with entities, including schools and other facilities providing recreational services, to establish programs for after school and weekend community activities that are designed to reduce childhood obesity;

(ii) forming partnerships with daycare facilities to establish programs that promote healthy eating behaviors and physical activity; and

(iii) developing and evaluating community educational activities targeting good nutrition and promoting healthy eating behaviors;

(B) carry out age-appropriate school-based activities that are designed to reduce childhood obesity, including by—

(i) developing and testing educational curricula and intervention programs designed to promote healthy eating behaviors and habits in youth, which may include—

(I) after hours physical activity programs; and

(II) science-based interventions with multiple components to prevent eating disorders including nutritional content, understanding and responding to hunger and satiety, positive body image development, positive self-esteem development, and learning life skills (such as stress management, communication skills, problemsolving and decisionmaking skills), as well as consideration of cultural and developmental issues, and the role of family, school, and community;

(ii) providing education and training to educational professionals regarding how to promote a healthy lifestyle and a healthy school environment for children;

(iii) planning and implementing a healthy lifestyle curriculum or program with an emphasis on healthy eating behaviors and physical activity; and

(iv) planning and implementing healthy lifestyle classes or programs for parents or guardians, with an emphasis on healthy eating behaviors and physical activity for children;

(C) carry out educational, counseling, promotional, and training activities through the local health care delivery systems including by—

(i) promoting healthy eating behaviors and physical activity services to treat or prevent eating disorders, being overweight, and obesity;

(ii) providing patient education and counseling to increase physical activity and promote healthy eating behaviors;

(iii) training health professionals on how to identify and treat obese and overweight individuals which may include nutrition and physical activity counseling; and

(iv) providing community education by a health professional on good nutrition and physical activity to develop a better understanding of the relationship between diet, physical activity, and eating disorders, obesity, or being overweight; and

(D) provide, through qualified health professionals, training and supervision for community health workers to—

(i) educate families regarding the relationship between nutrition, eating habits, physical activity, and obesity;

(ii) educate families about effective strategies to improve nutrition, establish healthy eating patterns, and establish appropriate levels of physical activity; and

(iii) educate and guide parents regarding the ability to model and communicate positive health behaviors.

(4) PRIORITY.—In awarding grants under paragraph (1), the Secretary shall give priority to awarding grants to eligible entities—

(A) that demonstrate that they have previously applied successfully for funds to carry out activities that seek to promote individual and community health and to prevent the incidence of chronic disease and that can cite published and peer-reviewed research demonstrating that the activities that the entities propose to carry out with funds made available under the grant are effective;

(B) that will carry out programs or activities that seek to accomplish a goal or goals set by the State in the Healthy People 2010 plan of the State;

(C) that provide non-Federal contributions, either in cash or in-kind, to the costs of funding activities under the grants;

(D) that develop comprehensive plans that include a strategy for extending program activities developed under grants in the years following the fiscal years for which they receive grants under this subsection;

(E) located in communities that are medically underserved, as determined by the Secretary;

(F) located in areas in which the average poverty rate is at least 150 percent or higher of the average poverty rate in the State involved, as determined by the Secretary; and

(G) that submit plans that exhibit multisectoral, cooperative conduct that includes the involvement of a broad range of stakeholders, including—

(i) community-based organizations;

(ii) local governments;

(iii) local educational agencies;

(iv) the private sector;

(v) State or local departments of health;

(vi) accredited colleges, universities, and community colleges;

(vii) health care providers;

(viii) State and local departments of transportation and city planning; and

(ix) other entities determined appropriate by the Secretary.

(5) PROGRAM DESIGN.—

(A) INITIAL DESIGN.—Not later than 1 year after the date of enactment of the Children's Health Insurance Program Reauthorization Act of 2009, the Secretary shall design the demonstration project. The demonstration should draw upon promising, innovative models and incentives to reduce behavioral risk factors. The Administrator of the Centers for Medicare & Medicaid Services shall consult with the Director of the Centers for Disease Control and Prevention, the Director of the Office of Minority Health, the heads of other agencies in the Department of Health and Human Services, and such professional organizations,

as the Secretary determines to be appropriate, on the design, conduct, and evaluation of the demonstration.

(B) NUMBER AND PROJECT AREAS.—Not later than 2 years after the date of enactment of the Children's Health Insurance Program Reauthorization Act of 2009, the Secretary shall award 1 grant that is specifically designed to determine whether programs similar to programs to be conducted by other grantees under this subsection should be implemented with respect to the general population of children who are eligible for child health assistance under State child health plans under title XXI in order to reduce the incidence of childhood obesity among such population.

(6) REPORT TO CONGRESS.—Not later than 3 years after the date the Secretary implements the demonstration project under this subsection, the Secretary shall submit to Congress a report that describes the project, evaluates the effectiveness and cost effectiveness of the project, evaluates the beneficiary satisfaction under the project, and includes any such other information as the Secretary determines to be appropriate.

(7) DEFINITIONS.—In this subsection:

(A) FEDERALLY-QUALIFIED HEALTH CENTER.—The term "Federally-qualified health center" has the meaning given that term in section 1905(l)(2)(B).

(B) INDIAN TRIBE.—The term "Indian tribe" has the meaning given that term in section 4 of the Indian Health Care Improvement Act (25 U.S.C. 1603).

(C) SELF-ASSESSMENT.—The term "self-assessment" means a form that—

(i) includes questions regarding—

(I) behavioral risk factors;

(II) needed preventive and screening services; and

(III) target individuals' preferences for receiving follow-up information;

(ii) is assessed using such computer generated assessment programs; and

(iii) allows for the provision of such ongoing support to the individual as the Secretary determines appropriate.

(D) ONGOING SUPPORT.—The term "ongoing support" means—

(i) to provide any target individual with information, feedback, health coaching, and recommendations regarding—

(I) the results of a self-assessment given to the individual;

(II) behavior modification based on the self-assessment; and

(III) any need for clinical preventive and screening services or treatment including medical nutrition therapy;

(ii) to provide any target individual with referrals to community resources and programs available to assist the target individual in reducing health risks; and

(iii) to provide the information described in clause (i) to a health care provider, if designated by the target individual to receive such information.

(8) APPROPRIATION.—Out of any funds in the Treasury not otherwise appropriated, there is appropriated to carry out this subsection, $25,000,000 for the period of fiscal years 2010 through 2014,, $10,000,000 for the period of fiscal years 2016 and 2017, and $30,000,000 for the period of fiscal years 2018 through 2023.

(f) DEVELOPMENT OF MODEL ELECTRONIC HEALTH RECORD FORMAT FOR CHILDREN ENROLLED IN MEDICAID OR CHIP.—

(1) IN GENERAL.—Not later than January 1, 2010, the Secretary shall establish a program to encourage the development and dissemination of a model electronic health record format for children enrolled in the State plan under title XIX or the State child health plan under title XXI that is—

(A) subject to State laws, accessible to parents, caregivers, and other consumers for the sole purpose of demonstrating compliance with school or leisure activity requirements, such as appropriate immunizations or physicals;

(B) designed to allow interoperable exchanges that conform with Federal and State privacy and security requirements;

(C) structured in a manner that permits parents and caregivers to view and understand the extent to which the care their children receive is clinically appropriate and of high quality; and

(D) capable of being incorporated into, and otherwise compatible with, other standards developed for electronic health records.

(2) FUNDING.—$5,000,000 of the amount appropriated under subsection (i) for a fiscal year shall be used to carry out this subsection.

(g) STUDY OF PEDIATRIC HEALTH AND HEALTH CARE QUALITY MEASURES.—

(1) IN GENERAL.—Not later than July 1, 2010, the Institute of Medicine shall study and report to Congress on the extent and quality of efforts to measure child health status and the quality of health care for children across the age span and in relation to preventive care, treatments for acute conditions, and treatments aimed at ameliorating or correcting physical, mental, and developmental conditions in children. In conducting such study and preparing such report, the Institute of Medicine shall—

(A) consider all of the major national population-based reporting systems sponsored by the Federal Government that are currently in place, including reporting requirements under Federal grant programs and national population surveys and estimates conducted directly by the Federal Government;

(B) identify the information regarding child health and health care quality that each system is designed to capture and generate, the study and reporting periods covered by

each system, and the extent to which the information so generated is made widely available through publication;

(C) identify gaps in knowledge related to children's health status, health disparities among subgroups of children, the effects of social conditions on children's health status and use and effectiveness of health care, and the relationship between child health status and family income, family stability and preservation, and children's school readiness and educational achievement and attainment; and

(D) make recommendations regarding improving and strengthening the timeliness, quality, and public transparency and accessibility of information about child health and health care quality.

(2) FUNDING.—Up to $1,000,000 of the amount appropriated under subsection (i) for a fiscal year shall be used to carry out this subsection.

(h) RULE OF CONSTRUCTION.—Notwithstanding any other provision in this section, no evidence based quality measure developed, published, or used as a basis of measurement or reporting under this section may be used to establish an irrebuttable presumption regarding either the medical necessity of care or the maximum permissible coverage for any individual child who is eligible for and receiving medical assistance under title XIX or child health assistance under title XXI.

(i) APPROPRIATION.—

(1) IN GENERAL.—Out of any funds in the Treasury not otherwise appropriated, there is appropriated—

(A) for each of fiscal years 2009 through 2013, $45,000,000 for the purpose of carrying out this section (other than subsection (e));

(B) for the period of fiscal years 2016 and 2017, $20,000,000 for the purpose of carrying out this section (other than subsections (e), (f), and (g));

(C) for the period of fiscal years 2018 through 2023, $90,000,000 for the purpose of carrying out this section (other than subsections (e), (f), and (g));

(D) for the period of fiscal years 2024 through 2027, $60,000,000 for the purpose of carrying out this section (other than subsections (e), (f), and (g)); and

(E) for each of fiscal years 2028 and 2029, $15,000,000 for the purpose of carrying out this section (other than subsections (e), (f), and (g)).

(2) AVAILABILITY.—Funds appropriated under this subsection shall remain available until expended.

SEC. 1139B. [42 U.S.C. 1320b–9b] ADULT HEALTH QUALITY MEASURES.

(a) DEVELOPMENT OF CORE SET OF HEALTH CARE QUALITY MEASURES FOR ADULTS ELIGIBLE FOR BENEFITS UNDER MEDICAID.—The Secretary shall identify and publish a recommended core set of adult health quality measures for Medicaid eligible adults in the same manner as the Secretary identifies and publishes a core set of child health quality measures under section 1139A, including with respect to identifying and publishing exist-

ing adult health quality measures that are in use under public and privately sponsored health care coverage arrangements, or that are part of reporting systems that measure both the presence and duration of health insurance coverage over time, that may be applicable to Medicaid eligible adults.

(b) DEADLINES.—

(1) RECOMMENDED MEASURES.—Not later than January 1, 2011, the Secretary shall identify and publish for comment a recommended core set of adult health quality measures for Medicaid eligible adults.

(2) DISSEMINATION.—Not later than January 1, 2012, the Secretary shall publish an initial core set of adult health quality measures that are applicable to Medicaid eligible adults.

(3) STANDARDIZED REPORTING.—

(A) VOLUNTARY REPORTING.—Not later than January 1, 2013, the Secretary, in consultation with States, shall develop a standardized format for reporting information based on the initial core set of adult health quality measures and create procedures to encourage States to use such measures to voluntarily report information regarding the quality of health care for Medicaid eligible adults.

(B) MANDATORY REPORTING WITH RESPECT TO BEHAVIORAL HEALTH MEASURES.—Beginning with the State report required under subsection (d)(1) for 2024, the Secretary shall require States to use all behavioral health measures included in the core set of adult health quality measures and any updates or changes to such measures to report information, using the standardized format for reporting information and procedures developed under subparagraph (A), regarding the quality of behavioral health care for Medicaid eligible adults.

(4) REPORTS TO CONGRESS.—Not later than January 1, 2014, and every 3 years thereafter, the Secretary shall include in the report to Congress required under section 1139A(a)(6) information similar to the information required under that section with respect to the measures established under this section.

(5) ESTABLISHMENT OF MEDICAID QUALITY MEASUREMENT PROGRAM.—

(A) IN GENERAL.—Not later than 12 months after the release of the recommended core set of adult health quality measures under paragraph (1)), the Secretary shall establish a Medicaid Quality Measurement Program in the same manner as the Secretary establishes the pediatric quality measures program under section 1139A(b).

(B) REVISING, STRENGTHENING, AND IMPROVING INITIAL CORE MEASURES.—Beginning not later than 24 months after the establishment of the Medicaid Quality Measurement Program, and annually thereafter, the Secretary shall publish recommended changes to the initial core set of adult health quality measures that shall reflect the results of the testing, validation, and consensus process for the development of adult health quality measures.

(C) BEHAVIORAL HEALTH MEASURES.—Beginning with respect to State reports required under subsection (d)(1) for 2024, the core set of adult health quality measures maintained under this paragraph (and any updates or changes to such measures) shall include behavioral health measures.

(c) CONSTRUCTION.—Nothing in this section shall be construed as supporting the restriction of coverage, under title XIX or XXI or otherwise, to only those services that are evidence-based, or in anyway limiting available services.

(d) ANNUAL STATE REPORTS REGARDING STATE-SPECIFIC QUALITY OF CARE MEASURES APPLIED UNDER MEDICAID.—

(1) ANNUAL STATE REPORTS.—Each State with a State plan or waiver approved under title XIX shall annually report (separately or as part of the annual report required under section 1139A(c)), to the Secretary on the—

(A) State-specific adult health quality measures applied by the State under such plan, including measures described in subsection (b)(5) and, beginning with the report for 2024, all behavioral health measures included in the core set of adult health quality measures maintained under such subsection (b)(5) and any updates or changes to such measures (as required under subsection (b)(3)); and

(B) State-specific information on the quality of health care furnished to Medicaid eligible adults under such plan, including information collected through external quality reviews of managed care organizations under section 1932 and benchmark plans under section 1937.

(2) PUBLICATION.—Not later than September 30, 2014, and annually thereafter, the Secretary shall collect, analyze, and make publicly available the information reported by States under paragraph (1).

(e) APPROPRIATION.—Out of any funds in the Treasury not otherwise appropriated, there is appropriated for each of fiscal years 2010 through 2014, $60,000,000 for the purpose of carrying out this section. Funds appropriated under this subsection shall remain available until expended. Of the funds appropriated under this subsection, not less than $15,000,000 shall be used to carry out section 1139A(b).

PROHIBITIONS RELATING TO REFERENCES TO SOCIAL SECURITY OR MEDICARE

SEC. 1140. [42 U.S.C. 1320b–10] (a)(1) No person may use, in connection with any item constituting an advertisement, solicitation, circular, book, pamphlet, or other communication (including any Internet or other electronic communication), or a play, motion picture, broadcast, telecast, or other production, alone or with other words, letters, symbols, or emblems—

(A) the words "Social Security", "Social Security Account", "Social Security System", "Social Security Administration", "Medicare", "Centers for Medicare & Medicaid Services[22]",

[22] Section 207(a) of public Law 108–203 in several places purported to amend section 1140(a)(1) to add references to the "Centers for Medicare & Medicaid Services" and "CMS".

"Department of Health and Human Services", "Health and Human Services", "Supplemental Security Income Program", "Medicaid", "Death Benefits Update", "Federal Benefit Information", "Funeral Expenses", or "Final Supplemental Plan", the letters "SSA", "CMS", "DHHS", "HHS", or "SSI", or any other combination or variation of such words or letters, or

(B) a symbol or emblem of the Social Security Administration, Centers for Medicare & Medicaid Services [22], or Department of Health and Human Services (including the design of, or a reasonable facsimile of the design of, the social security card issued pursuant to section 205(c)(2)(F), or the Medicare card the check used for payment of benefits under title II, or envelopes or other stationery used by the Social Security Administration, Centers for Medicare & Medicaid Services [22], or Department of Health and Human Services) or any other combination or variation of such symbols or emblems,

in a manner which such person knows or should know would convey, or in a manner which reasonably could be interpreted or construed as conveying, the false impression that such item is approved, endorsed, or authorized by the Social Security Administration, the Centers for Medicare & Medicaid Services [22], or the Department of Health and Human Services or that such person has some connection with, or authorization from, the Social Security Administration, the Centers for Medicare & Medicaid Services [22], or the Department of Health and Human Services. The preceding provisions of this subsection shall not apply with respect to the use by any agency or instrumentality of a State or political subdivision of a State of any words or letters which identify an agency or instrumentality of such State or of a political subdivision of such State or the use by any such agency or instrumentality of any symbol or emblem of an agency or instrumentality of such State or a political subdivision of such State.

(2)(A) No person may, for a fee, reproduce, reprint, or distribute any item consisting of a form, application, or other publication of the Social Security Administration unless such person has obtained specific, written authorization for such activity in accordance with regulations which the Commissioner of Social Security shall prescribe.

(B) No person may, for a fee, reproduce, reprint, or distribute any item consisting of a form, application, or other publication of the Department of Health and Human Services unless such person has obtained specific, written authorization for such activity in accordance with regulations which the Secretary shall prescribe.

(3) Any determination of whether the use of one or more words, letters, symbols, or emblems (or any combination or variation thereof) in connection with an item described in paragraph (1) or the reproduction, reprinting, or distribution of an item described in paragraph (2) is a violation of this subsection shall be made without regard to any inclusion in such item (or any so reproduced, reprinted, or distributed copy thereof) of a disclaimer of af-

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These amendments were not executable by reason of the ealier enactment of Public Law 108–173.

filiation with the United States Government or any particular agency or instrumentality thereof.

(4)(A) No person shall offer, for a fee, to assist an individual to obtain a product or service that the person knows or should know is provided free of charge by the Social Security Administration unless, at the time the offer is made, the person provides to the individual to whom the offer is tendered a notice that—

(i) explains that the product or service is available free of charge from the Social Security Administration, and

(ii) complies with standards prescribed by the Commissioner of Social Security respecting the content of such notice and its placement, visibility, and legibility.

(B) Subparagraph (A) shall not apply to any offer—

(i) to serve as a claimant representative in connection with a claim arising under title II, title VIII, or title XVI; or

(ii) to prepare, or assist in the preparation of, an individual's plan for achieving self-support under title XVI.

(b) The Commissioner or the Secretary (as applicable) may, pursuant to regulations, impose a civil money penalty not to exceed—

(1) except as provided in paragraph (2), $5,000, or

(2) in the case of a violation consisting of a broadcast or telecast, $25,000,

against any person for each violation by such person of subsection (a). In the case of any items referred to in subsection (a)(1) consisting of pieces of mail, each such piece of mail which contains one or more words, letters, symbols, or emblems in violation of subsection (a) shall represent a separate violation. In the case of any items referred to in subsection (a)(1) consisting of Internet or other electronic communications, each dissemination, viewing, or accessing of such a communication which contains one or more words, letters, symbols, or emblems in violation of subsection (a) shall represent a separate violation [23] In the case of any item referred to in subsection (a)(2), the reproduction, reprinting, or distribution of such item shall be treated as a separate violation with respect to each copy thereof so reproduced, reprinted, or distributed.

(c)(1) The provisions of section 1128A (other than subsections (a), (b), (f), (h), and (i) and the first sentence of subsection (c)) shall apply to civil money penalties under subsection (b) in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(2) Penalties imposed against a person under subsection (b) may be compromised by the Commissioner or the Secretary (as applicable) and may be recovered in a civil action in the name of the United States brought in the district court of the United States for the district in which the violation occurred or where the person resides, has its principal office, or may be found, as determined by the Commissioner or the Secretary (as applicable). Amounts recovered under this section shall be paid to the Secretary and shall be deposited as miscellaneous receipts of the Treasury of the United States, except that (A) to the extent that such amounts are recov-

[23] There is no period at the end of the third sentence. See amendment made to insert such sentence after the second sentence by section 814(b) of Public Law 114–74.

ered under this section as penalties imposed for misuse of words, letters, symbols, or emblems relating to the Social Security Administration, such amounts shall be deposited into the Federal Old-Age and Survivors Insurance Trust Fund, and (B) to the extent that such amounts are recovered under this section as penalties imposed for misuse of words, letters, symbols, or emblems relating to the Department of Health and Human Services, such amounts shall be deposited into the Federal Hospital Insurance Trust Fund or the Federal Supplementary Medical Insurance Trust Fund, as appropriate. The amount of such penalty when finally determined, or the amount agreed upon in compromise, may be deducted from any sum then or later owing by the United States to the person against whom the penalty has been imposed.

(d) The preceding provisions of this section may be enforced through the Office of the Inspector General of the Social Security Administration or the Office of the Inspector General of the Department of Health and Human Services (as appropriate).

BLOOD DONOR LOCATOR SERVICE

SEC. 1141. [42 U.S.C. 1320b–11] (a) IN GENERAL.—The Secretary shall establish and conduct a Blood Donor Locator Service, under the direction of the Commissioner of Social Security, which shall be used to obtain and transmit to any authorized person (as defined in subsection (h)(1)) the most recent mailing address of any blood donor who, as indicated by the donated blood or products derived therefrom or by the history of the subsequent use of such blood or blood products, has or may have the virus for acquired immune deficiency syndrome, in order to inform such donor of the possible need for medical care and treatment.

(b) PROVISION OF ADDRESS INFORMATION.—Whenever the Secretary receives a request, filed by an authorized person (as defined in subsection (h)(1)), for the mailing address of a donor described in subsection (a) and the Secretary is reasonably satisfied that the requirements of this section have been met with respect to such request, the Secretary shall promptly undertake to provide the requested address information from—

(1) the files and records maintained by the Social Security Administration, and

(2) such files and records obtained pursuant to section 6103(m)(6) of the Internal Revenue Code of 1986 as the Secretary considers necessary to comply with such request.

(c) MANNER AND FORM OF REQUESTS.—A request for address information under this section shall be filed in such manner and form as the Secretary shall by regulation prescribe, shall include the blood donor's social security account number, and shall be accompanied or supported by such documents as the Secretary may determine to be necessary.

(d) PROCEDURES AND SAFEGUARDS.—Any authorized person shall, as a condition for receiving address information from the Blood Donor Locator Service—

(1) establish and maintain, to the satisfaction of the Secretary, a system for standardizing records with respect to any request, the reason for such request, and the date of such re-

quest made by or of it and any disclosure of address information made by or to it,

(2) establish and maintain, to the satisfaction of the Secretary, a secure area or place in which such address information and all related blood donor records shall be stored,

(3) restrict, to the satisfaction of the Secretary, access to the address information and related blood donor records only to persons whose duties or responsibilities require access and to whom disclosure may be made under the provisions of this section,

(4) provide such other safeguards which the Secretary determines (and which the Secretary prescribes in regulations) to be necessary or appropriate to protect the confidentiality of the address information and related blood donor records,

(5) furnish a report to the Secretary, at such time and containing such information as the Secretary may prescribe, which describes the procedures established and utilized by the authorized person for ensuring the confidentiality of address information and related blood donor records required under this subsection, and

(6) destroy such address information and related blood donor records, upon completion of their use in providing the notification for which the information was obtained, so as to make such information and records undisclosable.

If the Secretary determines that any authorized person has failed to, or does not, meet the requirements of this subsection, the Secretary may, after any proceedings for review established under subsection (f), take such actions as are necessary to ensure such requirements are met, including refusing to disclose address information to such authorized person until the Secretary determines that such requirements have been or will be met. In the case of any authorized person who discloses any address information received pursuant to this section or any related blood donor records to any agent, this subsection shall apply to such authorized person and each such agent (except that, in the case of an agent, any report to the Secretary or other action with respect to the Secretary shall be made or taken through such authorized person). The Secretary shall destroy all related blood donor records in the possession of the Department of Health and Human Services upon completion of their use in transmitting mailing addresses as required under subsection (a), so as to make such records undisclosable.

(e) ARRANGEMENTS WITH STATE AGENCIES AND AUTHORIZED PERSONS.—The Secretary, in carrying out the Secretary's duties and functions under this section, shall enter into arrangements—

(1) with State agencies to accept and to transmit to the Secretary requests for address information under this section and to accept and to transmit such information to authorized persons, and

(2) with State agencies and authorized persons otherwise to cooperate with the Secretary in carrying out the purposes of this section.

(f) PROCEDURES FOR ADMINISTRATIVE REVIEW.—The Secretary shall by regulation prescribe procedures which provide for adminis-

trative review of any determination that any authorized person has failed to meet the requirements of this section.

(g) UNAUTHORIZED DISCLOSURE OF INFORMATION.—Paragraphs (1), (2), and (3) of section 7213(a) of the Internal Revenue Code of 1986 shall apply with respect to the unauthorized willful disclosure to any person of address information or related blood donor records acquired or maintained by or under the Secretary, or pursuant to this section by any authorized person, or of information derived from any such address information or related blood donor records, in the same manner and to the same extent as such paragraphs apply with respect to unauthorized disclosures of return and return information described in such paragraphs. Paragraph (4) of section 7213(a) of such Code shall apply with respect to the willful offer of any item of material value in exchange for any such address information or related blood donor record in the same manner and to the same extent as such paragraph applies with respect to offers (in exchange for any return or return information) described in such paragraph.

(h) DEFINITIONS.—For purposes of this section—

(1) AUTHORIZED PERSON.—The term "authorized person" means—

(A) any agency of a State (or of a political subdivision of a State) which has duties or authority under State law relating to the public health or otherwise has the duty or authority under State law to regulate blood donations, and

(B) any entity engaged in the acceptance of blood donations which is licensed or registered by the Food and Drug Administration in connection with the acceptance of such blood donations, and which, in accordance with such regulations as may be prescribed by the Secretary, provides for—

(i) the confidentiality of any address information received pursuant to this section and related blood donor records,

(ii) blood donor notification procedures for individuals with respect to whom such information is requested and a finding has been made that they have or may have the virus for acquired immune deficiency syndrome, and

(iii) counseling services for such individuals who have been found to have such virus.

(2) RELATED BLOOD DONOR RECORD.—The term "related blood donor record" means any record, list, or compilation which indicates, directly or indirectly, the identity of any individual with respect to whom a request for address information has been made pursuant to this section.

(3) STATE.—The term "State" includes the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Commonwealth of the Northern Marianas, and the Trust Territory of the Pacific Islands.

RESEARCH ON OUTCOMES OF HEALTH CARE SERVICES AND PROCEDURES

SEC. 1142. [42 U.S.C. 1320b–12] (a) ESTABLISHMENT OF PROGRAM.—

(1) IN GENERAL.—The Secretary, acting through the Administrator for Health Care Policy and Research [24], shall—

(A) conduct and support research with respect to the outcomes, effectiveness, and appropriateness of health care services and procedures in order to identify the manner in which diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically; and

(B) assure that the needs and priorities of the program under title XVIII are appropriately reflected in the development and periodic review and updating (through the process set forth in section 913 of the Public Health Service Act) of treatment-specific or condition-specific practice guidelines for clinical treatments and conditions in forms appropriate for use in clinical practice, for use in educational programs, and for use in reviewing quality and appropriateness of medical care.

(2) EVALUATIONS OF ALTERNATIVE SERVICES AND PROCEDURES.—In carrying out paragraph (1), the Secretary shall conduct or support evaluations of the comparative effects, on health and functional capacity, of alternative services and procedures utilized in preventing, diagnosing, treating, and clinically managing diseases, disorders, and other health conditions.

(3) INITIAL GUIDELINES.—

(A) In carrying out paragraph (1)(B) of this subsection, and section 912(d) of the Public Health Service Act, the Secretary shall, by not later than January 1, 1991, assure the development of an initial set of the guidelines specified in paragraph (1)(B) that shall include not less than 3 clinical treatments or conditions that—

(i)(I) account for a significant portion of expenditures under title XVIII; and

(II) have a significant variation in the frequency or the type of treatment provided; or

(ii) otherwise meet the needs and priorities of the program under title XVIII, as set forth under subsection (b)(3).

(B)(i) The Secretary shall provide for the use of guidelines developed under subparagrah [25] (A) to improve the quality, effectiveness, and appropriateness of care provided under title XVIII. The Secretary shall determine the impact of such use on the quality, appropriateness, effectiveness, and cost of medical care provided under such title

[24] Pursuant to section 2(b)(2) of Public Law 106–129 (113 Stat. 1670), the reference shall be considered to be a reference to the Director of the Agency for Healthcare Research and Quality.

[25] As in original; should be "subparagraph".

and shall report to the Congress on such determination by not later than January 1, 1993.

(ii) For the purpose of carrying out clause (i), the Secretary shall expend, from the amounts specified in clause (iii), $1,000,000 for fiscal year 1990 and $1,500,000 for each of the fiscal years 1991 and 1992.

(iii) For each fiscal year, for purposes of expenditures required in clause (ii)—

(I) 60 percent of an amount equal to the expenditure involved is appropriated from the Federal Hospital Insurance Trust Fund (established under section 1817); and

(II) 40 percent of an amount equal to the expenditure involved is appropriated from the Federal Supplementary Medical Insurance Trust Fund (established under section 1841).

(b) PRIORITIES.—

(1) IN GENERAL.—The Secretary shall establish priorities with respect to the diseases, disorders, and other health conditions for which research and evaluations are to be conducted or supported under subsection (a). In establishing such priorities, the Secretary shall, with respect to a disease, disorder, or other health condition, consider the extent to which—

(A) improved methods of prevention, diagnosis, treatment, and clinical management can benefit a significant number of individuals;

(B) there is significant variation among physicians in the particular services and procedures utilized in making diagnoses and providing treatments or there is significant variation in the outcomes of health care services or procedures due to different patterns of diagnosis or treatment;

(C) the services and procedures utilized for diagnosis and treatment result in relatively substantial expenditures; and

(D) the data necessary for such evaluations are readily available or can readily be developed.

(2) PRELIMINARY ASSESSMENTS.—For the purpose of establishing priorities under paragraph (1), the Secretary may, with respect to services and procedures utilized in preventing, diagnosing, treating, and clinically managing diseases, disorders, and other health conditions, conduct or support assessments of the extent to which—

(A) rates of utilization vary among similar populations for particular diseases, disorders, and other health conditions;

(B) uncertainties exist on the effect of utilizing a particular service or procedure; or

(C) inappropriate services and procedures are provided.

(3) RELATIONSHIP WITH MEDICARE PROGRAM.—In establishing priorities under paragraph (1) for research and evaluation, and under section 914(a) of the Public Health Service Act for the agenda under such section, the Secretary shall assure that such priorities appropriately reflect the needs and prior-

ities of the program under title XVIII, as set forth by the Administrator of the Centers for Medicare & Medicaid Services.

(c) METHODOLOGIES AND CRITERIA FOR EVALUATIONS.—For the purpose of facilitating research under subsection (a), the Secretary shall—

(1) conduct and support research with respect to the improvement of methodologies and criteria utilized in conducting research with respect to outcomes of health care services and procedures;

(2) conduct and support reviews and evaluations of existing research findings with respect to such treatment or conditions;

(3) conduct and support reviews and evaluations of the existing methodologies that use large data bases in conducting such research and shall develop new research methodologies, including data-based methods of advancing knowledge and methodologies that measure clinical and functional status of patients, with respect to such research;

(4) provide grants and contracts to research centers, and contracts to other entities, to conduct such research on such treatment or conditions, including research on the appropriate use of prescription drugs;

(5) conduct and support research and demonstrations on the use of claims data and data on clinical and functional status of patients in determining the outcomes, effectiveness, and appropriateness of such treatment; and

(6) conduct and support supplementation of existing data bases, including the collection of new information, to enhance data bases for research purposes, and the design and development of new data bases that would be used in outcomes and effectiveness research.

(d) STANDARDS FOR DATA BASES.—In carrying out this section, the Secretary shall develop—

(1) uniform definitions of data to be collected and used in describing a patient's clinical and functional status;

(2) common reporting formats and linkages for such data; and

(3) standards to assure the security, confidentiality, accuracy, and appropriate maintenance of such data.

(e) DISSEMINATION OF RESEARCH FINDINGS AND GUIDELINES.—

(1) IN GENERAL.—The Secretary shall provide for the dissemination of the findings of research and the guidelines described in subsection (a), and for the education of providers and others in the application of such research findings and guidelines.

(2) COOPERATIVE EDUCATIONAL ACTIVITIES.—In disseminating findings and guidelines under paragraph (1), and in providing for education under such paragraph, the Secretary shall work with professional associations, medical specialty and subspecialty organizations, and other relevant groups to identify and implement effective means to educate physicians, other providers, consumers, and others in using such findings and guidelines, including training for physician managers within provider organizations.

(f) EVALUATIONS.—The Secretary shall conduct and support evaluations of the activities carried out under this section to determine the extent to which such activities have had an effect on the practices of physicians in providing medical treatment, the delivery of health care, and the outcomes of health care services and procedures.

(g) RESEARCH WITH RESPECT TO DISSEMINATION.—The Secretary may conduct or support research with respect to improving methods of disseminating information on the effectiveness and appropriateness of health care services and procedures.

(h) REPORT TO CONGRESS.—Not later than February 1 of each of the years 1991 and 1992, and of each second year thereafter, the Secretary shall report to the Congress on the progress of the activities under this section during the preceding fiscal year (or preceding 2 fiscal years, as appropriate), including the impact of such activities on medical care (particularly medical care for individuals receiving benefits under title XVIII).

(i) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.—There are authorized to be appropriated to carry out this section—

(A) $50,000,000 for fiscal year 1990;
(B) $75,000,000 for fiscal year 1991;
(C) $110,000,000 for fiscal year 1992;
(D) $148,000,000 for fiscal year 1993; and
(E) $185,000,000 for fiscal year 1994.

(2) SPECIFICATIONS.—For the purpose of carrying out this section, for each of the fiscal years 1990 through 1992 an amount equal to two-thirds of the amounts authorized to be appropriated under paragraph (1), and for each of the fiscal years 1993 and 1994 an amount equal to 70 percent of such amounts, are to be appropriated in the following proportions from the following trust funds:

(A) 60 percent from the Federal Hospital Insurance Trust Fund (established under section 1817).

(B) 40 percent from the Federal Supplementary Medical Insurance Trust Fund (established under section 1841).

(3) ALLOCATIONS.—

(A) For each fiscal year, of the amounts transferred or otherwise appropriated to carry out this section, the Secretary shall reserve appropriate amounts for each of the purposes specified in clauses (i) through (iv) of subparagraph (B).

(B) The purposes referred to in subparagraph (A) are—

(i) the development of guidelines, standards, performance measures, and review criteria;
(ii) research and evaluation;
(iii) data-base standards and development; and
(iv) education and information dissemination.

SOCIAL SECURITY ACCOUNT STATEMENTS

Provision Upon Request

SEC. 1143. [42 U.S.C. 1320b–13] (a)(1) Beginning not later than October 1, 1990, the Commissioner of Social Security shall provide upon the request of an eligible individual a social security account statement (hereinafter referred to as the "statement").

(2) Each statement shall contain—

(A) the amount of wages paid to and self-employment income derived by the eligible individual as shown by the records of the Commissioner at the date of the request;

(B) an estimate of the aggregate of the employer, employee, and self-employment contributions of the eligible individual for old-age, survivors, and disability insurance as shown by the records of the Commissioner on the date of the request;

(C) a separate estimate of the aggregate of the employer, employee, and self-employment contributions of the eligible individual for hospital insurance as shown by the records of the Commissioner on the date of the request;

(D) an estimate of the potential monthly retirement, disability, survivor, and auxiliary benefits payable on the eligible individual's account together with a description of the benefits payable under the medicare program of title XVIII; and

(E) in the case of an eligible individual described in paragraph (3)(C)(ii), an explanation, in language calculated to be understood by the average eligible individual, of the operation of the provisions under sections 202(k)(5) and 215(a)(7) and an explanation of the maximum potential effects of such provisions on the eligible individual's monthly retirement, survivor, and auxiliary benefits.

(3) For purposes of this section, the term "eligible individual" means an individual—

(A) who has a social security account number,

(B) who has attained age 25 or over, and

(C)(i) has wages or net earnings from self-employment, or (ii) with respect to whom the Commissioner has information that the pattern of wages or self-employment income indicate a likelihood of noncovered employment.

Notice to Eligible Individuals

(b) The Commissioner shall, to the maximum extent practicable, take such steps as are necessary to assure that eligible individuals are informed of the availability of the statement described in subsection (a).

Mandatory Provision of Statements

(c)(1) By not later than September 30, 1995, the Commissioner shall provide a statement to each eligible individual who has attained age 60 by October 1, 1994, and who is not receiving benefits under title II and for whom a current mailing address can be determined through such methods as the Commissioner determines to be appropriate. In fiscal years 1995 through 1999 the Commissioner shall provide a statement to each eligible individual who at-

tains age 60 in such fiscal years and who is not receiving benefits under title II and for whom a current mailing address can be determined through such methods as the Commissioner determines to be appropriate. The Commissioner shall provide with each statement to an eligible individual notice that such statement is updated annually and is available upon request.

(2) Beginning not later than October 1, 1999, the Commissioner shall provide a statement on an annual basis to each eligible individual who is not receiving benefits under title II and for whom a mailing address can be determined through such methods as the Commissioner determines to be appropriate. With respect to statements provided to eligible individuals who have not attained age 50, such statements need not include estimates of monthly retirement benefits. However, if such statements provided to eligible individuals who have not attained age 50 do not include estimates of retirement benefit amounts, such statements shall include a description of the benefits (including auxiliary benefits) that are available upon retirement.

Disclosure to Governmental Employees of Effect of Noncovered Employment

(d)(1) In the case of any individual commencing employment on or after January 1, 2005, in any agency or instrumentality of any State (or political subdivision thereof, as defined in section 218(b)(2)) in a position in which service performed by the individual does not constitute "employment" as defined in section 210, the head of the agency or instrumentality shall ensure that, prior to the date of the commencement of the individual's employment in the position, the individual is provided a written notice setting forth an explanation, in language calculated to be understood by the average individual, of the maximum effect on computations of primary insurance amounts (under section 215(a)(7)) and the effect on benefit amounts (under section 202(k)(5)) of monthly periodic payments or benefits payable based on earnings derived in such service. Such notice shall be in a form which shall be prescribed by the Commissioner of Social Security.

(2) The written notice provided to an individual pursuant to paragraph (1) shall include a form which, upon completion and signature by the individual, would constitute certification by the individual of receipt of the notice. The agency or instrumentality providing the notice to the individual shall require that the form be completed and signed by the individual and submitted to the agency or instrumentality and to the pension, annuity, retirement, or similar fund or system established by the governmental entity involved responsible for paying the monthly periodic payments or benefits, before commencement of service with the agency or instrumentality.

OUTREACH EFFORTS TO INCREASE AWARENESS OF THE AVAILABILITY OF MEDICARE COST-SHARING AND SUBSIDIES FOR LOW-INCOME INDIVIDUALS UNDER TITLE XVIII

SEC. 1144. [42 U.S.C. 1320b–14] (a) OUTREACH.—

(1) IN GENERAL.—The Commissioner of Social Security (in this section referred to as the "Commissioner") shall conduct outreach efforts to—

(A) identify individuals entitled to benefits under the medicare program under title XVIII who may be eligible for medical assistance for payment of the cost of medicare cost-sharing under the medicaid program pursuant to sections 1902(a)(10)(E) and 1933 for the transitional assistance under section 1860D–31(f), or for premium and cost-sharing subsidies under section 1860D–14; and

(B) notify such individuals of the availability of such medical assistance, program, and subsidies under such sections.

(2) CONTENT OF NOTICE.—Any notice furnished under paragraph (1) shall state that eligibility for medicare cost-sharing assistance, the transitional assistance under section 1860D–31(f), or premium and cost-sharing subsidies under section 1860D–14 under such sections is conditioned upon—

(A) the individual providing to the State information about income and resources (in the case of an individual residing in a State that imposes an assets test for eligibility for medicare cost-sharing under the medicaid program); and

(B) meeting the applicable eligibility criteria.

(b) COORDINATION WITH STATES.—

(1) IN GENERAL.—In conducting the outreach efforts under this section, the Commissioner shall—

(A) furnish the agency of each State responsible for the administration of the medicaid program and any other appropriate State agency with information consisting of the name and address of individuals residing in the State that the Commissioner determines may be eligible for medical assistance for payment of the cost of medicare cost-sharing under the medicaid program pursuant to sections 1902(a)(10)(E) and 1933, for transitional assistance under section 1860D–31(f), or for premium and cost-sharing subsidies for low-income individuals under section 1860D–14; and

(B) update any such information not less frequently than once per year.

(2) INFORMATION IN PERIODIC UPDATES.—The periodic updates described in paragraph (1)(B) shall include information on individuals who are or may be eligible for the medical assistance, program, and subsidies described in paragraph (1)(A) because such individuals have experienced reductions in benefits under title II.

(c)[26] ASSISTANCE WITH MEDICARE SAVINGS PROGRAM AND LOW-INCOME SUBSIDY PROGRAM APPLICATIONS.—

(1) DISTRIBUTION OF APPLICATIONS AND INFORMATION TO INDIVIDUALS WHO ARE POTENTIALLY ELIGIBLE FOR LOW-INCOME SUBSIDY PROGRAM.—For each individual who submits an appli-

[26] Subsection (c), as added by section 113(a) of Public Law 110–275, takes effect on January 1, 2010.

cation for low-income subsidies under section 1860D–14, requests an application for such subsidies, or is otherwise identified as an individual who is potentially eligible for such subsidies, the Commissioner shall do the following:

(A) Provide information describing the low-income subsidy program under section 1860D–14 and the Medicare Savings Program (as defined in paragraph (7)).

(B) Provide an application for enrollment under such low-income subsidy program (if not already received by the Commissioner).

(C) In accordance with paragraph (3), transmit data from such an application for purposes of initiating an application for benefits under the Medicare Savings Program.

(D) Provide information on how the individual may obtain assistance in completing such application and an application under the Medicare Savings Program, including information on how the individual may contact the State health insurance assistance program (SHIP).

(E) Make the application described in subparagraph (B) and the information described in subparagraphs (A) and (D) available at local offices of the Social Security Administration.

(2) TRAINING PERSONNEL IN EXPLAINING BENEFIT PROGRAMS AND ASSISTING IN COMPLETING LIS APPLICATION.—The Commissioner shall provide training to those employees of the Social Security Administration who are involved in receiving applications for benefits described in paragraph (1)(B) in order that they may promote beneficiary understanding of the low-income subsidy program and the Medicare Savings Program in order to increase participation in these programs. Such employees shall provide assistance in completing an application described in paragraph (1)(B) upon request.

(3) TRANSMITTAL OF DATA TO STATES.—Beginning on January 1, 2010, with the consent of an individual completing an application for benefits described in paragraph (1)(B), the Commissioner shall electronically transmit to the appropriate State Medicaid agency data from such application, as determined by the Commissioner, which transmittal shall initiate an application of the individual for benefits under the Medicare Savings Program with the State Medicaid agency. In order to ensure that such data transmittal provides effective assistance for purposes of State adjudication of applications for benefits under the Medicare Savings Program, the Commissioner shall consult with the Secretary, after the Secretary has consulted with the States, regarding the content, form, frequency, and manner in which data (on a uniform basis for all States) shall be transmitted under this subparagraph.

(4) COORDINATION WITH OUTREACH.—The Commissioner shall coordinate outreach activities under this subsection in connection with the low-income subsidy program and the Medicare Savings Program.

(5) REIMBURSEMENT OF SOCIAL SECURITY ADMINISTRATION ADMINISTRATIVE COSTS.—

(A) INITIAL MEDICARE SAVINGS PROGRAM COSTS; ADDITIONAL LOW-INCOME SUBSIDY COSTS.—

(i) INITIAL MEDICARE SAVINGS PROGRAM COSTS.—There are hereby appropriated to the Commissioner to carry out this subsection, out of any funds in the Treasury not otherwise appropriated, $24,100,000. The amount appropriated under ths clause shall be available on October 1, 2008, and shall remain available until expended.

(ii) ADDITIONAL AMOUNT FOR LOW-INCOME SUBSIDY ACTIVITIES.—There are hereby appropriated to the Commissioner, out of any funds in the Treasury not otherwise appropriated, $24,800,000 for fiscal year 2009 to carry out low-income subsidy activities under section 1860D–14 and the Medicare Savings Program (in accordance with this subsection), to remain available until expended. Such funds shall be in addition to the Social Security Administration's Limitation on Administrative Expenditure appropriations for such fiscal year.

(B) SUBSEQUENT FUNDING UNDER AGREEMENTS.—

(i) IN GENERAL.—Effective for fiscal years beginning on or after October 1, 2010, the Commissioner and the Secretary shall enter into an agreement which shall provide funding (subject to the amount appropriated under clause (ii)) to cover the administrative costs of the Commissioner's activities under this subsection. Such agreement shall—

(I) provide funds to the Commissioner for the full cost of the Social Security Administration's work related to the Medicare Savings Program required under this section;

(II) provide such funding quarterly in advance of the applicable quarter based on estimating methodology agreed to by the Commissioner and the Secretary; and

(III) require an annual accounting and reconciliation of the actual costs incurred and funds provided under this subsection.

(ii) APPROPRIATION.—There are hereby appropriated to the Secretary solely for the purpose of providing payments to the Commissioner pursuant to an agreement specified in clause (i) that is in effect, out of any funds in the Treasury not otherwise appropriated, not more than $3,000,000 for fiscal year 2011 and each fiscal year thereafter.

(C) LIMITATION.—In no case shall funds from the Social Security Administration's Limitation on Administrative Expenses be used to carry out activities related to the Medicare Savings Program. For fiscal years beginning on or after October 1, 2010, no such activities shall be undertaken by the Social Security Administration unless the agreement specified in subparagraph (B) is in effect and

full funding has been provided to the Commissioner as specified in such subparagraph.

(6) GAO ANALYSIS AND REPORT.—

(A) ANALYSIS.—The Comptroller General of the United States shall prepare an analysis of the impact of this subsection—

(i) in increasing participation in the Medicare Savings Program, and

(ii) on States and the Social Security Administration.

(B) REPORT.—Not later than January 1, 2012, the Comptroller General shall submit to Congress, the Commissioner, and the Secretary a report on the analysis conducted under subparagraph (A).

(7) MEDICARE SAVINGS PROGRAM DEFINED.—For purposes of this subsection, the term "Medicare Savings Program" means the program of medical assistance for payment of the cost of medicare cost-sharing under the Medicaid program pursuant to sections 1902(a)(10)(E) and 1933.

PROTECTION OF SOCIAL SECURITY AND MEDICARE TRUST FUNDS

SEC. 1145. [42 U.S.C. 1320b–15] (a) IN GENERAL.—No officer or employee of the United States shall—

(1) delay the deposit of any amount into (or delay the credit of any amount to) any Federal fund or otherwise vary from the normal terms, procedures, or timing for making such deposits or credits,

(2) refrain from the investment in public debt obligations of amounts in any Federal fund, or

(3) redeem prior to maturity amounts in any Federal fund which are invested in public debt obligations for any purpose other than the payment of benefits or administrative expenses from such Federal fund.

(b) PUBLIC DEBT OBLIGATION.—For purposes of this section, the term "public debt obligation" means any obligation subject to the public debt limit established under section 3101 of title 31, United States Code.

(c) FEDERAL FUND.—For purposes of this section, the term "Federal fund" means—

(1) the Federal Old-Age and Survivors Insurance Trust Fund;

(2) the Federal Disability Insurance Trust Fund;

(3) the Federal Hospital Insurance Trust Fund; and

(4) the Federal Supplementary Medical Insurance Trust Fund.

PUBLIC DISCLOSURE OF CERTAIN INFORMATION ON HOSPITAL FINANCIAL INTEREST AND REFERRAL PATTERNS

SEC. 1146. [42 U.S.C. 1320b–16] The Secretary shall make available to the public, in a form and manner specified by the Secretary, information disclosed to the Secretary pursuant to section 1866(a)(1)(S).

CROSS-PROGRAM RECOVERY OF OVERPAYMENTS FROM BENEFITS

[42 U.S.C. 1320b–17]

(a)[27] IN GENERAL.—Subject to subsection (b), whenever the Commissioner of Social Security determines that more than the correct amount of any payment has been made to a person under a program described in subsection (e), the Commissioner of Social Security may recover the amount incorrectly paid by decreasing any amount which is payable to such person under any other program specified in that subsection.

(b) LIMITATION APPLICABLE TO CURRENT BENEFITS.—

(1) IN GENERAL.—In carrying out subsection (a), the Commissioner of Social Security may not decrease the monthly amount payable to an individual under a program described in subsection (e) that is paid when regularly due—

(A) in the case of benefits under title II or VIII, by more than 10 percent of the amount of the benefit payable to the person for that month under such title; and

(B) in the case of benefits under title XVI, by an amount greater than the lesser of—

(i) the amount of the benefit payable to the person for that month; or

(ii) an amount equal to 10 percent of the person's income for that month (including such monthly benefit but excluding payments under title II when recovery is also made from title II payments and excluding income excluded pursuant to section 1612(b)).

(2) EXCEPTION.—Paragraph (1) shall not apply if—

(A) the person or the spouse of the person was involved in willful misrepresentation or concealment of material information in connection with the amount incorrectly paid; or

(B) the person so requests.

(c) NO EFFECT ON ELIGIBILITY OR BENEFIT AMOUNT UNDER TITLE VIII OR XVI.—In any case in which the Commissioner of Social Security takes action in accordance with subsection (a) to recover an amount incorrectly paid to any person, neither that person, nor (with respect to the program described in subsection (e)(3)) any individual whose eligibility for benefits under such program or whose amount of such benefits, is determined by considering any part of that person's income, shall, as a result of such action—

(1) become eligible for benefits under the program described in paragraph (2) or (3) of subsection (e); or

(2) if such person or individual is otherwise so eligible, become eligible for increased benefits under such program.

(d) INAPPLICABILITY OF PROHIBITION AGAINST ASSESSMENT AND LEGAL PROCESS.—Section 207 shall not apply to actions taken under the provisions of this section to decrease amounts payable under titles II and XVI.

(e) PROGRAMS DESCRIBED.—The programs described in this subsection are the following:

[27] So in original. The section designator and enumerator "SEC. 1147." are missing.

(1) The old-age, survivors, and disability insurance benefits program under title II.

(2) The special benefits for certain World War II veterans program under title VIII.

(3) The supplemental security income benefits program under title XVI (including, for purposes of this section, State supplementary payments paid by the Commissioner pursuant to an agreement under section 1616(a) of this Act or section 212(b) of Public Law 93–66).

THE TICKET TO WORK AND SELF-SUFFICIENCY PROGRAM

SEC. 1148. [42 U.S.C. 1320b–19] (a) IN GENERAL.—The Commissioner shall establish a Ticket to Work and Self-Sufficiency Program, under which a disabled beneficiary may use a ticket to work and self-sufficiency issued by the Commissioner in accordance with this section to obtain employment services, vocational rehabilitation services, or other support services from an employment network which is of the beneficiary's choice and which is willing to provide such services to such beneficiary.

(b) TICKET SYSTEM.—

(1) DISTRIBUTION OF TICKETS.—The Commissioner may issue a ticket to work and self-sufficiency to disabled beneficiaries for participation in the Program.

(2) ASSIGNMENT OF TICKETS.—A disabled beneficiary holding a ticket to work and self-sufficiency may assign the ticket to any employment network of the beneficiary's choice which is serving under the Program and is willing to accept the assignment.

(3) TICKET TERMS.—A ticket issued under paragraph (1) shall consist of a document which evidences the Commissioner's agreement to pay (as provided in paragraph (4)) an employment network, which is serving under the Program and to which such ticket is assigned by the beneficiary, for such employment services, vocational rehabilitation services, and other support services as the employment network may provide to the beneficiary.

(4) PAYMENTS TO EMPLOYMENT NETWORKS.—The Commissioner shall pay an employment network under the Program in accordance with the outcome payment system under subsection (h)(2) or under the outcome-milestone payment system under subsection (h)(3) (whichever is elected pursuant to subsection (h)(1)). An employment network may not request or receive compensation for such services from the beneficiary.

(c) STATE PARTICIPATION.—

(1) IN GENERAL.—Each State agency administering or supervising the administration of the State plan approved under title I of the Rehabilitation Act of 1973 (29 U.S.C. 720 et seq.) may elect to participate in the Program as an employment network with respect to a disabled beneficiary. If the State agency does elect to participate in the Program, the State agency also shall elect to be paid under the outcome payment system or the outcome-milestone payment system in accordance with subsection (h)(1). With respect to a disabled beneficiary that

the State agency does not elect to have participate in the Program, the State agency shall be paid for services provided to that beneficiary under the system for payment applicable under section 222(d) and subsections (d) and (e) of section 1615. The Commissioner shall provide for periodic opportunities for exercising such elections.

(2) EFFECT OF PARTICIPATION BY STATE AGENCY.—

(A) STATE AGENCIES PARTICIPATING.—In any case in which a State agency described in paragraph (1) elects under that paragraph to participate in the Program, the employment services, vocational rehabilitation services, and other support services which, upon assignment of tickets to work and self-sufficiency, are provided to disabled beneficiaries by the State agency acting as an employment network shall be governed by plans for vocational rehabilitation services approved under title I of the Rehabilitation Act of 1973 (29 U.S.C. 720 et seq.).

(B) STATE AGENCIES ADMINISTERING MATERNAL AND CHILD HEALTH SERVICES PROGRAMS.—Subparagraph (A) shall not apply with respect to any State agency administering a program under title V of this Act.

(3) AGREEMENTS BETWEEN STATE AGENCIES AND EMPLOYMENT NETWORKS.—State agencies and employment networks shall enter into agreements regarding the conditions under which services will be provided when an individual is referred by an employment network to a State agency for services. The Commissioner shall establish by regulations the timeframe within which such agreements must be entered into and the mechanisms for dispute resolution between State agencies and employment networks with respect to such agreements.

(d) RESPONSIBILITIES OF THE COMMISSIONER.—

(1) SELECTION AND QUALIFICATIONS OF PROGRAM MANAGERS.—The Commissioner shall enter into agreements with 1 or more organizations in the private or public sector for service as a program manager to assist the Commissioner in administering the Program. Any such program manager shall be selected by means of a competitive bidding process, from among organizations in the private or public sector with available expertise and experience in the field of vocational rehabilitation or employment services.

(2) TENURE, RENEWAL, AND EARLY TERMINATION.—Each agreement entered into under paragraph (1) shall provide for early termination upon failure to meet performance standards which shall be specified in the agreement and which shall be weighted to take into account any performance in prior terms. Such performance standards shall include—

(A) measures for ease of access by beneficiaries to services; and

(B) measures for determining the extent to which failures in obtaining services for beneficiaries fall within acceptable parameters, as determined by the Commissioner.

(3) PRECLUSION FROM DIRECT PARTICIPATION IN DELIVERY OF SERVICES IN OWN SERVICE AREA.—Agreements under paragraph (1) shall preclude—

(A) direct participation by a program manager in the delivery of employment services, vocational rehabilitation services, or other support services to beneficiaries in the service area covered by the program manager's agreement; and

(B) the holding by a program manager of a financial interest in an employment network or service provider which provides services in a geographic area covered under the program manager's agreement.

(4) SELECTION OF EMPLOYMENT NETWORKS.—

(A) IN GENERAL.—The Commissioner shall select and enter into agreements with employment networks for service under the Program. Such employment networks shall be in addition to State agencies serving as employment networks pursuant to elections under subsection (c).

(B) ALTERNATE PARTICIPANTS.—In any State where the Program is being implemented, the Commissioner shall enter into an agreement with any alternate participant that is operating under the authority of section 222(d)(2) in the State as of the date of the enactment of this section and chooses to serve as an employment network under the Program.

(5) TERMINATION OF AGREEMENTS WITH EMPLOYMENT NETWORKS.—The Commissioner shall terminate agreements with employment networks for inadequate performance, as determined by the Commissioner.

(6) QUALITY ASSURANCE.—The Commissioner shall provide for such periodic reviews as are necessary to provide for effective quality assurance in the provision of services by employment networks. The Commissioner shall solicit and consider the views of consumers and the program manager under which the employment networks serve and shall consult with providers of services to develop performance measurements. The Commissioner shall ensure that the results of the periodic reviews are made available to beneficiaries who are prospective service recipients as they select employment networks. The Commissioner shall ensure that the periodic surveys of beneficiaries receiving services under the Program are designed to measure customer service satisfaction.

(7) DISPUTE RESOLUTION.—The Commissioner shall provide for a mechanism for resolving disputes between beneficiaries and employment networks, between program managers and employment networks, and between program managers and providers of services. The Commissioner shall afford a party to such a dispute a reasonable opportunity for a full and fair review of the matter in dispute.

(e) PROGRAM MANAGERS.—

(1) IN GENERAL.—A program manager shall conduct tasks appropriate to assist the Commissioner in carrying out the Commissioner's duties in administering the Program.

(2) RECRUITMENT OF EMPLOYMENT NETWORKS.—A program manager shall recruit, and recommend for selection by the Commissioner, employment networks for service under the Program. The program manager shall carry out such recruit-

ment and provide such recommendations, and shall monitor all employment networks serving in the Program in the geographic area covered under the program manager's agreement, to the extent necessary and appropriate to ensure that adequate choices of services are made available to beneficiaries. Employment networks may serve under the Program only pursuant to an agreement entered into with the Commissioner under the Program incorporating the applicable provisions of this section and regulations thereunder, and the program manager shall provide and maintain assurances to the Commissioner that payment by the Commissioner to employment networks pursuant to this section is warranted based on compliance by such employment networks with the terms of such agreement and this section. The program manager shall not impose numerical limits on the number of employment networks to be recommended pursuant to this paragraph.

(3) FACILITATION OF ACCESS BY BENEFICIARIES TO EMPLOYMENT NETWORKS.—A program manager shall facilitate access by beneficiaries to employment networks. The program manager shall ensure that each beneficiary is allowed changes in employment networks without being deemed to have rejected services under the Program. When such a change occurs, the program manager shall reassign the ticket based on the choice of the beneficiary. Upon the request of the employment network, the program manager shall make a determination of the allocation of the outcome or milestone-outcome payments based on the services provided by each employment network. The program manager shall establish and maintain lists of employment networks available to beneficiaries and shall make such lists generally available to the public. The program manager shall ensure that all information provided to disabled beneficiaries pursuant to this paragraph is provided in accessible formats.

(4) ENSURING AVAILABILITY OF ADEQUATE SERVICES.—The program manager shall ensure that employment services, vocational rehabilitation services, and other support services are provided to beneficiaries throughout the geographic area covered under the program manager's agreement, including rural areas.

(5) REASONABLE ACCESS TO SERVICES.—The program manager shall take such measures as are necessary to ensure that sufficient employment networks are available and that each beneficiary receiving services under the Program has reasonable access to employment services, vocational rehabilitation services, and other support services. Services provided under the Program may include case management, work incentives planning, supported employment, career planning, career plan development, vocational assessment, job training, placement, follow-up services, and such other services as may be specified by the Commissioner under the Program. The program manager shall ensure that such services are available in each service area.

(f) EMPLOYMENT NETWORKS.—

(1) QUALIFICATIONS FOR EMPLOYMENT NETWORKS.—

(A) IN GENERAL.—Each employment network serving under the Program shall consist of an agency or instrumentality of a State (or a political subdivision thereof) or a private entity, that assumes responsibility for the coordination and delivery of services under the Program to individuals assigning to the employment network tickets to work and self-sufficiency issued under subsection (b).

(B) ONE-STOP DELIVERY SYSTEMS.—An employment network serving under the Program may consist of a one-stop delivery system established under section 121(e) of the Workforce Innovation and Opportunity Act.

(C) COMPLIANCE WITH SELECTION CRITERIA.—No employment network may serve under the Program unless it meets and maintains compliance with both general selection criteria (such as professional and educational qualifications, where applicable) and specific selection criteria (such as substantial expertise and experience in providing relevant employment services and supports).

(D) SINGLE OR ASSOCIATED PROVIDERS ALLOWED.—An employment network shall consist of either a single provider of such services or of an association of such providers organized so as to combine their resources into a single entity. An employment network may meet the requirements of subsection (e)(4) by providing services directly, or by entering into agreements with other individuals or entities providing appropriate employment services, vocational rehabilitation services, or other support services.

(2) REQUIREMENTS RELATING TO PROVISION OF SERVICES.—Each employment network serving under the Program shall be required under the terms of its agreement with the Commissioner to—

(A) serve prescribed service areas; and

(B) take such measures as are necessary to ensure that employment services, vocational rehabilitation services, and other support services provided under the Program by, or under agreements entered into with, the employment network are provided under appropriate individual work plans that meet the requirements of subsection (g).

(3) ANNUAL FINANCIAL REPORTING.—Each employment network shall meet financial reporting requirements as prescribed by the Commissioner.

(4) PERIODIC OUTCOMES REPORTING.—Each employment network shall prepare periodic reports, on at least an annual basis, itemizing for the covered period specific outcomes achieved with respect to specific services provided by the employment network. Such reports shall conform to a national model prescribed under this section. Each employment network shall provide a copy of the latest report issued by the employment network pursuant to this paragraph to each beneficiary upon enrollment under the Program for services to be received through such employment network. Upon issuance of each report to each beneficiary, a copy of the report shall be maintained in the files of the employment network. The program

manager shall ensure that copies of all such reports issued under this paragraph are made available to the public under reasonable terms.

(g) INDIVIDUAL WORK PLANS.—

(1) REQUIREMENTS.—Each employment network shall—

(A) take such measures as are necessary to ensure that employment services, vocational rehabilitation services, and other support services provided under the Program by, or under agreements entered into with, the employment network are provided under appropriate individual work plans that meet the requirements of subparagraph (C);

(B) develop and implement each such individual work plan, in partnership with each beneficiary receiving such services, in a manner that affords such beneficiary the opportunity to exercise informed choice in selecting an employment goal and specific services needed to achieve that employment goal;

(C) ensure that each individual work plan includes at least—

(i) a statement of the vocational goal developed with the beneficiary, including, as appropriate, goals for earnings and job advancement;

(ii) a statement of the services and supports that have been deemed necessary for the beneficiary to accomplish that goal;

(iii) a statement of any terms and conditions related to the provision of such services and supports; and

(iv) a statement of understanding regarding the beneficiary's rights under the Program (such as the right to retrieve the ticket to work and self-sufficiency if the beneficiary is dissatisfied with the services being provided by the employment network) and remedies available to the individual, including information on the availability of advocacy services and assistance in resolving disputes through the State grant program authorized under section 1150;

(D) provide a beneficiary the opportunity to amend the individual work plan if a change in circumstances necessitates a change in the plan; and

(E) make each beneficiary's individual work plan available to the beneficiary in, as appropriate, an accessible format chosen by the beneficiary.

An individual work plan established pursuant to this subsection shall be treated, for purposes of section 51(d)(6)(B)(i) of the Internal Revenue Code of 1986, as an individualized written plan for employment under a State plan for vocational rehabilitation services approved under the Rehabilitation Act of 1973.

(2) EFFECTIVE UPON WRITTEN APPROVAL.—A beneficiary's individual work plan shall take effect upon written approval by the beneficiary or a representative of the beneficiary and a representative of the employment network that, in providing such

written approval, acknowledges assignment of the beneficiary's ticket to work and self-sufficiency.

(h) EMPLOYMENT NETWORK PAYMENT SYSTEMS.—

(1) ELECTION OF PAYMENT SYSTEM BY EMPLOYMENT NETWORKS.—

(A) IN GENERAL.—The Program shall provide for payment authorized by the Commissioner to employment networks under either an outcome payment system or an outcome-milestone payment system. Each employment network shall elect which payment system will be utilized by the employment network, and, for such period of time as such election remains in effect, the payment system so elected shall be utilized exclusively in connection with such employment network (except as provided in subparagraph (B)).

(B) NO CHANGE IN METHOD OF PAYMENT FOR BENEFICIARIES WITH TICKETS ALREADY ASSIGNED TO THE EMPLOYMENT NETWORKS.—Any election of a payment system by an employment network that would result in a change in the method of payment to the employment network for services provided to a beneficiary who is receiving services from the employment network at the time of the election shall not be effective with respect to payment for services provided to that beneficiary and the method of payment previously selected shall continue to apply with respect to such services.

(2) OUTCOME PAYMENT SYSTEM.—

(A) IN GENERAL.—The outcome payment system shall consist of a payment structure governing employment networks electing such system under paragraph (1)(A) which meets the requirements of this paragraph.

(B) PAYMENTS MADE DURING OUTCOME PAYMENT PERIOD.—The outcome payment system shall provide for a schedule of payments to an employment network, in connection with each individual who is a beneficiary, for each month, during the individual's outcome payment period, for which benefits (described in paragraphs (3) and (4) of subsection (k)) are not payable to such individual because of work or earnings.

(C) COMPUTATION OF PAYMENTS TO EMPLOYMENT NETWORK.—The payment schedule of the outcome payment system shall be designed so that—

(i) the payment for each month during the outcome payment period for which benefits (described in paragraphs (3) and (4) of subsection (k)) are not payable is equal to a fixed percentage of the payment calculation base for the calendar year in which such month occurs; and

(ii) such fixed percentage is set at a percentage which does not exceed 40 percent.

(3) OUTCOME-MILESTONE PAYMENT SYSTEM.—

(A) IN GENERAL.—The outcome-milestone payment system shall consist of a payment structure governing em-

ployment networks electing such system under paragraph (1)(A) which meets the requirements of this paragraph.

(B) EARLY PAYMENTS UPON ATTAINMENT OF MILESTONES IN ADVANCE OF OUTCOME PAYMENT PERIODS.—The outcome-milestone payment system shall provide for 1 or more milestones, with respect to beneficiaries receiving services from an employment network under the Program, that are directed toward the goal of permanent employment. Such milestones shall form a part of a payment structure that provides, in addition to payments made during outcome payment periods, payments made prior to outcome payment periods in amounts based on the attainment of such milestones.

(C) LIMITATION ON TOTAL PAYMENTS TO EMPLOYMENT NETWORK.—The payment schedule of the outcome milestone payment system shall be designed so that the total of the payments to the employment network with respect to each beneficiary is less than, on a net present value basis (using an interest rate determined by the Commissioner that appropriately reflects the cost of funds faced by providers), the total amount to which payments to the employment network with respect to the beneficiary would be limited if the employment network were paid under the outcome payment system.

(4) DEFINITIONS.—In this subsection:

(A) PAYMENT CALCULATION BASE.—The term "payment calculation base" means, for any calendar year—

(i) in connection with a title II disability beneficiary, the average disability insurance benefit payable under section 223 for all beneficiaries for months during the preceding calendar year; and

(ii) in connection with a title XVI disability beneficiary (who is not concurrently a title II disability beneficiary), the average payment of supplemental security income benefits based on disability payable under title XVI (excluding State supplementation) for months during the preceding calendar year to all beneficiaries who have attained 18 years of age but have not attained 65 years of age.

(B) OUTCOME PAYMENT PERIOD.—The term "outcome payment period" means, in connection with any individual who had assigned a ticket to work and self-sufficiency to an employment network under the Program, a period—

(i) beginning with the first month, ending after the date on which such ticket was assigned to the employment network, for which benefits (described in paragraphs (3) and (4) of subsection (k)) are not payable to such individual by reason of engagement in substantial gainful activity or by reason of earnings from work activity; and

(ii) ending with the 60th month (consecutive or otherwise), ending after such date, for which such benefits are not payable to such individual by reason of

engagement in substantial gainful activity or by reason of earnings from work activity.

(5) PERIODIC REVIEW AND ALTERATIONS OF PRESCRIBED SCHEDULES.—

(A) PERCENTAGES AND PERIODS.—The Commissioner shall periodically review the percentage specified in paragraph (2)(C), the total payments permissible under paragraph (3)(C), and the period of time specified in paragraph (4)(B) to determine whether such percentages, such permissible payments, and such period provide an adequate incentive for employment networks to assist beneficiaries to enter the workforce, while providing for appropriate economies. The Commissioner may alter such percentage, such total permissible payments, or such period of time to the extent that the Commissioner determines, on the basis of the Commissioner's review under this paragraph, that such an alteration would better provide the incentive and economies described in the preceding sentence.

(B) NUMBER AND AMOUNTS OF MILESTONE PAYMENTS.—The Commissioner shall periodically review the number and amounts of milestone payments established by the Commissioner pursuant to this section to determine whether they provide an adequate incentive for employment networks to assist beneficiaries to enter the workforce, taking into account information provided to the Commissioner by program managers, the Ticket to Work and Work Incentives Advisory Panel established by section 101(f) of the Ticket to Work and Work Incentives Improvement Act of 1999, and other reliable sources. The Commissioner may from time to time alter the number and amounts of milestone payments initially established by the Commissioner pursuant to this section to the extent that the Commissioner determines that such an alteration would allow an adequate incentive for employment networks to assist beneficiaries to enter the workforce. Such alteration shall be based on information provided to the Commissioner by program managers, the Ticket to Work and Work Incentives Advisory Panel established by section 101(f) of the Ticket to Work and Work Incentives Improvement Act of 1999, or other reliable sources.

(C) REPORT ON THE ADEQUACY OF INCENTIVES.—The Commissioner shall submit to the Congress not later than 36 months after the date of the enactment of the Ticket to Work and Work Incentives Improvement Act of 1999 a report with recommendations for a method or methods to adjust payment rates under subparagraphs (A) and (B), that would ensure adequate incentives for the provision of services by employment networks of—

(i) individuals with a need for ongoing support and services;

(ii) individuals with a need for high-cost accommodations;

(iii) individuals who earn a subminimum wage; and

(iv) individuals who work and receive partial cash benefits.

The Commissioner shall consult with the Ticket to Work and Work Incentives Advisory Panel established under section 101(f) of the Ticket to Work and Work Incentives Improvement Act of 1999 during the development and evaluation of the study. The Commissioner shall implement the necessary adjusted payment rates prior to full implementation of the Ticket to Work and Self-Sufficiency Program.

(i) SUSPENSION OF DISABILITY REVIEWS.—During any period for which an individual is using, as defined by the Commissioner, a ticket to work and self-sufficiency issued under this section, the Commissioner (and any applicable State agency) may not initiate a continuing disability review or other review under section 221 of whether the individual is or is not under a disability or a review under title XVI similar to any such review under section 221.

(j) AUTHORIZATIONS.—

(1) PAYMENTS TO EMPLOYMENT NETWORKS.—

(A) TITLE II DISABILITY BENEFICIARIES.—There are authorized to be transferred from the Federal Old-Age and Survivors Insurance Trust Fund and the Federal Disability Insurance Trust Fund each fiscal year such sums as may be necessary to make payments to employment networks under this section. Money paid from the Trust Funds under this section with respect to title II disability beneficiaries who are entitled to benefits under section 223 or who are entitled to benefits under section 202(d) on the basis of the wages and self-employment income of such beneficiaries, shall be charged to the Federal Disability Insurance Trust Fund, and all other money paid from the Trust Funds under this section shall be charged to the Federal Old-Age and Survivors Insurance Trust Fund.

(B) TITLE XVI DISABILITY BENEFICIARIES.—Amounts authorized to be appropriated to the Social Security Administration under section 1601 (as in effect pursuant to the amendments made by section 301 of the Social Security Amendments of 1972) shall include amounts necessary to carry out the provisions of this section with respect to title XVI disability beneficiaries.

(2) ADMINISTRATIVE EXPENSES.—The costs of administering this section (other than payments to employment networks) shall be paid from amounts made available for the administration of title II and amounts made available for the administration of title XVI, and shall be allocated among such amounts as appropriate.

(k) DEFINITIONS.—In this section:

(1) COMMISSIONER.—The term "Commissioner" means the Commissioner of Social Security.

(2) DISABLED BENEFICIARY.—The term "disabled beneficiary" means a title II disability beneficiary or a title XVI disability beneficiary.

(3) TITLE II DISABILITY BENEFICIARY.—The term "title II disability beneficiary" means an individual entitled to dis-

ability insurance benefits under section 223 or to monthly insurance benefits under section 202 based on such individual's disability (as defined in section 223(d)). An individual is a title II disability beneficiary for each month for which such individual is entitled to such benefits.

(4) TITLE XVI DISABILITY BENEFICIARY.—The term "title XVI disability beneficiary" means an individual eligible for supplemental security income benefits under title XVI on the basis of blindness (within the meaning of section 1614(a)(2)) or disability (within the meaning of section 1614(a)(3)). An individual is a title XVI disability beneficiary for each month for which such individual is eligible for such benefits.

(5) SUPPLEMENTAL SECURITY INCOME BENEFIT.—The term "supplemental security income benefit under title XVI" means a cash benefit under section 1611 or 1619(a), and does not include a State supplementary payment, administered federally or otherwise.

(l) REGULATIONS.—Not later than 1 year after the date of the enactment of the Ticket to Work and Work Incentives Improvement Act of 1999, the Commissioner shall prescribe such regulations as are necessary to carry out the provisions of this section.

WORK INCENTIVES OUTREACH PROGRAM

SEC. 1149. [42 U.S.C. 1320b–20] (a) ESTABLISHMENT.—

(1) IN GENERAL.—The Commissioner, in consultation with the Ticket to Work and Work Incentives Advisory Panel established under section 101(f) of the Ticket to Work and Work Incentives Improvement Act of 1999, shall establish a community-based work incentives planning and assistance program for the purpose of disseminating accurate information to disabled beneficiaries on work incentives programs and issues related to such programs.

(2) GRANTS, COOPERATIVE AGREEMENTS, CONTRACTS, AND OUTREACH.—Under the program established under this section, the Commissioner shall—

(A) establish a competitive program of grants, cooperative agreements, or contracts to provide benefits planning and assistance, including information on the availability of protection and advocacy services, to disabled beneficiaries, including individuals participating in the Ticket to Work and Self-Sufficiency Program established under section 1148, the program established under section 1619, and other programs that are designed to encourage disabled beneficiaries to work;

(B) conduct directly, or through grants, cooperative agreements, or contracts, ongoing outreach efforts to disabled beneficiaries (and to the families of such beneficiaries) who are potentially eligible to participate in Federal or State work incentive programs that are designed to assist disabled beneficiaries to work, including—

(i) preparing and disseminating information explaining such programs; and

(ii) working in cooperation with other Federal, State, and private agencies and nonprofit organizations that serve disabled beneficiaries, and with agencies and organizations that focus on vocational rehabilitation and work-related training and counseling;

(C) establish a corps of trained, accessible, and responsive work incentives specialists within the Social Security Administration who will specialize in disability work incentives under titles II and XVI for the purpose of disseminating accurate information with respect to inquiries and issues relating to work incentives to—

(i) disabled beneficiaries;

(ii) benefit applicants under titles II and XVI; and

(iii) individuals or entities awarded grants under subparagraphs (A) or (B); and

(D) provide—

(i) training for work incentives specialists and individuals providing planning assistance described in subparagraph (C); and

(ii) technical assistance to organizations and entities that are designed to encourage disabled beneficiaries to return to work.

(3) COORDINATION WITH OTHER PROGRAMS.—The responsibilities of the Commissioner established under this section shall be coordinated with other public and private programs that provide information and assistance regarding rehabilitation services and independent living supports and benefits planning for disabled beneficiaries including the program under section 1619, the plans for achieving self-support program (PASS), and any other Federal or State work incentives programs that are designed to assist disabled beneficiaries, including educational agencies that provide information and assistance regarding rehabilitation, school-to-work programs, transition services (as defined in, and provided in accordance with, the Individuals with Disabilities Education Act (20 U.S.C. 1400 et seq.)), a one-stop delivery system established under section 121(e) of the Workforce Innovation and Opportunity Act, and other services.

(b) CONDITIONS.—

(1) SELECTION OF ENTITIES.—

(A) APPLICATION.—An entity shall submit an application for a grant, cooperative agreement, or contract to provide benefits planning and assistance to the Commissioner at such time, in such manner, and containing such information as the Commissioner may determine is necessary to meet the requirements of this section.

(B) STATEWIDENESS.—The Commissioner shall ensure that the planning, assistance, and information described in paragraph (2) shall be available on a statewide basis.

(C) ELIGIBILITY OF STATES AND PRIVATE ORGANIZATIONS.—

(i) IN GENERAL.—The Commissioner may award a grant, cooperative agreement, or contract under this section to a State or a private agency or organization

(other than Social Security Administration Field Offices and the State agency administering the State medicaid program under title XIX, including any agency or entity described in clause (ii), that the Commissioner determines is qualified to provide the planning, assistance, and information described in paragraph (2)).

(ii) AGENCIES AND ENTITIES DESCRIBED.—The agencies and entities described in this clause are the following:

(I) Any public or private agency or organization (including Centers for Independent Living established under title VII of the Rehabilitation Act of 1973 (29 U.S.C. 796 et seq.), protection and advocacy organizations, client assistance programs established in accordance with section 112 of the Rehabilitation Act of 1973 (29 U.S.C. 732), and State Developmental Disabilities Councils established in accordance with section 124 of the Developmental Disabilities Assistance and Bill of Rights Act (42 U.S.C. 6024)) that the Commissioner determines satisfies the requirements of this section.

(II) The State agency administering the State program funded under part A of title IV.

(D) EXCLUSION FOR CONFLICT OF INTEREST.—The Commissioner may not award a grant, cooperative agreement, or contract under this section to any entity that the Commissioner determines would have a conflict of interest if the entity were to receive a grant, cooperative agreement, or contract under this section.

(2) SERVICES PROVIDED.—A recipient of a grant, cooperative agreement, or contract to provide benefits planning and assistance shall select individuals who will act as planners and provide information, guidance, and planning to disabled beneficiaries on the—

(A) availability and interrelation of any Federal or State work incentives programs designed to assist disabled beneficiaries that the individual may be eligible to participate in;

(B) adequacy of any health benefits coverage that may be offered by an employer of the individual and the extent to which other health benefits coverage may be available to the individual; and

(C) availability of protection and advocacy services for disabled beneficiaries and how to access such services.

(3) AMOUNT OF GRANTS, COOPERATIVE AGREEMENTS, OR CONTRACTS.—

(A) BASED ON POPULATION OF DISABLED BENEFICIARIES.—Subject to subparagraph (B), the Commissioner shall award a grant, cooperative agreement, or contract under this section to an entity based on the percentage of the population of the State where the entity is located who are disabled beneficiaries.

(B) LIMITATIONS.—

(i) PER GRANT.—No entity shall receive a grant, cooperative agreement, or contract under this section for a fiscal year that is less than $50,000 or more than $300,000.

(ii) TOTAL AMOUNT FOR ALL GRANTS, COOPERATIVE AGREEMENTS, AND CONTRACTS.—The total amount of all grants, cooperative agreements, and contracts awarded under this section for a fiscal year may not exceed $23,000,000.

(4) FUNDING.—

(A) ALLOCATION OF COSTS.—The costs of carrying out this section shall be paid from amounts made available for the administration of title II and amounts made available for the administration of title XVI, and shall be allocated among those amounts as appropriate.

(B) CARRYOVER.—An amount not in excess of 10 percent of the total amount obligated through a grant, cooperative agreement, or contract awarded under this section for a fiscal year to a State or a private agency or organization shall remain available for obligation to such State or private agency or organization until the end of the succeeding fiscal year. Any such amount remaining available for obligation during such succeeding fiscal year shall be available for providing benefits planning and assistance only for individuals who are within the caseload of the recipient of the grant, agreement, or contract as of immediately before the beginning of such fiscal year.

(c) ANNUAL REPORT.—Each entity awarded a grant, cooperative agreement, or contract under this section shall submit an annual report to the Commissioner on the benefits planning and assistance provided to individuals under such grant, agreement, or contract.

(d) DEFINITIONS.—In this section:

(1) COMMISSIONER.—The term "Commissioner" means the Commissioner of Social Security.

(2) DISABLED BENEFICIARY.—The term "disabled beneficiary" means an individual—

(A) who is a disabled beneficiary as defined in section 1148(k)(2) of this Act;

(B) who is receiving a cash payment described in section 1616(a) of this Act or a supplementary payment described in section 212(a)(3) of Public Law 93–66 (without regard to whether such payment is paid by the Commissioner pursuant to an agreement under section 1616(a) of this Act or under section 212(b) of Public Law 93–66);

(C) who, pursuant to section 1619(b) of this Act, is considered to be receiving benefits under title XVI of this Act; or

(D) who is entitled to benefits under part A of title XVIII of this Act by reason of the penultimate sentence of section 226(b) of this Act.

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $23,000,000 for each of the fiscal years 2000 through 2011.

STATE GRANTS FOR WORK INCENTIVES ASSISTANCE TO DISABLED BENEFICIARIES

SEC. 1150. [42 U.S.C. 1320b–21] (a) IN GENERAL.—Subject to subsection (c), the Commissioner may make payments in each State to the protection and advocacy system established pursuant to part C of title I of the Developmental Disabilities Assistance and Bill of Rights Act (42 U.S.C. 6041 et seq.) for the purpose of providing services to disabled beneficiaries.

(b) SERVICES PROVIDED.—Services provided to disabled beneficiaries pursuant to a payment made under this section may include—

(1) information and advice about obtaining vocational rehabilitation and employment services; and

(2) advocacy or other services that a disabled beneficiary may need to secure, maintain, or regain gainful employment.

(c) APPLICATION.—In order to receive payments under this section, a protection and advocacy system shall submit an application to the Commissioner, at such time, in such form and manner, and accompanied by such information and assurances as the Commissioner may require.

(d) AMOUNT OF PAYMENTS.—

(1) IN GENERAL.—Subject to the amount appropriated for a fiscal year for making payments under this section, a protection and advocacy system shall not be paid an amount that is less than—

(A) in the case of a protection and advocacy system located in a State (including the District of Columbia and Puerto Rico) other than Guam, American Samoa, the United States Virgin Islands, and the Commonwealth of the Northern Mariana Islands, the greater of—

(i) $100,000; or

(ii) ⅓ of 1 percent of the amount available for payments under this section; and

(B) in the case of a protection and advocacy system located in Guam, American Samoa, the United States Virgin Islands, and the Commonwealth of the Northern Mariana Islands, $50,000.

(2) INFLATION ADJUSTMENT.—For each fiscal year in which the total amount appropriated to carry out this section exceeds the total amount appropriated to carry out this section in the preceding fiscal year, the Commissioner shall increase each minimum payment under subparagraphs (A) and (B) of paragraph (1) by a percentage equal to the percentage increase in the total amount so appropriated to carry out this section.

(e) ANNUAL REPORT.—Each protection and advocacy system that receives a payment under this section shall submit an annual report to the Commissioner and the Ticket to Work and Work Incentives Advisory Panel established under section 101(f) of the Ticket to Work and Work Incentives Improvement Act of 1999 on the services provided to individuals by the system.

(f) FUNDING.—

(1) ALLOCATION OF PAYMENTS.—Payments under this section shall be made from amounts made available for the ad-

ministration of title II and amounts made available for the administration of title XVI, and shall be allocated among those amounts as appropriate.

(2) CARRYOVER.—Any amounts allotted for payment to a protection and advocacy system under this section for a fiscal year shall remain available for payment to or on behalf of the protection and advocacy system until the end of the succeeding fiscal year.

(g) DEFINITIONS.—In this section:

(1) COMMISSIONER.—The term "Commissioner" means the Commissioner of Social Security.

(2) DISABLED BENEFICIARY.—The term "disabled beneficiary" means an individual—

(A) who is a disabled beneficiary as defined in section 1148(k)(2) of this Act;

(B) who is receiving a cash payment described in section 1616(a) of this Act or a supplementary payment described in section 212(a)(3) of Public Law 93–66 (without regard to whether such payment is paid by the Commissioner pursuant to an agreement under section 1616(a) of this Act or under section 212(b) of Public Law 93–66);

(C) who, pursuant to section 1619(b) of this Act, is considered to be receiving benefits under title XVI of this Act; or

(D) who is entitled to benefits under part A of title XVIII of this Act by reason of the penultimate sentence of section 226(b) of this Act.

(3) PROTECTION AND ADVOCACY SYSTEM.—The term "protection and advocacy system" means a protection and advocacy system established pursuant to part C of title I of the Developmental Disabilities Assistance and Bill of Rights Act (42 U.S.C. 6041 et seq.).

(h) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $7,000,000 for each of the fiscal years 2000 through 2011.

SEC. 1150A. [42 U.S.C. 1320b–23] PHARMACY BENEFIT MANAGERS TRANSPARENCY REQUIREMENTS.

(a) PROVISION OF INFORMATION.—A health benefits plan or any entity that provides pharmacy benefits management services on behalf of a health benefits plan (in this section referred to as a "PBM") that manages prescription drug coverage under a contract with—

(1) a PDP sponsor of a prescription drug plan or an MA organization offering an MA–PD plan under part D of title XVIII; or

(2) a qualified health benefits plan offered through an exchange established by a State under section 1311 of the Patient Protection and Affordable Care Act,

shall provide the information described in subsection (b) to the Secretary and, in the case of a PBM, to the plan with which the PBM is under contract with, at such times, and in such form and manner, as the Secretary shall specify.

(b) INFORMATION DESCRIBED.—The information described in this subsection is the following with respect to services provided by a health benefits plan or PBM for a contract year:

(1) The percentage of all prescriptions that were provided through retail pharmacies compared to mail order pharmacies, and the percentage of prescriptions for which a generic drug was available and dispensed (generic dispensing rate), by pharmacy type (which includes an independent pharmacy, chain pharmacy, supermarket pharmacy, or mass merchandiser pharmacy that is licensed as a pharmacy by the State and that dispenses medication to the general public), that is paid by the health benefits plan or PBM under the contract.

(2) The aggregate amount, and the type of rebates, discounts, or price concessions (excluding bona fide service fees, which include but are 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)) that the PBM negotiates that are attributable to patient utilization under the plan, and the aggregate amount of the rebates, discounts, or price concessions that are passed through to the plan sponsor, and the total number of prescriptions that were dispensed.

(3) The aggregate amount of the difference between the amount the health benefits plan pays the PBM and the amount that the PBM pays retail pharmacies, and mail order pharmacies, and the total number of prescriptions that were dispensed.

(c) CONFIDENTIALITY.—Information disclosed by a health benefits plan or PBM under this section is confidential and shall not be disclosed by the Secretary or by a plan receiving the information, except that the Secretary may disclose the information in a form which does not disclose the identity of a specific PBM, plan, or prices charged for drugs, for the following purposes:

(1) As the Secretary determines to be necessary to carry out this section or part D of title XVIII.

(2) To permit the Comptroller General to review the information provided.

(3) To permit the Director of the Congressional Budget Office to review the information provided.

(4) To States to carry out section 1311 of the Patient Protection and Affordable Care Act.

(d) PENALTIES.—The provisions of subsection (b)(3)(C) of section 1927 shall apply to a health benefits plan or PBM that fails to provide information required under subsection (a) on a timely basis or that knowingly provides false information in the same manner as such provisions apply to a manufacturer with an agreement under that section.

REPORTING TO LAW ENFORCEMENT OF CRIMES OCCURRING IN FEDERALLY FUNDED LONG-TERM CARE FACILITIES

SEC. 1150B. [42 U.S.C. 1320b–25] (a) DETERMINATION AND NOTIFICATION.—

(1) DETERMINATION.—The owner or operator of each long-term care facility that receives Federal funds under this Act shall annually determine whether the facility received at least $10,000 in such Federal funds during the preceding year.

(2) NOTIFICATION.—If the owner or operator determines under paragraph (1) that the facility received at least $10,000 in such Federal funds during the preceding year, such owner or operator shall annually notify each covered individual (as defined in paragraph (3)) of that individual's obligation to comply with the reporting requirements described in subsection (b).

(3) COVERED INDIVIDUAL DEFINED.—In this section, the term "covered individual" means each individual who is an owner, operator, employee, manager, agent, or contractor of a long-term care facility that is the subject of a determination described in paragraph (1).

(b) REPORTING REQUIREMENTS.—

(1) IN GENERAL.—Each covered individual shall report to the Secretary and 1 or more law enforcement entities for the political subdivision in which the facility is located any reasonable suspicion of a crime (as defined by the law of the applicable political subdivision) against any individual who is a resident of, or is receiving care from, the facility.

(2) TIMING.—If the events that cause the suspicion—

(A) result in serious bodily injury, the individual shall report the suspicion immediately, but not later than 2 hours after forming the suspicion; and

(B) do not result in serious bodily injury, the individual shall report the suspicion not later than 24 hours after forming the suspicion.

(c) PENALTIES.—

(1) IN GENERAL.—If a covered individual violates subsection (b)—

(A) the covered individual shall be subject to a civil money penalty of not more than $200,000; and

(B) the Secretary may make a determination in the same proceeding to exclude the covered individual from participation in any Federal health care program (as defined in section 1128B(f)).

(2) INCREASED HARM.—If a covered individual violates subsection (b) and the violation exacerbates the harm to the victim of the crime or results in harm to another individual—

(A) the covered individual shall be subject to a civil money penalty of not more than $300,000; and

(B) the Secretary may make a determination in the same proceeding to exclude the covered individual from participation in any Federal health care program (as defined in section 1128B(f)).

(3) EXCLUDED INDIVIDUAL.—During any period for which a covered individual is classified as an excluded individual under paragraph (1)(B) or (2)(B), a long-term care facility that employs such individual shall be ineligible to receive Federal funds under this Act.

(4) EXTENUATING CIRCUMSTANCES.—

(A) IN GENERAL.—The Secretary may take into account the financial burden on providers with underserved populations in determining any penalty to be imposed under this subsection.

(B) UNDERSERVED POPULATION DEFINED.—In this paragraph, the term "underserved population" means the population of an area designated by the Secretary as an area with a shortage of elder justice programs or a population group designated by the Secretary as having a shortage of such programs. Such areas or groups designated by the Secretary may include—

(i) areas or groups that are geographically isolated (such as isolated in a rural area);

(ii) racial and ethnic minority populations; and

(iii) populations underserved because of special needs (such as language barriers, disabilities, alien status, or age).

(d) ADDITIONAL PENALTIES FOR RETALIATION.—

(1) IN GENERAL.—A long-term care facility may not—

(A) discharge, demote, suspend, threaten, harass, or deny a promotion or other employment-related benefit to an employee, or in any other manner discriminate against an employee in the terms and conditions of employment because of lawful acts done by the employee; or

(B) file a complaint or a report against a nurse or other employee with the appropriate State professional disciplinary agency because of lawful acts done by the nurse or employee,

for making a report, causing a report to be made, or for taking steps in furtherance of making a report pursuant to subsection (b)(1).

(2) PENALTIES FOR RETALIATION.—If a long-term care facility violates subparagraph (A) or (B) of paragraph (1) the facility shall be subject to a civil money penalty of not more than $200,000 or the Secretary may classify the entity as an excluded entity for a period of 2 years pursuant to section 1128(b), or both.

(3) REQUIREMENT TO POST NOTICE.—Each long-term care facility shall post conspicuously in an appropriate location a sign (in a form specified by the Secretary) specifying the rights of employees under this section. Such sign shall include a statement that an employee may file a complaint with the Secretary against a long-term care facility that violates the provisions of this subsection and information with respect to the manner of filing such a complaint.

(e) PROCEDURE.—The provisions of section 1128A (other than subsections (a) and (b) and the second sentence of subsection (f)) shall apply to a civil money penalty or exclusion under this section in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

(f) DEFINITIONS.—In this section, the terms "elder justice", "long-term care facility", and "law enforcement" have the meanings given those terms in section 2011.

SEC. 1150C. [42 U.S.C. 1320b-26] FUNDING FOR PROVIDERS RELATING TO COVID–19.

(a) FUNDING.—In addition to amounts otherwise available, there is appropriated to the Secretary, for fiscal year 2021, out of any monies in the Treasury not otherwise appropriated, $8,500,000,000 for purposes of making payments to eligible health care providers for health care related expenses and lost revenues that are attributable to COVID–19. Amounts appropriated under the preceding sentence shall remain available until expended.

(b) APPLICATION REQUIREMENT.—To be eligible for a payment under this section, an eligible health care provider shall submit to the Secretary an application in such form and manner as the Secretary shall prescribe. Such application shall contain the following:

(1) A statement justifying the need of the provider for the payment, including documentation of the health care related expenses attributable to COVID–19 and lost revenues attributable to COVID–19.

(2) The tax identification number of the provider.

(3) Such assurances as the Secretary determines appropriate that the eligible health care provider will maintain and make available such documentation and submit such reports (at such time, in such form, and containing such information as the Secretary shall prescribe) as the Secretary determines is necessary to ensure compliance with any conditions imposed by the Secretary under this section.

(4) Any other information determined appropriate by the Secretary.

(c) LIMITATION.—Payments made to an eligible health care provider under this section may not be used to reimburse any expense or loss that—

(1) has been reimbursed from another source; or

(2) another source is obligated to reimburse.

(d) APPLICATION OF REQUIREMENTS, RULES, AND PROCEDURES.—The Secretary shall apply any requirements, rules, or procedures as the Secretary deems appropriate for the efficient execution of this section.

(e) DEFINITIONS.—In this section:

(1) ELIGIBLE HEALTH CARE PROVIDER.—The term "eligible health care provider" means—

(A) a provider of services (as defined in section 1861(u)) or a supplier (as defined in section 1861(d)) that—

(i) is enrolled in the Medicare program under title XVIII under section 1866(j) (including temporarily enrolled during the emergency period described in section 1135(g)(1)(B) for such period);

(ii) provides diagnoses, testing, or care for individuals with possible or actual cases of COVID–19; and

(iii) is a rural provider or supplier; or

(B) a provider or supplier that—

(i) is enrolled with a State Medicaid plan under title XIX (or a waiver of such plan) in accordance with subsections (a)(77) and (kk) of section 1902 (including enrolled pursuant to section 1902(a)(78) or section 1932(d)(6)) or enrolled with a State child health plan

under title XXI (or a waiver of such plan) in accordance with subparagraph (G) of section 2107(e)(1) (including enrolled pursuant to subparagraph (D) or (Q) of such section);

(ii) provides diagnoses, testing, or care for individuals with possible or actual cases of COVID–19; and

(iii) is a rural provider or supplier.

(2) HEALTH CARE RELATED EXPENSES ATTRIBUTABLE TO COVID–19.—The term "health care related expenses attributable to COVID–19" means health care related expenses to prevent, prepare for, and respond to COVID–19, including the building or construction of a temporary structure, the leasing of a property, the purchase of medical supplies and equipment, including personal protective equipment and testing supplies, providing for increased workforce and training (including maintaining staff, obtaining additional staff, or both), the operation of an emergency operation center, retrofitting a facility, providing for surge capacity, and other expenses determined appropriate by the Secretary.

(3) LOST REVENUE ATTRIBUTABLE TO COVID–19.—The term "lost revenue attributable to COVID–19" has the meaning given that term in the Frequently Asked Questions guidance released by the Department of Health and Human Services in June 2020, including the difference between such provider's budgeted and actual revenue if such budget had been established and approved prior to March 27, 2020.

(4) PAYMENT.— The term "payment" includes, as determined appropriate by the Secretary, a pre-payment, a prospective payment, a retrospective payment, or a payment through a grant or other mechanism.

(5) RURAL PROVIDER OR SUPPLIER.—The term "rural provider or supplier" means—

(A) a—

(i) provider or supplier located in a rural area (as defined in section 1886(d)(2)(D)); or

(ii) provider treated as located in a rural area pursuant to section 1886(d)(8)(E);

(B) a provider or supplier located in any other area that serves rural patients (as defined by the Secretary), which may include, but is not required to include, a metropolitan statistical area with a population of less than 500,000 (determined based on the most recently available data);

(C) a rural health clinic (as defined in section 1861(aa)(2));

(D) a provider or supplier that furnishes home health, hospice, or long-term services and supports in an individual's home located in a rural area (as defined in section 1886(d)(2)(D)); or

(E) any other rural provider or supplier (as defined by the Secretary).

PART B—PEER REVIEW OF THE UTILIZATION AND QUALITY OF HEALTH CARE SERVICES

PURPOSE

SEC. 1151. [42 U.S.C. 1320c] The purpose of this part is to establish the contracting process which the Secretary must follow pursuant to the requirements of section 1862(g) of this Act, including the definition of the quality improvement organizations with which the Secretary shall contract, the functions such quality improvement organizations are to perform, the confidentiality of medical records, and related administrative matters to facilitate the carrying out of the purposes of this part.

DEFINITION OF QUALITY IMPROVEMENT ORGANIZATION

SEC. 1152. [42 U.S.C. 1320c–1] The term "quality improvement organization" means an entity which—

(1) is able, as determined by the Secretary, to perform its functions under this part in a manner consistent with the efficient and effective administration of this part and title XVIII;

(2) has at least one individual who is a representative of health care providers on its governing body; and

(3) has at least one individual who is a representative of consumers on its governing body.

CONTRACTS WITH QUALITY IMPROVEMENT ORGANIZATIONS

SEC. 1153. [42 U.S.C. 1320c–2] (a) The Secretary shall establish throughout the United States such local, State, regional, national, or other geographic areas as the Secretary determines appropriate with respect to which contracts under this part will be made.

(b)(1) The Secretary shall enter into contracts with one or more quality improvement organizations for each area established under subsection (a) if a qualified organization is available in such area and such organization and the Secretary have negotiated a proposed contract which the Secretary determines will be carried out by such organization in a manner consistent with the efficient and effective administration of this part. In entering into contracts with such qualified organizations, the Secretary shall, to the extent appropriate, seek to ensure that each of the functions described in section 1154(a) are carried out within an area established under subsection (a). If more than one such qualified organization will be operating in an area, the Secretary shall ensure that there is no duplication of the functions carried out by such organizations within the area.

(2)(A) Prior to November 15, 1984, the Secretary shall not enter into a contract under this part with any entity which is, or is affiliated with (through management, ownership, or common control), an entity (other than a self-insured employer) which directly or indirectly makes payments to any practitioner or provider whose health care services are reviewed by such entity or would be reviewed by such entity if it entered into a contract with the Secretary under this part. For purposes of this paragraph, an entity shall not be considered to be affiliated with another entity which

makes payments (directly or indirectly) to any practitioner or provider, by reason of management, ownership, or common control, if the management, ownership, or common control consists only of members of the governing board being affiliated (through management, ownership, or common control) with a health maintenance organization or competitive medical plan which is an "eligible organization" as defined in section 1876(b).

(B) If, after November 14, 1984, the Secretary determines that there is no other entity available for an area with which the Secretary can enter into a contract under this part or the Secretary determines that there is a more qualified entity to perform one or more of the functions in section 1154(a), the Secretary may then enter into a contract under this part with an entity described in subparagraph (A) for such area if such entity otherwise meets the requirements of this part.

(3)(A) The Secretary shall not enter into a contract under this part with any entity which is, or is affiliated with (through management, ownership, or common control), a health care facility within the area served by such entity or which would be served by such entity if it entered into a contract with the Secretary under this part.

(B) For purposes of subparagraph (A), an entity shall not be considered to be affiliated with a health care facility by reason of management, ownership, or common control if the management, ownership, or common control consists only of not more than 20 percent of the members of the governing board of the entity being affiliated (through management, ownership, or common control) with one or more of such facilities.

(4) The Secretary may consider a variety of factors in selecting the contractors that the Secretary determines would provide for the most efficient and effective administration of this part, such as geographic location, size, and prior experience in health care quality improvement. Quality improvement organizations operating as of January 1, 2012, shall be allowed to compete for new contracts (as determined appropriate by the Secretary) along with other qualified organizations and are eligible for renewal of contracts for terms five years thereafter (as determined appropriate by the Secretary).

(c) Each contract with an organization under this section shall provide that—

(1) the organization shall perform a function or functions under section 1154 directly or may subcontract for the performance of all or some of such function or functions (and for purposes of paragraphs (2) and (3) of subsection (b), a subcontract under this paragraph shall not constitute an affiliation with the subcontractor);

(2) the Secretary shall have the right to evaluate the quality and effectiveness of the organization in carrying out the functions specified in the contract;

(3) the contract shall be for an initial term of five years and shall be renewable for terms of five years thereafter;

(4) the Secretary shall include in the contract negotiated objectives against which the organization's performance will be judged, and negotiated specifications for use of regional norms,

or modifications thereof based on national norms, for performing review functions under the contract; and

(5) reimbursement shall be made to the organization on a monthly basis, with payments for any month being made consistent with the Federal Acquisition Regulation.

In evaluating the performance of quality improvement organizations under contracts under this part, the Secretary shall place emphasis on the performance of such organizations in educating providers and practitioners (particularly those in rural areas) concerning the review process and criteria being applied by the organization.

[Subsection (d) was repealed by section 261(b)(3)(C) of PL 112–40]

(e)(1) Except as provided in paragraph (2), contracting authority of the Secretary under this section may be carried out without regard to any provision of law relating to the making, performance, amendment, or modification of contracts of the United States as the Secretary may determine to be inconsistent with the purposes of this part. The Secretary may use different contracting methods with respect to different geographical areas.

(2) If a quality improvement organization with a contract under this section is required to carry out a review function in addition to any function required to be carried out at the time the Secretary entered into or renewed the contract with the organization, the Secretary shall, before requiring such organization to carry out such additional function, negotiate the necessary contractual modifications, including modifications that provide for an appropriate adjustment (in light of the cost of such additional function) to the amount of reimbursement made to the organization.

(f) Any determination by the Secretary to terminate or not to renew a contract under this section shall not be subject to judicial review.

(g) The Secretary shall provide that fiscal intermediaries furnish to quality improvement organizations, each month on a timely basis, data necessary to initiate the review process under section 1154(a) on a timely basis. If the Secretary determines that a fiscal intermediary is unable to furnish such data on a timely basis, the Secretary shall require the hospital to do so.

(h)(1) The Secretary shall publish in the Federal Register any new policy or procedure adopted by the Secretary that affects substantially the performance of contract obligations under this section not less than 30 days before the date on which such policy or procedure is to take effect. This paragraph shall not apply to the extent it is inconsistent with a statutory deadline.

(2) The Secretary shall publish in the Federal Register the general criteria and standards used for evaluating the efficient and effective performance of contract obligations under this section and shall provide opportunity for public comment with respect to such criteria and standards.

(3) The Secretary shall regularly furnish each quality improvement organization with a contract under this section with a report that documents the performance of the organization in relation to the performance of other such organizations.

FUNCTIONS OF QUALITY IMPROVEMENT ORGANIZATIONS

SEC. 1154. [42 U.S.C. 1320c–3] (a) Subject to subsection (b), any quality improvement organization entering into a contract with the Secretary under this part must perform one or more of the following functions:

(1) The organization shall review some or all of the professional activities in the area, subject to the terms of the contract and subject to the requirements of subsection (d), of physicians and other health care practitioners and institutional and noninstitutional providers of health care services in the provision of health care services and items for which payment may be made (in whole or in part) under title XVIII (including where payment is made for such services to eligible organizations pursuant to contracts under section 1876, to Medicare Advantage organizations pursuant to contracts under part C, and to prescription drug sponsors pursuant to contracts under part D) for the purpose of determining whether—

(A) such services and items are or were reasonable and medically necessary and whether such services and items are not allowable under subsection (a)(1) or (a)(9) of section 1862;

(B) the quality of such services meets professionally recognized standards of health care; and

(C) in case such services and items are proposed to be provided in a hospital or other health care facility on an inpatient basis, such services and items could, consistent with the provision of appropriate medical care, be effectively provided more economically on an outpatient basis or in an inpatient health care facility of a different type.

If the organization performs such reviews with respect to a type of health care practitioner other than medical doctors, the organization shall establish procedures for the involvement of health care practitioners of that type in such reviews.

(2) The organization shall determine, on the basis of the review carried out under subparagraphs (A), (B), and (C) of paragraph (1), whether payment shall be made for services under title XVIII. Such determination shall constitute the conclusive determination on those issues for purposes of payment under title XVIII, except that payment may be made if—

(A) such payment is allowed by reason of section 1879;

(B) in the case of inpatient hospital services or extended care services, the quality improvement organization determines that additional time is required in order to arrange for postdischarge care, but payment may be continued under this subparagraph for not more than two days, but only in the case where the provider of such services did not know and could not reasonably have been expected to know (as determined under section 1879) that payment would not otherwise be made for such services under title XVIII prior to notification by the organization under paragraph (3);

(C) such determination is changed as the result of any hearing or review of the determination under section 1155; or

(D) such payment is authorized under section 1861(v)(1)(G).

The organization shall identify cases for which payment should not be made by reason of paragraph (1)(B) only through the use of criteria developed pursuant to guidelines established by the Secretary.

(3)(A) Subject to subparagraphs (B) and (D), whenever the organization makes a determination that any health care services or items furnished or to be furnished to a patient by any practitioner or provider are disapproved, the organization shall promptly notify such patient and the agency or organization responsible for the payment of claims under title XVIII of this Act of such determination.

(B) The notification under subparagraph (A) with respect to services or items disapproved by reason of subparagraph (A) or (C) of paragraph (1) shall not occur until 20 days after the date that the organization has—

(i) made a preliminary notification to such practitioner or provider of such proposed determination, and

(ii) provided such practitioner or provider an opportunity for discussion and review of the proposed determination.

(C) The discussion and review conducted under subparagraph (B)(ii) shall not affect the rights of a practitioner or provider to a formal reconsideration of a determination under this part (as provided under section 1155).

(D) The notification under subparagraph (A) with respect to services or items disapproved by reason of paragraph (1)(B) shall not occur until after—

(i) the organization has notified the practitioner or provider involved of the determination and of the practitioner's or provider's right to a formal reconsideration of the determination under section 1155, and

(ii) if the provider or practitioner requests such a reconsideration, the organization has made such a reconsideration.

If a provider or practitioner is provided a reconsideration, such reconsideration shall be in lieu of any subsequent reconsideration to which the provider or practitioner may be otherwise entitled under section 1155, but shall not affect the right of a beneficiary from seeking reconsideration under such section of the organization's determination (after any reconsideration requested by the provider or physician under clause (ii)).

(E)(i) In the case of services and items provided by a physician that were disapproved by reason of paragraph (1)(B), the notice to the patient shall state the following: "In the judgment of the quality improvement organization, the medical care received was not acceptable under the medicare program. The reasons for the denial have been discussed with your physician.

(ii) In the case of services or items provided by an entity or practitioner other than a physician, the Secretary may substitute the entity or practitioner which provided the services or items for the term "physician" in the notice described in clause (i).

(4)(A) The organization shall, after consultation with the Secretary, determine the types and kinds of cases (whether by type of health care or diagnosis involved, or whether in terms of other relevant criteria relating to the provision of health care services) with respect to which such organization will, in order to most effectively carry out the purposes of this part, exercise review authority under the contract. The organization shall notify the Secretary periodically with respect to such determinations.Each quality improvement organization shall provide that a reasonable proportion of its activities are involved with reviewing, under paragraph (1)(B), the quality of services and that a reasonable allocation of such activities is made among the different cases and settings (including post-acute-care settings, ambulatory settings, and health maintenance organizations). In establishing such allocation, the organization shall consider (i) whether there is reason to believe that there is a particular need for reviews of particular cases or settings because of previous problems regarding quality of care, (ii) the cost of such reviews and the likely yield of such reviews in terms of number and seriousness of quality of care problems likely to be discovered as a result of such reviews, and (iii) the availability and adequacy of alternative quality review and assurance mechanisms.

(B) The contract of each organization shall provide for the review of services (including both inpatient and outpatient services) provided by eligible organizations pursuant to a risk-sharing contract under section 1876 (or that is subject to review under section 1882(t)(3)) for the purpose of determining whether the quality of such services meets professionally recognized standards of health care, including whether appropriate health care services have not been provided or have been provided in inappropriate settings and whether individuals enrolled with an eligible organization have adequate access to health care services provided by or through such organization (as determined, in part, by a survey of individuals enrolled with the organization who have not yet used the organization to receive such services). The contract of each organization shall also provide that with respect to health care provided by a health maintenance organization or competitive medical plan under section 1876, the organization shall maintain a beneficiary outreach program designed to apprise individuals receiving care under such section of the role of the peer review system, of the rights of the individual under such system, and of the method and purposes for contacting the organization. The previous two sentences shall not apply with respect to a contract year if another entity has been awarded a contract

under subparagraph (C)[28]. Under the contract the level of effort expended by the organization on reviews under this subparagraph shall be equivalent, on a per enrollee basis, to the level of effort expended by the organization on utilization and quality reviews performed with respect to individuals not enrolled with an eligible organization.

(5) The organization shall consult with nurses and other professional health care practitioners (other than physicians described in section 1861(r)(1)) and with representatives of institutional and noninstitutional providers of health care services, with respect to the organization's responsibility for the review under paragraph (1) of the professional activities of such practitioners and providers.

(6)(A) The organization shall, consistent with the provisions of its contract under this part, apply professionally developed norms of care, diagnosis, and treatment based upon typical patterns of practice within the geographic area served by the organization as principal points of evaluation and review, taking into consideration national norms where appropriate. Such norms with respect to treatment for particular illnesses or health conditions shall include—

(i) the types and extent of the health care services which, taking into account differing, but acceptable, modes of treatment and methods of organizing and delivering care, are considered within the range of appropriate diagnosis and treatment of such illness or health condition, consistent with professionally recognized and accepted patterns of care; and

(ii) the type of health care facility which is considered, consistent with such standards, to be the type in which health care services which are medically appropriate for such illness or condition can most economically be provided.

As a component of the norms described in clause (i) or (ii), the organization shall take into account the special problems associated with delivering care in remote rural areas, the availability of service alternatives to inpatient hospitalization, and other appropriate factors (such as the distance from a patient's residence to the site of care, family support, availability of proximate alternative sites of care, and the patient's ability to carry out necessary or prescribed self-care regimens) that could adversely affect the safety or effectiveness of treatment provided on an outpatient basis.

(B) The organization shall—

(i) offer to provide, several times each year, for a physician representing the organization to meet (at a hospital or at a regional meeting) with medical and administrative staff of each hospital (the services of which are reviewed by the organization) respecting the organization's review of the hospital's services for which payment may be made under title XVIII, and

[28] Subparagraph (C) was repealed by section 261(c)(2)(A)(ii) of Public Law 112–40.

(ii) publish (not less often than annually) and distribute to providers and practitioners whose services are subject to review a report that describes the organization's findings with respect to the types of cases in which the organization has frequently determined that (I) inappropriate or unnecessary care has been provided, (II) services were rendered in an inappropriate setting, or (III) services did not meet professionally recognized standards of health care.

(7) The organization, to the extent necessary and appropriate to the performance of the contract, shall—

(A)(i) make arrangements to utilize the services of persons who are practitioners of, or specialists in, the various areas of medicine (including dentistry, optometry, and podiatry, or other types of health care, which persons shall, to the maximum extent practicable, be individuals engaged in the practice of their profession within the area served by such organization; and

(ii) in the case of psychiatric and physical rehabilitation services, make arrangements to ensure that (to the extent possible) initial review of such services be made by a physician who is trained in psychiatry or physical rehabilitation (as appropriate). [29]

(B) undertake such professional inquiries either before or after, or both before and after, the provision of services with respect to which such organization has a responsibility for review which in the judgment of such organization will facilitate its activities;

(C) examine the pertinent records of any practitioner or provider of health care services providing services with respect to which such organization has a responsibility for review under paragraph (1); and

(D) inspect the facilities in which care is rendered or services are provided (which are located in such area) of any practitioner or provider of health care services providing services with respect to which such organization has a responsibility for review under paragraph (1).

(8) The organization shall perform such duties and functions and assume such responsibilities and comply with such other requirements as may be required by this part or under regulations of the Secretary promulgated to carry out the provisions of this part or as may be required to carry out section 1862(a)(15).

(9)(A) The organization shall collect such information relevant to its functions, and keep and maintain such records, in such form as the Secretary may require to carry out the purposes of this part, and shall permit access to and use of any such information and records as the Secretary may require for such purposes, subject to the provisions of section 1160.

(B) If the organization finds, after reasonable notice to and opportunity for discussion with the physician or practitioner concerned, that the physician or practitioner has furnished

[29] Punctuation as in original.

services in violation of section 1156(a) and the organization determines that the physician or practitioner should enter into a corrective action plan under section 1156(b)(1), the organization shall notify the State board or boards responsible for the licensing or disciplining of the physician or practitioner of its finding and of any action taken as a result of the finding.

(10) The organization shall coordinate activities, including information exchanges, which are consistent with economical and efficient operation of programs among appropriate public and private agencies or organizations including—

(A) agencies under contract pursuant to sections 1816 and 1842 of this Act;

(B) other quality improvement organizations having contracts under this part; and

(C) other public or private review organizations as may be appropriate.

(11) The organization shall make available its facilities and resources for contracting with private and public entities paying for health care in its area for review, as feasible and appropriate, of services reimbursed by such entities.

(12) As part of the organization's review responsibility under paragraph (1), the organization shall review all ambulatory surgical procedures specified pursuant to section 1833(i)(1)(A) which are performed in the area, or, at the discretion of the Secretary, a sample of such procedures.

(13) Notwithstanding paragraph (4), the organization shall perform the review described in paragraph (1) with respect to early readmission cases to determine if the previous inpatient hospital services and the post-hospital services met professionally recognized standards of health care. Such reviews may be performed on a sample basis if the organization and the Secretary determine it to be appropriate. In this paragraph, an "early readmission case" is a case in which an individual, after discharge from a hospital, is readmitted to a hospital less than 31 days after the date of the most recent previous discharge.

(14) The organization shall conduct an appropriate review of all written complaints about the quality of services (for which payment may otherwise be made under title XVIII) not meeting professionally recognized standards of health care, if the complaint is filed with the organization by an individual entitled to benefits for such services under such title (or a person acting on the individual's behalf). The organization shall inform the individual (or representative) of the organization's final disposition of the complaint. Before the organization concludes that the quality of services does not meet professionally recognized standards of health care, the organization must provide the practitioner or person concerned with reasonable notice and opportunity for discussion.

(15) During each year of the contract entered into under section 1153(b), the organization shall perform on-site review activities as the Secretary determines appropriate.

(16) The organization shall provide for a review and report to the Secretary when requested by the Secretary under section 1867(d)(3). The organization shall provide reasonable no-

tice of the review to the physician and hospital involved. Within the time period permitted by the Secretary, the organization shall provide a reasonable opportunity for discussion with the physician and hospital involved, and an opportunity for the physician and hospital to submit additional information, before issuing its report to the Secretary under such section.

(17) The organization shall execute its responsibilities under subparagraphs (A) and (B) of paragraph (1) by offering to providers, practitioners, Medicare Advantage organizations offering Medicare Advantage plans under part C, and prescription drug sponsors offering prescription drug plans under part D quality improvement assistance pertaining to prescription drug therapy. For purposes of this part and title XVIII, the functions described in this paragraph shall be treated as a review function.

(18) The organization shall perform, subject to the terms of the contract, such other activities as the Secretary determines may be necessary for the purposes of improving the quality of care furnished to individuals with respect to items and services for which payment may be made under title XVIII.

(b) A quality improvement organization entering into a contract with the Secretary to perform a function described in a paragraph under subsection (a) must perform all of the activities described in such paragraph, except to the extent otherwise negotiated with the Secretary pursuant to the contract or except for a function for which the Secretary determines it is not appropriate for the organization to perform, such as a function that could cause a conflict of interest with another function.

(c)(1) No physician shall be permitted to review—

(A) health care services provided to a patient if he was directly responsible for providing such services; or

(B) health care services provided in or by an institution, organization, or agency, if he or any member of his family has, directly or indirectly, a significant financial interest in such institution, organization, or agency.

(2) For purposes of this subsection, a physician's family includes only his spouse (other than a spouse who is legally separated from him under a decree of divorce or separate maintenance), children (including legally adopted children), grandchildren, parents, and grandparents.

(d) No quality improvement organization shall utilize the services of any individual who is not a duly licensed doctor of medicine, osteopathy, dentistry, optometry, or podiatry to make final determinations of denial decisions in accordance with its duties and functions under this part with respect to the professional conduct of any other duly licensed doctor of medicine, osteopathy, dentistry, optometry, or podiatry, or any act performed by any duly licensed doctor of medicine, osteopathy, dentistry, optometry, or podiatry in the exercise of his profession.

(e)(1) If—

(A) a hospital has determined that a patient no longer requires inpatient hospital care, and

(B) the attending physician has agreed with the hospital's determination,

the hospital may provide the patient (or the patient's representative) with a notice (meeting conditions prescribed by the Secretary under section 1879) of the determination.

[(2)–(5) Repealed]

(f) The Secretary, in consultation with appropriate experts, shall identify methods that would be available to assist quality improvement organizations (under subsection (a)(4)) in identifying those cases which are more likely than others to be associated with a quality of services which does not meet professionally recognized standards of health care.

RIGHT TO HEARING AND JUDICIAL REVIEW

SEC. 1155. [42 U.S.C. 1320c–4] Any beneficiary who is entitled to benefits under title XVIII, and, subject to section 1154(a)(3)(D), any practitioner or provider, who is dissatisfied with a determination made by a contracting quality improvement organization in conducting its review responsibilities under this part, shall be entitled to a reconsideration of such determination by the reviewing organization. Where the reconsideration is adverse to the beneficiary and where the matter in controversy is $200 or more, such beneficiary shall be entitled to a hearing by the Secretary (to the same extent as beneficiaries under title II are entitled to a hearing by the Commissioner of Social Security under section 205(b)). For purposes of the preceding sentence, subsection (l) of section 205 shall apply, except that any reference in such subsection to the Commissioner of Social Security or the Social Security Administration shall be deemed a reference to the Secretary or the Department of Health and Human Services, respectively. Where the amount in controversy is $2,000 or more, such beneficiary shall be entitled to judicial review of any final decision relating to a reconsideration described in this subsection.

OBLIGATIONS OF HEALTH CARE PRACTITIONERS AND PROVIDERS OF HEALTH CARE SERVICES; SANCTIONS AND PENALTIES; HEARINGS AND REVIEW

SEC. 1156. [42 U.S.C. 1320c–5] (a) It shall be the obligation of any health care practitioner and any other person (including a hospital or other health care facility, organization, or agency) who provides health care services for which payment may be made (in whole or in part) under this Act, to assure, to the extent of his authority that services or items ordered or provided by such practitioner or person to beneficiaries and recipients under this Act—

(1) will be provided economically and only when, and to the extent, medically necessary;

(2) will be of a quality which meets professionally recognized standards of health care; and

(3) will be supported by evidence of medical necessity and quality in such form and fashion and at such time as may reasonably be required by a reviewing quality improvement organization in the exercise of its duties and responsibilities.

(b)(1) If after reasonable notice and opportunity for discussion with the practitioner or person concerned, and, if appropriate, after the practitioner or person has been given a reasonable opportunity to enter into and complete a corrective action plan (which may include remedial education) agreed to by the organization, and has failed successfully to complete such plan, any organization having a contract with the Secretary under this part determines that such practitioner or person has—

(A) failed in a substantial number of cases substantially to comply with any obligation imposed on him under subsection (a), or

(B) grossly and flagrantly violated any such obligation in one or more instances,

such organization shall submit a report and recommendations to the Secretary. If the Secretary agrees with such determination, the Secretary (in addition to any other sanction provided under law) may exclude (permanently or for such period as the Secretary may prescribe, except that such period may not be less than 1 year) such practitioner or person from eligibility to provide services under this Act on a reimbursable basis. If the Secretary fails to act upon the recommendations submitted to him by such organization within 120 days after such submission, such practitioner or person shall be excluded from eligibility to provide services on a reimbursable basis until such time as the Secretary determines otherwise.

(2) A determination made by the Secretary under this subsection to exclude a practitioner or person shall be effective on the same date and in the same manner as an exclusion from participation under the programs under this Act becomes effective under section 1128(c), and shall (subject to the minimum period specified in the second sentence of paragraph (1)) remain in effect until the Secretary finds and gives reasonable notice to the public that the basis for such determination has been removed and that there is reasonable assurance that it will not recur.

(3) In lieu of the sanction authorized by paragraph (1), the Secretary may require that (as a condition to the continued eligibility of such practitioner or person to provide such health care services on a reimbursable basis) such practitioner or person pays to the United States, in case such acts or conduct involved the provision or ordering by such practitioner or person of health care services which were medically improper or unnecessary, an amount not in excess of up to $10,000 for each instance of the medically improper or unnecessary services so provided. Such amount may be deducted from any sums owing by the United States (or any instrumentality thereof) to the practitioner or person from whom such amount is claimed.

(4) Any practitioner or person furnishing services described in paragraph (1) who is dissatisfied with a determination made by the Secretary under this subsection shall be entitled to reasonable notice and opportunity for a hearing thereon by the Secretary to the same extent as is provided in section 205(b), and to judicial review of the Secretary's final decision after such hearing as is provided in section 205(g).

(5) Before the Secretary may effect an exclusion under paragraph (2) in the case of a provider or practitioner located in a rural

health professional shortage area or in a county with a population of less than 70,000, the provider or practitioner adversely affected by the determination is entitled to a hearing before an administrative law judge (described in section 205(b)) respecting whether the provider or practitioner should be able to continue furnishing services to individuals entitled to benefits under this Act, pending completion of the administrative review procedure under paragraph (4). If the judge does not determine, by a preponderance of the evidence, that the provider or practitioner will pose a serious risk to such individuals if permitted to continue furnishing such services, the Secretary shall not effect the exclusion under paragraph (2) until the provider or practitioner has been provided reasonable notice and opportunity for an administrative hearing thereon under paragraph (4).

(6) When the Secretary effects an exclusion of a physician under paragraph (2), the Secretary shall notify the State board responsible for the licensing of the physician of the exclusion.

(c) It shall be the duty of each quality improvement organization to use such authority or influence it may possess as a professional organization, and to enlist the support of any other professional or governmental organization having influence or authority over health care practitioners and any other person (including a hospital or other health care facility, organization, or agency) providing health care services in the area served by such review organization, in assuring that each practitioner or person (referred to in subsection (a)) providing health care services in such area shall comply with all obligations imposed on him under subsection (a).

LIMITATION ON LIABILITY

SEC. 1157. [42 U.S.C. 1320c–6] (a) Notwithstanding any other provision of law, no person providing information to any organization having a contract with the Secretary under this part shall be held, by reason of having provided such information, to have violated any criminal law, or to be civilly liable under any law of the United States or of any State (or political subdivision thereof) unless—

(1) such information is unrelated to the performance of the contract of such organization; or

(2) such information is false and the person providing it knew, or had reason to believe, that such information was false.

(b) No organization having a contract with the Secretary under this part and no person who is employed by, or who has a fiduciary relationship with, any such organization or who furnishes professional services to such organization, shall be held by reason of the performance of any duty, function, or activity required or authorized pursuant to this part or to a valid contract entered into under this part, to have violated any criminal law, or to be civilly liable under any law of the United States or of any State (or political subdivision thereof) provided due care was exercised in the performance of such duty, function, or activity.

(c) No doctor of medicine or osteopathy and no provider (including directors, trustees, employees, or officials thereof) of health care

services shall be civilly liable to any person under any law of the United States or of any State (or political subdivision thereof) on account of any action taken by him in compliance with or reliance upon professionally developed norms of care and treatment applied by an organization under contract pursuant to section 1153 operating in the area where such doctor of medicine or osteopathy or provider took such action; but only if—

(1) he takes such action in the exercise of his profession as a doctor of medicine or osteopathy or in the exercise of his functions as a provider of health care services; and

(2) he exercised due care in all professional conduct taken or directed by him and reasonably related to, and resulting from, the actions taken in compliance with or reliance upon such professionally accepted norms of care and treatment.

(d) The Secretary shall make payment to an organization under contract with him pursuant to this part, or to any member or employee thereof, or to any person who furnishes legal counsel or services to such organization, in an amount equal to the reasonable amount of the expenses incurred, as determined by the Secretary, in connection with the defense of any suit, action, or proceeding brought against such organization, member, or employee related to the performance of any duty or function under such contract by such organization, member, or employee.

APPLICATION OF THIS PART TO CERTAIN STATE PROGRAMS RECEIVING FEDERAL FINANCIAL ASSISTANCE

SEC. 1158. [42 U.S.C. 1320c–7] (a) A State plan approved under title XIX of this Act may provide that the functions specified in section 1154 may be performed in an area by contract with a quality improvement organization that has entered into a contract with the Secretary in accordance with the provisions of section 1862(g).

(b) In the event a State enters into a contract in accordance with subsection (a), the Federal share of the expenditures made to the contracting organization for its costs in the performance of its functions under the State plan shall be 75 percent (as provided in section 1903(a)(3)(C)).

AUTHORIZATION FOR USE OF CERTAIN FUNDS TO ADMINISTER THE PROVISIONS OF THIS PART

SEC. 1159. [42 U.S.C. 1320c–8] Expenses incurred in the administration of the contracts described in section 1862(g) shall be payable from—

(1) funds in the Federal Hospital Insurance Trust Fund; and

(2) funds in the Federal Supplementary Medical Insurance Trust Fund,

in such amounts from each of such Trust Funds as the Secretary shall deem to be fair and equitable after taking into consideration the expenses attributable to the administration of this part with respect to each of such programs. The Secretary shall make such transfers of moneys between such Trust Funds as may be appropriate to settle accounts between them in cases where expenses

properly payable from one such Trust Fund have been paid from the other such Trust Fund.

PROHIBITION AGAINST DISCLOSURE OF INFORMATION

SEC. 1160. [42 U.S.C. 1320c–9] (a) An organization, in carrying out its functions under a contract entered into under this part, shall not be a Federal agency for purposes of the provisions of section 552 of title 5, United States Code (commonly referred to as the Freedom of Information Act). Any data or information acquired by any such organization in the exercise of its duties and functions shall be held in confidence and shall not be disclosed to any person except—

(1) to the extent that may be necessary to carry out the purposes of this part,

(2) in such cases and under such circumstances as the Secretary shall by regulations provide to assure adequate protection of the rights and interests of patients, health care practitioners, or providers of health care, or

(3) in accordance with subsection (b).

(b) An organization having a contract with the Secretary under this part shall provide in accordance with procedures and safeguards established by the Secretary, data and information—

(1) which may identify specific providers or practitioners as may be necessary—

(A) to assist Federal and State agencies recognized by the Secretary as having responsibility for identifying and investigating cases or patterns of fraud or abuse, which data and information shall be provided by the quality improvement organization to any such agency at the request of such agency relating to a specific case or pattern;

(B) to assist appropriate Federal and State agencies recognized by the Secretary as having responsibility for identifying cases or patterns involving risks to the public health, which data and information shall be provided by the quality improvement organization to any such agency—

(i) at the discretion of the quality improvement organization, at the request of such agency relating to a specific case or pattern with respect to which such agency has made a finding, or has a reasonable belief, that there may be a substantial risk to the public health, or

(ii) upon a finding by, or the reasonable belief of, the quality improvement organization that there may be a substantial risk to the public health;

(C) to assist appropriate State agencies recognized by the Secretary as having responsibility for licensing or certification of providers or practitioners or to assist national accreditation bodies acting pursuant to section 1865 in accrediting providers for purposes of meeting the conditions described in title XVIII, which data and information shall be provided by the quality improvement organization to any such agency or body at the request of such agency or

body relating to a specific case or to a possible pattern of substandard care, but only to the extent that such data and information are required by the agency or body to carry out its respective function which is within the jurisdiction of the agency or body under State law or under section 1865; and

(D) to provide notice in accordance with section 1154(a)(9)(B);

(2) to assist the Secretary, and such Federal and State agencies recognized by the Secretary as having health planning or related responsibilities under Federal or State law (including health systems agencies and State health planning and development agencies), in carrying out appropriate health care planning and related activities, which data and information shall be provided in such format and manner as may be prescribed by the Secretary or agreed upon by the responsible Federal and State agencies and such organization, and shall be in the form of aggregate statistical data (without explicitly identifying any individual) on a geographic, institutional, or other basis reflecting the volume and frequency of services furnished, as well as the demographic characteristics of the population subject to review by such organization.

The penalty provided in subsection (c) shall not apply to the disclosure of any information received under this subsection, except that such penalty shall apply to the disclosure (by the agency receiving such information) of any such information described in paragraph (1) unless such disclosure is made in a judicial, administrative, or other formal legal proceeding resulting from an investigation conducted by the agency receiving the information. An organization may require payment of a reasonable fee for providing information under this subsection in response to a request for such information.

(c) It shall be unlawful for any person to disclose any such information described in subsection (a) other than for the purposes provided in subsections (a) and (b), and any person violating the provisions of this section shall, upon conviction, be fined not more than $1,000, and imprisoned for not more than 6 months, or both, and shall be required to pay the costs of prosecution.

(d) No patient record in the possession of an organization having a contract with the Secretary under this part shall be subject to subpoena or discovery proceedings in a civil action. No document or other information produced by such an organization in connection with its deliberations in making determinations under section 1154(a)(1)(B) or 1156(a)(2) shall be subject to subpoena or discovery in any administrative or civil proceeding; except that such an organization shall provide, upon request of a practitioner or other person adversely affected by such a determination, a summary of the organization's findings and conclusions in making the determination.

(e) For purposes of this section and section 1157, the term "organization with a contract with the Secretary under this part" includes an entity with a contract with the Secretary under section 1154(a)(4)(C).

ANNUAL REPORTS

SEC. 1161. [42 U.S.C. 1320c–10] The Secretary shall submit to the Congress not later than April 1 of each year, a full and complete report on the administration, impact, and cost of the program under this part during the preceding fiscal year, including data and information on—

(1) the number, status, and service areas of all quality improvement organizations participating in the program;

(2) the number of health care institutions and practitioners whose services are subject to review by such organizations, and the number of beneficiaries and recipients who received services subject to such review during such year;

(3) the various methods of reimbursement utilized in contracts under this part, and the relative efficiency of each such method of reimbursement;

(4) the imposition of penalties and sanctions under this title for violations of law and for failure to comply with the obligations imposed by this part;

(5) the total costs incurred under titles XVIII and XIX of this Act in the implementation and operation of all procedures required by such titles for the review of services to determine their medical necessity, appropriateness of use, and quality; and

(6) descriptions of the criteria upon which decisions are made, and the selection and relative weights of such criteria.

EXEMPTIONS FOR RELIGIOUS NONMEDICAL HEALTH CARE INSTITUTIONS

SEC. 1162. [42 U.S.C. 1320c–11] The provisions of this part shall not apply with respect to a religious nonmedical health care institution (as defined in section 1861(ss)(1)).

MEDICAL OFFICERS IN AMERICAN SAMOA, THE NORTHERN MARIANA ISLANDS, AND THE TRUST TERRITORY OF THE PACIFIC ISLANDS TO BE INCLUDED IN THE UTILIZATION AND QUALITY CONTROL PEER REVIEW PROGRAM

SEC. 1163. [42 U.S.C 1320c–12] For purposes of applying this part to American Samoa, the Northern Mariana Islands, and the Trust Territory of the Pacific Islands, individuals licensed to practice medicine in those places shall be considered to be physicians and doctors of medicine.

[SEC. 1164. Repealed.]

PART C—ADMINISTRATIVE SIMPLIFICATION

DEFINITIONS

SEC. 1171. [42 U.S.C. 1320d] For purposes of this part:

(1) CODE SET.—The term "code set" means any set of codes used for encoding data elements, such as tables of terms, medical concepts, medical diagnostic codes, or medical procedure codes.

(2) HEALTH CARE CLEARINGHOUSE.—The term "health care clearinghouse" means a public or private entity that processes or facilitates the processing of nonstandard data elements of health information into standard data elements.

(3) HEALTH CARE PROVIDER.—The term "health care provider" includes a provider of services (as defined in section 1861(u)), a provider of medical or other health services (as defined in section 1861(s)), and any other person furnishing health care services or supplies.

(4) HEALTH INFORMATION.—The term "health information" means any information, whether oral or recorded in any form or medium, that—

(A) is created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse; and

(B) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual.

(5) HEALTH PLAN.—The term "health plan" means an individual or group plan that provides, or pays the cost of, medical care (as such term is defined in section 2791 of the Public Health Service Act). Such term includes the following, and any combination thereof:

(A) A group health plan (as defined in section 2791(a) of the Public Health Service Act), but only if the plan—

(i) has 50 or more participants (as defined in section 3(7) of the Employee Retirement Income Security Act of 1974); or

(ii) is administered by an entity other than the employer who established and maintains the plan.

(B) A health insurance issuer (as defined in section 2791(b) of the Public Health Service Act).

(C) A health maintenance organization (as defined in section 2791(b) of the Public Health Service Act).

(D) Parts A, B, C, or D of the Medicare program under title XVIII.

(E) The medicaid program under title XIX.

(F) A Medicare supplemental policy (as defined in section 1882(g)(1)).

(G) A long-term care policy, including a nursing home fixed indemnity policy (unless the Secretary determines that such a policy does not provide sufficiently comprehensive coverage of a benefit so that the policy should be treated as a health plan).

(H) An employee welfare benefit plan or any other arrangement which is established or maintained for the purpose of offering or providing health benefits to the employees of 2 or more employers.

(I) The health care program for active military personnel under title 10, United States Code.

(J) The veterans health care program under chapter 17 of title 38, United States Code.

(K) The Civilian Health and Medical Program of the Uniformed Services (CHAMPUS), as defined in section 1072(4) of title 10, United States Code.

(L) The Indian health service program under the Indian Health Care Improvement Act (25 U.S.C. 1601 et seq.).

(M) The Federal Employees Health Benefit Plan under chapter 89 of title 5, United States Code.

(6) INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION.—The term "individually identifiable health information" means any information, including demographic information collected from an individual, that—

(A) is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

(B) relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual, and—

(i) identifies the individual; or

(ii) with respect to which there is a reasonable basis to believe that the information can be used to identify the individual.

(7) STANDARD.—The term "standard", when used with reference to a data element of health information or a transaction referred to in section 1173(a)(1), means any such data element or transaction that meets each of the standards and implementation specifications adopted or established by the Secretary with respect to the data element or transaction under sections 1172 through 1174.

(8) STANDARD SETTING ORGANIZATION.—The term "standard setting organization" means a standard setting organization accredited by the American National Standards Institute, including the National Council for Prescription Drug Programs, that develops standards for information transactions, data elements, or any other standard that is necessary to, or will facilitate, the implementation of this part.

(9) OPERATING RULES.—The term "operating rules" means the necessary business rules and guidelines for the electronic exchange of information that are not defined by a standard or its implementation specifications as adopted for purposes of this part.

GENERAL REQUIREMENTS FOR ADOPTION OF STANDARDS

SEC. 1172. [42 U.S.C. 1320d–1] (a) APPLICABILITY.—Any standard adopted under this part shall apply, in whole or in part, to the following persons:

(1) A health plan.

(2) A health care clearinghouse.

(3) A health care provider who transmits any health information in electronic form in connection with a transaction referred to in section 1173(a)(1).

(b) REDUCTION OF COSTS.—Any standard adopted under this part shall be consistent with the objective of reducing the administrative costs of providing and paying for health care.

(c) ROLE OF STANDARD SETTING ORGANIZATIONS.—

(1) IN GENERAL.—Except as provided in paragraph (2), any standard adopted under this part shall be a standard that has been developed, adopted, or modified by a standard setting organization.

(2) SPECIAL RULES.—

(A) DIFFERENT STANDARDS.—The Secretary may adopt a standard that is different from any standard developed, adopted, or modified by a standard setting organization, if—

(i) the different standard will substantially reduce administrative costs to health care providers and health plans compared to the alternatives; and

(ii) the standard is promulgated in accordance with the rulemaking procedures of subchapter III of chapter 5 of title 5, United States Code.

(B) NO STANDARD BY STANDARD SETTING ORGANIZATION.—If no standard setting organization has developed, adopted, or modified any standard relating to a standard that the Secretary is authorized or required to adopt under this part—

(i) paragraph (1) shall not apply; and

(ii) subsection (f) shall apply.

(3) CONSULTATION REQUIREMENT.—

(A) IN GENERAL.—A standard may not be adopted under this part unless—

(i) in the case of a standard that has been developed, adopted, or modified by a standard setting organization, the organization consulted with each of the organizations described in subparagraph (B) in the course of such development, adoption, or modification; and

(ii) in the case of any other standard, the Secretary, in complying with the requirements of subsection (f), consulted with each of the organizations described in subparagraph (B) before adopting the standard.

(B) ORGANIZATIONS DESCRIBED.—The organizations referred to in subparagraph (A) are the following:

(i) The National Uniform Billing Committee.

(ii) The National Uniform Claim Committee.

(iii) The Workgroup for Electronic Data Interchange.

(iv) The American Dental Association.

(d) IMPLEMENTATION SPECIFICATIONS.—The Secretary shall establish specifications for implementing each of the standards adopted under this part.

(e) PROTECTION OF TRADE SECRETS.—Except as otherwise required by law, a standard adopted under this part shall not require disclosure of trade secrets or confidential commercial information by a person required to comply with this part.

(f) ASSISTANCE TO THE SECRETARY.—In complying with the requirements of this part, the Secretary shall rely on the recommendations of the National Committee on Vital and Health Statistics established under section 306(k) of the Public Health Service Act (42 U.S.C. 242k(k)), and shall consult with appropriate Federal and State agencies and private organizations. The Secretary shall publish in the Federal Register any recommendation of the National Committee on Vital and Health Statistics regarding the adoption of a standard under this part.

(g) APPLICATION TO MODIFICATIONS OF STANDARDS.—This section shall apply to a modification to a standard (including an addition to a standard) adopted under section 1174(b) in the same manner as it applies to an initial standard adopted under section 1174(a).

STANDARDS FOR INFORMATION TRANSACTIONS AND DATA ELEMENTS

SEC. 1173. [42 U.S.C. 1320d–2] (a) STANDARDS TO ENABLE ELECTRONIC EXCHANGE.—

(1) IN GENERAL.—The Secretary shall adopt standards for transactions, and data elements for such transactions, to enable health information to be exchanged electronically, that are appropriate for—

(A) the financial and administrative transactions described in paragraph (2); and

(B) other financial and administrative transactions determined appropriate by the Secretary, consistent with the goals of improving the operation of the health care system and reducing administrative costs, and subject to the requirements under paragraph (5).

(2) TRANSACTIONS.—The transactions referred to in paragraph (1)(A) are transactions with respect to the following:

(A) Health claims or equivalent encounter information.

(B) Health claims attachments.

(C) Enrollment and disenrollment in a health plan.

(D) Eligibility for a health plan.

(E) Health care payment and remittance advice.

(F) Health plan premium payments.

(G) First report of injury.

(H) Health claim status.

(I) Referral certification and authorization.

(J) Electronic funds transfers.

(3) ACCOMMODATION OF SPECIFIC PROVIDERS.—The standards adopted by the Secretary under paragraph (1) shall accommodate the needs of different types of health care providers.

(4) REQUIREMENTS FOR FINANCIAL AND ADMINISTRATIVE TRANSACTIONS.—

(A) IN GENERAL.—The standards and associated operating rules adopted by the Secretary shall—

(i) to the extent feasible and appropriate, enable determination of an individual's eligibility and financial responsibility for specific services prior to or at the point of care;

(ii) be comprehensive, requiring minimal augmentation by paper or other communications;

(iii) provide for timely acknowledgment, response, and status reporting that supports a transparent claims and denial management process (including adjudication and appeals); and

(iv) describe all data elements (including reason and remark codes) in unambiguous terms, require that such data elements be required or conditioned upon set values in other fields, and prohibit additional conditions (except where necessary to implement State or Federal law, or to protect against fraud and abuse).

(B) REDUCTION OF CLERICAL BURDEN.—In adopting standards and operating rules for the transactions referred to under paragraph (1), the Secretary shall seek to reduce the number and complexity of forms (including paper and electronic forms) and data entry required by patients and providers.

(5) CONSIDERATION OF STANDARDIZATION OF ACTIVITIES AND ITEMS.—

(A) IN GENERAL.—For purposes of carrying out paragraph (1)(B), the Secretary shall solicit, not later than January 1, 2012, and not less than every 3 years thereafter, input from entities described in subparagraph (B) on—

(i) whether there could be greater uniformity in financial and administrative activities and items, as determined appropriate by the Secretary; and

(ii) whether such activities should be considered financial and administrative transactions (as described in paragraph (1)(B)) for which the adoption of standards and operating rules would improve the operation of the health care system and reduce administrative costs.

(B) SOLICITATION OF INPUT.—For purposes of subparagraph (A), the Secretary shall seek input from—

(i) the National Committee on Vital and Health Statistics, the Health Information Technology Policy Committee, and the Health Information Technology Standards Committee; and

(ii) standard setting organizations and stakeholders, as determined appropriate by the Secretary.

(b) UNIQUE HEALTH IDENTIFIERS.—

(1) IN GENERAL.—The Secretary shall adopt standards providing for a standard unique health identifier for each individual, employer, health plan, and health care provider for use in the health care system. In carrying out the preceding sentence for each health plan and health care provider, the Secretary shall take into account multiple uses for identifiers and multiple locations and specialty classifications for health care providers.

(2) USE OF IDENTIFIERS.—The standards adopted under paragraph (1) shall specify the purposes for which a unique health identifier may be used.

(c) CODE SETS.—

(1) IN GENERAL.—The Secretary shall adopt standards that—

(A) select code sets for appropriate data elements for the transactions referred to in subsection (a)(1) from among the code sets that have been developed by private and public entities; or

(B) establish code sets for such data elements if no code sets for the data elements have been developed.

(2) DISTRIBUTION.—The Secretary shall establish efficient and low-cost procedures for distribution (including electronic distribution) of code sets and modifications made to such code sets under section 1174(b).

(d) SECURITY STANDARDS FOR HEALTH INFORMATION.—

(1) SECURITY STANDARDS.—The Secretary shall adopt security standards that—

(A) take into account—

(i) the technical capabilities of record systems used to maintain health information;

(ii) the costs of security measures;

(iii) the need for training persons who have access to health information;

(iv) the value of audit trails in computerized record systems; and

(v) the needs and capabilities of small health care providers and rural health care providers (as such providers are defined by the Secretary); and

(B) ensure that a health care clearinghouse, if it is part of a larger organization, has policies and security procedures which isolate the activities of the health care clearinghouse with respect to processing information in a manner that prevents unauthorized access to such information by such larger organization.

(2) SAFEGUARDS.—Each person described in section 1172(a) who maintains or transmits health information shall maintain reasonable and appropriate administrative, technical, and physical safeguards—

(A) to ensure the integrity and confidentiality of the information;

(B) to protect against any reasonably anticipated—

(i) threats or hazards to the security or integrity of the information; and

(ii) unauthorized uses or disclosures of the information; and

(C) otherwise to ensure compliance with this part by the officers and employees of such person.

(e) ELECTRONIC SIGNATURE.—

(1) STANDARDS.—The Secretary, in coordination with the Secretary of Commerce, shall adopt standards specifying procedures for the electronic transmission and authentication of signatures with respect to the transactions referred to in subsection (a)(1).

(2) EFFECT OF COMPLIANCE.—Compliance with the standards adopted under paragraph (1) shall be deemed to satisfy Federal and State statutory requirements for written signa-

tures with respect to the transactions referred to in subsection (a)(1).

(f) TRANSFER OF INFORMATION AMONG HEALTH PLANS.—The Secretary shall adopt standards for transferring among health plans appropriate standard data elements needed for the coordination of benefits, the sequential processing of claims, and other data elements for individuals who have more than one health plan.

(g) OPERATING RULES.—

(1) IN GENERAL.—The Secretary shall adopt a single set of operating rules for each transaction referred to under subsection (a)(1) with the goal of creating as much uniformity in the implementation of the electronic standards as possible. Such operating rules shall be consensus-based and reflect the necessary business rules affecting health plans and health care providers and the manner in which they operate pursuant to standards issued under Health Insurance Portability and Accountability Act of 1996.

(2) OPERATING RULES DEVELOPMENT.—In adopting operating rules under this subsection, the Secretary shall consider recommendations for operating rules developed by a qualified nonprofit entity that meets the following requirements:

(A) The entity focuses its mission on administrative simplification.

(B) The entity demonstrates a multi-stakeholder and consensus-based process for development of operating rules, including representation by or participation from health plans, health care providers, vendors, relevant Federal agencies, and other standard development organizations.

(C) The entity has a public set of guiding principles that ensure the operating rules and process are open and transparent, and supports nondiscrimination and conflict of interest policies that demonstrate a commitment to open, fair, and nondiscriminatory practices.

(D) The entity builds on the transaction standards issued under Health Insurance Portability and Accountability Act of 1996.

(E) The entity allows for public review and updates of the operating rules.

(3) REVIEW AND RECOMMENDATIONS.—The National Committee on Vital and Health Statistics shall—

(A) advise the Secretary as to whether a nonprofit entity meets the requirements under paragraph (2);

(B) review the operating rules developed and recommended by such nonprofit entity;

(C) determine whether such operating rules represent a consensus view of the health care stakeholders and are consistent with and do not conflict with other existing standards;

(D) evaluate whether such operating rules are consistent with electronic standards adopted for health information technology; and

(E) submit to the Secretary a recommendation as to whether the Secretary should adopt such operating rules.

(4) IMPLEMENTATION.—

(A) IN GENERAL.—The Secretary shall adopt operating rules under this subsection, by regulation in accordance with subparagraph (C), following consideration of the operating rules developed by the non-profit entity described in paragraph (2) and the recommendation submitted by the National Committee on Vital and Health Statistics under paragraph (3)(E) and having ensured consultation with providers.

(B) ADOPTION REQUIREMENTS; EFFECTIVE DATES.—

(i) ELIGIBILITY FOR A HEALTH PLAN AND HEALTH CLAIM STATUS.—The set of operating rules for eligibility for a health plan and health claim status transactions shall be adopted not later than July 1, 2011, in a manner ensuring that such operating rules are effective not later than January 1, 2013, and may allow for the use of a machine readable identification card.

(ii) ELECTRONIC FUNDS TRANSFERS AND HEALTH CARE PAYMENT AND REMITTANCE ADVICE.—The set of operating rules for electronic funds transfers and health care payment and remittance advice transactions shall—

(I) allow for automated reconciliation of the electronic payment with the remittance advice; and

(II) be adopted not later than July 1, 2012, in a manner ensuring that such operating rules are effective not later than January 1, 2014.

(iii) HEALTH CLAIMS OR EQUIVALENT ENCOUNTER INFORMATION, ENROLLMENT AND DISENROLLMENT IN A HEALTH PLAN, HEALTH PLAN PREMIUM PAYMENTS, REFERRAL CERTIFICATION AND AUTHORIZATION.—The set of operating rules for health claims or equivalent encounter information, enrollment and disenrollment in a health plan, health plan premium payments, and referral certification and authorization transactions shall be adopted not later than July 1, 2014, in a manner ensuring that such operating rules are effective not later than January 1, 2016.

(C) EXPEDITED RULEMAKING.—The Secretary shall promulgate an interim final rule applying any standard or operating rule recommended by the National Committee on Vital and Health Statistics pursuant to paragraph (3). The Secretary shall accept and consider public comments on any interim final rule published under this subparagraph for 60 days after the date of such publication.

(h) COMPLIANCE.—

(1) HEALTH PLAN CERTIFICATION.—

(A) ELIGIBILITY FOR A HEALTH PLAN, HEALTH CLAIM STATUS, ELECTRONIC FUNDS TRANSFERS, HEALTH CARE PAYMENT AND REMITTANCE ADVICE.—Not later than December 31, 2013, a health plan shall file a statement with the Secretary, in such form as the Secretary may require, certifying that the data and information systems for such plan

are in compliance with any applicable standards (as described under paragraph (7) of section 1171) and associated operating rules (as described under paragraph (9) of such section) for electronic funds transfers, eligibility for a health plan, health claim status, and health care payment and remittance advice, respectively.

(B) HEALTH CLAIMS OR EQUIVALENT ENCOUNTER INFORMATION, ENROLLMENT AND DISENROLLMENT IN A HEALTH PLAN, HEALTH PLAN PREMIUM PAYMENTS, HEALTH CLAIMS ATTACHMENTS, REFERRAL CERTIFICATION AND AUTHORIZATION.—Not later than December 31, 2015, a health plan shall file a statement with the Secretary, in such form as the Secretary may require, certifying that the data and information systems for such plan are in compliance with any applicable standards and associated operating rules for health claims or equivalent encounter information, enrollment and disenrollment in a health plan, health plan premium payments, health claims attachments, and referral certification and authorization, respectively. A health plan shall provide the same level of documentation to certify compliance with such transactions as is required to certify compliance with the transactions specified in subparagraph (A).

(2) DOCUMENTATION OF COMPLIANCE.—A health plan shall provide the Secretary, in such form as the Secretary may require, with adequate documentation of compliance with the standards and operating rules described under paragraph (1). A health plan shall not be considered to have provided adequate documentation and shall not be certified as being in compliance with such standards, unless the health plan—

(A) demonstrates to the Secretary that the plan conducts the electronic transactions specified in paragraph (1) in a manner that fully complies with the regulations of the Secretary; and

(B) provides documentation showing that the plan has completed end-to-end testing for such transactions with their partners, such as hospitals and physicians.

(3) SERVICE CONTRACTS.—A health plan shall be required to ensure that any entities that provide services pursuant to a contract with such health plan shall comply with any applicable certification and compliance requirements (and provide the Secretary with adequate documentation of such compliance) under this subsection.

(4) CERTIFICATION BY OUTSIDE ENTITY.—The Secretary may designate independent, outside entities to certify that a health plan has complied with the requirements under this subsection, provided that the certification standards employed by such entities are in accordance with any standards or operating rules issued by the Secretary.

(5) COMPLIANCE WITH REVISED STANDARDS AND OPERATING RULES.—

(A) IN GENERAL.—A health plan (including entities described under paragraph (3)) shall file a statement with the Secretary, in such form as the Secretary may require,

certifying that the data and information systems for such plan are in compliance with any applicable revised standards and associated operating rules under this subsection for any interim final rule promulgated by the Secretary under subsection (i) that—

(i) amends any standard or operating rule described under paragraph (1) of this subsection; or

(ii) establishes a standard (as described under subsection (a)(1)(B)) or associated operating rules (as described under subsection (i)(5)) for any other financial and administrative transactions.

(B) DATE OF COMPLIANCE.—A health plan shall comply with such requirements not later than the effective date of the applicable standard or operating rule.

(6) AUDITS OF HEALTH PLANS.—The Secretary shall conduct periodic audits to ensure that health plans (including entities described under paragraph (3)) are in compliance with any standards and operating rules that are described under paragraph (1) or subsection (i)(5).

(i) REVIEW AND AMENDMENT OF STANDARDS AND OPERATING RULES.—

(1) ESTABLISHMENT.—Not later than January 1, 2014, the Secretary shall establish a review committee (as described under paragraph (4)).

(2) EVALUATIONS AND REPORTS.—

(A) HEARINGS.—Not later than April 1, 2014, and not less than biennially thereafter, the Secretary, acting through the review committee, shall conduct hearings to evaluate and review the adopted standards and operating rules established under this section.

(B) REPORT.—Not later than July 1, 2014, and not less than biennially thereafter, the review committee shall provide recommendations for updating and improving such standards and operating rules. The review committee shall recommend a single set of operating rules per transaction standard and maintain the goal of creating as much uniformity as possible in the implementation of the electronic standards.

(3) INTERIM FINAL RULEMAKING.—

(A) IN GENERAL.—Any recommendations to amend adopted standards and operating rules that have been approved by the review committee and reported to the Secretary under paragraph (2)(B) shall be adopted by the Secretary through promulgation of an interim final rule not later than 90 days after receipt of the committee's report.

(B) PUBLIC COMMENT.—

(i) PUBLIC COMMENT PERIOD.—The Secretary shall accept and consider public comments on any interim final rule published under this paragraph for 60 days after the date of such publication.

(ii) EFFECTIVE DATE.—The effective date of any amendment to existing standards or operating rules that is adopted through an interim final rule pub-

lished under this paragraph shall be 25 months following the close of such public comment period.

(4) REVIEW COMMITTEE.—

(A) DEFINITION.—For the purposes of this subsection, the term "review committee" means a committee chartered by or within the Department of Health and Human services that has been designated by the Secretary to carry out this subsection, including—

(i) the National Committee on Vital and Health Statistics; or

(ii) any appropriate committee as determined by the Secretary.

(B) COORDINATION OF HIT STANDARDS.—In developing recommendations under this subsection, the review committee shall ensure coordination, as appropriate, with the standards that support the certified electronic health record technology approved by the Office of the National Coordinator for Health Information Technology.

(5) OPERATING RULES FOR OTHER STANDARDS ADOPTED BY THE SECRETARY.—The Secretary shall adopt a single set of operating rules (pursuant to the process described under subsection (g)) for any transaction for which a standard had been adopted pursuant to subsection (a)(1)(B).

(j) PENALTIES.—

(1) PENALTY FEE.—

(A) IN GENERAL.—Not later than April 1, 2014, and annually thereafter, the Secretary shall assess a penalty fee (as determined under subparagraph (B)) against a health plan that has failed to meet the requirements under subsection (h) with respect to certification and documentation of compliance with—

(i) the standards and associated operating rules described under paragraph (1) of such subsection; and

(ii) a standard (as described under subsection (a)(1)(B)) and associated operating rules (as described under subsection (i)(5)) for any other financial and administrative transactions.

(B) FEE AMOUNT.—Subject to subparagraphs (C), (D), and (E), the Secretary shall assess a penalty fee against a health plan in the amount of $1 per covered life until certification is complete. The penalty shall be assessed per person covered by the plan for which its data systems for major medical policies are not in compliance and shall be imposed against the health plan for each day that the plan is not in compliance with the requirements under subsection (h).

(C) ADDITIONAL PENALTY FOR MISREPRESENTATION.—A health plan that knowingly provides inaccurate or incomplete information in a statement of certification or documentation of compliance under subsection (h) shall be subject to a penalty fee that is double the amount that would otherwise be imposed under this subsection.

(D) ANNUAL FEE INCREASE.—The amount of the penalty fee imposed under this subsection shall be increased

on an annual basis by the annual percentage increase in total national health care expenditures, as determined by the Secretary.

(E) PENALTY LIMIT.—A penalty fee assessed against a health plan under this subsection shall not exceed, on an annual basis—

(i) an amount equal to $20 per covered life under such plan; or

(ii) an amount equal to $40 per covered life under the plan if such plan has knowingly provided inaccurate or incomplete information (as described under subparagraph (C)).

(F) DETERMINATION OF COVERED INDIVIDUALS.—The Secretary shall determine the number of covered lives under a health plan based upon the most recent statements and filings that have been submitted by such plan to the Securities and Exchange Commission.

(2) NOTICE AND DISPUTE PROCEDURE.—The Secretary shall establish a procedure for assessment of penalty fees under this subsection that provides a health plan with reasonable notice and a dispute resolution procedure prior to provision of a notice of assessment by the Secretary of the Treasury (as described under paragraph (4)(B)).

(3) PENALTY FEE REPORT.—Not later than May 1, 2014, and annually thereafter, the Secretary shall provide the Secretary of the Treasury with a report identifying those health plans that have been assessed a penalty fee under this subsection.

(4) COLLECTION OF PENALTY FEE.—

(A) IN GENERAL.—The Secretary of the Treasury, acting through the Financial Management Service, shall administer the collection of penalty fees from health plans that have been identified by the Secretary in the penalty fee report provided under paragraph (3).

(B) NOTICE.—Not later than August 1, 2014, and annually thereafter, the Secretary of the Treasury shall provide notice to each health plan that has been assessed a penalty fee by the Secretary under this subsection. Such notice shall include the amount of the penalty fee assessed by the Secretary and the due date for payment of such fee to the Secretary of the Treasury (as described in subparagraph (C)).

(C) PAYMENT DUE DATE.—Payment by a health plan for a penalty fee assessed under this subsection shall be made to the Secretary of the Treasury not later than November 1, 2014, and annually thereafter.

(D) UNPAID PENALTY FEES.—Any amount of a penalty fee assessed against a health plan under this subsection for which payment has not been made by the due date provided under subparagraph (C) shall be—

(i) increased by the interest accrued on such amount, as determined pursuant to the underpayment rate established under section 6621 of the Internal Revenue Code of 1986; and

(ii) treated as a past-due, legally enforceable debt owed to a Federal agency for purposes of section 6402(d) of the Internal Revenue Code of 1986.

(E) ADMINISTRATIVE FEES.—Any fee charged or allocated for collection activities conducted by the Financial Management Service will be passed on to a health plan on a pro-rata basis and added to any penalty fee collected from the plan.

TIMETABLES FOR ADOPTION OF STANDARDS

SEC. 1174. [42 U.S.C. 1320d–3] (a) INITIAL STANDARDS.—The Secretary shall carry out section 1173 not later than 18 months after the date of the enactment of the Health Insurance Portability and Accountability Act of 1996, except that standards relating to claims attachments shall be adopted not later than 30 months after such date.

(b) ADDITIONS AND MODIFICATIONS TO STANDARDS.—

(1) IN GENERAL.—Except as provided in paragraph (2), the Secretary shall review the standards adopted under section 1173, and shall adopt modifications to the standards (including additions to the standards), as determined appropriate, but not more frequently than once every 12 months. Any addition or modification to a standard shall be completed in a manner which minimizes the disruption and cost of compliance.

(2) SPECIAL RULES.—

(A) FIRST 12-MONTH PERIOD.—Except with respect to additions and modifications to code sets under subparagraph (B), the Secretary may not adopt any modification to a standard adopted under this part during the 12-month period beginning on the date the standard is initially adopted, unless the Secretary determines that the modification is necessary in order to permit compliance with the standard.

(B) ADDITIONS AND MODIFICATIONS TO CODE SETS.—

(i) IN GENERAL.—The Secretary shall ensure that procedures exist for the routine maintenance, testing, enhancement, and expansion of code sets.

(ii) ADDITIONAL RULES.—If a code set is modified under this subsection, the modified code set shall include instructions on how data elements of health information that were encoded prior to the modification may be converted or translated so as to preserve the informational value of the data elements that existed before the modification. Any modification to a code set under this subsection shall be implemented in a manner that minimizes the disruption and cost of complying with such modification.

REQUIREMENTS

SEC. 1175. [42 U.S.C. 1320d–4] (a) CONDUCT OF TRANSACTIONS BY PLANS.—

(1) IN GENERAL.—If a person desires to conduct a transaction referred to in section 1173(a)(1) with a health plan as a standard transaction—

(A) the health plan may not refuse to conduct such transaction as a standard transaction;

(B) the insurance plan may not delay such transaction, or otherwise adversely affect, or attempt to adversely affect, the person or the transaction on the ground that the transaction is a standard transaction; and

(C) the information transmitted and received in connection with the transaction shall be in the form of standard data elements of health information.

(2) SATISFACTION OF REQUIREMENTS.—A health plan may satisfy the requirements under paragraph (1) by—

(A) directly transmitting and receiving standard data elements of health information; or

(B) submitting nonstandard data elements to a health care clearinghouse for processing into standard data elements and transmission by the health care clearinghouse, and receiving standard data elements through the health care clearinghouse.

(3) TIMETABLE FOR COMPLIANCE.—Paragraph (1) shall not be construed to require a health plan to comply with any standard, implementation specification, or modification to a standard or specification adopted or established by the Secretary under sections 1172 through 1174 at any time prior to the date on which the plan is required to comply with the standard or specification under subsection (b).

(b) COMPLIANCE WITH STANDARDS.—

(1) INITIAL COMPLIANCE.—

(A) IN GENERAL.—Not later than 24 months after the date on which an initial standard or implementation specification is adopted or established under sections 1172 and 1173, each person to whom the standard or implementation specification applies shall comply with the standard or specification.

(B) SPECIAL RULE FOR SMALL HEALTH PLANS.—In the case of a small health plan, paragraph (1) shall be applied by substituting "36 months" for "24 months". For purposes of this subsection, the Secretary shall determine the plans that qualify as small health plans.

(2) COMPLIANCE WITH MODIFIED STANDARDS.—If the Secretary adopts a modification to a standard or implementation specification under this part, each person to whom the standard or implementation specification applies shall comply with the modified standard or implementation specification at such time as the Secretary determines appropriate, taking into account the time needed to comply due to the nature and extent of the modification. The time determined appropriate under the preceding sentence may not be earlier than the last day of the 180-day period beginning on the date such modification is adopted. The Secretary may extend the time for compliance for small health plans, if the Secretary determines that such extension is appropriate.

(3) CONSTRUCTION.—Nothing in this subsection shall be construed to prohibit any person from complying with a standard or specification by—

(A) submitting nonstandard data elements to a health care clearinghouse for processing into standard data elements and transmission by the health care clearinghouse; or

(B) receiving standard data elements through a health care clearinghouse.

GENERAL PENALTY FOR FAILURE TO COMPLY WITH REQUIREMENTS AND STANDARDS

SEC. 1176. [42 U.S.C. 1320d–5] (a) GENERAL PENALTY.—

(1) IN GENERAL.—Except as provided in subsection (b), the Secretary shall impose on any person who violates a provision of this part—

(A) in the case of a violation of such provision in which it is established that the person did not know (and by exercising reasonable diligence would not have known) that such person violated such provision, a penalty for each such violation of an amount that is at least the amount described in paragraph (3)(A) but not to exceed the amount described in paragraph (3)(D);

(B) in the case of a violation of such provision in which it is established that the violation was due to reasonable cause and not to willful neglect, a penalty for each such violation of an amount that is at least the amount described in paragraph (3)(B) but not to exceed the amount described in paragraph (3)(D); and

(C) in the case of a violation of such provision in which it is established that the violation was due to willful neglect—

(i) if the violation is corrected as described in subsection (b)(3)(A), a penalty in an amount that is at least the amount described in paragraph (3)(C) but not to exceed the amount described in paragraph (3)(D); and

(ii) if the violation is not corrected as described in such subsection, a penalty in an amount that is at least the amount described in paragraph (3)(D).

In determining the amount of a penalty under this section for a violation, the Secretary shall base such determination on the nature and extent of the violation and the nature and extent of the harm resulting from such violation.

(2) PROCEDURES.—The provisions of section 1128A (other than subsections (a) and (b) and the second sentence of subsection (f)) shall apply to the imposition of a civil money penalty under this subsection in the same manner as such provisions apply to the imposition of a penalty under such section 1128A.

(3) TIERS OF PENALTIES DESCRIBED.—For purposes of paragraph (1), with respect to a violation by a person of a provision of this part—

(A) the amount described in this subparagraph is $100 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed $25,000;

(B) the amount described in this subparagraph is $1,000 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed $100,000;

(C) the amount described in this subparagraph is $10,000 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed $250,000; and

(D) the amount described in this subparagraph is $50,000 for each such violation, except that the total amount imposed on the person for all such violations of an identical requirement or prohibition during a calendar year may not exceed $1,500,000.

(b) LIMITATIONS.—

(1) OFFENSES OTHERWISE PUNISHABLE.—No penalty may be imposed under subsection (a) and no damages obtained under subsection (d) with respect to an act if the act constitutes an offense punishable under section 1177 [30].

(2) FAILURES DUE TO REASONABLE CAUSE.—

(A) IN GENERAL.—Except as provided in subparagraph (B) or subsection (a)(1)(C), no penalty may be imposed under subsection (a) and no damages obtained under subsection (d) if the failure to comply is corrected during the 30-day period beginning on the first date the person liable for the penalty or damages knew, or by exercising reasonable diligence would have known, that the failure to comply occurred.

(B) EXTENSION OF PERIOD.—

(i) NO PENALTY.—With respect to the imposition of a penalty by the Secretary under subsection (a), the period referred to in subparagraph (A) may be extended as determined appropriate by the Secretary based on the nature and extent of the failure to comply.

(ii) ASSISTANCE.—If the Secretary determines that a person failed to comply because the person was un-

[30] Section 13410(a)(1)(A) of division A of Public Law 111–5 provides as follows:

(1) NONCOMPLIANCE DUE TO WILLFUL NEGLECT.—Section 1176 of the Social Security Act (42 U.S.C. 1320d–5) is amended—

(A) in subsection (b)(1), by striking "the act constitutes an offense punishable under section 1177" and inserting "a penalty has been imposed under section 1177 with respect to such act"; and

Subsection (b) of such section provides as follows:

(b) EFFECTIVE DATE; REGULATIONS.—

(1) The amendments made by subsection (a) shall apply to penalties imposed on or after the date that is 24 months after the date of the enactment of this title.

(2) Not later than 18 months after the date of the enactment of this title, the Secretary of Health and Human Services shall promulgate regulations to implement such amendments.

able to comply, the Secretary may provide technical assistance to the person during the period described in subparagraph (A). Such assistance shall be provided in any manner determined appropriate by the Secretary.

(3) REDUCTION.—In the case of a failure to comply which is due to reasonable cause and not to willful neglect, any penalty under subsection (a) and any damages under subsection (d) that is not entirely waived under paragraph (3) may be waived to the extent that the payment of such penalty would be excessive relative to the compliance failure involved.

[Note: Subsection (c) shown here in italic type face was added by section 13410(a)(1)(B) of division A of Public Law 111–5. For the effective date of this amendment, see subsection (b) of section 13410 of such Public Law set out in a footnote to subsection (b)(1).]

(c) NONCOMPLIANCE DUE TO WILLFUL NEGLECT.—

(1) IN GENERAL.—A violation of a provision of this part due to willful neglect is a violation for which the Secretary is required to impose a penalty under subsection (a)(1).

(2) REQUIRED INVESTIGATION.—For purposes of paragraph (1), the Secretary shall formally investigate any complaint of a violation of a provision of this part if a preliminary investigation of the facts of the complaint indicate such a possible violation due to willful neglect.

(d) ENFORCEMENT BY STATE ATTORNEYS GENERAL.—

(1) CIVIL ACTION.—Except as provided in subsection (b), in any case in which the attorney general of a State has reason to believe that an interest of one or more of the residents of that State has been or is threatened or adversely affected by any person who violates a provision of this part, the attorney general of the State, as parens patriae, may bring a civil action on behalf of such residents of the State in a district court of the United States of appropriate jurisdiction—

(A) to enjoin further such violation by the defendant; or

(B) to obtain damages on behalf of such residents of the State, in an amount equal to the amount determined under paragraph (2).

(2) STATUTORY DAMAGES.—

(A) IN GENERAL.—For purposes of paragraph (1)(B), the amount determined under this paragraph is the amount calculated by multiplying the number of violations by up to $100. For purposes of the preceding sentence, in the case of a continuing violation, the number of violations shall be determined consistent with the HIPAA privacy regulations (as defined in section 1180(b)(3)) for violations of subsection (a).

(B) LIMITATION.—The total amount of damages imposed on the person for all violations of an identical requirement or prohibition during a calendar year may not exceed $25,000.

(C) REDUCTION OF DAMAGES.—In assessing damages under subparagraph (A), the court may consider the factors the Secretary may consider in determining the amount of a civil money penalty under subsection (a) under the HIPAA privacy regulations.

(3) ATTORNEY FEES.—In the case of any successful action under paragraph (1), the court, in its discretion, may award the costs of the action and reasonable attorney fees to the State.

(4) NOTICE TO SECRETARY.—The State shall serve prior written notice of any action under paragraph (1) upon the Secretary and provide the Secretary with a copy of its complaint, except in any case in which such prior notice is not feasible, in which case the State shall serve such notice immediately upon instituting such action. The Secretary shall have the right—

(A) to intervene in the action;

(B) upon so intervening, to be heard on all matters arising therein; and

(C) to file petitions for appeal.

(5) CONSTRUCTION.—For purposes of bringing any civil action under paragraph (1), nothing in this section shall be construed to prevent an attorney general of a State from exercising the powers conferred on the attorney general by the laws of that State.

(6) VENUE; SERVICE OF PROCESS.—

(A) VENUE.—Any action brought under paragraph (1) may be brought in the district court of the United States that meets applicable requirements relating to venue under section 1391 of title 28, United States Code.

(B) SERVICE OF PROCESS.—In an action brought under paragraph (1), process may be served in any district in which the defendant—

(i) is an inhabitant; or

(ii) maintains a physical place of business.

(7) LIMITATION ON STATE ACTION WHILE FEDERAL ACTION IS PENDING.—If the Secretary has instituted an action against a person under subsection (a) with respect to a specific violation of this part, no State attorney general may bring an action under this subsection against the person with respect to such violation during the pendency of that action.

(8) APPLICATION OF CMP STATUTE OF LIMITATION.—A civil action may not be instituted with respect to a violation of this part unless an action to impose a civil money penalty may be instituted under subsection (a) with respect to such violation consistent with the second sentence of section 1128A(c)(1).

[Note: Subsection (e) shown here in italic type face was added by section 13410(f) of division A of Public Law 111–5. Section 13423 of division A of such Public Law provides that this amendment "shall take effect on the date that is 12 months after the date of the enactment of this title" (enactment date is February 17, 2009).]

(e) ALLOWING CONTINUED USE OF CORRECTIVE ACTION.—Nothing in this section shall be construed as preventing the Office for Civil Rights of the Department of Health and Human Services from continuing, in its discretion, to use corrective action without a penalty in cases where the person did not know (and by exercising reasonable diligence would not have known) of the violation involved.

WRONGFUL DISCLOSURE OF INDIVIDUALLY IDENTIFIABLE HEALTH INFORMATION

SEC. 1177. [42 U.S.C. 1320d–6] (a) OFFENSE.—A person who knowingly and in violation of this part—

(1) uses or causes to be used a unique health identifier;

(2) obtains individually identifiable health information relating to an individual; or

(3) discloses individually identifiable health information to another person,

shall be punished as provided in subsection (b). [31]

(b) PENALTIES.—A person described in subsection (a) shall—

(1) be fined not more than $50,000, imprisoned not more than 1 year, or both;

(2) if the offense is committed under false pretenses, be fined not more than $100,000, imprisoned not more than 5 years, or both; and

(3) if the offense is committed with intent to sell, transfer, or use individually identifiable health information for commercial advantage, personal gain, or malicious harm, be fined not more than $250,000, imprisoned not more than 10 years, or both.

EFFECT ON STATE LAW

SEC. 1178. [42 U.S.C. 1320d–7] (a) GENERAL EFFECT.—

(1) GENERAL RULE.—Except as provided in paragraph (2), a provision or requirement under this part, or a standard or implementation specification adopted or established under sections 1172 through 1174, shall supersede any contrary provision of State law, including a provision of State law that requires medical or health plan records (including billing information) to be maintained or transmitted in written rather than electronic form.

(2) EXCEPTIONS.—A provision or requirement under this part, or a standard or implementation specification adopted or

[31] Section 13409 of division A of Public Law 111–5 provides for an amendment to section 1177(a) as follows:

SEC. 13409. CLARIFICATION OF APPLICATION OF WRONGFUL DISCLOSURES CRIMINAL PENALTIES.

Section 1177(a) of the Social Security Act (42 U.S.C. 1320d–6(a)) is amended by adding at the end the following new sentence: "For purposes of the previous sentence, a person (including an employee or other individual) shall be considered to have obtained or disclosed individually identifiable health information in violation of this part if the information is maintained by a covered entity (as defined in the HIPAA privacy regulation described in section 1180(b)(3)) and the individual obtained or disclosed such information without authorization.".

Section 13423 of division A of such Public Law provides that this amendment "shall take effect on the date that is 12 months after the date of the enactment of this title".

established under sections 1172 through 1174, shall not supersede a contrary provision of State law, if the provision of State law—

(A) is a provision the Secretary determines—

(i) is necessary—

(I) to prevent fraud and abuse;

(II) to ensure appropriate State regulation of insurance and health plans;

(III) for State reporting on health care delivery or costs; or

(IV) for other purposes; or

(ii) addresses controlled substances; or

(B) subject to section 264(c)(2) of the Health Insurance Portability and Accountability Act of 1996, relates to the privacy of individually identifiable health information.

(b) PUBLIC HEALTH.—Nothing in this part shall be construed to invalidate or limit the authority, power, or procedures established under any law providing for the reporting of disease or injury, child abuse, birth, or death, public health surveillance, or public health investigation or intervention.

(c) STATE REGULATORY REPORTING.—Nothing in this part shall limit the ability of a State to require a health plan to report, or to provide access to, information for management audits, financial audits, program monitoring and evaluation, facility licensure or certification, or individual licensure or certification.

PROCESSING PAYMENT TRANSACTIONS BY FINANCIAL INSTITUTIONS

SEC. 1179. [42 U.S.C. 1320d–8] To the extent that an entity is engaged in activities of a financial institution (as defined in section 1101 of the Right to Financial Privacy Act of 1978), or is engaged in authorizing, processing, clearing, settling, billing, transferring, reconciling, or collecting payments, for a financial institution, this part, and any standard adopted under this part, shall not apply to the entity with respect to such activities, including the following:

(1) The use or disclosure of information by the entity for authorizing, processing, clearing, settling, billing, transferring, reconciling or collecting, a payment for, or related to, health plan premiums or health care, where such payment is made by any means, including a credit, debit, or other payment card, an account, check, or electronic funds transfer.

(2) The request for, or the use or disclosure of, information by the entity with respect to a payment described in paragraph (1)—

(A) for transferring receivables;

(B) for auditing;

(C) in connection with—

(i) a customer dispute; or

(ii) an inquiry from, or to, a customer;

(D) in a communication to a customer of the entity regarding the customer's transactions, payment card, account, check, or electronic funds transfer;

(E) for reporting to consumer reporting agencies; or

(F) for complying with—

(i) a civil or criminal subpoena; or

(ii) a Federal or State law regulating the entity.

APPLICATION OF HIPAA REGULATIONS TO GENETIC INFORMATION [32]

SEC. 1180. [42 U.S.C. 1320d–9] (a) IN GENERAL.—The Secretary shall revise the HIPAA privacy regulation (as defined in subsection (b)) so it is consistent with the following:

(1) Genetic information shall be treated as health information described in section 1171(4)(B).

(2) The use or disclosure by a covered entity that is a group health plan, health insurance issuer that issues health insurance coverage, or issuer of a medicare supplemental policy of protected health information that is genetic information about an individual for underwriting purposes under the group health plan, health insurance coverage, or medicare supplemental policy shall not be a permitted use or disclosure.

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

(1) GENETIC INFORMATION; GENETIC TEST; FAMILY MEMBER.—The terms "genetic information", "genetic test", and "family member" have the meanings given such terms in section 2791 of the Public Health Service Act (42 U.S.C. 300gg–91), as amended by the Genetic Information Nondiscrimination Act of 2007.

(2) GROUP HEALTH PLAN; HEALTH INSURANCE COVERAGE; MEDICARE SUPPLEMENTAL POLICY.—The terms "group health plan" and "health insurance coverage" have the meanings given such terms under section 2791 of the Public Health Service Act (42 U.S.C. 300gg–91), and the term "medicare supplemental policy" has the meaning given such term in section 1882(g).

(3) HIPAA PRIVACY REGULATION.—The term "HIPAA privacy regulation" means the regulations promulgated by the Secretary under this part and section 264 of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

(4) UNDERWRITING PURPOSES.—The term "underwriting purposes" means, with respect to a group health plan, health insurance coverage, or a medicare supplemental policy—

(A) rules for, or determination of, eligibility (including enrollment and continued eligibility) for, or determination of, benefits under the plan, coverage, or policy;

(B) the computation of premium or contribution amounts under the plan, coverage, or policy;

(C) the application of any pre-existing condition exclusion under the plan, coverage, or policy; and

(D) other activities related to the creation, renewal, or replacement of a contract of health insurance or health benefits.

[32] Section 105(a) of Public Law 110–233 (enacted May 21, 2008) adds section 1180 at the end of part C of title XI. Subsection (b)(2) of such section 105 provides that "[t]he amendment made by subsection (a) shall take effect on the date that is 1 year after the date of the enactment of this Act".

(c) PROCEDURE.—The revisions under subsection (a) shall be made by notice in the Federal Register published not later than 60 days after the date of the enactment of this section and shall be effective upon publication, without opportunity for any prior public comment, but may be revised, consistent with this section, after opportunity for public comment.

(d) ENFORCEMENT.—In addition to any other sanctions or remedies that may be available under law, a covered entity that is a group health plan, health insurance issuer, or issuer of a medicare supplemental policy and that violates the HIPAA privacy regulation (as revised under subsection (a) or otherwise) with respect to the use or disclosure of genetic information shall be subject to the penalties described in sections 1176 and 1177 in the same manner and to the same extent that such penalties apply to violations of this part.

PART D—COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH

COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH

SEC. 1181. [42 U.S.C. 1320e] (a) DEFINITIONS.—In this section:

(1) BOARD.—The term "Board" means the Board of Governors established under subsection (f).

(2) COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH; RESEARCH.—

(A) IN GENERAL.—The terms "comparative clinical effectiveness research" and "research" mean research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of 2 or more medical treatments, services, and items described in subparagraph (B).

(B) MEDICAL TREATMENTS, SERVICES, AND ITEMS DESCRIBED.—The medical treatments, services, and items described in this subparagraph are health care interventions, protocols for treatment, care management, and delivery, procedures, medical devices, diagnostic tools, pharmaceuticals (including drugs and biologicals), integrative health practices, and any other strategies or items being used in the treatment, management, and diagnosis of, or prevention of illness or injury in, individuals.

(3) CONFLICT OF INTEREST.—The term "conflict of interest" means an association, including a financial or personal association, that have the potential to bias or have the appearance of biasing an individual's decisions in matters related to the Institute or the conduct of activities under this section.

(4) REAL CONFLICT OF INTEREST.—The term "real conflict of interest" means any instance where a member of the Board, the methodology committee established under subsection (d)(6), or an advisory panel appointed under subsection (d)(4), or a close relative of such member, has received or could receive either of the following:

(A) A direct financial benefit of any amount deriving from the result or findings of a study conducted under this section.

(B) A financial benefit from individuals or companies that own or manufacture medical treatments, services, or

items to be studied under this section that in the aggregate exceeds $10,000 per year. For purposes of the preceding sentence, a financial benefit includes honoraria, fees, stock, or other financial benefit and the current value of the member or close relative's already existing stock holdings, in addition to any direct financial benefit deriving from the results or findings of a study conducted under this section.

(b) PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE.—

(1) ESTABLISHMENT.—There is authorized to be established a nonprofit corporation, to be known as the "Patient-Centered Outcomes Research Institute" (referred to in this section as the "Institute") which is neither an agency nor establishment of the United States Government.

(2) APPLICATION OF PROVISIONS.—The Institute shall be subject to the provisions of this section, and, to the extent consistent with this section, to the District of Columbia Nonprofit Corporation Act.

(3) FUNDING OF COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH.—For fiscal year 2010 and each subsequent fiscal year, amounts in the Patient-Centered Outcomes Research Trust Fund (referred to in this section as the "PCORTF") under section 9511 of the Internal Revenue Code of 1986 shall be available, without further appropriation, to the Institute to carry out this section.

(c) PURPOSE.—The purpose of the Institute is to assist patients, clinicians, purchasers, and policy-makers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations, and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services, and items described in subsection (a)(2)(B).

(d) DUTIES.—

(1) IDENTIFYING RESEARCH PRIORITIES AND ESTABLISHING RESEARCH PROJECT AGENDA.—

(A) IDENTIFYING RESEARCH PRIORITIES.—The Institute shall identify national priorities for research, taking into account factors of disease incidence, prevalence, and burden in the United States (with emphasis on chronic conditions), gaps in evidence in terms of clinical outcomes, practice variations and health disparities in terms of delivery and outcomes of care, the potential for new evidence to improve patient health, well-being, and the quality of care, the effect on national expenditures associated with a health care treatment, strategy, or health conditions, as well as patient needs, outcomes, and preferences, the relevance to patients and clinicians in making informed health decisions, and priorities in the National Strategy for quality care established under section 399H of the Public Health Service Act that are consistent with this section.

Such national priorities shall include research with respect to intellectual and developmental disabilities and maternal mortality. Such priorities should reflect a balance between long-term priorities and short-term priorities, and be responsive to changes in medical evidence and in health care treatments.

(B) ESTABLISHING RESEARCH PROJECT AGENDA.—The Institute shall establish and update a research project agenda for research to address the priorities identified under subparagraph (A), taking into consideration the types of research that might address each priority and the relative value (determined based on the cost of conducting research compared to the potential usefulness of the information produced by research) associated with the different types of research, and such other factors as the Institute determines appropriate.

(2) CARRYING OUT RESEARCH PROJECT AGENDA.—

(A) RESEARCH.—The Institute shall carry out the research project agenda established under paragraph (1)(B) in accordance with the methodological standards adopted under paragraph (9) using methods, including the following:

(i) Systematic reviews and assessments of existing and future research and evidence including original research conducted subsequent to the date of the enactment of this section.

(ii) Primary research, such as randomized clinical trials, molecularly informed trials, and observational studies.

(iii) Any other methodologies recommended by the methodology committee established under paragraph (6) that are adopted by the Board under paragraph (9).

(B) CONTRACTS FOR THE MANAGEMENT OF FUNDING AND CONDUCT OF RESEARCH.—

(i) CONTRACTS.—

(I) IN GENERAL.—In accordance with the research project agenda established under paragraph (1)(B), the Institute shall enter into contracts for the management of funding and conduct of research in accordance with the following:

(aa) Appropriate agencies and instrumentalities of the Federal Government.

(bb) Appropriate academic research, private sector research, or study-conducting entities.

(II) PREFERENCE.—In entering into contracts under subclause (I), the Institute shall give preference to the Agency for Healthcare Research and Quality and the National Institutes of Health, but only if the research to be conducted or managed under such contract is authorized by the governing statutes of such Agency or Institutes.

(ii) CONDITIONS FOR CONTRACTS.—A contract entered into under this subparagraph shall require that the agency, instrumentality, or other entity—

(I) abide by the transparency and conflicts of interest requirements under subsection (h) that apply to the Institute with respect to the research managed or conducted under such contract;

(II) comply with the methodological standards adopted under paragraph (9) with respect to such research;

(III) consult with the expert advisory panels for clinical trials and rare disease appointed under clauses (ii) and (iii), respectively, of paragraph (4)(A);

(IV) subject to clause (iv), permit a researcher who conducts original research, as described in subparagraph (A)(ii), under the contract for the agency, instrumentality, or other entity to have such research published in a peer-reviewed journal or other publication, as long as the researcher enters into a data use agreement with the Institute for use of the data from the original research, as appropriate;

(V) have appropriate processes in place to manage data privacy and meet ethical standards for the research;

(VI) comply with the requirements of the Institute for making the information available to the public under paragraph (8); and

(VII) comply with other terms and conditions determined necessary by the Institute to carry out the research agenda adopted under paragraph (2).

(iii) COVERAGE OF COPAYMENTS OR COINSURANCE.—A contract entered into under this subparagraph may allow for the coverage of copayments or coinsurance, or allow for other appropriate measures, to the extent that such coverage or other measures are necessary to preserve the validity of a research project, such as in the case where the research project must be blinded.

(iv) SUBSEQUENT USE OF THE DATA.—The Institute shall not allow the subsequent use of data from original research in work-for-hire contracts with individuals, entities, or instrumentalities that have a financial interest in the results, unless approved under a data use agreement with the Institute.

(C) REVIEW AND UPDATE OF EVIDENCE.—The Institute shall review and update evidence on a periodic basis as appropriate.

(D) TAKING INTO ACCOUNT POTENTIAL DIFFERENCES.—Research shall be designed, as appropriate, to take into account the potential for differences in the effectiveness of health care treatments, services, and items as used with various subpopulations, such as racial and ethnic minori-

ties, women, age, and groups of individuals with different comorbidities, genetic and molecular sub-types, or quality of life preferences and include members of such subpopulations as subjects in the research as feasible and appropriate.

(E) DIFFERENCES IN TREATMENT MODALITIES.—Research shall be designed, as appropriate, to take into account different characteristics of treatment modalities that may affect research outcomes, such as the phase of the treatment modality in the innovation cycle and the impact of the skill of the operator of the treatment modality.

(F) CONSIDERATION OF FULL RANGE OF OUTCOMES DATA.—Research shall be designed, as appropriate, to take into account and capture the full range of clinical and patient-centered outcomes relevant to, and that meet the needs of, patients, clinicians, purchasers, and policy-makers in making informed health decisions. In addition to the relative health outcomes and clinical effectiveness, clinical and patient-centered outcomes shall include the potential burdens and economic impacts of the utilization of medical treatments, items, and services on different stakeholders and decision-makers respectively. These potential burdens and economic impacts include medical out-of-pocket costs, including health plan benefit and formulary design, non-medical costs to the patient and family, including caregiving, effects on future costs of care, workplace productivity and absenteeism, and healthcare utilization.

(3) DATA COLLECTION.—

(A) IN GENERAL.—The Secretary shall, with appropriate safeguards for privacy, make available to the Institute such data collected by the Centers for Medicare & Medicaid Services under the programs under titles XVIII, XIX, and XXI, as well as provide access to the data networks developed under section 937(f) of the Public Health Service Act, as the Institute and its contractors may require to carry out this section. The Institute may also request and obtain data from Federal, State, or private entities, including data from clinical databases and registries.

(B) USE OF DATA.—The Institute shall only use data provided to the Institute under subparagraph (A) in accordance with laws and regulations governing the release and use of such data, including applicable confidentiality and privacy standards.

(4) APPOINTING EXPERT ADVISORY PANELS.—

(A) APPOINTMENT.—

(i) IN GENERAL.—The Institute may appoint permanent or ad hoc expert advisory panels as determined appropriate to assist in identifying research priorities and establishing the research project agenda under paragraph (1) and for other purposes.

(ii) EXPERT ADVISORY PANELS FOR CLINICAL TRIALS.—The Institute shall appoint expert advisory panels in carrying out randomized clinical trials under the research project agenda under paragraph (2)(A)(ii).

Such expert advisory panels shall advise the Institute and the agency, instrumentality, or entity conducting the research on the research question involved and the research design or protocol, including important patient subgroups and other parameters of the research. Such panels shall be available as a resource for technical questions that may arise during the conduct of such research.

(iii) EXPERT ADVISORY PANEL FOR RARE DISEASE.—In the case of a research study for rare disease, the Institute shall appoint an expert advisory panel for purposes of assisting in the design of the research study and determining the relative value and feasibility of conducting the research study.

(B) COMPOSITION.—An expert advisory panel appointed under subparagraph (A) shall include representatives of practicing and research clinicians, patients, and experts in scientific and health services research, health services delivery, and evidence-based medicine who have experience in the relevant topic, and as appropriate, experts in integrative health and primary prevention strategies. The Institute may include a technical expert of each manufacturer or each medical technology that is included under the relevant topic, project, or category for which the panel is established.

(5) SUPPORTING PATIENT AND CONSUMER REPRESENTATIVES.—The Institute shall provide support and resources to help patient and consumer representatives effectively participate on the Board and expert advisory panels appointed by the Institute under paragraph (4).

(6) ESTABLISHING METHODOLOGY COMMITTEE.—

(A) IN GENERAL.—The Institute shall establish a standing methodology committee to carry out the functions described in subparagraph (C).

(B) APPOINTMENT AND COMPOSITION.—The methodology committee established under subparagraph (A) shall be composed of not more than 15 members appointed by the Board. Members appointed to the methodology committee shall be experts in their scientific field, such as health services research, clinical research, comparative clinical effectiveness research, biostatistics, genomics, and research methodologies. Stakeholders with such expertise may be appointed to the methodology committee. In addition to the members appointed under the first sentence, the Directors of the National Institutes of Health and the Agency for Healthcare Research and Quality (or their designees) shall each be included as members of the methodology committee.

(C) FUNCTIONS.—Subject to subparagraph (D), the methodology committee shall work to develop and improve the science and methods of comparative clinical effectiveness research by, not later than 18 months after the establishment of the Institute, directly or through subcontract, developing and periodically updating the following:

(i) Methodological standards for research. Such methodological standards shall provide specific criteria for internal validity, generalizability, feasibility, and timeliness of research and for health outcomes measures, risk adjustment, and other relevant aspects of research and assessment with respect to the design of research. Any methodological standards developed and updated under this subclause shall be scientifically based and include methods by which new information, data, or advances in technology are considered and incorporated into ongoing research projects by the Institute, as appropriate. The process for developing and updating such standards shall include input from relevant experts, stakeholders, and decisionmakers, and shall provide opportunities for public comment. Such standards shall also include methods by which patient subpopulations can be accounted for and evaluated in different types of research. As appropriate, such standards shall build on existing work on methodological standards for defined categories of health interventions and for each of the major categories of comparative clinical effectiveness research methods (determined as of the date of enactment of the Patient Protection and Affordable Care Act).

(ii) A translation table that is designed to provide guidance and act as a reference for the Board to determine research methods that are most likely to address each specific research question.

(D) CONSULTATION AND CONDUCT OF EXAMINATIONS.—The methodology committee may consult and contract with the Institute of Medicine of the National Academies and academic, nonprofit, or other private and governmental entities with relevant expertise to carry out activities described in subparagraph (C) and may consult with relevant stakeholders to carry out such activities.

(E) REPORTS.—The methodology committee shall submit reports to the Board on the committee's performance of the functions described in subparagraph (C). Reports shall contain recommendations for the Institute to adopt methodological standards developed and updated by the methodology committee as well as other actions deemed necessary to comply with such methodological standards.

(7) PROVIDING FOR A PEER-REVIEW PROCESS FOR PRIMARY RESEARCH.—

(A) IN GENERAL.—The Institute shall ensure that there is a process for peer review of primary research described in subparagraph (A)(ii) of paragraph (2) that is conducted under such paragraph. Under such process—

(i) evidence from such primary research shall be reviewed to assess scientific integrity and adherence to methodological standards adopted under paragraph (9); and

(ii) a list of the names of individuals contributing to any peer-review process during the preceding year

or years shall be made public and included in annual reports in accordance with paragraph (10)(D).

(B) COMPOSITION.—Such peer-review process shall be designed in a manner so as to avoid bias and conflicts of interest on the part of the reviewers and shall be composed of experts in the scientific field relevant to the research under review.

(C) USE OF EXISTING PROCESSES.—

(i) PROCESSES OF ANOTHER ENTITY.—In the case where the Institute enters into a contract or other agreement with another entity for the conduct or management of research under this section, the Institute may utilize the peer-review process of such entity if such process meets the requirements under subparagraphs (A) and (B).

(ii) PROCESSES OF APPROPRIATE MEDICAL JOURNALS.—The Institute may utilize the peer-review process of appropriate medical journals if such process meets the requirements under subparagraphs (A) and (B).

(8) RELEASE OF RESEARCH FINDINGS.—

(A) IN GENERAL.—The Institute shall, not later than 90 days after the conduct or receipt of research findings under this part, make such research findings available to clinicians, patients, and the general public. The Institute shall ensure that the research findings—

(i) convey the findings of research in a manner that is comprehensible and useful to patients and providers in making health care decisions;

(ii) fully convey findings and discuss considerations specific to certain subpopulations, risk factors, and comorbidities, as appropriate;

(iii) include limitations of the research and what further research may be needed as appropriate;

(iv) do not include practice guidelines, coverage recommendations, payment, or policy recommendations; and

(v) not include any data which would violate the privacy of research participants or any confidentiality agreements made with respect to the use of data under this section.

(B) DEFINITION OF RESEARCH FINDINGS.—In this paragraph, the term "research findings" means the results of a study or assessment.

(9) ADOPTION.—Subject to subsection (h)(1), the Institute shall adopt the national priorities identified under paragraph (1)(A), the research project agenda established under paragraph (1)(B), the methodological standards developed and updated by the methodology committee under paragraph (6)(C)(i), and any peer-review process provided under paragraph (7) by majority vote. In the case where the Institute does not adopt such processes in accordance with the preceding sentence, the processes shall be referred to the appropriate staff or entity

within the Institute (or, in the case of the methodological standards, the methodology committee) for further review.

(10) ANNUAL REPORTS.—The Institute shall submit an annual report to Congress and the President, and shall make the annual report available to the public. Such report shall contain—

(A) a description of the activities conducted under this section, research priorities identified under paragraph (1)(A) and methodological standards developed and updated by the methodology committee under paragraph (6)(C)(i) that are adopted under paragraph (9) during the preceding year;

(B) the research project agenda and budget of the Institute for the following year;

(C) any administrative activities conducted by the Institute during the preceding year;

(D) the names of individuals contributing to any peer-review process under paragraph (7), without identifying them with a particular research project; and

(E) any other relevant information (including information on the membership of the Board, expert advisory panels, methodology committee, and the executive staff of the Institute, any conflicts of interest with respect to these individuals, and any bylaws adopted by the Board during the preceding year).

(e) ADMINISTRATION.—

(1) IN GENERAL.—Subject to paragraph (2), the Board shall carry out the duties of the Institute.

(2) NONDELEGABLE DUTIES.—The activities described in subsections (d)(1) and (d)(9) are nondelegable.

(f) BOARD OF GOVERNORS.—

(1) IN GENERAL.—The Institute shall have a Board of Governors, which shall consist of the following members:

(A) The Director of Agency for Healthcare Research and Quality (or the Director's designee).

(B) The Director of the National Institutes of Health (or the Director's designee).

(C) At least nineteen, but no more than twenty-one members appointed by the Comptroller General of the United States as follows:

(i) 3 members representing patients and health care consumers.

(ii) 7 members representing physicians and providers, including 4 members representing physicians (at least 1 of whom is a surgeon), 1 nurse, 1 State-licensed integrative health care practitioner, and 1 representative of a hospital.

(iii) at least 3, but no more than 5 members representing private payers, of whom at least 1 member shall represent health insurance issuers and at least 1 member shall represent employers who self-insure employee benefits.

(iv) 3 members representing pharmaceutical, device, and diagnostic manufacturers or developers.

(v) 1 member representing quality improvement or independent health service researchers.

(vi) 2 members representing the Federal Government or the States, including at least 1 member representing a Federal health program or agency.

(2) QUALIFICATIONS.—The Board shall represent a broad range of perspectives and collectively have scientific expertise in clinical health sciences research, including epidemiology, decisions sciences, health economics, and statistics. In appointing the Board, the Comptroller General of the United States shall consider and disclose any conflicts of interest in accordance with subsection (h)(4)(B). Members of the Board shall be recused from relevant Institute activities in the case where the member (or an immediate family member of such member) has a real conflict of interest directly related to the research project or the matter that could affect or be affected by such participation.

(3) TERMS; VACANCIES.—A member of the Board shall be appointed for a term of 6 years, except with respect to members first appointed, whose terms of appointment shall be staggered evenly over 2-year increments to the extent necessary to preserve the evenly staggered terms of the Board..[33].Any member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed for the remainder of that term and thereafter may be eligible for reappointment to a full term. A member may serve after the expiration of that member's term until a successor has been appointed. No individual shall be appointed to the Board for more than 2 terms. Vacancies shall be filled in the same manner as the original appointment was made.

(4) CHAIRPERSON AND VICE-CHAIRPERSON.—The Comptroller General of the United States shall designate a Chairperson and Vice Chairperson of the Board from among the members of the Board. Such members shall serve as Chairperson or Vice Chairperson for a period of 3 years.

(5) COMPENSATION.—Each member of the Board who is not an officer or employee of the Federal Government shall be entitled to compensation (equivalent to the rate provided for level IV of the Executive Schedule under section 5315 of title 5, United States Code) and expenses incurred while performing the duties of the Board. An officer or employee of the Federal government who is a member of the Board shall be exempt from compensation.

(6) DIRECTOR AND STAFF; EXPERTS AND CONSULTANTS.—The Board may employ and fix the compensation of an Executive Director and such other personnel as may be necessary to carry out the duties of the Institute and may seek such assistance and support of, or contract with, experts and consultants that may be necessary for the performance of the duties of the Institute.

[33] Double period so in law. See amendment made by section 104(f)(2)(A)(ii) of division N of Public Law 116-94.

(7) MEETINGS AND HEARINGS.—The Board shall meet and hold hearings at the call of the Chairperson or a majority of its members. Meetings not solely concerning matters of personnel shall be advertised at least 7 days in advance and open to the public. A majority of the Board members shall constitute a quorum, but a lesser number of members may meet and hold hearings.

(g) FINANCIAL AND GOVERNMENTAL OVERSIGHT.—

(1) CONTRACT FOR AUDIT.—The Institute shall provide for the conduct of financial audits of the Institute on an annual basis by a private entity with expertise in conducting financial audits.

(2) REVIEW AND ANNUAL REPORTS.—

(A) REVIEW.—The Comptroller General of the United States shall review the following:

(i) Not less frequently than on an annual basis, the financial audits conducted under paragraph (1).

(ii) Not less frequently than every 5 years, the processes established by the Institute, including the research priorities and the conduct of research projects, in order to determine whether information produced by such research projects is objective and credible, is produced in a manner consistent with the requirements under this section, and is developed through a transparent process.

(iii) Not less frequently than every 5 years, the dissemination and training activities and data networks established under section 937 of the Public Health Service Act, including the methods and products used to disseminate research, the types of training conducted and supported, and the types and functions of the data networks established, in order to determine whether the activities and data are produced in a manner consistent with the requirements under such section.

(iv) Not less frequently than every 5 years, the overall effectiveness of activities conducted under this section and the dissemination, training, and capacity building activities conducted under section 937 of the Public Health Service Act. Such review shall include the following:

(I) A description of those activities and the financial commitments related to research, training, data capacity building, and dissemination and uptake of research findings.

(II) The extent to which the Institute and the Agency for Healthcare Research and Quality have collaborated with stakeholders, including provider and payer organizations, to facilitate the dissemination and uptake of research findings.

(III) An analysis of available data and performance metrics, such as the estimated public availability and dissemination of research findings and uptake and utilization of research findings in

clinical guidelines and decision support tools, on the extent to which such research findings are used by health care decision-makers, the effect of the dissemination of such findings on changes in medical practice and reducing practice variation and disparities in health care, and the effect of the research conducted and disseminated on innovation and the health care economy of the United States.

(v) Not later than 8 years after the date of enactment of this section, the adequacy and use of the funding for the Institute and the activities conducted under section 937 of the Public Health Service Act, including a determination as to whether, based on the utilization of research findings by public and private payers, funding sources for the Patient-Centered Outcomes Research Trust Fund under section 9511 of the Internal Revenue Code of 1986 are appropriate and whether such sources of funding should be continued or adjusted.

(vi) Not less frequently than every 5 years, any barriers that researchers funded by the Institute have encountered in conducting studies or clinical trials, including challenges covering the cost of any medical treatments, services, and items described in subsection (a)(2)(B) for purposes of the research study.

(B) ANNUAL REPORTS.—Not later than April 1 of each year, the Comptroller General of the United States shall submit to Congress a report containing the results of the review conducted under subparagraph (A) with respect to the preceding year (or years, if applicable), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

(h) ENSURING TRANSPARENCY, CREDIBILITY, AND ACCESS.—The Institute shall establish procedures to ensure that the following requirements for ensuring transparency, credibility, and access are met:

(1) PUBLIC COMMENT PERIODS.—The Institute shall provide for a public comment period of not less than 45 days and not more than 60 days prior to the adoption under subsection (d)(9) of the national priorities identified under subsection (d)(1)(A), the research project agenda established under subsection (d)(1)(B), the methodological standards developed and updated by the methodology committee under subsection (d)(6)(C)(i), and the peer-review process provided under paragraph (7), and after the release of draft findings with respect to systematic reviews of existing research and evidence.

(2) ADDITIONAL FORUMS.—The Institute shall support forums to increase public awareness and obtain and incorporate public input and feedback through media (such as an Internet website) on research priorities, research findings, and other duties, activities, or processes the Institute determines appropriate.

(3) PUBLIC AVAILABILITY.—The Institute shall make available to the public and disclose through the official public Internet website of the Institute the following:

(A) Information contained in research findings as specified in subsection (d)(9).

(B) The process and methods for the conduct of research, including the identity of the entity and the investigators conducing such research and any conflicts of interests of such parties, any direct or indirect links the entity has to industry, and research protocols, including measures taken, methods of research and analysis, research results, and such other information the Institute determines appropriate) concurrent with the release of research findings.

(C) Notice of public comment periods under paragraph (1), including deadlines for public comments.

(D) Subsequent comments received during each of the public comment periods.

(E) In accordance with applicable laws and processes and as the Institute determines appropriate, proceedings of the Institute.

(4) DISCLOSURE OF CONFLICTS OF INTEREST.—

(A) IN GENERAL.—A conflict of interest shall be disclosed in the following manner:

(i) By the Institute in appointing members to an expert advisory panel under subsection (d)(4), in selecting individuals to contribute to any peer-review process under subsection (d)(7), and for employment as executive staff of the Institute.

(ii) By the Board in appointing members of the methodology committee under subsection (d)(6);

(iii) By the Institute in the annual report under subsection (d)(10), except that, in the case of individuals contributing to any such peer review process, such description shall be in a manner such that those individuals cannot be identified with a particular research project.

(B) MANNER OF DISCLOSURE.—Conflicts of interest shall be disclosed as described in subparagraph (A) as soon as practicable on the Internet web site of the Institute. The information disclosed under the preceding sentence shall include the type, nature, and magnitude of the interests of the individual involved, except to the extent that the individual recuses himself or herself from participating in the consideration of or any other activity with respect to the study as to which the potential conflict exists.

(i) RULES.—The Institute, its Board or staff, shall be prohibited from accepting gifts, bequeaths, or donations of services or property. In addition, the Institute shall be prohibited from establishing a corporation or generating revenues from activities other than as provided under this section.

(j) RULES OF CONSTRUCTION.—

(1) COVERAGE.—Nothing in this section shall be construed—

(A) to permit the Institute to mandate coverage, reimbursement, or other policies for any public or private payer; or

(B) as preventing the Secretary from covering the routine costs of clinical care received by an individual entitled to, or enrolled for, benefits under title XVIII, XIX, or XXI in the case where such individual is participating in a clinical trial and such costs would otherwise be covered under such title with respect to the beneficiary.

LIMITATIONS ON CERTAIN USES OF COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH

SEC. 1182. [42 U.S.C. 1320e–1] (a) The Secretary may only use evidence and findings from research conducted under section 1181 to make a determination regarding coverage under title XVIII if such use is through an iterative and transparent process which includes public comment and considers the effect on subpopulations.

(b) Nothing in section 1181 shall be construed as—

(1) superceding or modifying the coverage of items or services under title XVIII that the Secretary determines are reasonable and necessary under section 1862(l)(1); or

(2) authorizing the Secretary to deny coverage of items or services under such title solely on the basis of comparative clinical effectiveness research.

(c)(1) The Secretary shall not use evidence or findings from comparative clinical effectiveness research conducted under section 1181 in determining coverage, reimbursement, or incentive programs under title XVIII in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

(2) Paragraph (1) shall not be construed as preventing the Secretary from using evidence or findings from such comparative clinical effectiveness research in determining coverage, reimbursement, or incentive programs under title XVIII based upon a comparison of the difference in the effectiveness of alternative treatments in extending an individual's life due to the individual's age, disability, or terminal illness.

(d)(1) The Secretary shall not use evidence or findings from comparative clinical effectiveness research conducted under section 1181 in determining coverage, reimbursement, or incentive programs under title XVIII in a manner that precludes, or with the intent to discourage, an individual from choosing a health care treatment based on how the individual values the tradeoff between extending the length of their life and the risk of disability.

(2)(A) Paragraph (1) shall not be construed to—

(i) limit the application of differential copayments under title XVIII based on factors such as cost or type of service; or

(ii) prevent the Secretary from using evidence or findings from such comparative clinical effectiveness research in determining coverage, reimbursement, or incentive programs under such title based upon a comparison of the difference in the ef-

fectiveness of alternative health care treatments in extending an individual's life due to that individual's age, disability, or terminal illness.

(3) Nothing in the provisions of, or amendments made by the Patient Protection and Affordable Care Act, shall be construed to limit comparative clinical effectiveness research or any other research, evaluation, or dissemination of information concerning the likelihood that a health care treatment will result in disability.

(e) The Patient-Centered Outcomes Research Institute established under section 1181(b)(1) shall not develop or employ a dollars-per-quality adjusted life year (or similar measure that discounts the value of a life because of an individual's disability) as a threshold to establish what type of health care is cost effective or recommended. The Secretary shall not utilize such an adjusted life year (or such a similar measure) as a threshold to determine coverage, reimbursement, or incentive programs under title XVIII.

TRUST FUND TRANSFERS TO PATIENT-CENTERED OUTCOMES RESEARCH TRUST FUND

SEC. 1183. [42 U.S.C. 1320e–2] (a) IN GENERAL.—The Secretary shall provide for the transfer, from the Federal Hospital Insurance Trust Fund under section 1817 and the Federal Supplementary Medical Insurance Trust Fund under section 1841, in proportion (as estimated by the Secretary) to the total expenditures during such fiscal year that are made under title XVIII from the respective trust fund, to the Patient-Centered Outcomes Research Trust Fund (referred to in this section as the "PCORTF") under section 9511 of the Internal Revenue Code of 1986, of the following:

(1) For fiscal year 2013, an amount equal to $1 multiplied by the average number of individuals entitled to benefits under part A, or enrolled under part B, of title XVIII during such fiscal year.

(2) For each of fiscal years 2014, 2015, 2016, 2017, 2018, and 2019, an amount equal to $2 multiplied by the average number of individuals entitled to benefits under part A, or enrolled under part B, of title XVIII during such fiscal year.

(b) ADJUSTMENTS FOR INCREASES IN HEALTH CARE SPENDING.—In the case of any fiscal year beginning after September 30, 2014, the dollar amount in effect under subsection (a)(2) for such fiscal year shall be equal to the sum of such dollar amount for the previous fiscal year (determined after the application of this subsection), plus an amount equal to the product of—

(1) such dollar amount for the previous fiscal year, multiplied by

(2) the percentage increase in the projected per capita amount of National Health Expenditures, as most recently published by the Secretary before the beginning of the fiscal year.

INFORMATION EXCHANGE WITH PAYROLL DATA PROVIDERS.

SEC. 1184. [42 U.S.C. 1320e–3] (a) IN GENERAL.—The Commissioner of Social Security may enter into an information exchange with a payroll data provider for purposes of—

(1) efficiently administering—

(A) monthly insurance benefits under subsections (d)(1)(B)(ii), (d)(6)(A)(ii), (d)(6)(B), (e)(1)(B)(ii), and (f)(1)(B)(ii) of section 202 and subsection (a)(1) of section 223; and

(B) supplemental security income benefits under title XVI; and

(2) preventing improper payments of such benefits without the need for verification by independent or collateral sources.

(b) NOTIFICATION REQUIREMENTS.—Before entering into an information exchange pursuant to subsection (a), the Commissioner shall publish in the Federal Register a notice describing the information exchange and the extent to which the information received through such exchange is—

(1) relevant and necessary to—

(A) accurately determine entitlement to, and the amount of, benefits described under subparagraph (A) of subsection (a)(1);

(B) accurately determine eligibility for, and the amount of, benefits described in subparagraph (B) of such subsection; and

(C) prevent improper payment of such benefits; and

(2) sufficiently accurate, up-to-date, and complete.

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

(1) PAYROLL DATA PROVIDER.—The term "payroll data provider" means payroll providers, wage verification companies, and other commercial or non-commercial entities that collect and maintain data regarding employment and wages, without regard to whether the entity provides such data for a fee or without cost.

(2) INFORMATION EXCHANGE.—The term "information exchange" means the automated comparison of a system of records maintained by the Commissioner of Social Security with records maintained by a payroll data provider.

PART E—PRICE NEGOTIATION PROGRAM TO LOWER PRICES FOR CERTAIN HIGH-PRICED SINGLE SOURCE DRUGS

SEC. 1191. [42 U.S.C. 1320f] ESTABLISHMENT OF PROGRAM.

(a) IN GENERAL.—The Secretary shall establish a Drug Price Negotiation Program (in this part referred to as the "program"). Under the program, with respect to each price applicability period, the Secretary shall—

(1) publish a list of selected drugs in accordance with section 1192;

(2) enter into agreements with manufacturers of selected drugs with respect to such period, in accordance with section 1193;

(3) negotiate and, if applicable, renegotiate maximum fair prices for such selected drugs, in accordance with section 1194;

(4) carry out the publication and administrative duties and compliance monitoring in accordance with sections 1195 and 1196.

(b) DEFINITIONS RELATING TO TIMING.—For purposes of this part:

(1) INITIAL PRICE APPLICABILITY YEAR.—The term "initial price applicability year" means a year (beginning with 2026).

(2) PRICE APPLICABILITY PERIOD.—The term "price applicability period" means, with respect to a qualifying single source drug, the period beginning with the first initial price applicability year with respect to which such drug is a selected drug and ending with the last year during which the drug is a selected drug.

(3) SELECTED DRUG PUBLICATION DATE.—The term "selected drug publication date" means, with respect to each initial price applicability year, February 1 of the year that begins 2 years prior to such year.

(4) NEGOTIATION PERIOD.—The term "negotiation period" means, with respect to an initial price applicability year with respect to a selected drug, the period—

(A) beginning on the sooner of—

(i) the date on which the manufacturer of the drug and the Secretary enter into an agreement under section 1193 with respect to such drug; or

(ii) February 28 following the selected drug publication date with respect to such selected drug; and

(B) ending on November 1 of the year that begins 2 years prior to the initial price applicability year.

(c) OTHER DEFINITIONS.—For purposes of this part:

(1) MANUFACTURER.—The term "manufacturer" has the meaning given that term in section 1847A(c)(6)(A).

(2) MAXIMUM FAIR PRICE ELIGIBLE INDIVIDUAL.—The term "maximum fair price eligible individual" means, with respect to a selected drug—

(A) in the case such drug is dispensed to the individual at a pharmacy, by a mail order service, or by another dispenser, an individual who is enrolled in a prescription drug plan under part D of title XVIII or an MA–PD plan under part C of such title if coverage is provided under such plan for such selected drug; and

(B) in the case such drug is furnished or administered to the individual by a hospital, physician, or other provider of services or supplier, an individual who is enrolled under part B of title XVIII, including an individual who is enrolled in an MA plan under part C of such title, if payment may be made under part B for such selected drug.

(3) MAXIMUM FAIR PRICE.—The term "maximum fair price" means, with respect to a year during a price applicability period and with respect to a selected drug (as defined in section 1192(c)) with respect to such period, the price negotiated pursuant to section 1194, and updated pursuant to section 1195(b), as applicable, for such drug and year.

(4) REFERENCE PRODUCT.—The term "reference product" has the meaning given such term in section 351(i) of the Public Health Service Act.

(5) TOTAL EXPENDITURES.—The term "total expenditures" includes, in the case of expenditures with respect to part D of title XVIII, the total gross covered prescription drug costs (as defined in section 1860D–15(b)(3)). The term "total expenditures" excludes, in the case of expenditures with respect to part B of such title, expenditures for a drug or biological product that are bundled or packaged into the payment for another service.

(6) UNIT.—The term "unit" means, with respect to a drug or biological product, the lowest identifiable amount (such as a capsule or tablet, milligram of molecules, or grams) of the drug or biological product that is dispensed or furnished.

(d) TIMING FOR INITIAL PRICE APPLICABILITY YEAR 2026.—Notwithstanding the provisions of this part, in the case of initial price applicability year 2026, the following rules shall apply for purposes of implementing the program:

(1) Subsection (b)(3) shall be applied by substituting "September 1, 2023" for ", with respect to each initial price applicability year, February 1 of the year that begins 2 years prior to such year".

(2) Subsection (b)(4) shall be applied—

(A) in subparagraph (A)(ii), by substituting "October 1, 2023" for "February 28 following the selected drug publication date with respect to such selected drug"; and

(B) in subparagraph (B), by substituting "August 1, 2024" for "November 1 of the year that begins 2 years prior to the initial price applicability year".

(3) Section 1192 shall be applied—

(A) in subsection (b)(1)(A), by substituting "during the period beginning on June 1, 2022, and ending on May 31, 2023" for "during the most recent period of 12 months prior to the selected drug publication date (but ending not later than October 31 of the year prior to the year of such drug publication date), with respect to such year, for which data are available"; and

(B) in subsection (d)(1)(A), by substituting "during the period beginning on June 1, 2022, and ending on May 31, 2023" for "during the most recent period for which data are available of at least 12 months prior to the selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date), with respect to such year".

(4) Section 1193(a) shall be applied by substituting "October 1, 2023" for "February 28 following the selected drug publication date with respect to such selected drug".

(5) Section 1194(b)(2) shall be applied—

(A) in subparagraph (A), by substituting "October 2, 2023" for "March 1 of the year of the selected drug publication date, with respect to the selected drug";

(B) in subparagraph (B), by substituting "February 1, 2024" for "the June 1 following the selected drug publication date"; and

(C) in subparagraph (E), by substituting "August 1, 2024" for "the first day of November following the selected drug publication date, with respect to the initial price applicability year ".

(6) Section 1195(a)(1) shall be applied by substituting "September 1, 2024" for "November 30 of the year that is 2 years prior to such initial price applicability year".

SEC. 1192. [42 U.S.C. 1320f-1] SELECTION OF NEGOTIATION-ELIGIBLE DRUGS AS SELECTED DRUGS.

(a) IN GENERAL.—Not later than the selected drug publication date with respect to an initial price applicability year, in accordance with subsection (b), the Secretary shall select and publish a list of—

(1) with respect to the initial price applicability year 2026, 10 negotiation-eligible drugs described in subparagraph (A) of subsection (d)(1), but not subparagraph (B) of such subsection, with respect to such year (or, all (if such number is less than 10) such negotiation-eligible drugs with respect to such year);

(2) with respect to the initial price applicability year 2027, 15 negotiation-eligible drugs described in subparagraph (A) of subsection (d)(1), but not subparagraph (B) of such subsection, with respect to such year (or, all (if such number is less than 15) such negotiation-eligible drugs with respect to such year);

(3) with respect to the initial price applicability year 2028, 15 negotiation-eligible drugs described in subparagraph (A) or (B) of subsection (d)(1) with respect to such year (or, all (if such number is less than 15) such negotiation-eligible drugs with respect to such year); and

(4) with respect to the initial price applicability year 2029 or a subsequent year, 20 negotiation-eligible drugs described in subparagraph (A) or (B) of subsection (d)(1), with respect to such year (or, all (if such number is less than 20) such negotiation-eligible drugs with respect to such year).

Subject to subsection (c)(2) and section 1194(f)(5), each drug published on the list pursuant to the previous sentence and subsection (b)(3) shall be subject to the negotiation process under section 1194 for the negotiation period with respect to such initial price applicability year (and the renegotiation process under such section as applicable for any subsequent year during the applicable price applicability period).

(b) SELECTION OF DRUGS.—

(1) IN GENERAL.—In carrying out subsection (a), subject to paragraph (2), the Secretary shall, with respect to an initial price applicability year, do the following:

(A) Rank negotiation-eligible drugs described in subsection (d)(1) according to the total expenditures for such drugs under parts B and D of title XVIII, as determined by the Secretary, during the most recent period of 12 months prior to the selected drug publication date (but ending not later than October 31 of the year prior to the year of such drug publication date), with respect to such

year, for which data are available, with the negotiation-eligible drugs with the highest total expenditures being ranked the highest.

(B) Select from such ranked drugs with respect to such year the negotiation-eligible drugs with the highest such rankings.

(C) In the case of a biological product for which the inclusion of the biological product as a selected drug on a list published under subsection (a) has been delayed under subsection (f)(2), remove such biological product from the rankings under subparagraph (A) before making the selections under subparagraph (B).

(2) HIGH SPEND PART D DRUGS FOR 2026 AND 2027.—With respect to the initial price applicability year 2026 and with respect to the initial price applicability year 2027, the Secretary shall apply paragraph (1) as if the reference to "negotiation-eligible drugs described in subsection (d)(1)" were a reference to "negotiation-eligible drugs described in subsection (d)(1)(A)" and as if the reference to "total expenditures for such drugs under parts B and D of title XVIII" were a reference to "total expenditures for such drugs under part D of title XVIII".

(3) INCLUSION OF DELAYED BIOLOGICAL PRODUCTS.—Pursuant to subparagraphs (B)(ii)(I) and (C)(i) of subsection (f)(2), the Secretary shall select and include on the list published under subsection (a) the biological products described in such subparagraphs. Such biological products shall count towards the required number of drugs to be selected under subsection (a)(1).

(c) SELECTED DRUG.—

(1) IN GENERAL.—For purposes of this part, in accordance with subsection (e)(2) and subject to paragraph (2), each negotiation-eligible drug included on the list published under subsection (a) with respect to an initial price applicability year shall be referred to as a "selected drug" with respect to such year and each subsequent year beginning before the first year that begins at least 9 months after the date on which the Secretary determines at least one drug or biological product—

(A) is approved or licensed (as applicable)—

(i) under section 505(j) of the Federal Food, Drug, and Cosmetic Act using such drug as the listed drug; or

(ii) under section 351(k) of the Public Health Service Act using such drug as the reference product; and

(B) is marketed pursuant to such approval or licensure.

(2) CLARIFICATION.—A negotiation-eligible drug—

(A) that is included on the list published under subsection (a) with respect to an initial price applicability year; and

(B) for which the Secretary makes a determination described in paragraph (1) before or during the negotiation period with respect to such initial price applicability year;

shall not be subject to the negotiation process under section 1194 with respect to such negotiation period and shall continue

to be considered a selected drug under this part with respect to the number of negotiation-eligible drugs published on the list under subsection (a) with respect to such initial price applicability year.

(d) NEGOTIATION-ELIGIBLE DRUG.—

(1) IN GENERAL.—For purposes of this part, subject to paragraph (2), the term "negotiation-eligible drug" means, with respect to the selected drug publication date with respect to an initial price applicability year, a qualifying single source drug, as defined in subsection (e), that is described in either of the following subparagraphs (or, with respect to the initial price applicability year 2026 or 2027, that is described in subparagraph (A)):

(A) PART D HIGH SPEND DRUGS.—The qualifying single source drug is, determined in accordance with subsection (e)(2), among the 50 qualifying single source drugs with the highest total expenditures under part D of title XVIII, as determined by the Secretary in accordance with paragraph (3), during the most recent 12-month period for which data are available prior to such selected drug publication date (but ending no later than October 31 of the year prior to the year of such drug publication date).

(B) PART B HIGH SPEND DRUGS.—The qualifying single source drug is, determined in accordance with subsection (e)(2), among the 50 qualifying single source drugs with the highest total expenditures under part B of title XVIII, as determined by the Secretary in accordance with paragraph (3), during such most recent 12-month period, as described in subparagraph (A).

(2) EXCEPTION FOR SMALL BIOTECH DRUGS.—

(A) IN GENERAL.—Subject to subparagraph (C), the term "negotiation-eligible drug" shall not include, with respect to the initial price applicability years 2026, 2027, and 2028, a qualifying single source drug that meets either of the following:

(i) PART D DRUGS.—The total expenditures for the qualifying single source drug under part D of title XVIII, as determined by the Secretary in accordance with paragraph (3)(B), during 2021—

(I) are equal to or less than 1 percent of the total expenditures under such part D, as so determined, for all covered part D drugs (as defined in section 1860D–2(e)) during such year; and

(II) are equal to at least 80 percent of the total expenditures under such part D, as so determined, for all covered part D drugs for which the manufacturer of the drug has an agreement in effect under section 1860D–14A during such year.

(ii) PART B DRUGS.—The total expenditures for the qualifying single source drug under part B of title XVIII, as determined by the Secretary in accordance with paragraph (3)(B), during 2021—

(I) are equal to or less than 1 percent of the total expenditures under such part B, as so deter-

mined, for all qualifying single source drugs for which payment may be made under such part B during such year; and

(II) are equal to at least 80 percent of the total expenditures under such part B, as so determined, for all qualifying single source drugs of the manufacturer for which payment may be made under such part B during such year.

(B) CLARIFICATIONS RELATING TO MANUFACTURERS.—

(i) AGGREGATION RULE.—All persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986 shall be treated as one manufacturer for purposes of this paragraph.

(ii) LIMITATION.—A drug shall not be considered to be a qualifying single source drug described in clause (i) or (ii) of subparagraph (A) if the manufacturer of such drug is acquired after 2021 by another manufacturer that does not meet the definition of a specified manufacturer under section 1860D–14C(g)(4)(B)(ii), effective at the beginning of the plan year immediately following such acquisition or, in the case of an acquisition before 2025, effective January 1, 2025.

(C) DRUGS NOT INCLUDED AS SMALL BIOTECH DRUGS.—A new formulation, such as an extended release formulation, of a qualifying single source drug shall not be considered a qualifying single source drug described in subparagraph (A).

(3) CLARIFICATIONS AND DETERMINATIONS.—

(A) PREVIOUSLY SELECTED DRUGS AND SMALL BIOTECH DRUGS EXCLUDED.—In applying subparagraphs (A) and (B) of paragraph (1), the Secretary shall not consider or count—

(i) drugs that are already selected drugs; and

(ii) for initial price applicability years 2026, 2027, and 2028, qualifying single source drugs described in paragraph (2)(A).

(B) USE OF DATA.—In determining whether a qualifying single source drug satisfies any of the criteria described in paragraph (1) or (2), the Secretary shall use data that is aggregated across dosage forms and strengths of the drug, including new formulations of the drug, such as an extended release formulation, and not based on the specific formulation or package size or package type of the drug.

(e) QUALIFYING SINGLE SOURCE DRUG.—

(1) IN GENERAL.—For purposes of this part, the term "qualifying single source drug" means, with respect to an initial price applicability year, subject to paragraphs (2) through (4), a covered part D drug (as defined in section 1860D–2(e)) that is described in any of the following or a drug or biological product for which payment may be made under part B of title XVIII that is described in any of the following:

(A) DRUG PRODUCTS.—A drug—

(i) that is approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act and is marketed pursuant to such approval;

(ii) for which, as of the selected drug publication date with respect to such initial price applicability year, at least 7 years will have elapsed since the date of such approval; and

(iii) that is not the listed drug for any drug that is approved and marketed under section 505(j) of such Act.

(B) BIOLOGICAL PRODUCTS.—A biological product—

(i) that is licensed under section 351(a) of the Public Health Service Act and is marketed under section 351 of such Act;

(ii) for which, as of the selected drug publication date with respect to such initial price applicability year, at least 11 years will have elapsed since the date of such licensure; and

(iii) that is not the reference product for any biological product that is licensed and marketed under section 351(k) of such Act.

(2) TREATMENT OF AUTHORIZED GENERIC DRUGS.—

(A) IN GENERAL.—In the case of a qualifying single source drug described in subparagraph (A) or (B) of paragraph (1) that is the listed drug (as such term is used in section 505(j) of the Federal Food, Drug, and Cosmetic Act) or a product described in clause (ii) of subparagraph (B), with respect to an authorized generic drug, in applying the provisions of this part, such authorized generic drug and such listed drug or such product shall be treated as the same qualifying single source drug.

(B) AUTHORIZED GENERIC DRUG DEFINED.—For purposes of this paragraph, the term "authorized generic drug" means—

(i) in the case of a drug, an authorized generic drug (as such term is defined in section 505(t)(3) of the Federal Food, Drug, and Cosmetic Act); and

(ii) in the case of a biological product, a product that—

(I) has been licensed under section 351(a) of such Act; and

(II) is marketed, sold, or distributed directly or indirectly to retail class of trade under a different labeling, packaging (other than repackaging as the reference product in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trade mark than the reference product.

(3) EXCLUSIONS.—In this part, the term "qualifying single source drug" does not include any of the following:

(A) CERTAIN ORPHAN DRUGS.—A drug that is designated as a drug for one or more rare diseases or conditions under section 526 of the Federal Food, Drug, and Cosmetic Act and for which the only approved indication

(or indications) is for one or more such rare diseases or conditions (as such term is defined in section 526(a)(2) of the Federal Food, Drug, and Cosmetic Act).

(B) LOW SPEND MEDICARE DRUGS.—A drug or biological product with respect to which the total expenditures under parts B and D of title XVIII, as determined by the Secretary in accordance with subsection (d)(3)(B)—

(i) with respect to initial price applicability year 2026, is less than, during the period beginning on June 1, 2022, and ending on May 31, 2023, $200,000,000;

(ii) with respect to initial price applicability year 2027, is less than, during the most recent 12-month period applicable under subparagraphs (A) and (B) of subsection (d)(1) for such year, the dollar amount specified in clause (i) increased by the annual percentage increase in the consumer price index for all urban consumers (all items; United States city average) for the period beginning on June 1, 2023, and ending on September 30, 2024; or

(iii) with respect to a subsequent initial price applicability year, is less than, during the most recent 12-month period applicable under subparagraphs (A) and (B) of subsection (d)(1) for such year, the dollar amount specified in this subparagraph for the previous initial price applicability year increased by the annual percentage increase in such consumer price index for the 12-month period ending on September 30 of the year prior to the year of the selected drug publication date with respect to such subsequent initial price applicability year.

(C) PLASMA-DERIVED PRODUCTS.—A biological product that is derived from human whole blood or plasma.

(4) TREATMENT OF FORMER ORPHAN DRUGS.—In the case of a drug or biological product that, as of the date of the approval or licensure of such drug or biological product, is a drug or biological product described in paragraph (3)(A), paragraph (1)(A)(ii) or (1)(B)(ii) (as applicable) shall apply as if the reference to "the date of such approval" or "the date of such licensure", respectively, were instead a reference to "the first day after the date of such approval for which such drug is not a drug described in paragraph (3)(A)" or "the first day after the date of such licensure for which such biological product is not a biological product described in paragraph (3)(A)", respectively.

(f) SPECIAL RULE TO DELAY SELECTION AND NEGOTIATION OF BIOLOGICS FOR BIOSIMILAR MARKET ENTRY.—

(1) APPLICATION.—

(A) IN GENERAL.—Subject to subparagraph (B), in the case of a biological product that would (but for this subsection) be an extended-monopoly drug (as defined in section 1194(c)(4)) included as a selected drug on the list published under subsection (a) with respect to an initial price applicability year, the rules described in paragraph (2)

shall apply if the Secretary determines that there is a high likelihood (as described in paragraph (3)) that a biosimilar biological product (for which such biological product will be the reference product) will be licensed and marketed under section 351(k) of the Public Health Service Act before the date that is 2 years after the selected drug publication date with respect to such initial price applicability year.

(B) REQUEST REQUIRED.—

(i) IN GENERAL.—The Secretary shall not provide for a delay under—

(I) paragraph (2)(A) unless a request is made for such a delay by a manufacturer of a biosimilar biological product prior to the selected drug publication date for the list published under subsection (a) with respect to the initial price applicability year for which the biological product may have been included as a selected drug on such list but for subparagraph (2)(A); or

(II) paragraph (2)(B)(iii) unless a request is made for such a delay by such a manufacturer prior to the selected drug publication date for the list published under subsection (a) with respect to the initial price applicability year that is 1 year after the initial price applicability year for which the biological product described in subsection (a) would have been included as a selected drug on such list but for paragraph (2)(A).

(ii) INFORMATION AND DOCUMENTS.—

(I) IN GENERAL.—A request made under clause (i) shall be submitted to the Secretary by such manufacturer at a time and in a form and manner specified by the Secretary, and contain—

(aa) information and documents necessary for the Secretary to make determinations under this subsection, as specified by the Secretary and including, to the extent available, items described in subclause (III); and

(bb) all agreements related to the biosimilar biological product filed with the Federal Trade Commission or the Assistant Attorney General pursuant to subsections (a) and (c) of section 1112 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

(II) ADDITIONAL INFORMATION AND DOCUMENTS.—After the Secretary has reviewed the request and materials submitted under subclause (I), the manufacturer shall submit any additional information and documents requested by the Secretary necessary to make determinations under this subsection.

(III) ITEMS DESCRIBED.—The items described in this clause are the following:

(aa) The manufacturing schedule for such biosimilar biological product submitted to the Food and Drug Administration during its review of the application under such section 351(k).

(bb) Disclosures (in filings by the manufacturer of such biosimilar biological product with the Securities and Exchange Commission required under section 12(b), 12(g), 13(a), or 15(d) of the Securities Exchange Act of 1934 about capital investment, revenue expectations, and actions taken by the manufacturer that are typical of the normal course of business in the year (or the 2 years, as applicable) before marketing of a biosimilar biological product) that pertain to the marketing of such biosimilar biological product, or comparable documentation that is distributed to the shareholders of privately held companies.

(C) AGGREGATION RULE.—

(i) IN GENERAL.—All persons treated as a single employer under subsection (a) or (b) of section 52 of the Internal Revenue Code of 1986, or in a partnership, shall be treated as one manufacturer for purposes of paragraph (2)(D)(iv).

(ii) PARTNERSHIP DEFINED.—In clause (i), the term "partnership" means a syndicate, group, pool, joint venture, or other organization through or by means of which any business, financial operation, or venture is carried on by the manufacturer of the biological product and the manufacturer of the biosimilar biological product.

(2) RULES DESCRIBED.—The rules described in this paragraph are the following:

(A) DELAYED SELECTION AND NEGOTIATION FOR 1 YEAR.—If a determination of high likelihood is made under paragraph (3), the Secretary shall delay the inclusion of the biological product as a selected drug on the list published under subsection (a) until such list is published with respect to the initial price applicability year that is 1 year after the initial price applicability year for which the biological product would have been included as a selected drug on such list.

(B) IF NOT LICENSED AND MARKETED DURING THE INITIAL DELAY.—

(i) IN GENERAL.—If, during the time period between the selected drug publication date on which the biological product would have been included on the list as a selected drug pursuant to subsection (a) but for subparagraph (A) and the selected drug publication date with respect to the initial price applicability year that is 1 year after the initial price applicability year for which such biological product would have been included as a selected drug on such list, the Secretary

determines that the biosimilar biological product for which the manufacturer submitted the request under paragraph (1)(B)(i)(II) (and for which the Secretary previously made a high likelihood determination under paragraph (3)) has not been licensed and marketed under section 351(k) of the Public Health Service Act, the Secretary shall, at the request of such manufacturer—

(I) reevaluate whether there is a high likelihood (as described in paragraph (3)) that such biosimilar biological product will be licensed and marketed under such section 351(k) before the date that is 2 years after the selected drug publication date for which such biological product would have been included as a selected drug on such list published but for subparagraph (A); and

(II) evaluate whether, on the basis of clear and convincing evidence, the manufacturer of such biosimilar biological product has made a significant amount of progress (as determined by the Secretary) towards both such licensure and the marketing of such biosimilar biological product (based on information from items described in subclauses (I)(bb) and (II) of paragraph (1)(B)(ii)) since the receipt by the Secretary of the request made by such manufacturer under paragraph (1)(B)(i)(I).

(ii) SELECTION AND NEGOTIATION.—If the Secretary determines that there is not a high likelihood that such biosimilar biological product will be licensed and marketed as described in clause (i)(I) or there has not been a significant amount of progress as described in clause (i)(II)—

(I) the Secretary shall include the biological product as a selected drug on the list published under subsection (a) with respect to the initial price applicability year that is 1 year after the initial price applicability year for which such biological product would have been included as a selected drug on such list but for subparagraph (A); and

(II) the manufacturer of such biological product shall pay a rebate under paragraph (4) with respect to the year for which such manufacturer would have provided access to a maximum fair price for such biological product but for subparagraph (A).

(iii) SECOND 1-YEAR DELAY.—If the Secretary determines that there is a high likelihood that such biosimilar biological product will be licensed and marketed (as described in clause (i)(I)) and a significant amount of progress has been made by the manufacturer of such biosimilar biological product towards such licensure and marketing (as described in clause

(i)(II)), the Secretary shall delay the inclusion of the biological product as a selected drug on the list published under subsection (a) until the selected drug publication date of such list with respect to the initial price applicability year that is 2 years after the initial price applicability year for which such biological product would have been included as a selected drug on such list but for this subsection.

(C) IF NOT LICENSED AND MARKETED DURING THE YEAR TWO DELAY.—If, during the time period between the selected drug publication date of the list for which the biological product would have been included as a selected drug but for subparagraph (B)(iii) and the selected drug publication date with respect to the initial price applicability year that is 2 years after the initial price applicability year for which such biological product would have been included as a selected drug on such list but for this subsection, the Secretary determines that such biosimilar biological product has not been licensed and marketed—

(i) the Secretary shall include such biological product as a selected drug on such list with respect to the initial price applicability year that is 2 years after the initial price applicability year for which such biological product would have been included as a selected drug on such list; and

(ii) the manufacturer of such biological product shall pay a rebate under paragraph (4) with respect to the years for which such manufacturer would have provided access to a maximum fair price for such biological product but for this subsection.

(D) LIMITATIONS ON DELAYS.—

(i) LIMITED TO 2 YEARS.—In no case shall the Secretary delay the inclusion of a biological product on the list published under subsection (a) for more than 2 years.

(ii) EXCLUSION OF BIOLOGICAL PRODUCTS THAT TRANSITIONED TO A LONG-MONOPOLY DRUG DURING THE DELAY.—In the case of a biological product for which the inclusion on the list published pursuant to subsection (a) was delayed by 1 year under subparagraph (A) and for which there would have been a change in status to a long-monopoly drug (as defined in section 1194(c)(5)) if such biological product had been a selected drug, in no case may the Secretary provide for a second 1-year delay under subparagraph (B)(iii).

(iii) EXCLUSION OF BIOLOGICAL PRODUCTS IF MORE THAN 1 YEAR SINCE LICENSURE.—In no case shall the Secretary delay the inclusion of a biological product on the list published under subsection (a) if more than 1 year has elapsed since the biosimilar biological product has been licensed under section 351(k) of the Public Health Service Act and marketing has not commenced for such biosimilar biological product.

(iv) CERTAIN MANUFACTURERS OF BIOSIMILAR BIOLOGICAL PRODUCTS EXCLUDED.—In no case shall the Secretary delay the inclusion of a biological product as a selected drug on the list published under subsection (a) if Secretary determined that the manufacturer of the biosimilar biological product described in paragraph (1)(A)—

(I) is the same as the manufacturer of the reference product described in such paragraph or is treated as being the same pursuant to paragraph (1)(C); or

(II) has, based on information from items described in paragraph (1)(B)(ii)(I)(bb), entered into any agreement described in such paragraph with the manufacturer of the reference product described in paragraph (1)(A) that—

(aa) requires or incentivizes the manufacturer of the biosimilar biological product to submit a request described in paragraph (1)(B); or

(bb) restricts the quantity (either directly or indirectly) of the biosimilar biological product that may be sold in the United States over a specified period of time.

(3) HIGH LIKELIHOOD.—For purposes of this subsection, there is a high likelihood described in paragraph (1) or paragraph (2), as applicable, if the Secretary finds that—

(A) an application for licensure under section 351(k) of the Public Health Service Act for the biosimilar biological product has been accepted for review or approved by the Food and Drug Administration; and

(B) information from items described in sub clauses (I)(bb) and (III) of paragraph (1)(B)(ii) submitted to the Secretary by the manufacturer requesting a delay under such paragraph provides clear and convincing evidence that such biosimilar biological product will, within the time period specified under paragraph (1)(A) or (2)(B)(i)(I), be marketed.

(4) REBATE.—

(A) IN GENERAL.—For purposes of subparagraphs (B)(ii)(II) and (C)(ii) of paragraph (2), in the case of a biological product for which the inclusion on the list under subsection (a) was delayed under this subsection and for which the Secretary has negotiated and entered into an agreement under section 1193 with respect to such biological product, the manufacturer shall be required to pay a rebate to the Secretary at such time and in such manner as determined by the Secretary.

(B) AMOUNT.—Subject to subparagraph (C), the amount of the rebate under subparagraph (A) with respect to a biological product shall be equal to the estimated amount—

(i) in the case of a biological product that is a covered part D drug (as defined in section 1860D–2(e)), that is the sum of the products of—

(I) 75 percent of the amount by which—

(aa) the average manufacturer price, as reported by the manufacturer of such covered part D drug under section 1927 (or, if not reported by such manufacturer under section 1927, as reported by such manufacturer to the Secretary pursuant to the agreement under section 1193(a)) for such biological product, with respect to each of the calendar quarters of the price applicability period that would have applied but for this subsection; exceeds

(bb) in the initial price applicability year that would have applied but for a delay under—

(AA) paragraph (2)(A), the maximum fair price negotiated under section 1194 for such biological product under such agreement; or

(BB) paragraph (2)(B)(iii), such maximum fair price, increased as described in section 1195(b)(1)(A); and

(II) the number of units dispensed under part D of title XVIII for such covered part D drug during each such calendar quarter of such price applicability period; and

(ii) in the case of a biological product for which payment may be made under part B of title XVIII, that is the sum of the products of—

(I) 80 percent of the amount by which—

(aa) the payment amount for such biological product under section 1847A(b), with respect to each of the calendar quarters of the price applicability period that would have applied but for this subsection; exceeds

(bb) in the initial price applicability year that would have applied but for a delay under—

(AA) paragraph (2)(A), the maximum fair price negotiated under section 1194 for such biological product under such agreement; or

(BB) paragraph (2)(B)(iii), such maximum fair price, increased as described in section 1195(b)(1)(A); and

(II) the number of units (excluding units that are packaged into the payment amount for an item or service and are not separately payable under such part B) of the billing and payment code of such biological product administered or furnished under such part B during each such calendar quarter of such price applicability period.

(C) SPECIAL RULE FOR DELAYED BIOLOGICAL PRODUCTS THAT ARE LONG-MONOPOLY DRUGS.—

(i) IN GENERAL.—In the case of a biological product with respect to which a rebate is required to be paid under this paragraph, if such biological product qualifies as a long-monopoly drug (as defined in section 1194(c)(5)) at the time of its inclusion on the list published under subsection (a), in determining the amount of the rebate for such biological product under subparagraph (B), the amount described in clause (ii) shall be substituted for the maximum fair price described in clause (i)(I) or (ii)(I) of such subparagraph (B), as applicable.

(ii) AMOUNT DESCRIBED.—The amount described in this clause is an amount equal to 65 percent of the average non-Federal average manufacturer price for the biological product for 2021 (or, in the case that there is not an average non-Federal average manufacturer price available for such biological product for 2021, for the first full year following the market entry for such biological product), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the selected drug publication date with respect to the initial price applicability year that would have applied but for this subsection.

(D) REBATE DEPOSITS.—Amounts paid as rebates under this paragraph shall be deposited into—

(i) in the case payment is made for such biological product under part B of title XVIII, the Federal Supplementary Medical Insurance Trust Fund established under section 1841; and

(ii) in the case such biological product is a covered part D drug (as defined in section 1860D–2(e)), the Medicare Prescription Drug Account under section 1860D–16 in such Trust Fund.

(5) DEFINITIONS OF BIOSIMILAR BIOLOGICAL PRODUCT.—In this subsection, the term "biosimilar biological product" has the meaning given such term in section 1847A(c)(6).

SEC. 1193. [42 U.S.C. 1320f-2] MANUFACTURER AGREEMENTS.

(a) IN GENERAL.—For purposes of section 1191(a)(2), the Secretary shall enter into agreements with manufacturers of selected drugs with respect to a price applicability period, by not later than February 28 following the selected drug publication date with respect to such selected drug, under which—

(1) during the negotiation period for the initial price applicability year for the selected drug, the Secretary and the manufacturer, in accordance with section 1194, negotiate to determine (and, by not later than the last date of such period, agree to) a maximum fair price for such selected drug of the manu-

facturer in order for the manufacturer to provide access to such price—

(A) to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (A) of section 1191(c)(2) and are dispensed such drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such drugs) during, subject to paragraph (2), the price applicability period; and

(B) to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug during, subject to paragraph (2), the price applicability period;

(2) the Secretary and the manufacturer shall, in accordance with section 1194, renegotiate (and, by not later than the last date of the period of renegotiation, agree to) the maximum fair price for such drug, in order for the manufacturer to provide access to such maximum fair price (as so renegotiated)—

(A) to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (A) of section 1191(c)(2) and are dispensed such drug (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such drugs) during any year during the price applicability period (beginning after such renegotiation) with respect to such selected drug; and

(B) to hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug during any year described in subparagraph (A);

(3) subject to subsection (d), access to the maximum fair price (including as renegotiated pursuant to paragraph (2)), with respect to such a selected drug, shall be provided by the manufacturer to—

(A) maximum fair price eligible individuals, who with respect to such drug are described in subparagraph (A) of section 1191(c)(2), at the pharmacy, mail order service, or other dispenser at the point-of-sale of such drug (and shall be provided by the manufacturer to the pharmacy, mail order service, or other dispenser, with respect to such maximum fair price eligible individuals who are dispensed such drugs), as described in paragraph (1)(A) or (2)(A), as applicable; and

(B) hospitals, physicians, and other providers of services and suppliers with respect to maximum fair price eligible individuals who with respect to such drug are described in subparagraph (B) of such section and are furnished or administered such drug, as described in paragraph (1)(B) or (2)(B), as applicable;

(4) the manufacturer submits to the Secretary, in a form and manner specified by the Secretary, for the negotiation period for the price applicability period (and, if applicable, before any period of renegotiation pursuant to section 1194(f)), and for section 1192(f), with respect to such drug—

(A) information on the non-Federal average manufacturer price (as defined in section 8126(h)(5) of title 38, United States Code) for the drug for the applicable year or period;

(B) information that the Secretary requires to carry out the negotiation (or renegotiation process) under this part; and

(C) information that the Secretary requires to carry out section 1192(f), including rebates under paragraph (4) of such section; and

(5) the manufacturer complies with requirements determined by the Secretary to be necessary for purposes of administering the program and monitoring compliance with the program.

(b) AGREEMENT IN EFFECT UNTIL DRUG IS NO LONGER A SELECTED DRUG.—An agreement entered into under this section shall be effective, with respect to a selected drug, until such drug is no longer considered a selected drug under section 1192(c).

(c) CONFIDENTIALITY OF INFORMATION.—Information submitted to the Secretary under this part by a manufacturer of a selected drug that is proprietary information of such manufacturer (as determined by the Secretary) shall be used only by the Secretary or disclosed to and used by the Comptroller General of the United States for purposes of carrying out this part.

(d) NONDUPLICATION WITH 340B CEILING PRICE.—Under an agreement entered into under this section, the manufacturer of a selected drug—

(1) shall not be required to provide access to the maximum fair price under subsection (a)(3), with respect to such selected drug and maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at a covered entity described in section 340B(a)(4) of the Public Health Service Act, to such covered entity if such selected drug is subject to an agreement described in section 340B(a)(1) of such Act and the ceiling price (defined in section 340B(a)(1) of such Act) is lower than the maximum fair price for such selected drug; and

(2) shall be required to provide access to the maximum fair price to such covered entity with respect to maximum fair price eligible individuals who are eligible to be furnished, administered, or dispensed such selected drug at such entity at such ceiling price in a nonduplicated amount to the ceiling price if such maximum fair price is below the ceiling price for such selected drug.

SEC. 1194. [42 U.S.C. 1320f-3] NEGOTIATION AND RENEGOTIATION PROCESS.

(a) IN GENERAL.—For purposes of this part, under an agreement under section 1193 between the Secretary and a manufacturer of a selected drug (or selected drugs), with respect to the pe-

riod for which such agreement is in effect and in accordance with subsections (b), (c), and (d), the Secretary and the manufacturer—

(1) shall during the negotiation period with respect to such drug, in accordance with this section, negotiate a maximum fair price for such drug for the purpose described in section 1193(a)(1); and

(2) renegotiate, in accordance with the process specified pursuant to subsection (f), such maximum fair price for such drug for the purpose described in section 1193(a)(2) if such drug is a renegotiation-eligible drug under such subsection.

(b) NEGOTIATION PROCESS REQUIREMENTS.—

(1) METHODOLOGY AND PROCESS.—The Secretary shall develop and use a consistent methodology and process, in accordance with paragraph (2), for negotiations under subsection (a) that aims to achieve the lowest maximum fair price for each selected drug.

(2) SPECIFIC ELEMENTS OF NEGOTIATION PROCESS.—As part of the negotiation process under this section, with respect to a selected drug and the negotiation period with respect to the initial price applicability year with respect to such drug, the following shall apply:

(A) SUBMISSION OF INFORMATION.—Not later than March 1 of the year of the selected drug publication date, with respect to the selected drug, the manufacturer of the drug shall submit to the Secretary, in accordance with section 1193(a)(4), the information described in such section.

(B) INITIAL OFFER BY SECRETARY.—Not later than the June 1 following the selected drug publication date, the Secretary shall provide the manufacturer of the selected drug with a written initial offer that contains the Secretary's proposal for the maximum fair price of the drug and a concise justification based on the factors described in section 1194(e) that were used in developing such offer.

(C) RESPONSE TO INITIAL OFFER.—

(i) IN GENERAL.—Not later than 30 days after the date of receipt of an initial offer under subparagraph (B), the manufacturer shall either accept such offer or propose a counteroffer to such offer.

(ii) COUNTEROFFER REQUIREMENTS.—If a manufacturer proposes a counteroffer, such counteroffer—

(I) shall be in writing; and

(II) shall be justified based on the factors described in subsection (e).

(D) RESPONSE TO COUNTEROFFER.—After receiving a counteroffer under subparagraph (C), the Secretary shall respond in writing to such counteroffer.

(E) DEADLINE.—All negotiations between the Secretary and the manufacturer of the selected drug shall end prior to the first day of November following the selected drug publication date, with respect to the initial price applicability year.

(F) LIMITATIONS ON OFFER AMOUNT.—In negotiating the maximum fair price of a selected drug, with respect to the initial price applicability year for the selected drug,

and, as applicable, in renegotiating the maximum fair price for such drug, with respect to a subsequent year during the price applicability period for such drug, the Secretary shall not offer (or agree to a counteroffer for) a maximum fair price for the selected drug that—

(i) exceeds the ceiling determined under subsection (c) for the selected drug and year; or

(ii) as applicable, is less than the floor determined under subsection (d) for the selected drug and year.

(c) CEILING FOR MAXIMUM FAIR PRICE.—

(1) GENERAL CEILING.—

(A) IN GENERAL.—The maximum fair price negotiated under this section for a selected drug, with respect to the first initial price applicability year of the price applicability period with respect to such drug, shall not exceed the lower of the amount under subparagraph (B) or the amount under subparagraph (C).

(B) SUBPARAGRAPH (B) AMOUNT.—An amount equal to the following:

(i) COVERED PART D DRUG.—In the case of a covered part D drug (as defined in section 1860D–2(e)), the sum of the plan specific enrollment weighted amounts for each prescription drug plan or MA–PD plan (as determined under paragraph (2)).

(ii) PART B DRUG OR BIOLOGICAL.—In the case of a drug or biological product for which payment may be made under part B of title XVIII, the payment amount under section 1847A(b)(4) for the drug or biological product for the year prior to the year of the selected drug publication date with respect to the initial price applicability year for the drug or biological product.

(C) SUBPARAGRAPH (C) AMOUNT.—An amount equal to the applicable percent described in paragraph (3), with respect to such drug, of the following:

(i) INITIAL PRICE APPLICABILITY YEAR 2026.—In the case of a selected drug with respect to which such initial price applicability year is 2026, the average non-Federal average manufacturer price for such drug for 2021 (or, in the case that there is not an average non-Federal average manufacturer price available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the year of the selected drug publication date with respect to such initial price applicability year.

(ii) INITIAL PRICE APPLICABILITY YEAR 2027 AND SUBSEQUENT YEARS.—In the case of a selected drug with respect to which such initial price applicability year is 2027 or a subsequent year, the lower of—

(I) the average non-Federal average manufacturer price for such drug for 2021 (or, in the case that there is not an average non-Federal average manufacturer price available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the year of the selected drug publication date with respect to such initial price applicability year; or

(II) the average non-Federal average manufacturer price for such drug for the year prior to the selected drug publication date with respect to such initial price applicability year.

(2) PLAN SPECIFIC ENROLLMENT WEIGHTED AMOUNT.—For purposes of paragraph (1)(B)(i), the plan specific enrollment weighted amount for a prescription drug plan or an MA–PD plan with respect to a covered Part D drug is an amount equal to the product of—

(A) the negotiated price of the drug under such plan under part D of title XVIII, net of all price concessions received by such plan or pharmacy benefit managers on behalf of such plan, for the most recent year for which data is available; and

(B) a fraction—

(i) the numerator of which is the total number of individuals enrolled in such plan in such year; and

(ii) the denominator of which is the total number of individuals enrolled in a prescription drug plan or an MA–PD plan in such year.

(3) APPLICABLE PERCENT DESCRIBED.—For purposes of this subsection, the applicable percent described in this paragraph is the following:

(A) SHORT-MONOPOLY DRUGS AND VACCINES.—With respect to a selected drug (other than an extended-monopoly drug and a long-monopoly drug), 75 percent.

(B) EXTENDED-MONOPOLY DRUGS.—With respect to an extended-monopoly drug, 65 percent.

(C) LONG-MONOPOLY DRUGS.—With respect to a long-monopoly drug, 40 percent.

(4) EXTENDED-MONOPOLY DRUG DEFINED.—

(A) IN GENERAL.—In this part, subject to subparagraph (B), the term "extended-monopoly drug" means, with respect to an initial price applicability year, a selected drug for which at least 12 years, but fewer than 16 years, have elapsed since the date of approval of such drug under section 505(c) of the Federal Food, Drug, and Cosmetic Act or since the date of licensure of such drug under section 351(a) of the Public Health Service Act, as applicable.

(B) EXCLUSIONS.—The term "extended-monopoly drug" shall not include any of the following:

(i) A vaccine that is licensed under section 351 of the Public Health Service Act and marketed pursuant to such section.

(ii) A selected drug for which a manufacturer had an agreement under this part with the Secretary with respect to an initial price applicability year that is before 2030.

(C) CLARIFICATION.—Nothing in subparagraph (B)(ii) shall limit the transition of a selected drug described in paragraph (3)(A) to a long-monopoly drug if the selected drug meets the definition of a long-monopoly drug.

(5) LONG-MONOPOLY DRUG DEFINED.—

(A) IN GENERAL.—In this part, subject to subparagraph (B), the term "long-monopoly drug" means, with respect to an initial price applicability year, a selected drug for which at least 16 years have elapsed since the date of approval of such drug under section 505(c) of the Federal Food, Drug, and Cosmetic Act or since the date of licensure of such drug under section 351(a) of the Public Health Service Act, as applicable.

(B) EXCLUSION.—The term "long-monopoly drug" shall not include a vaccine that is licensed under section 351 of the Public Health Service Act and marketed pursuant to such section.

(6) AVERAGE NON-FEDERAL AVERAGE MANUFACTURER PRICE.—In this part, the term "average non-Federal average manufacturer price" means the average of the non-Federal average manufacturer price (as defined in section 8126(h)(5) of title 38, United States Code) for the 4 calendar quarters of the year involved.

(d) TEMPORARY FLOOR FOR SMALL BIOTECH DRUGS.—In the case of a selected drug that is a qualifying single source drug described in section 1192(d)(2) and with respect to which the first initial price applicability year of the price applicability period with respect to such drug is 2029 or 2030, the maximum fair price negotiated under this section for such drug for such initial price applicability year may not be less than 66 percent of the average non-Federal average manufacturer price for such drug (as defined in subsection (c)(6)) for 2021 (or, in the case that there is not an average non-Federal average manufacturer price available for such drug for 2021, for the first full year following the market entry for such drug), increased by the percentage increase in the consumer price index for all urban consumers (all items; United States city average) from September 2021 (or December of such first full year following the market entry), as applicable, to September of the year prior to the selected drug publication date with respect to the initial price applicability year.

(e) FACTORS.—For purposes of negotiating the maximum fair price of a selected drug under this part with the manufacturer of the drug, the Secretary shall consider the following factors, as applicable to the drug, as the basis for determining the offers and counteroffers under subsection (b) for the drug:

(1) MANUFACTURER-SPECIFIC DATA.—The following data, with respect to such selected drug, as submitted by the manufacturer:

(A) Research and development costs of the manufacturer for the drug and the extent to which the manufacturer has recouped research and development costs.

(B) Current unit costs of production and distribution of the drug.

(C) Prior Federal financial support for novel therapeutic discovery and development with respect to the drug.

(D) Data on pending and approved patent applications, exclusivities recognized by the Food and Drug Administration, and applications and approvals under section 505(c) of the Federal Food, Drug, and Cosmetic Act or section 351(a) of the Public Health Service Act for the drug.

(E) Market data and revenue and sales volume data for the drug in the United States.

(2) EVIDENCE ABOUT ALTERNATIVE TREATMENTS.—The following evidence, as available, with respect to such selected drug and therapeutic alternatives to such drug:

(A) The extent to which such drug represents a therapeutic advance as compared to existing therapeutic alternatives and the costs of such existing therapeutic alternatives.

(B) Prescribing information approved by the Food and Drug Administration for such drug and therapeutic alternatives to such drug.

(C) Comparative effectiveness of such drug and therapeutic alternatives to such drug, taking into consideration the effects of such drug and therapeutic alternatives to such drug on specific populations, such as individuals with disabilities, the elderly, the terminally ill, children, and other patient populations.

(D) The extent to which such drug and therapeutic alternatives to such drug address unmet medical needs for a condition for which treatment or diagnosis is not addressed adequately by available therapy.

In using evidence described in subparagraph (C), the Secretary shall not use evidence from comparative clinical effectiveness research in a manner that treats extending the life of an elderly, disabled, or terminally ill individual as of lower value than extending the life of an individual who is younger, nondisabled, or not terminally ill.

(f) RENEGOTIATION PROCESS.—

(1) IN GENERAL.—In the case of a renegotiation-eligible drug (as defined in paragraph (2)) that is selected under paragraph (3), the Secretary shall provide for a process of renegotiation (for years (beginning with 2028) during the price applicability period, with respect to such drug) of the maximum fair price for such drug consistent with paragraph (4).

(2) RENEGOTIATION-ELIGIBLE DRUG DEFINED.—In this section, the term "renegotiation-eligible drug" means a selected drug that is any of the following:

(A) ADDITION OF NEW INDICATION.—A selected drug for which a new indication is added to the drug.

(B) CHANGE OF STATUS TO AN EXTENDED-MONOPOLY DRUG.—A selected drug that—

(i) is not an extended-monopoly or a long-monopoly drug; and

(ii) for which there is a change in status to that of an extended-monopoly drug.

(C) CHANGE OF STATUS TO A LONG-MONOPOLY DRUG.—A selected drug that—

(i) is not a long-monopoly drug; and

(ii) for which there is a change in status to that of a long-monopoly drug.

(D) MATERIAL CHANGES.—A selected drug for which the Secretary determines there has been a material change of any of the factors described in paragraph (1) or (2) of subsection (e).

(3) SELECTION OF DRUGS FOR RENEGOTIATION.—For each year (beginning with 2028), the Secretary shall select among renegotiation-eligible drugs for renegotiation as follows:

(A) ALL EXTENDED-MONOPOLY NEGOTIATION-ELIGIBLE DRUGS.—The Secretary shall select all renegotiation-eligible drugs described in paragraph (2)(B).

(B) ALL LONG-MONOPOLY NEGOTIATION-ELIGIBLE DRUGS.—The Secretary shall select all renegotiation-eligible drugs described in paragraph (2)(C).

(C) REMAINING DRUGS.—Among the remaining renegotiation-eligible drugs described in subparagraphs (A) and (D) of paragraph (2), the Secretary shall select renegotiation-eligible drugs for which the Secretary expects renegotiation is likely to result in a significant change in the maximum fair price otherwise negotiated.

(4) RENEGOTIATION PROCESS.—

(A) IN GENERAL.—The Secretary shall specify the process for renegotiation of maximum fair prices with the manufacturer of a renegotiation-eligible drug selected for renegotiation under this subsection.

(B) CONSISTENT WITH NEGOTIATION PROCESS.—The process specified under subparagraph (A) shall, to the extent practicable, be consistent with the methodology and process established under subsection (b) and in accordance with subsections (c), (d), and (e), and for purposes of applying subsections (c)(1)(A) and (d), the reference to the first initial price applicability year of the price applicability period with respect to such drug shall be treated as the first initial price applicability year of such period for which the maximum fair price established pursuant to such renegotiation applies, including for applying subsection (c)(3)(B) in the case of renegotiation-eligible drugs described in paragraph (3)(A) of this subsection and subsection (c)(3)(C) in the case of renegotiation-eligible drugs described in paragraph (3)(B) of this subsection.

(5) CLARIFICATION.—A renegotiation-eligible drug for which the Secretary makes a determination described in sec-

tion 1192(c)(1) before or during the period of renegotiation shall not be subject to the renegotiation process under this section.

(g) CLARIFICATION.—The maximum fair price for a selected drug described in subparagraph (A) or (B) of paragraph (1) shall take effect no later than the first day of the first calendar quarter that begins after the date described in subparagraph (A) or (B), as applicable.

SEC. 1195. [42 U.S.C. 1320f-4] PUBLICATION OF MAXIMUM FAIR PRICES.

(a) IN GENERAL.—With respect to an initial price applicability year and a selected drug with respect to such year—

(1) not later than November 30 of the year that is 2 years prior to such initial price applicability year, the Secretary shall publish the maximum fair price for such drug negotiated with the manufacturer of such drug under this part; and

(2) not later than March 1 of the year prior to such initial price applicability year, the Secretary shall publish, subject to section 1193(c), the explanation for the maximum fair price with respect to the factors as applied under section 1194(e) for such drug described in paragraph (1).

(b) UPDATES.—

(1) SUBSEQUENT YEAR MAXIMUM FAIR PRICES.—For a selected drug, for each year subsequent to the first initial price applicability year of the price applicability period with respect to such drug, with respect to which an agreement for such drug is in effect under section 1193, not later than November 30 of the year that is 2 years prior to such subsequent year, the Secretary shall publish the maximum fair price applicable to such drug and year, which shall be—

(A) subject to subparagraph (B), the amount equal to the maximum fair price published for such drug for the previous year, increased by the annual percentage increase in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending with the July immediately preceding such November 30; or

(B) in the case the maximum fair price for such drug was renegotiated, for the first year for which such price as so renegotiated applies, such renegotiated maximum fair price.

(2) PRICES NEGOTIATED AFTER DEADLINE.—In the case of a selected drug with respect to an initial price applicability year for which the maximum fair price is determined under this part after the date of publication under this section, the Secretary shall publish such maximum fair price by not later than 30 days after the date such maximum price is so determined.

SEC. 1196. [42 U.S.C. 1320f-5] ADMINISTRATIVE DUTIES AND COMPLIANCE MONITORING.

(a) ADMINISTRATIVE DUTIES.—For purposes of section 1191(a)(4), the administrative duties described in this section are the following:

(1) The establishment of procedures to ensure that the maximum fair price for a selected drug is applied before—

(A) any coverage or financial assistance under other health benefit plans or programs that provide coverage or financial assistance for the purchase or provision of prescription drug coverage on behalf of maximum fair price eligible individuals; and

(B) any other discounts.

(2) The establishment of procedures to compute and apply the maximum fair price across different strengths and dosage forms of a selected drug and not based on the specific formulation or package size or package type of such drug.

(3) The establishment of procedures to carry out the provisions of this part, as applicable, with respect to—

(A) maximum fair price eligible individuals who are enrolled in a prescription drug plan under part D of title XVIII or an MA–PD plan under part C of such title; and

(B) maximum fair price eligible individuals who are enrolled under part B of such title, including who are enrolled in an MA plan under part C of such title.

(4) The establishment of a negotiation process and renegotiation process in accordance with section 1194.

(5) The establishment of a process for manufacturers to submit information described in section 1194(b)(2)(A).

(6) The sharing with the Secretary of the Treasury of such information as is necessary to determine the tax imposed by section 5000D of the Internal Revenue Code of 1986, including the application of such tax to a manufacturer, producer, or importer or the determination of any date described in section 5000D(c)(1) of such Code. For purposes of the preceding sentence, such information shall include—

(A) the date on which the Secretary receives notification of any termination of an agreement under the Medicare coverage gap discount program under section 1860D-14A and the date on which any subsequent agreement under such program is entered into;

(B) the date on which the Secretary receives notification of any termination of an agreement under the manufacturer discount program under section 1860D-14C and the date on which any subsequent agreement under such program is entered into; and

(C) the date on which the Secretary receives notification of any termination of a rebate agreement described in section 1927(b) and the date on which any subsequent rebate agreement described in such section is entered into.

(7) The establishment of procedures for purposes of applying subsections (d)(2)(B) and (f)(1)(C) of section 1192.

(b) COMPLIANCE MONITORING.—The Secretary shall monitor compliance by a manufacturer with the terms of an agreement under section 1193 and establish a mechanism through which violations of such terms shall be reported.

SEC. 1197. [42 U.S.C. 1320f-6] CIVIL MONETARY PENALTIES.

(a) VIOLATIONS RELATING TO OFFERING OF MAXIMUM FAIR PRICE.—Any manufacturer of a selected drug that has entered into an agreement under section 1193, with respect to a year during the

price applicability period with respect to such drug, that does not provide access to a price that is equal to or less than the maximum fair price for such drug for such year—

(1) to a maximum fair price eligible individual who with respect to such drug is described in subparagraph (A) of section 1191(c)(2) and who is dispensed such drug during such year (and to pharmacies, mail order services, and other dispensers, with respect to such maximum fair price eligible individuals who are dispensed such drugs); or

(2) to a hospital, physician, or other provider of services or supplier with respect to maximum fair price eligible individuals who with respect to such drug is described in subparagraph (B) of such section and is furnished or administered such drug by such hospital, physician, or provider or supplier during such year;

shall be subject to a civil monetary penalty equal to ten times the amount equal to the product of the number of units of such drug so furnished, dispensed, or administered during such year and the difference between the price for such drug made available for such year by such manufacturer with respect to such individual or hospital, physician, provider of services, or supplier and the maximum fair price for such drug for such year.

(b) VIOLATIONS RELATING TO PROVIDING REBATES.—Any manufacturer that fails to comply with the rebate requirements under section 1192(f)(4) shall be subject to a civil monetary penalty equal to 10 times the amount of the rebate the manufacturer failed to pay under such section.

(c) VIOLATIONS OF CERTAIN TERMS OF AGREEMENT.—Any manufacturer of a selected drug that has entered into an agreement under section 1193, with respect to a year during the price applicability period with respect to such drug, that is in violation of a requirement imposed pursuant to section 1193(a)(5), including the requirement to submit information pursuant to section 1193(a)(4), shall be subject to a civil monetary penalty equal to $1,000,000 for each day of such violation.

(d) FALSE INFORMATION.—Any manufacturer that knowingly provides false information pursuant to section 1196(a)(7) shall be subject to a civil monetary penalty equal to $100,000,000 for each item of such false information.

(e) APPLICATION.—The provisions of section 1128A (other than subsections (a) and (b)) shall apply to a civil monetary penalty under this section in the same manner as such provisions apply to a penalty or proceeding under section 1128A(a).

SEC. 1198. [42 U.S.C. 1320f-7] LIMITATION ON ADMINISTRATIVE AND JUDICIAL REVIEW.

There shall be no administrative or judicial review of any of the following:

(1) The determination of a unit, with respect to a drug or biological product, pursuant to section 1191(c)(6).

(2) The selection of drugs under section 1192(b), the determination of negotiation-eligible drugs under section 1192(d),

and the determination of qualifying single source drugs under section 1192(e) the application of section 1192(f),.[34]

(3) The determination of a maximum fair price under subsection (b) or (f) of section 1194.

(4) The determination of renegotiation-eligible drugs under section 1194(f)(2) and the selection of renegotiation-eligible drugs under section 1194(f)(3).

[34] The comma followed by a period at the end of paragraph (2) is so in law. Section 11002(a)(5) of Public Law 117–169 provides for an amendment to insert "the application of section 1192(f)," after "section 1192(e)". Such amendment was made to "section 1198(b)(2)" and probably should have been made to "section 1198(2)".