(2) GAO FINANCIAL AUDIT.—If an Institute is established under this section, the Comptroller General shall conduct an annual audit of the financial statements of the Institute, in accordance with generally accepted government auditing standards and submit a report on such audit to the Commission and the appropriate authorizing committees of Congress.

(3) GAO PROGRAMMATIC REVIEW.—The Comptroller General of the United States shall conduct programmatic assessments of the Institute established under this section as determined necessary by the Comptroller General and report the findings to the Commission and to the appropriate authorizing committees of Congress.

(e) AUTHORIZATION OF APPROPRIATIONS.—

(1) IN GENERAL.——There are authorized to be appropriated to carry out the purposes of this section, $10,000,000 for fiscal year 2010, and $7,500,000 for each of fiscal year 2011 through 2018.

(2) AVAILABILITY.——Amounts appropriated under paragraph (1) shall remain available until expended.

Subtitle H—General Provisions

SEC. 5701. REPORTS.

(a) REPORTS BY SECRETARY OF HEALTH AND HUMAN SERVICES.—On an annual basis, the Secretary of Health and Human Services shall submit to the appropriate Committees of Congress a report on the activities carried out under the amendments made by this title, and the effectiveness of such activities.

(b) REPORTS BY RECIPIENTS OF FUNDS.—The Secretary of Health and Human Services may require, as a condition of receiving funds under the amendments made by this title, that the entity receiving such award submit to such Secretary such reports as the such Secretary may require on activities carried out with such award, and the effectiveness of such activities.

TITLE VI—TRANSPARENCY AND PROGRAM INTEGRITY

Subtitle A—Physician Ownership and Other Transparency

SEC. 6001. LIMITATION ON MEDICARE EXCEPTION TO THE PROHIBITION ON CERTAIN PHYSICIAN REFERRALS FOR HOSPITALS.

(a) IN GENERAL.—Section 1877 of the Social Security Act (42 U.S.C. 1395nn) is amended—

(1) in subsection (d)(2)—

(A) in subparagraph (A), by striking "and" at the end;

(B) in subparagraph (B), by striking the period at the end and inserting "; and"; and

(C) by adding at the end the following new subparagraph:

"(C) in the case where the entity is a hospital, the hospital meets the requirements of paragraph (3)(D).";

(2) in subsection (d)(3)—

(A) in subparagraph (B), by striking "and" at the end;

(B) in subparagraph (C), by striking the period at the end and inserting "; and"; and

(C) by adding at the end the following new subparagraph:

"(D) the hospital meets the requirements described in subsection (i)(1) not later than 18 months after the date of the enactment of this subparagraph."; and

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

"(i) REQUIREMENTS FOR HOSPITALS TO QUALIFY FOR RURAL PROVIDER AND HOSPITAL EXCEPTION TO OWNERSHIP OR INVESTMENT PROHIBITION.—

"(1) REQUIREMENTS DESCRIBED.—For purposes of subsection (d)(3)(D), the requirements described in this paragraph for a hospital are as follows:

"(A) PROVIDER AGREEMENT.—The hospital had—

"(i) physician ownership or investment on February 1, 2010; and

"(ii) a provider agreement under section 1866 in effect on such date.

"(B) LIMITATION ON EXPANSION OF FACILITY CAPACITY.—Except as provided in paragraph (3), the number of operating rooms, procedure rooms, and beds for which the hospital is licensed at any time on or after the date of the enactment of this subsection is no greater than the number of operating rooms, procedure rooms, and beds for which the hospital is licensed as of such date.

"(C) PREVENTING CONFLICTS OF INTEREST.—

"(i) The hospital submits to the Secretary an annual report containing a detailed description of—

"(I) the identity of each physician owner or investor and any other owners or investors of the hospital; and

"(II) the nature and extent of all ownership and investment interests in the hospital.

"(ii) The hospital has procedures in place to require that any referring physician owner or investor discloses to the patient being referred, by a time that permits the patient to make a meaningful decision regarding the receipt of care, as determined by the Secretary—

"(I) the ownership or investment interest, as applicable, of such referring physician in the hospital; and

"(II) if applicable, any such ownership or investment interest of the treating physician.

"(iii) The hospital does not condition any physician ownership or investment interests either directly or indirectly on the physician owner or investor making or influencing referrals to the hospital or otherwise generating business for the hospital.

"(iv) The hospital discloses the fact that the hospital is partially owned or invested in by physicians—

"(I) on any public website for the hospital; and

"(II) in any public advertising for the hospital.

"(D) ENSURING BONA FIDE INVESTMENT.—

"(i) The percentage of the total value of the ownership or investment interests held in the hospital, or in an entity whose assets include the hospital, by physician owners or investors in the aggregate does not exceed such percentage as of the date of enactment of this subsection.

"(ii) Any ownership or investment interests that the hospital offers to a physician owner or investor are not offered on more favorable terms than the terms offered to a person who is not a physician owner or investor.

"(iii) The hospital (or any owner or investor in the hospital) does not directly or indirectly provide loans or financing for any investment in the hospital by a physician owner or investor.

"(iv) The hospital (or any owner or investor in the hospital) does not directly or indirectly guarantee a loan, make a payment toward a loan, or otherwise subsidize a loan, for any individual physician owner or investor or group of physician owners or investors that is related to acquiring any ownership or investment interest in the hospital.

"(v) Ownership or investment returns are distributed to each owner or investor in the hospital in an amount that is directly proportional to the ownership or investment interest of such owner or investor in the hospital.

"(vi) Physician owners and investors do not receive, directly or indirectly, any guaranteed receipt of or right to purchase other business interests related to the hospital, including the purchase or lease of any property under the control of other owners or investors in the hospital or located near the premises of the hospital.

"(vii) The hospital does not offer a physician owner or investor the opportunity to purchase or lease any property under the control of the hospital or any other owner or investor in the hospital on more favorable terms than the terms offered to an individual who is not a physician owner or investor.

"(E) PATIENT SAFETY.—

"(i) Insofar as the hospital admits a patient and does not have any physician available on the premises to provide services during all hours in which the hospital is providing services to such patient, before admitting the patient—

"(I) the hospital discloses such fact to a patient; and

"(II) following such disclosure, the hospital receives from the patient a signed acknowledgment that the patient understands such fact.

"(ii) The hospital has the capacity to—

"(I) provide assessment and initial treatment for patients; and

"(II) refer and transfer patients to hospitals with the capability to treat the needs of the patient involved.

"(F) LIMITATION ON APPLICATION TO CERTAIN CONVERTED FACILITIES.—The hospital was not converted from an ambulatory surgical center to a hospital on or after the date of enactment of this subsection.

"(2) PUBLICATION OF INFORMATION REPORTED.—The Secretary shall publish, and update on an annual basis, the information submitted by hospitals under paragraph (1)(C)(i) on the public Internet website of the Centers for Medicare & Medicaid Services.

"(3) EXCEPTION TO PROHIBITION ON EXPANSION OF FACILITY CAPACITY.—

"(A) PROCESS.—

"(i) ESTABLISHMENT.—The Secretary shall establish and implement a process under which an applicable hospital (as defined in subparagraph (E)) may apply for an exception from the requirement under paragraph (1)(B).

"(ii) OPPORTUNITY FOR COMMUNITY INPUT.—The process under clause (i) shall provide individuals and entities in the community in which the applicable hospital applying for an exception is located with the opportunity to provide input with respect to the application.

"(iii) TIMING FOR IMPLEMENTATION.—The Secretary shall implement the process under clause (i) on August 1, 2011.

"(iv) REGULATIONS.—Not later than July 1, 2011, the Secretary shall promulgate regulations to carry out the process under clause (i).

"(B) FREQUENCY.—The process described in subparagraph (A) shall permit an applicable hospital to apply for an exception up to once every 2 years.

"(C) PERMITTED INCREASE.—

"(i) IN GENERAL.—Subject to clause (ii) and subparagraph (D), an applicable hospital granted an exception under the process described in subparagraph (A) may increase the number of operating rooms, procedure rooms, and beds for which the applicable hospital is licensed above the baseline number of operating rooms, procedure rooms, and beds of the applicable hospital (or, if the applicable hospital has been granted a previous exception under this paragraph, above the number of operating rooms, procedure rooms, and beds for which the hospital is licensed after the application of the most recent increase under such an exception).

"(ii) 100 PERCENT INCREASE LIMITATION.—The Secretary shall not permit an increase in the number of operating rooms, procedure rooms, and beds for which an applicable hospital is licensed under clause (i) to the extent such increase would result in the number of operating rooms, procedure rooms, and beds for which the applicable hospital is licensed exceeding 200 percent of the baseline number of operating rooms, procedure rooms, and beds of the applicable hospital.

"(iii) BASELINE NUMBER OF OPERATING ROOMS, PROCEDURE ROOMS, AND BEDS.—In this paragraph, the term 'baseline number of operating rooms, procedure

rooms, and beds' means the number of operating rooms, procedure rooms, and beds for which the applicable hospital is licensed as of the date of enactment of this subsection.

"(D) INCREASE LIMITED TO FACILITIES ON THE MAIN CAMPUS OF THE HOSPITAL.—Any increase in the number of operating rooms, procedure rooms, and beds for which an applicable hospital is licensed pursuant to this paragraph may only occur in facilities on the main campus of the applicable hospital.

"(E) APPLICABLE HOSPITAL.—In this paragraph, the term 'applicable hospital' means a hospital—

"(i) that is located in a county in which the percentage increase in the population during the most recent 5-year period (as of the date of the application under subparagraph (A)) is at least 150 percent of the percentage increase in the population growth of the State in which the hospital is located during that period, as estimated by Bureau of the Census;

"(ii) whose annual percent of total inpatient admissions that represent inpatient admissions under the program under title XIX is equal to or greater than the average percent with respect to such admissions for all hospitals located in the county in which the hospital is located;

"(iii) that does not discriminate against beneficiaries of Federal health care programs and does not permit physicians practicing at the hospital to discriminate against such beneficiaries;

"(iv) that is located in a State in which the average bed capacity in the State is less than the national average bed capacity; and

"(v) that has an average bed occupancy rate that is greater than the average bed occupancy rate in the State in which the hospital is located.

"(F) PROCEDURE ROOMS.—In this subsection, the term 'procedure rooms' includes rooms in which catheterizations, angiographies, angiograms, and endoscopies are performed, except such term shall not include emergency rooms or departments (exclusive of rooms in which catheterizations, angiographies, angiograms, and endoscopies are performed).

"(G) PUBLICATION OF FINAL DECISIONS.—Not later than 60 days after receiving a complete application under this paragraph, the Secretary shall publish in the Federal Register the final decision with respect to such application.

"(H) LIMITATION ON REVIEW.—There shall be no administrative or judicial review under section 1869, section 1878, or otherwise of the process under this paragraph (including the establishment of such process).

"(4) COLLECTION OF OWNERSHIP AND INVESTMENT INFORMATION.—For purposes of subparagraphs (A)(i) and (D)(i) of paragraph (1), the Secretary shall collect physician ownership and investment information for each hospital.

"(5) PHYSICIAN OWNER OR INVESTOR DEFINED.—For purposes of this subsection, the term 'physician owner or investor' means a physician (or an immediate family member of such

physician) with a direct or an indirect ownership or investment interest in the hospital.

"(6) CLARIFICATION.—Nothing in this subsection shall be construed as preventing the Secretary from revoking a hospital's provider agreement if not in compliance with regulations implementing section 1866.".

(b) ENFORCEMENT.—

(1) ENSURING COMPLIANCE.—The Secretary of Health and Human Services shall establish policies and procedures to ensure compliance with the requirements described in subsection (i)(1) of section 1877 of the Social Security Act, as added by subsection (a)(3), beginning on the date such requirements first apply. Such policies and procedures may include unannounced site reviews of hospitals.

(2) AUDITS.—Beginning not later than November 1, 2011, the Secretary of Health and Human Services shall conduct audits to determine if hospitals violate the requirements referred to in paragraph (1).

SEC. 6002. TRANSPARENCY REPORTS AND REPORTING OF PHYSICIAN OWNERSHIP OR INVESTMENT INTERESTS.

Part A of title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by inserting after section 1128F the following new section:

"SEC. 1128G. 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 definition 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) 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

(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 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.

"(B) EXCLUSION.—Such term does not include a physician 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, biological, 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. 6003. DISCLOSURE REQUIREMENTS FOR IN-OFFICE ANCILLARY SERVICES EXCEPTION TO THE PROHIBITION ON PHYSICIAN SELF-REFERRAL FOR CERTAIN IMAGING SERVICES.

(a) IN GENERAL.—Section 1877(b)(2) of the Social Security Act (42 U.S.C. 1395nn(b)(2)) is amended by adding at the end the following new sentence: "Such requirements shall, with respect to magnetic resonance imaging, computed tomography, positron emission tomography, and any other designated health services specified under subsection (h)(6)(D) that the Secretary determines appropriate, include a requirement that the referring physician inform the individual in writing at the time of the referral that the individual may obtain the services for which the individual is being referred from a person other than a person described in subparagraph (A)(i) and provide such individual with a written list of suppliers (as defined in section 1861(d)) who furnish such services in the area in which such individual resides.".

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to services furnished on or after January 1, 2010.

SEC. 6004. PRESCRIPTION DRUG SAMPLE TRANSPARENCY.

Part A of title XI of the Social Security Act (42 U.S.C. 1301 et seq.), as amended by section 6002, is amended by inserting after section 1128G the following new section:

"SEC. 1128H. 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. 6005. PHARMACY BENEFIT MANAGERS TRANSPARENCY REQUIREMENTS.

Part A of title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by inserting after section 1150 the following new section:

"SEC. 1150A. 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.".

Subtitle B—Nursing Home Transparency and Improvement

PART I—IMPROVING TRANSPARENCY OF INFORMATION

SEC. 6101. REQUIRED DISCLOSURE OF OWNERSHIP AND ADDITIONAL DISCLOSABLE PARTIES INFORMATION.

(a) IN GENERAL.—Section 1124 of the Social Security Act (42 U.S.C. 1320a–3) is amended by adding at the end the following new subsection:

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

"(1) DISCLOSURE.—A facility 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.".

(b) PUBLIC AVAILABILITY OF INFORMATION.—Not later than the date that is 1 year after the date on which the final regulations promulgated under section 1124(c)(3)(A) of the Social Security Act, as added by subsection (a), are published in the Federal Register, the Secretary of Health and Human Services shall make the information reported in accordance with such final regulations available to the public in accordance with procedures established by the Secretary.

(c) CONFORMING AMENDMENTS.—

(1) IN GENERAL.—

(A) SKILLED NURSING FACILITIES.—Section 1819(d)(1) of the Social Security Act (42 U.S.C. 1395i–3(d)(1)) is amended by striking subparagraph (B) and redesignating subparagraph (C) as subparagraph (B).

(B) NURSING FACILITIES.—Section 1919(d)(1) of the Social Security Act (42 U.S.C. 1396r(d)(1)) is amended by striking subparagraph (B) and redesignating subparagraph (C) as subparagraph (B).

(2) EFFECTIVE DATE.—The amendments made by paragraph (1) shall take effect on the date on which the Secretary makes the information described in subsection (b)(1) available to the public under such subsection.

SEC. 6102. ACCOUNTABILITY REQUIREMENTS FOR SKILLED NURSING FACILITIES AND NURSING FACILITIES.

Part A of title XI of the Social Security Act (42 U.S.C. 1301 et seq.), as amended by sections 6002 and 6004, is amended by inserting after section 1128H the following new section:

"SEC. 1128I. 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.".

SEC. 6103. NURSING HOME COMPARE MEDICARE WEBSITE.

(a) SKILLED NURSING FACILITIES.—

(1) IN GENERAL.—Section 1819 of the Social Security Act (42 U.S.C. 1395i–3) is amended—

(A) by redesignating subsection (i) as subsection (j); and

(B) by inserting after subsection (h) the following new subsection:

"(i) NURSING HOME COMPARE WEBSITE.—

"(1) INCLUSION OF ADDITIONAL INFORMATION.—

"(A) IN GENERAL.—The Secretary shall ensure that the Department of Health and Human Services includes, as part of the information provided for comparison of nursing homes on the official Internet website of the Federal Government for Medicare beneficiaries (commonly referred to as the 'Nursing Home Compare' Medicare website) (or a successor website), the following information in a manner that is prominent, updated on a timely basis, easily accessible, readily understandable to consumers of long-term care services, and searchable:

"(i) Staffing data for each facility (including resident census data and data on the hours of care provided per resident per day) based on data submitted under section 1128I(g), including information on staffing turnover and tenure, in a format that is clearly understandable to consumers of long-term care services and allows such consumers to compare differences in staffing between facilities and State and national averages for the facilities. Such format shall include—

"(I) concise explanations of how to interpret the data (such as a plain English explanation of data reflecting 'nursing home staff hours per resident day');

"(II) differences in types of staff (such as training associated with different categories of staff);

"(III) the relationship between nurse staffing levels and quality of care; and

"(IV) an explanation that appropriate staffing levels vary based on patient case mix.

"(ii) Links to State Internet websites with information regarding State survey and certification programs, links to Form 2567 State inspection reports (or a successor form) on such websites, information to guide consumers in how to interpret and understand such reports, and the facility plan of correction or other response to such report. Any such links shall be posted on a timely basis.

"(iii) The standardized complaint form developed under section 1128I(f), including explanatory material on what complaint forms are, how they are used, and how to file a complaint with the State survey and certification program and the State long-term care ombudsman program.

"(iv) Summary information on the number, type, severity, and outcome of substantiated complaints.

"(v) The number of adjudicated instances of criminal violations by a facility or the employees of a facility—

"(I) that were committed inside the facility;

"(II) with respect to such instances of violations or crimes committed inside of the facility that were the violations or crimes of abuse, neglect, and exploitation, criminal sexual abuse, or other violations or crimes that resulted in serious bodily injury; and

"(III) the number of civil monetary penalties levied against the facility, employees, contractors, and other agents.

"(B) DEADLINE FOR PROVISION OF INFORMATION.—

"(i) IN GENERAL.—Except as provided in clause (ii), the Secretary shall ensure that the information described in subparagraph (A) is included on such website (or a successor website) not later than 1 year after the date of the enactment of this subsection.

"(ii) EXCEPTION.—The Secretary shall ensure that the information described in subparagraph (A)(i) is included on such website (or a successor website) not later than the date on which the requirements under section 1128I(g) are implemented.

"(2) REVIEW AND MODIFICATION OF WEBSITE.—

"(A) IN GENERAL.—The Secretary shall establish a process—

"(i) to review the accuracy, clarity of presentation, timeliness, and comprehensiveness of information reported on such website as of the day before the date of the enactment of this subsection; and

"(ii) not later than 1 year after the date of the enactment of this subsection, to modify or revamp such website in accordance with the review conducted under clause (i).

"(B) CONSULTATION.—In conducting the review under subparagraph (A)(i), the Secretary shall consult with—

"(i) State long-term care ombudsman programs;

"(ii) consumer advocacy groups;

"(iii) provider stakeholder groups; and

"(iv) any other representatives of programs or groups the Secretary determines appropriate.".

(2) TIMELINESS OF SUBMISSION OF SURVEY AND CERTIFICATION INFORMATION.—

(A) IN GENERAL.—Section 1819(g)(5) of the Social Security Act (42 U.S.C. 1395i–3(g)(5)) is amended by adding at the end the following new subparagraph:

"(E) SUBMISSION OF SURVEY AND CERTIFICATION INFORMATION TO THE SECRETARY.—In order to improve the timeliness of information made available to the public under subparagraph (A) and provided on the Nursing Home Compare Medicare website under subsection (i), each State shall submit information respecting any survey or certification made respecting a skilled nursing facility (including any enforcement actions taken by the State) to the Secretary not later than the date on which the State sends such information to the facility. The Secretary shall use the information submitted under the preceding sentence to update the information provided on the Nursing Home Compare Medicare website as expeditiously as practicable but not less frequently than quarterly.".

(B) EFFECTIVE DATE.—The amendment made by this paragraph shall take effect 1 year after the date of the enactment of this Act.

(3) SPECIAL FOCUS FACILITY PROGRAM.—Section 1819(f) of the Social Security Act (42 U.S.C. 1395i–3(f)) is amended by adding at the end the following new paragraph:

"(8) SPECIAL FOCUS FACILITY PROGRAM.—

"(A) IN GENERAL.—The Secretary shall conduct a special focus facility program for enforcement of requirements for skilled nursing facilities that the Secretary has identified as having substantially failed to meet applicable requirement of this Act.

"(B) PERIODIC SURVEYS.—Under such program the Secretary shall conduct surveys of each facility in the program not less than once every 6 months.".

(b) NURSING FACILITIES.—

(1) IN GENERAL.—Section 1919 of the Social Security Act (42 U.S.C. 1396r) is amended—

(A) by redesignating subsection (i) as subsection (j); and

(B) by inserting after subsection (h) the following new subsection:

"(i) NURSING HOME COMPARE WEBSITE.—

"(1) INCLUSION OF ADDITIONAL INFORMATION.—

"(A) IN GENERAL.—The Secretary shall ensure that the Department of Health and Human Services includes, as part of the information provided for comparison of nursing homes on the official Internet website of the Federal Government for Medicare beneficiaries (commonly referred to as the 'Nursing Home Compare' Medicare website) (or a successor website), the following information in a manner that is prominent, updated on a timely basis, easily accessible, readily understandable to consumers of long-term care services, and searchable:

"(i) Staffing data for each facility (including resident census data and data on the hours of care provided per resident per day) based on data submitted under section 1128I(g), including information on staffing turnover and tenure, in a format that is clearly understandable to consumers of long-term care services and allows such consumers to compare differences in staffing between facilities and State and national averages for the facilities. Such format shall include—

"(I) concise explanations of how to interpret the data (such as plain English explanation of data reflecting 'nursing home staff hours per resident day');

"(II) differences in types of staff (such as training associated with different categories of staff);

"(III) the relationship between nurse staffing levels and quality of care; and

"(IV) an explanation that appropriate staffing levels vary based on patient case mix.

"(ii) Links to State Internet websites with information regarding State survey and certification programs, links to Form 2567 State inspection reports (or a successor form) on such websites, information to guide consumers in how to interpret and understand such reports, and the facility plan of correction or other response to such report. Any such links shall be posted on a timely basis.

"(iii) The standardized complaint form developed under section 1128I(f), including explanatory material on what complaint forms are, how they are used, and how to file a complaint with the State survey and certification program and the State long-term care ombudsman program.

"(iv) Summary information on the number, type, severity, and outcome of substantiated complaints.

"(v) The number of adjudicated instances of criminal violations by a facility or the employees of a facility—

"(I) that were committed inside of the facility; and

"(II) with respect to such instances of violations or crimes committed outside of the facility, that were violations or crimes that resulted in the serious bodily injury of an elder.

"(B) DEADLINE FOR PROVISION OF INFORMATION.—

"(i) IN GENERAL.—Except as provided in clause (ii), the Secretary shall ensure that the information described in subparagraph (A) is included on such website (or a successor website) not later than 1 year after the date of the enactment of this subsection.

"(ii) EXCEPTION.—The Secretary shall ensure that the information described in subparagraph (A)(i) is included on such website (or a successor website) not later than the date on which the requirements under section 1128I(g) are implemented.

"(2) REVIEW AND MODIFICATION OF WEBSITE.—

"(A) IN GENERAL.—The Secretary shall establish a process—

"(i) to review the accuracy, clarity of presentation, timeliness, and comprehensiveness of information reported on such website as of the day before the date of the enactment of this subsection; and

"(ii) not later than 1 year after the date of the enactment of this subsection, to modify or revamp such website in accordance with the review conducted under clause (i).

"(B) CONSULTATION.—In conducting the review under subparagraph (A)(i), the Secretary shall consult with—

"(i) State long-term care ombudsman programs;

"(ii) consumer advocacy groups;

"(iii) provider stakeholder groups;

"(iv) skilled nursing facility employees and their representatives; and

"(v) any other representatives of programs or groups the Secretary determines appropriate.".

(2) TIMELINESS OF SUBMISSION OF SURVEY AND CERTIFICATION INFORMATION.—

(A) IN GENERAL.—Section 1919(g)(5) of the Social Security Act (42 U.S.C. 1396r(g)(5)) is amended by adding at the end the following new subparagraph:

"(E) SUBMISSION OF SURVEY AND CERTIFICATION INFORMATION TO THE SECRETARY.—In order to improve the timeliness of information made available to the public under subparagraph (A) and provided on the Nursing Home

Compare Medicare website under subsection (i), each State shall submit information respecting any survey or certification made respecting a nursing facility (including any enforcement actions taken by the State) to the Secretary not later than the date on which the State sends such information to the facility. The Secretary shall use the information submitted under the preceding sentence to update the information provided on the Nursing Home Compare Medicare website as expeditiously as practicable but not less frequently than quarterly.".

(B) EFFECTIVE DATE.—The amendment made by this paragraph shall take effect 1 year after the date of the enactment of this Act.

(3) SPECIAL FOCUS FACILITY PROGRAM.—Section 1919(f) of the Social Security Act (42 U.S.C. 1396r(f)) is amended by adding at the end of the following new paragraph:

"(10) SPECIAL FOCUS FACILITY PROGRAM.—

"(A) IN GENERAL.—The Secretary shall conduct a special focus facility program for enforcement of requirements for nursing facilities that the Secretary has identified as having substantially failed to meet applicable requirements of this Act.

"(B) PERIODIC SURVEYS.—Under such program the Secretary shall conduct surveys of each facility in the program not less often than once every 6 months.".

(c) AVAILABILITY OF REPORTS ON SURVEYS, CERTIFICATIONS, AND COMPLAINT INVESTIGATIONS.—

(1) SKILLED NURSING FACILITIES.—Section 1819(d)(1) of the Social Security Act (42 U.S.C. 1395i–3(d)(1)), as amended by section 6101, is amended by adding at the end the following new subparagraph:

"(C) AVAILABILITY OF SURVEY, CERTIFICATION, AND COMPLAINT INVESTIGATION REPORTS.—A skilled nursing facility must—

"(i) have reports with respect to any surveys, certifications, and complaint investigations made respecting the facility during the 3 preceding years available for any individual to review upon request; and

"(ii) post notice of the availability of such reports in areas of the facility that are prominent and accessible to the public.

The facility shall not make available under clause (i) identifying information about complainants or residents.".

(2) NURSING FACILITIES.—Section 1919(d)(1) of the Social Security Act (42 U.S.C. 1396r(d)(1)), as amended by section 6101, is amended by adding at the end the following new subparagraph:

"(V) AVAILABILITY OF SURVEY, CERTIFICATION, AND COMPLAINT INVESTIGATION REPORTS.—A nursing facility must—

"(i) have reports with respect to any surveys, certifications, and complaint investigations made respecting the facility during the 3 preceding years available for any individual to review upon request; and

"(ii) post notice of the availability of such reports in areas of the facility that are prominent and accessible to the public.

The facility shall not make available under clause (i) identifying information about complainants or residents.".

(3) EFFECTIVE DATE.—The amendments made by this subsection shall take effect 1 year after the date of the enactment of this Act.

(d) GUIDANCE TO STATES ON FORM 2567 STATE INSPECTION REPORTS AND COMPLAINT INVESTIGATION REPORTS.—

(1) GUIDANCE.—The Secretary of Health and Human Services (in this subtitle referred to as the "Secretary") shall provide guidance to States on how States can establish electronic links to Form 2567 State inspection reports (or a successor form), complaint investigation reports, and a facility's plan of correction or other response to such Form 2567 State inspection reports (or a successor form) on the Internet website of the State that provides information on skilled nursing facilities and nursing facilities and the Secretary shall, if possible, include such information on Nursing Home Compare.

(2) REQUIREMENT.—Section 1902(a)(9) of the Social Security Act (42 U.S.C. 1396a(a)(9)) is amended—

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

(B) by striking the semicolon at the end of subparagraph (C) and inserting ", and"; and

(C) by adding at the end the following new subparagraph:

"(D) that the State maintain a consumer-oriented website providing useful information to consumers regarding all skilled nursing facilities and all nursing facilities in the State, including for each facility, Form 2567 State inspection reports (or a successor form), complaint investigation reports, the facility's plan of correction, and such other information that the State or the Secretary considers useful in assisting the public to assess the quality of long term care options and the quality of care provided by individual facilities;".

(3) DEFINITIONS.—In this subsection:

(A) NURSING FACILITY.—The term "nursing facility" has the meaning given such term in section 1919(a) of the Social Security Act (42 U.S.C. 1396r(a)).

(B) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

(C) SKILLED NURSING FACILITY.—The term "skilled nursing facility" has the meaning given such term in section 1819(a) of the Social Security Act (42 U.S.C. 1395i–3(a)).

(e) DEVELOPMENT OF CONSUMER RIGHTS INFORMATION PAGE ON NURSING HOME COMPARE WEBSITE.—Not later than 1 year after the date of enactment of this Act, the Secretary shall ensure that the Department of Health and Human Services, as part of the information provided for comparison of nursing facilities on the Nursing Home Compare Medicare website develops and includes a consumer rights information page that contains links to descriptions of, and information with respect to, the following:

(1) The documentation on nursing facilities that is available to the public.

(2) General information and tips on choosing a nursing facility that meets the needs of the individual.

(3) General information on consumer rights with respect to nursing facilities.

(4) The nursing facility survey process (on a national and State-specific basis).

(5) On a State-specific basis, the services available through the State long-term care ombudsman for such State.

SEC. 6104. REPORTING OF EXPENDITURES.

Section 1888 of the Social Security Act (42 U.S.C. 1395yy) is amended by adding at the end the following new subsection:

"(f) REPORTING OF DIRECT CARE EXPENDITURES.—

"(1) IN GENERAL.—For cost reports submitted under this title for cost reporting periods beginning on or after the date that is 2 years after the date of the enactment of this subsection, skilled nursing facilities shall separately report expenditures for wages and benefits for direct care staff (breaking out (at a minimum) registered nurses, licensed professional nurses, certified nurse assistants, and other medical and therapy staff).

"(2) MODIFICATION OF FORM.—The Secretary, in consultation with private sector accountants experienced with Medicare and Medicaid nursing facility home cost reports, shall redesign such reports to meet the requirement of paragraph (1) not later than 1 year after the date of the enactment of this subsection.

"(3) CATEGORIZATION BY FUNCTIONAL ACCOUNTS.—Not later than 30 months after the date of the enactment of this subsection, the Secretary, working in consultation with the Medicare Payment Advisory Commission, the Medicaid and CHIP Payment and Access Commission, the Inspector General of the Department of Health and Human Services, and other expert parties the Secretary determines appropriate, shall take the expenditures listed on cost reports, as modified under paragraph (1), submitted by skilled nursing facilities and categorize such expenditures, regardless of any source of payment for such expenditures, for each skilled nursing facility into the following functional accounts on an annual basis:

"(A) Spending on direct care services (including nursing, therapy, and medical services).

"(B) Spending on indirect care (including housekeeping and dietary services).

"(C) Capital assets (including building and land costs).

"(D) Administrative services costs.

"(4) AVAILABILITY OF INFORMATION SUBMITTED.—The Secretary shall establish procedures to make information on expenditures submitted under this subsection readily available to interested parties upon request, subject to such requirements as the Secretary may specify under the procedures established under this paragraph.".

SEC. 6105. STANDARDIZED COMPLAINT FORM.

(a) IN GENERAL.—Section 1128I of the Social Security Act, as added and amended by this Act, is amended by adding at the end the following new 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 complaint in a manner or format other than by using the standardized complaint form developed under paragraph (1) (including submitting a complaint orally).".

(b) EFFECTIVE DATE.—The amendment made by this section shall take effect 1 year after the date of the enactment of this Act.

SEC. 6106. ENSURING STAFFING ACCOUNTABILITY.

Section 1128I of the Social Security Act, as added and amended by this Act, is amended by adding at the end the following new subsection:

"(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.".

SEC. 6107. GAO STUDY AND REPORT ON FIVE-STAR QUALITY RATING SYSTEM.

(a) STUDY.—The Comptroller General of the United States (in this section referred to as the "Comptroller General") shall conduct a study on the Five-Star Quality Rating System for nursing homes of the Centers for Medicare & Medicaid Services. Such study shall include an analysis of—

(1) how such system is being implemented;

(2) any problems associated with such system or its implementation; and

(3) how such system could be improved.

(b) REPORT.—Not later than 2 years after the date of enactment of this Act, the Comptroller General shall submit to Congress a report containing the results of the study conducted under subsection (a), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

PART II—TARGETING ENFORCEMENT

SEC. 6111. CIVIL MONEY PENALTIES.

(a) SKILLED NURSING FACILITIES.—

(1) IN GENERAL.—Section 1819(h)(2)(B)(ii) of the Social Security Act (42 U.S.C. 1395i–3(h)(2)(B)(ii)) is amended—

(A) by striking "PENALTIES.—The Secretary" and inserting "PENALTIES.—

"(I) IN GENERAL.—Subject to subclause (II), the Secretary"; and

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

"(II) REDUCTION OF CIVIL MONEY PENALTIES IN CERTAIN CIRCUMSTANCES.—Subject to subclause (III), in the case where a facility self-reports and promptly corrects a deficiency for which a penalty was imposed under this clause not later than 10 calendar days after the date of such imposition, the Secretary may reduce the amount of the penalty imposed by not more than 50 percent.

"(III) PROHIBITIONS ON REDUCTION FOR CERTAIN DEFICIENCIES.—

"(aa) REPEAT DEFICIENCIES.—The Secretary may not reduce the amount of a penalty under subclause (II) if the Secretary had

reduced a penalty imposed on the facility in the preceding year under such subclause with respect to a repeat deficiency.

"(bb) CERTAIN OTHER DEFICIENCIES.—The Secretary may not reduce the amount of a penalty under subclause (II) if the penalty is imposed on the facility for a deficiency that is found to result in a pattern of harm or widespread harm, immediately jeopardizes the health or safety of a resident or residents of the facility, or results in the death of a resident of the facility.

"(IV) COLLECTION OF CIVIL MONEY PENALTIES.—In the case of a civil money penalty imposed under this clause, the Secretary shall issue regulations that—

"(aa) subject to item (cc), not later than 30 days after the imposition of the penalty, provide for the facility to have the opportunity to participate in an independent informal dispute resolution process which generates a written record prior to the collection of such penalty;

"(bb) in the case where the penalty is imposed for each day of noncompliance, provide that a penalty may not be imposed for any day during the period beginning on the initial day of the imposition of the penalty and ending on the day on which the informal dispute resolution process under item (aa) is completed;

"(cc) may provide for the collection of such civil money penalty and the placement of such amounts collected in an escrow account under the direction of the Secretary on the earlier of the date on which the informal dispute resolution process under item (aa) is completed or the date that is 90 days after the date of the imposition of the penalty;

"(dd) may provide that such amounts collected are kept in such account pending the resolution of any subsequent appeals;

"(ee) in the case where the facility successfully appeals the penalty, may provide for the return of such amounts collected (plus interest) to the facility; and

"(ff) in the case where all such appeals are unsuccessful, may provide that some portion of such amounts collected may be used to support activities that benefit residents, including assistance to support and protect residents of a facility that closes (voluntarily or involuntarily) or is decertified (including offsetting costs of relocating residents to home and community-based settings or another facility), projects that support resident and

family councils and other consumer involvement in assuring quality care in facilities, and facility improvement initiatives approved by the Secretary (including joint training of facility staff and surveyors, technical assistance for facilities implementing quality assurance programs, the appointment of temporary management firms, and other activities approved by the Secretary).".

(2) CONFORMING AMENDMENT.—The second sentence of section 1819(h)(5) of the Social Security Act (42 U.S.C. 1395i–3(h)(5)) is amended by inserting "(ii)(IV)," after "(i),".

(b) NURSING FACILITIES.—

(1) IN GENERAL.—Section 1919(h)(3)(C)(ii) of the Social Security Act (42 U.S.C. 1396r(h)(3)(C)) is amended—

(A) by striking "PENALTIES.—The Secretary" and inserting "PENALTIES.—

"(I) IN GENERAL.—Subject to subclause (II), the Secretary"; and

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

"(II) REDUCTION OF CIVIL MONEY PENALTIES IN CERTAIN CIRCUMSTANCES.—Subject to subclause (III), in the case where a facility self-reports and promptly corrects a deficiency for which a penalty was imposed under this clause not later than 10 calendar days after the date of such imposition, the Secretary may reduce the amount of the penalty imposed by not more than 50 percent.

"(III) PROHIBITIONS ON REDUCTION FOR CERTAIN DEFICIENCIES.—

"(aa) REPEAT DEFICIENCIES.—The Secretary may not reduce the amount of a penalty under subclause (II) if the Secretary had reduced a penalty imposed on the facility in the preceding year under such subclause with respect to a repeat deficiency.

"(bb) CERTAIN OTHER DEFICIENCIES.—The Secretary may not reduce the amount of a penalty under subclause (II) if the penalty is imposed on the facility for a deficiency that is found to result in a pattern of harm or widespread harm, immediately jeopardizes the health or safety of a resident or residents of the facility, or results in the death of a resident of the facility.

"(IV) COLLECTION OF CIVIL MONEY PENALTIES.—In the case of a civil money penalty imposed under this clause, the Secretary shall issue regulations that—

"(aa) subject to item (cc), not later than 30 days after the imposition of the penalty, provide for the facility to have the opportunity to participate in an independent informal dispute resolution process which generates a written record prior to the collection of such penalty;

"(bb) in the case where the penalty is imposed for each day of noncompliance, provide that a penalty may not be imposed for any day during the period beginning on the initial day of the imposition of the penalty and ending on the day on which the informal dispute resolution process under item (aa) is completed;

"(cc) may provide for the collection of such civil money penalty and the placement of such amounts collected in an escrow account under the direction of the Secretary on the earlier of the date on which the informal dispute resolution process under item (aa) is completed or the date that is 90 days after the date of the imposition of the penalty;

"(dd) may provide that such amounts collected are kept in such account pending the resolution of any subsequent appeals;

"(ee) in the case where the facility successfully appeals the penalty, may provide for the return of such amounts collected (plus interest) to the facility; and

"(ff) in the case where all such appeals are unsuccessful, may provide that some portion of such amounts collected may be used to support activities that benefit residents, including assistance to support and protect residents of a facility that closes (voluntarily or involuntarily) or is decertified (including offsetting costs of relocating residents to home and community-based settings or another facility), projects that support resident and family councils and other consumer involvement in assuring quality care in facilities, and facility improvement initiatives approved by the Secretary (including joint training of facility staff and surveyors, technical assistance for facilities implementing quality assurance programs, the appointment of temporary management firms, and other activities approved by the Secretary).".

(2) CONFORMING AMENDMENT.—Section 1919(h)(5)(8) of the Social Security Act (42 U.S.C. 1396r(h)(5)(8)) is amended by inserting "(ii)(IV)," after "(i),".

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect 1 year after the date of the enactment of this Act.

SEC. 6112. NATIONAL INDEPENDENT MONITOR DEMONSTRATION PROJECT.

(a) ESTABLISHMENT.—

(1) IN GENERAL.—The Secretary, in consultation with the Inspector General of the Department of Health and Human Services, shall conduct a demonstration project to develop, test, and implement an independent monitor program to oversee

interstate and large intrastate chains of skilled nursing facilities and nursing facilities.

(2) SELECTION.—The Secretary shall select chains of skilled nursing facilities and nursing facilities described in paragraph (1) to participate in the demonstration project under this section from among those chains that submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

(3) DURATION.—The Secretary shall conduct the demonstration project under this section for a 2-year period.

(4) IMPLEMENTATION.—The Secretary shall implement the demonstration project under this section not later than 1 year after the date of the enactment of this Act.

(b) REQUIREMENTS.—The Secretary shall evaluate chains selected to participate in the demonstration project under this section based on criteria selected by the Secretary, including where evidence suggests that a number of the facilities of the chain are experiencing serious safety and quality of care problems. Such criteria may include the evaluation of a chain that includes a number of facilities participating in the "Special Focus Facility" program (or a successor program) or multiple facilities with a record of repeated serious safety and quality of care deficiencies.

(c) RESPONSIBILITIES.—An independent monitor that enters into a contract with the Secretary to participate in the conduct of the demonstration project under this section shall—

(1) conduct periodic reviews and prepare root-cause quality and deficiency analyses of a chain to assess if facilities of the chain are in compliance with State and Federal laws and regulations applicable to the facilities;

(2) conduct sustained oversight of the efforts of the chain, whether publicly or privately held, to achieve compliance by facilities of the chain with State and Federal laws and regulations applicable to the facilities;

(3) analyze the management structure, distribution of expenditures, and nurse staffing levels of facilities of the chain in relation to resident census, staff turnover rates, and tenure;

(4) report findings and recommendations with respect to such reviews, analyses, and oversight to the chain and facilities of the chain, to the Secretary, and to relevant States; and

(5) publish the results of such reviews, analyses, and oversight.

(d) IMPLEMENTATION OF RECOMMENDATIONS.—

(1) RECEIPT OF FINDING BY CHAIN.—Not later than 10 days after receipt of a finding of an independent monitor under subsection (c)(4), a chain participating in the demonstration project shall submit to the independent monitor a report—

(A) outlining corrective actions the chain will take to implement the recommendations in such report; or

(B) indicating that the chain will not implement such recommendations, and why it will not do so.

(2) RECEIPT OF REPORT BY INDEPENDENT MONITOR.—Not later than 10 days after receipt of a report submitted by a chain under paragraph (1), an independent monitor shall finalize its recommendations and submit a report to the chain and facilities of the chain, the Secretary, and the State or States, as appropriate, containing such final recommendations.

(e) COST OF APPOINTMENT.—A chain shall be responsible for a portion of the costs associated with the appointment of independent monitors under the demonstration project under this section. The chain shall pay such portion to the Secretary (in an amount and in accordance with procedures established by the Secretary).

(f) WAIVER AUTHORITY.—The Secretary may waive such requirements of titles XVIII and XIX of the Social Security Act (42 U.S.C. 1395 et seq.; 1396 et seq.) as may be necessary for the purpose of carrying out the demonstration project under this section.

(g) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.

(h) DEFINITIONS.—In this section:

(1) ADDITIONAL DISCLOSABLE PARTY.—The term "additional disclosable party" has the meaning given such term in section 1124(c)(5)(A) of the Social Security Act, as added by section 4201(a).

(2) FACILITY.—The term "facility" means a skilled nursing facility or a nursing facility.

(3) NURSING FACILITY.—The term "nursing facility" has the meaning given such term in section 1919(a) of the Social Security Act (42 U.S.C. 1396r(a)).

(4) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services, acting through the Assistant Secretary for Planning and Evaluation.

(5) SKILLED NURSING FACILITY.—The term "skilled nursing facility" has the meaning given such term in section 1819(a) of the Social Security Act (42 U.S.C. 1395(a)).

(i) EVALUATION AND REPORT.—

(1) EVALUATION.—The Secretary, in consultation with the Inspector General of the Department of Health and Human Services, shall evaluate the demonstration project conducted under this section.

(2) REPORT.—Not later than 180 days after the completion of the demonstration project under this section, the Secretary shall submit to Congress a report containing the results of the evaluation conducted under paragraph (1), together with recommendations—

(A) as to whether the independent monitor program should be established on a permanent basis;

(B) if the Secretary recommends that such program be so established, on appropriate procedures and mechanisms for such establishment; and

(C) for such legislation and administrative action as the Secretary determines appropriate.

SEC. 6113. NOTIFICATION OF FACILITY CLOSURE.

(a) IN GENERAL.—Section 1128I of the Social Security Act, as added and amended by this Act, is amended by adding at the end the following new subsection:

"(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).".

(b) CONFORMING AMENDMENTS.—Section 1819(h)(4) of the Social Security Act (42 U.S.C. 1395i–3(h)(4)) is amended—

(1) in the first sentence, by striking "the Secretary shall terminate" and inserting "the Secretary, subject to section 1128I(h), shall terminate"; and

(2) in the second sentence, by striking "subsection (c)(2)" and inserting "subsection (c)(2) and section 1128I(h)".

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect 1 year after the date of the enactment of this Act.

SEC. 6114. NATIONAL DEMONSTRATION PROJECTS ON CULTURE CHANGE AND USE OF INFORMATION TECHNOLOGY IN NURSING HOMES.

(a) IN GENERAL.—The Secretary shall conduct 2 demonstration projects, 1 for the development of best practices in skilled nursing facilities and nursing facilities that are involved in the culture change movement (including the development of resources for facilities to find and access funding in order to undertake culture change) and 1 for the development of best practices in skilled nursing facilities and nursing facilities for the use of information technology to improve resident care.

(b) CONDUCT OF DEMONSTRATION PROJECTS.—

(1) GRANT AWARD.—Under each demonstration project conducted under this section, the Secretary shall award 1 or more grants to facility-based settings for the development of best practices described in subsection (a) with respect to the demonstration project involved. Such award shall be made on a competitive basis and may be allocated in 1 lump-sum payment.

(2) CONSIDERATION OF SPECIAL NEEDS OF RESIDENTS.—Each demonstration project conducted under this section shall take into consideration the special needs of residents of skilled nursing facilities and nursing facilities who have cognitive impairment, including dementia.

(c) DURATION AND IMPLEMENTATION.—

(1) DURATION.—The demonstration projects shall each be conducted for a period not to exceed 3 years.

(2) IMPLEMENTATION.—The demonstration projects shall each be implemented not later than 1 year after the date of the enactment of this Act.

(d) DEFINITIONS.—In this section:

(1) NURSING FACILITY.—The term "nursing facility" has the meaning given such term in section 1919(a) of the Social Security Act (42 U.S.C. 1396r(a)).

(2) SECRETARY.—The term "Secretary" means the Secretary of Health and Human Services.

(3) SKILLED NURSING FACILITY.—The term "skilled nursing facility" has the meaning given such term in section 1819(a) of the Social Security Act (42 U.S.C. 1395(a)).

(e) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this section.

(f) REPORT.—Not later than 9 months after the completion of the demonstration project, the Secretary shall submit to Congress a report on such project, together with recommendations for such legislation and administrative action as the Secretary determines appropriate.

PART III—IMPROVING STAFF TRAINING

SEC. 6121. DEMENTIA AND ABUSE PREVENTION TRAINING.

(a) SKILLED NURSING FACILITIES.—

(1) IN GENERAL.—Section 1819(f)(2)(A)(i)(I) of the Social Security Act (42 U.S.C. 1395i–3(f)(2)(A)(i)(I)) is amended by

inserting "(including, in the case of initial training and, if the Secretary determines appropriate, in the case of ongoing training, dementia management training, and patient abuse prevention training" before ", (II)".

(2) CLARIFICATION OF DEFINITION OF NURSE AIDE.—Section 1819(b)(5)(F) of the Social Security Act (42 U.S.C. 1395i–3(b)(5)(F)) is amended by adding at the end the following flush sentence:

"Such term includes an individual who provides such services through an agency or under a contract with the facility.".

(b) NURSING FACILITIES.—

(1) IN GENERAL.—Section 1919(f)(2)(A)(i)(I) of the Social Security Act (42 U.S.C. 1396r(f)(2)(A)(i)(I)) is amended by inserting "(including, in the case of initial training and, if the Secretary determines appropriate, in the case of ongoing training, dementia management training, and patient abuse prevention training" before ", (II)".

(2) CLARIFICATION OF DEFINITION OF NURSE AIDE.—Section 1919(b)(5)(F) of the Social Security Act (42 U.S.C. 1396r(b)(5)(F)) is amended by adding at the end the following flush sentence:

"Such term includes an individual who provides such services through an agency or under a contract with the facility.".

(c) EFFECTIVE DATE.—The amendments made by this section shall take effect 1 year after the date of the enactment of this Act.

Subtitle C—Nationwide Program for National and State Background Checks on Direct Patient Access Employees of Long-term Care Facilities and Providers

SEC. 6201. NATIONWIDE PROGRAM FOR NATIONAL AND STATE BACKGROUND CHECKS ON DIRECT PATIENT ACCESS EMPLOYEES OF LONG-TERM CARE FACILITIES AND PROVIDERS.

(a) IN GENERAL.—The Secretary of Health and Human Services (in this section referred to as the "Secretary"), shall establish a program to identify efficient, effective, and economical procedures for long term care facilities or providers to conduct background checks on prospective direct patient access employees on a nationwide basis (in this subsection, such program shall be referred to as the "nationwide program"). Except for the following modifications, the Secretary shall carry out the nationwide program under similar terms and conditions as the pilot program under section 307 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173; 117 Stat. 2257), including the prohibition on hiring abusive workers and the authorization of the imposition of penalties by a participating State under subsection (b)(3)(A) and (b)(6), respectively, of such section 307:

(1) AGREEMENTS.—

(A) NEWLY PARTICIPATING STATES.—The Secretary shall enter into agreements with each State—

(i) that the Secretary has not entered into an agreement with under subsection (c)(1) of such section 307;

(ii) that agrees to conduct background checks under the nationwide program on a Statewide basis; and

(iii) that submits an application to the Secretary containing such information and at such time as the Secretary may specify.

(B) CERTAIN PREVIOUSLY PARTICIPATING STATES.—The Secretary shall enter into agreements with each State—

(i) that the Secretary has entered into an agreement with under such subsection (c)(1), but only in the case where such agreement did not require the State to conduct background checks under the program established under subsection (a) of such section 307 on a Statewide basis;

(ii) that agrees to conduct background checks under the nationwide program on a Statewide basis; and

(iii) that submits an application to the Secretary containing such information and at such time as the Secretary may specify.

(2) NONAPPLICATION OF SELECTION CRITERIA.—The selection criteria required under subsection (c)(3)(B) of such section 307 shall not apply.

(3) REQUIRED FINGERPRINT CHECK AS PART OF CRIMINAL HISTORY BACKGROUND CHECK.—The procedures established under subsection (b)(1) of such section 307 shall—

(A) require that the long-term care facility or provider (or the designated agent of the long-term care facility or provider) obtain State and national criminal history background checks on the prospective employee through such means as the Secretary determines appropriate, efficient, and effective that utilize a search of State-based abuse and neglect registries and databases, including the abuse and neglect registries of another State in the case where a prospective employee previously resided in that State, State criminal history records, the records of any proceedings in the State that may contain disqualifying information about prospective employees (such as proceedings conducted by State professional licensing and disciplinary boards and State Medicaid Fraud Control Units), and Federal criminal history records, including a fingerprint check using the Integrated Automated Fingerprint Identification System of the Federal Bureau of Investigation;

(B) require States to describe and test methods that reduce duplicative fingerprinting, including providing for the development of "rap back" capability by the State such that, if a direct patient access employee of a long-term care facility or provider is convicted of a crime following the initial criminal history background check conducted

with respect to such employee, and the employee's fingerprints match the prints on file with the State law enforcement department, the department will immediately inform the State and the State will immediately inform the long-term care facility or provider which employs the direct patient access employee of such conviction; and

(C) require that criminal history background checks conducted under the nationwide program remain valid for a period of time specified by the Secretary.

(4) STATE REQUIREMENTS.—An agreement entered into under paragraph (1) shall require that a participating State—

(A) be responsible for monitoring compliance with the requirements of the nationwide program;

(B) have procedures in place to—

(i) conduct screening and criminal history background checks under the nationwide program in accordance with the requirements of this section;

(ii) monitor compliance by long-term care facilities and providers with the procedures and requirements of the nationwide program;

(iii) as appropriate, provide for a provisional period of employment by a long-term care facility or provider of a direct patient access employee, not to exceed 60 days, pending completion of the required criminal history background check and, in the case where the employee has appealed the results of such background check, pending completion of the appeals process, during which the employee shall be subject to direct on-site supervision (in accordance with procedures established by the State to ensure that a long-term care facility or provider furnishes such direct on-site supervision);

(iv) provide an independent process by which a provisional employee or an employee may appeal or dispute the accuracy of the information obtained in a background check performed under the nationwide program, including the specification of criteria for appeals for direct patient access employees found to have disqualifying information which shall include consideration of the passage of time, extenuating circumstances, demonstration of rehabilitation, and relevancy of the particular disqualifying information with respect to the current employment of the individual;

(v) provide for the designation of a single State agency as responsible for—

(I) overseeing the coordination of any State and national criminal history background checks requested by a long-term care facility or provider (or the designated agent of the long-term care facility or provider) utilizing a search of State and Federal criminal history records, including a fingerprint check of such records;

(II) overseeing the design of appropriate privacy and security safeguards for use in the review of the results of any State or national criminal history background checks conducted regarding a

prospective direct patient access employee to determine whether the employee has any conviction for a relevant crime;

(III) immediately reporting to the long-term care facility or provider that requested the criminal history background check the results of such review; and

(IV) in the case of an employee with a conviction for a relevant crime that is subject to reporting under section 1128E of the Social Security Act (42 U.S.C. 1320a–7e), reporting the existence of such conviction to the database established under that section;

(vi) determine which individuals are direct patient access employees (as defined in paragraph (6)(B)) for purposes of the nationwide program;

(vii) as appropriate, specify offenses, including convictions for violent crimes, for purposes of the nationwide program; and

(viii) describe and test methods that reduce duplicative fingerprinting, including providing for the development of "rap back" capability such that, if a direct patient access employee of a long-term care facility or provider is convicted of a crime following the initial criminal history background check conducted with respect to such employee, and the employee's fingerprints match the prints on file with the State law enforcement department—

(I) the department will immediately inform the State agency designated under clause (v) and such agency will immediately inform the facility or provider which employs the direct patient access employee of such conviction; and

(II) the State will provide, or will require the facility to provide, to the employee a copy of the results of the criminal history background check conducted with respect to the employee at no charge in the case where the individual requests such a copy.

(5) PAYMENTS.—

(A) NEWLY PARTICIPATING STATES.—

(i) IN GENERAL.—As part of the application submitted by a State under paragraph (1)(A)(iii), the State shall guarantee, with respect to the costs to be incurred by the State in carrying out the nationwide program, that the State will make available (directly or through donations from public or private entities) a particular amount of non-Federal contributions, as a condition of receiving the Federal match under clause (ii).

(ii) FEDERAL MATCH.—The payment amount to each State that the Secretary enters into an agreement with under paragraph (1)(A) shall be 3 times the amount that the State guarantees to make available under clause (i), except that in no case may the payment amount exceed $3,000,000.

(B) PREVIOUSLY PARTICIPATING STATES.—

(i) IN GENERAL.—As part of the application submitted by a State under paragraph (1)(B)(iii), the State shall guarantee, with respect to the costs to be incurred by the State in carrying out the nationwide program, that the State will make available (directly or through donations from public or private entities) a particular amount of non-Federal contributions, as a condition of receiving the Federal match under clause (ii).

(ii) FEDERAL MATCH.—The payment amount to each State that the Secretary enters into an agreement with under paragraph (1)(B) shall be 3 times the amount that the State guarantees to make available under clause (i), except that in no case may the payment amount exceed $1,500,000.

(6) DEFINITIONS.—Under the nationwide program:

(A) CONVICTION FOR A RELEVANT CRIME.—The term "conviction for a relevant crime" means any Federal or State criminal conviction for—

(i) any offense described in section 1128(a) of the Social Security Act (42 U.S.C. 1320a–7); or

(ii) such other types of offenses as a participating State may specify for purposes of conducting the program in such State.

(B) DISQUALIFYING INFORMATION.—The term "disqualifying information" means a conviction for a relevant crime or a finding of patient or resident abuse.

(C) FINDING OF PATIENT OR RESIDENT ABUSE.—The term "finding of patient or resident abuse" means any substantiated finding by a State agency under section 1819(g)(1)(C) or 1919(g)(1)(C) of the Social Security Act (42 U.S.C. 1395i–3(g)(1)(C), 1396r(g)(1)(C)) or a Federal agency that a direct patient access employee has committed—

(i) an act of patient or resident abuse or neglect or a misappropriation of patient or resident property; or

(ii) such other types of acts as a participating State may specify for purposes of conducting the program in such State.

(D) DIRECT PATIENT ACCESS EMPLOYEE.—The term "direct patient access employee" means any individual who has access to a patient or resident of a long-term care facility or provider through employment or through a contract with such facility or provider and has duties that involve (or may involve) one-on-one contact with a patient or resident of the facility or provider, as determined by the State for purposes of the nationwide program. Such term does not include a volunteer unless the volunteer has duties that are equivalent to the duties of a direct patient access employee and those duties involve (or may involve) one-on-one contact with a patient or resident of the long-term care facility or provider.

(E) LONG-TERM CARE FACILITY OR PROVIDER.—The term "long-term care facility or provider" means the following facilities or providers which receive payment for services under title XVIII or XIX of the Social Security Act:

(i) A skilled nursing facility (as defined in section 1819(a) of the Social Security Act (42 U.S.C. 1395i–3(a))).

(ii) A nursing facility (as defined in section 1919(a) of such Act (42 U.S.C. 1396r(a))).

(iii) A home health agency.

(iv) A provider of hospice care (as defined in section 1861(dd)(1) of such Act (42 U.S.C. 1395x(dd)(1))).

(v) A long-term care hospital (as described in section 1886(d)(1)(B)(iv) of such Act (42 U.S.C. 1395ww(d)(1)(B)(iv))).

(vi) A provider of personal care services.

(vii) A provider of adult day care.

(viii) A residential care provider that arranges for, or directly provides, long-term care services, including an assisted living facility that provides a level of care established by the Secretary.

(ix) An intermediate care facility for the mentally retarded (as defined in section 1905(d) of such Act (42 U.S.C. 1396d(d))).

(x) Any other facility or provider of long-term care services under such titles as the participating State determines appropriate.

(7) EVALUATION AND REPORT.—

(A) EVALUATION.—

(i) IN GENERAL.—The Inspector General of the Department of Health and Human Services shall conduct an evaluation of the nationwide program.

(ii) INCLUSION OF SPECIFIC TOPICS.—The evaluation conducted under clause (i) shall include the following:

(I) A review of the various procedures implemented by participating States for long-term care facilities or providers, including staffing agencies, to conduct background checks of direct patient access employees under the nationwide program and identification of the most appropriate, efficient, and effective procedures for conducting such background checks.

(II) An assessment of the costs of conducting such background checks (including start up and administrative costs).

(III) A determination of the extent to which conducting such background checks leads to any unintended consequences, including a reduction in the available workforce for long-term care facilities or providers.

(IV) An assessment of the impact of the nationwide program on reducing the number of incidents of neglect, abuse, and misappropriation of resident property to the extent practicable.

(V) An evaluation of other aspects of the nationwide program, as determined appropriate by the Secretary.

(B) REPORT.—Not later than 180 days after the completion of the nationwide program, the Inspector General of the Department of Health and Human Services shall

submit a report to Congress containing the results of the evaluation conducted under subparagraph (A).

(b) FUNDING.—

(1) NOTIFICATION.—The Secretary of Health and Human Services shall notify the Secretary of the Treasury of the amount necessary to carry out the nationwide program under this section for the period of fiscal years 2010 through 2012, except that in no case shall such amount exceed $160,000,000.

(2) TRANSFER OF FUNDS.—

(A) IN GENERAL.—Out of any funds in the Treasury not otherwise appropriated, the Secretary of the Treasury shall provide for the transfer to the Secretary of Health and Human Services of the amount specified as necessary to carry out the nationwide program under paragraph (1). Such amount shall remain available until expended.

(B) RESERVATION OF FUNDS FOR CONDUCT OF EVALUATION.—The Secretary may reserve not more than $3,000,000 of the amount transferred under subparagraph (A) to provide for the conduct of the evaluation under subsection (a)(7)(A).

Subtitle D—Patient-Centered Outcomes Research

SEC. 6301. PATIENT-CENTERED OUTCOMES RESEARCH.

(a) IN GENERAL.—Title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended by adding at the end the following new part:

"PART D—COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH

"COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH

"SEC. 1181. (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.

"(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 under the contract for the agency, instrumentality, or other entity to have such research published in a peer-reviewed journal or other publication;

"(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) REQUIREMENTS FOR PUBLICATION OF RESEARCH.—Any research published under clause (ii)(IV) shall be within the bounds of and entirely consistent with the evidence and findings produced under the contract with the Institute under this subparagraph. If the Institute determines that those requirements are not met, the Institute shall not enter into another contract with the agency, instrumentality, or entity which managed or conducted such research for a period determined appropriate by the Institute (but not less than 5 years).

"(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 minorities, 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.

"(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 Comptroller General of the United States. 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) not be construed as mandates for 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) Seventeen members appointed, not later than 6 months after the date of enactment of this section, by the Comptroller General of the United States as follows:

"(i) 3 members representing patients and health care consumers.

"(ii) 5 members representing physicians and providers, including at least 1 surgeon, nurse, State-licensed integrative health care practitioner, and representative of a hospital.

"(iii) 3 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 the members first appointed, whose terms of appointment shall be staggered evenly over 2-year increments. 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.

"(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 an analysis of the extent to which research findings are used by health care decision-makers, the effect of the dissemination of such findings on 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.

"(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 Comptroller General 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 and of the Government Accountability Office. 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.".

(b) DISSEMINATION AND BUILDING CAPACITY FOR RESEARCH.—Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.), as amended by section 3606, is further amended by inserting after section 936 the following:

"SEC. 937. DISSEMINATION AND BUILDING CAPACITY FOR RESEARCH.

"(a) IN GENERAL.—

"(1) DISSEMINATION.—The Office of Communication and Knowledge Transfer (referred to in this section as the 'Office') at the Agency for Healthcare Research and Quality (or any other relevant office designated by Agency for Healthcare Research and Quality), in consultation with the National Institutes of Health, shall broadly disseminate the research findings that are published by the Patient Centered Outcomes Research Institute established under section 1181(b) of the Social Security Act (referred to in this section as the 'Institute') and other government-funded research relevant to comparative clinical effectiveness research. The Office shall create informational tools that organize and disseminate research findings for physicians, health care providers, patients, payers, and policy makers. The Office shall also develop a publicly available resource database that collects and contains government-funded evidence and research from public, private, not-for profit, and academic sources.

"(2) REQUIREMENTS.—The Office shall provide for the dissemination of the Institute's research findings and government-funded research relevant to comparative clinical effectiveness research to physicians, health care providers, patients, vendors of health information technology focused on clinical decision support, appropriate professional associations, and Federal and private health plans. Materials, forums, and media used to disseminate the findings, informational tools, and resource databases shall—

"(A) include a description of considerations for specific subpopulations, the research methodology, and the limitations of the research, and the names of the entities, agencies, instrumentalities, and individuals who conducted any research which was published by the Institute; and

"(B) not be construed as mandates, guidelines, or recommendations for payment, coverage, or treatment.

"(b) INCORPORATION OF RESEARCH FINDINGS.—The Office, in consultation with relevant medical and clinical associations, shall assist users of health information technology focused on clinical decision support to promote the timely incorporation of research findings disseminated under subsection (a) into clinical practices and to promote the ease of use of such incorporation.

"(c) FEEDBACK.—The Office shall establish a process to receive feedback from physicians, health care providers, patients, and vendors of health information technology focused on clinical decision support, appropriate professional associations, and Federal and private health plans about the value of the information disseminated and the assistance provided under this section.

"(d) RULE OF CONSTRUCTION.—Nothing in this section shall preclude the Institute from making its research findings publicly available as required under section 1181(d)(8) of the Social Security Act.

"(e) TRAINING OF RESEARCHERS.—The Agency for Health Care Research and Quality, in consultation with the National Institutes of Health, shall build capacity for comparative clinical effectiveness research by establishing a grant program that provides for the training of researchers in the methods used to conduct such research, including systematic reviews of existing research and primary research such as clinical trials. At a minimum, such

training shall be in methods that meet the methodological standards adopted under section 1181(d)(9) of the Social Security Act.

"(f) BUILDING DATA FOR RESEARCH.—The Secretary shall provide for the coordination of relevant Federal health programs to build data capacity for comparative clinical effectiveness research, including the development and use of clinical registries and health outcomes research data networks, in order to develop and maintain a comprehensive, interoperable data network to collect, link, and analyze data on outcomes and effectiveness from multiple sources, including electronic health records.

"(g) AUTHORITY TO CONTRACT WITH THE INSTITUTE.—Agencies and instrumentalities of the Federal Government may enter into agreements with the Institute, and accept and retain funds, for the conduct and support of research described in this part, provided that the research to be conducted or supported under such agreements is authorized under the governing statutes of such agencies and instrumentalities.".

(c) IN GENERAL.—Part D of title XI of the Social Security Act, as added by subsection (a), is amended by adding at the end the following new section:

"LIMITATIONS ON CERTAIN USES OF COMPARATIVE CLINICAL EFFECTIVENESS RESEARCH

"SEC. 1182. (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 effectiveness 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.".

(d) IN GENERAL.—Part D of title XI of the Social Security Act, as added by subsection (a) and amended by subsection (c), is amended by adding at the end the following new section:

"TRUST FUND TRANSFERS TO PATIENT-CENTERED OUTCOMES RESEARCH TRUST FUND

"SEC. 1183. (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.".

(e) PATIENT-CENTERED OUTCOMES RESEARCH TRUST FUND; FINANCING FOR TRUST FUND.—

(1) ESTABLISHMENT OF TRUST FUND.—

(A) IN GENERAL.—Subchapter A of chapter 98 of the Internal Revenue Code of 1986 (relating to establishment of trust funds) is amended by adding at the end the following new section:

"SEC. 9511. PATIENT-CENTERED OUTCOMES RESEARCH TRUST FUND.

"(a) CREATION OF TRUST FUND.—There is established in the Treasury of the United States a trust fund to be known as the 'Patient-Centered Outcomes Research Trust Fund' (hereafter in this section referred to as the 'PCORTF'), consisting of such amounts as may be appropriated or credited to such Trust Fund as provided in this section and section 9602(b).

"(b) TRANSFERS TO FUND.—

"(1) APPROPRIATION.—There are hereby appropriated to the Trust Fund the following:

"(A) For fiscal year 2010, $10,000,000.

"(B) For fiscal year 2011, $50,000,000.

"(C) For fiscal year 2012, $150,000,000.

"(D) For fiscal year 2013—

"(i) an amount equivalent to the net revenues received in the Treasury from the fees imposed under subchapter B of chapter 34 (relating to fees on health insurance and self-insured plans) for such fiscal year; and

"(ii) $150,000,000.

"(E) For each of fiscal years 2014, 2015, 2016, 2017, 2018, and 2019—

"(i) an amount equivalent to the net revenues received in the Treasury from the fees imposed under subchapter B of chapter 34 (relating to fees on health insurance and self-insured plans) for such fiscal year; and

"(ii) $150,000,000.

The amounts appropriated under subparagraphs (A), (B), (C), (D)(ii), and (E)(ii) shall be transferred from the general fund of the Treasury, from funds not otherwise appropriated.

"(2) TRUST FUND TRANSFERS.—In addition to the amounts appropriated under paragraph (1), there shall be credited to the PCORTF the amounts transferred under section 1183 of the Social Security Act.

"(3) LIMITATION ON TRANSFERS TO PCORTF.—No amount may be appropriated or transferred to the PCORTF on and after the date of any expenditure from the PCORTF which is not an expenditure permitted under this section. The determination of whether an expenditure is so permitted shall be made without regard to—

"(A) any provision of law which is not contained or referenced in this chapter or in a revenue Act, and

"(B) whether such provision of law is a subsequently enacted provision or directly or indirectly seeks to waive the application of this paragraph.

"(c) TRUSTEE.—The Secretary of the Treasury shall be a trustee of the PCORTF.

"(d) EXPENDITURES FROM FUND.—

"(1) AMOUNTS AVAILABLE TO THE PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE.—Subject to paragraph (2), amounts in the PCORTF are available, without further appropriation, to the Patient-Centered Outcomes Research Institute established under section 1181(b) of the Social Security Act for carrying out part D of title XI of the Social Security Act (as in effect on the date of enactment of such Act).

"(2) TRANSFER OF FUNDS.—

"(A) IN GENERAL.—The trustee of the PCORTF shall provide for the transfer from the PCORTF of 20 percent of the amounts appropriated or credited to the PCORTF for each of fiscal years 2011 through 2019 to the Secretary of Health and Human Services to carry out section 937 of the Public Health Service Act.

"(B) AVAILABILITY.—Amounts transferred under subparagraph (A) shall remain available until expended.

"(C) REQUIREMENTS.—Of the amounts transferred under subparagraph (A) with respect to a fiscal year, the Secretary of Health and Human Services shall distribute—

"(i) 80 percent to the Office of Communication and Knowledge Transfer of the Agency for Healthcare Research and Quality (or any other relevant office designated by Agency for Healthcare Research and Quality) to carry out the activities described in section 937 of the Public Health Service Act; and

"(ii) 20 percent to the Secretary to carry out the activities described in such section 937.

"(e) NET REVENUES.—For purposes of this section, the term 'net revenues' means the amount estimated by the Secretary of the Treasury based on the excess of—

"(1) the fees received in the Treasury under subchapter B of chapter 34, over

"(2) the decrease in the tax imposed by chapter 1 resulting from the fees imposed by such subchapter.

"(f) TERMINATION.—No amounts shall be available for expenditure from the PCORTF after September 30, 2019, and any amounts in such Trust Fund after such date shall be transferred to the general fund of the Treasury.".

(B) CLERICAL AMENDMENT.—The table of sections for subchapter A of chapter 98 of such Code is amended by adding at the end the following new item:

"Sec. 9511. Patient-centered outcomes research trust fund.".

(2) FINANCING FOR FUND FROM FEES ON INSURED AND SELF-INSURED HEALTH PLANS.—

(A) GENERAL RULE.—Chapter 34 of the Internal Revenue Code of 1986 is amended by adding at the end the following new subchapter:

"Subchapter B—Insured and Self-Insured Health Plans

"SEC. 4375. HEALTH INSURANCE.

"(a) IMPOSITION OF FEE.—There is hereby imposed on each specified health insurance policy for each policy year ending after

September 30, 2012, a fee equal to the product of $2 ($1 in the case of policy years ending during fiscal year 2013) multiplied by the average number of lives covered under the policy.

"(b) LIABILITY FOR FEE.—The fee imposed by subsection (a) shall be paid by the issuer of the policy.

"(c) SPECIFIED HEALTH INSURANCE POLICY.—For purposes of this section:

"(1) IN GENERAL.—Except as otherwise provided in this section, the term 'specified health insurance policy' means any accident or health insurance policy (including a policy under a group health plan) issued with respect to individuals residing in the United States.

"(2) EXEMPTION FOR CERTAIN POLICIES.—The term 'specified health insurance policy' does not include any insurance if substantially all of its coverage is of excepted benefits described in section 9832(c).

"(3) TREATMENT OF PREPAID HEALTH COVERAGE ARRANGEMENTS.—

"(A) IN GENERAL.—In the case of any arrangement described in subparagraph (B), such arrangement shall be treated as a specified health insurance policy, and the person referred to in such subparagraph shall be treated as the issuer.

"(B) DESCRIPTION OF ARRANGEMENTS.—An arrangement is described in this subparagraph if under such arrangement fixed payments or premiums are received as consideration for any person's agreement to provide or arrange for the provision of accident or health coverage to residents of the United States, regardless of how such coverage is provided or arranged to be provided.

"(d) ADJUSTMENTS FOR INCREASES IN HEALTH CARE SPENDING.—In the case of any policy year ending in any fiscal year beginning after September 30, 2014, the dollar amount in effect under subsection (a) for such policy year shall be equal to the sum of such dollar amount for policy years ending in the previous fiscal year (determined after the application of this subsection), plus an amount equal to the product of—

"(1) such dollar amount for policy years ending in 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.

"(e) TERMINATION.—This section shall not apply to policy years ending after September 30, 2019.

"SEC. 4376. SELF-INSURED HEALTH PLANS.

"(a) IMPOSITION OF FEE.—In the case of any applicable self-insured health plan for each plan year ending after September 30, 2012, there is hereby imposed a fee equal to $2 ($1 in the case of plan years ending during fiscal year 2013) multiplied by the average number of lives covered under the plan.

"(b) LIABILITY FOR FEE.—

"(1) IN GENERAL.—The fee imposed by subsection (a) shall be paid by the plan sponsor.

"(2) PLAN SPONSOR.—For purposes of paragraph (1) the term 'plan sponsor' means—

"(A) the employer in the case of a plan established or maintained by a single employer,

"(B) the employee organization in the case of a plan established or maintained by an employee organization,

"(C) in the case of—

"(i) a plan established or maintained by 2 or more employers or jointly by 1 or more employers and 1 or more employee organizations,

"(ii) a multiple employer welfare arrangement, or

"(iii) a voluntary employees' beneficiary association described in section 501(c)(9), the association, committee, joint board of trustees, or other similar group of representatives of the parties who establish or maintain the plan, or

"(D) the cooperative or association described in subsection (c)(2)(F) in the case of a plan established or maintained by such a cooperative or association.

"(c) APPLICABLE SELF-INSURED HEALTH PLAN.—For purposes of this section, the term 'applicable self-insured health plan' means any plan for providing accident or health coverage if—

"(1) any portion of such coverage is provided other than through an insurance policy, and

"(2) such plan is established or maintained—

"(A) by 1 or more employers for the benefit of their employees or former employees,

"(B) by 1 or more employee organizations for the benefit of their members or former members,

"(C) jointly by 1 or more employers and 1 or more employee organizations for the benefit of employees or former employees,

"(D) by a voluntary employees' beneficiary association described in section 501(c)(9),

"(E) by any organization described in section 501(c)(6), or

"(F) in the case of a plan not described in the preceding subparagraphs, by a multiple employer welfare arrangement (as defined in section 3(40) of Employee Retirement Income Security Act of 1974), a rural electric cooperative (as defined in section 3(40)(B)(iv) of such Act), or a rural telephone cooperative association (as defined in section 3(40)(B)(v) of such Act).

"(d) ADJUSTMENTS FOR INCREASES IN HEALTH CARE SPENDING.—In the case of any plan year ending in any fiscal year beginning after September 30, 2014, the dollar amount in effect under subsection (a) for such plan year shall be equal to the sum of such dollar amount for plan years ending in the previous fiscal year (determined after the application of this subsection), plus an amount equal to the product of—

"(1) such dollar amount for plan years ending in 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.

"(e) TERMINATION.—This section shall not apply to plan years ending after September 30, 2019.

"SEC. 4377. DEFINITIONS AND SPECIAL RULES.

"(a) DEFINITIONS.—For purposes of this subchapter—

"(1) ACCIDENT AND HEALTH COVERAGE.—The term 'accident and health coverage' means any coverage which, if provided by an insurance policy, would cause such policy to be a specified health insurance policy (as defined in section 4375(c)).

"(2) INSURANCE POLICY.—The term 'insurance policy' means any policy or other instrument whereby a contract of insurance is issued, renewed, or extended.

"(3) UNITED STATES.—The term 'United States' includes any possession of the United States.

"(b) TREATMENT OF GOVERNMENTAL ENTITIES.—

"(1) IN GENERAL.—For purposes of this subchapter—

"(A) the term 'person' includes any governmental entity, and

"(B) notwithstanding any other law or rule of law, governmental entities shall not be exempt from the fees imposed by this subchapter except as provided in paragraph (2).

"(2) TREATMENT OF EXEMPT GOVERNMENTAL PROGRAMS.—In the case of an exempt governmental program, no fee shall be imposed under section 4375 or section 4376 on any covered life under such program.

"(3) EXEMPT GOVERNMENTAL PROGRAM DEFINED.—For purposes of this subchapter, the term 'exempt governmental program' means—

"(A) any insurance program established under title XVIII of the Social Security Act,

"(B) the medical assistance program established by title XIX or XXI of the Social Security Act,

"(C) any program established by Federal law for providing medical care (other than through insurance policies) to individuals (or the spouses and dependents thereof) by reason of such individuals being members of the Armed Forces of the United States or veterans, and

"(D) any program established by Federal law for providing medical care (other than through insurance policies) to members of Indian tribes (as defined in section 4(d) of the Indian Health Care Improvement Act).

"(c) TREATMENT AS TAX.—For purposes of subtitle F, the fees imposed by this subchapter shall be treated as if they were taxes.

"(d) NO COVER OVER TO POSSESSIONS.—Notwithstanding any other provision of law, no amount collected under this subchapter shall be covered over to any possession of the United States.".

(B) CLERICAL AMENDMENTS.—

(i) Chapter 34 of such Code is amended by striking the chapter heading and inserting the following:

"CHAPTER 34—TAXES ON CERTAIN INSURANCE POLICIES

"SUBCHAPTER A. POLICIES ISSUED BY FOREIGN INSURERS

"SUBCHAPTER B. INSURED AND SELF-INSURED HEALTH PLANS

"Subchapter A—Policies Issued By Foreign Insurers".

(ii) The table of chapters for subtitle D of such Code is amended by striking the item relating to chapter 34 and inserting the following new item:

"CHAPTER 34—TAXES ON CERTAIN INSURANCE POLICIES".

(f) TAX-EXEMPT STATUS OF THE PATIENT-CENTERED OUTCOMES RESEARCH INSTITUTE.—Subsection 501(l) of the Internal Revenue Code of 1986 is amended by adding at the end the following new paragraph:

"(4) The Patient-Centered Outcomes Research Institute established under section 1181(b) of the Social Security Act.".

SEC. 6302. FEDERAL COORDINATING COUNCIL FOR COMPARATIVE EFFECTIVENESS RESEARCH.

Notwithstanding any other provision of law, the Federal Coordinating Council for Comparative Effectiveness Research established under section 804 of Division A of the American Recovery and Reinvestment Act of 2009 (42 U.S.C. 299b–8), including the requirement under subsection (e)(2) of such section, shall terminate on the date of enactment of this Act.

Subtitle E—Medicare, Medicaid, and CHIP Program Integrity Provisions

SEC. 6401. PROVIDER SCREENING AND OTHER ENROLLMENT REQUIREMENTS UNDER MEDICARE, MEDICAID, AND CHIP.

(a) MEDICARE.—Section 1866(j) of the Social Security Act (42 U.S.C. 1395cc(j)) is amended—

(1) in paragraph (1)(A), by adding at the end the following: "Such process shall include screening of providers and suppliers in accordance with paragraph (2), a provisional period of enhanced oversight in accordance with paragraph (3), disclosure requirements in accordance with paragraph (4), the imposition of temporary enrollment moratoria in accordance with paragraph (5), and the establishment of compliance programs in accordance with paragraph (6).";

(2) by redesignating paragraph (2) as paragraph (7); and

(3) by inserting after paragraph (1) the following:

"(2) PROVIDER SCREENING.—

"(A) PROCEDURES.—Not later than 180 days after the date of enactment of this paragraph, the Secretary, in consultation with the Inspector General of the Department of Health and Human Services, shall establish procedures under which screening is conducted with respect to providers of medical or other items or services and suppliers under the program under this title, the Medicaid program under title XIX, and the CHIP program under title XXI.

"(B) LEVEL OF SCREENING.—The Secretary shall determine the level of screening conducted under this paragraph according to the risk of fraud, waste, and abuse, as determined by the Secretary, with respect to the category of provider of medical or other items or services or supplier. Such screening—

"(i) shall include a licensure check, which may include such checks across States; and

"(ii) may, as the Secretary determines appropriate based on the risk of fraud, waste, and abuse described in the preceding sentence, include—

"(I) a criminal background check;

"(II) fingerprinting;

"(III) unscheduled and unannounced site visits, including preenrollment site visits;

"(IV) database checks (including such checks across States); and

"(V) such other screening as the Secretary determines appropriate.

"(C) APPLICATION FEES.—

"(i) INDIVIDUAL PROVIDERS.—Except as provided in clause (iii), the Secretary shall impose a fee on each individual provider of medical or other items or services or supplier (such as a physician, physician assistant, nurse practitioner, or clinical nurse specialist) with respect to which screening is conducted under this paragraph in an amount equal to—

"(I) for 2010, $200; and

"(II) for 2011 and each subsequent year, the amount determined under this clause for the preceding year, adjusted by the percentage change in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending with June of the previous year.

"(ii) INSTITUTIONAL PROVIDERS.—Except as provided in clause (iii), the Secretary shall impose a fee on each institutional provider of medical or other items or services or supplier (such as a hospital or skilled nursing facility) with respect to which screening is conducted under this paragraph in an amount equal to—

"(I) for 2010, $500; and

"(II) for 2011 and each subsequent year, the amount determined under this clause for the preceding year, adjusted by the percentage change in the consumer price index for all urban consumers (all items; United States city average) for the 12-month period ending with June of the previous year.

"(iii) HARDSHIP EXCEPTION; WAIVER FOR CERTAIN MEDICAID PROVIDERS.—The Secretary may, on a case-by-case basis, exempt a provider of medical or other items or services or supplier from the imposition of an application fee under this subparagraph if the Secretary determines that the imposition of the application fee would result in a hardship. The Secretary may

waive the application fee under this subparagraph for providers enrolled in a State Medicaid program for whom the State demonstrates that imposition of the fee would impede beneficiary access to care.

"(iv) USE OF FUNDS.—Amounts collected as a result of the imposition of a fee under this subparagraph shall be used by the Secretary for program integrity efforts, including to cover the costs of conducting screening under this paragraph and to carry out this subsection and section 1128J.

"(D) APPLICATION AND ENFORCEMENT.—

"(i) NEW PROVIDERS OF SERVICES AND SUPPLIERS.—The screening under this paragraph shall apply, in the case of a provider of medical or other items or services or supplier who is not enrolled in the program under this title, title XIX , or title XXI as of the date of enactment of this paragraph, on or after the date that is 1 year after such date of enactment.

"(ii) CURRENT PROVIDERS OF SERVICES AND SUPPLIERS.—The screening under this paragraph shall apply, in the case of a provider of medical or other items or services or supplier who is enrolled in the program under this title, title XIX, or title XXI as of such date of enactment, on or after the date that is 2 years after such date of enactment.

"(iii) REVALIDATION OF ENROLLMENT.—Effective beginning on the date that is 180 days after such date of enactment, the screening under this paragraph shall apply with respect to the revalidation of enrollment of a provider of medical or other items or services or supplier in the program under this title, title XIX, or title XXI.

"(iv) LIMITATION ON ENROLLMENT AND REVALIDATION OF ENROLLMENT.—In no case may a provider of medical or other items or services or supplier who has not been screened under this paragraph be initially enrolled or reenrolled in the program under this title, title XIX, or title XXI on or after the date that is 3 years after such date of enactment.

"(E) EXPEDITED RULEMAKING.—The Secretary may promulgate an interim final rule to carry out this paragraph.

"(3) PROVISIONAL PERIOD OF ENHANCED OVERSIGHT FOR NEW PROVIDERS OF SERVICES AND SUPPLIERS.—

"(A) IN GENERAL.—The Secretary shall establish procedures to provide for a provisional period of not less than 30 days and not more than 1 year during which new providers of medical or other items or services and suppliers, as the Secretary determines appropriate, including categories of providers or suppliers, would be subject to enhanced oversight, such as prepayment review and payment caps, under the program under this title, the Medicaid program under title XIX. and the CHIP program under title XXI.

"(B) IMPLEMENTATION.—The Secretary may establish by program instruction or otherwise the procedures under this paragraph.

"(4) INCREASED DISCLOSURE REQUIREMENTS.—

"(A) DISCLOSURE.—A provider of medical or other items or services or supplier who submits an application for enrollment or revalidation of enrollment in the program under this title, title XIX, or title XXI on or after the date that is 1 year after the date of enactment of this paragraph shall disclose (in a form and manner and at such time as determined by the Secretary) any current or previous affiliation (directly or indirectly) with a provider of medical or other items or services or supplier that has uncollected debt, has been or is subject to a payment suspension under a Federal health care program (as defined in section 1128B(f)), has been excluded from participation under the program under this title, the Medicaid program under title XIX, or the CHIP program under title XXI, or has had its billing privileges denied or revoked.

"(B) AUTHORITY TO DENY ENROLLMENT.—If the Secretary determines that such previous affiliation poses an undue risk of fraud, waste, or abuse, the Secretary may deny such application. Such a denial shall be subject to appeal in accordance with paragraph (7).

"(5) AUTHORITY TO ADJUST PAYMENTS OF PROVIDERS OF SERVICES AND SUPPLIERS WITH THE SAME TAX IDENTIFICATION NUMBER FOR PAST-DUE OBLIGATIONS.—

"(A) IN GENERAL.—Notwithstanding any other provision of this title, in the case of an applicable provider of services or supplier, the Secretary may make any necessary adjustments to payments to the applicable provider of services or supplier under the program under this title in order to satisfy any past-due obligations described in subparagraph (B)(ii) of an obligated provider of services or supplier.

"(B) DEFINITIONS.—In this paragraph:

"(i) IN GENERAL.—The term 'applicable provider of services or supplier' means a provider of services or supplier that has the same taxpayer identification number assigned under section 6109 of the Internal Revenue Code of 1986 as is assigned to the obligated provider of services or supplier under such section, regardless of whether the applicable provider of services or supplier is assigned a different billing number or national provider identification number under the program under this title than is assigned to the obligated provider of services or supplier.

"(ii) OBLIGATED PROVIDER OF SERVICES OR SUPPLIER.—The term 'obligated provider of services or supplier' means a provider of services or supplier that owes a past-due obligation under the program under this title (as determined by the Secretary).

"(6) TEMPORARY MORATORIUM ON ENROLLMENT OF NEW PROVIDERS.—

"(A) IN GENERAL.—The Secretary may impose a temporary moratorium on the enrollment of new providers of services and suppliers, including categories of providers of services and suppliers, in the program under this title, under the Medicaid program under title XIX, or under

the CHIP program under title XXI if the Secretary determines such moratorium is necessary to prevent or combat fraud, waste, or abuse under either such program.

"(B) LIMITATION ON REVIEW.—There shall be no judicial review under section 1869, section 1878, or otherwise, of a temporary moratorium imposed under subparagraph (A).

"(7) COMPLIANCE PROGRAMS.—

"(A) IN GENERAL.—On or after the date of implementation determined by the Secretary under subparagraph (C), a provider of medical or other items or services or supplier within a particular industry sector or category shall, as a condition of enrollment in the program under this title, title XIX, or title XXI, establish a compliance program that contains the core elements established under subparagraph (B) with respect to that provider or supplier and industry or category.

"(B) ESTABLISHMENT OF CORE ELEMENTS.—The Secretary, in consultation with the Inspector General of the Department of Health and Human Services, shall establish core elements for a compliance program under subparagraph (A) for providers or suppliers within a particular industry or category.

"(C) TIMELINE FOR IMPLEMENTATION.—The Secretary shall determine the timeline for the establishment of the core elements under subparagraph (B) and the date of the implementation of subparagraph (A) for providers or suppliers within a particular industry or category. The Secretary shall, in determining such date of implementation, consider the extent to which the adoption of compliance programs by a provider of medical or other items or services or supplier is widespread in a particular industry sector or with respect to a particular provider or supplier category.".

(b) MEDICAID.—

(1) STATE PLAN AMENDMENT.—Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)), as amended by section 4302(b), is amended—

(A) in subsection (a)—

(i) by striking "and" at the end of paragraph (75);

(ii) by striking the period at the end of paragraph (76) and inserting a semicolon; and

(iii) by inserting after paragraph (76) the following:

"(77) provide that the State shall comply with provider and supplier screening, oversight, and reporting requirements in accordance with subsection (ii);"; and

(B) by adding at the end the following:

"(ii) PROVIDER AND SUPPLIER SCREENING, OVERSIGHT, AND REPORTING REQUIREMENTS.—For purposes of subsection (a)(77), the requirements of this subsection are the following:

"(1) SCREENING.—The State complies with the process for screening providers and suppliers under this title, as established by the Secretary under section 1886(j)(2).

"(2) PROVISIONAL PERIOD OF ENHANCED OVERSIGHT FOR NEW PROVIDERS AND SUPPLIERS.—The State complies with procedures to provide for a provisional period of enhanced oversight for new providers and suppliers under this title, as established by the Secretary under section 1886(j)(3).

"(3) DISCLOSURE REQUIREMENTS.—The State requires providers and suppliers under the State plan or under a waiver of the plan to comply with the disclosure requirements established by the Secretary under section 1886(j)(4).

"(4) TEMPORARY MORATORIUM ON ENROLLMENT OF NEW PROVIDERS OR SUPPLIERS.—

"(A) TEMPORARY MORATORIUM IMPOSED BY THE SECRETARY.—

"(i) IN GENERAL.—Subject to clause (ii), the State complies with any temporary moratorium on the enrollment of new providers or suppliers imposed by the Secretary under section 1886(j)(6).

"(ii) EXCEPTION.—A State shall not be required to comply with a temporary moratorium described in clause (i) if the State determines that the imposition of such temporary moratorium would adversely impact beneficiaries' access to medical assistance.

"(B) MORATORIUM ON ENROLLMENT OF PROVIDERS AND SUPPLIERS.—At the option of the State, the State imposes, for purposes of entering into participation agreements with providers or suppliers under the State plan or under a waiver of the plan, periods of enrollment moratoria, or numerical caps or other limits, for providers or suppliers identified by the Secretary as being at high-risk for fraud, waste, or abuse as necessary to combat fraud, waste, or abuse, but only if the State determines that the imposition of any such period, cap, or other limits would not adversely impact beneficiaries' access to medical assistance.

"(5) COMPLIANCE PROGRAMS.—The State requires providers and suppliers under the State plan or under a waiver of the plan to establish, in accordance with the requirements of section 1866(j)(7), a compliance program that contains the core elements established under subparagraph (B) of that section 1866(j)(7) for providers or suppliers within a particular industry or category.

"(6) REPORTING OF ADVERSE PROVIDER ACTIONS.—The State complies with the national system for reporting criminal and civil convictions, sanctions, negative licensure actions, and other adverse provider actions to the Secretary, through the Administrator of the Centers for Medicare & Medicaid Services, in accordance with regulations of the Secretary.

"(7) ENROLLMENT AND NPI OF ORDERING OR REFERRING PROVIDERS.—The State requires—

"(A) all ordering or referring physicians or other professionals to be enrolled under the State plan or under a waiver of the plan as a participating provider; and

"(B) the national provider identifier of any ordering or referring physician or other professional to be specified on any claim for payment that is based on an order or referral of the physician or other professional.

"(8) OTHER STATE OVERSIGHT.—Nothing in this subsection shall be interpreted to preclude or limit the ability of a State to engage in provider and supplier screening or enhanced provider and supplier oversight activities beyond those required by the Secretary.".

(2) DISCLOSURE OF MEDICARE TERMINATED PROVIDERS AND SUPPLIERS TO STATES.—The Administrator of the Centers for

Medicare & Medicaid Services shall establish a process for making available to the each State agency with responsibility for administering a State Medicaid plan (or a waiver of such plan) under title XIX of the Social Security Act or a child health plan under title XXI the name, national provider identifier, and other identifying information for any provider of medical or other items or services or supplier under the Medicare program under title XVIII or under the CHIP program under title XXI that is terminated from participation under that program within 30 days of the termination (and, with respect to all such providers or suppliers who are terminated from the Medicare program on the date of enactment of this Act, within 90 days of such date).

(3) CONFORMING AMENDMENT.—Section 1902(a)(23) of the Social Security Act (42 U.S.C. 1396a), is amended by inserting before the semicolon at the end the following: "or by a provider or supplier to which a moratorium under subsection (ii)(4) is applied during the period of such moratorium".

(c) CHIP.—Section 2107(e)(1) of the Social Security Act (42 U.S.C. 1397gg(e)(1)), as amended by section 2101(d), is amended—

(1) by redesignating subparagraphs (D) through (M) as subparagraphs (E) through (N), respectively; and

(2) by inserting after subparagraph (C), the following:

"(D) Subsections (a)(77) and (ii) of section 1902 (relating to provider and supplier screening, oversight, and reporting requirements).".

SEC. 6402. ENHANCED MEDICARE AND MEDICAID PROGRAM INTEGRITY PROVISIONS.

(a) IN GENERAL.—Part A of title XI of the Social Security Act (42 U.S.C. 1301 et seq.), as amended by sections 6002, 6004, and 6102, is amended by inserting after section 1128I the following new section:

"SEC. 1128J. 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" 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.".

(b) ACCESS TO DATA.—

(1) MEDICARE PART D.—Section 1860D–15(f)(2) of the Social Security Act (42 U.S.C. 1395w–116(f)(2)) is amended by striking "may be used by" and all that follows through the period at the end and inserting "may be used—

"(A) by officers, employees, and contractors of the Department of Health and Human Services for the purposes of, and to the extent necessary in—

"(i) carrying out this section; and

"(ii) conducting oversight, evaluation, and enforcement under this title; and

"(B) by the Attorney General and the Comptroller General of the United States for the purposes of, and to the extent necessary in, carrying out health oversight activities.".

(2) DATA MATCHING.—Section 552a(a)(8)(B) of title 5, United States Code, is amended—

(A) in clause (vii), by striking "or" at the end;

(B) in clause (viii), by inserting "or" after the semicolon; and

(C) by adding at the end the following new clause:

"(ix) matches performed by the Secretary of Health and Human Services or the Inspector General of the Department of Health and Human Services with respect to potential fraud, waste, and abuse, including matches of a system of records with non-Federal records;".

(3) MATCHING AGREEMENTS WITH THE COMMISSIONER OF SOCIAL SECURITY.—Section 205(r) of the Social Security Act (42 U.S.C. 405(r)) is amended by adding at the end the following new paragraph:

"(9)(A) The Commissioner of Social Security shall, upon the request of the Secretary or the Inspector General of the Department of Health and Human Services—

"(i) enter into an agreement with the Secretary or such Inspector General for the purpose of matching data in the system of records of the Social Security Administration and the system of records of the Department of Health and Human Services; and

"(ii) include in such agreement safeguards to assure the maintenance of the confidentiality of any information disclosed.

"(B) 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.".

(c) WITHHOLDING OF FEDERAL MATCHING PAYMENTS FOR STATES THAT FAIL TO REPORT ENROLLEE ENCOUNTER DATA IN THE MEDICAID STATISTICAL INFORMATION SYSTEM.—Section 1903(i) of the Social Security Act (42 U.S.C. 1396b(i)) is amended—

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

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

(3) by adding at the end the following new paragraph:.

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

(d) PERMISSIVE EXCLUSIONS AND CIVIL MONETARY PENALTIES.—

(1) PERMISSIVE EXCLUSIONS.—Section 1128(b) of the Social Security Act (42 U.S.C. 1320a–7(b)) is amended by adding at the end the following new paragraph:

"(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.".

(2) CIVIL MONETARY PENALTIES.—

(A) IN GENERAL.—Section 1128A(a) of the Social Security Act (42 U.S.C. 1320a–7a(a)) is amended—

(i) in paragraph (1)(D), by striking "was excluded" and all that follows through the period at the end and inserting "was excluded from the Federal health care program (as defined in section 1128B(f)) under which the claim was made pursuant to Federal law.";

(ii) in paragraph (6), by striking "or" at the end;

(iii) by inserting after paragraph (7), the following new paragraphs:

"(8) 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) 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;";

(iv) in the first sentence—

(I) by striking the "or" after "prohibited relationship occurs;"; and

(II) by striking "act)" and inserting "act; or in cases under paragraph (9), $50,000 for each false statement or misrepresentation of a material fact)"; and

(v) in the second sentence, by striking "purpose)" and inserting "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)".

(B) CLARIFICATION OF TREATMENT OF CERTAIN CHARITABLE AND OTHER INNOCUOUS PROGRAMS.—Section 1128A(i)(6) of the Social Security Act (42 U.S.C. 1320a–7a(i)(6)) is amended—

(i) in subparagraph (C), by striking "or" at the end;

(ii) in subparagraph (D), as redesignated by section 4331(e) of the Balanced Budget Act of 1997 (Public Law 105–33), by striking the period at the end and inserting a semicolon;

(iii) by redesignating subparagraph (D), as added by section 4523(c) of such Act, as subparagraph (E) and striking the period at the end and inserting "; or"; and

(iv) by adding at the end the following new subparagraphs:

"(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; or

"(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.".

(e) TESTIMONIAL SUBPOENA AUTHORITY IN EXCLUSION-ONLY CASES.—Section 1128(f) of the Social Security Act (42 U.S.C. 1320a–7(f)) is amended by adding at the end the following new paragraph:

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

(f) HEALTH CARE FRAUD.—

(1) KICKBACKS.—Section 1128B of the Social Security Act (42 U.S.C. 1320a–7b) is amended by adding at the end the following new subsection:

"(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.".

(2) REVISING THE INTENT REQUIREMENT.—Section 1128B of the Social Security Act (42 U.S.C. 1320a–7b), as amended by paragraph (1), is amended by adding at the end the following new subsection:

"(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.".

(g) SURETY BOND REQUIREMENTS.—

(1) DURABLE MEDICAL EQUIPMENT.—Section 1834(a)(16)(B) of the Social Security Act (42 U.S.C. 1395m(a)(16)(B)) is amended by inserting "that the Secretary determines is commensurate with the volume of the billing of the supplier" before the period at the end.

(2) HOME HEALTH AGENCIES.—Section 1861(o)(7)(C) of the Social Security Act (42 U.S.C. 1395x(o)(7)(C)) is amended by inserting "that the Secretary determines is commensurate with the volume of the billing of the home health agency" before the semicolon at the end.

(3) REQUIREMENTS FOR CERTAIN OTHER PROVIDERS OF SERVICES AND SUPPLIERS.—Section 1862 of the Social Security Act

(42 U.S.C. 1395y) is amended by adding at the end the following new subsection:

"(n) REQUIREMENT OF A SURETY BOND FOR CERTAIN PROVIDERS OF SERVICES AND SUPPLIERS.—

"(1) IN GENERAL.—The Secretary may require a provider of services or supplier described in paragraph (2) to provide the Secretary on a continuing basis with a surety bond in a form specified by the Secretary in an amount (not less than $50,000) that the Secretary determines is commensurate with the volume of the billing of the provider of services or supplier. The Secretary may waive the requirement of a bond under the preceding sentence in the case of a provider of services or supplier that provides a comparable surety bond under State law.

"(2) PROVIDER OF SERVICES OR SUPPLIER DESCRIBED.—A provider of services or supplier described in this paragraph is a provider of services or supplier the Secretary determines appropriate based on the level of risk involved with respect to the provider of services or supplier, and consistent with the surety bond requirements under sections 1834(a)(16)(B) and 1861(o)(7)(C).".

(h) SUSPENSION OF MEDICARE AND MEDICAID PAYMENTS PENDING INVESTIGATION OF CREDIBLE ALLEGATIONS OF FRAUD.—

(1) MEDICARE.—Section 1862 of the Social Security Act (42 U.S.C. 1395y), as amended by subsection (g)(3), is amended by adding at the end the following new subsection:

"(o) SUSPENSION OF PAYMENTS PENDING INVESTIGATION OF CREDIBLE ALLEGATIONS OF FRAUD.—

"(1) IN GENERAL.—The Secretary may suspend payments to a provider of services or supplier under this title pending an investigation of a credible allegation of fraud against the provider of services or supplier, unless the Secretary determines there is good cause not to suspend such payments.

"(2) CONSULTATION.—The Secretary shall consult with the Inspector General of the Department of Health and Human Services in determining whether there is a credible allegation of fraud against a provider of services or supplier.

"(3) PROMULGATION OF REGULATIONS.—The Secretary shall promulgate regulations to carry out this subsection and section 1903(i)(2)(C).".

(2) MEDICAID.—Section 1903(i)(2) of such Act (42 U.S.C. 1396b(i)(2)) is amended—

(A) in subparagraph (A), by striking "or" at the end; and

(B) by inserting after subparagraph (B), the following:

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

(i) INCREASED FUNDING TO FIGHT FRAUD AND ABUSE.—

(1) IN GENERAL.—Section 1817(k) of the Social Security Act (42 U.S.C. 1395i(k)) is amended—

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

"(7) ADDITIONAL FUNDING.—In addition to the funds otherwise appropriated to the Account from the Trust Fund under paragraphs (3) and (4) and for purposes described in paragraphs (3)(C) and (4)(A), there are hereby appropriated an additional $10,000,000 to such Account from such Trust Fund for each of fiscal years 2011 through 2020. The funds appropriated under this paragraph shall be allocated in the same proportion as the total funding appropriated with respect to paragraphs (3)(A) and (4)(A) was allocated with respect to fiscal year 2010, and shall be available without further appropriation until expended."; and

(B) in paragraph (4)(A), by inserting "until expended" after "appropriation".

(2) INDEXING OF AMOUNTS APPROPRIATED.—

(A) DEPARTMENTS OF HEALTH AND HUMAN SERVICES AND JUSTICE.—Section 1817(k)(3)(A)(i) of the Social Security Act (42 U.S.C. 1395i(k)(3)(A)(i)) is amended—

(i) in subclause (III), by inserting "and" at the end;

(ii) in subclause (IV)—

(I) by striking "for each of fiscal years 2007, 2008, 2009, and 2010" and inserting "for each fiscal year after fiscal year 2006"; and

(II) by striking "; and" and inserting a period; and

(iii) by striking subclause (V).

(B) OFFICE OF THE INSPECTOR GENERAL OF THE DEPARTMENT OF HEALTH AND HUMAN SERVICES.—Section 1817(k)(3)(A)(ii) of such Act (42 U.S.C. 1395i(k)(3)(A)(ii)) is amended—

(i) in subclause (VIII), by inserting "and" at the end;

(ii) in subclause (IX)—

(I) by striking "for each of fiscal years 2008, 2009, and 2010" and inserting "for each fiscal year after fiscal year 2007"; and

(II) by striking "; and" and inserting a period; and

(iii) by striking subclause (X).

(C) FEDERAL BUREAU OF INVESTIGATION.—Section 1817(k)(3)(B) of the Social Security Act (42 U.S.C. 1395i(k)(3)(B)) is amended—

(i) in clause (vii), by inserting "and" at the end;

(ii) in clause (viii)—

(I) by striking "for each of fiscal years 2007, 2008, 2009, and 2010" and inserting "for each fiscal year after fiscal year 2006"; and

(II) by striking "; and" and inserting a period; and

(iii) by striking clause (ix).

(D) MEDICARE INTEGRITY PROGRAM.—Section 1817(k)(4)(C) of the Social Security Act (42 U.S.C. 1395i(k)(4)(C)) is amended by adding at the end the following new clause:

"(ii) For each fiscal year after 2010, by the percentage increase in the consumer price index for all urban

consumers (all items; United States city average) over the previous year.".

(j) MEDICARE INTEGRITY PROGRAM AND MEDICAID INTEGRITY PROGRAM.—

(1) MEDICARE INTEGRITY PROGRAM.—

(A) REQUIREMENT TO PROVIDE PERFORMANCE STATISTICS.—Section 1893(c) of the Social Security Act (42 U.S.C. 1395ddd(c)) is amended—

(i) in paragraph (3), by striking "and" at the end;

(ii) by redesignating paragraph (4) as paragraph (5); and

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

"(4) the entity agrees to provide the Secretary and the Inspector General of the Department of Health and Human Services with such performance statistics (including the number and amount of overpayments recovered, the number of fraud referrals, and the return on investment of such activities by the entity) as the Secretary or the Inspector General may request; and".

(B) EVALUATIONS AND ANNUAL REPORT.—Section 1893 of the Social Security Act (42 U.S.C. 1395ddd) is amended by adding at the end the following new subsection:

"(i) EVALUATIONS AND ANNUAL REPORT.—

"(1) EVALUATIONS.—The Secretary shall conduct evaluations of eligible entities which the Secretary contracts with under the Program not less frequently than every 3 years.

"(2) ANNUAL REPORT.—Not later than 180 days after the end of each fiscal year (beginning with fiscal year 2011), the Secretary shall submit a report to Congress which identifies—

"(A) the use of funds, including funds transferred from the Federal Hospital Insurance Trust Fund under section 1817 and the Federal Supplementary Insurance Trust Fund under section 1841, to carry out this section; and

"(B) the effectiveness of the use of such funds.".

(C) FLEXIBILITY IN PURSUING FRAUD AND ABUSE.—Section 1893(a) of the Social Security Act (42 U.S.C. 1395ddd(a)) is amended by inserting ", or otherwise," after "entities".

(2) MEDICAID INTEGRITY PROGRAM.—

(A) REQUIREMENT TO PROVIDE PERFORMANCE STATISTICS.—Section 1936(c)(2) of the Social Security Act (42 U.S.C. 1396u–6(c)(2)) is amended—

(i) by redesignating subparagraph (D) as subparagraph (E); and

(ii) by inserting after subparagraph (C) the following new subparagraph:

"(D) The entity agrees to provide the Secretary and the Inspector General of the Department of Health and Human Services with such performance statistics (including the number and amount of overpayments recovered, the number of fraud referrals, and the return on investment of such activities by the entity) as the Secretary or the Inspector General may request.".

(B) EVALUATIONS AND ANNUAL REPORT.—Section 1936(e) of the Social Security Act (42 U.S.C. 1396u–7(e)) is amended—

(i) by redesignating paragraph (4) as paragraph (5); and

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

"(4) EVALUATIONS.—The Secretary shall conduct evaluations of eligible entities which the Secretary contracts with under the Program not less frequently than every 3 years.".

(k) EXPANDED APPLICATION OF HARDSHIP WAIVERS FOR EXCLUSIONS.—Section 1128(c)(3)(B) of the Social Security Act (42 U.S.C. 1320a–7(c)(3)(B)) is amended by striking "individuals entitled to benefits under part A of title XVIII or enrolled under part B of such title, or both" and inserting "beneficiaries (as defined in section 1128A(i)(5)) of that program".

SEC. 6403. ELIMINATION OF DUPLICATION BETWEEN THE HEALTHCARE INTEGRITY AND PROTECTION DATA BANK AND THE NATIONAL PRACTITIONER DATA BANK.

(a) INFORMATION REPORTED BY FEDERAL AGENCIES AND HEALTH PLANS.—Section 1128E of the Social Security Act (42 U.S.C. 1320a–7e) is amended—

(1) by striking subsection (a) and inserting the following:

"(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.).";

(2) by striking subsection (d) and inserting the following:

"(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.";

(3) by striking subsection (f) and inserting the following:

"(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."; and

(4) in subsection (g)—

(A) in paragraph (1)(A)—

(i) in clause (iii)—

(I) by striking "or State" each place it appears;

(II) by redesignating subclauses (II) and (III) as subclauses (III) and (IV), respectively; and

(III) by inserting after subclause (I) the following new subclause:

"(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"; and

(ii) by striking clause (iv) and inserting the following:

"(iv) Exclusion from participation in a Federal health care program (as defined in section 1128B(f))."; (B) in paragraph (3)—

(i) by striking subparagraphs (D) and (E); and

(ii) by redesignating subparagraph (F) as subparagraph (D); and

(C) in subparagraph (D) (as so redesignated), by striking "or State".

(b) INFORMATION REPORTED BY STATE LAW OR FRAUD ENFORCEMENT AGENCIES.—Section 1921 of the Social Security Act (42 U.S.C. 1396r–2) is amended—

(1) in subsection (a)—

(A) in paragraph (1)—

(i) by striking "SYSTEM.—The State" and all that follows through the semicolon and inserting SYSTEM.—

"(A) LICENSING OR CERTIFICATION ACTIONS.—The State must have in effect a system of reporting the following information with respect to formal proceedings (as defined by the Secretary in regulations) concluded against a health care practitioner or entity by a State licensing or certification agency:";

(ii) by redesignating subparagraphs (A) through (D) as clauses (i) through (iv), respectively, and indenting appropriately;

(iii) in subparagraph (A)(iii) (as so redesignated)—

(I) by striking "the license of" and inserting "license or the right to apply for, or renew, a license by"; and

(II) by inserting "nonrenewability," after "voluntary surrender,"; and

(iv) by adding at the end the following new subparagraph:

"(B) OTHER FINAL ADVERSE ACTIONS.—The State must have in effect a system of reporting information with respect to 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 by a State law or fraud enforcement agency."; and

(B) in paragraph (2), by striking "the authority described in paragraph (1)" and inserting "a State licensing or certification agency or State law or fraud enforcement agency";

(2) in subsection (b)—

(A) by striking paragraph (2) and inserting the following:

"(2) to State licensing or certification agencies and Federal agencies responsible for the licensing and certification of health care providers, suppliers, and licensed health care practitioners;";

(B) in each of paragraphs (4) and (6), by inserting ", but only with respect to information provided pursuant to subsection (a)(1)(A)" before the comma at the end;

(C) by striking paragraph (5) and inserting the following:

"(5) to State law or fraud enforcement agencies,";

(D) by redesignating paragraphs (7) and (8) as paragraphs (8) and (9), respectively; and

(E) by inserting after paragraph (6) the following new paragraph:

"(7) to health plans (as defined in section 1128C(c));";

(3) by redesignating subsection (d) as subsection (h), and by inserting after subsection (c) the following new subsections:

"(d) DISCLOSURE AND CORRECTION OF INFORMATION.—

"(1) DISCLOSURE.—With respect to information reported pursuant to subsection (a)(1), the Secretary shall—

"(A) provide for disclosure of the information, upon request, to the health care practitioner who, or the entity that, is the subject of the information reported; and

"(B) establish procedures for the case where the health care practitioner or entity disputes the accuracy of the information reported.

"(2) CORRECTIONS.—Each State licensing or certification agency and State law or fraud enforcement agency shall report corrections of information already reported about any formal proceeding or final adverse action described in subsection (a), in such form and manner as the Secretary prescribes by regulation.

"(e) 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.

"(f) PROTECTION FROM LIABILITY FOR REPORTING.—No person or entity, including any agency designated by the Secretary in subsection (b), shall be held liable in any civil action with respect to any reporting of information as required under this section, without knowledge of the falsity of the information contained in the report.

"(g) REFERENCES.—For purposes of this section:

"(1) STATE LICENSING OR CERTIFICATION AGENCY.—The term 'State licensing or certification agency' includes any authority of a State (or of a political subdivision thereof) responsible for the licensing of health care practitioners (or any peer review organization or private accreditation entity reviewing the services provided by health care practitioners) or entities.

"(2) STATE LAW OR FRAUD ENFORCEMENT AGENCY.—The term 'State law or fraud enforcement agency' includes—

"(A) a State law enforcement agency; and

"(B) a State medicaid fraud control unit (as defined in section 1903(q)).

"(3) FINAL ADVERSE ACTION.—

"(A) IN GENERAL.—Subject to subparagraph (B), the term 'final adverse action' includes—

"(i) civil judgments against a health care provider, supplier, or practitioner in State court related to the delivery of a health care item or service;

"(ii) State criminal convictions related to the delivery of a health care item or service;

"(iii) exclusion from participation in State health care programs (as defined in section 1128(h));

"(iv) any licensing or certification action described in subsection (a)(1)(A) taken against a supplier by a State licensing or certification agency; and

"(v) any other adjudicated actions or decisions that the Secretary shall establish by regulation.

"(B) EXCEPTION.—Such term does not include any action with respect to a malpractice claim."; and

(4) in subsection (h), as so redesignated, by striking "The Secretary" and all that follows through the period at the end and inserting "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 1128E.".

(c) CONFORMING AMENDMENT.—Section 1128C(a)(1) of the Social Security Act (42 U.S.C. 1320a–7c(a)(1)) is amended—

(1) in subparagraph (C), by adding "and" after the comma at the end;

(2) in subparagraph (D), by striking ", and" and inserting a period; and

(3) by striking subparagraph (E).

(d) TRANSITION PROCESS; EFFECTIVE DATE.—

(1) IN GENERAL.—Effective on the date of enactment of this Act, the Secretary of Health and Human Services (in this section referred to as the "Secretary") shall implement a transition process under which, by not later than the end of the transition period described in paragraph (5), the Secretary shall cease operating the Healthcare Integrity and Protection Data Bank established under section 1128E of the Social Security Act (as in effect before the effective date specified in paragraph (6)) and shall transfer all data collected in the Healthcare Integrity and Protection Data Bank to the National Practitioner Data Bank established pursuant to the Health Care Quality Improvement Act of 1986 (42 U.S.C. 11101 et seq.). During such transition process, the Secretary shall have in effect appropriate procedures to ensure that data collection and access to the Healthcare Integrity and Protection Data Bank and the National Practitioner Data Bank are not disrupted.

(2) REGULATIONS.—The Secretary shall promulgate regulations to carry out the amendments made by subsections (a) and (b).

(3) FUNDING.—

(A) AVAILABILITY OF FEES.—Fees collected pursuant to section 1128E(d)(2) of the Social Security Act prior to the effective date specified in paragraph (6) for the disclosure of information in the Healthcare Integrity and Protection Data Bank shall be available to the Secretary, without fiscal year limitation, for payment of costs related to the transition process described in paragraph (1). Any such fees remaining after the transition period is complete shall

be available to the Secretary, without fiscal year limitation, for payment of the costs of operating the National Practitioner Data Bank.

(B) AVAILABILITY OF ADDITIONAL FUNDS.—In addition to the fees described in subparagraph (A), any funds available to the Secretary or to the Inspector General of the Department of Health and Human Services for a purpose related to combating health care fraud, waste, or abuse shall be available to the extent necessary for operating the Healthcare Integrity and Protection Data Bank during the transition period, including systems testing and other activities necessary to ensure that information formerly reported to the Healthcare Integrity and Protection Data Bank will be accessible through the National Practitioner Data Bank after the end of such transition period.

(4) SPECIAL PROVISION FOR ACCESS TO THE NATIONAL PRACTITIONER DATA BANK BY THE DEPARTMENT OF VETERANS AFFAIRS.—

(A) IN GENERAL.—Notwithstanding any other provision of law, during the 1-year period that begins on the effective date specified in paragraph (6), the information described in subparagraph (B) shall be available from the National Practitioner Data Bank to the Secretary of Veterans Affairs without charge.

(B) INFORMATION DESCRIBED.—For purposes of subparagraph (A), the information described in this subparagraph is the information that would, but for the amendments made by this section, have been available to the Secretary of Veterans Affairs from the Healthcare Integrity and Protection Data Bank.

(5) TRANSITION PERIOD DEFINED.—For purposes of this subsection, the term "transition period" means the period that begins on the date of enactment of this Act and ends on the later of—

(A) the date that is 1 year after such date of enactment; or

(B) the effective date of the regulations promulgated under paragraph (2).

(6) EFFECTIVE DATE.—The amendments made by subsections (a), (b), and (c) shall take effect on the first day after the final day of the transition period.

SEC. 6404. MAXIMUM PERIOD FOR SUBMISSION OF MEDICARE CLAIMS REDUCED TO NOT MORE THAN 12 MONTHS.

(a) REDUCING MAXIMUM PERIOD FOR SUBMISSION.—

(1) PART A.—Section 1814(a) of the Social Security Act (42 U.S.C. 1395f(a)(1)) is amended—

(A) in paragraph (1), by striking "period of 3 calendar years" and all that follows through the semicolon and inserting "period ending 1 calendar year after the date of service;"; and

(B) by adding at the end the following new sentence: "In applying paragraph (1), the Secretary may specify exceptions to the 1 calendar year period specified in such paragraph."

(2) PART B.—

(A) Section 1842(b)(3) of such Act (42 U.S.C. 1395u(b)(3)(B)) is amended—

(i) in subparagraph (B), in the flush language following clause (ii), by striking "close of the calendar year following the year in which such service is furnished (deeming any service furnished in the last 3 months of any calendar year to have been furnished in the succeeding calendar year)" and inserting "period ending 1 calendar year after the date of service"; and

(ii) by adding at the end the following new sentence: "In applying subparagraph (B), the Secretary may specify exceptions to the 1 calendar year period specified in such subparagraph."

(B) Section 1835(a) of such Act (42 U.S.C. 1395n(a)) is amended—

(i) in paragraph (1), by striking "period of 3 calendar years" and all that follows through the semicolon and inserting "period ending 1 calendar year after the date of service;"; and

(ii) by adding at the end the following new sentence: "In applying paragraph (1), the Secretary may specify exceptions to the 1 calendar year period specified in such paragraph."

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendments made by subsection (a) shall apply to services furnished on or after January 1, 2010.

(2) SERVICES FURNISHED BEFORE 2010.—In the case of services furnished before January 1, 2010, a bill or request for payment under section 1814(a)(1), 1842(b)(3)(B), or 1835(a) shall be filed not later that December 31, 2010.

SEC. 6405. PHYSICIANS WHO ORDER ITEMS OR SERVICES REQUIRED TO BE MEDICARE ENROLLED PHYSICIANS OR ELIGIBLE PROFESSIONALS.

(a) DME.—Section 1834(a)(11)(B) of the Social Security Act (42 U.S.C. 1395m(a)(11)(B)) is amended by striking "physician" and inserting "physician enrolled under section 1866(j) or an eligible professional under section 1848(k)(3)(B) that is enrolled under section 1866(j)".

(b) HOME HEALTH SERVICES.—

(1) PART A.—Section 1814(a)(2) of such Act (42 U.S.C. 1395(a)(2)) is amended in the matter preceding subparagraph (A) by inserting "in the case of services described in subparagraph (C), a physician enrolled under section 1866(j) or an eligible professional under section 1848(k)(3)(B)," before "or, in the case of services".

(2) PART B.—Section 1835(a)(2) of such Act (42 U.S.C. 1395n(a)(2)) is amended in the matter preceding subparagraph (A) by inserting ", or in the case of services described in subparagraph (A), a physician enrolled under section 1866(j) or an eligible professional under section 1848(k)(3)(B)," after "a physician".

(c) APPLICATION TO OTHER ITEMS OR SERVICES.—The Secretary may extend the requirement applied by the amendments made by subsections (a) and (b) to durable medical equipment and home health services (relating to requiring certifications and written

orders to be made by enrolled physicians and health professions) to all other categories of items or services under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.), including covered part D drugs as defined in section 1860D–2(e) of such Act (42 U.S.C. 1395w–102), that are ordered, prescribed, or referred by a physician enrolled under section 1866(j) of such Act (42 U.S.C. 1395cc(j)) or an eligible professional under section 1848(k)(3)(B) of such Act (42 U.S.C. 1395w–4(k)(3)(B)).

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to written orders and certifications made on or after July 1, 2010.

SEC. 6406. REQUIREMENT FOR PHYSICIANS TO PROVIDE DOCUMENTATION ON REFERRALS TO PROGRAMS AT HIGH RISK OF WASTE AND ABUSE.

(a) PHYSICIANS AND OTHER SUPPLIERS.—Section 1842(h) of the Social Security Act (42 U.S.C. 1395u(h)) is amended by adding at the end the following new paragraph:

"(9) The Secretary may revoke enrollment, for a period of not more than one year for each act, for a physician or supplier under section 1866(j) if such physician or supplier fails to maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by such physician or supplier under this title, as specified by the Secretary.".

(b) PROVIDERS OF SERVICES.—Section 1866(a)(1) of such Act (42 U.S.C. 1395cc) is further amended—

(1) in subparagraph (U), by striking at the end "and";

(2) in subparagraph (V), by striking the period at the end and adding "; and"; and

(3) by adding at the end the following new subparagraph:

"(W) maintain and, upon request of the Secretary, provide access to documentation relating to written orders or requests for payment for durable medical equipment, certifications for home health services, or referrals for other items or services written or ordered by the provider under this title, as specified by the Secretary.".

(c) OIG PERMISSIVE EXCLUSION AUTHORITY.—Section 1128(b)(11) of the Social Security Act (42 U.S.C. 1320a–7(b)(11)) is amended by inserting ", ordering, referring for furnishing, or certifying the need for" after "furnishing".

(d) EFFECTIVE DATE.—The amendments made by this section shall apply to orders, certifications, and referrals made on or after January 1, 2010.

SEC. 6407. FACE TO FACE ENCOUNTER WITH PATIENT REQUIRED BEFORE PHYSICIANS MAY CERTIFY ELIGIBILITY FOR HOME HEALTH SERVICES OR DURABLE MEDICAL EQUIPMENT UNDER MEDICARE.

(a) CONDITION OF PAYMENT FOR HOME HEALTH SERVICES.—

(1) PART A.—Section 1814(a)(2)(C) of such Act is amended—

(A) by striking "and such services" and inserting "such services"; and

(B) by inserting after "care of a physician" the following: ", and, in the case of a certification made by a physician after January 1, 2010, prior to making such

certification the physician must document that the physician himself or herself has had a face-to-face encounter (including through use of telehealth, subject to the requirements in section 1834(m), and other than with respect to encounters that are incident to services involved) with the individual within a reasonable timeframe as determined by the Secretary".

(2) PART B.—Section 1835(a)(2)(A) of the Social Security Act is amended—

(A) by striking "and" before "(iii)"; and

(B) by inserting after "care of a physician" the following: ", and (iv) in the case of a certification after January 1, 2010, prior to making such certification the physician must document that the physician has had a face-to-face encounter (including through use of telehealth and other than with respect to encounters that are incident to services involved) with the individual during the 6-month period preceding such certification, or other reasonable timeframe as determined by the Secretary".

(b) CONDITION OF PAYMENT FOR DURABLE MEDICAL EQUIPMENT.—Section 1834(a)(11)(B) of the Social Security Act (42 U.S.C. 1395m(a)(11)(B)) is amended—

(1) by striking "ORDER.—The Secretary" and inserting "ORDER.—

"(i) IN GENERAL.—The Secretary"; and

(2) by adding at the end the following new clause:

"(ii) REQUIREMENT FOR FACE TO FACE ENCOUNTER.—The Secretary shall require that such an order be written pursuant to the physician documenting that a physician, a physician assistant, a nurse practitioner, or a clinical nurse specialist (as those terms are defined in section 1861(aa)(5)) has had a face-to-face encounter (including through use of telehealth under subsection (m) and other than with respect to encounters that are incident to services involved) with the individual involved during the 6-month period preceding such written order, or other reasonable timeframe as determined by the Secretary.".

(c) APPLICATION TO OTHER AREAS UNDER MEDICARE.—The Secretary may apply the face-to-face encounter requirement described in the amendments made by subsections (a) and (b) to other items and services for which payment is provided under title XVIII of the Social Security Act based upon a finding that such an decision would reduce the risk of waste, fraud, or abuse.

(d) APPLICATION TO MEDICAID.—The requirements pursuant to the amendments made by subsections (a) and (b) shall apply in the case of physicians making certifications for home health services under title XIX of the Social Security Act in the same manner and to the same extent as such requirements apply in the case of physicians making such certifications under title XVIII of such Act.

SEC. 6408. ENHANCED PENALTIES.

(a) CIVIL MONETARY PENALTIES FOR FALSE STATEMENTS OR DELAYING INSPECTIONS.—Section 1128A(a) of the Social Security Act (42 U.S.C. 1320a–7a(a)), as amended by section 5002(d)(2)(A), is amended—

(1) in paragraph (6), by striking "or" at the end; and

(2) by inserting after paragraph (7) the following new paragraphs:

"(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;"; and

(3) in the first sentence—

(A) by striking "or in cases under paragraph (7)" and inserting "in cases under paragraph (7)"; and

(B) by striking "act)" and inserting "act, in cases under paragraph (8), $50,000 for each false record or statement, or in cases under paragraph (9), $15,000 for each day of the failure described in such paragraph)".

(b) MEDICARE ADVANTAGE AND PART D PLANS.—

(1) ENSURING TIMELY INSPECTIONS RELATING TO CONTRACTS WITH MA ORGANIZATIONS.—Section 1857(d)(2) of such Act (42 U.S.C. 1395w–27(d)(2)) is amended—

(A) in subparagraph (A), by inserting "timely" before "inspect"; and

(B) in subparagraph (B), by inserting "timely" before "audit and inspect".

(2) MARKETING VIOLATIONS.—Section 1857(g)(1) of the Social Security Act (42 U.S.C. 1395w–27(g)(1)) is amended—

(A) in subparagraph (F), by striking "or" at the end;

(B) by inserting after subparagraph (G) the following new subparagraphs:

"(H) except as provided under subparagraph (C) or (D) of section 1860D–1(b)(1), enrolls an individual in any plan under this part without the prior consent of the individual or the designee of the individual;

"(I) transfers an individual enrolled under this part from one plan to another without the prior consent of the individual or the designee of the individual or solely for the purpose of earning a commission;

"(J) fails to comply with marketing restrictions described in subsections (h) and (j) of section 1851 or applicable implementing regulations or guidance; or

"(K) employs or contracts with any individual or entity who engages in the conduct described in subparagraphs (A) through (J) of this paragraph;"; and

(C) by adding at the end the following new sentence: "The Secretary may provide, in addition to any other remedies authorized by law, for any of the remedies described in paragraph (2), if the Secretary determines that any employee or agent of such organization, or any provider or supplier who contracts with such organization, has engaged in any conduct described in subparagraphs (A) through (K) of this paragraph.".

(3) PROVISION OF FALSE INFORMATION.—Section 1857(g)(2)(A) of the Social Security Act (42 U.S.C. 1395w–

27(g)(2)(A)) is amended by inserting "except with respect to a determination under subparagraph (E), an assessment of not more than the amount claimed by such plan or plan sponsor based upon the misrepresentation or falsified information involved," after "for each such determination,".

(c) OBSTRUCTION OF PROGRAM AUDITS.—Section 1128(b)(2) of the Social Security Act (42 U.S.C. 1320a–7(b)(2)) is amended—

(1) in the heading, by inserting "OR AUDIT" after "INVESTIGATION"; and

(2) by striking "investigation into" and all that follows through the period and inserting "investigation or audit related to—"

"(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)).".

(d) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as provided in paragraph (2), the amendments made by this section shall apply to acts committed on or after January 1, 2010.

(2) EXCEPTION.—The amendments made by subsection (b)(1) take effect on the date of enactment of this Act.

SEC. 6409. MEDICARE SELF-REFERRAL DISCLOSURE PROTOCOL.

(a) DEVELOPMENT OF SELF-REFERRAL DISCLOSURE PROTOCOL.—

(1) IN GENERAL.—The Secretary of Health and Human Services, in cooperation with the Inspector General of the Department of Health and Human Services, shall establish, not later than 6 months after the date of the enactment of this Act, a protocol to enable health care providers of services and suppliers to disclose an actual or potential violation of section 1877 of the Social Security Act (42 U.S.C. 1395nn) pursuant to a self-referral disclosure protocol (in this section referred to as an "SRDP"). The SRDP shall include direction to health care providers of services and suppliers on—

(A) a specific person, official, or office to whom such disclosures shall be made; and

(B) instruction on the implication of the SRDP on corporate integrity agreements and corporate compliance agreements.

(2) PUBLICATION ON INTERNET WEBSITE OF SRDP INFORMATION.—The Secretary of Health and Human Services shall post information on the public Internet website of the Centers for Medicare & Medicaid Services to inform relevant stakeholders of how to disclose actual or potential violations pursuant to an SRDP.

(3) RELATION TO ADVISORY OPINIONS.—The SRDP shall be separate from the advisory opinion process set forth in regulations implementing section 1877(g) of the Social Security Act.

(b) REDUCTION IN AMOUNTS OWED.—The Secretary of Health and Human Services is authorized to reduce the amount due and owing for all violations under section 1877 of the Social Security Act to an amount less than that specified in subsection (g) of such section. In establishing such amount for a violation, the Secretary may consider the following factors:

(1) The nature and extent of the improper or illegal practice.

(2) The timeliness of such self-disclosure.

(3) The cooperation in providing additional information related to the disclosure.

(4) Such other factors as the Secretary considers appropriate.

(c) REPORT.—Not later than 18 months after the date on which the SRDP protocol is established under subsection (a)(1), the Secretary shall submit to Congress a report on the implementation of this section. Such report shall include—

(1) the number of health care providers of services and suppliers making disclosures pursuant to the SRDP;

(2) the amounts collected pursuant to the SRDP;

(3) the types of violations reported under the SRDP; and

(4) such other information as may be necessary to evaluate the impact of this section.

SEC. 6410. ADJUSTMENTS TO THE MEDICARE DURABLE MEDICAL EQUIPMENT, PROSTHETICS, ORTHOTICS, AND SUPPLIES COMPETITIVE ACQUISITION PROGRAM.

(a) EXPANSION OF ROUND 2 OF THE DME COMPETITIVE BIDDING PROGRAM.—Section 1847(a)(1) of the Social Security Act (42 U.S.C. 1395w–3(a)(1)) is amended—

(1) in subparagraph (B)(i)(II), by striking "70" and inserting "91"; and

(2) in subparagraph (D)(ii)—

(A) in subclause (I), by striking "and" at the end;

(B) by redesignating subclause (II) as subclause (III); and

(C) by inserting after subclause (I) the following new subclause:

"(II) the Secretary shall include the next 21 largest metropolitan statistical areas by total population (after those selected under subclause (I)) for such round; and".

(b) REQUIREMENT TO EITHER COMPETITIVELY BID AREAS OR USE COMPETITIVE BID PRICES BY 2016.—Section 1834(a)(1)(F) of the Social Security Act (42 U.S.C. 1395m(a)(1)(F)) is amended—

(1) in clause (i), by striking "and" at the end;

(2) in clause (ii)—

(A) by inserting "(and, in the case of covered items furnished on or after January 1, 2016, subject to clause (iii), shall)" after "may"; and

(B) by striking the period at the end and inserting "; and"; and

(3) by adding at the end the following new clause:

"(iii) in the case of covered items furnished on or after January 1, 2016, the Secretary shall continue to make such adjustments described in clause (ii) as, under such competitive acquisition programs, additional covered items are phased in or information is updated as contracts under section 1847 are recompeted in accordance with section 1847(b)(3)(B).".

SEC. 6411. EXPANSION OF THE RECOVERY AUDIT CONTRACTOR (RAC) PROGRAM.

(a) EXPANSION TO MEDICAID.—

(1) STATE PLAN AMENDMENT.—Section 1902(a)(42) of the Social Security Act (42 U.S.C. 1396a(a)(42)) is amended—

(A) by striking "that the records" and inserting "that—
"(A) the records";

(B) by inserting "and" after the semicolon; and

(C) by adding at the end the following:

"(B) not later than December 31, 2010, the State shall—

"(i) establish a program under which the State contracts (consistent with State law and in the same manner as the Secretary enters into contracts with recovery audit contractors under section 1893(h), subject to such exceptions or requirements as the Secretary may require for purposes of this title or a particular State) with 1 or more recovery audit contractors for the purpose of identifying underpayments and overpayments and recouping overpayments under the State plan and under any waiver of the State plan with respect to all services for which payment is made to any entity under such plan or waiver; and

"(ii) provide assurances satisfactory to the Secretary that—

"(I) under such contracts, payment shall be made to such a contractor only from amounts recovered;

"(II) from such amounts recovered, payment—

"(aa) shall be made on a contingent basis for collecting overpayments; and

"(bb) may be made in such amounts as the State may specify for identifying underpayments;

"(III) the State has an adequate process for entities to appeal any adverse determination made by such contractors; and

"(IV) such program is carried out in accordance with such requirements as the Secretary shall specify, including—

"(aa) for purposes of section 1903(a)(7), that amounts expended by the State to carry out the program shall be considered amounts expended as necessary for the proper and efficient administration of the State plan or a waiver of the plan;

"(bb) that section 1903(d) shall apply to amounts recovered under the program; and

"(cc) that the State and any such contractors under contract with the State shall coordinate such recovery audit efforts with other contractors or entities performing audits of entities receiving payments under the State plan or waiver in the State, including efforts with Federal and State law enforcement with respect to the Department of Justice, including the Federal Bureau of Investigations, the Inspector General of the Department of Health and Human Services, and the State medicaid fraud control unit; and".

(2) COORDINATION; REGULATIONS.—

(A) IN GENERAL.—The Secretary of Health and Human Services, acting through the Administrator of the Centers for Medicare & Medicaid Services, shall coordinate the expansion of the Recovery Audit Contractor program to Medicaid with States, particularly with respect to each State that enters into a contract with a recovery audit contractor for purposes of the State's Medicaid program prior to December 31, 2010.

(B) REGULATIONS.—The Secretary of Health and Human Services shall promulgate regulations to carry out this subsection and the amendments made by this subsection, including with respect to conditions of Federal financial participation, as specified by the Secretary.

(b) EXPANSION TO MEDICARE PARTS C AND D.—Section 1893(h) of the Social Security Act (42 U.S.C. 1395ddd(h)) is amended—

(1) in paragraph (1), in the matter preceding subparagraph (A), by striking "part A or B" and inserting "this title";

(2) in paragraph (2), by striking "parts A and B" and inserting "this title";

(3) in paragraph (3), by inserting "(not later than December 31, 2010, in the case of contracts relating to payments made under part C or D)" after "2010";

(4) in paragraph (4), in the matter preceding subparagraph (A), by striking "part A or B" and inserting "this title"; and

(5) by adding at the end the following:

"(9) SPECIAL RULES RELATING TO PARTS C AND D.—The Secretary shall enter into contracts under paragraph (1) to require recovery audit contractors to—

"(A) ensure that each MA plan under part C has an anti-fraud plan in effect and to review the effectiveness of each such anti-fraud plan;

"(B) ensure that each prescription drug plan under part D has an anti-fraud plan in effect and to review the effectiveness of each such anti-fraud plan;

"(C) examine claims for reinsurance payments under section 1860D–15(b) to determine whether prescription drug plans submitting such claims incurred costs in excess of the allowable reinsurance costs permitted under paragraph (2) of that section; and

"(D) review estimates submitted by prescription drug plans by private plans with respect to the enrollment of high cost beneficiaries (as defined by the Secretary) and to compare such estimates with the numbers of such beneficiaries actually enrolled by such plans.".

(c) ANNUAL REPORT.—The Secretary of Health and Human Services, acting through the Administrator of the Centers for Medicare & Medicaid Services, shall submit an annual report to Congress concerning the effectiveness of the Recovery Audit Contractor program under Medicaid and Medicare and shall include such reports recommendations for expanding or improving the program.

Subtitle F—Additional Medicaid Program Integrity Provisions

SEC. 6501. TERMINATION OF PROVIDER PARTICIPATION UNDER MEDICAID IF TERMINATED UNDER MEDICARE OR OTHER STATE PLAN.

Section 1902(a)(39) of the Social Security Act (42 U.S.C. 42 U.S.C. 1396a(a)) is amended by inserting after "1128A," the following: "terminate the participation of any individual or entity in such program if (subject to such exceptions as are permitted with respect to exclusion under sections 1128(c)(3)(B) and 1128(d)(3)(B)) participation of such individual or entity is terminated under title XVIII or any other State plan under this title,".

SEC. 6502. MEDICAID EXCLUSION FROM PARTICIPATION RELATING TO CERTAIN OWNERSHIP, CONTROL, AND MANAGEMENT AFFILIATIONS.

Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)), as amended by section 6401(b), is amended by inserting after paragraph (77) the following:

"(78) provide that the State agency described in paragraph (9) exclude, with respect to a period, any individual or entity from participation in the program under the State plan if such individual or entity owns, controls, or manages an entity that (or if such entity is owned, controlled, or managed by an individual or entity that)—

"(A) has unpaid overpayments (as defined by the Secretary) under this title during such period determined by the Secretary or the State agency to be delinquent;

"(B) is suspended or excluded from participation under or whose participation is terminated under this title during such period; or

"(C) is affiliated with an individual or entity that has been suspended or excluded from participation under this title or whose participation is terminated under this title during such period;".

SEC. 6503. BILLING AGENTS, CLEARINGHOUSES, OR OTHER ALTERNATE PAYEES REQUIRED TO REGISTER UNDER MEDICAID.

(a) IN GENERAL.—Section 1902(a) of the Social Security Act (42 U.S.C. 42 U.S.C. 1396a(a)), as amended by section 6502(a), is amended by inserting after paragraph (78), the following:

"(79) provide that any agent, clearinghouse, or other alternate payee (as defined by the Secretary) that submits claims on behalf of a health care provider must register with the State and the Secretary in a form and manner specified by the Secretary;".

SEC. 6504. REQUIREMENT TO REPORT EXPANDED SET OF DATA ELEMENTS UNDER MMIS TO DETECT FRAUD AND ABUSE.

(a) IN GENERAL.—Section 1903(r)(1)(F) of the Social Security Act (42 U.S.C. 1396b(r)(1)(F)) is amended by inserting after "necessary" the following: "and including, for data submitted to the Secretary on or after January 1, 2010, data elements from the

automated data system that the Secretary determines to be necessary for program integrity, program oversight, and administration, at such frequency as the Secretary shall determine".

(b) MANAGED CARE ORGANIZATIONS.—

(1) IN GENERAL.—Section 1903(m)(2)(A)(xi) of the Social Security Act (42 U.S.C. 1396b(m)(2)(A)(xi)) is amended by inserting "and for the provision of such data to the State at a frequency and level of detail to be specified by the Secretary" after "patients".

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply with respect to contract years beginning on or after January 1, 2010.

SEC. 6505. PROHIBITION ON PAYMENTS TO INSTITUTIONS OR ENTITIES LOCATED OUTSIDE OF THE UNITED STATES.

Section 1902(a) of the Social Security Act (42 U.S.C. 1396b(a)), as amended by section 6503, is amended by inserting after paragraph (79) the following new paragraph:

"(80) provide that the State shall not provide any payments for items or services provided under the State plan or under a waiver to any financial institution or entity located outside of the United States;".

SEC. 6506. OVERPAYMENTS.

(a) EXTENSION OF PERIOD FOR COLLECTION OF OVERPAYMENTS DUE TO FRAUD.—

(1) IN GENERAL.—Section 1903(d)(2) of the Social Security Act (42 U.S.C. 1396b(d)(2)) is amended—

(A) in subparagraph (C)—

(i) in the first sentence, by striking "60 days" and inserting "1 year"; and

(ii) in the second sentence, by striking "60 days" and inserting "1-year period"; and

(B) in subparagraph (D)—

(i) in inserting "(i)" after "(D)"; and

(ii) by adding at the end the following:

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

(2) EFFECTIVE DATE.—The amendments made by this subsection take effect on the date of enactment of this Act and apply to overpayments discovered on or after that date.

(b) CORRECTIVE ACTION.—The Secretary shall promulgate regulations that require States to correct Federally identified claims overpayments, of an ongoing or recurring nature, with new Medicaid Management Information System (MMIS) edits, audits, or other appropriate corrective action.

SEC. 6507. MANDATORY STATE USE OF NATIONAL CORRECT CODING INITIATIVE.

Section 1903(r) of the Social Security Act (42 U.S.C. 1396b(r)) is amended—

(1) in paragraph (1)(B)—

(A) in clause (ii), by striking "and" at the end;

(B) in clause (iii), by adding "and" after the semicolon; and

(C) by adding at the end the following new clause:

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

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

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

"(A) Not later than September 1, 2010:

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

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

"(iii) Notify States of—

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

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

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

SEC. 6508. GENERAL EFFECTIVE DATE.

(a) IN GENERAL.—Except as otherwise provided in this subtitle, this subtitle and the amendments made by this subtitle take effect on January 1, 2011, without regard to whether final regulations to carry out such amendments and subtitle have been promulgated by that date.

(b) DELAY IF STATE LEGISLATION REQUIRED.—In the case of a State plan for medical assistance under title XIX of the Social Security Act or a child health plan under title XXI of such Act which the Secretary of Health and Human Services determines

requires State legislation (other than legislation appropriating funds) in order for the plan to meet the additional requirement imposed by the amendments made by this subtitle, the State plan or child health plan shall not be regarded as failing to comply with the requirements of such title solely on the basis of its failure to meet this additional requirement before the first day of the first calendar quarter beginning after the close of the first regular session of the State legislature that begins after the date of the enactment of this Act. For purposes of the previous sentence, in the case of a State that has a 2-year legislative session, each year of such session shall be deemed to be a separate regular session of the State legislature.

Subtitle G—Additional Program Integrity Provisions

SEC. 6601. PROHIBITION ON FALSE STATEMENTS AND REPRESENTATIONS.

(a) PROHIBITION.—Part 5 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1131 et seq.) is amended by adding at the end the following:

"SEC. 519. PROHIBITION ON FALSE STATEMENTS AND REPRESENTATIONS.

"No person, in connection with a plan or other arrangement that is multiple employer welfare arrangement described in section 3(40), shall make a false statement or false representation of fact, knowing it to be false, in connection with the marketing or sale of such plan or arrangement, to any employee, any member of an employee organization, any beneficiary, any employer, any employee organization, the Secretary, or any State, or the representative or agent of any such person, State, or the Secretary, concerning—

"(1) the financial condition or solvency of such plan or arrangement;

"(2) the benefits provided by such plan or arrangement;

"(3) the regulatory status of such plan or other arrangement under any Federal or State law governing collective bargaining, labor management relations, or intern union affairs; or

"(4) the regulatory status of such plan or other arrangement regarding exemption from state regulatory authority under this Act.

This section shall not apply to any plan or arrangement that does not fall within the meaning of the term 'multiple employer welfare arrangement' under section 3(40)(A).".

(b) CRIMINAL PENALTIES.—Section 501 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1131) is amended—

(1) by inserting "(a)" before "Any person"; and

(2) by adding at the end the following:

"(b) Any person that violates section 519 shall upon conviction be imprisoned not more than 10 years or fined under title 18, United States Code, or both.".

(c) CONFORMING AMENDMENT.—The table of sections for part 5 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 is amended by adding at the end the following:

"Sec. 519. Prohibition on false statement and representations.".

SEC. 6602. CLARIFYING DEFINITION.

Section 24(a)(2) of title 18, United States Code, is amended by inserting "or section 411, 518, or 511 of the Employee Retirement Income Security Act of 1974," after "1954 of this title".

SEC. 6603. DEVELOPMENT OF MODEL UNIFORM REPORT FORM.

Part C of title XXVII of the Public Health Service Act (42 U.S.C. 300gg–91 et seq.) is amended by adding at the end the following:

"SEC. 2794. UNIFORM FRAUD AND ABUSE REFERRAL FORMAT.

"The Secretary shall request the National Association of Insurance Commissioners to develop a model uniform report form for private health insurance issuer seeking to refer suspected fraud and abuse to State insurance departments or other responsible State agencies for investigation. The Secretary shall request that the National Association of Insurance Commissioners develop recommendations for uniform reporting standards for such referrals.".

SEC. 6604. APPLICABILITY OF STATE LAW TO COMBAT FRAUD AND ABUSE.

(a) IN GENERAL.—Part 5 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1131 et seq.), as amended by section 6601, is further amended by adding at the end the following:

"SEC. 520. APPLICABILITY OF STATE LAW TO COMBAT FRAUD AND ABUSE.

"The Secretary may, for the purpose of identifying, preventing, or prosecuting fraud and abuse, adopt regulatory standards establishing, or issue an order relating to a specific person establishing, that a person engaged in the business of providing insurance through a multiple employer welfare arrangement described in section 3(40) is subject to the laws of the States in which such person operates which regulate insurance in such State, notwithstanding section 514(b)(6) of this Act or the Liability Risk Retention Act of 1986, and regardless of whether the law of the State is otherwise preempted under any of such provisions. This section shall not apply to any plan or arrangement that does not fall within the meaning of the term 'multiple employer welfare arrangement' under section 3(40)(A).".

(b) CONFORMING AMENDMENT.—The table of sections for part 5 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, as amended by section 6601, is further amended by adding at the end the following:

"Sec. 520. Applicability of State law to combat fraud and abuse.".

SEC. 6605. ENABLING THE DEPARTMENT OF LABOR TO ISSUE ADMINISTRATIVE SUMMARY CEASE AND DESIST ORDERS AND SUMMARY SEIZURES ORDERS AGAINST PLANS THAT ARE IN FINANCIALLY HAZARDOUS CONDITION.

(a) IN GENERAL.—Part 5 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1131 et seq.), as amended by section 6604, is further amended by adding at the end the following:

"SEC. 521. ADMINISTRATIVE SUMMARY CEASE AND DESIST ORDERS AND SUMMARY SEIZURE ORDERS AGAINST MULTIPLE EMPLOYER WELFARE ARRANGEMENTS IN FINANCIALLY HAZARDOUS CONDITION.

"(a) IN GENERAL.—The Secretary may issue a cease and desist (ex parte) order under this title if it appears to the Secretary that the alleged conduct of a multiple employer welfare arrangement described in section 3(40), other than a plan or arrangement described in subsection (g), is fraudulent, or creates an immediate danger to the public safety or welfare, or is causing or can be reasonably expected to cause significant, imminent, and irreparable public injury.

"(b) HEARING.—A person that is adversely affected by the issuance of a cease and desist order under subsection (a) may request a hearing by the Secretary regarding such order. The Secretary may require that a proceeding under this section, including all related information and evidence, be conducted in a confidential manner.

"(c) BURDEN OF PROOF.—The burden of proof in any hearing conducted under subsection (b) shall be on the party requesting the hearing to show cause why the cease and desist order should be set aside.

"(d) DETERMINATION.—Based upon the evidence presented at a hearing under subsection (b), the cease and desist order involved may be affirmed, modified, or set aside by the Secretary in whole or in part.

"(e) SEIZURE.—The Secretary may issue a summary seizure order under this title if it appears that a multiple employer welfare arrangement is in a financially hazardous condition.

"(f) REGULATIONS.—The Secretary may promulgate such regulations or other guidance as may be necessary or appropriate to carry out this section.

"(g) EXCEPTION.—This section shall not apply to any plan or arrangement that does not fall within the meaning of the term 'multiple employer welfare arrangement' under section 3(40)(A).".

(b) CONFORMING AMENDMENT.—The table of sections for part 5 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, as amended by section 6604, is further amended by adding at the end the following:

"Sec. 521. Administrative summary cease and desist orders and summary seizure orders against health plans in financially hazardous condition.".

SEC. 6606. MEWA PLAN REGISTRATION WITH DEPARTMENT OF LABOR.

Section 101(g) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1021(g)) is amended—

(1) by striking "Secretary may" and inserting "Secretary shall"; and

(2) by inserting "to register with the Secretary prior to operating in a State and may, by regulation, require such multiple employer welfare arrangements" after "not group health plans".

SEC. 6607. PERMITTING EVIDENTIARY PRIVILEGE AND CONFIDENTIAL COMMUNICATIONS.

Section 504 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1134) is amended by adding at the end the following:

"(d) The Secretary may promulgate a regulation that provides an evidentiary privilege for, and provides for the confidentiality of communications between or among, any of the following entities or their agents, consultants, or employees:

"(1) A State insurance department.

"(2) A State attorney general.

"(3) The National Association of Insurance Commissioners.

"(4) The Department of Labor.

"(5) The Department of the Treasury.

"(6) The Department of Justice.

"(7) The Department of Health and Human Services.

"(8) Any other Federal or State authority that the Secretary determines is appropriate for the purposes of enforcing the provisions of this title.

"(e) The privilege established under subsection (d) shall apply to communications related to any investigation, audit, examination, or inquiry conducted or coordinated by any of the agencies. A communication that is privileged under subsection (d) shall not waive any privilege otherwise available to the communicating agency or to any person who provided the information that is communicated.".

Subtitle H—Elder Justice Act

SEC. 6701. SHORT TITLE OF SUBTITLE.

This subtitle may be cited as the "Elder Justice Act of 2009".

SEC. 6702. DEFINITIONS.

Except as otherwise specifically provided, any term that is defined in section 2011 of the Social Security Act (as added by section 6703(a)) and is used in this subtitle has the meaning given such term by such section.

SEC. 6703. ELDER JUSTICE.

(a) ELDER JUSTICE.—

(1) IN GENERAL.—Title XX of the Social Security Act (42 U.S.C. 1397 et seq.) is amended—

(A) in the heading, by inserting "**AND ELDER JUSTICE**" after "**SOCIAL SERVICES**";

(B) by inserting before section 2001 the following:

"Subtitle A—Block Grants to States for Social Services";

and

(C) by adding at the end the following:

"Subtitle B—Elder Justice

"SEC. 2011. DEFINITIONS.

"In this subtitle:

"(1) ABUSE.—The term 'abuse' means the knowing infliction of physical or psychological harm or the knowing deprivation of goods or services that are necessary to meet essential needs or to avoid physical or psychological harm.

"(2) ADULT PROTECTIVE SERVICES.—The term 'adult protective services' means such services provided to adults as the Secretary may specify and includes services such as—

"(A) receiving reports of adult abuse, neglect, or exploitation;

"(B) investigating the reports described in subparagraph (A);

"(C) case planning, monitoring, evaluation, and other case work and services; and

"(D) providing, arranging for, or facilitating the provision of medical, social service, economic, legal, housing, law enforcement, or other protective, emergency, or support services.

"(3) CAREGIVER.—The term 'caregiver' means an individual who has the responsibility for the care of an elder, either voluntarily, by contract, by receipt of payment for care, or as a result of the operation of law, and means a family member or other individual who provides (on behalf of such individual or of a public or private agency, organization, or institution) compensated or uncompensated care to an elder who needs supportive services in any setting.

"(4) DIRECT CARE.—The term 'direct care' means care by an employee or contractor who provides assistance or long-term care services to a recipient.

"(5) ELDER.—The term 'elder' means an individual age 60 or older.

"(6) ELDER JUSTICE.—The term 'elder justice' means—

"(A) from a societal perspective, efforts to—

"(i) prevent, detect, treat, intervene in, and prosecute elder abuse, neglect, and exploitation; and

"(ii) protect elders with diminished capacity while maximizing their autonomy; and

"(B) from an individual perspective, the recognition of an elder's rights, including the right to be free of abuse, neglect, and exploitation.

"(7) ELIGIBLE ENTITY.—The term 'eligible entity' means a State or local government agency, Indian tribe or tribal organization, or any other public or private entity that is engaged in and has expertise in issues relating to elder justice or in a field necessary to promote elder justice efforts.

"(8) EXPLOITATION.—The term 'exploitation' means the fraudulent or otherwise illegal, unauthorized, or improper act or process of an individual, including a caregiver or fiduciary, that uses the resources of an elder for monetary or personal benefit, profit, or gain, or that results in depriving an elder of rightful access to, or use of, benefits, resources, belongings, or assets.

"(9) FIDUCIARY.—The term 'fiduciary'—

"(A) means a person or entity with the legal responsibility—

"(i) to make decisions on behalf of and for the benefit of another person; and

"(ii) to act in good faith and with fairness; and

"(B) includes a trustee, a guardian, a conservator, an executor, an agent under a financial power of attorney or health care power of attorney, or a representative payee.

"(10) GRANT.—The term 'grant' includes a contract, cooperative agreement, or other mechanism for providing financial assistance.

"(11) GUARDIANSHIP.—The term 'guardianship' means—

"(A) the process by which a State court determines that an adult individual lacks capacity to make decisions about self-care or property, and appoints another individual or entity known as a guardian, as a conservator, or by a similar term, as a surrogate decisionmaker;

"(B) the manner in which the court-appointed surrogate decisionmaker carries out duties to the individual and the court; or

"(C) the manner in which the court exercises oversight of the surrogate decisionmaker.

"(12) INDIAN TRIBE.—

"(A) IN GENERAL.—The term 'Indian tribe' has the meaning given such term in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b).

"(B) INCLUSION OF PUEBLO AND RANCHERIA.—The term 'Indian tribe' includes any Pueblo or Rancheria.

"(13) LAW ENFORCEMENT.—The term 'law enforcement' means the full range of potential responders to elder abuse, neglect, and exploitation including—

"(A) police, sheriffs, detectives, public safety officers, and corrections personnel;

"(B) prosecutors;

"(C) medical examiners;

"(D) investigators; and

"(E) coroners.

"(14) LONG-TERM CARE.—

"(A) IN GENERAL.—The term 'long-term care' means supportive and health services specified by the Secretary for individuals who need assistance because the individuals have a loss of capacity for self-care due to illness, disability, or vulnerability.

"(B) LOSS OF CAPACITY FOR SELF-CARE.—For purposes of subparagraph (A), the term 'loss of capacity for self-care' means an inability to engage in 1 or more activities of daily living, including eating, dressing, bathing, management of one's financial affairs, and other activities the Secretary determines appropriate.

"(15) LONG-TERM CARE FACILITY.—The term 'long-term care facility' means a residential care provider that arranges for, or directly provides, long-term care.

"(16) NEGLECT.—The term 'neglect' means—

"(A) the failure of a caregiver or fiduciary to provide the goods or services that are necessary to maintain the health or safety of an elder; or

"(B) self-neglect.

"(17) NURSING FACILITY.—

"(A) IN GENERAL.—The term 'nursing facility' has the meaning given such term under section 1919(a).

"(B) INCLUSION OF SKILLED NURSING FACILITY.—The term 'nursing facility' includes a skilled nursing facility (as defined in section 1819(a)).

"(18) SELF-NEGLECT.—The term 'self-neglect' means an adult's inability, due to physical or mental impairment or diminished capacity, to perform essential self-care tasks including—

"(A) obtaining essential food, clothing, shelter, and medical care;

"(B) obtaining goods and services necessary to maintain physical health, mental health, or general safety; or

"(C) managing one's own financial affairs.

"(19) SERIOUS BODILY INJURY.—

"(A) IN GENERAL.—The term 'serious bodily injury' means an injury—

"(i) involving extreme physical pain;

"(ii) involving substantial risk of death;

"(iii) involving protracted loss or impairment of the function of a bodily member, organ, or mental faculty; or

"(iv) requiring medical intervention such as surgery, hospitalization, or physical rehabilitation.

"(B) CRIMINAL SEXUAL ABUSE.—Serious bodily injury shall be considered to have occurred if the conduct causing the injury is conduct described in section 2241 (relating to aggravated sexual abuse) or 2242 (relating to sexual abuse) of title 18, United States Code, or any similar offense under State law.

"(20) SOCIAL.—The term 'social', when used with respect to a service, includes adult protective services.

"(21) STATE LEGAL ASSISTANCE DEVELOPER.—The term 'State legal assistance developer' means an individual described in section 731 of the Older Americans Act of 1965.

"(22) STATE LONG-TERM CARE OMBUDSMAN.—The term 'State Long-Term Care Ombudsman' means the State Long-Term Care Ombudsman described in section 712(a)(2) of the Older Americans Act of 1965.

"SEC. 2012. GENERAL PROVISIONS.

"(a) PROTECTION OF PRIVACY.—In pursuing activities under this subtitle, the Secretary shall ensure the protection of individual health privacy consistent with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 and applicable State and local privacy regulations.

"(b) RULE OF CONSTRUCTION.—Nothing in this subtitle shall be construed to interfere with or abridge an elder's right to practice his or her religion through reliance on prayer alone for healing when this choice—

"(1) is contemporaneously expressed, either orally or in writing, with respect to a specific illness or injury which the elder has at the time of the decision by an elder who is competent at the time of the decision;

"(2) is previously set forth in a living will, health care proxy, or other advance directive document that is validly executed and applied under State law; or

"(3) may be unambiguously deduced from the elder's life history.

"PART I—NATIONAL COORDINATION OF ELDER JUSTICE ACTIVITIES AND RESEARCH

"Subpart A—Elder Justice Coordinating Council and Advisory Board on Elder Abuse, Neglect, and Exploitation

"SEC. 2021. ELDER JUSTICE COORDINATING COUNCIL.

"(a) ESTABLISHMENT.—There is established within the Office of the Secretary an Elder Justice Coordinating Council (in this section referred to as the 'Council').

"(b) MEMBERSHIP.—

"(1) IN GENERAL.—The Council shall be composed of the following members:

"(A) The Secretary (or the Secretary's designee).

"(B) The Attorney General (or the Attorney General's designee).

"(C) The head of each Federal department or agency or other governmental entity identified by the Chair referred to in subsection (d) as having responsibilities, or administering programs, relating to elder abuse, neglect, and exploitation.

"(2) REQUIREMENT.—Each member of the Council shall be an officer or employee of the Federal Government.

"(c) VACANCIES.—Any vacancy in the Council shall not affect its powers, but shall be filled in the same manner as the original appointment was made.

"(d) CHAIR.—The member described in subsection (b)(1)(A) shall be Chair of the Council.

"(e) MEETINGS.—The Council shall meet at least 2 times per year, as determined by the Chair.

"(f) DUTIES.—

"(1) IN GENERAL.—The Council shall make recommendations to the Secretary for the coordination of activities of the Department of Health and Human Services, the Department of Justice, and other relevant Federal, State, local, and private agencies and entities, relating to elder abuse, neglect, and exploitation and other crimes against elders.

"(2) REPORT.—Not later than the date that is 2 years after the date of enactment of the Elder Justice Act of 2009 and every 2 years thereafter, the Council shall submit to the Committee on Finance of the Senate and the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives a report that—

"(A) describes the activities and accomplishments of, and challenges faced by—

"(i) the Council; and

"(ii) the entities represented on the Council; and

"(B) makes such recommendations for legislation, model laws, or other action as the Council determines to be appropriate.

"(g) POWERS OF THE COUNCIL.—

"(1) INFORMATION FROM FEDERAL AGENCIES.—Subject to the requirements of section 2012(a), the Council may secure directly from any Federal department or agency such information as the Council considers necessary to carry out this section. Upon

request of the Chair of the Council, the head of such department or agency shall furnish such information to the Council.

"(2) POSTAL SERVICES.—The Council may use the United States mails in the same manner and under the same conditions as other departments and agencies of the Federal Government.

"(h) TRAVEL EXPENSES.—The members of the Council shall not receive compensation for the performance of services for the Council. The members shall be allowed travel expenses, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, United States Code, while away from their homes or regular places of business in the performance of services for the Council. Notwithstanding section 1342 of title 31, United States Code, the Secretary may accept the voluntary and uncompensated services of the members of the Council.

"(i) DETAIL OF GOVERNMENT EMPLOYEES.—Any Federal Government employee may be detailed to the Council without reimbursement, and such detail shall be without interruption or loss of civil service status or privilege.

"(j) STATUS AS PERMANENT COUNCIL.—Section 14 of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the Council.

"(k) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary to carry out this section.

"SEC. 2022. ADVISORY BOARD ON ELDER ABUSE, NEGLECT, AND EXPLOITATION.

"(a) ESTABLISHMENT.—There is established a board to be known as the 'Advisory Board on Elder Abuse, Neglect, and Exploitation' (in this section referred to as the 'Advisory Board') to create short- and long-term multidisciplinary strategic plans for the development of the field of elder justice and to make recommendations to the Elder Justice Coordinating Council established under section 2021.

"(b) COMPOSITION.—The Advisory Board shall be composed of 27 members appointed by the Secretary from among members of the general public who are individuals with experience and expertise in elder abuse, neglect, and exploitation prevention, detection, treatment, intervention, or prosecution.

"(c) SOLICITATION OF NOMINATIONS.—The Secretary shall publish a notice in the Federal Register soliciting nominations for the appointment of members of the Advisory Board under subsection (b).

"(d) TERMS.—

"(1) IN GENERAL.—Each member of the Advisory Board shall be appointed for a term of 3 years, except that, of the members first appointed—

"(A) 9 shall be appointed for a term of 3 years;

"(B) 9 shall be appointed for a term of 2 years; and

"(C) 9 shall be appointed for a term of 1 year.

"(2) VACANCIES.—

"(A) IN GENERAL.—Any vacancy on the Advisory Board shall not affect its powers, but shall be filled in the same manner as the original appointment was made.

"(B) FILLING UNEXPIRED TERM.—An individual chosen to fill a vacancy shall be appointed for the unexpired term of the member replaced.

"(3) EXPIRATION OF TERMS.—The term of any member shall not expire before the date on which the member's successor takes office.

"(e) ELECTION OF OFFICERS.—The Advisory Board shall elect a Chair and Vice Chair from among its members. The Advisory Board shall elect its initial Chair and Vice Chair at its initial meeting.

"(f) DUTIES.—

"(1) ENHANCE COMMUNICATION ON PROMOTING QUALITY OF, AND PREVENTING ABUSE, NEGLECT, AND EXPLOITATION IN, LONG-TERM CARE.—The Advisory Board shall develop collaborative and innovative approaches to improve the quality of, including preventing abuse, neglect, and exploitation in, long-term care.

"(2) COLLABORATIVE EFFORTS TO DEVELOP CONSENSUS AROUND THE MANAGEMENT OF CERTAIN QUALITY-RELATED FACTORS.—

"(A) IN GENERAL.—The Advisory Board shall establish multidisciplinary panels to address, and develop consensus on, subjects relating to improving the quality of long-term care. At least 1 such panel shall address, and develop consensus on, methods for managing resident-to-resident abuse in long-term care.

"(B) ACTIVITIES CONDUCTED.—The multidisciplinary panels established under subparagraph (A) shall examine relevant research and data, identify best practices with respect to the subject of the panel, determine the best way to carry out those best practices in a practical and feasible manner, and determine an effective manner of distributing information on such subject.

"(3) REPORT.—Not later than the date that is 18 months after the date of enactment of the Elder Justice Act of 2009, and annually thereafter, the Advisory Board shall prepare and submit to the Elder Justice Coordinating Council, the Committee on Finance of the Senate, and the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives a report containing—

"(A) information on the status of Federal, State, and local public and private elder justice activities;

"(B) recommendations (including recommended priorities) regarding—

"(i) elder justice programs, research, training, services, practice, enforcement, and coordination;

"(ii) coordination between entities pursuing elder justice efforts and those involved in related areas that may inform or overlap with elder justice efforts, such as activities to combat violence against women and child abuse and neglect; and

"(iii) activities relating to adult fiduciary systems, including guardianship and other fiduciary arrangements;

"(C) recommendations for specific modifications needed in Federal and State laws (including regulations) or for programs, research, and training to enhance prevention, detection, and treatment (including diagnosis) of, intervention in (including investigation of), and prosecution of elder abuse, neglect, and exploitation;

"(D) recommendations on methods for the most effective coordinated national data collection with respect to elder justice, and elder abuse, neglect, and exploitation; and

"(E) recommendations for a multidisciplinary strategic plan to guide the effective and efficient development of the field of elder justice.

"(g) POWERS OF THE ADVISORY BOARD.—

"(1) INFORMATION FROM FEDERAL AGENCIES.—Subject to the requirements of section 2012(a), the Advisory Board may secure directly from any Federal department or agency such information as the Advisory Board considers necessary to carry out this section. Upon request of the Chair of the Advisory Board, the head of such department or agency shall furnish such information to the Advisory Board.

"(2) SHARING OF DATA AND REPORTS.—The Advisory Board may request from any entity pursuing elder justice activities under the Elder Justice Act of 2009 or an amendment made by that Act, any data, reports, or recommendations generated in connection with such activities.

"(3) POSTAL SERVICES.—The Advisory Board may use the United States mails in the same manner and under the same conditions as other departments and agencies of the Federal Government.

"(h) TRAVEL EXPENSES.—The members of the Advisory Board shall not receive compensation for the performance of services for the Advisory Board. The members shall be allowed travel expenses for up to 4 meetings per year, including per diem in lieu of subsistence, at rates authorized for employees of agencies under subchapter I of chapter 57 of title 5, United States Code, while away from their homes or regular places of business in the performance of services for the Advisory Board. Notwithstanding section 1342 of title 31, United States Code, the Secretary may accept the voluntary and uncompensated services of the members of the Advisory Board.

"(i) DETAIL OF GOVERNMENT EMPLOYEES.—Any Federal Government employee may be detailed to the Advisory Board without reimbursement, and such detail shall be without interruption or loss of civil service status or privilege.

"(j) STATUS AS PERMANENT ADVISORY COMMITTEE.—Section 14 of the Federal Advisory Committee Act (5 U.S.C. App.) shall not apply to the advisory board.

"(k) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary to carry out this section.

"SEC. 2023. RESEARCH PROTECTIONS.

"(a) GUIDELINES.—The Secretary shall promulgate guidelines to assist researchers working in the area of elder abuse, neglect, and exploitation, with issues relating to human subject protections.

"(b) DEFINITION OF LEGALLY AUTHORIZED REPRESENTATIVE FOR APPLICATION OF REGULATIONS.—For purposes of the application of subpart A of part 46 of title 45, Code of Federal Regulations, to research conducted under this subpart, the term 'legally authorized representative' means, unless otherwise provided by law, the individual or judicial or other body authorized under the applicable law to consent to medical treatment on behalf of another person.

"SEC. 2024. AUTHORIZATION OF APPROPRIATIONS.

"There are authorized to be appropriated to carry out this subpart—

"(1) for fiscal year 2011, $6,500,000; and

"(2) for each of fiscal years 2012 through 2014, $7,000,000.

"Subpart B—Elder Abuse, Neglect, and Exploitation Forensic Centers

"SEC. 2031. ESTABLISHMENT AND SUPPORT OF ELDER ABUSE, NEGLECT, AND EXPLOITATION FORENSIC CENTERS.

"(a) IN GENERAL.—The Secretary, in consultation with the Attorney General, shall make grants to eligible entities to establish and operate stationary and mobile forensic centers, to develop forensic expertise regarding, and provide services relating to, elder abuse, neglect, and exploitation.

"(b) STATIONARY FORENSIC CENTERS.—The Secretary shall make 4 of the grants described in subsection (a) to institutions of higher education with demonstrated expertise in forensics or commitment to preventing or treating elder abuse, neglect, or exploitation, to establish and operate stationary forensic centers.

"(c) MOBILE CENTERS.—The Secretary shall make 6 of the grants described in subsection (a) to appropriate entities to establish and operate mobile forensic centers.

"(d) AUTHORIZED ACTIVITIES.—

"(1) DEVELOPMENT OF FORENSIC MARKERS AND METHODOLOGIES.—An eligible entity that receives a grant under this section shall use funds made available through the grant to assist in determining whether abuse, neglect, or exploitation occurred and whether a crime was committed and to conduct research to describe and disseminate information on—

"(A) forensic markers that indicate a case in which elder abuse, neglect, or exploitation may have occurred; and

"(B) methodologies for determining, in such a case, when and how health care, emergency service, social and protective services, and legal service providers should intervene and when the providers should report the case to law enforcement authorities.

"(2) DEVELOPMENT OF FORENSIC EXPERTISE.—An eligible entity that receives a grant under this section shall use funds made available through the grant to develop forensic expertise regarding elder abuse, neglect, and exploitation in order to provide medical and forensic evaluation, therapeutic intervention, victim support and advocacy, case review, and case tracking.

"(3) COLLECTION OF EVIDENCE.—The Secretary, in coordination with the Attorney General, shall use data made available by grant recipients under this section to develop the capacity of geriatric health care professionals and law enforcement to collect forensic evidence, including collecting forensic evidence relating to a potential determination of elder abuse, neglect, or exploitation.

"(e) APPLICATION.—To be eligible to receive a grant under this section, an entity shall submit an application to the Secretary

at such time, in such manner, and containing such information as the Secretary may require.

"(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section—

"(1) for fiscal year 2011, $4,000,000;

"(2) for fiscal year 2012, $6,000,000; and

"(3) for each of fiscal years 2013 and 2014, $8,000,000.

"PART II—PROGRAMS TO PROMOTE ELDER JUSTICE

"SEC. 2041. ENHANCEMENT OF LONG-TERM CARE.

"(a) GRANTS AND INCENTIVES FOR LONG-TERM CARE STAFFING.—

"(1) IN GENERAL.—The Secretary shall carry out activities, including activities described in paragraphs (2) and (3), to provide incentives for individuals to train for, seek, and maintain employment providing direct care in long-term care.

"(2) SPECIFIC PROGRAMS TO ENHANCE TRAINING, RECRUITMENT, AND RETENTION OF STAFF.—

"(A) COORDINATION WITH SECRETARY OF LABOR TO RECRUIT AND TRAIN LONG-TERM CARE STAFF.—The Secretary shall coordinate activities under this subsection with the Secretary of Labor in order to provide incentives for individuals to train for and seek employment providing direct care in long-term care.

"(B) CAREER LADDERS AND WAGE OR BENEFIT INCREASES TO INCREASE STAFFING IN LONG-TERM CARE.—

"(i) IN GENERAL.—The Secretary shall make grants to eligible entities to carry out programs through which the entities—

"(I) offer, to employees who provide direct care to residents of an eligible entity or individuals receiving community-based long-term care from an eligible entity, continuing training and varying levels of certification, based on observed clinical care practices and the amount of time the employees spend providing direct care; and

"(II) provide, or make arrangements to provide, bonuses or other increased compensation or benefits to employees who achieve certification under such a program.

"(ii) APPLICATION.—To be eligible to receive a grant under this subparagraph, an eligible entity shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require (which may include evidence of consultation with the State in which the eligible entity is located with respect to carrying out activities funded under the grant).

"(iii) AUTHORITY TO LIMIT NUMBER OF APPLICANTS.—Nothing in this subparagraph shall be construed as prohibiting the Secretary from limiting the number of applicants for a grant under this subparagraph.

"(3) SPECIFIC PROGRAMS TO IMPROVE MANAGEMENT PRACTICES.—

"(A) IN GENERAL.—The Secretary shall make grants to eligible entities to enable the entities to provide training and technical assistance.

"(B) AUTHORIZED ACTIVITIES.—An eligible entity that receives a grant under subparagraph (A) shall use funds made available through the grant to provide training and technical assistance regarding management practices using methods that are demonstrated to promote retention of individuals who provide direct care, such as—

"(i) the establishment of standard human resource policies that reward high performance, including policies that provide for improved wages and benefits on the basis of job reviews;

"(ii) the establishment of motivational and thoughtful work organization practices;

"(iii) the creation of a workplace culture that respects and values caregivers and their needs;

"(iv) the promotion of a workplace culture that respects the rights of residents of an eligible entity or individuals receiving community-based long-term care from an eligible entity and results in improved care for the residents or the individuals; and

"(v) the establishment of other programs that promote the provision of high quality care, such as a continuing education program that provides additional hours of training, including on-the-job training, for employees who are certified nurse aides.

"(C) APPLICATION.—To be eligible to receive a grant under this paragraph, an eligible entity shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require (which may include evidence of consultation with the State in which the eligible entity is located with respect to carrying out activities funded under the grant).

"(D) AUTHORITY TO LIMIT NUMBER OF APPLICANTS.—Nothing in this paragraph shall be construed as prohibiting the Secretary from limiting the number of applicants for a grant under this paragraph.

"(4) ACCOUNTABILITY MEASURES.—The Secretary shall develop accountability measures to ensure that the activities conducted using funds made available under this subsection benefit individuals who provide direct care and increase the stability of the long-term care workforce.

"(5) DEFINITIONS.—In this subsection:

"(A) COMMUNITY-BASED LONG-TERM CARE.—The term 'community-based long-term care' has the meaning given such term by the Secretary.

"(B) ELIGIBLE ENTITY.—The term 'eligible entity' means the following:

"(i) A long-term care facility.

"(ii) A community-based long-term care entity (as defined by the Secretary).

"(b) CERTIFIED EHR TECHNOLOGY GRANT PROGRAM.—

"(1) GRANTS AUTHORIZED.—The Secretary is authorized to make grants to long-term care facilities for the purpose of assisting such entities in offsetting the costs related to purchasing, leasing, developing, and implementing certified EHR

technology (as defined in section 1848(o)(4)) designed to improve patient safety and reduce adverse events and health care complications resulting from medication errors.

"(2) USE OF GRANT FUNDS.—Funds provided under grants under this subsection may be used for any of the following:

"(A) Purchasing, leasing, and installing computer software and hardware, including handheld computer technologies.

"(B) Making improvements to existing computer software and hardware.

"(C) Making upgrades and other improvements to existing computer software and hardware to enable e-prescribing.

"(D) Providing education and training to eligible long-term care facility staff on the use of such technology to implement the electronic transmission of prescription and patient information.

"(3) APPLICATION.—

"(A) IN GENERAL.—To be eligible to receive a grant under this subsection, a long-term care facility shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require (which may include evidence of consultation with the State in which the long-term care facility is located with respect to carrying out activities funded under the grant).

"(B) AUTHORITY TO LIMIT NUMBER OF APPLICANTS.—Nothing in this subsection shall be construed as prohibiting the Secretary from limiting the number of applicants for a grant under this subsection.

"(4) PARTICIPATION IN STATE HEALTH EXCHANGES.—A long-term care facility that receives a grant under this subsection shall, where available, participate in activities conducted by a State or a qualified State-designated entity (as defined in section 3013(f) of the Public Health Service Act) under a grant under section 3013 of the Public Health Service Act to coordinate care and for other purposes determined appropriate by the Secretary.

"(5) ACCOUNTABILITY MEASURES.—The Secretary shall develop accountability measures to ensure that the activities conducted using funds made available under this subsection help improve patient safety and reduce adverse events and health care complications resulting from medication errors.

"(c) ADOPTION OF STANDARDS FOR TRANSACTIONS INVOLVING CLINICAL DATA BY LONG-TERM CARE FACILITIES.—

"(1) STANDARDS AND COMPATIBILITY.—The Secretary shall adopt electronic standards for the exchange of clinical data by long-term care facilities, including, where available, standards for messaging and nomenclature. Standards adopted by the Secretary under the preceding sentence shall be compatible with standards established under part C of title XI, standards established under subsections (b)(2)(B)(i) and (e)(4) of section 1860D–4, standards adopted under section 3004 of the Public Health Service Act, and general health information technology standards.

"(2) ELECTRONIC SUBMISSION OF DATA TO THE SECRETARY.—

"(A) IN GENERAL.—Not later than 10 years after the date of enactment of the Elder Justice Act of 2009, the Secretary shall have procedures in place to accept the optional electronic submission of clinical data by long-term care facilities pursuant to the standards adopted under paragraph (1).

"(B) RULE OF CONSTRUCTION.—Nothing in this subsection shall be construed to require a long-term care facility to submit clinical data electronically to the Secretary.

"(3) REGULATIONS.—The Secretary shall promulgate regulations to carry out this subsection. Such regulations shall require a State, as a condition of the receipt of funds under this part, to conduct such data collection and reporting as the Secretary determines are necessary to satisfy the requirements of this subsection.

"(d) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section—

"(1) for fiscal year 2011, $20,000,000;

"(2) for fiscal year 2012, $17,500,000; and

"(3) for each of fiscal years 2013 and 2014, $15,000,000.

"SEC. 2042. ADULT PROTECTIVE SERVICES FUNCTIONS AND GRANT PROGRAMS.

"(a) SECRETARIAL RESPONSIBILITIES.—

"(1) IN GENERAL.—The Secretary shall ensure that the Department of Health and Human Services—

"(A) provides funding authorized by this part to State and local adult protective services offices that investigate reports of the abuse, neglect, and exploitation of elders;

"(B) collects and disseminates data annually relating to the abuse, exploitation, and neglect of elders in coordination with the Department of Justice;

"(C) develops and disseminates information on best practices regarding, and provides training on, carrying out adult protective services;

"(D) conducts research related to the provision of adult protective services; and

"(E) provides technical assistance to States and other entities that provide or fund the provision of adult protective services, including through grants made under subsections (b) and (c).

"(2) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection, $3,000,000 for fiscal year 2011 and $4,000,000 for each of fiscal years 2012 through 2014.

"(b) GRANTS TO ENHANCE THE PROVISION OF ADULT PROTECTIVE SERVICES.—

"(1) ESTABLISHMENT.—There is established an adult protective services grant program under which the Secretary shall annually award grants to States in the amounts calculated under paragraph (2) for the purposes of enhancing adult protective services provided by States and local units of government.

"(2) AMOUNT OF PAYMENT.—

"(A) IN GENERAL.—Subject to the availability of appropriations and subparagraphs (B) and (C), the amount paid to a State for a fiscal year under the program under this

subsection shall equal the amount appropriated for that year to carry out this subsection multiplied by the percentage of the total number of elders who reside in the United States who reside in that State.

"(B) GUARANTEED MINIMUM PAYMENT AMOUNT.—

"(i) 50 STATES.—Subject to clause (ii), if the amount determined under subparagraph (A) for a State for a fiscal year is less than 0.75 percent of the amount appropriated for such year, the Secretary shall increase such determined amount so that the total amount paid under this subsection to the State for the year is equal to 0.75 percent of the amount so appropriated.

"(ii) TERRITORIES.—In the case of a State other than 1 of the 50 States, clause (i) shall be applied as if each reference to '0.75' were a reference to '0.1'.

"(C) PRO RATA REDUCTIONS.—The Secretary shall make such pro rata reductions to the amounts described in subparagraph (A) as are necessary to comply with the requirements of subparagraph (B).

"(3) AUTHORIZED ACTIVITIES.—

"(A) ADULT PROTECTIVE SERVICES.—Funds made available pursuant to this subsection may only be used by States and local units of government to provide adult protective services and may not be used for any other purpose.

"(B) USE BY AGENCY.—Each State receiving funds pursuant to this subsection shall provide such funds to the agency or unit of State government having legal responsibility for providing adult protective services within the State.

"(C) SUPPLEMENT NOT SUPPLANT.—Each State or local unit of government shall use funds made available pursuant to this subsection to supplement and not supplant other Federal, State, and local public funds expended to provide adult protective services in the State.

"(4) STATE REPORTS.—Each State receiving funds under this subsection shall submit to the Secretary, at such time and in such manner as the Secretary may require, a report on the number of elders served by the grants awarded under this subsection.

"(5) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection, $100,000,000 for each of fiscal years 2011 through 2014.

"(c) STATE DEMONSTRATION PROGRAMS.—

"(1) ESTABLISHMENT.—The Secretary shall award grants to States for the purposes of conducting demonstration programs in accordance with paragraph (2).

"(2) DEMONSTRATION PROGRAMS.—Funds made available pursuant to this subsection may be used by States and local units of government to conduct demonstration programs that test—

"(A) training modules developed for the purpose of detecting or preventing elder abuse;

"(B) methods to detect or prevent financial exploitation of elders;

"(C) methods to detect elder abuse;

"(D) whether training on elder abuse forensics enhances the detection of elder abuse by employees of the State or local unit of government; or

"(E) other matters relating to the detection or prevention of elder abuse.

"(3) APPLICATION.—To be eligible to receive a grant under this subsection, a State shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

"(4) STATE REPORTS.—Each State that receives funds under this subsection shall submit to the Secretary a report at such time, in such manner, and containing such information as the Secretary may require on the results of the demonstration program conducted by the State using funds made available under this subsection.

"(5) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection, $25,000,000 for each of fiscal years 2011 through 2014.

"SEC. 2043. LONG-TERM CARE OMBUDSMAN PROGRAM GRANTS AND TRAINING.

"(a) GRANTS TO SUPPORT THE LONG-TERM CARE OMBUDSMAN PROGRAM.—

"(1) IN GENERAL.—The Secretary shall make grants to eligible entities with relevant expertise and experience in abuse and neglect in long-term care facilities or long-term care ombudsman programs and responsibilities, for the purpose of—

"(A) improving the capacity of State long-term care ombudsman programs to respond to and resolve complaints about abuse and neglect;

"(B) conducting pilot programs with State long-term care ombudsman offices or local ombudsman entities; and

"(C) providing support for such State long-term care ombudsman programs and such pilot programs (such as through the establishment of a national long-term care ombudsman resource center).

"(2) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection—

"(A) for fiscal year 2011, $5,000,000;

"(B) for fiscal year 2012, $7,500,000; and

"(C) for each of fiscal years 2013 and 2014, $10,000,000.

"(b) OMBUDSMAN TRAINING PROGRAMS.—

"(1) IN GENERAL.—The Secretary shall establish programs to provide and improve ombudsman training with respect to elder abuse, neglect, and exploitation for national organizations and State long-term care ombudsman programs.

"(2) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection, for each of fiscal years 2011 through 2014, $10,000,000.

"SEC. 2044. PROVISION OF INFORMATION REGARDING, AND EVALUATIONS OF, ELDER JUSTICE PROGRAMS.

"(a) PROVISION OF INFORMATION.—To be eligible to receive a grant under this part, an applicant shall agree—

"(1) except as provided in paragraph (2), to provide the eligible entity conducting an evaluation under subsection (b) of the activities funded through the grant with such information

as the eligible entity may require in order to conduct such evaluation; or

"(2) in the case of an applicant for a grant under section 2041(b), to provide the Secretary with such information as the Secretary may require to conduct an evaluation or audit under subsection (c).

"(b) USE OF ELIGIBLE ENTITIES TO CONDUCT EVALUATIONS.—

"(1) EVALUATIONS REQUIRED.—Except as provided in paragraph (2), the Secretary shall—

"(A) reserve a portion (not less than 2 percent) of the funds appropriated with respect to each program carried out under this part; and

"(B) use the funds reserved under subparagraph (A) to provide assistance to eligible entities to conduct evaluations of the activities funded under each program carried out under this part.

"(2) CERTIFIED EHR TECHNOLOGY GRANT PROGRAM NOT INCLUDED.—The provisions of this subsection shall not apply to the certified EHR technology grant program under section 2041(b).

"(3) AUTHORIZED ACTIVITIES.—A recipient of assistance described in paragraph (1)(B) shall use the funds made available through the assistance to conduct a validated evaluation of the effectiveness of the activities funded under a program carried out under this part.

"(4) APPLICATIONS.—To be eligible to receive assistance under paragraph (1)(B), an entity shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require, including a proposal for the evaluation.

"(5) REPORTS.—Not later than a date specified by the Secretary, an eligible entity receiving assistance under paragraph (1)(B) shall submit to the Secretary, the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives, and the Committee on Finance of the Senate a report containing the results of the evaluation conducted using such assistance together with such recommendations as the entity determines to be appropriate.

"(c) EVALUATIONS AND AUDITS OF CERTIFIED EHR TECHNOLOGY GRANT PROGRAM BY THE SECRETARY.—

"(1) EVALUATIONS.—The Secretary shall conduct an evaluation of the activities funded under the certified EHR technology grant program under section 2041(b). Such evaluation shall include an evaluation of whether the funding provided under the grant is expended only for the purposes for which it is made.

"(2) AUDITS.—The Secretary shall conduct appropriate audits of grants made under section 2041(b).

"SEC. 2045. REPORT.

"Not later than October 1, 2014, the Secretary shall submit to the Elder Justice Coordinating Council established under section 2021, the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives, and the Committee on Finance of the Senate a report—

"(1) compiling, summarizing, and analyzing the information contained in the State reports submitted under subsections (b)(4) and (c)(4) of section 2042; and

"(2) containing such recommendations for legislative or administrative action as the Secretary determines to be appropriate.

"SEC. 2046. RULE OF CONSTRUCTION.

"Nothing in this subtitle shall be construed as—

"(1) limiting any cause of action or other relief related to obligations under this subtitle that is available under the law of any State, or political subdivision thereof; or

"(2) creating a private cause of action for a violation of this subtitle.".

(2) OPTION FOR STATE PLAN UNDER PROGRAM FOR TEMPORARY ASSISTANCE FOR NEEDY FAMILIES.—

(A) IN GENERAL.—Section 402(a)(1)(B) of the Social Security Act (42 U.S.C. 602(a)(1)(B)) is amended by adding at the end the following new clause:

"(v) The document shall indicate whether the State intends to assist individuals to train for, seek, and maintain employment—

"(I) providing direct care in a long-term care facility (as such terms are defined under section 2011); or

"(II) in other occupations related to elder care determined appropriate by the State for which the State identifies an unmet need for service personnel,

and, if so, shall include an overview of such assistance.".

(B) EFFECTIVE DATE.—The amendment made by subparagraph (A) shall take effect on January 1, 2011.

(b) PROTECTING RESIDENTS OF LONG-TERM CARE FACILITIES.—

(1) NATIONAL TRAINING INSTITUTE FOR SURVEYORS.—

(A) IN GENERAL.—The Secretary of Health and Human Services shall enter into a contract with an entity for the purpose of establishing and operating a National Training Institute for Federal and State surveyors. Such Institute shall provide and improve the training of surveyors with respect to investigating allegations of abuse, neglect, and misappropriation of property in programs and long-term care facilities that receive payments under title XVIII or XIX of the Social Security Act.

(B) ACTIVITIES CARRIED OUT BY THE INSTITUTE.—The contract entered into under subparagraph (A) shall require the Institute established and operated under such contract to carry out the following activities:

(i) Assess the extent to which State agencies use specialized surveyors for the investigation of reported allegations of abuse, neglect, and misappropriation of property in such programs and long-term care facilities.

(ii) Evaluate how the competencies of surveyors may be improved to more effectively investigate reported allegations of such abuse, neglect, and misappropriation of property, and provide feedback to Federal and State agencies on the evaluations conducted.

(iii) Provide a national program of training, tools, and technical assistance to Federal and State surveyors on investigating reports of such abuse, neglect, and misappropriation of property.

(iv) Develop and disseminate information on best practices for the investigation of such abuse, neglect, and misappropriation of property.

(v) Assess the performance of State complaint intake systems, in order to ensure that the intake of complaints occurs 24 hours per day, 7 days a week (including holidays).

(vi) To the extent approved by the Secretary of Health and Human Services, provide a national 24 hours per day, 7 days a week (including holidays), back-up system to State complaint intake systems in order to ensure optimum national responsiveness to complaints of such abuse, neglect, and misappropriation of property.

(vii) Analyze and report annually on the following:

(I) The total number and sources of complaints of such abuse, neglect, and misappropriation of property.

(II) The extent to which such complaints are referred to law enforcement agencies.

(III) General results of Federal and State investigations of such complaints.

(viii) Conduct a national study of the cost to State agencies of conducting complaint investigations of skilled nursing facilities and nursing facilities under sections 1819 and 1919, respectively, of the Social Security Act (42 U.S.C. 1395i–3; 1396r), and making recommendations to the Secretary of Health and Human Services with respect to options to increase the efficiency and cost-effectiveness of such investigations.

(C) AUTHORIZATION.—There are authorized to be appropriated to carry out this paragraph, for the period of fiscal years 2011 through 2014, $12,000,000.

(2) GRANTS TO STATE SURVEY AGENCIES.—

(A) IN GENERAL.—The Secretary of Health and Human Services shall make grants to State agencies that perform surveys of skilled nursing facilities or nursing facilities under sections 1819 or 1919, respectively, of the Social Security Act (42 U.S.C. 1395i–3; 1395r).

(B) USE OF FUNDS.—A grant awarded under subparagraph (A) shall be used for the purpose of designing and implementing complaint investigations systems that—

(i) promptly prioritize complaints in order to ensure a rapid response to the most serious and urgent complaints;

(ii) respond to complaints with optimum effectiveness and timeliness; and

(iii) optimize the collaboration between local authorities, consumers, and providers, including—

(I) such State agency;

(II) the State Long-Term Care Ombudsman;

(III) local law enforcement agencies;

(IV) advocacy and consumer organizations;

(V) State aging units;
(VI) Area Agencies on Aging; and
(VII) other appropriate entities.

(C) AUTHORIZATION.—There are authorized to be appropriated to carry out this paragraph, for each of fiscal years 2011 through 2014, $5,000,000.

(3) REPORTING OF CRIMES IN FEDERALLY FUNDED LONG-TERM CARE FACILITIES.—Part A of title XI of the Social Security Act (42 U.S.C. 1301 et seq.), as amended by section 6005, is amended by inserting after section 1150A the following new section:

"REPORTING TO LAW ENFORCEMENT OF CRIMES OCCURRING IN FEDERALLY FUNDED LONG-TERM CARE FACILITIES

"SEC. 1150B. (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.".

(c) NATIONAL NURSE AIDE REGISTRY.—

(1) DEFINITION OF NURSE AIDE.—In this subsection, the term "nurse aide" has the meaning given that term in sections 1819(b)(5)(F) and 1919(b)(5)(F) of the Social Security Act (42 U.S.C. 1395i–3(b)(5)(F); 1396r(b)(5)(F)).

(2) STUDY AND REPORT.—

(A) IN GENERAL.—The Secretary, in consultation with appropriate government agencies and private sector organizations, shall conduct a study on establishing a national nurse aide registry.

(B) AREAS EVALUATED.—The study conducted under this subsection shall include an evaluation of—

(i) who should be included in the registry;

(ii) how such a registry would comply with Federal and State privacy laws and regulations;

(iii) how data would be collected for the registry;

(iv) what entities and individuals would have access to the data collected;

(v) how the registry would provide appropriate information regarding violations of Federal and State law by individuals included in the registry;

(vi) how the functions of a national nurse aide registry would be coordinated with the nationwide program for national and State background checks on direct patient access employees of long-term care facilities and providers under section 4301; and

(vii) how the information included in State nurse aide registries developed and maintained under sections 1819(e)(2) and 1919(e)(2) of the Social Security Act (42 U.S.C. 1395i–3(e)(2); 1396r(e)(2)(2)) would be provided as part of a national nurse aide registry.

(C) CONSIDERATIONS.—In conducting the study and preparing the report required under this subsection, the Secretary shall take into consideration the findings and conclusions of relevant reports and other relevant resources, including the following:

(i) The Department of Health and Human Services Office of Inspector General Report, Nurse Aide Registries: State Compliance and Practices (February 2005).

(ii) The General Accounting Office (now known as the Government Accountability Office) Report, Nursing Homes: More Can Be Done to Protect Residents from Abuse (March 2002).

(iii) The Department of Health and Human Services Office of the Inspector General Report, Nurse Aide Registries: Long-Term Care Facility Compliance and Practices (July 2005).

(iv) The Department of Health and Human Services Health Resources and Services Administration Report, Nursing Aides, Home Health Aides, and Related Health Care Occupations—National and Local Workforce Shortages and Associated Data Needs (2004) (in particular with respect to chapter 7 and appendix F).

(v) The 2001 Report to CMS from the School of Rural Public Health, Texas A&M University, Preventing Abuse and Neglect in Nursing Homes: The Role of Nurse Aide Registries.

(vi) Information included in State nurse aide registries developed and maintained under sections 1819(e)(2) and 1919(e)(2) of the Social Security Act (42 U.S.C. 1395i–3(e)(2); 1396r(e)(2)(2)).

(D) REPORT.—Not later than 18 months after the date of enactment of this Act, the Secretary shall submit to the Elder Justice Coordinating Council established under section 2021 of the Social Security Act, as added by section 1805(a), the Committee on Finance of the Senate, and the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives a report containing the findings and recommendations of the study conducted under this paragraph.

(E) FUNDING LIMITATION.—Funding for the study conducted under this subsection shall not exceed $500,000.

(3) CONGRESSIONAL ACTION.—After receiving the report submitted by the Secretary under paragraph (2)(D), the Committee on Finance of the Senate and the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives shall, as they deem appropriate, take action based on the recommendations contained in the report.

(4) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as are necessary for the purpose of carrying out this subsection.

(d) CONFORMING AMENDMENTS.—

(1) TITLE XX.—Title XX of the Social Security Act (42 U.S.C. 1397 et seq.), as amended by section 6703(a), is amended—

(A) in the heading of section 2001, by striking "TITLE" and inserting "SUBTITLE"; and

(B) in subtitle 1, by striking "this title" each place it appears and inserting "this subtitle".

(2) TITLE IV.—Title IV of the Social Security Act (42 U.S.C. 601 et seq.) is amended—

(A) in section 404(d)—

(i) in paragraphs (1)(A), (2)(A), and (3)(B), by inserting "subtitle 1 of" before "title XX" each place it appears;

(ii) in the heading of paragraph (2), by inserting "SUBTITLE 1 OF" before "TITLE XX"; and

(iii) in the heading of paragraph (3)(B), by inserting "SUBTITLE 1 OF" before "TITLE XX"; and

(B) in sections 422(b), 471(a)(4), 472(h)(1), and 473(b)(2), by inserting "subtitle 1 of" before "title XX" each place it appears.

(3) TITLE XI.—Title XI of the Social Security Act (42 U.S.C. 1301 et seq.) is amended—

(A) in section 1128(h)(3)—

(i) by inserting "subtitle 1 of" before "title XX"; and

(ii) by striking "such title" and inserting "such subtitle"; and

(B) in section 1128A(i)(1), by inserting "subtitle 1 of" before "title XX".

Subtitle I—Sense of the Senate Regarding Medical Malpractice

SEC. 6801. SENSE OF THE SENATE REGARDING MEDICAL MALPRACTICE.

It is the sense of the Senate that—

(1) health care reform presents an opportunity to address issues related to medical malpractice and medical liability insurance;

(2) States should be encouraged to develop and test alternatives to the existing civil litigation system as a way of improving patient safety, reducing medical errors, encouraging the efficient resolution of disputes, increasing the availability of prompt and fair resolution of disputes, and improving access to liability insurance, while preserving an individual's right to seek redress in court; and

(3) Congress should consider establishing a State demonstration program to evaluate alternatives to the existing civil litigation system with respect to the resolution of medical malpractice claims.

TITLE VII—IMPROVING ACCESS TO INNOVATIVE MEDICAL THERAPIES

Subtitle A—Biologics Price Competition and Innovation

SEC. 7001. SHORT TITLE.

(a) IN GENERAL.—This subtitle may be cited as the "Biologics Price Competition and Innovation Act of 2009".

(b) SENSE OF THE SENATE.—It is the sense of the Senate that a biosimilars pathway balancing innovation and consumer interests should be established.

SEC. 7002. APPROVAL PATHWAY FOR BIOSIMILAR BIOLOGICAL PRODUCTS.

(a) LICENSURE OF BIOLOGICAL PRODUCTS AS BIOSIMILAR OR INTERCHANGEABLE.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended—

(1) in subsection (a)(1)(A), by inserting "under this subsection or subsection (k)" after "biologics license"; and

(2) by adding at the end the following: