

H.R.3590

Patient Protection and Affordable Care Act (Enrolled as Agreed to or Passed by Both House and Senate)

TITLE V--HEALTH CARE WORKFORCE

Subtitle A--Purpose and Definitions

SEC. 5001. PURPOSE.

The purpose of this title is to improve access to and the delivery of health care services for all individuals, particularly low income, underserved, uninsured, minority, health disparity, and rural populations by--

- (1) gathering and assessing comprehensive data in order for the health care workforce to meet the health care needs of individuals, including research on the supply, demand, distribution, diversity, and skills needs of the health care workforce;
- (2) increasing the supply of a qualified health care workforce to improve access to and the delivery of health care services for all individuals;
- (3) enhancing health care workforce education and training to improve access to and the delivery of health care services for all individuals; and
- (4) providing support to the existing health care workforce to improve access to and the delivery of health care services for all individuals.

SEC. 5002. DEFINITIONS.

(a) This Title- In this title:

(1) ALLIED HEALTH PROFESSIONAL- The term `allied health professional' means an allied health professional as defined in section 799B(5) of the Public Health Service Act (42 U.S.C. 295p(5)) who--

- (A) has graduated and received an allied health professions degree or certificate from an institution of higher education; and
- (B) is employed with a Federal, State, local or tribal public health agency, or in a setting where patients might require health care services, including acute care facilities, ambulatory care facilities, personal residences, and other settings located in health professional shortage areas, medically underserved areas, or medically underserved populations, as recognized by the Secretary of Health and Human Services.

(2) HEALTH CARE CAREER PATHWAY- The term `healthcare career pathway' means a rigorous, engaging, and high quality set of courses and services that--

- (A) includes an articulated sequence of academic and career courses, including 21st century skills;
- (B) is aligned with the needs of healthcare industries in a region or State;
- (C) prepares students for entry into the full range of postsecondary education options, including registered apprenticeships, and careers;
- (D) provides academic and career counseling in student-to-counselor ratios that allow students to make informed decisions about academic and career options;
- (E) meets State academic standards, State requirements for secondary school graduation and is aligned with requirements for entry into

postsecondary education, and applicable industry standards; and

(F) leads to 2 or more credentials, including--

(i) a secondary school diploma; and

(ii) a postsecondary degree, an apprenticeship or other occupational certification, a certificate, or a license.

(3) INSTITUTION OF HIGHER EDUCATION- The term 'institution of higher education' has the meaning given the term in sections 101 and 102 of the Higher Education Act of 1965 (20 U.S.C. 1001 and 1002).

(4) LOW INCOME INDIVIDUAL, STATE WORKFORCE INVESTMENT BOARD, AND LOCAL WORKFORCE INVESTMENT BOARD-

(A) LOW-INCOME INDIVIDUAL- The term 'low-income individual' has the meaning given that term in section 101 of the Workforce investment Act of 1998 (29 U.S.C. 2801).

(B) STATE WORKFORCE INVESTMENT BOARD; LOCAL WORKFORCE INVESTMENT BOARD-

The terms 'State workforce investment board' and 'local workforce investment board', refer to a State workforce investment board established under section 111 of the Workforce Investment Act of 1998 (29 U.S.C. 2821) and a local workforce investment board established under section 117 of such Act (29 U.S.C. 2832), respectively.

(5) POSTSECONDARY EDUCATION- The term 'postsecondary education' means--

(A) a 4-year program of instruction, or not less than a 1-year program of instruction that is acceptable for credit toward an associate or a baccalaureate degree, offered by an institution of higher education; or

(B) a certificate or registered apprenticeship program at the postsecondary level offered by an institution of higher education or a non-profit educational institution.

(6) REGISTERED APPRENTICESHIP PROGRAM- The term 'registered apprenticeship program' means an industry skills training program at the postsecondary level that combines technical and theoretical training through structure on the job learning with related instruction (in a classroom or through distance learning) while an individual is employed, working under the direction of qualified personnel or a mentor, and earning incremental wage increases aligned to enhance job proficiency, resulting in the acquisition of a nationally recognized and portable certificate, under a plan approved by the Office of Apprenticeship or a State agency recognized by the Department of Labor.

(b) Title VII of the Public Health Service Act- Section 799B of the Public Health Service Act (42 U.S.C. 295p) is amended--

(1) by striking paragraph (3) and inserting the following:

'(3) PHYSICIAN ASSISTANT EDUCATION PROGRAM- The term 'physician assistant education program' means an educational program in a public or private institution in a State that--

'(A) has as its objective the education of individuals who, upon completion of their studies in the program, be qualified to provide primary care medical services with the supervision of a physician; and

'(B) is accredited by the Accreditation Review Commission on Education for the Physician Assistant.'; and

(2) by adding at the end the following:

`(12) AREA HEALTH EDUCATION CENTER- The term `area health education center' means a public or nonprofit private organization that has a cooperative agreement or contract in effect with an entity that has received an award under subsection (a)(1) or (a)(2) of section 751, satisfies the requirements in section 751(d)(1), and has as one of its principal functions the operation of an area health education center. Appropriate organizations may include hospitals, health organizations with accredited primary care training programs, accredited physician assistant educational programs associated with a college or university, and universities or colleges not operating a school of medicine or osteopathic medicine.

`(13) AREA HEALTH EDUCATION CENTER PROGRAM- The term `area health education center program' means cooperative program consisting of an entity that has received an award under subsection (a)(1) or (a)(2) of section 751 for the purpose of planning, developing, operating, and evaluating an area health education center program and one or more area health education centers, which carries out the required activities described in section 751(c), satisfies the program requirements in such section, has as one of its principal functions identifying and implementing strategies and activities that address health care workforce needs in its service area, in coordination with the local workforce investment boards.

`(14) CLINICAL SOCIAL WORKER- The term `clinical social worker' has the meaning given the term in section 1861(hh)(1) of the Social Security Act (42 U.S.C. 1395x(hh)(1)).

`(15) CULTURAL COMPETENCY- The term `cultural competency' shall be defined by the Secretary in a manner consistent with section 1707(d)(3).

`(16) DIRECT CARE WORKER- The term `direct care worker' has the meaning given that term in the 2010 Standard Occupational Classifications of the Department of Labor for Home Health Aides [31-1011], Psychiatric Aides [31-1013], Nursing Assistants [31-1014], and Personal Care Aides [39-9021].

`(17) FEDERALLY QUALIFIED HEALTH CENTER- The term `Federally qualified health center' has the meaning given that term in section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa)).

`(18) FRONTIER HEALTH PROFESSIONAL SHORTAGE AREA- The term `frontier health professional shortage area' means an area--

`(A) with a population density less than 6 persons per square mile within the service area; and

`(B) with respect to which the distance or time for the population to access care is excessive.

`(19) GRADUATE PSYCHOLOGY- The term `graduate psychology' means an accredited program in professional psychology.

`(20) HEALTH DISPARITY POPULATION- The term `health disparity population' has the meaning given such term in section 903(d)(1).

`(21) HEALTH LITERACY- The term `health literacy' means the degree to which an individual has the capacity to obtain, communicate, process, and understand health information and services in order to make appropriate health decisions.

`(22) MENTAL HEALTH SERVICE PROFESSIONAL- The term `mental health service professional' means an individual with a graduate or postgraduate degree

from an accredited institution of higher education in psychiatry, psychology, school psychology, behavioral pediatrics, psychiatric nursing, social work, school social work, substance abuse disorder prevention and treatment, marriage and family counseling, school counseling, or professional counseling.

`(23) ONE-STOP DELIVERY SYSTEM CENTER- The term `one-stop delivery system' means a one-stop delivery system described in section 134(c) of the Workforce Investment Act of 1998 (29 U.S.C. 2864(c)).

`(24) PARAPROFESSIONAL CHILD AND ADOLESCENT MENTAL HEALTH WORKER- The term `paraprofessional child and adolescent mental health worker' means an individual who is not a mental or behavioral health service professional, but who works at the first stage of contact with children and families who are seeking mental or behavioral health services, including substance abuse prevention and treatment services.

`(25) RACIAL AND ETHNIC MINORITY GROUP; RACIAL AND ETHNIC MINORITY POPULATION- The terms `racial and ethnic minority group' and `racial and ethnic minority population' have the meaning given the term `racial and ethnic minority group' in section 1707.

`(26) RURAL HEALTH CLINIC- The term `rural health clinic' has the meaning given that term in section 1861(aa) of the Social Security Act (42 U.S.C. 1395x(aa)).'

(c) Title VIII of the Public Health Service Act- Section 801 of the Public Health Service Act (42 U.S.C. 296) is amended--

(1) in paragraph (2)--

(A) by striking `means a' and inserting `means an accredited (as defined in paragraph 6)'; and

(B) by striking the period as inserting the following: `where graduates are--

`(A) authorized to sit for the National Council Licensure EXamination-Registered Nurse (NCLEX-RN); or

`(B) licensed registered nurses who will receive a graduate or equivalent degree or training to become an advanced education nurse as defined by section 811(b).'; and

(2) by adding at the end the following:

`(16) ACCELERATED NURSING DEGREE PROGRAM- The term `accelerated nursing degree program' means a program of education in professional nursing offered by an accredited school of nursing in which an individual holding a bachelors degree in another discipline receives a BSN or MSN degree in an accelerated time frame as determined by the accredited school of nursing.

`(17) BRIDGE OR DEGREE COMPLETION PROGRAM- The term `bridge or degree completion program' means a program of education in professional nursing offered by an accredited school of nursing, as defined in paragraph (2), that leads to a baccalaureate degree in nursing. Such programs may include, Registered Nurse (RN) to Bachelor's of Science of Nursing (BSN) programs, RN to MSN (Master of Science of Nursing) programs, or BSN to Doctoral programs.'

Subtitle B--Innovations in the Health Care Workforce

SEC. 5101. NATIONAL HEALTH CARE WORKFORCE COMMISSION.

(a) Purpose- It is the purpose of this section to establish a National Health Care Workforce Commission that--

- (1) serves as a national resource for Congress, the President, States, and localities;
- (2) communicates and coordinates with the Departments of Health and Human Services, Labor, Veterans Affairs, Homeland Security, and Education on related activities administered by one or more of such Departments;
- (3) develops and commissions evaluations of education and training activities to determine whether the demand for health care workers is being met;
- (4) identifies barriers to improved coordination at the Federal, State, and local levels and recommend ways to address such barriers; and
- (5) encourages innovations to address population needs, constant changes in technology, and other environmental factors.

(b) Establishment- There is hereby established the National Health Care Workforce Commission (in this section referred to as the 'Commission').

(c) Membership-

(1) NUMBER AND APPOINTMENT- The Commission shall be composed of 15 members to be appointed by the Comptroller General, without regard to section 5 of the Federal Advisory Committee Act (5 U.S.C. App.).

(2) QUALIFICATIONS-

(A) IN GENERAL- The membership of the Commission shall include individuals--

- (i) with national recognition for their expertise in health care labor market analysis, including health care workforce analysis; health care finance and economics; health care facility management; health care plans and integrated delivery systems; health care workforce education and training; health care philanthropy; providers of health care services; and other related fields; and
- (ii) who will provide a combination of professional perspectives, broad geographic representation, and a balance between urban, suburban, rural, and frontier representatives.

(B) INCLUSION-

(i) IN GENERAL- The membership of the Commission shall include no less than one representative of--

- (I) the health care workforce and health professionals;
- (II) employers;
- (III) third-party payers;
- (IV) individuals skilled in the conduct and interpretation of health care services and health economics research;
- (V) representatives of consumers;
- (VI) labor unions;
- (VII) State or local workforce investment boards; and
- (VIII) educational institutions (which may include elementary and secondary institutions, institutions of higher education, including 2 and 4 year institutions, or registered apprenticeship programs).

(ii) ADDITIONAL MEMBERS- The remaining membership may include additional representatives from clause (i) and other individuals as determined

appropriate by the Comptroller General of the United States.

(C) MAJORITY NON-PROVIDERS- Individuals who are directly involved in health professions education or practice shall not constitute a majority of the membership of the Commission.

(D) ETHICAL DISCLOSURE- The Comptroller General shall establish a system for public disclosure by members of the Commission of financial and other potential conflicts of interest relating to such members. Members of the Commission shall be treated as employees of Congress for purposes of applying title I of the Ethics in Government Act of 1978. Members of the Commission shall not be treated as special government employees under title 18, United States Code.

(3) TERMS-

(A) IN GENERAL- The terms of members of the Commission shall be for 3 years except that the Comptroller General shall designate staggered terms for the members first appointed.

(B) VACANCIES- Any member appointed to fill a vacancy occurring before the expiration of the term for which the member's predecessor was appointed shall be appointed only for the remainder of that term. A member may serve after the expiration of that member's term until a successor has taken office. A vacancy in the Commission shall be filled in the manner in which the original appointment was made.

(C) INITIAL APPOINTMENTS- The Comptroller General shall make initial appointments of members to the Commission not later than September 30, 2010.

(4) COMPENSATION- While serving on the business of the Commission (including travel time), a member of the Commission shall be entitled to compensation at the per diem equivalent of the rate provided for level IV of the Executive Schedule under section 5315 of title 5, United States Code, and while so serving away from home and the member's regular place of business, a member may be allowed travel expenses, as authorized by the Chairman of the Commission. Physicians serving as personnel of the Commission may be provided a physician comparability allowance by the Commission in the same manner as Government physicians may be provided such an allowance by an agency under section 5948 of title 5, United States Code, and for such purpose subsection (i) of such section shall apply to the Commission in the same manner as it applies to the Tennessee Valley Authority. For purposes of pay (other than pay of members of the Commission) and employment benefits, rights, and privileges, all personnel of the Commission shall be treated as if they were employees of the United States Senate. Personnel of the Commission shall not be treated as employees of the Government Accountability Office for any purpose.

(5) CHAIRMAN, VICE CHAIRMAN- The Comptroller General shall designate a member of the Commission, at the time of appointment of the member, as Chairman and a member as Vice Chairman for that term of appointment, except that in the case of vacancy of the chairmanship or vice chairmanship, the Comptroller General may designate another member for the remainder of that member's term.

(6) MEETINGS- The Commission shall meet at the call of the chairman, but no

less frequently than on a quarterly basis.

(d) Duties-

(1) RECOGNITION, DISSEMINATION, AND COMMUNICATION- The Commission shall--

- (A) recognize efforts of Federal, State, and local partnerships to develop and offer health care career pathways of proven effectiveness;
- (B) disseminate information on promising retention practices for health care professionals; and
- (C) communicate information on important policies and practices that affect the recruitment, education and training, and retention of the health care workforce.

(2) REVIEW OF HEALTH CARE WORKFORCE AND ANNUAL REPORTS- In order to develop a fiscally sustainable integrated workforce that supports a high-quality, readily accessible health care delivery system that meets the needs of patients and populations, the Commission, in consultation with relevant Federal, State, and local agencies, shall--

- (A) review current and projected health care workforce supply and demand, including the topics described in paragraph (3);
- (B) make recommendations to Congress and the Administration concerning national health care workforce priorities, goals, and policies;
- (C) by not later than October 1 of each year (beginning with 2011), submit a report to Congress and the Administration containing the results of such reviews and recommendations concerning related policies; and
- (D) by not later than April 1 of each year (beginning with 2011), submit a report to Congress and the Administration containing a review of, and recommendations on, at a minimum one high priority area as described in paragraph (4).

(3) SPECIFIC TOPICS TO BE REVIEWED- The topics described in this paragraph include--

- (A) current health care workforce supply and distribution, including demographics, skill sets, and demands, with projected demands during the subsequent 10 and 25 year periods;
- (B) health care workforce education and training capacity, including the number of students who have completed education and training, including registered apprenticeships; the number of qualified faculty; the education and training infrastructure; and the education and training demands, with projected demands during the subsequent 10 and 25 year periods;
- (C) the education loan and grant programs in titles VII and VIII of the Public Health Service Act (42 U.S.C. 292 et seq. and 296 et seq.), with recommendations on whether such programs should become part of the Higher Education Act of 1965 (20 U.S.C. 1001 et seq);
- (D) the implications of new and existing Federal policies which affect the health care workforce, including Medicare and Medicaid graduate medical education policies, titles VII and VIII of the Public Health Service Act (42 U.S.C. 292 et seq. and 296 et seq.), the National Health Service Corps (with recommendations for aligning such programs with national health workforce priorities and goals), and other health care workforce programs, including those supported through the Workforce Investment Act of 1998 (29 U.S.C. 2801 et seq.), the Carl D. Perkins Career and Technical Education

Act of 2006 (20 U.S.C. 2301 et seq.), the Higher Education Act of 1965 (20 U.S.C. 1001 et seq.), and any other Federal health care workforce programs;

- (E) the health care workforce needs of special populations, such as minorities, rural populations, medically underserved populations, gender specific needs, individuals with disabilities, and geriatric and pediatric populations with recommendations for new and existing Federal policies to meet the needs of these special populations; and
- (F) recommendations creating or revising national loan repayment programs and scholarship programs to require low-income, minority medical students to serve in their home communities, if designated as medical underserved community.

(4) HIGH PRIORITY AREAS-

(A) IN GENERAL- The initial high priority topics described in this paragraph include each of the following:

- (i) Integrated health care workforce planning that identifies health care professional skills needed and maximizes the skill sets of health care professionals across disciplines.
- (ii) An analysis of the nature, scopes of practice, and demands for health care workers in the enhanced information technology and management workplace.
- (iii) An analysis of how to align Medicare and Medicaid graduate medical education policies with national workforce goals.
- (iv) The education and training capacity, projected demands, and integration with the health care delivery system of each of the following:
 - (I) Nursing workforce capacity at all levels.
 - (II) Oral health care workforce capacity at all levels.
 - (III) Mental and behavioral health care workforce capacity at all levels.
 - (IV) Allied health and public health care workforce capacity at all levels.
 - (V) Emergency medical service workforce capacity, including the retention and recruitment of the volunteer workforce, at all levels.
 - (VI) The geographic distribution of health care providers as compared to the identified health care workforce needs of States and regions.

(B) FUTURE DETERMINATIONS- The Commission may require that additional topics be included under subparagraph (A). The appropriate committees of Congress may recommend to the Commission the inclusion of other topics for health care workforce development areas that require special attention.

(5) GRANT PROGRAM- The Commission shall--

- (A) review implementation progress reports on, and report to Congress about, the State Health Care Workforce Development Grant program established in section 5102;
- (B) in collaboration with the Department of Labor and in coordination with the Department of Education and other relevant Federal agencies, make recommendations to the fiscal and administrative agent under section 5102(b) for grant recipients under section 5102;

(C) assess the implementation of the grants under such section; and
(D) collect performance and report information, including identified models and best practices, on grants from the fiscal and administrative agent under such section and distribute this information to Congress, relevant Federal agencies, and to the public.

(6) STUDY- The Commission shall study effective mechanisms for financing education and training for careers in health care, including public health and allied health.

(7) RECOMMENDATIONS- The Commission shall submit recommendations to Congress, the Department of Labor, and the Department of Health and Human Services about improving safety, health, and worker protections in the workplace for the health care workforce.

(8) ASSESSMENT- The Commission shall assess and receive reports from the National Center for Health Care Workforce Analysis established under section 761(b) of the Public Service Health Act (as amended by section 5103).

(e) Consultation With Federal, State, and Local Agencies, Congress, and Other Organizations-

(1) IN GENERAL- The Commission shall consult with Federal agencies (including the Departments of Health and Human Services, Labor, Education, Commerce, Agriculture, Defense, and Veterans Affairs and the Environmental Protection Agency), Congress, the Medicare Payment Advisory Commission, the Medicaid and CHIP Payment and Access Commission, and, to the extent practicable, with State and local agencies, Indian tribes, voluntary health care organizations, professional societies, and other relevant public-private health care partnerships.

(2) OBTAINING OFFICIAL DATA- The Commission, consistent with established privacy rules, may secure directly from any department or agency of the Executive Branch information necessary to enable the Commission to carry out this section.

(3) DETAIL OF FEDERAL GOVERNMENT EMPLOYEES- An employee of the Federal Government may be detailed to the Commission without reimbursement. The detail of such an employee shall be without interruption or loss of civil service status.

(f) Director and Staff; Experts and Consultants- Subject to such review as the Comptroller General of the United States determines to be necessary to ensure the efficient administration of the Commission, the Commission may--

(1) employ and fix the compensation of an executive director that shall not exceed the rate of basic pay payable for level V of the Executive Schedule and such other personnel as may be necessary to carry out its duties (without regard to the provisions of title 5, United States Code, governing appointments in the competitive service);

(2) seek such assistance and support as may be required in the performance of its duties from appropriate Federal departments and agencies;

(3) enter into contracts or make other arrangements, as may be necessary for the conduct of the work of the Commission (without regard to section 3709 of the Revised Statutes (41 U.S.C. 5));

(4) make advance, progress, and other payments which relate to the work of the Commission;

- (5) provide transportation and subsistence for persons serving without compensation; and
- (6) prescribe such rules and regulations as the Commission determines to be necessary with respect to the internal organization and operation of the Commission.

(g) Powers-

(1) DATA COLLECTION- In order to carry out its functions under this section, the Commission shall--

(A) utilize existing information, both published and unpublished, where possible, collected and assessed either by its own staff or under other arrangements made in accordance with this section, including coordination with the Bureau of Labor Statistics;

(B) carry out, or award grants or contracts for the carrying out of, original research and development, where existing information is inadequate, and

(C) adopt procedures allowing interested parties to submit information for the Commission's use in making reports and recommendations.

(2) ACCESS OF THE GOVERNMENT ACCOUNTABILITY OFFICE TO INFORMATION- The Comptroller General of the United States shall have unrestricted access to all deliberations, records, and data of the Commission, immediately upon request.

(3) PERIODIC AUDIT- The Commission shall be subject to periodic audit by an independent public accountant under contract to the Commission.

(h) Authorization of Appropriations-

(1) REQUEST FOR APPROPRIATIONS- The Commission shall submit requests for appropriations in the same manner as the Comptroller General of the United States submits requests for appropriations. Amounts so appropriated for the Commission shall be separate from amounts appropriated for the Comptroller General.

(2) AUTHORIZATION- There are authorized to be appropriated such sums as may be necessary to carry out this section.

(3) GIFTS AND SERVICES- The Commission may not accept gifts, bequeaths, or donations of property, but may accept and use donations of services for purposes of carrying out this section.

(i) Definitions- In this section:

(1) HEALTH CARE WORKFORCE- The term `health care workforce' includes all health care providers with direct patient care and support responsibilities, such as physicians, nurses, nurse practitioners, primary care providers, preventive medicine physicians, optometrists, ophthalmologists, physician assistants, pharmacists, dentists, dental hygienists, and other oral healthcare professionals, allied health professionals, doctors of chiropractic, community health workers, health care paraprofessionals, direct care workers, psychologists and other behavioral and mental health professionals (including substance abuse prevention and treatment providers), social workers, physical and occupational therapists, certified nurse midwives, podiatrists, the EMS workforce (including professional and volunteer ambulance personnel and firefighters who perform emergency medical services), licensed complementary and alternative medicine providers,

integrative health practitioners, public health professionals, and any other health professional that the Comptroller General of the United States determines appropriate.

(2) HEALTH PROFESSIONALS- The term `health professionals' includes--

(A) dentists, dental hygienists, primary care providers, specialty physicians, nurses, nurse practitioners, physician assistants, psychologists and other behavioral and mental health professionals (including substance abuse prevention and treatment providers), social workers, physical and occupational therapists, public health professionals, clinical pharmacists, allied health professionals, doctors of chiropractic, community health workers, school nurses, certified nurse midwives, podiatrists, licensed complementary and alternative medicine providers, the EMS workforce (including professional and volunteer ambulance personnel and firefighters who perform emergency medical services), and integrative health practitioners;

(B) national representatives of health professionals;

(C) representatives of schools of medicine, osteopathy, nursing, dentistry, optometry, pharmacy, chiropractic, allied health, educational programs for public health professionals, behavioral and mental health professionals (as so defined), social workers, pharmacists, physical and occupational therapists, oral health care industry dentistry and dental hygiene, and physician assistants;

(D) representatives of public and private teaching hospitals, and ambulatory health facilities, including Federal medical facilities; and

(E) any other health professional the Comptroller General of the United States determines appropriate.

SEC. 5102. STATE HEALTH CARE WORKFORCE DEVELOPMENT GRANTS.

(a) Establishment- There is established a competitive health care workforce development grant program (referred to in this section as the `program') for the purpose of enabling State partnerships to complete comprehensive planning and to carry out activities leading to coherent and comprehensive health care workforce development strategies at the State and local levels.

(b) Fiscal and Administrative Agent- The Health Resources and Services Administration of the Department of Health and Human Services (referred to in this section as the `Administration') shall be the fiscal and administrative agent for the grants awarded under this section. The Administration is authorized to carry out the program, in consultation with the National Health Care Workforce Commission (referred to in this section as the `Commission'), which shall review reports on the development, implementation, and evaluation activities of the grant program, including--

(1) administering the grants;

(2) providing technical assistance to grantees; and

(3) reporting performance information to the Commission.

(c) Planning Grants-

(1) AMOUNT AND DURATION- A planning grant shall be awarded under this subsection for a period of not more than one year and the maximum award may not be more than \$150,000.

(2) ELIGIBILITY- To be eligible to receive a planning grant, an entity shall

be an eligible partnership. An eligible partnership shall be a State workforce investment board, if it includes or modifies the members to include at least one representative from each of the following: health care employer, labor organization, a public 2-year institution of higher education, a public 4-year institution of higher education, the recognized State federation of labor, the State public secondary education agency, the State P-16 or P-20 Council if such a council exists, and a philanthropic organization that is actively engaged in providing learning, mentoring, and work opportunities to recruit, educate, and train individuals for, and retain individuals in, careers in health care and related industries.

(3) FISCAL AND ADMINISTRATIVE AGENT- The Governor of the State receiving a planning grant has the authority to appoint a fiscal and an administrative agency for the partnership.

(4) APPLICATION- Each State partnership desiring a planning grant shall submit an application to the Administrator of the Administration at such time and in such manner, and accompanied by such information as the Administrator may reasonable require. Each application submitted for a planning grant shall describe the members of the State partnership, the activities for which assistance is sought, the proposed performance benchmarks to be used to measure progress under the planning grant, a budget for use of the funds to complete the required activities described in paragraph (5), and such additional assurance and information as the Administrator determines to be essential to ensure compliance with the grant program requirements.

(5) REQUIRED ACTIVITIES- A State partnership receiving a planning grant shall carry out the following:

(A) Analyze State labor market information in order to create health care career pathways for students and adults, including dislocated workers.

(B) Identify current and projected high demand State or regional health care sectors for purposes of planning career pathways.

(C) Identify existing Federal, State, and private resources to recruit, educate or train, and retain a skilled health care workforce and strengthen partnerships.

(D) Describe the academic and health care industry skill standards for high school graduation, for entry into postsecondary education, and for various credentials and licensure.

(E) Describe State secondary and postsecondary education and training policies, models, or practices for the health care sector, including career information and guidance counseling.

(F) Identify Federal or State policies or rules to developing a coherent and comprehensive health care workforce development strategy and barriers and a plan to resolve these barriers.

(G) Participate in the Administration's evaluation and reporting activities.

(6) PERFORMANCE AND EVALUATION- Before the State partnership receives a planning grant, such partnership and the Administrator of the Administration shall jointly determine the performance benchmarks that will be established for the purposes of the planning grant.

(7) MATCH- Each State partnership receiving a planning grant shall provide an amount, in cash or in kind, that is not less than 15 percent of the amount of the grant, to carry out the activities supported by the grant. The matching requirement may be provided from funds available under other Federal, State, local or private sources to carry out the activities.

(8) REPORT-

(A) REPORT TO ADMINISTRATION- Not later than 1 year after a State partnership receives a planning grant, the partnership shall submit a report to the Administration on the State's performance of the activities under the grant, including the use of funds, including matching funds, to carry out required activities, and a description of the progress of the State workforce investment board in meeting the performance benchmarks.

(B) REPORT TO CONGRESS- The Administration shall submit a report to Congress analyzing the planning activities, performance, and fund utilization of each State grant recipient, including an identification of promising practices and a profile of the activities of each State grant recipient.

(d) Implementation Grants-

(1) IN GENERAL- The Administration shall--

(A) competitively award implementation grants to State partnerships to enable such partnerships to implement activities that will result in a coherent and comprehensive plan for health workforce development that will address current and projected workforce demands within the State; and

(B) inform the Commission and Congress about the awards made.

(2) DURATION- An implementation grant shall be awarded for a period of no more than 2 years, except in those cases where the Administration determines that the grantee is high performing and the activities supported by the grant warrant up to 1 additional year of funding.

(3) ELIGIBILITY- To be eligible for an implementation grant, a State partnership shall have--

(A) received a planning grant under subsection (c) and completed all requirements of such grant; or

(B) completed a satisfactory application, including a plan to coordinate with required partners and complete the required activities during the 2 year period of the implementation grant.

(4) FISCAL AND ADMINISTRATIVE AGENT- A State partnership receiving an implementation grant shall appoint a fiscal and an administration agent for the implementation of such grant.

(5) APPLICATION- Each eligible State partnership desiring an implementation grant shall submit an application to the Administration at such time, in such manner, and accompanied by such information as the Administration may reasonably require. Each application submitted shall include--

(A) a description of the members of the State partnership;

(B) a description of how the State partnership completed the required activities under the planning grant, if applicable;

(C) a description of the activities for which implementation grant funds are sought, including grants to regions by the State partnership to advance coherent and comprehensive regional health care workforce planning

activities;

(D) a description of how the State partnership will coordinate with required partners and complete the required partnership activities during the duration of an implementation grant;

(E) a budget proposal of the cost of the activities supported by the implementation grant and a timeline for the provision of matching funds required;

(F) proposed performance benchmarks to be used to assess and evaluate the progress of the partnership activities;

(G) a description of how the State partnership will collect data to report progress in grant activities; and

(H) such additional assurances as the Administration determines to be essential to ensure compliance with grant requirements.

(6) REQUIRED ACTIVITIES-

(A) IN GENERAL- A State partnership that receives an implementation grant may reserve not less than 60 percent of the grant funds to make grants to be competitively awarded by the State partnership, consistent with State procurement rules, to encourage regional partnerships to address health care workforce development needs and to promote innovative health care workforce career pathway activities, including career counseling, learning, and employment.

(B) ELIGIBLE PARTNERSHIP DUTIES- An eligible State partnership receiving an implementation grant shall--

(i) identify and convene regional leadership to discuss opportunities to engage in statewide health care workforce development planning, including the potential use of competitive grants to improve the development, distribution, and diversity of the regional health care workforce; the alignment of curricula for health care careers; and the access to quality career information and guidance and education and training opportunities;

(ii) in consultation with key stakeholders and regional leaders, take appropriate steps to reduce Federal, State, or local barriers to a comprehensive and coherent strategy, including changes in State or local policies to foster coherent and comprehensive health care workforce development activities, including health care career pathways at the regional and State levels, career planning information, retraining for dislocated workers, and as appropriate, requests for Federal program or administrative waivers;

(iii) develop, disseminate, and review with key stakeholders a preliminary statewide strategy that addresses short- and long-term health care workforce development supply versus demand;

(iv) convene State partnership members on a regular basis, and at least on a semiannual basis;

(v) assist leaders at the regional level to form partnerships, including technical assistance and capacity building activities;

(vi) collect and assess data on and report on the performance benchmarks selected by the State partnership and the Administration for implementation activities carried out by regional and State

partnerships; and

(vii) participate in the Administration's evaluation and reporting activities.

(7) PERFORMANCE AND EVALUATION- Before the State partnership receives an implementation grant, it and the Administrator shall jointly determine the performance benchmarks that shall be established for the purposes of the implementation grant.

(8) MATCH- Each State partnership receiving an implementation grant shall provide an amount, in cash or in kind that is not less than 25 percent of the amount of the grant, to carry out the activities supported by the grant. The matching funds may be provided from funds available from other Federal, State, local, or private sources to carry out such activities.

(9) REPORTS-

(A) REPORT TO ADMINISTRATION- For each year of the implementation grant, the State partnership receiving the implementation grant shall submit a report to the Administration on the performance of the State of the grant activities, including a description of the use of the funds, including matched funds, to complete activities, and a description of the performance of the State partnership in meeting the performance benchmarks.

(B) REPORT TO CONGRESS- The Administration shall submit a report to Congress analyzing implementation activities, performance, and fund utilization of the State grantees, including an identification of promising practices and a profile of the activities of each State grantee.

(e) Authorization for Appropriations-

(1) PLANNING GRANTS- There are authorized to be appropriated to award planning grants under subsection (c) \$8,000,000 for fiscal year 2010, and such sums as may be necessary for each subsequent fiscal year.

(2) IMPLEMENTATION GRANTS- There are authorized to be appropriated to award implementation grants under subsection (d), \$150,000,000 for fiscal year 2010, and such sums as may be necessary for each subsequent fiscal year.

SEC. 5103. HEALTH CARE WORKFORCE ASSESSMENT.

(a) In General- Section 761 of the Public Health Service Act (42 U.S.C. 294m) is amended--

(1) by redesignating subsection (c) as subsection (e);

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

`(b) National Center for Health Care Workforce Analysis-

`(1) ESTABLISHMENT- The Secretary shall establish the National Center for Health Workforce Analysis (referred to in this section as the `National Center').

`(2) PURPOSES- The National Center, in coordination to the extent practicable with the National Health Care Workforce Commission (established in section 5101 of the Patient Protection and Affordable Care Act), and relevant regional and State centers and agencies, shall--

`(A) provide for the development of information describing and analyzing the health care workforce and workforce related issues;

`(B) carry out the activities under section 792(a);

`(C) annually evaluate programs under this title;

`(D) develop and publish performance measures and benchmarks for programs under this title; and

`(E) establish, maintain, and publicize a national Internet registry of each grant awarded under this title and a database to collect data from longitudinal evaluations (as described in subsection (d)(2)) on performance measures (as developed under sections 749(d)(3), 757(d)(3), and 762(a)(3)).

`(3) COLLABORATION AND DATA SHARING-

`(A) IN GENERAL- The National Center shall collaborate with Federal agencies and relevant professional and educational organizations or societies for the purpose of linking data regarding grants awarded under this title.

`(B) CONTRACTS FOR HEALTH WORKFORCE ANALYSIS- For the purpose of carrying out the activities described in subparagraph (A), the National Center may enter into contracts with relevant professional and educational organizations or societies.

`(c) State and Regional Centers for Health Workforce Analysis-

`(1) IN GENERAL- The Secretary shall award grants to, or enter into contracts with, eligible entities for purposes of--

`(A) collecting, analyzing, and reporting data regarding programs under this title to the National Center and to the public; and

`(B) providing technical assistance to local and regional entities on the collection, analysis, and reporting of data.

`(2) ELIGIBLE ENTITIES- To be eligible for a grant or contract under this subsection, an entity shall--

`(A) be a State, a State workforce investment board, a public health or health professions school, an academic health center, or an appropriate public or private nonprofit entity; and

`(B) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

`(d) Increase in Grants for Longitudinal Evaluations-

`(1) IN GENERAL- The Secretary shall increase the amount awarded to an eligible entity under this title for a longitudinal evaluation of individuals who have received education, training, or financial assistance from programs under this title.

`(2) CAPABILITY- A longitudinal evaluation shall be capable of--

`(A) studying practice patterns; and

`(B) collecting and reporting data on performance measures developed under sections 749(d)(3), 757(d)(3), and 762(a)(3).

`(3) GUIDELINES- A longitudinal evaluation shall comply with guidelines issued under sections 749(d)(4), 757(d)(4), and 762(a)(4).

`(4) ELIGIBLE ENTITIES- To be eligible to obtain an increase under this section, an entity shall be a recipient of a grant or contract under this title.'; and

(3) in subsection (e), as so redesignated--

(A) by striking paragraph (1) and inserting the following:

`(1) IN GENERAL-

`(A) NATIONAL CENTER- To carry out subsection (b), there are authorized to

be appropriated \$7,500,000 for each of fiscal years 2010 through 2014.

`(B) STATE AND REGIONAL CENTERS- To carry out subsection (c), there are authorized to be appropriated \$4,500,000 for each of fiscal years 2010 through 2014.

`(C) GRANTS FOR LONGITUDINAL EVALUATIONS- To carry out subsection (d), there are authorized to be appropriated such sums as may be necessary for fiscal years 2010 through 2014.'; and

(4) in paragraph (2), by striking `subsection (a)' and inserting `paragraph (1)'.

(b) Transfers- Not later than 180 days after the date of enactment of this Act, the responsibilities and resources of the National Center for Health Workforce Analysis, as in effect on the date before the date of enactment of this Act, shall be transferred to the National Center for Health Care Workforce Analysis established under section 761 of the Public Health Service Act, as amended by subsection (a).

(c) Use of Longitudinal Evaluations- Section 791(a)(1) of the Public Health Service Act (42 U.S.C. 295j(a)(1)) is amended--

(1) in subparagraph (A), by striking `or' at the end;

(2) in subparagraph (B), by striking the period and inserting `; or'; and

(3) by adding at the end the following:

`(C) utilizes a longitudinal evaluation (as described in section 761(d)(2)) and reports data from such system to the national workforce database (as established under section 761(b)(2)(E)).'.

(d) Performance Measures; Guidelines for Longitudinal Evaluations-

(1) ADVISORY COMMITTEE ON TRAINING IN PRIMARY CARE MEDICINE AND DENTISTRY-

Section 748(d) of the Public Health Service Act is amended--

(A) in paragraph (1), by striking `and' at the end;

(B) in paragraph (2), by striking the period and inserting a semicolon;

and

(C) by adding at the end the following:

`(3) develop, publish, and implement performance measures for programs under this part;

`(4) develop and publish guidelines for longitudinal evaluations (as described in section 761(d)(2)) for programs under this part; and

`(5) recommend appropriation levels for programs under this part.'.

(2) ADVISORY COMMITTEE ON INTERDISCIPLINARY, COMMUNITY-BASED LINKAGES-

Section 756(d) of the Public Health Service Act is amended--

(A) in paragraph (1), by striking `and' at the end;

(B) in paragraph (2), by striking the period and inserting a semicolon;

and

(C) by adding at the end the following:

`(3) develop, publish, and implement performance measures for programs under this part;

`(4) develop and publish guidelines for longitudinal evaluations (as described in section 761(d)(2)) for programs under this part; and

`(5) recommend appropriation levels for programs under this part.'.

(3) ADVISORY COUNCIL ON GRADUATE MEDICAL EDUCATION- Section 762(a) of the Public Health Service Act (42 U.S.C. 294o(a)) is amended--

- (A) in paragraph (1), by striking `and' at the end;
 - (B) in paragraph (2), by striking the period and inserting a semicolon;
- and
- (C) by adding at the end the following:
 - `(3) develop, publish, and implement performance measures for programs under this title, except for programs under part C or D;
 - `(4) develop and publish guidelines for longitudinal evaluations (as described in section 761(d)(2)) for programs under this title, except for programs under part C or D; and
 - `(5) recommend appropriation levels for programs under this title, except for programs under part C or D.'

Subtitle C--Increasing the Supply of the Health Care Workforce

SEC. 5201. FEDERALLY SUPPORTED STUDENT LOAN FUNDS.

(a) Medical Schools and Primary Health Care- Section 723 of the Public Health Service Act (42 U.S.C. 292s) is amended--

(1) in subsection (a)--

(A) in paragraph (1), by striking subparagraph (B) and inserting the following:

`(B) to practice in such care for 10 years (including residency training in primary health care) or through the date on which the loan is repaid in full, whichever occurs first.'; and

(B) by striking paragraph (3) and inserting the following:

`(3) NONCOMPLIANCE BY STUDENT- Each agreement entered into with a student pursuant to paragraph (1) shall provide that, if the student fails to comply with such agreement, the loan involved will begin to accrue interest at a rate of 2 percent per year greater than the rate at which the student would pay if compliant in such year.'; and

(2) by adding at the end the following:

`(d) Sense of Congress- It is the sense of Congress that funds repaid under the loan program under this section should not be transferred to the Treasury of the United States or otherwise used for any other purpose other than to carry out this section.'

(b) Student Loan Guidelines- The Secretary of Health and Human Services shall not require parental financial information for an independent student to determine financial need under section 723 of the Public Health Service Act (42 U.S.C. 292s) and the determination of need for such information shall be at the discretion of applicable school loan officer. The Secretary shall amend guidelines issued by the Health Resources and Services Administration in accordance with the preceding sentence.

SEC. 5202. NURSING STUDENT LOAN PROGRAM.

(a) Loan Agreements- Section 836(a) of the Public Health Service Act (42 U.S.C. 297b(a)) is amended--

(1) by striking `\$2,500' and inserting `\$3,300';

(2) by striking `\$4,000' and inserting `\$5,200'; and

(3) by striking `\$13,000' and all that follows through the period and inserting `\$17,000 in the case of any student during fiscal years 2010 and 2011. After fiscal year 2011, such amounts shall be adjusted to provide for a cost-of-attendance increase for the yearly loan rate and the aggregate of

the loans.'

(b) Loan Provisions- Section 836(b) of the Public Health Service Act (42 U.S.C. 297b(b)) is amended--

- (1) in paragraph (1)(C), by striking '1986' and inserting '2000'; and
- (2) in paragraph (3), by striking 'the date of enactment of the Nurse Training Amendments of 1979' and inserting 'September 29, 1995'.

SEC. 5203. HEALTH CARE WORKFORCE LOAN REPAYMENT PROGRAMS.

Part E of title VII of the Public Health Service Act (42 U.S.C. 294n et seq.) is amended by adding at the end the following:

Subpart 3--Recruitment and Retention Programs

SEC. 775. INVESTMENT IN TOMORROW'S PEDIATRIC HEALTH CARE WORKFORCE.

(a) Establishment- The Secretary shall establish and carry out a pediatric specialty loan repayment program under which the eligible individual agrees to be employed full-time for a specified period (which shall not be less than 2 years) in providing pediatric medical subspecialty, pediatric surgical specialty, or child and adolescent mental and behavioral health care, including substance abuse prevention and treatment services.

(b) Program Administration- Through the program established under this section, the Secretary shall enter into contracts with qualified health professionals under which--

- (1) such qualified health professionals will agree to provide pediatric medical subspecialty, pediatric surgical specialty, or child and adolescent mental and behavioral health care in an area with a shortage of the specified pediatric subspecialty that has a sufficient pediatric population to support such pediatric subspecialty, as determined by the Secretary; and
- (2) the Secretary agrees to make payments on the principal and interest of undergraduate, graduate, or graduate medical education loans of professionals described in paragraph (1) of not more than \$35,000 a year for each year of agreed upon service under such paragraph for a period of not more than 3 years during the qualified health professional's--
 - (A) participation in an accredited pediatric medical subspecialty, pediatric surgical specialty, or child and adolescent mental health subspecialty residency or fellowship; or
 - (B) employment as a pediatric medical subspecialist, pediatric surgical specialist, or child and adolescent mental health professional serving an area or population described in such paragraph.

(c) In General-

(1) ELIGIBLE INDIVIDUALS-

(A) PEDIATRIC MEDICAL SPECIALISTS AND PEDIATRIC SURGICAL SPECIALISTS- For purposes of contracts with respect to pediatric medical specialists and pediatric surgical specialists, the term 'qualified health professional' means a licensed physician who--

- (i) is entering or receiving training in an accredited pediatric medical subspecialty or pediatric surgical specialty residency or fellowship; or
- (ii) has completed (but not prior to the end of the calendar year in which this section is enacted) the training described in subparagraph (B).

`(B) CHILD AND ADOLESCENT MENTAL AND BEHAVIORAL HEALTH- For purposes of contracts with respect to child and adolescent mental and behavioral health care, the term `qualified health professional' means a health care professional who--

`(i) has received specialized training or clinical experience in child and adolescent mental health in psychiatry, psychology, school psychology, behavioral pediatrics, psychiatric nursing, social work, school social work, substance abuse disorder prevention and treatment, marriage and family therapy, school counseling, or professional counseling;

`(ii) has a license or certification in a State to practice allopathic medicine, osteopathic medicine, psychology, school psychology, psychiatric nursing, social work, school social work, marriage and family therapy, school counseling, or professional counseling; or

`(iii) is a mental health service professional who completed (but not before the end of the calendar year in which this section is enacted) specialized training or clinical experience in child and adolescent mental health described in clause (i).

`(2) ADDITIONAL ELIGIBILITY REQUIREMENTS- The Secretary may not enter into a contract under this subsection with an eligible individual unless--

`(A) the individual agrees to work in, or for a provider serving, a health professional shortage area or medically underserved area, or to serve a medically underserved population;

`(B) the individual is a United States citizen or a permanent legal United States resident; and

`(C) if the individual is enrolled in a graduate program, the program is accredited, and the individual has an acceptable level of academic standing (as determined by the Secretary).

`(d) Priority- In entering into contracts under this subsection, the Secretary shall give priority to applicants who--

`(1) are or will be working in a school or other pre-kindergarten, elementary, or secondary education setting;

`(2) have familiarity with evidence-based methods and cultural and linguistic competence health care services; and

`(3) demonstrate financial need.

`(e) Authorization of Appropriations- There is authorized to be appropriated \$30,000,000 for each of fiscal years 2010 through 2014 to carry out subsection (c)(1)(A) and \$20,000,000 for each of fiscal years 2010 through 2013 to carry out subsection (c)(1)(B).'

SEC. 5204. PUBLIC HEALTH WORKFORCE RECRUITMENT AND RETENTION PROGRAMS.

Part E of title VII of the Public Health Service Act (42 U.S.C. 294n et seq.), as amended by section 5203, is further amended by adding at the end the following:

`SEC. 776. PUBLIC HEALTH WORKFORCE LOAN REPAYMENT PROGRAM.

`(a) Establishment- The Secretary shall establish the Public Health Workforce Loan Repayment Program (referred to in this section as the `Program') to assure an adequate supply of public health professionals to eliminate critical public health workforce shortages in Federal, State, local, and tribal public

health agencies.

`(b) Eligibility- To be eligible to participate in the Program, an individual shall--

`(1)(A) be accepted for enrollment, or be enrolled, as a student in an accredited academic educational institution in a State or territory in the final year of a course of study or program leading to a public health or health professions degree or certificate; and have accepted employment with a Federal, State, local, or tribal public health agency, or a related training fellowship, as recognized by the Secretary, to commence upon graduation;

`(B)(i) have graduated, during the preceding 10-year period, from an accredited educational institution in a State or territory and received a public health or health professions degree or certificate; and

`(ii) be employed by, or have accepted employment with, a Federal, State, local, or tribal public health agency or a related training fellowship, as recognized by the Secretary;

`(2) be a United States citizen; and

`(3)(A) submit an application to the Secretary to participate in the Program;

`(B) execute a written contract as required in subsection (c); and

`(4) not have received, for the same service, a reduction of loan obligations under section 455(m), 428J, 428K, 428L, or 460 of the Higher Education Act of 1965.

`(c) Contract- The written contract (referred to in this section as the 'written contract') between the Secretary and an individual shall contain--

`(1) an agreement on the part of the Secretary that the Secretary will repay on behalf of the individual loans incurred by the individual in the pursuit of the relevant degree or certificate in accordance with the terms of the contract;

`(2) an agreement on the part of the individual that the individual will serve in the full-time employment of a Federal, State, local, or tribal public health agency or a related fellowship program in a position related to the course of study or program for which the contract was awarded for a period of time (referred to in this section as the 'period of obligated service') equal to the greater of--

`(A) 3 years; or

`(B) such longer period of time as determined appropriate by the Secretary and the individual;

`(3) an agreement, as appropriate, on the part of the individual to relocate to a priority service area (as determined by the Secretary) in exchange for an additional loan repayment incentive amount to be determined by the Secretary;

`(4) a provision that any financial obligation of the United States arising out of a contract entered into under this section and any obligation of the individual that is conditioned thereon, is contingent on funds being appropriated for loan repayments under this section;

`(5) a statement of the damages to which the United States is entitled, under this section for the individual's breach of the contract; and

`(6) such other statements of the rights and liabilities of the Secretary and of the individual, not inconsistent with this section.

`(d) Payments-

`(1) IN GENERAL- A loan repayment provided for an individual under a written contract under the Program shall consist of payment, in accordance with paragraph (2), on behalf of the individual of the principal, interest, and related expenses on government and commercial loans received by the individual regarding the undergraduate or graduate education of the individual (or both), which loans were made for tuition expenses incurred by the individual.

`(2) PAYMENTS FOR YEARS SERVED- For each year of obligated service that an individual contracts to serve under subsection (c) the Secretary may pay up to \$35,000 on behalf of the individual for loans described in paragraph (1). With respect to participants under the Program whose total eligible loans are less than \$105,000, the Secretary shall pay an amount that does not exceed 1/3 of the eligible loan balance for each year of obligated service of the individual.

`(3) TAX LIABILITY- For the purpose of providing reimbursements for tax liability resulting from payments under paragraph (2) on behalf of an individual, the Secretary shall, in addition to such payments, make payments to the individual in an amount not to exceed 39 percent of the total amount of loan repayments made for the taxable year involved.

`(e) Postponing Obligated Service- With respect to an individual receiving a degree or certificate from a health professions or other related school, the date of the initiation of the period of obligated service may be postponed as approved by the Secretary.

`(f) Breach of Contract- An individual who fails to comply with the contract entered into under subsection (c) shall be subject to the same financial penalties as provided for under section 338E for breaches of loan repayment contracts under section 338B.

`(g) Authorization of Appropriations- There is authorized to be appropriated to carry out this section \$195,000,000 for fiscal year 2010, and such sums as may be necessary for each of fiscal years 2011 through 2015.'

SEC. 5205. ALLIED HEALTH WORKFORCE RECRUITMENT AND RETENTION PROGRAMS.

(a) Purpose- The purpose of this section is to assure an adequate supply of allied health professionals to eliminate critical allied health workforce shortages in Federal, State, local, and tribal public health agencies or in settings where patients might require health care services, including acute care facilities, ambulatory care facilities, personal residences and other settings, as recognized by the Secretary of Health and Human Services by authorizing an Allied Health Loan Forgiveness Program.

(b) Allied Health Workforce Recruitment and Retention Program- Section 428K of the Higher Education Act of 1965 (20 U.S.C. 1078-11) is amended--

(1) in subsection (b), by adding at the end the following:

`(18) ALLIED HEALTH PROFESSIONALS- The individual is employed full-time as an allied health professional--

`(A) in a Federal, State, local, or tribal public health agency; or

`(B) in a setting where patients might require health care services,

including acute care facilities, ambulatory care facilities, personal residences and other settings located in health professional shortage areas, medically underserved areas, or medically underserved populations, as recognized by the Secretary of Health and Human Services.'; and

(2) in subsection (g)--

(A) by redesignating paragraphs (1) through (9) as paragraphs (2) through (10), respectively; and

(B) by inserting before paragraph (2) (as redesignated by subparagraph (A)) the following:

`(1) ALLIED HEALTH PROFESSIONAL- The term `allied health professional' means an allied health professional as defined in section 799B(5) of the Public Health Service Act (42 U.S.C. 295p(5)) who--

`(A) has graduated and received an allied health professions degree or certificate from an institution of higher education; and

`(B) is employed with a Federal, State, local or tribal public health agency, or in a setting where patients might require health care services, including acute care facilities, ambulatory care facilities, personal residences and other settings located in health professional shortage areas, medically underserved areas, or medically underserved populations, as recognized by the Secretary of Health and Human Services.'.

SEC. 5206. GRANTS FOR STATE AND LOCAL PROGRAMS.

(a) In General- Section 765(d) of the Public Health Service Act (42 U.S.C. 295(d)) is amended--

(1) in paragraph (7), by striking `; or' and inserting a semicolon;

(2) by redesignating paragraph (8) as paragraph (9); and

(3) by inserting after paragraph (7) the following:

`(8) public health workforce loan repayment programs; or'.

(b) Training for Mid-career Public Health Professionals- Part E of title VII of the Public Health Service Act (42 U.S.C. 294n et seq.), as amended by section 5204, is further amended by adding at the end the following:

`SEC. 777. TRAINING FOR MID-CAREER PUBLIC AND ALLIED HEALTH PROFESSIONALS.

`(a) In General- The Secretary may make grants to, or enter into contracts with, any eligible entity to award scholarships to eligible individuals to enroll in degree or professional training programs for the purpose of enabling mid-career professionals in the public health and allied health workforce to receive additional training in the field of public health and allied health.

`(b) Eligibility-

`(1) ELIGIBLE ENTITY- The term `eligible entity' indicates an accredited educational institution that offers a course of study, certificate program, or professional training program in public or allied health or a related discipline, as determined by the Secretary

`(2) ELIGIBLE INDIVIDUALS- The term `eligible individuals' includes those individuals employed in public and allied health positions at the Federal, State, tribal, or local level who are interested in retaining or upgrading their education.

`(c) Authorization of Appropriations- There is authorized to be appropriated to carry out this section, \$60,000,000 for fiscal year 2010 and such sums as may be necessary for each of fiscal years 2011 through 2015. Fifty percent of

appropriated funds shall be allotted to public health mid-career professionals and 50 percent shall be allotted to allied health mid-career professionals.'.

SEC. 5207. FUNDING FOR NATIONAL HEALTH SERVICE CORPS.

Section 338H(a) of the Public Health Service Act (42 U.S.C. 254q(a)) is amended to read as follows:

`(a) Authorization of Appropriations- For the purpose of carrying out this section, there is authorized to be appropriated, out of any funds in the Treasury not otherwise appropriated, the following:

`(1) For fiscal year 2010, \$320,461,632.

`(2) For fiscal year 2011, \$414,095,394.

`(3) For fiscal year 2012, \$535,087,442.

`(4) For fiscal year 2013, \$691,431,432.

`(5) For fiscal year 2014, \$893,456,433.

`(6) For fiscal year 2015, \$1,154,510,336.

`(7) For fiscal year 2016, and each subsequent fiscal year, the amount appropriated for the preceding fiscal year adjusted by the product of--

`(A) one plus the average percentage increase in the costs of health professions education during the prior fiscal year; and

`(B) one plus the average percentage change in the number of individuals residing in health professions shortage areas designated under section 333 during the prior fiscal year, relative to the number of individuals residing in such areas during the previous fiscal year.'.

SEC. 5208. NURSE-MANAGED HEALTH CLINICS.

(a) Purpose- The purpose of this section is to fund the development and operation of nurse-managed health clinics.

(b) Grants- Subpart 1 of part D of title III of the Public Health Service Act (42 U.S.C. 254b et seq.) is amended by inserting after section 330A the following:

SEC. 330A-1. GRANTS TO NURSE-MANAGED HEALTH CLINICS.

`(a) Definitions-

`(1) COMPREHENSIVE PRIMARY HEALTH CARE SERVICES- In this section, the term 'comprehensive primary health care services' means the primary health services described in section 330(b)(1).

`(2) NURSE-MANAGED HEALTH CLINIC- The term 'nurse-managed health clinic' means a nurse-practice arrangement, managed by advanced practice nurses, that provides primary care or wellness services to underserved or vulnerable populations and that is associated with a school, college, university or department of nursing, federally qualified health center, or independent nonprofit health or social services agency.

`(b) Authority to Award Grants- The Secretary shall award grants for the cost of the operation of nurse-managed health clinics that meet the requirements of this section.

`(c) Applications- To be eligible to receive a grant under this section, an entity shall--

`(1) be an NMHC; and

`(2) submit to the Secretary an application at such time, in such manner, and containing--

`(A) assurances that nurses are the major providers of services at the

NMHC and that at least 1 advanced practice nurse holds an executive management position within the organizational structure of the NMHC;

`(B) an assurance that the NMHC will continue providing comprehensive primary health care services or wellness services without regard to income or insurance status of the patient for the duration of the grant period; and

`(C) an assurance that, not later than 90 days of receiving a grant under this section, the NMHC will establish a community advisory committee, for which a majority of the members shall be individuals who are served by the NMHC.

`(d) Grant Amount- The amount of any grant made under this section for any fiscal year shall be determined by the Secretary, taking into account--

`(1) the financial need of the NMHC, considering State, local, and other operational funding provided to the NMHC; and

`(2) other factors, as the Secretary determines appropriate.

`(e) Authorization of Appropriations- For the purposes of carrying out this section, there are authorized to be appropriated \$50,000,000 for the fiscal year 2010 and such sums as may be necessary for each of the fiscal years 2011 through 2014.'

SEC. 5209. ELIMINATION OF CAP ON COMMISSIONED CORPS.

Section 202 of the Department of Health and Human Services Appropriations Act, 1993 (Public Law 102-394) is amended by striking 'not to exceed 2,800'.

SEC. 5210. ESTABLISHING A READY RESERVE CORPS.

Section 203 of the Public Health Service Act (42 U.S.C. 204) is amended to read as follows:

`SEC. 203. COMMISSIONED CORPS AND READY RESERVE CORPS.

`(a) Establishment-

`(1) IN GENERAL- There shall be in the Service a commissioned Regular Corps and a Ready Reserve Corps for service in time of national emergency.

`(2) REQUIREMENT- All commissioned officers shall be citizens of the United States and shall be appointed without regard to the civil-service laws and compensated without regard to the Classification Act of 1923, as amended.

`(3) APPOINTMENT- Commissioned officers of the Ready Reserve Corps shall be appointed by the President and commissioned officers of the Regular Corps shall be appointed by the President with the advice and consent of the Senate.

`(4) ACTIVE DUTY- Commissioned officers of the Ready Reserve Corps shall at all times be subject to call to active duty by the Surgeon General, including active duty for the purpose of training.

`(5) WARRANT OFFICERS- Warrant officers may be appointed to the Service for the purpose of providing support to the health and delivery systems maintained by the Service and any warrant officer appointed to the Service shall be considered for purposes of this Act and title 37, United States Code, to be a commissioned officer within the Commissioned Corps of the Service.

`(b) Assimilating Reserve Corp Officers Into the Regular Corps- Effective on the date of enactment of the Patient Protection and Affordable Care Act, all individuals classified as officers in the Reserve Corps under this section (as

such section existed on the day before the date of enactment of such Act) and serving on active duty shall be deemed to be commissioned officers of the Regular Corps.

`(c) Purpose and Use of Ready Research-

`(1) PURPOSE- The purpose of the Ready Reserve Corps is to fulfill the need to have additional Commissioned Corps personnel available on short notice (similar to the uniformed service's reserve program) to assist regular Commissioned Corps personnel to meet both routine public health and emergency response missions.

`(2) USES- The Ready Reserve Corps shall--

`(A) participate in routine training to meet the general and specific needs of the Commissioned Corps;

`(B) be available and ready for involuntary calls to active duty during national emergencies and public health crises, similar to the uniformed service reserve personnel;

`(C) be available for backfilling critical positions left vacant during deployment of active duty Commissioned Corps members, as well as for deployment to respond to public health emergencies, both foreign and domestic; and

`(D) be available for service assignment in isolated, hardship, and medically underserved communities (as defined in section 799B) to improve access to health services.

`(d) Funding- For the purpose of carrying out the duties and responsibilities of the Commissioned Corps under this section, there are authorized to be appropriated \$5,000,000 for each of fiscal years 2010 through 2014 for recruitment and training and \$12,500,000 for each of fiscal years 2010 through 2014 for the Ready Reserve Corps.'

Subtitle D--Enhancing Health Care Workforce Education and Training

SEC. 5301. TRAINING IN FAMILY MEDICINE, GENERAL INTERNAL MEDICINE, GENERAL PEDIATRICS, AND PHYSICIAN ASSISTANTSHIP.

Part C of title VII (42 U.S.C. 293k et seq.) is amended by striking section 747 and inserting the following:

'SEC. 747. PRIMARY CARE TRAINING AND ENHANCEMENT.

`(a) Support and Development of Primary Care Training Programs-

`(1) IN GENERAL- The Secretary may make grants to, or enter into contracts with, an accredited public or nonprofit private hospital, school of medicine or osteopathic medicine, academically affiliated physician assistant training program, or a public or private nonprofit entity which the Secretary has determined is capable of carrying out such grant or contract--

`(A) to plan, develop, operate, or participate in an accredited professional training program, including an accredited residency or internship program in the field of family medicine, general internal medicine, or general pediatrics for medical students, interns, residents, or practicing physicians as defined by the Secretary;

`(B) to provide need-based financial assistance in the form of traineeships and fellowships to medical students, interns, residents, practicing physicians, or other medical personnel, who are participants in any such program, and who plan to specialize or work in the practice of

the fields defined in subparagraph (A);

`(C) to plan, develop, and operate a program for the training of physicians who plan to teach in family medicine, general internal medicine, or general pediatrics training programs;

`(D) to plan, develop, and operate a program for the training of physicians teaching in community-based settings;

`(E) to provide financial assistance in the form of traineeships and fellowships to physicians who are participants in any such programs and who plan to teach or conduct research in a family medicine, general internal medicine, or general pediatrics training program;

`(F) to plan, develop, and operate a physician assistant education program, and for the training of individuals who will teach in programs to provide such training;

`(G) to plan, develop, and operate a demonstration program that provides training in new competencies, as recommended by the Advisory Committee on Training in Primary Care Medicine and Dentistry and the National Health Care Workforce Commission established in section 5101 of the Patient Protection and Affordable Care Act, which may include--

`(i) providing training to primary care physicians relevant to providing care through patient-centered medical homes (as defined by the Secretary for purposes of this section);

`(ii) developing tools and curricula relevant to patient-centered medical homes; and

`(iii) providing continuing education to primary care physicians relevant to patient-centered medical homes; and

`(H) to plan, develop, and operate joint degree programs to provide interdisciplinary and interprofessional graduate training in public health and other health professions to provide training in environmental health, infectious disease control, disease prevention and health promotion, epidemiological studies and injury control.

`(2) DURATION OF AWARDS- The period during which payments are made to an entity from an award of a grant or contract under this subsection shall be 5 years.

`(b) Capacity Building in Primary Care-

`(1) IN GENERAL- The Secretary may make grants to or enter into contracts with accredited schools of medicine or osteopathic medicine to establish, maintain, or improve--

`(A) academic units or programs that improve clinical teaching and research in fields defined in subsection (a)(1)(A); or

`(B) programs that integrate academic administrative units in fields defined in subsection (a)(1)(A) to enhance interdisciplinary recruitment, training, and faculty development.

`(2) PREFERENCE IN MAKING AWARDS UNDER THIS SUBSECTION- In making awards of grants and contracts under paragraph (1), the Secretary shall give preference to any qualified applicant for such an award that agrees to expend the award for the purpose of--

`(A) establishing academic units or programs in fields defined in subsection (a)(1)(A); or

`(B) substantially expanding such units or programs.

`(3) PRIORITIES IN MAKING AWARDS- In awarding grants or contracts under paragraph (1), the Secretary shall give priority to qualified applicants that--

`(A) proposes a collaborative project between academic administrative units of primary care;

`(B) proposes innovative approaches to clinical teaching using models of primary care, such as the patient centered medical home, team management of chronic disease, and interprofessional integrated models of health care that incorporate transitions in health care settings and integration physical and mental health provision;

`(C) have a record of training the greatest percentage of providers, or that have demonstrated significant improvements in the percentage of providers trained, who enter and remain in primary care practice;

`(D) have a record of training individuals who are from underrepresented minority groups or from a rural or disadvantaged background;

`(E) provide training in the care of vulnerable populations such as children, older adults, homeless individuals, victims of abuse or trauma, individuals with mental health or substance-related disorders, individuals with HIV/AIDS, and individuals with disabilities;

`(F) establish formal relationships and submit joint applications with federally qualified health centers, rural health clinics, area health education centers, or clinics located in underserved areas or that serve underserved populations;

`(G) teach trainees the skills to provide interprofessional, integrated care through collaboration among health professionals;

`(H) provide training in enhanced communication with patients, evidence-based practice, chronic disease management, preventive care, health information technology, or other competencies as recommended by the Advisory Committee on Training in Primary Care Medicine and Dentistry and the National Health Care Workforce Commission established in section 5101 of the Patient Protection and Affordable Care Act; or

`(I) provide training in cultural competency and health literacy.

`(4) DURATION OF AWARDS- The period during which payments are made to an entity from an award of a grant or contract under this subsection shall be 5 years.

`(c) Authorization of Appropriations-

`(1) IN GENERAL- For purposes of carrying out this section (other than subsection (b)(1)(B)), there are authorized to be appropriated \$125,000,000 for fiscal year 2010, and such sums as may be necessary for each of fiscal years 2011 through 2014.

`(2) TRAINING PROGRAMS- Fifteen percent of the amount appropriated pursuant to paragraph (1) in each such fiscal year shall be allocated to the physician assistant training programs described in subsection (a)(1)(F), which prepare students for practice in primary care.

`(3) INTEGRATING ACADEMIC ADMINISTRATIVE UNITS- For purposes of carrying out subsection (b)(1)(B), there are authorized to be appropriated \$750,000 for each of fiscal years 2010 through 2014.'.

SEC. 5302. TRAINING OPPORTUNITIES FOR DIRECT CARE WORKERS.

Part C of title VII of the Public Health Service Act (42 U.S.C. 293k et seq.) is amended by inserting after section 747, as amended by section 5301, the following:

SEC. 747A. TRAINING OPPORTUNITIES FOR DIRECT CARE WORKERS.

(a) In General- The Secretary shall award grants to eligible entities to enable such entities to provide new training opportunities for direct care workers who are employed in long-term care settings such as nursing homes (as defined in section 1908(e)(1) of the Social Security Act (42 U.S.C. 1396g(e)(1))), assisted living facilities and skilled nursing facilities, intermediate care facilities for individuals with mental retardation, home and community based settings, and any other setting the Secretary determines to be appropriate.

(b) Eligibility- To be eligible to receive a grant under this section, an entity shall--

(1) be an institution of higher education (as defined in section 102 of the Higher Education Act of 1965 (20 U.S.C. 1002)) that--

(A) is accredited by a nationally recognized accrediting agency or association listed under section 101(c) of the Higher Education Act of 1965 (20 U.S.C. 1001(c)); and

(B) has established a public-private educational partnership with a nursing home or skilled nursing facility, agency or entity providing home and community based services to individuals with disabilities, or other long-term care provider; and

(2) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

(c) Use of Funds- An eligible entity shall use amounts awarded under a grant under this section to provide assistance to eligible individuals to offset the cost of tuition and required fees for enrollment in academic programs provided by such entity.

(d) Eligible Individual-

(1) ELIGIBILITY- To be eligible for assistance under this section, an individual shall be enrolled in courses provided by a grantee under this subsection and maintain satisfactory academic progress in such courses.

(2) CONDITION OF ASSISTANCE- As a condition of receiving assistance under this section, an individual shall agree that, following completion of the assistance period, the individual will work in the field of geriatrics, disability services, long term services and supports, or chronic care management for a minimum of 2 years under guidelines set by the Secretary.

(e) Authorization of Appropriations- There is authorized to be appropriated to carry out this section, \$10,000,000 for the period of fiscal years 2011 through 2013.'

SEC. 5303. TRAINING IN GENERAL, PEDIATRIC, AND PUBLIC HEALTH DENTISTRY.

Part C of Title VII of the Public Health Service Act (42 U.S.C. 293k et seq.) is amended by--

(1) redesignating section 748, as amended by section 5103 of this Act, as section 749; and

(2) inserting after section 747A, as added by section 5302, the following:

SEC. 748. TRAINING IN GENERAL, PEDIATRIC, AND PUBLIC HEALTH DENTISTRY.

(a) Support and Development of Dental Training Programs-

(1) IN GENERAL- The Secretary may make grants to, or enter into contracts with, a school of dentistry, public or nonprofit private hospital, or a public or private nonprofit entity which the Secretary has determined is capable of carrying out such grant or contract--

(A) to plan, develop, and operate, or participate in, an approved professional training program in the field of general dentistry, pediatric dentistry, or public health dentistry for dental students, residents, practicing dentists, dental hygienists, or other approved primary care dental trainees, that emphasizes training for general, pediatric, or public health dentistry;

(B) to provide financial assistance to dental students, residents, practicing dentists, and dental hygiene students who are in need thereof, who are participants in any such program, and who plan to work in the practice of general, pediatric, public health dentistry, or dental hygiene;

(C) to plan, develop, and operate a program for the training of oral health care providers who plan to teach in general, pediatric, public health dentistry, or dental hygiene;

(D) to provide financial assistance in the form of traineeships and fellowships to dentists who plan to teach or are teaching in general, pediatric, or public health dentistry;

(E) to meet the costs of projects to establish, maintain, or improve dental faculty development programs in primary care (which may be departments, divisions or other units);

(F) to meet the costs of projects to establish, maintain, or improve predoctoral and postdoctoral training in primary care programs;

(G) to create a loan repayment program for faculty in dental programs;

and

(H) to provide technical assistance to pediatric training programs in developing and implementing instruction regarding the oral health status, dental care needs, and risk-based clinical disease management of all pediatric populations with an emphasis on underserved children.

(2) FACULTY LOAN REPAYMENT-

(A) IN GENERAL- A grant or contract under subsection (a)(1)(G) may be awarded to a program of general, pediatric, or public health dentistry described in such subsection to plan, develop, and operate a loan repayment program under which--

(i) individuals agree to serve full-time as faculty members; and

(ii) the program of general, pediatric or public health dentistry agrees to pay the principal and interest on the outstanding student loans of the individuals.

(B) MANNER OF PAYMENTS- With respect to the payments described in subparagraph (A)(ii), upon completion by an individual of each of the first, second, third, fourth, and fifth years of service, the program shall pay an amount equal to 10, 15, 20, 25, and 30 percent, respectively, of the individual's student loan balance as calculated based on principal and interest owed at the initiation of the agreement.

`(b) Eligible Entity- For purposes of this subsection, entities eligible for such grants or contracts in general, pediatric, or public health dentistry shall include entities that have programs in dental or dental hygiene schools, or approved residency or advanced education programs in the practice of general, pediatric, or public health dentistry. Eligible entities may partner with schools of public health to permit the education of dental students, residents, and dental hygiene students for a master's year in public health at a school of public health.

`(c) Priorities in Making Awards- With respect to training provided for under this section, the Secretary shall give priority in awarding grants or contracts to the following:

`(1) Qualified applicants that propose collaborative projects between departments of primary care medicine and departments of general, pediatric, or public health dentistry.

`(2) Qualified applicants that have a record of training the greatest percentage of providers, or that have demonstrated significant improvements in the percentage of providers, who enter and remain in general, pediatric, or public health dentistry.

`(3) Qualified applicants that have a record of training individuals who are from a rural or disadvantaged background, or from underrepresented minorities.

`(4) Qualified applicants that establish formal relationships with Federally qualified health centers, rural health centers, or accredited teaching facilities and that conduct training of students, residents, fellows, or faculty at the center or facility.

`(5) Qualified applicants that conduct teaching programs targeting vulnerable populations such as older adults, homeless individuals, victims of abuse or trauma, individuals with mental health or substance-related disorders, individuals with disabilities, and individuals with HIV/AIDS, and in the risk-based clinical disease management of all populations.

`(6) Qualified applicants that include educational activities in cultural competency and health literacy.

`(7) Qualified applicants that have a high rate for placing graduates in practice settings that serve underserved areas or health disparity populations, or who achieve a significant increase in the rate of placing graduates in such settings.

`(8) Qualified applicants that intend to establish a special populations oral health care education center or training program for the didactic and clinical education of dentists, dental health professionals, and dental hygienists who plan to teach oral health care for people with developmental disabilities, cognitive impairment, complex medical problems, significant physical limitations, and vulnerable elderly.

`(d) Application- An eligible entity desiring a grant under this section shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

`(e) Duration of Award- The period during which payments are made to an entity from an award of a grant or contract under subsection (a) shall be 5 years. The provision of such payments shall be subject to annual approval by the

Secretary and subject to the availability of appropriations for the fiscal year involved to make the payments.

`(f) Authorizations of Appropriations- For the purpose of carrying out subsections (a) and (b), there is authorized to be appropriated \$30,000,000 for fiscal year 2010 and such sums as may be necessary for each of fiscal years 2011 through 2015.

`(g) Carryover Funds- An entity that receives an award under this section may carry over funds from 1 fiscal year to another without obtaining approval from the Secretary. In no case may any funds be carried over pursuant to the preceding sentence for more than 3 years.'

SEC. 5304. ALTERNATIVE DENTAL HEALTH CARE PROVIDERS DEMONSTRATION PROJECT.

Subpart X of part D of title III of the Public Health Service Act (42 U.S.C. 256f et seq.) is amended by adding at the end the following:

`SEC. 340G-1. DEMONSTRATION PROGRAM.

`(a) In General-

`(1) AUTHORIZATION- The Secretary is authorized to award grants to 15 eligible entities to enable such entities to establish a demonstration program to establish training programs to train, or to employ, alternative dental health care providers in order to increase access to dental health care services in rural and other underserved communities.

`(2) DEFINITION- The term `alternative dental health care providers' includes community dental health coordinators, advance practice dental hygienists, independent dental hygienists, supervised dental hygienists, primary care physicians, dental therapists, dental health aides, and any other health professional that the Secretary determines appropriate.

`(b) Timeframe- The demonstration projects funded under this section shall begin not later than 2 years after the date of enactment of this section, and shall conclude not later than 7 years after such date of enactment.

`(c) Eligible Entities- To be eligible to receive a grant under subsection (a), an entity shall--

`(1) be--

`(A) an institution of higher education, including a community college;

`(B) a public-private partnership;

`(C) a federally qualified health center;

`(D) an Indian Health Service facility or a tribe or tribal organization (as such terms are defined in section 4 of the Indian Self-Determination and Education Assistance Act);

`(E) a State or county public health clinic, a health facility operated by an Indian tribe or tribal organization, or urban Indian organization providing dental services; or

`(F) a public hospital or health system;

`(2) be within a program accredited by the Commission on Dental Accreditation or within a dental education program in an accredited institution; and

`(3) shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

`(d) Administrative Provisions-

`(1) AMOUNT OF GRANT- Each grant under this section shall be in an amount

that is not less than \$4,000,000 for the 5-year period during which the demonstration project being conducted.

`(2) DISBURSEMENT OF FUNDS-

`(A) PRELIMINARY DISBURSEMENTS- Beginning 1 year after the enactment of this section, the Secretary may disperse to any entity receiving a grant under this section not more than 20 percent of the total funding awarded to such entity under such grant, for the purpose of enabling the entity to plan the demonstration project to be conducted under such grant.

`(B) SUBSEQUENT DISBURSEMENTS- The remaining amount of grant funds not dispersed under subparagraph (A) shall be dispersed such that not less than 15 percent of such remaining amount is dispersed each subsequent year.

`(e) Compliance With State Requirements- Each entity receiving a grant under this section shall certify that it is in compliance with all applicable State licensing requirements.

`(f) Evaluation- The Secretary shall contract with the Director of the Institute of Medicine to conduct a study of the demonstration programs conducted under this section that shall provide analysis, based upon quantitative and qualitative data, regarding access to dental health care in the United States.

`(g) Clarification Regarding Dental Health Aide Program- Nothing in this section shall prohibit a dental health aide training program approved by the Indian Health Service from being eligible for a grant under this section.

`(h) Authorization of Appropriations- There is authorized to be appropriated such sums as may be necessary to carry out this section.'

SEC. 5305. GERIATRIC EDUCATION AND TRAINING; CAREER AWARDS; COMPREHENSIVE GERIATRIC EDUCATION.

(a) Workforce Development; Career Awards- Section 753 of the Public Health Service Act (42 U.S.C. 294c) is amended by adding at the end the following:

`(d) Geriatric Workforce Development-

`(1) IN GENERAL- The Secretary shall award grants or contracts under this subsection to entities that operate a geriatric education center pursuant to subsection (a)(1).

`(2) APPLICATION- To be eligible for an award under paragraph (1), an entity described in such paragraph shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

`(3) USE OF FUNDS- Amounts awarded under a grant or contract under paragraph (1) shall be used to--

`(A) carry out the fellowship program described in paragraph (4); and

`(B) carry out 1 of the 2 activities described in paragraph (5).

`(4) FELLOWSHIP PROGRAM-

`(A) IN GENERAL- Pursuant to paragraph (3), a geriatric education center that receives an award under this subsection shall use such funds to offer short-term intensive courses (referred to in this subsection as a 'fellowship') that focus on geriatrics, chronic care management, and long-term care that provide supplemental training for faculty members in medical schools and other health professions schools with programs in

psychology, pharmacy, nursing, social work, dentistry, public health, allied health, or other health disciplines, as approved by the Secretary. Such a fellowship shall be open to current faculty, and appropriately credentialed volunteer faculty and practitioners, who do not have formal training in geriatrics, to upgrade their knowledge and clinical skills for the care of older adults and adults with functional limitations and to enhance their interdisciplinary teaching skills.

`(B) LOCATION- A fellowship shall be offered either at the geriatric education center that is sponsoring the course, in collaboration with other geriatric education centers, or at medical schools, schools of dentistry, schools of nursing, schools of pharmacy, schools of social work, graduate programs in psychology, or allied health and other health professions schools approved by the Secretary with which the geriatric education centers are affiliated.

`(C) CME CREDIT- Participation in a fellowship under this paragraph shall be accepted with respect to complying with continuing health profession education requirements. As a condition of such acceptance, the recipient shall agree to subsequently provide a minimum of 18 hours of voluntary instructional support through a geriatric education center that is providing clinical training to students or trainees in long-term care settings.

`(5) ADDITIONAL REQUIRED ACTIVITIES DESCRIBED- Pursuant to paragraph (3), a geriatric education center that receives an award under this subsection shall use such funds to carry out 1 of the following 2 activities.

`(A) FAMILY CAREGIVER AND DIRECT CARE PROVIDER TRAINING- A geriatric education center that receives an award under this subsection shall offer at least 2 courses each year, at no charge or nominal cost, to family caregivers and direct care providers that are designed to provide practical training for supporting frail elders and individuals with disabilities. The Secretary shall require such Centers to work with appropriate community partners to develop training program content and to publicize the availability of training courses in their service areas. All family caregiver and direct care provider training programs shall include instruction on the management of psychological and behavioral aspects of dementia, communication techniques for working with individuals who have dementia, and the appropriate, safe, and effective use of medications for older adults.

`(B) INCORPORATION OF BEST PRACTICES- A geriatric education center that receives an award under this subsection shall develop and include material on depression and other mental disorders common among older adults, medication safety issues for older adults, and management of the psychological and behavioral aspects of dementia and communication techniques with individuals who have dementia in all training courses, where appropriate.

`(6) TARGETS- A geriatric education center that receives an award under this subsection shall meet targets approved by the Secretary for providing geriatric training to a certain number of faculty or practitioners during the term of the award, as well as other parameters established by the

Secretary.

`(7) AMOUNT OF AWARD- An award under this subsection shall be in an amount of \$150,000. Not more than 24 geriatric education centers may receive an award under this subsection.

`(8) MAINTENANCE OF EFFORT- A geriatric education center that receives an award under this subsection shall provide assurances to the Secretary that funds provided to the geriatric education center under this subsection will be used only to supplement, not to supplant, the amount of Federal, State, and local funds otherwise expended by the geriatric education center.

`(9) AUTHORIZATION OF APPROPRIATIONS- In addition to any other funding available to carry out this section, there is authorized to be appropriated to carry out this subsection, \$10,800,000 for the period of fiscal year 2011 through 2014.

`(e) Geriatric Career Incentive Awards-

`(1) IN GENERAL- The Secretary shall award grants or contracts under this section to individuals described in paragraph (2) to foster greater interest among a variety of health professionals in entering the field of geriatrics, long-term care, and chronic care management.

`(2) ELIGIBLE INDIVIDUALS- To be eligible to received an award under paragraph (1), an individual shall--

`(A) be an advanced practice nurse, a clinical social worker, a pharmacist, or student of psychology who is pursuing a doctorate or other advanced degree in geriatrics or related fields in an accredited health professions school; and

`(B) submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

`(3) CONDITION OF AWARD- As a condition of receiving an award under this subsection, an individual shall agree that, following completion of the award period, the individual will teach or practice in the field of geriatrics, long-term care, or chronic care management for a minimum of 5 years under guidelines set by the Secretary.

`(4) AUTHORIZATION OF APPROPRIATIONS- There is authorized to be appropriated to carry out this subsection, \$10,000,000 for the period of fiscal years 2011 through 2013.'

(b) Expansion of Eligibility for Geriatric Academic Career Awards; Payment to Institution- Section 753(c) of the Public Health Service Act 294(c) is amended--

(1) by redesignating paragraphs (4) and (5) as paragraphs (5) and (6), respectively;

(2) by striking paragraph (2) through paragraph (3) and inserting the following:

`(2) ELIGIBLE INDIVIDUALS- To be eligible to receive an Award under paragraph (1), an individual shall--

`(A) be board certified or board eligible in internal medicine, family practice, psychiatry, or licensed dentistry, or have completed any required training in a discipline and employed in an accredited health professions school that is approved by the Secretary;

`(B) have completed an approved fellowship program in geriatrics or have

completed specialty training in geriatrics as required by the discipline and any additional geriatrics training as required by the Secretary; and
(C) have a junior (non-tenured) faculty appointment at an accredited (as determined by the Secretary) school of medicine, osteopathic medicine, nursing, social work, psychology, dentistry, pharmacy, or other allied health disciplines in an accredited health professions school that is approved by the Secretary.

(3) LIMITATIONS- No Award under paragraph (1) may be made to an eligible individual unless the individual--

(A) has submitted to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require, and the Secretary has approved such application;

(B) provides, in such form and manner as the Secretary may require, assurances that the individual will meet the service requirement described in paragraph (6); and

(C) provides, in such form and manner as the Secretary may require, assurances that the individual has a full-time faculty appointment in a health professions institution and documented commitment from such institution to spend 75 percent of the total time of such individual on teaching and developing skills in interdisciplinary education in geriatrics.

(4) MAINTENANCE OF EFFORT- An eligible individual that receives an Award under paragraph (1) shall provide assurances to the Secretary that funds provided to the eligible individual under this subsection will be used only to supplement, not to supplant, the amount of Federal, State, and local funds otherwise expended by the eligible individual.'; and

(3) in paragraph (5), as so designated--

(A) in subparagraph (A)--

(i) by inserting 'for individuals who are physicians' after 'this section'; and

(ii) by inserting after the period at the end the following: 'The Secretary shall determine the amount of an Award under this section for individuals who are not physicians.'; and

(B) by adding at the end the following:

(C) PAYMENT TO INSTITUTION- The Secretary shall make payments to institutions which include schools of medicine, osteopathic medicine, nursing, social work, psychology, dentistry, and pharmacy, or other allied health discipline in an accredited health professions school that is approved by the Secretary.'

(c) Comprehensive Geriatric Education- Section 855 of the Public Health Service Act (42 U.S.C. 298) is amended--

(1) in subsection (b)--

(A) in paragraph (3), by striking 'or' at the end;

(B) in paragraph (4), by striking the period and inserting '; or'; and

(C) by adding at the end the following:

(5) establish traineeships for individuals who are preparing for advanced education nursing degrees in geriatric nursing, long-term care, gero-psychiatric nursing or other nursing areas that specialize in the care

of the elderly population.'; and
(2) in subsection (e), by striking '2003 through 2007' and inserting '2010 through 2014'.

SEC. 5306. MENTAL AND BEHAVIORAL HEALTH EDUCATION AND TRAINING GRANTS.

(a) In General- Part D of title VII (42 U.S.C. 294 et seq.) is amended by--

(1) striking section 757;

(2) redesignating section 756 (as amended by section 5103) as section 757;
and

(3) inserting after section 755 the following:

SEC. 756. MENTAL AND BEHAVIORAL HEALTH EDUCATION AND TRAINING GRANTS.

(a) Grants Authorized- The Secretary may award grants to eligible institutions of higher education to support the recruitment of students for, and education and clinical experience of the students in--

(1) baccalaureate, master's, and doctoral degree programs of social work, as well as the development of faculty in social work;

(2) accredited master's, doctoral, internship, and post-doctoral residency programs of psychology for the development and implementation of interdisciplinary training of psychology graduate students for providing behavioral and mental health services, including substance abuse prevention and treatment services;

(3) accredited institutions of higher education or accredited professional training programs that are establishing or expanding internships or other field placement programs in child and adolescent mental health in psychiatry, psychology, school psychology, behavioral pediatrics, psychiatric nursing, social work, school social work, substance abuse prevention and treatment, marriage and family therapy, school counseling, or professional counseling; and

(4) State-licensed mental health nonprofit and for-profit organizations to enable such organizations to pay for programs for preservice or in-service training of paraprofessional child and adolescent mental health workers.

(b) Eligibility Requirements- To be eligible for a grant under this section, an institution shall demonstrate--

(1) participation in the institutions' programs of individuals and groups from different racial, ethnic, cultural, geographic, religious, linguistic, and class backgrounds, and different genders and sexual orientations;

(2) knowledge and understanding of the concerns of the individuals and groups described in subsection (a);

(3) any internship or other field placement program assisted under the grant will prioritize cultural and linguistic competency;

(4) the institution will provide to the Secretary such data, assurances, and information as the Secretary may require; and

(5) with respect to any violation of the agreement between the Secretary and the institution, the institution will pay such liquidated damages as prescribed by the Secretary by regulation.

(c) Institutional Requirement- For grants authorized under subsection (a)(1), at least 4 of the grant recipients shall be historically black colleges or universities or other minority-serving institutions.

(d) Priority-

`(1) In selecting the grant recipients in social work under subsection (a)(1), the Secretary shall give priority to applicants that--

- `(A) are accredited by the Council on Social Work Education;
- `(B) have a graduation rate of not less than 80 percent for social work students; and
- `(C) exhibit an ability to recruit social workers from and place social workers in areas with a high need and high demand population.

`(2) In selecting the grant recipients in graduate psychology under subsection (a)(2), the Secretary shall give priority to institutions in which training focuses on the needs of vulnerable groups such as older adults and children, individuals with mental health or substance-related disorders, victims of abuse or trauma and of combat stress disorders such as posttraumatic stress disorder and traumatic brain injuries, homeless individuals, chronically ill persons, and their families.

`(3) In selecting the grant recipients in training programs in child and adolescent mental health under subsections (a)(3) and (a)(4), the Secretary shall give priority to applicants that--

- `(A) have demonstrated the ability to collect data on the number of students trained in child and adolescent mental health and the populations served by such students after graduation or completion of preservice or in-service training;
- `(B) have demonstrated familiarity with evidence-based methods in child and adolescent mental health services, including substance abuse prevention and treatment services;
- `(C) have programs designed to increase the number of professionals and paraprofessionals serving high-priority populations and to applicants who come from high-priority communities and plan to serve medically underserved populations, in health professional shortage areas, or in medically underserved areas;
- `(D) offer curriculum taught collaboratively with a family on the consumer and family lived experience or the importance of family-professional or family-paraprofessional partnerships; and
- `(E) provide services through a community mental health program described in section 1913(b)(1).

`(e) Authorization of Appropriation- For the fiscal years 2010 through 2013, there is authorized to be appropriated to carry out this section--

- `(1) \$8,000,000 for training in social work in subsection (a)(1);
- `(2) \$12,000,000 for training in graduate psychology in subsection (a)(2), of which not less than \$10,000,000 shall be allocated for doctoral, postdoctoral, and internship level training;
- `(3) \$10,000,000 for training in professional child and adolescent mental health in subsection (a)(3); and
- `(4) \$5,000,000 for training in paraprofessional child and adolescent work in subsection (a)(4).'

(b) Conforming Amendments- Section 757(b)(2) of the Public Health Service Act, as redesignated by subsection (a), is amended by striking `sections 751(a)(1)(A), 751(a)(1)(B), 753(b), 754(3)(A), and 755(b)' and inserting `sections 751(b)(1)(A), 753(b), and 755(b)'.

SEC. 5307. CULTURAL COMPETENCY, PREVENTION, AND PUBLIC HEALTH AND INDIVIDUALS WITH DISABILITIES TRAINING.

(a) Title VII- Section 741 of the Public Health Service Act (42 U.S.C. 293e) is amended--

(1) in subsection (a)--

(A) by striking the subsection heading and inserting 'Cultural Competency, Prevention, and Public Health and Individuals With Disability Grants'; and
(B) in paragraph (1), by striking 'for the purpose of' and all that follows through the period at the end and inserting 'for the development, evaluation, and dissemination of research, demonstration projects, and model curricula for cultural competency, prevention, public health proficiency, reducing health disparities, and aptitude for working with individuals with disabilities training for use in health professions schools and continuing education programs, and for other purposes determined as appropriate by the Secretary.'; and

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

'(b) Collaboration- In carrying out subsection (a), the Secretary shall collaborate with health professional societies, licensing and accreditation entities, health professions schools, and experts in minority health and cultural competency, prevention, and public health and disability groups, community-based organizations, and other organizations as determined appropriate by the Secretary. The Secretary shall coordinate with curricula and research and demonstration projects developed under section 807.

'(c) Dissemination-

'(1) IN GENERAL- Model curricula developed under this section shall be disseminated through the Internet Clearinghouse under section 270 and such other means as determined appropriate by the Secretary.

'(2) EVALUATION- The Secretary shall evaluate the adoption and the implementation of cultural competency, prevention, and public health, and working with individuals with a disability training curricula, and the facilitate inclusion of these competency measures in quality measurement systems as appropriate.

'(d) Authorization of Appropriations- There is authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2010 through 2015.'

(b) Title VIII- Section 807 of the Public Health Service Act (42 U.S.C. 296e-1) is amended--

(1) in subsection (a)--

(A) by striking the subsection heading and inserting 'Cultural Competency, Prevention, and Public Health and Individuals With Disability Grants'; and
(B) by striking 'for the purpose of' and all that follows through 'health care.' and inserting 'for the development, evaluation, and dissemination of research, demonstration projects, and model curricula for cultural competency, prevention, public health proficiency, reducing health disparities, and aptitude for working with individuals with disabilities training for use in health professions schools and continuing education programs, and for other purposes determined as appropriate by the Secretary.'; and

(2) by redesignating subsection (b) as subsection (d);

(3) by inserting after subsection (a) the following:

`(b) Collaboration- In carrying out subsection (a), the Secretary shall collaborate with the entities described in section 741(b). The Secretary shall coordinate with curricula and research and demonstration projects developed under such section 741.

`(c) Dissemination- Model curricula developed under this section shall be disseminated and evaluated in the same manner as model curricula developed under section 741, as described in subsection (c) of such section.'; and

(4) in subsection (d), as so redesignated--

(A) by striking `subsection (a)' and inserting `this section'; and

(B) by striking `2001 through 2004' and inserting `2010 through 2015'.

SEC. 5308. ADVANCED NURSING EDUCATION GRANTS.

Section 811 of the Public Health Service Act (42 U.S.C. 296j) is amended--

(1) in subsection (c)--

(A) in the subsection heading, by striking `and Nurse Midwifery Programs'; and

(B) by striking `and nurse midwifery';

(2) in subsection (f)--

(A) by striking paragraph (2); and

(B) by redesignating paragraph (3) as paragraph (2); and

(3) by redesignating subsections (d), (e), and (f) as subsections (e), (f), and (g), respectively; and

(4) by inserting after subsection (c), the following:

`(d) Authorized Nurse-midwifery Programs- Midwifery programs that are eligible for support under this section are educational programs that--

`(1) have as their objective the education of midwives; and

`(2) are accredited by the American College of Nurse-Midwives Accreditation Commission for Midwifery Education.'.

SEC. 5309. NURSE EDUCATION, PRACTICE, AND RETENTION GRANTS.

(a) In General- Section 831 of the Public Health Service Act (42 U.S.C. 296p) is amended--

(1) in the section heading, by striking `retention' and inserting `quality';

(2) in subsection (a)--

(A) in paragraph (1), by adding `or' after the semicolon;

(B) by striking paragraph (2); and

(C) by redesignating paragraph (3) as paragraph (2);

(3) in subsection (b)(3), by striking `managed care, quality improvement' and inserting `coordinated care';

(4) in subsection (g), by inserting `, as defined in section 801(2),' after `school of nursing'; and

(5) in subsection (h), by striking `2003 through 2007' and inserting `2010 through 2014'.

(b) Nurse Retention Grants- Title VIII of the Public Health Service Act is amended by inserting after section 831 (42 U.S.C. 296b) the following:

SEC. 831A. NURSE RETENTION GRANTS.

`(a) Retention Priority Areas- The Secretary may award grants to, and enter into contracts with, eligible entities to enhance the nursing workforce by

initiating and maintaining nurse retention programs pursuant to subsection (b) or (c).

`(b) Grants for Career Ladder Program- The Secretary may award grants to, and enter into contracts with, eligible entities for programs--

`(1) to promote career advancement for individuals including licensed practical nurses, licensed vocational nurses, certified nurse assistants, home health aides, diploma degree or associate degree nurses, to become baccalaureate prepared registered nurses or advanced education nurses in order to meet the needs of the registered nurse workforce;

`(2) developing and implementing internships and residency programs in collaboration with an accredited school of nursing, as defined by section 801(2), to encourage mentoring and the development of specialties; or

`(3) to assist individuals in obtaining education and training required to enter the nursing profession and advance within such profession.

`(c) Enhancing Patient Care Delivery Systems-

`(1) GRANTS- The Secretary may award grants to eligible entities to improve the retention of nurses and enhance patient care that is directly related to nursing activities by enhancing collaboration and communication among nurses and other health care professionals, and by promoting nurse involvement in the organizational and clinical decision-making processes of a health care facility.

`(2) PRIORITY- In making awards of grants under this subsection, the Secretary shall give preference to applicants that have not previously received an award under this subsection (or section 831(c) as such section existed on the day before the date of enactment of this section).

`(3) CONTINUATION OF AN AWARD- The Secretary shall make continuation of any award under this subsection beyond the second year of such award contingent on the recipient of such award having demonstrated to the Secretary measurable and substantive improvement in nurse retention or patient care.

`(d) Other Priority Areas- The Secretary may award grants to, or enter into contracts with, eligible entities to address other areas that are of high priority to nurse retention, as determined by the Secretary.

`(e) Report- The Secretary shall submit to the Congress before the end of each fiscal year a report on the grants awarded and the contracts entered into under this section. Each such report shall identify the overall number of such grants and contracts and provide an explanation of why each such grant or contract will meet the priority need of the nursing workforce.

`(f) Eligible Entity- For purposes of this section, the term 'eligible entity' includes an accredited school of nursing, as defined by section 801(2), a health care facility, or a partnership of such a school and facility.

`(g) Authorization of Appropriations- There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2010 through 2012.'

SEC. 5310. LOAN REPAYMENT AND SCHOLARSHIP PROGRAM.

(a) Loan Repayments and Scholarships- Section 846(a)(3) of the Public Health Service Act (42 U.S.C. 297n(a)(3)) is amended by inserting before the semicolon the following: ', or in a accredited school of nursing, as defined by section 801(2), as nurse faculty'.

(b) Technical and Conforming Amendments- Title VIII (42 U.S.C. 296 et seq.) is amended--

- (1) by redesignating section 810 (relating to prohibition against discrimination by schools on the basis of sex) as section 809 and moving such section so that it follows section 808;
- (2) in sections 835, 836, 838, 840, and 842, by striking the term `this subpart' each place it appears and inserting `this part';
- (3) in section 836(h), by striking the last sentence;
- (4) in section 836, by redesignating subsection (l) as subsection (k);
- (5) in section 839, by striking `839' and all that follows through `(a)' and inserting `839. (a)';
- (6) in section 835(b), by striking `841' each place it appears and inserting `871';
- (7) by redesignating section 841 as section 871, moving part F to the end of the title, and redesignating such part as part I;
- (8) in part G--
 - (A) by redesignating section 845 as section 851; and
 - (B) by redesignating part G as part F;
- (9) in part H--
 - (A) by redesignating sections 851 and 852 as sections 861 and 862, respectively; and
 - (B) by redesignating part H as part G; and
- (10) in part I--
 - (A) by redesignating section 855, as amended by section 5305, as section 865; and
 - (B) by redesignating part I as part H.

SEC. 5311. NURSE FACULTY LOAN PROGRAM.

(a) In General- Section 846A of the Public Health Service Act (42 U.S.C. 297n-1) is amended--

- (1) in subsection (a)--
 - (A) in the subsection heading, by striking `Establishment' and inserting `School of Nursing Student Loan Fund'; and
 - (B) by inserting `accredited' after `agreement with any';
- (2) in subsection (c)--
 - (A) in paragraph (2), by striking `\$30,000' and all that follows through the semicolon and inserting `\$35,500, during fiscal years 2010 and 2011 fiscal years (after fiscal year 2011, such amounts shall be adjusted to provide for a cost-of-attendance increase for the yearly loan rate and the aggregate loan;'; and
 - (B) in paragraph (3)(A), by inserting `an accredited' after `faculty member in';
- (3) in subsection (e), by striking `a school' and inserting `an accredited school'; and
- (4) in subsection (f), by striking `2003 through 2007' and inserting `2010 through 2014'.

(b) Eligible Individual Student Loan Repayment- Title VIII of the Public Health Service Act is amended by inserting after section 846A (42 U.S.C. 297n-1) the following:

SEC. 847. ELIGIBLE INDIVIDUAL STUDENT LOAN REPAYMENT.

(a) In General- The Secretary, acting through the Administrator of the Health Resources and Services Administration, may enter into an agreement with eligible individuals for the repayment of education loans, in accordance with this section, to increase the number of qualified nursing faculty.

(b) Agreements- Each agreement entered into under this subsection shall require that the eligible individual shall serve as a full-time member of the faculty of an accredited school of nursing, for a total period, in the aggregate, of at least 4 years during the 6-year period beginning on the later of--

(1) the date on which the individual receives a master's or doctorate nursing degree from an accredited school of nursing; or

(2) the date on which the individual enters into an agreement under this subsection.

(c) Agreement Provisions- Agreements entered into pursuant to subsection (b) shall be entered into on such terms and conditions as the Secretary may determine, except that--

(1) not more than 10 months after the date on which the 6-year period described under subsection (b) begins, but in no case before the individual starts as a full-time member of the faculty of an accredited school of nursing the Secretary shall begin making payments, for and on behalf of that individual, on the outstanding principal of, and interest on, any loan of that individual obtained to pay for such degree;

(2) for an individual who has completed a master's in nursing or equivalent degree in nursing--

(A) payments may not exceed \$10,000 per calendar year; and

(B) total payments may not exceed \$40,000 during the 2010 and 2011 fiscal years (after fiscal year 2011, such amounts shall be adjusted to provide for a cost-of-attendance increase for the yearly loan rate and the aggregate loan); and

(3) for an individual who has completed a doctorate or equivalent degree in nursing--

(A) payments may not exceed \$20,000 per calendar year; and

(B) total payments may not exceed \$80,000 during the 2010 and 2011 fiscal years (adjusted for subsequent fiscal years as provided for in the same manner as in paragraph (2)(B)).

(d) Breach of Agreement-

(1) IN GENERAL- In the case of any agreement made under subsection (b), the individual is liable to the Federal Government for the total amount paid by the Secretary under such agreement, and for interest on such amount at the maximum legal prevailing rate, if the individual fails to meet the agreement terms required under such subsection.

(2) WAIVER OR SUSPENSION OF LIABILITY- In the case of an individual making an agreement for purposes of paragraph (1), the Secretary shall provide for the waiver or suspension of liability under such paragraph if compliance by the individual with the agreement involved is impossible or would involve extreme hardship to the individual or if enforcement of the agreement with respect to the individual would be unconscionable.

`(3) DATE CERTAIN FOR RECOVERY- Subject to paragraph (2), any amount that the Federal Government is entitled to recover under paragraph (1) shall be paid to the United States not later than the expiration of the 3-year period beginning on the date the United States becomes so entitled.

`(4) AVAILABILITY- Amounts recovered under paragraph (1) shall be available to the Secretary for making loan repayments under this section and shall remain available for such purpose until expended.

`(e) Eligible Individual Defined- For purposes of this section, the term 'eligible individual' means an individual who--

`(1) is a United States citizen, national, or lawful permanent resident;

`(2) holds an unencumbered license as a registered nurse; and

`(3) has either already completed a master's or doctorate nursing program at an accredited school of nursing or is currently enrolled on a full-time or part-time basis in such a program.

`(f) Priority- For the purposes of this section and section 846A, funding priority will be awarded to School of Nursing Student Loans that support doctoral nursing students or Individual Student Loan Repayment that support doctoral nursing students.

`(g) Authorization of Appropriations- There are authorized to be appropriated to carry out this section such sums as may be necessary for each of fiscal years 2010 through 2014.'

SEC. 5312. AUTHORIZATION OF APPROPRIATIONS FOR PARTS B THROUGH D OF TITLE VIII.

Section 871 of the Public Health Service Act, as redesignated and moved by section 5310, is amended to read as follows:

SEC. 871. AUTHORIZATION OF APPROPRIATIONS.

`For the purpose of carrying out parts B, C, and D (subject to section 851(g)), there are authorized to be appropriated \$338,000,000 for fiscal year 2010, and such sums as may be necessary for each of the fiscal years 2011 through 2016.'

SEC. 5313. GRANTS TO PROMOTE THE COMMUNITY HEALTH WORKFORCE.

(a) In General- Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.) is amended by adding at the end the following:

SEC. 399V. GRANTS TO PROMOTE POSITIVE HEALTH BEHAVIORS AND OUTCOMES.

`(a) Grants Authorized- The Director of the Centers for Disease Control and Prevention, in collaboration with the Secretary, shall award grants to eligible entities to promote positive health behaviors and outcomes for populations in medically underserved communities through the use of community health workers.

`(b) Use of Funds- Grants awarded under subsection (a) shall be used to support community health workers--

`(1) to educate, guide, and provide outreach in a community setting regarding health problems prevalent in medically underserved communities, particularly racial and ethnic minority populations;

`(2) to educate and provide guidance regarding effective strategies to promote positive health behaviors and discourage risky health behaviors;

`(3) to educate and provide outreach regarding enrollment in health insurance including the Children's Health Insurance Program under title XXI of the Social Security Act, Medicare under title XVIII of such Act and

Medicaid under title XIX of such Act;

`(4) to identify, educate, refer, and enroll underserved populations to appropriate healthcare agencies and community-based programs and organizations in order to increase access to quality healthcare services and to eliminate duplicative care; or

`(5) to educate, guide, and provide home visitation services regarding maternal health and prenatal care.

`(c) Application- Each eligible entity that desires to receive a grant under subsection (a) shall submit an application to the Secretary, at such time, in such manner, and accompanied by such information as the Secretary may require.

`(d) Priority- In awarding grants under subsection (a), the Secretary shall give priority to applicants that--

`(1) propose to target geographic areas--

`(A) with a high percentage of residents who are eligible for health insurance but are uninsured or underinsured;

`(B) with a high percentage of residents who suffer from chronic diseases; or

`(C) with a high infant mortality rate;

`(2) have experience in providing health or health-related social services to individuals who are underserved with respect to such services; and

`(3) have documented community activity and experience with community health workers.

`(e) Collaboration With Academic Institutions and the One-stop Delivery System- The Secretary shall encourage community health worker programs receiving funds under this section to collaborate with academic institutions and one-stop delivery systems under section 134(c) of the Workforce Investment Act of 1998. Nothing in this section shall be construed to require such collaboration.

`(f) Evidence-based Interventions- The Secretary shall encourage community health worker programs receiving funding under this section to implement a process or an outcome-based payment system that rewards community health workers for connecting underserved populations with the most appropriate services at the most appropriate time. Nothing in this section shall be construed to require such a payment.

`(g) Quality Assurance and Cost Effectiveness- The Secretary shall establish guidelines for assuring the quality of the training and supervision of community health workers under the programs funded under this section and for assuring the cost-effectiveness of such programs.

`(h) Monitoring- The Secretary shall monitor community health worker programs identified in approved applications under this section and shall determine whether such programs are in compliance with the guidelines established under subsection (g).

`(i) Technical Assistance- The Secretary may provide technical assistance to community health worker programs identified in approved applications under this section with respect to planning, developing, and operating programs under the grant.

`(j) Authorization of Appropriations- There are authorized to be appropriated, such sums as may be necessary to carry out this section for each of fiscal

years 2010 through 2014.

`(k) Definitions- In this section:

`(1) COMMUNITY HEALTH WORKER- The term `community health worker', as defined by the Department of Labor as Standard Occupational Classification [21-1094] means an individual who promotes health or nutrition within the community in which the individual resides--

`(A) by serving as a liaison between communities and healthcare agencies;

`(B) by providing guidance and social assistance to community residents;

`(C) by enhancing community residents' ability to effectively communicate with healthcare providers;

`(D) by providing culturally and linguistically appropriate health or nutrition education;

`(E) by advocating for individual and community health;

`(F) by providing referral and follow-up services or otherwise coordinating care; and

`(G) by proactively identifying and enrolling eligible individuals in Federal, State, local, private or nonprofit health and human services programs.

`(2) COMMUNITY SETTING- The term `community setting' means a home or a community organization located in the neighborhood in which a participant in the program under this section resides.

`(3) ELIGIBLE ENTITY- The term `eligible entity' means a public or nonprofit private entity (including a State or public subdivision of a State, a public health department, a free health clinic, a hospital, or a Federally-qualified health center (as defined in section 1861(aa) of the Social Security Act)), or a consortium of any such entities.

`(4) MEDICALLY UNDERSERVED COMMUNITY- The term `medically underserved community' means a community identified by a State--

`(A) that has a substantial number of individuals who are members of a medically underserved population, as defined by section 330(b)(3); and

`(B) a significant portion of which is a health professional shortage area as designated under section 332.'

SEC. 5314. FELLOWSHIP TRAINING IN PUBLIC HEALTH.

Part E of title VII of the Public Health Service Act (42 U.S.C. 294n et seq.), as amended by section 5206, is further amended by adding at the end the following:

`SEC. 778. FELLOWSHIP TRAINING IN APPLIED PUBLIC HEALTH EPIDEMIOLOGY, PUBLIC HEALTH LABORATORY SCIENCE, PUBLIC HEALTH INFORMATICS, AND EXPANSION OF THE EPIDEMIC INTELLIGENCE SERVICE.

`(a) In General- The Secretary may carry out activities to address documented workforce shortages in State and local health departments in the critical areas of applied public health epidemiology and public health laboratory science and informatics and may expand the Epidemic Intelligence Service.

`(b) Specific Uses- In carrying out subsection (a), the Secretary shall provide for the expansion of existing fellowship programs operated through the Centers for Disease Control and Prevention in a manner that is designed to alleviate shortages of the type described in subsection (a).

`(c) Other Programs- The Secretary may provide for the expansion of other

applied epidemiology training programs that meet objectives similar to the objectives of the programs described in subsection (b).

`(d) Work Obligation- Participation in fellowship training programs under this section shall be deemed to be service for purposes of satisfying work obligations stipulated in contracts under section 3381(j).

`(e) General Support- Amounts may be used from grants awarded under this section to expand the Public Health Informatics Fellowship Program at the Centers for Disease Control and Prevention to better support all public health systems at all levels of government.

`(f) Authorization of Appropriations- There are authorized to be appropriated to carry out this section \$39,500,000 for each of fiscal years 2010 through 2013, of which--

`(1) \$5,000,000 shall be made available in each such fiscal year for epidemiology fellowship training program activities under subsections (b) and (c);

`(2) \$5,000,000 shall be made available in each such fiscal year for laboratory fellowship training programs under subsection (b);

`(3) \$5,000,000 shall be made available in each such fiscal year for the Public Health Informatics Fellowship Program under subsection (e); and

`(4) \$24,500,000 shall be made available for expanding the Epidemic Intelligence Service under subsection (a).'

SEC. 5315. UNITED STATES PUBLIC HEALTH SCIENCES TRACK.

Title II of the Public Health Service Act (42 U.S.C. 202 et seq.) is amended by adding at the end the following:

`PART D--UNITED STATES PUBLIC HEALTH SCIENCES TRACK

`SEC. 271. ESTABLISHMENT.

`(a) United States Public Health Services Track-

`(1) IN GENERAL- There is hereby authorized to be established a United States Public Health Sciences Track (referred to in this part as the 'Track'), at sites to be selected by the Secretary, with authority to grant appropriate advanced degrees in a manner that uniquely emphasizes team-based service, public health, epidemiology, and emergency preparedness and response. It shall be so organized as to graduate not less than--

`(A) 150 medical students annually, 10 of whom shall be awarded studentships to the Uniformed Services University of Health Sciences;

`(B) 100 dental students annually;

`(C) 250 nursing students annually;

`(D) 100 public health students annually;

`(E) 100 behavioral and mental health professional students annually;

`(F) 100 physician assistant or nurse practitioner students annually; and

`(G) 50 pharmacy students annually.

`(2) LOCATIONS- The Track shall be located at existing and accredited, affiliated health professions education training programs at academic health centers located in regions of the United States determined appropriate by the Surgeon General, in consultation with the National Health Care Workforce Commission established in section 5101 of the Patient Protection and Affordable Care Act.

`(b) Number of Graduates- Except as provided in subsection (a), the number of

persons to be graduated from the Track shall be prescribed by the Secretary. In so prescribing the number of persons to be graduated from the Track, the Secretary shall institute actions necessary to ensure the maximum number of first-year enrollments in the Track consistent with the academic capacity of the affiliated sites and the needs of the United States for medical, dental, and nursing personnel.

`(c) Development- The development of the Track may be by such phases as the Secretary may prescribe subject to the requirements of subsection (a).

`(d) Integrated Longitudinal Plan- The Surgeon General shall develop an integrated longitudinal plan for health professions continuing education throughout the continuum of health-related education, training, and practice. Training under such plan shall emphasize patient-centered, interdisciplinary, and care coordination skills. Experience with deployment of emergency response teams shall be included during the clinical experiences.

`(e) Faculty Development- The Surgeon General shall develop faculty development programs and curricula in decentralized venues of health care, to balance urban, tertiary, and inpatient venues.

`SEC. 272. ADMINISTRATION.

`(a) In General- The business of the Track shall be conducted by the Surgeon General with funds appropriated for and provided by the Department of Health and Human Services. The National Health Care Workforce Commission shall assist the Surgeon General in an advisory capacity.

`(b) Faculty-

`(1) IN GENERAL- The Surgeon General, after considering the recommendations of the National Health Care Workforce Commission, shall obtain the services of such professors, instructors, and administrative and other employees as may be necessary to operate the Track, but utilize when possible, existing affiliated health professions training institutions. Members of the faculty and staff shall be employed under salary schedules and granted retirement and other related benefits prescribed by the Secretary so as to place the employees of the Track faculty on a comparable basis with the employees of fully accredited schools of the health professions within the United States.

`(2) TITLES- The Surgeon General may confer academic titles, as appropriate, upon the members of the faculty.

`(3) NONAPPLICATION OF PROVISIONS- The limitations in section 5373 of title 5, United States Code, shall not apply to the authority of the Surgeon General under paragraph (1) to prescribe salary schedules and other related benefits.

`(c) Agreements- The Surgeon General may negotiate agreements with agencies of the Federal Government to utilize on a reimbursable basis appropriate existing Federal medical resources located in the United States (or locations selected in accordance with section 271(a)(2)). Under such agreements the facilities concerned will retain their identities and basic missions. The Surgeon General may negotiate affiliation agreements with accredited universities and health professions training institutions in the United States. Such agreements may include provisions for payments for educational services provided students participating in Department of Health and Human Services educational programs.

`(d) Programs- The Surgeon General may establish the following educational

programs for Track students:

- `(1) Postdoctoral, postgraduate, and technological programs.
- `(2) A cooperative program for medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing students.
- `(3) Other programs that the Surgeon General determines necessary in order to operate the Track in a cost-effective manner.
- `(e) Continuing Medical Education- The Surgeon General shall establish programs in continuing medical education for members of the health professions to the end that high standards of health care may be maintained within the United States.
- `(f) Authority of the Surgeon General-
 - `(1) IN GENERAL- The Surgeon General is authorized--
 - `(A) to enter into contracts with, accept grants from, and make grants to any nonprofit entity for the purpose of carrying out cooperative enterprises in medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing research, consultation, and education;
 - `(B) to enter into contracts with entities under which the Surgeon General may furnish the services of such professional, technical, or clerical personnel as may be necessary to fulfill cooperative enterprises undertaken by the Track;
 - `(C) to accept, hold, administer, invest, and spend any gift, devise, or bequest of personal property made to the Track, including any gift, devise, or bequest for the support of an academic chair, teaching, research, or demonstration project;
 - `(D) to enter into agreements with entities that may be utilized by the Track for the purpose of enhancing the activities of the Track in education, research, and technological applications of knowledge; and
 - `(E) to accept the voluntary services of guest scholars and other persons.
 - `(2) LIMITATION- The Surgeon General may not enter into any contract with an entity if the contract would obligate the Track to make outlays in advance of the enactment of budget authority for such outlays.
 - `(3) SCIENTISTS- Scientists or other medical, dental, or nursing personnel utilized by the Track under an agreement described in paragraph (1) may be appointed to any position within the Track and may be permitted to perform such duties within the Track as the Surgeon General may approve.
 - `(4) VOLUNTEER SERVICES- A person who provides voluntary services under the authority of subparagraph (E) of paragraph (1) shall be considered to be an employee of the Federal Government for the purposes of chapter 81 of title 5, relating to compensation for work-related injuries, and to be an employee of the Federal Government for the purposes of chapter 171 of title 28, relating to tort claims. Such a person who is not otherwise employed by the Federal Government shall not be considered to be a Federal employee for any other purpose by reason of the provision of such services.

`SEC. 273. STUDENTS; SELECTION; OBLIGATION.

- `(a) Student Selection-
 - `(1) IN GENERAL- Medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing students at the Track shall be

selected under procedures prescribed by the Surgeon General. In so prescribing, the Surgeon General shall consider the recommendations of the National Health Care Workforce Commission.

`(2) PRIORITY- In developing admissions procedures under paragraph (1), the Surgeon General shall ensure that such procedures give priority to applicant medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing students from rural communities and underrepresented minorities.

`(b) Contract and Service Obligation-

`(1) CONTRACT- Upon being admitted to the Track, a medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, or nursing student shall enter into a written contract with the Surgeon General that shall contain--

`(A) an agreement under which--

`(i) subject to subparagraph (B), the Surgeon General agrees to provide the student with tuition (or tuition remission) and a student stipend (described in paragraph (2)) in each school year for a period of years (not to exceed 4 school years) determined by the student, during which period the student is enrolled in the Track at an affiliated or other participating health professions institution pursuant to an agreement between the Track and such institution; and

`(ii) subject to subparagraph (B), the student agrees--

`(I) to accept the provision of such tuition and student stipend to the student;

`(II) to maintain enrollment at the Track until the student completes the course of study involved;

`(III) while enrolled in such course of study, to maintain an acceptable level of academic standing (as determined by the Surgeon General);

`(IV) if pursuing a degree from a school of medicine or osteopathic medicine, dental, public health, or nursing school or a physician assistant, pharmacy, or behavioral and mental health professional program, to complete a residency or internship in a specialty that the Surgeon General determines is appropriate; and

`(V) to serve for a period of time (referred to in this part as the `period of obligated service') within the Commissioned Corps of the Public Health Service equal to 2 years for each school year during which such individual was enrolled at the College, reduced as provided for in paragraph (3);

`(B) a provision that any financial obligation of the United States arising out of a contract entered into under this part and any obligation of the student which is conditioned thereon, is contingent upon funds being appropriated to carry out this part;

`(C) a statement of the damages to which the United States is entitled for the student's breach of the contract; and

`(D) such other statements of the rights and liabilities of the Secretary and of the individual, not inconsistent with the provisions of this part.

`(2) TUITION AND STUDENT STIPEND-

`(A) TUITION REMISSION RATES- The Surgeon General, based on the recommendations of the National Health Care Workforce Commission, shall establish Federal tuition remission rates to be used by the Track to provide reimbursement to affiliated and other participating health professions institutions for the cost of educational services provided by such institutions to Track students. The agreement entered into by such participating institutions under paragraph (1)(A)(i) shall contain an agreement to accept as payment in full the established remission rate under this subparagraph.

`(B) STIPEND- The Surgeon General, based on the recommendations of the National Health Care Workforce Commission, shall establish and update Federal stipend rates for payment to students under this part.

`(3) REDUCTIONS IN THE PERIOD OF OBLIGATED SERVICE- The period of obligated service under paragraph (1)(A)(ii)(V) shall be reduced--

`(A) in the case of a student who elects to participate in a high-needs speciality residency (as determined by the National Health Care Workforce Commission), by 3 months for each year of such participation (not to exceed a total of 12 months); and

`(B) in the case of a student who, upon completion of their residency, elects to practice in a Federal medical facility (as defined in section 781(e)) that is located in a health professional shortage area (as defined in section 332), by 3 months for year of full-time practice in such a facility (not to exceed a total of 12 months).

`(c) Second 2 Years of Service- During the third and fourth years in which a medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, or nursing student is enrolled in the Track, training should be designed to prioritize clinical rotations in Federal medical facilities in health professional shortage areas, and emphasize a balance of hospital and community-based experiences, and training within interdisciplinary teams.

`(d) Dentist, Physician Assistant, Pharmacist, Behavioral and Mental Health Professional, Public Health Professional, and Nurse Training- The Surgeon General shall establish provisions applicable with respect to dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing students that are comparable to those for medical students under this section, including service obligations, tuition support, and stipend support. The Surgeon General shall give priority to health professions training institutions that train medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing students for some significant period of time together, but at a minimum have a discrete and shared core curriculum.

`(e) Elite Federal Disaster Teams- The Surgeon General, in consultation with the Secretary, the Director of the Centers for Disease Control and Prevention, and other appropriate military and Federal government agencies, shall develop criteria for the appointment of highly qualified Track faculty, medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, and nursing students, and graduates to elite Federal disaster preparedness teams to train and to respond to public health emergencies, natural disasters, bioterrorism events, and other emergencies.

`f) Student Dropped From Track in Affiliate School- A medical, dental, physician assistant, pharmacy, behavioral and mental health, public health, or nursing student who, under regulations prescribed by the Surgeon General, is dropped from the Track in an affiliated school for deficiency in conduct or studies, or for other reasons, shall be liable to the United States for all tuition and stipend support provided to the student.

`SEC. 274. FUNDING.

`Beginning with fiscal year 2010, the Secretary shall transfer from the Public Health and Social Services Emergency Fund such sums as may be necessary to carry out this part.'.

Subtitle E--Supporting the Existing Health Care Workforce

SEC. 5401. CENTERS OF EXCELLENCE.

Section 736 of the Public Health Service Act (42 U.S.C. 293) is amended by striking subsection (h) and inserting the following:

`(h) Formula for Allocations-

`(1) ALLOCATIONS- Based on the amount appropriated under subsection (i) for a fiscal year, the following subparagraphs shall apply as appropriate:

`(A) IN GENERAL- If the amounts appropriated under subsection (i) for a fiscal year are \$24,000,000 or less--

`(i) the Secretary shall make available \$12,000,000 for grants under subsection (a) to health professions schools that meet the conditions described in subsection (c)(2)(A); and

`(ii) and available after grants are made with funds under clause (i), the Secretary shall make available--

`(I) 60 percent of such amount for grants under subsection (a) to health professions schools that meet the conditions described in paragraph (3) or (4) of subsection (c) (including meeting the conditions under subsection (e)); and

`(II) 40 percent of such amount for grants under subsection (a) to health professions schools that meet the conditions described in subsection (c)(5).

`(B) FUNDING IN EXCESS OF \$24,000,000- If amounts appropriated under subsection (i) for a fiscal year exceed \$24,000,000 but are less than \$30,000,000--

`(i) 80 percent of such excess amounts shall be made available for grants under subsection (a) to health professions schools that meet the requirements described in paragraph (3) or (4) of subsection (c) (including meeting conditions pursuant to subsection (e)); and

`(ii) 20 percent of such excess amount shall be made available for grants under subsection (a) to health professions schools that meet the conditions described in subsection (c)(5).

`(C) FUNDING IN EXCESS OF \$30,000,000- If amounts appropriated under subsection (i) for a fiscal year exceed \$30,000,000 but are less than \$40,000,000, the Secretary shall make available--

`(i) not less than \$12,000,000 for grants under subsection (a) to health professions schools that meet the conditions described in subsection (c)(2)(A);

`(ii) not less than \$12,000,000 for grants under subsection (a) to

health professions schools that meet the conditions described in paragraph (3) or (4) of subsection (c) (including meeting conditions pursuant to subsection (e));

`(iii) not less than \$6,000,000 for grants under subsection (a) to health professions schools that meet the conditions described in subsection (c)(5); and

`(iv) after grants are made with funds under clauses (i) through (iii), any remaining excess amount for grants under subsection (a) to health professions schools that meet the conditions described in paragraph (2)(A), (3), (4), or (5) of subsection (c).

`(D) FUNDING IN EXCESS OF \$40,000,000- If amounts appropriated under subsection (i) for a fiscal year are \$40,000,000 or more, the Secretary shall make available--

`(i) not less than \$16,000,000 for grants under subsection (a) to health professions schools that meet the conditions described in subsection (c)(2)(A);

`(ii) not less than \$16,000,000 for grants under subsection (a) to health professions schools that meet the conditions described in paragraph (3) or (4) of subsection (c) (including meeting conditions pursuant to subsection (e));

`(iii) not less than \$8,000,000 for grants under subsection (a) to health professions schools that meet the conditions described in subsection (c)(5); and

`(iv) after grants are made with funds under clauses (i) through (iii), any remaining funds for grants under subsection (a) to health professions schools that meet the conditions described in paragraph (2)(A), (3), (4), or (5) of subsection (c).

`(2) NO LIMITATION- Nothing in this subsection shall be construed as limiting the centers of excellence referred to in this section to the designated amount, or to preclude such entities from competing for grants under this section.

`(3) MAINTENANCE OF EFFORT-

`(A) IN GENERAL- With respect to activities for which a grant made under this part are authorized to be expended, the Secretary may not make such a grant to a center of excellence for any fiscal year unless the center agrees to maintain expenditures of non-Federal amounts for such activities at a level that is not less than the level of such expenditures maintained by the center for the fiscal year preceding the fiscal year for which the school receives such a grant.

`(B) USE OF FEDERAL FUNDS- With respect to any Federal amounts received by a center of excellence and available for carrying out activities for which a grant under this part is authorized to be expended, the center shall, before expending the grant, expend the Federal amounts obtained from sources other than the grant, unless given prior approval from the Secretary.

`(i) Authorization of Appropriations- There are authorized to be appropriated to carry out this section--

`(1) \$50,000,000 for each of the fiscal years 2010 through 2015; and

`(2) and such sums as are necessary for each subsequent fiscal year.'.
SEC. 5402. HEALTH CARE PROFESSIONALS TRAINING FOR DIVERSITY.

(a) Loan Repayments and Fellowships Regarding Faculty Positions- Section 738(a)(1) of the Public Health Service Act (42 U.S.C. 293b(a)(1)) is amended by striking ` \$20,000 of the principal and interest of the educational loans of such individuals.' and inserting ` \$30,000 of the principal and interest of the educational loans of such individuals.'.

(b) Scholarships for Disadvantaged Students- Section 740(a) of such Act (42 U.S.C. 293d(a)) is amended by striking ` \$37,000,000' and all that follows through ` 2002' and inserting ` \$51,000,000 for fiscal year 2010, and such sums as may be necessary for each of the fiscal years 2011 through 2014'.

(c) Reauthorization for Loan Repayments and Fellowships Regarding Faculty Positions- Section 740(b) of such Act (42 U.S.C. 293d(b)) is amended by striking ` appropriated' and all that follows through the period at the end and inserting ` appropriated, \$5,000,000 for each of the fiscal years 2010 through 2014.'.

(d) Reauthorization for Educational Assistance in the Health Professions Regarding Individuals From a Disadvantaged Background- Section 740(c) of such Act (42 U.S.C. 293d(c)) is amended by striking the first sentence and inserting the following: ` For the purpose of grants and contracts under section 739(a)(1), there is authorized to be appropriated \$60,000,000 for fiscal year 2010 and such sums as may be necessary for each of the fiscal years 2011 through 2014.'.

SEC. 5403. INTERDISCIPLINARY, COMMUNITY-BASED LINKAGES.

(a) Area Health Education Centers- Section 751 of the Public Health Service Act (42 U.S.C. 294a) is amended to read as follows:

`SEC. 751. AREA HEALTH EDUCATION CENTERS.

`(a) Establishment of Awards- The Secretary shall make the following 2 types of awards in accordance with this section:

`(1) INFRASTRUCTURE DEVELOPMENT AWARD- The Secretary shall make awards to eligible entities to enable such entities to initiate health care workforce educational programs or to continue to carry out comparable programs that are operating at the time the award is made by planning, developing, operating, and evaluating an area health education center program.

`(2) POINT OF SERVICE MAINTENANCE AND ENHANCEMENT AWARD- The Secretary shall make awards to eligible entities to maintain and improve the effectiveness and capabilities of an existing area health education center program, and make other modifications to the program that are appropriate due to changes in demographics, needs of the populations served, or other similar issues affecting the area health education center program. For the purposes of this section, the term ` Program' refers to the area health education center program.

`(b) Eligible Entities; Application-

`(1) ELIGIBLE ENTITIES-

`(A) INFRASTRUCTURE DEVELOPMENT- For purposes of subsection (a)(1), the term `eligible entity' means a school of medicine or osteopathic medicine, an incorporated consortium of such schools, or the parent institutions of such a school. With respect to a State in which no area health education

center program is in operation, the Secretary may award a grant or contract under subsection (a)(1) to a school of nursing.

`(B) POINT OF SERVICE MAINTENANCE AND ENHANCEMENT- For purposes of subsection (a)(2), the term 'eligible entity' means an entity that has received funds under this section, is operating an area health education center program, including an area health education center or centers, and has a center or centers that are no longer eligible to receive financial assistance under subsection (a)(1).

`(2) APPLICATION- An eligible entity desiring to receive an award under this section shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

`(c) Use of Funds-

`(1) REQUIRED ACTIVITIES- An eligible entity shall use amounts awarded under a grant under subsection (a)(1) or (a)(2) to carry out the following activities:

`(A) Develop and implement strategies, in coordination with the applicable one-stop delivery system under section 134(c) of the Workforce Investment Act of 1998, to recruit individuals from underrepresented minority populations or from disadvantaged or rural backgrounds into health professions, and support such individuals in attaining such careers.

`(B) Develop and implement strategies to foster and provide community-based training and education to individuals seeking careers in health professions within underserved areas for the purpose of developing and maintaining a diverse health care workforce that is prepared to deliver high-quality care, with an emphasis on primary care, in underserved areas or for health disparity populations, in collaboration with other Federal and State health care workforce development programs, the State workforce agency, and local workforce investment boards, and in health care safety net sites.

`(C) Prepare individuals to more effectively provide health services to underserved areas and health disparity populations through field placements or preceptorships in conjunction with community-based organizations, accredited primary care residency training programs, Federally qualified health centers, rural health clinics, public health departments, or other appropriate facilities.

`(D) Conduct and participate in interdisciplinary training that involves physicians, physician assistants, nurse practitioners, nurse midwives, dentists, psychologists, pharmacists, optometrists, community health workers, public and allied health professionals, or other health professionals, as practicable.

`(E) Deliver or facilitate continuing education and information dissemination programs for health care professionals, with an emphasis on individuals providing care in underserved areas and for health disparity populations.

`(F) Propose and implement effective program and outcomes measurement and evaluation strategies.

`(G) Establish a youth public health program to expose and recruit high school students into health careers, with a focus on careers in public

health.

`(2) INNOVATIVE OPPORTUNITIES- An eligible entity may use amounts awarded under a grant under subsection (a)(1) or subsection (a)(2) to carry out any of the following activities:

`(A) Develop and implement innovative curricula in collaboration with community-based accredited primary care residency training programs, Federally qualified health centers, rural health clinics, behavioral and mental health facilities, public health departments, or other appropriate facilities, with the goal of increasing the number of primary care physicians and other primary care providers prepared to serve in underserved areas and health disparity populations.

`(B) Coordinate community-based participatory research with academic health centers, and facilitate rapid flow and dissemination of evidence-based health care information, research results, and best practices to improve quality, efficiency, and effectiveness of health care and health care systems within community settings.

`(C) Develop and implement other strategies to address identified workforce needs and increase and enhance the health care workforce in the area served by the area health education center program.

`(d) Requirements-

`(1) AREA HEALTH EDUCATION CENTER PROGRAM- In carrying out this section, the Secretary shall ensure the following:

`(A) An entity that receives an award under this section shall conduct at least 10 percent of clinical education required for medical students in community settings that are removed from the primary teaching facility of the contracting institution for grantees that operate a school of medicine or osteopathic medicine. In States in which an entity that receives an award under this section is a nursing school or its parent institution, the Secretary shall alternatively ensure that--

`(i) the nursing school conducts at least 10 percent of clinical education required for nursing students in community settings that are remote from the primary teaching facility of the school; and
` (ii) the entity receiving the award maintains a written agreement with a school of medicine or osteopathic medicine to place students from that school in training sites in the area health education center program area.

`(B) An entity receiving funds under subsection (a)(2) does not distribute such funding to a center that is eligible to receive funding under subsection (a)(1).

`(2) AREA HEALTH EDUCATION CENTER- The Secretary shall ensure that each area health education center program includes at least 1 area health education center, and that each such center--

`(A) is a public or private organization whose structure, governance, and operation is independent from the awardee and the parent institution of the awardee;

`(B) is not a school of medicine or osteopathic medicine, the parent institution of such a school, or a branch campus or other subunit of a school of medicine or osteopathic medicine or its parent institution, or a

consortium of such entities;

`(C) designates an underserved area or population to be served by the center which is in a location removed from the main location of the teaching facilities of the schools participating in the program with such center and does not duplicate, in whole or in part, the geographic area or population served by any other center;

`(D) fosters networking and collaboration among communities and between academic health centers and community-based centers;

`(E) serves communities with a demonstrated need of health professionals in partnership with academic medical centers;

`(F) addresses the health care workforce needs of the communities served in coordination with the public workforce investment system; and

`(G) has a community-based governing or advisory board that reflects the diversity of the communities involved.

`(e) Matching Funds- With respect to the costs of operating a program through a grant under this section, to be eligible for financial assistance under this section, an entity shall make available (directly or through contributions from State, county or municipal governments, or the private sector) recurring non-Federal contributions in cash or in kind, toward such costs in an amount that is equal to not less than 50 percent of such costs. At least 25 percent of the total required non-Federal contributions shall be in cash. An entity may apply to the Secretary for a waiver of not more than 75 percent of the matching fund amount required by the entity for each of the first 3 years the entity is funded through a grant under subsection (a)(1).

`(f) Limitation- Not less than 75 percent of the total amount provided to an area health education center program under subsection (a)(1) or (a)(2) shall be allocated to the area health education centers participating in the program under this section. To provide needed flexibility to newly funded area health education center programs, the Secretary may waive the requirement in the sentence for the first 2 years of a new area health education center program funded under subsection (a)(1).

`(g) Award- An award to an entity under this section shall be not less than \$250,000 annually per area health education center included in the program involved. If amounts appropriated to carry out this section are not sufficient to comply with the preceding sentence, the Secretary may reduce the per center amount provided for in such sentence as necessary, provided the distribution established in subsection (j)(2) is maintained.

`(h) Project Terms-

`(1) IN GENERAL- Except as provided in paragraph (2), the period during which payments may be made under an award under subsection (a)(1) may not exceed--

`(A) in the case of a program, 12 years; or

`(B) in the case of a center within a program, 6 years.

`(2) EXCEPTION- The periods described in paragraph (1) shall not apply to programs receiving point of service maintenance and enhancement awards under subsection (a)(2) to maintain existing centers and activities.

`(i) Inapplicability of Provision- Notwithstanding any other provision of this title, section 791(a) shall not apply to an area health education center

funded under this section.

`(j) Authorization of Appropriations-

`(1) IN GENERAL- There is authorized to be appropriated to carry out this section \$125,000,000 for each of the fiscal years 2010 through 2014.

`(2) REQUIREMENTS- Of the amounts appropriated for a fiscal year under paragraph (1)--

`(A) not more than 35 percent shall be used for awards under subsection (a)(1);

`(B) not less than 60 percent shall be used for awards under subsection (a)(2);

`(C) not more than 1 percent shall be used for grants and contracts to implement outcomes evaluation for the area health education centers; and

`(D) not more than 4 percent shall be used for grants and contracts to provide technical assistance to entities receiving awards under this section.

`(3) CARRYOVER FUNDS- An entity that receives an award under this section may carry over funds from 1 fiscal year to another without obtaining approval from the Secretary. In no case may any funds be carried over pursuant to the preceding sentence for more than 3 years.

`(k) Sense of Congress- It is the sense of the Congress that every State have an area health education center program in effect under this section.'

(b) Continuing Educational Support for Health Professionals Serving in Underserved Communities- Part D of title VII of the Public Health Service Act (42 U.S.C. 294 et seq.) is amended by striking section 752 and inserting the following:

SEC. 752. CONTINUING EDUCATIONAL SUPPORT FOR HEALTH PROFESSIONALS SERVING IN UNDERSERVED COMMUNITIES.

`(a) In General- The Secretary shall make grants to, and enter into contracts with, eligible entities to improve health care, increase retention, increase representation of minority faculty members, enhance the practice environment, and provide information dissemination and educational support to reduce professional isolation through the timely dissemination of research findings using relevant resources.

`(b) Eligible Entities- For purposes of this section, the term 'eligible entity' means an entity described in section 799(b).

`(c) Application- An eligible entity desiring to receive an award under this section shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

`(d) Use of Funds- An eligible entity shall use amounts awarded under a grant or contract under this section to provide innovative supportive activities to enhance education through distance learning, continuing educational activities, collaborative conferences, and electronic and telelearning activities, with priority for primary care.

`(e) Authorization- There is authorized to be appropriated to carry out this section \$5,000,000 for each of the fiscal years 2010 through 2014, and such sums as may be necessary for each subsequent fiscal year.'

SEC. 5404. WORKFORCE DIVERSITY GRANTS.

Section 821 of the Public Health Service Act (42 U.S.C. 296m) is amended--

(1) in subsection (a)--

(A) by striking 'The Secretary may' and inserting the following:

'(1) AUTHORITY- The Secretary may';

(B) by striking 'pre-entry preparation, and retention activities' and inserting the following: 'stipends for diploma or associate degree nurses to enter a bridge or degree completion program, student scholarships or stipends for accelerated nursing degree programs, pre-entry preparation, advanced education preparation, and retention activities'; and

(2) in subsection (b)--

(A) by striking 'First' and all that follows through 'including the' and inserting 'National Advisory Council on Nurse Education and Practice and consult with nursing associations including the National Coalition of Ethnic Minority Nurse Associations,'; and

(B) by inserting before the period the following: ', and other organizations determined appropriate by the Secretary'.

SEC. 5405. PRIMARY CARE EXTENSION PROGRAM.

Part P of title III of the Public Health Service Act (42 U.S.C. 280g et seq.), as amended by section 5313, is further amended by adding at the end the following:

'SEC. 399W. PRIMARY CARE EXTENSION PROGRAM.

'(a) Establishment, Purpose and Definition-

'(1) IN GENERAL- The Secretary, acting through the Director of the Agency for Healthcare Research and Quality, shall establish a Primary Care Extension Program.

'(2) PURPOSE- The Primary Care Extension Program shall provide support and assistance to primary care providers to educate providers about preventive medicine, health promotion, chronic disease management, mental and behavioral health services (including substance abuse prevention and treatment services), and evidence-based and evidence-informed therapies and techniques, in order to enable providers to incorporate such matters into their practice and to improve community health by working with community-based health connectors (referred to in this section as 'Health Extension Agents').

'(3) DEFINITIONS- In this section:

'(A) HEALTH EXTENSION AGENT- The term 'Health Extension Agent' means any local, community-based health worker who facilitates and provides assistance to primary care practices by implementing quality improvement or system redesign, incorporating the principles of the patient-centered medical home to provide high-quality, effective, efficient, and safe primary care and to provide guidance to patients in culturally and linguistically appropriate ways, and linking practices to diverse health system resources.

'(B) PRIMARY CARE PROVIDER- The term 'primary care provider' means a clinician who provides integrated, accessible health care services and who is accountable for addressing a large majority of personal health care needs, including providing preventive and health promotion services for men, women, and children of all ages, developing a sustained partnership with patients, and practicing in the context of family and community, as

recognized by a State licensing or regulatory authority, unless otherwise specified in this section.

`(b) Grants To Establish State Hubs and Local Primary Care Extension Agencies-

`(1) GRANTS- The Secretary shall award competitive grants to States for the establishment of State- or multistate-level primary care Primary Care Extension Program State Hubs (referred to in this section as `Hubs').

`(2) COMPOSITION OF HUBS- A Hub established by a State pursuant to paragraph (1)--

`(A) shall consist of, at a minimum, the State health department, the entity responsible for administering the State Medicaid program (if other than the State health department), the State-level entity administering the Medicare program, and the departments of 1 or more health professions schools in the State that train providers in primary care; and

`(B) may include entities such as hospital associations, primary care practice-based research networks, health professional societies, State primary care associations, State licensing boards, organizations with a contract with the Secretary under section 1153 of the Social Security Act, consumer groups, and other appropriate entities.

`(c) State and Local Activities-

`(1) HUB ACTIVITIES- Hubs established under a grant under subsection (b) shall--

`(A) submit to the Secretary a plan to coordinate functions with quality improvement organizations and area health education centers if such entities are members of the Hub not described in subsection (b)(2)(A);

`(B) contract with a county- or local-level entity that shall serve as the Primary Care Extension Agency to administer the services described in paragraph (2);

`(C) organize and administer grant funds to county- or local-level Primary Care Extension Agencies that serve a catchment area, as determined by the State; and

`(D) organize State-wide or multistate networks of local-level Primary Care Extension Agencies to share and disseminate information and practices.

`(2) LOCAL PRIMARY CARE EXTENSION AGENCY ACTIVITIES-

`(A) REQUIRED ACTIVITIES- Primary Care Extension Agencies established by a Hub under paragraph (1) shall--

`(i) assist primary care providers to implement a patient-centered medical home to improve the accessibility, quality, and efficiency of primary care services, including health homes;

`(ii) develop and support primary care learning communities to enhance the dissemination of research findings for evidence-based practice, assess implementation of practice improvement, share best practices, and involve community clinicians in the generation of new knowledge and identification of important questions for research;

`(iii) participate in a national network of Primary Care Extension Hubs and propose how the Primary Care Extension Agency will share and disseminate lessons learned and best practices; and

`(iv) develop a plan for financial sustainability involving State,

local, and private contributions, to provide for the reduction in Federal funds that is expected after an initial 6-year period of program establishment, infrastructure development, and planning.

`(B) DISCRETIONARY ACTIVITIES- Primary Care Extension Agencies established by a Hub under paragraph (1) may--

`(i) provide technical assistance, training, and organizational support for community health teams established under section 3602 of the Patient Protection and Affordable Care Act;

`(ii) collect data and provision of primary care provider feedback from standardized measurements of processes and outcomes to aid in continuous performance improvement;

`(iii) collaborate with local health departments, community health centers, tribes and tribal entities, and other community agencies to identify community health priorities and local health workforce needs, and participate in community-based efforts to address the social and primary determinants of health, strengthen the local primary care workforce, and eliminate health disparities;

`(iv) develop measures to monitor the impact of the proposed program on the health of practice enrollees and of the wider community served; and

`(v) participate in other activities, as determined appropriate by the Secretary.

`(d) Federal Program Administration-

`(1) GRANTS; TYPES- Grants awarded under subsection (b) shall be--

`(A) program grants, that are awarded to State or multistate entities that submit fully-developed plans for the implementation of a Hub, for a period of 6 years; or

`(B) planning grants, that are awarded to State or multistate entities with the goal of developing a plan for a Hub, for a period of 2 years.

`(2) APPLICATIONS- To be eligible for a grant under subsection (b), a State or multistate entity shall submit to the Secretary an application, at such time, in such manner, and containing such information as the Secretary may require.

`(3) EVALUATION- A State that receives a grant under subsection (b) shall be evaluated at the end of the grant period by an evaluation panel appointed by the Secretary.

`(4) CONTINUING SUPPORT- After the sixth year in which assistance is provided to a State under a grant awarded under subsection (b), the State may receive additional support under this section if the State program has received satisfactory evaluations with respect to program performance and the merits of the State sustainability plan, as determined by the Secretary.

`(5) LIMITATION- A State shall not use in excess of 10 percent of the amount received under a grant to carry out administrative activities under this section. Funds awarded pursuant to this section shall not be used for funding direct patient care.

`(e) Requirements on the Secretary- In carrying out this section, the Secretary shall consult with the heads of other Federal agencies with demonstrated experience and expertise in health care and preventive medicine, such as the Centers for Disease Control and Prevention, the Substance Abuse

and Mental Health Administration, the Health Resources and Services Administration, the National Institutes of Health, the Office of the National Coordinator for Health Information Technology, the Indian Health Service, the Agricultural Cooperative Extension Service of the Department of Agriculture, and other entities, as the Secretary determines appropriate.

`(f) Authorization of Appropriations- To awards grants as provided in subsection (d), there are authorized to be appropriated \$120,000,000 for each of fiscal years 2011 and 2012, and such sums as may be necessary to carry out this section for each of fiscal years 2013 through 2014.'.

Subtitle F--Strengthening Primary Care and Other Workforce Improvements
SEC. 5501. EXPANDING ACCESS TO PRIMARY CARE SERVICES AND GENERAL SURGERY SERVICES.

(a) Incentive Payment Program for Primary Care Services-

(1) IN GENERAL- Section 1833 of the Social Security Act (42 U.S.C. 1395l) is amended by adding at the end the following new subsection:

`(x) Incentive Payments for Primary Care Services-

`(1) IN GENERAL- In the case of primary care services furnished on or after January 1, 2011, and before January 1, 2016, by a primary care practitioner, in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid (on a monthly or quarterly basis) an amount equal to 10 percent of the payment amount for the service under this part.

`(2) DEFINITIONS- In this subsection:

`(A) PRIMARY CARE PRACTITIONER- The term `primary care practitioner' means an individual--

`(i) who--

`(I) is a physician (as described in section 1861(r)(1)) who has a primary specialty designation of family medicine, internal medicine, geriatric medicine, or pediatric medicine; or

`(II) is a nurse practitioner, clinical nurse specialist, or physician assistant (as those terms are defined in section 1861(aa)(5)); and

`(ii) for whom primary care services accounted for at least 60 percent of the allowed charges under this part for such physician or practitioner in a prior period as determined appropriate by the Secretary.

`(B) PRIMARY CARE SERVICES- The term `primary care services' means services identified, as of January 1, 2009, by the following HCPCS codes (and as subsequently modified by the Secretary):

`(i) 99201 through 99215.

`(ii) 99304 through 99340.

`(iii) 99341 through 99350.

`(3) COORDINATION WITH OTHER PAYMENTS- The amount of the additional payment for a service under this subsection and subsection (m) shall be determined without regard to any additional payment for the service under subsection (m) and this subsection, respectively.

`(4) LIMITATION ON REVIEW- There shall be no administrative or judicial review under section 1869, 1878, or otherwise, respecting the identification of primary care practitioners under this subsection.'.

(2) CONFORMING AMENDMENT- Section 1834(g)(2)(B) of the Social Security Act (42 U.S.C. 1395m(g)(2)(B)) is amended by adding at the end the following sentence: `Section 1833(x) shall not be taken into account in determining the amounts that would otherwise be paid pursuant to the preceding sentence.'.

(b) Incentive Payment Program for Major Surgical Procedures Furnished in Health Professional Shortage Areas-

(1) IN GENERAL- Section 1833 of the Social Security Act (42 U.S.C. 1395I), as amended by subsection (a)(1), is amended by adding at the end the following new subsection:

`(y) Incentive Payments for Major Surgical Procedures Furnished in Health Professional Shortage Areas-

`(1) IN GENERAL- In the case of major surgical procedures furnished on or after January 1, 2011, and before January 1, 2016, by a general surgeon in an area that is designated (under section 332(a)(1)(A) of the Public Health Service Act) as a health professional shortage area as identified by the Secretary prior to the beginning of the year involved, in addition to the amount of payment that would otherwise be made for such services under this part, there also shall be paid (on a monthly or quarterly basis) an amount equal to 10 percent of the payment amount for the service under this part.

`(2) DEFINITIONS- In this subsection:

`(A) GENERAL SURGEON- In this subsection, the term `general surgeon' means a physician (as described in section 1861(r)(1)) who has designated CMS specialty code 02-General Surgery as their primary specialty code in the physician's enrollment under section 1866(j).

`(B) MAJOR SURGICAL PROCEDURES- The term `major surgical procedures' means physicians' services which are surgical procedures for which a 10-day or 90-day global period is used for payment under the fee schedule under section 1848(b).

`(3) COORDINATION WITH OTHER PAYMENTS- The amount of the additional payment for a service under this subsection and subsection (m) shall be determined without regard to any additional payment for the service under subsection (m) and this subsection, respectively.

`(4) APPLICATION- The provisions of paragraph (2) and (4) of subsection (m) shall apply to the determination of additional payments under this subsection in the same manner as such provisions apply to the determination of additional payments under subsection (m).'

(2) CONFORMING AMENDMENT- Section 1834(g)(2)(B) of the Social Security Act (42 U.S.C. 1395m(g)(2)(B)), as amended by subsection (a)(2), is amended by striking `Section 1833(x)' and inserting `Subsections (x) and (y) of section 1833' in the last sentence.

(c) Budget-neutrality Adjustment- Section 1848(c)(2)(B) of the Social Security Act (42 U.S.C. 1395w-4(c)(2)(B)) is amended by adding at the end the following new clause:

`(vii) ADJUSTMENT FOR CERTAIN PHYSICIAN INCENTIVE PAYMENTS- Fifty percent of the additional expenditures under this part attributable to subsections (x) and (y) of section 1833 for a year (as estimated by the Secretary) shall be taken into account in applying clause (ii)(II) for

2011 and subsequent years. In lieu of applying the budget-neutrality adjustments required under clause (ii)(II) to relative value units to account for such costs for the year, the Secretary shall apply such budget-neutrality adjustments to the conversion factor otherwise determined for the year. For 2011 and subsequent years, the Secretary shall increase the incentive payment otherwise applicable under section 1833(m) by a percent estimated to be equal to the additional expenditures estimated under the first sentence of this clause for such year that is applicable to physicians who primarily furnish services in areas designated (under section 332(a)(1)(A) of the Public Health Service Act) as health professional shortage areas.'.

SEC. 5502. MEDICARE FEDERALLY QUALIFIED HEALTH CENTER IMPROVEMENTS.

(a) Expansion of Medicare-Covered Preventive Services at Federally Qualified Health Centers-

(1) IN GENERAL- Section 1861(aa)(3)(A) of the Social Security Act (42 U.S.C. 1395w (aa)(3)(A)) is amended to read as follows:

`(A) services of the type described subparagraphs (A) through (C) of paragraph (1) and preventive services (as defined in section 1861(ddd)(3)); and'.

(2) EFFECTIVE DATE- The amendment made by paragraph (1) shall apply to services furnished on or after January 1, 2011.

(b) Prospective Payment System for Federally Qualified Health Centers- Section 1834 of the Social Security Act (42 U.S.C. 1395m) is amended by adding at the end the following new subsection:

`(n) Development and Implementation of Prospective Payment System-

`(1) DEVELOPMENT-

`(A) IN GENERAL- The Secretary shall develop a prospective payment system for payment for Federally qualified health services furnished by Federally qualified health centers under this title. Such system shall include a process for appropriately describing the services furnished by Federally qualified health centers.

`(B) COLLECTION OF DATA AND EVALUATION- The Secretary shall require Federally qualified health centers to submit to the Secretary such information as the Secretary may require in order to develop and implement the prospective payment system under this paragraph and paragraph (2), respectively, including the reporting of services using HCPCS codes.

`(2) IMPLEMENTATION-

`(A) IN GENERAL- Notwithstanding section 1833(a)(3)(B), the Secretary shall provide, for cost reporting periods beginning on or after October 1, 2014, for payments for Federally qualified health services furnished by Federally qualified health centers under this title in accordance with the prospective payment system developed by the Secretary under paragraph (1).

`(B) PAYMENTS-

`(i) INITIAL PAYMENTS- The Secretary shall implement such prospective payment system so that the estimated amount of expenditures under this title for Federally qualified health services in the first year that the prospective payment system is implemented is equal to 103 percent of the estimated amount of expenditures under this title that would have

occurred for such services in such year if the system had not been implemented.

`(ii) PAYMENTS IN SUBSEQUENT YEARS- In the year after the first year of implementation of such system, and in each subsequent year, the payment rate for Federally qualified health services furnished in the year shall be equal to the payment rate established for such services furnished in the preceding year under this subparagraph increased by the percentage increase in the MEI (as defined in 1842(i)(3)) for the year involved.'

SEC. 5503. DISTRIBUTION OF ADDITIONAL RESIDENCY POSITIONS.

(a) In General- Section 1886(h) of the Social Security Act (42 U.S.C. 1395ww(h)) is amended--

(1) in paragraph (4)(F)(i), by striking `paragraph (7)' and inserting `paragraphs (7) and (8)';

(2) in paragraph (4)(H)(i), by striking `paragraph (7)' and inserting `paragraphs (7) and (8)';

(3) in paragraph (7)(E), by inserting `or paragraph (8)' before the period at the end; and

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

`(8) DISTRIBUTION OF ADDITIONAL RESIDENCY POSITIONS-

`(A) REDUCTIONS IN LIMIT BASED ON UNUSED POSITIONS-

`(i) IN GENERAL- Except as provided in clause (ii), if a hospital's reference resident level (as defined in subparagraph (H)(i)) is less than the otherwise applicable resident limit (as defined in subparagraph (H)(iii)), effective for portions of cost reporting periods occurring on or after July 1, 2011, the otherwise applicable resident limit shall be reduced by 65 percent of the difference between such otherwise applicable resident limit and such reference resident level.

`(ii) EXCEPTIONS- This subparagraph shall not apply to--

`(I) a hospital located in a rural area (as defined in subsection (d)(2)(D)(ii)) with fewer than 250 acute care inpatient beds;

`(II) a hospital that was part of a qualifying entity which had a voluntary residency reduction plan approved under paragraph (6)(B) or under the authority of section 402 of Public Law 90-248, if the hospital demonstrates to the Secretary that it has a specified plan in place for filling the unused positions by not later than 2 years after the date of enactment of this paragraph; or

`(III) a hospital described in paragraph (4)(H)(v).

`(B) DISTRIBUTION-

`(i) IN GENERAL- The Secretary shall increase the otherwise applicable resident limit for each qualifying hospital that submits an application under this subparagraph by such number as the Secretary may approve for portions of cost reporting periods occurring on or after July 1, 2011.

The aggregate number of increases in the otherwise applicable resident limit under this subparagraph shall be equal to the aggregate reduction in such limits attributable to subparagraph (A) (as estimated by the Secretary).

`(ii) REQUIREMENTS- Subject to clause (iii), a hospital that receives an increase in the otherwise applicable resident limit under this

subparagraph shall ensure, during the 5-year period beginning on the date of such increase, that--

- `(I) the number of full-time equivalent primary care residents, as defined in paragraph (5)(H) (as determined by the Secretary), excluding any additional positions under subclause (II), is not less than the average number of full-time equivalent primary care residents (as so determined) during the 3 most recent cost reporting periods ending prior to the date of enactment of this paragraph; and
- `(II) not less than 75 percent of the positions attributable to such increase are in a primary care or general surgery residency (as determined by the Secretary).

The Secretary may determine whether a hospital has met the requirements under this clause during such 5-year period in such manner and at such time as the Secretary determines appropriate, including at the end of such 5-year period.

`(iii) REDISTRIBUTION OF POSITIONS IF HOSPITAL NO LONGER MEETS CERTAIN REQUIREMENTS- In the case where the Secretary determines that a hospital described in clause (ii) does not meet either of the requirements under subclause (I) or (II) of such clause, the Secretary shall--

- `(I) reduce the otherwise applicable resident limit of the hospital by the amount by which such limit was increased under this paragraph; and
- `(II) provide for the distribution of positions attributable to such reduction in accordance with the requirements of this paragraph.

`(C) CONSIDERATIONS IN REDISTRIBUTION- In determining for which hospitals the increase in the otherwise applicable resident limit is provided under subparagraph (B), the Secretary shall take into account--

- `(i) the demonstration likelihood of the hospital filling the positions made available under this paragraph within the first 3 cost reporting periods beginning on or after July 1, 2011, as determined by the Secretary; and
- `(ii) whether the hospital has an accredited rural training track (as described in paragraph (4)(H)(iv)).

`(D) PRIORITY FOR CERTAIN AREAS- In determining for which hospitals the increase in the otherwise applicable resident limit is provided under subparagraph (B), subject to subparagraph (E), the Secretary shall distribute the increase to hospitals based on the following factors:

- `(i) Whether the hospital is located in a State with a resident-to-population ratio in the lowest quartile (as determined by the Secretary).
- `(ii) Whether the hospital is located in a State, a territory of the United States, or the District of Columbia that is among the top 10 States, territories, or Districts in terms of the ratio of--
 - `(I) the total population of the State, territory, or District living in an area designated (under such section 332(a)(1)(A)) as a health professional shortage area (as of the date of enactment of this paragraph); to
 - `(II) the total population of the State, territory, or District (as determined by the Secretary based on the most recent available

population data published by the Bureau of the Census).

`(iii) Whether the hospital is located in a rural area (as defined in subsection (d)(2)(D)(ii)).

`(E) RESERVATION OF POSITIONS FOR CERTAIN HOSPITALS-

`(i) IN GENERAL- Subject to clause (ii), the Secretary shall reserve the positions available for distribution under this paragraph as follows:

`(I) 70 percent of such positions for distribution to hospitals described in clause (i) of subparagraph (D).

`(II) 30 percent of such positions for distribution to hospitals described in clause (ii) and (iii) of such subparagraph.

`(ii) EXCEPTION IF POSITIONS NOT REDISTRIBUTED BY JULY 1, 2011- In the case where the Secretary does not distribute positions to hospitals in accordance with clause (i) by July 1, 2011, the Secretary shall distribute such positions to other hospitals in accordance with the considerations described in subparagraph (C) and the priority described in subparagraph (D).

`(F) LIMITATION- A hospital may not receive more than 75 full-time equivalent additional residency positions under this paragraph.

`(G) APPLICATION OF PER RESIDENT AMOUNTS FOR PRIMARY CARE AND NONPRIMARY CARE- With respect to additional residency positions in a hospital attributable to the increase provided under this paragraph, the approved FTE per resident amounts are deemed to be equal to the hospital per resident amounts for primary care and nonprimary care computed under paragraph (2)(D) for that hospital.

`(H) DEFINITIONS- In this paragraph:

`(i) REFERENCE RESIDENT LEVEL- The term `reference resident level' means, with respect to a hospital, the highest resident level for any of the 3 most recent cost reporting periods (ending before the date of the enactment of this paragraph) of the hospital for which a cost report has been settled (or, if not, submitted (subject to audit)), as determined by the Secretary.

`(ii) RESIDENT LEVEL- The term `resident level' has the meaning given such term in paragraph (7)(C)(i).

`(iii) OTHERWISE APPLICABLE RESIDENT LIMIT- The term `otherwise applicable resident limit' means, with respect to a hospital, the limit otherwise applicable under subparagraphs (F)(i) and (H) of paragraph (4) on the resident level for the hospital determined without regard to this paragraph but taking into account paragraph (7)(A).'

(b) IME-

(1) IN GENERAL- Section 1886(d)(5)(B)(v) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(B)(v)), in the second sentence, is amended--

(A) by striking `subsection (h)(7)' and inserting `subsections (h)(7) and (h)(8)'; and

(B) by striking `it applies' and inserting `they apply'.

(2) CONFORMING AMENDMENT- Section 1886(d)(5)(B) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(B)) is amended by adding at the end the following clause:

`(x) For discharges occurring on or after July 1, 2011, insofar as an

additional payment amount under this subparagraph is attributable to resident positions distributed to a hospital under subsection (h)(8)(B), the indirect teaching adjustment factor shall be computed in the same manner as provided under clause (ii) with respect to such resident positions.'

(c) Conforming Amendment- Section 422(b)(2) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108-173) is amended by striking 'section 1886(h)(7)' and all that follows and inserting 'paragraphs (7) and (8) of subsection (h) of section 1886 of the Social Security Act'.

SEC. 5504. COUNTING RESIDENT TIME IN NONPROVIDER SETTINGS.

(a) GME- Section 1886(h)(4)(E) of the Social Security Act (42 U.S.C. 1395ww(h)(4)(E)) is amended--

(1) by striking 'shall be counted and that all the time' and inserting 'shall be counted and that--

'(i) effective for cost reporting periods beginning before July 1, 2010, all the time;';

(2) in clause (i), as inserted by paragraph (1), by striking the period at the end and inserting '; and';

(3) by inserting after clause (i), as so inserted, the following new clause:

'(ii) effective for cost reporting periods beginning on or after July 1, 2010, all the time so spent by a resident shall be counted towards the determination of full-time equivalency, without regard to the setting in which the activities are performed, if a hospital incurs the costs of the stipends and fringe benefits of the resident during the time the resident spends in that setting. If more than one hospital incurs these costs, either directly or through a third party, such hospitals shall count a proportional share of the time, as determined by written agreement between the hospitals, that a resident spends training in that setting.'; and

(4) by adding at the end the following flush sentence:

'Any hospital claiming under this subparagraph for time spent in a nonprovider setting shall maintain and make available to the Secretary records regarding the amount of such time and such amount in comparison with amounts of such time in such base year as the Secretary shall specify.'

(b) IME- Section 1886(d)(5)(B)(iv) of the Social Security Act (42 U.S.C. 1395ww(d)(5)) is amended--

(1) by striking '(iv) Effective for discharges occurring on or after October 1, 1997' and inserting '(iv)(I) Effective for discharges occurring on or after October 1, 1997, and before July 1, 2010'; and

(2) by inserting after clause (I), as inserted by paragraph (1), the following new subparagraph:

'(II) Effective for discharges occurring on or after July 1, 2010, all the time spent by an intern or resident in patient care activities in a nonprovider setting shall be counted towards the determination of full-time equivalency if a hospital incurs the costs of the stipends and fringe benefits of the intern or resident during the time the intern or resident spends in that setting. If more than one hospital incurs these costs, either directly or through a third party, such hospitals shall count a proportional

share of the time, as determined by written agreement between the hospitals, that a resident spends training in that setting.'.

(c) Application- The amendments made by this section shall not be applied in a manner that requires reopening of any settled hospital cost reports as to which there is not a jurisdictionally proper appeal pending as of the date of the enactment of this Act on the issue of payment for indirect costs of medical education under section 1886(d)(5)(B) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(B)) or for direct graduate medical education costs under section 1886(h) of such Act (42 U.S.C. 1395ww(h)).

SEC. 5505. RULES FOR COUNTING RESIDENT TIME FOR DIDACTIC AND SCHOLARLY ACTIVITIES AND OTHER ACTIVITIES.

(a) GME- Section 1886(h) of the Social Security Act (42 U.S.C. 1395ww(h)), as amended by section 5504, is amended--

(1) in paragraph (4)--

(A) in subparagraph (E), by striking 'Such rules' and inserting 'Subject to subparagraphs (J) and (K), such rules'; and

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

'(J) TREATMENT OF CERTAIN NONPROVIDER AND DIDACTIC ACTIVITIES- Such rules shall provide that all time spent by an intern or resident in an approved medical residency training program in a nonprovider setting that is primarily engaged in furnishing patient care (as defined in paragraph (5)(K)) in non-patient care activities, such as didactic conferences and seminars, but not including research not associated with the treatment or diagnosis of a particular patient, as such time and activities are defined by the Secretary, shall be counted toward the determination of full-time equivalency.

'(K) TREATMENT OF CERTAIN OTHER ACTIVITIES- In determining the hospital's number of full-time equivalent residents for purposes of this subsection, all the time that is spent by an intern or resident in an approved medical residency training program on vacation, sick leave, or other approved leave, as such time is defined by the Secretary, and that does not prolong the total time the resident is participating in the approved program beyond the normal duration of the program shall be counted toward the determination of full-time equivalency.'; and

(2) in paragraph (5), by adding at the end the following new subparagraph:

'(K) NONPROVIDER SETTING THAT IS PRIMARILY ENGAGED IN FURNISHING PATIENT CARE- The term 'nonprovider setting that is primarily engaged in furnishing patient care' means a nonprovider setting in which the primary activity is the care and treatment of patients, as defined by the Secretary.'

(b) IME Determinations- Section 1886(d)(5)(B) of such Act (42 U.S.C. 1395ww(d)(5)(B)) is amended by adding at the end the following new clause:

'(x)(I) The provisions of subparagraph (K) of subsection (h)(4) shall apply under this subparagraph in the same manner as they apply under such subsection.

'(II) In determining the hospital's number of full-time equivalent residents for purposes of this subparagraph, all the time spent by an intern or resident in an approved medical residency training program in

non-patient care activities, such as didactic conferences and seminars, as such time and activities are defined by the Secretary, that occurs in the hospital shall be counted toward the determination of full-time equivalency if the hospital--

`(aa) is recognized as a subsection (d) hospital;

`(bb) is recognized as a subsection (d) Puerto Rico hospital;

`(cc) is reimbursed under a reimbursement system authorized under section 1814(b)(3); or

`(dd) is a provider-based hospital outpatient department.

`(III) In determining the hospital's number of full-time equivalent residents for purposes of this subparagraph, all the time spent by an intern or resident in an approved medical residency training program in research activities that are not associated with the treatment or diagnosis of a particular patient, as such time and activities are defined by the Secretary, shall not be counted toward the determination of full-time equivalency.'

(c) Effective Dates-

(1) IN GENERAL- Except as otherwise provided, the Secretary of Health and Human Services shall implement the amendments made by this section in a manner so as to apply to cost reporting periods beginning on or after January 1, 1983.

(2) GME- Section 1886(h)(4)(J) of the Social Security Act, as added by subsection (a)(1)(B), shall apply to cost reporting periods beginning on or after July 1, 2009.

(3) IME- Section 1886(d)(5)(B)(x)(III) of the Social Security Act, as added by subsection (b), shall apply to cost reporting periods beginning on or after October 1, 2001. Such section, as so added, shall not give rise to any inference as to how the law in effect prior to such date should be interpreted.

SEC. 5506. PRESERVATION OF RESIDENT CAP POSITIONS FROM CLOSED HOSPITALS.

(a) GME- Section 1886(h)(4)(H) of the Social Security Act (42 U.S.C. Section 1395ww(h)(4)(H)) is amended by adding at the end the following new clause:

`(vi) REDISTRIBUTION OF RESIDENCY SLOTS AFTER A HOSPITAL CLOSES-

`(I) IN GENERAL- Subject to the succeeding provisions of this clause, the Secretary shall, by regulation, establish a process under which, in the case where a hospital (other than a hospital described in clause (v)) with an approved medical residency program closes on or after a date that is 2 years before the date of enactment of this clause, the Secretary shall increase the otherwise applicable resident limit under this paragraph for other hospitals in accordance with this clause.

`(II) PRIORITY FOR HOSPITALS IN CERTAIN AREAS- Subject to the succeeding provisions of this clause, in determining for which hospitals the increase in the otherwise applicable resident limit is provided under such process, the Secretary shall distribute the increase to hospitals in the following priority order (with preference given within each category to hospitals that are members of the same affiliated group (as defined by the Secretary under clause (ii)) as

the closed hospital):

- `(aa) First, to hospitals located in the same core-based statistical area as, or a core-based statistical area contiguous to, the hospital that closed.
- `(bb) Second, to hospitals located in the same State as the hospital that closed.
- `(cc) Third, to hospitals located in the same region of the country as the hospital that closed.
- `(dd) Fourth, only if the Secretary is not able to distribute the increase to hospitals described in item (cc), to qualifying hospitals in accordance with the provisions of paragraph (8).

`(III) REQUIREMENT HOSPITAL LIKELY TO FILL POSITION WITHIN CERTAIN TIME PERIOD- The Secretary may only increase the otherwise applicable resident limit of a hospital under such process if the Secretary determines the hospital has demonstrated a likelihood of filling the positions made available under this clause within 3 years.

`(IV) LIMITATION- The aggregate number of increases in the otherwise applicable resident limits for hospitals under this clause shall be equal to the number of resident positions in the approved medical residency programs that closed on or after the date described in subclause (I).

`(V) ADMINISTRATION- Chapter 35 of title 44, United States Code, shall not apply to the implementation of this clause.'

(b) IME- Section 1886(d)(5)(B)(v) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(B)(v)), in the second sentence, as amended by section 5503, is amended by striking `subsections (h)(7) and (h)(8)' and inserting `subsections (h)(4)(H)(vi), (h)(7), and (h)(8)'.

(c) Application- The amendments made by this section shall not be applied in a manner that requires reopening of any settled hospital cost reports as to which there is not a jurisdictionally proper appeal pending as of the date of the enactment of this Act on the issue of payment for indirect costs of medical education under section 1886(d)(5)(B) of the Social Security Act (42 U.S.C. 1395ww(d)(5)(B)) or for direct graduate medical education costs under section 1886(h) of such Act (42 U.S.C. Section 1395ww(h)).

(d) Effect on Temporary FTE Cap Adjustments- The Secretary of Health and Human Services shall give consideration to the effect of the amendments made by this section on any temporary adjustment to a hospital's FTE cap under section 413.79(h) of title 42, Code of Federal Regulations (as in effect on the date of enactment of this Act) in order to ensure that there is no duplication of FTE slots. Such amendments shall not affect the application of section 1886(h)(4)(H)(v) of the Social Security Act (42 U.S.C. 1395ww(h)(4)(H)(v)).

(e) Conforming Amendment- Section 1886(h)(7)(E) of the Social Security Act (42 U.S.C. 1395ww(h)(7)(E)), as amended by section 5503(a), is amended by striking `paragraph or paragraph (8)' and inserting `this paragraph, paragraph (8), or paragraph (4)(H)(vi)'.

SEC. 5507. DEMONSTRATION PROJECTS TO ADDRESS HEALTH PROFESSIONS WORKFORCE NEEDS; EXTENSION OF FAMILY-TO-FAMILY HEALTH INFORMATION CENTERS.

(a) Authority To Conduct Demonstration Projects- Title XX of the Social Security Act (42 U.S.C. 1397 et seq.) is amended by adding at the end the

following:

`SEC. 2008. DEMONSTRATION PROJECTS TO ADDRESS HEALTH PROFESSIONS WORKFORCE NEEDS.

`(a) Demonstration Projects To Provide Low-Income Individuals With Opportunities for Education, Training, and Career Advancement To Address Health Professions Workforce Needs-

`(1) AUTHORITY TO AWARD GRANTS- The Secretary, in consultation with the Secretary of Labor, shall award grants to eligible entities to conduct demonstration projects that are designed to provide eligible individuals with the opportunity to obtain education and training for occupations in the health care field that pay well and are expected to either experience labor shortages or be in high demand.

`(2) REQUIREMENTS-

`(A) AID AND SUPPORTIVE SERVICES-

`(i) IN GENERAL- A demonstration project conducted by an eligible entity awarded a grant under this section shall, if appropriate, provide eligible individuals participating in the project with financial aid, child care, case management, and other supportive services.

`(ii) TREATMENT- Any aid, services, or incentives provided to an eligible beneficiary participating in a demonstration project under this section shall not be considered income, and shall not be taken into account for purposes of determining the individual's eligibility for, or amount of, benefits under any means-tested program.

`(B) CONSULTATION AND COORDINATION- An eligible entity applying for a grant to carry out a demonstration project under this section shall demonstrate in the application that the entity has consulted with the State agency responsible for administering the State TANF program, the local workforce investment board in the area in which the project is to be conducted (unless the applicant is such board), the State workforce investment board established under section 111 of the Workforce Investment Act of 1998, and the State Apprenticeship Agency recognized under the Act of August 16, 1937 (commonly known as the `National Apprenticeship Act') (or if no agency has been recognized in the State, the Office of Apprenticeship of the Department of Labor) and that the project will be carried out in coordination with such entities.

`(C) ASSURANCE OF OPPORTUNITIES FOR INDIAN POPULATIONS- The Secretary shall award at least 3 grants under this subsection to an eligible entity that is an Indian tribe, tribal organization, or Tribal College or University.

`(3) REPORTS AND EVALUATION-

`(A) ELIGIBLE ENTITIES- An eligible entity awarded a grant to conduct a demonstration project under this subsection shall submit interim reports to the Secretary on the activities carried out under the project and a final report on such activities upon the conclusion of the entities' participation in the project. Such reports shall include assessments of the effectiveness of such activities with respect to improving outcomes for the eligible individuals participating in the project and with respect to addressing health professions workforce needs in the areas in which the

project is conducted.

`(B) EVALUATION- The Secretary shall, by grant, contract, or interagency agreement, evaluate the demonstration projects conducted under this subsection. Such evaluation shall include identification of successful activities for creating opportunities for developing and sustaining, particularly with respect to low-income individuals and other entry-level workers, a health professions workforce that has accessible entry points, that meets high standards for education, training, certification, and professional development, and that provides increased wages and affordable benefits, including health care coverage, that are responsive to the workforce's needs.

`(C) REPORT TO CONGRESS- The Secretary shall submit interim reports and, based on the evaluation conducted under subparagraph (B), a final report to Congress on the demonstration projects conducted under this subsection.

`(4) DEFINITIONS- In this subsection:

`(A) ELIGIBLE ENTITY- The term 'eligible entity' means a State, an Indian tribe or tribal organization, an institution of higher education, a local workforce investment board established under section 117 of the Workforce Investment Act of 1998, a sponsor of an apprenticeship program registered under the National Apprenticeship Act or a community-based organization.

`(B) ELIGIBLE INDIVIDUAL-

`(i) IN GENERAL- The term 'eligible individual' means a individual receiving assistance under the State TANF program.

`(ii) OTHER LOW-INCOME INDIVIDUALS- Such term may include other low-income individuals described by the eligible entity in its application for a grant under this section.

`(C) INDIAN TRIBE; TRIBAL ORGANIZATION- The terms 'Indian tribe' and 'tribal organization' have the meaning given such terms in section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b).

`(D) INSTITUTION OF HIGHER EDUCATION- The term 'institution of higher education' has the meaning given that term in section 101 of the Higher Education Act of 1965 (20 U.S.C. 1001).

`(E) STATE- The term 'State' means each of the 50 States, the District of Columbia, the Commonwealth of Puerto Rico, the United States Virgin Islands, Guam, and American Samoa.

`(F) STATE TANF PROGRAM- The term 'State TANF program' means the temporary assistance for needy families program funded under part A of title IV.

`(G) TRIBAL COLLEGE OR UNIVERSITY- The term 'Tribal College or University' has the meaning given that term in section 316(b) of the Higher Education Act of 1965 (20 U.S.C. 1059c(b)).

`(b) Demonstration Project To Develop Training and Certification Programs for Personal or Home Care Aides-

`(1) AUTHORITY TO AWARD GRANTS- Not later than 18 months after the date of enactment of this section, the Secretary shall award grants to eligible entities that are States to conduct demonstration projects for purposes of developing core training competencies and certification programs for personal or home care aides. The Secretary shall--

`(A) evaluate the efficacy of the core training competencies described in paragraph (3)(A) for newly hired personal or home care aides and the methods used by States to implement such core training competencies in accordance with the issues specified in paragraph (3)(B); and
`(B) ensure that the number of hours of training provided by States under the demonstration project with respect to such core training competencies are not less than the number of hours of training required under any applicable State or Federal law or regulation.

`(2) DURATION- A demonstration project shall be conducted under this subsection for not less than 3 years.

`(3) CORE TRAINING COMPETENCIES FOR PERSONAL OR HOME CARE AIDES-
`(A) IN GENERAL- The core training competencies for personal or home care aides described in this subparagraph include competencies with respect to the following areas:

`(i) The role of the personal or home care aide (including differences between a personal or home care aide employed by an agency and a personal or home care aide employed directly by the health care consumer or an independent provider).

`(ii) Consumer rights, ethics, and confidentiality (including the role of proxy decision-makers in the case where a health care consumer has impaired decision-making capacity).

`(iii) Communication, cultural and linguistic competence and sensitivity, problem solving, behavior management, and relationship skills.

`(iv) Personal care skills.

`(v) Health care support.

`(vi) Nutritional support.

`(vii) Infection control.

`(viii) Safety and emergency training.

`(ix) Training specific to an individual consumer's needs (including older individuals, younger individuals with disabilities, individuals with developmental disabilities, individuals with dementia, and individuals with mental and behavioral health needs).

`(x) Self-Care.

`(B) IMPLEMENTATION- The implementation issues specified in this subparagraph include the following:

`(i) The length of the training.

`(ii) The appropriate trainer to student ratio.

`(iii) The amount of instruction time spent in the classroom as compared to on-site in the home or a facility.

`(iv) Trainer qualifications.

`(v) Content for a `hands-on' and written certification exam.

`(vi) Continuing education requirements.

`(4) APPLICATION AND SELECTION CRITERIA-

`(A) IN GENERAL-

`(i) NUMBER OF STATES- The Secretary shall enter into agreements with not more than 6 States to conduct demonstration projects under this subsection.

`(ii) REQUIREMENTS FOR STATES- An agreement entered into under clause (i) shall require that a participating State--

`(I) implement the core training competencies described in paragraph (3)(A); and

`(II) develop written materials and protocols for such core training competencies, including the development of a certification test for personal or home care aides who have completed such training competencies.

`(iii) CONSULTATION AND COLLABORATION WITH COMMUNITY AND VOCATIONAL COLLEGES- The Secretary shall encourage participating States to consult with community and vocational colleges regarding the development of curricula to implement the project with respect to activities, as applicable, which may include consideration of such colleges as partners in such implementation.

`(B) APPLICATION AND ELIGIBILITY- A State seeking to participate in the project shall--

`(i) submit an application to the Secretary containing such information and at such time as the Secretary may specify;

`(ii) meet the selection criteria established under subparagraph (C);

and

`(iii) meet such additional criteria as the Secretary may specify.

`(C) SELECTION CRITERIA- In selecting States to participate in the program, the Secretary shall establish criteria to ensure (if applicable with respect to the activities involved)--

`(i) geographic and demographic diversity;

`(ii) that participating States offer medical assistance for personal care services under the State Medicaid plan;

`(iii) that the existing training standards for personal or home care aides in each participating State--

`(I) are different from such standards in the other participating States; and

`(II) are different from the core training competencies described in paragraph (3)(A);

`(iv) that participating States do not reduce the number of hours of training required under applicable State law or regulation after being selected to participate in the project; and

`(v) that participating States recruit a minimum number of eligible health and long-term care providers to participate in the project.

`(D) TECHNICAL ASSISTANCE- The Secretary shall provide technical assistance to States in developing written materials and protocols for such core training competencies.

`(5) EVALUATION AND REPORT-

`(A) EVALUATION- The Secretary shall develop an experimental or control group testing protocol in consultation with an independent evaluation contractor selected by the Secretary. Such contractor shall evaluate--

`(i) the impact of core training competencies described in paragraph (3)(A), including curricula developed to implement such core training competencies, for personal or home care aides within each participating

State on job satisfaction, mastery of job skills, beneficiary and family caregiver satisfaction with services, and additional measures determined by the Secretary in consultation with the expert panel;

`(ii) the impact of providing such core training competencies on the existing training infrastructure and resources of States; and

`(iii) whether a minimum number of hours of initial training should be required for personal or home care aides and, if so, what minimum number of hours should be required.

`(B) REPORTS-

`(i) REPORT ON INITIAL IMPLEMENTATION- Not later than 2 years after the date of enactment of this section, the Secretary shall submit to Congress a report on the initial implementation of activities conducted under the demonstration project, including any available results of the evaluation conducted under subparagraph (A) with respect to such activities, together with such recommendations for legislation or administrative action as the Secretary determines appropriate.

`(ii) FINAL REPORT- Not later than 1 year after the completion of the demonstration project, the Secretary shall submit to Congress a report containing the results of the evaluation conducted under subparagraph (A), together with such recommendations for legislation or administrative action as the Secretary determines appropriate.

`(6) DEFINITIONS- In this subsection:

`(A) ELIGIBLE HEALTH AND LONG-TERM CARE PROVIDER- The term 'eligible health and long-term care provider' means a personal or home care agency (including personal or home care public authorities), a nursing home, a home health agency (as defined in section 1861(o)), or any other health care provider the Secretary determines appropriate which--

`(i) is licensed or authorized to provide services in a participating State; and

`(ii) receives payment for services under title XIX.

`(B) PERSONAL CARE SERVICES- The term 'personal care services' has the meaning given such term for purposes of title XIX.

`(C) PERSONAL OR HOME CARE AIDE- The term 'personal or home care aide' means an individual who helps individuals who are elderly, disabled, ill, or mentally disabled (including an individual with Alzheimer's disease or other dementia) to live in their own home or a residential care facility (such as a nursing home, assisted living facility, or any other facility the Secretary determines appropriate) by providing routine personal care services and other appropriate services to the individual.

`(D) STATE- The term 'State' has the meaning given that term for purposes of title XIX.

`(c) Funding-

`(1) IN GENERAL- Subject to paragraph (2), out of any funds in the Treasury not otherwise appropriated, there are appropriated to the Secretary to carry out subsections (a) and (b), \$85,000,000 for each of fiscal years 2010 through 2014.

`(2) TRAINING AND CERTIFICATION PROGRAMS FOR PERSONAL AND HOME CARE AIDES- With respect to the demonstration projects under subsection (b), the

Secretary shall use \$5,000,000 of the amount appropriated under paragraph (1) for each of fiscal years 2010 through 2012 to carry out such projects. No funds appropriated under paragraph (1) shall be used to carry out demonstration projects under subsection (b) after fiscal year 2012.

`(d) Nonapplication-

`(1) IN GENERAL- Except as provided in paragraph (2), the preceding sections of this title shall not apply to grant awarded under this section.

`(2) LIMITATIONS ON USE OF GRANTS- Section 2005(a) (other than paragraph (6)) shall apply to a grant awarded under this section to the same extent and in the same manner as such section applies to payments to States under this title.'

(b) Extension of Family-To-Family Health Information Centers- Section 501(c)(1)(A)(iii) of the Social Security Act (42 U.S.C. 701(c)(1)(A)(iii)) is amended by striking 'fiscal year 2009' and inserting 'each of fiscal years 2009 through 2012'.

SEC. 5508. INCREASING TEACHING CAPACITY.

(a) Teaching Health Centers Training and Enhancement- Part C of title VII of the Public Health Service Act (42 U.S.C. 293k et. seq.), as amended by section 5303, is further amended by inserting after section 749 the following:

`SEC. 749A. TEACHING HEALTH CENTERS DEVELOPMENT GRANTS.

`(a) Program Authorized- The Secretary may award grants under this section to teaching health centers for the purpose of establishing new accredited or expanded primary care residency programs.

`(b) Amount and Duration- Grants awarded under this section shall be for a term of not more than 3 years and the maximum award may not be more than \$500,000.

`(c) Use of Funds- Amounts provided under a grant under this section shall be used to cover the costs of--

`(1) establishing or expanding a primary care residency training program described in subsection (a), including costs associated with--

`(A) curriculum development;

`(B) recruitment, training and retention of residents and faculty;

`(C) accreditation by the Accreditation Council for Graduate Medical Education (ACGME), the American Dental Association (ADA), or the American Osteopathic Association (AOA); and

`(D) faculty salaries during the development phase; and

`(2) technical assistance provided by an eligible entity.

`(d) Application- A teaching health center seeking a grant under this section shall submit an application to the Secretary at such time, in such manner, and containing such information as the Secretary may require.

`(e) Preference for Certain Applications- In selecting recipients for grants under this section, the Secretary shall give preference to any such application that documents an existing affiliation agreement with an area health education center program as defined in sections 751 and 799B.

`(f) Definitions- In this section:

`(1) ELIGIBLE ENTITY- The term 'eligible entity' means an organization capable of providing technical assistance including an area health education center program as defined in sections 751 and 799B.

`(2) PRIMARY CARE RESIDENCY PROGRAM- The term `primary care residency program' means an approved graduate medical residency training program (as defined in section 340H) in family medicine, internal medicine, pediatrics, internal medicine-pediatrics, obstetrics and gynecology, psychiatry, general dentistry, pediatric dentistry, and geriatrics.

`(3) TEACHING HEALTH CENTER-

`(A) IN GENERAL- The term `teaching health center' means an entity that--

`(i) is a community based, ambulatory patient care center; and

`(ii) operates a primary care residency program.

`(B) INCLUSION OF CERTAIN ENTITIES- Such term includes the following:

`(i) A Federally qualified health center (as defined in section 1905(l)(2)(B), of the Social Security Act).

`(ii) A community mental health center (as defined in section 1861(ff)(3)(B) of the Social Security Act).

`(iii) A rural health clinic, as defined in section 1861(aa) of the Social Security Act.

`(iv) A health center operated by the Indian Health Service, an Indian tribe or tribal organization, or an urban Indian organization (as defined in section 4 of the Indian Health Care Improvement Act).

`(v) An entity receiving funds under title X of the Public Health Service Act.

`(g) Authorization of Appropriations- There is authorized to be appropriated, \$25,000,000 for fiscal year 2010, \$50,000,000 for fiscal year 2011, \$50,000,000 for fiscal year 2012, and such sums as may be necessary for each fiscal year thereafter to carry out this section. Not to exceed \$5,000,000 annually may be used for technical assistance program grants.'

(b) National Health Service Corps Teaching Capacity- Section 338C(a) of the Public Health Service Act (42 U.S.C. 254m(a)) is amended to read as follows:

`(a) Service in Full-time Clinical Practice- Except as provided in section 338D, each individual who has entered into a written contract with the Secretary under section 338A or 338B shall provide service in the full-time clinical practice of such individual's profession as a member of the Corps for the period of obligated service provided in such contract. For the purpose of calculating time spent in full-time clinical practice under this subsection, up to 50 percent of time spent teaching by a member of the Corps may be counted toward his or her service obligation.'

(c) Payments to Qualified Teaching Health Centers- Part D of title III of the Public Health Service Act (42 U.S.C. 254b et seq.) is amended by adding at the end the following:

`Subpart XI--Support of Graduate Medical Education in Qualified Teaching Health Centers

`SEC. 340H. PROGRAM OF PAYMENTS TO TEACHING HEALTH CENTERS THAT OPERATE GRADUATE MEDICAL EDUCATION PROGRAMS.

`(a) Payments- Subject to subsection (h)(2), the Secretary shall make payments under this section for direct expenses and for indirect expenses to qualified teaching health centers that are listed as sponsoring institutions by the relevant accrediting body for expansion of existing or establishment of new approved graduate medical residency training programs.

`(b) Amount of Payments-

`(1) IN GENERAL- Subject to paragraph (2), the amounts payable under this section to qualified teaching health centers for an approved graduate medical residency training program for a fiscal year are each of the following amounts:

`(A) DIRECT EXPENSE AMOUNT- The amount determined under subsection (c) for direct expenses associated with sponsoring approved graduate medical residency training programs.

`(B) INDIRECT EXPENSE AMOUNT- The amount determined under subsection (d) for indirect expenses associated with the additional costs relating to teaching residents in such programs.

`(2) CAPPED AMOUNT-

`(A) IN GENERAL- The total of the payments made to qualified teaching health centers under paragraph (1)(A) or paragraph (1)(B) in a fiscal year shall not exceed the amount of funds appropriated under subsection (g) for such payments for that fiscal year.

`(B) LIMITATION- The Secretary shall limit the funding of full-time equivalent residents in order to ensure the direct and indirect payments as determined under subsection (c) and (d) do not exceed the total amount of funds appropriated in a fiscal year under subsection (g).

`(c) Amount of Payment for Direct Graduate Medical Education-

`(1) IN GENERAL- The amount determined under this subsection for payments to qualified teaching health centers for direct graduate expenses relating to approved graduate medical residency training programs for a fiscal year is equal to the product of--

`(A) the updated national per resident amount for direct graduate medical education, as determined under paragraph (2); and

`(B) the average number of full-time equivalent residents in the teaching health center's graduate approved medical residency training programs as determined under section 1886(h)(4) of the Social Security Act (without regard to the limitation under subparagraph (F) of such section) during the fiscal year.

`(2) UPDATED NATIONAL PER RESIDENT AMOUNT FOR DIRECT GRADUATE MEDICAL EDUCATION- The updated per resident amount for direct graduate medical education for a qualified teaching health center for a fiscal year is an amount determined as follows:

`(A) DETERMINATION OF QUALIFIED TEACHING HEALTH CENTER PER RESIDENT AMOUNT- The Secretary shall compute for each individual qualified teaching health center a per resident amount--

`(i) by dividing the national average per resident amount computed under section 340E(c)(2)(D) into a wage-related portion and a non-wage related portion by applying the proportion determined under subparagraph (B);

`(ii) by multiplying the wage-related portion by the factor applied under section 1886(d)(3)(E) of the Social Security Act (but without application of section 4410 of the Balanced Budget Act of 1997 (42 U.S.C. 1395ww note)) during the preceding fiscal year for the teaching health center's area; and

`(iii) by adding the non-wage-related portion to the amount computed

under clause (ii).

`(B) UPDATING RATE- The Secretary shall update such per resident amount for each such qualified teaching health center as determined appropriate by the Secretary.

`(d) Amount of Payment for Indirect Medical Education-

`(1) IN GENERAL- The amount determined under this subsection for payments to qualified teaching health centers for indirect expenses associated with the additional costs of teaching residents for a fiscal year is equal to an amount determined appropriate by the Secretary.

`(2) FACTORS- In determining the amount under paragraph (1), the Secretary shall--

`(A) evaluate indirect training costs relative to supporting a primary care residency program in qualified teaching health centers; and

`(B) based on this evaluation, assure that the aggregate of the payments for indirect expenses under this section and the payments for direct graduate medical education as determined under subsection (c) in a fiscal year do not exceed the amount appropriated for such expenses as determined in subsection (g).

`(3) INTERIM PAYMENT- Before the Secretary makes a payment under this subsection pursuant to a determination of indirect expenses under paragraph (1), the Secretary may provide to qualified teaching health centers a payment, in addition to any payment made under subsection (c), for expected indirect expenses associated with the additional costs of teaching residents for a fiscal year, based on an estimate by the Secretary.

`(e) Clarification Regarding Relationship to Other Payments for Graduate Medical Education- Payments under this section--

`(1) shall be in addition to any payments--

`(A) for the indirect costs of medical education under section 1886(d)(5)(B) of the Social Security Act;

`(B) for direct graduate medical education costs under section 1886(h) of such Act; and

`(C) for direct costs of medical education under section 1886(k) of such Act;

`(2) shall not be taken into account in applying the limitation on the number of total full-time equivalent residents under subparagraphs (F) and (G) of section 1886(h)(4) of such Act and clauses (v), (vi)(I), and (vi)(II) of section 1886(d)(5)(B) of such Act for the portion of time that a resident rotates to a hospital; and

`(3) shall not include the time in which a resident is counted toward full-time equivalency by a hospital under paragraph (2) or under section 1886(d)(5)(B)(iv) of the Social Security Act, section 1886(h)(4)(E) of such Act, or section 340E of this Act.

`(f) Reconciliation- The Secretary shall determine any changes to the number of residents reported by a hospital in the application of the hospital for the current fiscal year to determine the final amount payable to the hospital for the current fiscal year for both direct expense and indirect expense amounts. Based on such determination, the Secretary shall recoup any overpayments made to pay any balance due to the extent possible. The final amount so determined

shall be considered a final intermediary determination for the purposes of section 1878 of the Social Security Act and shall be subject to administrative and judicial review under that section in the same manner as the amount of payment under section 1186(d) of such Act is subject to review under such section.

`(g) Funding- To carry out this section, there are appropriated such sums as may be necessary, not to exceed \$230,000,000, for the period of fiscal years 2011 through 2015.

`(h) Annual Reporting Required-

`(1) ANNUAL REPORT- The report required under this paragraph for a qualified teaching health center for a fiscal year is a report that includes (in a form and manner specified by the Secretary) the following information for the residency academic year completed immediately prior to such fiscal year:

`(A) The types of primary care resident approved training programs that the qualified teaching health center provided for residents.

`(B) The number of approved training positions for residents described in paragraph (4).

`(C) The number of residents described in paragraph (4) who completed their residency training at the end of such residency academic year and care for vulnerable populations living in underserved areas.

`(D) Other information as deemed appropriate by the Secretary.

`(2) AUDIT AUTHORITY; LIMITATION ON PAYMENT-

`(A) AUDIT AUTHORITY- The Secretary may audit a qualified teaching health center to ensure the accuracy and completeness of the information submitted in a report under paragraph (1).

`(B) LIMITATION ON PAYMENT- A teaching health center may only receive payment in a cost reporting period for a number of such resident positions that is greater than the base level of primary care resident positions, as determined by the Secretary. For purposes of this subparagraph, the 'base level of primary care residents' for a teaching health center is the level of such residents as of a base period.

`(3) REDUCTION IN PAYMENT FOR FAILURE TO REPORT-

`(A) IN GENERAL- The amount payable under this section to a qualified teaching health center for a fiscal year shall be reduced by at least 25 percent if the Secretary determines that--

`(i) the qualified teaching health center has failed to provide the Secretary, as an addendum to the qualified teaching health center's application under this section for such fiscal year, the report required under paragraph (1) for the previous fiscal year; or

`(ii) such report fails to provide complete and accurate information required under any subparagraph of such paragraph.

`(B) NOTICE AND OPPORTUNITY TO PROVIDE ACCURATE AND MISSING INFORMATION-

Before imposing a reduction under subparagraph (A) on the basis of a qualified teaching health center's failure to provide complete and accurate information described in subparagraph (A)(ii), the Secretary shall provide notice to the teaching health center of such failure and the Secretary's intention to impose such reduction and shall provide the teaching health center with the opportunity to provide the required

information within the period of 30 days beginning on the date of such notice. If the teaching health center provides such information within such period, no reduction shall be made under subparagraph (A) on the basis of the previous failure to provide such information.

`(4) RESIDENTS- The residents described in this paragraph are those who are in part-time or full-time equivalent resident training positions at a qualified teaching health center in any approved graduate medical residency training program.

`(i) Regulations- The Secretary shall promulgate regulations to carry out this section.

`(j) Definitions- In this section:

`(1) APPROVED GRADUATE MEDICAL RESIDENCY TRAINING PROGRAM- The term `approved graduate medical residency training program' means a residency or other postgraduate medical training program--

`(A) participation in which may be counted toward certification in a specialty or subspecialty and includes formal postgraduate training programs in geriatric medicine approved by the Secretary; and

`(B) that meets criteria for accreditation (as established by the Accreditation Council for Graduate Medical Education, the American Osteopathic Association, or the American Dental Association).

`(2) PRIMARY CARE RESIDENCY PROGRAM- The term `primary care residency program' has the meaning given that term in section 749A.

`(3) QUALIFIED TEACHING HEALTH CENTER- The term `qualified teaching health center' has the meaning given the term `teaching health center' in section 749A.'

SEC. 5509. GRADUATE NURSE EDUCATION DEMONSTRATION.

(a) In General-

(1) ESTABLISHMENT-

(A) IN GENERAL- The Secretary shall establish a graduate nurse education demonstration under title XVIII of the Social Security Act (42 U.S.C. 1395 et seq.) under which an eligible hospital may receive payment for the hospital's reasonable costs (described in paragraph (2)) for the provision of qualified clinical training to advance practice nurses.

(B) NUMBER- The demonstration shall include up to 5 eligible hospitals.

(C) WRITTEN AGREEMENTS- Eligible hospitals selected to participate in the demonstration shall enter into written agreements pursuant to subsection (b) in order to reimburse the eligible partners of the hospital the share of the costs attributable to each partner.

(2) COSTS DESCRIBED-

(A) IN GENERAL- Subject to subparagraph (B) and subsection (d), the costs described in this paragraph are the reasonable costs (as described in section 1861(v) of the Social Security Act (42 U.S.C. 1395x(v))) of each eligible hospital for the clinical training costs (as determined by the Secretary) that are attributable to providing advanced practice registered nurses with qualified training.

(B) LIMITATION- With respect to a year, the amount reimbursed under subparagraph (A) may not exceed the amount of costs described in subparagraph (A) that are attributable to an increase in the number of

advanced practice registered nurses enrolled in a program that provides qualified training during the year and for which the hospital is being reimbursed under the demonstration, as compared to the average number of advanced practice registered nurses who graduated in each year during the period beginning on January 1, 2006, and ending on December 31, 2010 (as determined by the Secretary) from the graduate nursing education program operated by the applicable school of nursing that is an eligible partner of the hospital for purposes of the demonstration.

(3) WAIVER AUTHORITY- The Secretary may waive such requirements of titles XI and XVIII of the Social Security Act as may be necessary to carry out the demonstration.

(4) ADMINISTRATION- Chapter 35 of title 44, United States Code, shall not apply to the implementation of this section.

(b) Written Agreements With Eligible Partners- No payment shall be made under this section to an eligible hospital unless such hospital has in effect a written agreement with the eligible partners of the hospital. Such written agreement shall describe, at a minimum--

(1) the obligations of the eligible partners with respect to the provision of qualified training; and

(2) the obligation of the eligible hospital to reimburse such eligible partners applicable (in a timely manner) for the costs of such qualified training attributable to partner.

(c) Evaluation- Not later than October 17, 2017, the Secretary shall submit to Congress a report on the demonstration. Such report shall include an analysis of the following:

(1) The growth in the number of advanced practice registered nurses with respect to a specific base year as a result of the demonstration.

(2) The growth for each of the specialties described in subparagraphs (A) through (D) of subsection (e)(1).

(3) The costs to the Medicare program under title XVIII of the Social Security Act as a result of the demonstration.

(4) Other items the Secretary determines appropriate and relevant.

(d) Funding-

(1) IN GENERAL- There is hereby appropriated to the Secretary, out of any funds in the Treasury not otherwise appropriated, \$50,000,000 for each of fiscal years 2012 through 2015 to carry out this section, including the design, implementation, monitoring, and evaluation of the demonstration.

(2) PRORATION- If the aggregate payments to eligible hospitals under the demonstration exceed \$50,000,000 for a fiscal year described in paragraph (1), the Secretary shall prorate the payment amounts to each eligible hospital in order to ensure that the aggregate payments do not exceed such amount.

(3) WITHOUT FISCAL YEAR LIMITATION- Amounts appropriated under this subsection shall remain available without fiscal year limitation.

(e) Definitions- In this section:

(1) ADVANCED PRACTICE REGISTERED NURSE- The term 'advanced practice registered nurse' includes the following:

(A) A clinical nurse specialist (as defined in subsection (aa)(5) of

section 1861 of the Social Security Act (42 U.S.C. 1395x)).

(B) A nurse practitioner (as defined in such subsection).

(C) A certified registered nurse anesthetist (as defined in subsection (bb)(2) of such section).

(D) A certified nurse-midwife (as defined in subsection (gg)(2) of such section).

(2) APPLICABLE NON-HOSPITAL COMMUNITY-BASED CARE SETTING- The term `applicable non-hospital community-based care setting' means a non-hospital community-based care setting which has entered into a written agreement (as described in subsection (b)) with the eligible hospital participating in the demonstration. Such settings include Federally qualified health centers, rural health clinics, and other non-hospital settings as determined appropriate by the Secretary.

(3) APPLICABLE SCHOOL OF NURSING- The term `applicable school of nursing' means an accredited school of nursing (as defined in section 801 of the Public Health Service Act) which has entered into a written agreement (as described in subsection (b)) with the eligible hospital participating in the demonstration.

(4) DEMONSTRATION- The term `demonstration' means the graduate nurse education demonstration established under subsection (a).

(5) ELIGIBLE HOSPITAL- The term `eligible hospital' means a hospital (as defined in subsection (e) of section 1861 of the Social Security Act (42 U.S.C. 1395x)) or a critical access hospital (as defined in subsection (mm)(1) of such section) that has a written agreement in place with--

(A) 1 or more applicable schools of nursing; and

(B) 2 or more applicable non-hospital community-based care settings.

(6) ELIGIBLE PARTNERS- The term `eligible partners' includes the following:

(A) An applicable non-hospital community-based care setting.

(B) An applicable school of nursing.

(7) QUALIFIED TRAINING-

(A) IN GENERAL- The term `qualified training' means training--

(i) that provides an advanced practice registered nurse with the clinical skills necessary to provide primary care, preventive care, transitional care, chronic care management, and other services appropriate for individuals entitled to, or enrolled for, benefits under part A of title XVIII of the Social Security Act, or enrolled under part B of such title; and

(ii) subject to subparagraph (B), at least half of which is provided in a non-hospital community-based care setting.

(B) WAIVER OF REQUIREMENT HALF OF TRAINING BE PROVIDED IN NON-HOSPITAL COMMUNITY-BASED CARE SETTING IN CERTAIN AREAS- The Secretary may waive the requirement under subparagraph (A)(ii) with respect to eligible hospitals located in rural or medically underserved areas.

(8) SECRETARY- The term `Secretary' means the Secretary of Health and Human Services.

Subtitle G--Improving Access to Health Care Services

SEC. 5601. SPENDING FOR FEDERALLY QUALIFIED HEALTH CENTERS (FQHCs).

(a) In General- Section 330(r) of the Public Health Service Act (42 U.S.C.

254b(r)) is amended by striking paragraph (1) and inserting the following:

`(1) GENERAL AMOUNTS FOR GRANTS- For the purpose of carrying out this section, in addition to the amounts authorized to be appropriated under subsection (d), there is authorized to be appropriated the following:

`(A) For fiscal year 2010, \$2,988,821,592.

`(B) For fiscal year 2011, \$3,862,107,440.

`(C) For fiscal year 2012, \$4,990,553,440.

`(D) For fiscal year 2013, \$6,448,713,307.

`(E) For fiscal year 2014, \$7,332,924,155.

`(F) For fiscal year 2015, \$8,332,924,155.

`(G) For fiscal year 2016, and each subsequent fiscal year, the amount appropriated for the preceding fiscal year adjusted by the product of--

`(i) one plus the average percentage increase in costs incurred per patient served; and

`(ii) one plus the average percentage increase in the total number of patients served.'

(b) Rule of Construction- Section 330(r) of the Public Health Service Act (42 U.S.C. 254b(r)) is amended by adding at the end the following:

`(4) RULE OF CONSTRUCTION WITH RESPECT TO RURAL HEALTH CLINICS-

`(A) IN GENERAL- Nothing in this section shall be construed to prevent a community health center from contracting with a Federally certified rural health clinic (as defined in section 1861(aa)(2) of the Social Security Act), a low-volume hospital (as defined for purposes of section 1886 of such Act), a critical access hospital, a sole community hospital (as defined for purposes of section 1886(d)(5)(D)(iii) of such Act), or a medicare-dependent share hospital (as defined for purposes of section 1886(d)(5)(G)(iv) of such Act) for the delivery of primary health care services that are available at the clinic or hospital to individuals who would otherwise be eligible for free or reduced cost care if that individual were able to obtain that care at the community health center. Such services may be limited in scope to those primary health care services available in that clinic or hospitals.

`(B) ASSURANCES- In order for a clinic or hospital to receive funds under this section through a contract with a community health center under subparagraph (A), such clinic or hospital shall establish policies to ensure--

`(i) nondiscrimination based on the ability of a patient to pay; and

`(ii) the establishment of a sliding fee scale for low-income

patients.'

SEC. 5602. NEGOTIATED RULEMAKING FOR DEVELOPMENT OF METHODOLOGY AND CRITERIA FOR DESIGNATING MEDICALLY UNDERSERVED POPULATIONS AND HEALTH PROFESSIONS SHORTAGE AREAS.

(a) Establishment-

(1) IN GENERAL- The Secretary of Health and Human Services (in this section referred to as the `Secretary') shall establish, through a negotiated rulemaking process under subchapter 3 of chapter 5 of title 5, United States Code, a comprehensive methodology and criteria for designation of--

(A) medically underserved populations in accordance with section 330(b)(3)

of the Public Health Service Act (42 U.S.C. 254b(b)(3));
(B) health professions shortage areas under section 332 of the Public Health Service Act (42 U.S.C. 254e).

(2) FACTORS TO CONSIDER- In establishing the methodology and criteria under paragraph (1), the Secretary--

(A) shall consult with relevant stakeholders who will be significantly affected by a rule (such as national, State and regional organizations representing affected entities), State health offices, community organizations, health centers and other affected entities, and other interested parties; and

(B) shall take into account--

- (i) the timely availability and appropriateness of data used to determine a designation to potential applicants for such designations;
- (ii) the impact of the methodology and criteria on communities of various types and on health centers and other safety net providers;
- (iii) the degree of ease or difficulty that will face potential applicants for such designations in securing the necessary data; and
- (iv) the extent to which the methodology accurately measures various barriers that confront individuals and population groups in seeking health care services.

(b) Publication of Notice- In carrying out the rulemaking process under this subsection, the Secretary shall publish the notice provided for under section 564(a) of title 5, United States Code, by not later than 45 days after the date of the enactment of this Act.

(c) Target Date for Publication of Rule- As part of the notice under subsection (b), and for purposes of this subsection, the 'target date for publication', as referred to in section 564(a)(5) of title 5, United States Code, shall be July 1, 2010.

(d) Appointment of Negotiated Rulemaking Committee and Facilitator- The Secretary shall provide for--

(1) the appointment of a negotiated rulemaking committee under section 565(a) of title 5, United States Code, by not later than 30 days after the end of the comment period provided for under section 564(c) of such title; and

(2) the nomination of a facilitator under section 566(c) of such title 5 by not later than 10 days after the date of appointment of the committee.

(e) Preliminary Committee Report- The negotiated rulemaking committee appointed under subsection (d) shall report to the Secretary, by not later than April 1, 2010, regarding the committee's progress on achieving a consensus with regard to the rulemaking proceeding and whether such consensus is likely to occur before one month before the target date for publication of the rule. If the committee reports that the committee has failed to make significant progress toward such consensus or is unlikely to reach such consensus by the target date, the Secretary may terminate such process and provide for the publication of a rule under this section through such other methods as the Secretary may provide.

(f) Final Committee Report- If the committee is not terminated under subsection (e), the rulemaking committee shall submit a report containing a

proposed rule by not later than one month before the target publication date.

(g) Interim Final Effect- The Secretary shall publish a rule under this section in the Federal Register by not later than the target publication date. Such rule shall be effective and final immediately on an interim basis, but is subject to change and revision after public notice and opportunity for a period (of not less than 90 days) for public comment. In connection with such rule, the Secretary shall specify the process for the timely review and approval of applications for such designations pursuant to such rules and consistent with this section.

(h) Publication of Rule After Public Comment- The Secretary shall provide for consideration of such comments and republication of such rule by not later than 1 year after the target publication date.

SEC. 5603. REAUTHORIZATION OF THE WAKEFIELD EMERGENCY MEDICAL SERVICES FOR CHILDREN PROGRAM.

Section 1910 of the Public Health Service Act (42 U.S.C. 300w-9) is amended--

(1) in subsection (a), by striking `3-year period (with an optional 4th year' and inserting `4-year period (with an optional 5th year'; and

(2) in subsection (d)--

(A) by striking `and such sums' and inserting `such sums'; and

(B) by inserting before the period the following: `, \$25,000,000 for fiscal year 2010, \$26,250,000 for fiscal year 2011, \$27,562,500 for fiscal year 2012, \$28,940,625 for fiscal year 2013, and \$30,387,656 for fiscal year 2014'.

SEC. 5604. CO-LOCATING PRIMARY AND SPECIALTY CARE IN COMMUNITY-BASED MENTAL HEALTH SETTINGS.

Subpart 3 of part B of title V of the Public Health Service Act (42 U.S.C. 290bb-31 et seq.) is amended by adding at the end the following:

`SEC. 520K. AWARDS FOR CO-LOCATING PRIMARY AND SPECIALTY CARE IN COMMUNITY-BASED MENTAL HEALTH SETTINGS.

`(a) Definitions- In this section:

`(1) ELIGIBLE ENTITY- The term `eligible entity' means a qualified community mental health program defined under section 1913(b)(1).

`(2) SPECIAL POPULATIONS- The term `special populations' means adults with mental illnesses who have co-occurring primary care conditions and chronic diseases.

`(b) Program Authorized- The Secretary, acting through the Administrator shall award grants and cooperative agreements to eligible entities to establish demonstration projects for the provision of coordinated and integrated services to special populations through the co-location of primary and specialty care services in community-based mental and behavioral health settings.

`(c) Application- To be eligible to receive a grant or cooperative agreement under this section, an eligible entity shall submit an application to the Administrator at such time, in such manner, and accompanied by such information as the Administrator may require, including a description of partnerships, or other arrangements with local primary care providers, including community health centers, to provide services to special populations.

`(d) Use of Funds-

`(1) IN GENERAL- For the benefit of special populations, an eligible entity shall use funds awarded under this section for--

`(A) the provision, by qualified primary care professionals, of on site primary care services;

`(B) reasonable costs associated with medically necessary referrals to qualified specialty care professionals, other coordinators of care or, if permitted by the terms of the grant or cooperative agreement, by qualified specialty care professionals on a reasonable cost basis on site at the eligible entity;

`(C) information technology required to accommodate the clinical needs of primary and specialty care professionals; or

`(D) facility modifications needed to bring primary and specialty care professionals on site at the eligible entity.

`(2) LIMITATION- Not to exceed 15 percent of grant or cooperative agreement funds may be used for activities described in subparagraphs (C) and (D) of paragraph (1).

`(e) Evaluation- Not later than 90 days after a grant or cooperative agreement awarded under this section expires, an eligible entity shall submit to the Secretary the results of an evaluation to be conducted by the entity concerning the effectiveness of the activities carried out under the grant or agreement.

`(f) Authorization of Appropriations- There are authorized to be appropriated to carry out this section, \$50,000,000 for fiscal year 2010 and such sums as may be necessary for each of fiscal years 2011 through 2014.'

SEC. 5605. KEY NATIONAL INDICATORS.

(a) Definitions- In this section:

(1) ACADEMY- The term 'Academy' means the National Academy of Sciences.

(2) COMMISSION- The term 'Commission' means the Commission on Key National Indicators established under subsection (b).

(3) INSTITUTE- The term 'Institute' means a Key National Indicators Institute as designated under subsection (c)(3).

(b) Commission on Key National Indicators-

(1) ESTABLISHMENT- There is established a 'Commission on Key National Indicators'.

(2) MEMBERSHIP-

(A) NUMBER AND APPOINTMENT- The Commission shall be composed of 8 members, to be appointed equally by the majority and minority leaders of the Senate and the Speaker and minority leader of the House of Representatives.

(B) PROHIBITED APPOINTMENTS- Members of the Commission shall not include Members of Congress or other elected Federal, State, or local government officials.

(C) QUALIFICATIONS- In making appointments under subparagraph (A), the majority and minority leaders of the Senate and the Speaker and minority leader of the House of Representatives shall appoint individuals who have shown a dedication to improving civic dialogue and decision-making through the wide use of scientific evidence and factual information.

(D) PERIOD OF APPOINTMENT- Each member of the Commission shall be

appointed for a 2-year term, except that 1 initial appointment shall be for 3 years. Any vacancies shall not affect the power and duties of the Commission but shall be filled in the same manner as the original appointment and shall last only for the remainder of that term.

(E) DATE- Members of the Commission shall be appointed by not later than 30 days after the date of enactment of this Act.

(F) INITIAL ORGANIZING PERIOD- -Not later than 60 days after the date of enactment of this Act, the Commission shall develop and implement a schedule for completion of the review and reports required under subsection (d).

(G) CO-CHAIRPERSONS- The Commission shall select 2 Co-Chairpersons from among its members.

(c) Duties of the Commission-

(1) IN GENERAL- The Commission shall--

(A) conduct comprehensive oversight of a newly established key national indicators system consistent with the purpose described in this subsection;

(B) make recommendations on how to improve the key national indicators system;

(C) coordinate with Federal Government users and information providers to assure access to relevant and quality data; and

(D) enter into contracts with the Academy.

(2) REPORTS-

(A) ANNUAL REPORT TO CONGRESS- Not later than 1 year after the selection of the 2 Co-Chairpersons of the Commission, and each subsequent year thereafter, the Commission shall prepare and submit to the appropriate Committees of Congress and the President a report that contains a detailed statement of the recommendations, findings, and conclusions of the Commission on the activities of the Academy and a designated Institute related to the establishment of a Key National Indicator System.

(B) ANNUAL REPORT TO THE ACADEMY-

(i) IN GENERAL- Not later than 6 months after the selection of the 2 Co-Chairpersons of the Commission, and each subsequent year thereafter, the Commission shall prepare and submit to the Academy and a designated Institute a report making recommendations concerning potential issue areas and key indicators to be included in the Key National Indicators.

(ii) LIMITATION- The Commission shall not have the authority to direct the Academy or, if established, the Institute, to adopt, modify, or delete any key indicators.

(3) CONTRACT WITH THE NATIONAL ACADEMY OF SCIENCES-

(A) IN GENERAL- -As soon as practicable after the selection of the 2 Co-Chairpersons of the Commission, the Co-Chairpersons shall enter into an arrangement with the National Academy of Sciences under which the Academy shall--

(i) review available public and private sector research on the selection of a set of key national indicators;

(ii) determine how best to establish a key national indicator system for the United States, by either creating its own institutional capability

or designating an independent private nonprofit organization as an Institute to implement a key national indicator system;

(iii) if the Academy designates an independent Institute under clause (ii), provide scientific and technical advice to the Institute and create an appropriate governance mechanism that balances Academy involvement and the independence of the Institute; and

(iv) provide an annual report to the Commission addressing scientific and technical issues related to the key national indicator system and, if established, the Institute, and governance of the Institute's budget and operations.

(B) PARTICIPATION- In executing the arrangement under subparagraph (A), the National Academy of Sciences shall convene a multi-sector, multi-disciplinary process to define major scientific and technical issues associated with developing, maintaining, and evolving a Key National Indicator System and, if an Institute is established, to provide it with scientific and technical advice.

(C) ESTABLISHMENT OF A KEY NATIONAL INDICATOR SYSTEM-

(i) IN GENERAL- In executing the arrangement under subparagraph (A), the National Academy of Sciences shall enable the establishment of a key national indicator system by--

- (I) creating its own institutional capability; or
- (II) partnering with an independent private nonprofit organization as an Institute to implement a key national indicator system.

(ii) INSTITUTE- If the Academy designates an Institute under clause (i)(II), such Institute shall be a non-profit entity (as defined for purposes of section 501(c)(3) of the Internal Revenue Code of 1986) with an educational mission, a governance structure that emphasizes independence, and characteristics that make such entity appropriate for establishing a key national indicator system.

(iii) RESPONSIBILITIES- Either the Academy or the Institute designated under clause (i)(II) shall be responsible for the following:

- (I) Identifying and selecting issue areas to be represented by the key national indicators.
- (II) Identifying and selecting the measures used for key national indicators within the issue areas under subclause (I).
- (III) Identifying and selecting data to populate the key national indicators described under subclause (II).
- (IV) Designing, publishing, and maintaining a public website that contains a freely accessible database allowing public access to the key national indicators.
- (V) Developing a quality assurance framework to ensure rigorous and independent processes and the selection of quality data.
- (VI) Developing a budget for the construction and management of a sustainable, adaptable, and evolving key national indicator system that reflects all Commission funding of Academy and, if an Institute is established, Institute activities.

(VII) Reporting annually to the Commission regarding its selection of issue areas, key indicators, data, and progress toward establishing a

web-accessible database.

(VIII) Responding directly to the Commission in response to any Commission recommendations and to the Academy regarding any inquiries by the Academy.

(iv) GOVERNANCE- Upon the establishment of a key national indicator system, the Academy shall create an appropriate governance mechanism that incorporates advisory and control functions. If an Institute is designated under clause (i)(II), the governance mechanism shall balance appropriate Academy involvement and the independence of the Institute.

(v) MODIFICATION AND CHANGES- The Academy shall retain the sole discretion, at any time, to alter its approach to the establishment of a key national indicator system or, if an Institute is designated under clause (i)(II), to alter any aspect of its relationship with the Institute or to designate a different non-profit entity to serve as the Institute.

(vi) CONSTRUCTION- Nothing in this section shall be construed to limit the ability of the Academy or the Institute designated under clause (i)(II) to receive private funding for activities related to the establishment of a key national indicator system.

(D) ANNUAL REPORT- As part of the arrangement under subparagraph (A), the National Academy of Sciences shall, not later than 270 days after the date of enactment of this Act, and annually thereafter, submit to the Co-Chairpersons of the Commission a report that contains the findings and recommendations of the Academy.

(d) Government Accountability Office Study and Report-

(1) GAO STUDY- The Comptroller General of the United States shall conduct a study of previous work conducted by all public agencies, private organizations, or foreign countries with respect to best practices for a key national indicator system. The study shall be submitted to the appropriate authorizing committees of Congress.

(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 11281(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 11281(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 1128l 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, decision 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 conducting 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.

`Sec. 4376. Self-insured health plans.

`Sec. 4377. Definitions and special rules.

`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 pre-enrollment 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 than 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 recompleted 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 semi-colon; 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:
 - `(k) Licensure of Biological Products as Biosimilar or Interchangeable-
 - `(1) IN GENERAL- Any person may submit an application for licensure of a biological product under this subsection.
 - `(2) CONTENT-
 - `(A) IN GENERAL-

`(i) REQUIRED INFORMATION- An application submitted under this subsection shall include information demonstrating that--

`(I) the biological product is biosimilar to a reference product based upon data derived from--

`(aa) analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;

`(bb) animal studies (including the assessment of toxicity); and

`(cc) a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and potency in 1 or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product;

`(II) the biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product;

`(III) the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product;

`(IV) the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product; and

`(V) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent.

`(ii) DETERMINATION BY SECRETARY- The Secretary may determine, in the Secretary's discretion, that an element described in clause (i)(I) is unnecessary in an application submitted under this subsection.

`(iii) ADDITIONAL INFORMATION- An application submitted under this subsection--

`(I) shall include publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent; and

`(II) may include any additional information in support of the application, including publicly-available information with respect to the reference product or another biological product.

`(B) INTERCHANGEABILITY- An application (or a supplement to an application) submitted under this subsection may include information demonstrating that the biological product meets the standards described in paragraph (4).

`(3) EVALUATION BY SECRETARY- Upon review of an application (or a supplement to an application) submitted under this subsection, the Secretary shall license the biological product under this subsection if--

`(A) the Secretary determines that the information submitted in the application (or the supplement) is sufficient to show that the biological product--

- `(i) is biosimilar to the reference product; or
- `(ii) meets the standards described in paragraph (4), and therefore is interchangeable with the reference product; and
- `(B) the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

`(4) SAFETY STANDARDS FOR DETERMINING INTERCHANGEABILITY- Upon review of an application submitted under this subsection or any supplement to such application, the Secretary shall determine the biological product to be interchangeable with the reference product if the Secretary determines that the information submitted in the application (or a supplement to such application) is sufficient to show that--

- `(A) the biological product--
 - `(i) is biosimilar to the reference product; and
 - `(ii) can be expected to produce the same clinical result as the reference product in any given patient; and
- `(B) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

`(5) GENERAL RULES-

`(A) ONE REFERENCE PRODUCT PER APPLICATION- A biological product, in an application submitted under this subsection, may not be evaluated against more than 1 reference product.

`(B) REVIEW- An application submitted under this subsection shall be reviewed by the division within the Food and Drug Administration that is responsible for the review and approval of the application under which the reference product is licensed.

`(C) RISK EVALUATION AND MITIGATION STRATEGIES- The authority of the Secretary with respect to risk evaluation and mitigation strategies under the Federal Food, Drug, and Cosmetic Act shall apply to biological products licensed under this subsection in the same manner as such authority applies to biological products licensed under subsection (a).

`(6) EXCLUSIVITY FOR FIRST INTERCHANGEABLE BIOLOGICAL PRODUCT- Upon review of an application submitted under this subsection relying on the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, the Secretary shall not make a determination under paragraph (4) that the second or subsequent biological product is interchangeable for any condition of use until the earlier of--

- `(A) 1 year after the first commercial marketing of the first interchangeable biosimilar biological product to be approved as interchangeable for that reference product;
- `(B) 18 months after--
 - `(i) a final court decision on all patents in suit in an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar

biological product; or

`(ii) the dismissal with or without prejudice of an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

`(C)(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (l)(6) and such litigation is still ongoing within such 42-month period; or

`(ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued under subsection (l)(6).

For purposes of this paragraph, the term `final court decision' means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken.

`(7) EXCLUSIVITY FOR REFERENCE PRODUCT-

`(A) EFFECTIVE DATE OF BIOSIMILAR APPLICATION APPROVAL- Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).

`(B) FILING PERIOD- An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a).

`(C) FIRST LICENSURE- Subparagraphs (A) and (B) shall not apply to a license for or approval of--

`(i) a supplement for the biological product that is the reference product; or

`(ii) a subsequent application filed by the same sponsor or manufacturer of the biological product that is the reference product (or a licensor, predecessor in interest, or other related entity) for--

`(I) a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

`(II) a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

`(8) GUIDANCE DOCUMENTS-

`(A) IN GENERAL- The Secretary may, after opportunity for public comment, issue guidance in accordance, except as provided in subparagraph (B)(i), with section 701(h) of the Federal Food, Drug, and Cosmetic Act with respect to the licensure of a biological product under this subsection. Any such guidance may be general or specific.

`(B) PUBLIC COMMENT-

`(i) IN GENERAL- The Secretary shall provide the public an opportunity to comment on any proposed guidance issued under subparagraph (A) before issuing final guidance.

`(ii) INPUT REGARDING MOST VALUABLE GUIDANCE- The Secretary shall

establish a process through which the public may provide the Secretary with input regarding priorities for issuing guidance.

`(C) NO REQUIREMENT FOR APPLICATION CONSIDERATION- The issuance (or non-issuance) of guidance under subparagraph (A) shall not preclude the review of, or action on, an application submitted under this subsection.

`(D) REQUIREMENT FOR PRODUCT CLASS-SPECIFIC GUIDANCE- If the Secretary issues product class-specific guidance under subparagraph (A), such guidance shall include a description of--

`(i) the criteria that the Secretary will use to determine whether a biological product is highly similar to a reference product in such product class; and

`(ii) the criteria, if available, that the Secretary will use to determine whether a biological product meets the standards described in paragraph (4).

`(E) CERTAIN PRODUCT CLASSES-

`(i) GUIDANCE- The Secretary may indicate in a guidance document that the science and experience, as of the date of such guidance, with respect to a product or product class (not including any recombinant protein) does not allow approval of an application for a license as provided under this subsection for such product or product class.

`(ii) MODIFICATION OR REVERSAL- The Secretary may issue a subsequent guidance document under subparagraph (A) to modify or reverse a guidance document under clause (i).

`(iii) NO EFFECT ON ABILITY TO DENY LICENSE- Clause (i) shall not be construed to require the Secretary to approve a product with respect to which the Secretary has not indicated in a guidance document that the science and experience, as described in clause (i), does not allow approval of such an application.

`(I) Patents-

`(1) CONFIDENTIAL ACCESS TO SUBSECTION (k) APPLICATION-

`(A) APPLICATION OF PARAGRAPH- Unless otherwise agreed to by a person that submits an application under subsection (k) (referred to in this subsection as the `subsection (k) applicant') and the sponsor of the application for the reference product (referred to in this subsection as the `reference product sponsor'), the provisions of this paragraph shall apply to the exchange of information described in this subsection.

`(B) IN GENERAL-

`(i) PROVISION OF CONFIDENTIAL INFORMATION- When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to the persons described in clause (ii), subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate (referred to in this subsection as the `confidential information').

`(ii) RECIPIENTS OF INFORMATION- The persons described in this clause are the following:

`(I) OUTSIDE COUNSEL- One or more attorneys designated by the

reference product sponsor who are employees of an entity other than the reference product sponsor (referred to in this paragraph as the 'outside counsel'), provided that such attorneys do not engage, formally or informally, in patent prosecution relevant or related to the reference product.

`(II) IN-HOUSE COUNSEL- One attorney that represents the reference product sponsor who is an employee of the reference product sponsor, provided that such attorney does not engage, formally or informally, in patent prosecution relevant or related to the reference product.

`(iii) PATENT OWNER ACCESS- A representative of the owner of a patent exclusively licensed to a reference product sponsor with respect to the reference product and who has retained a right to assert the patent or participate in litigation concerning the patent may be provided the confidential information, provided that the representative informs the reference product sponsor and the subsection (k) applicant of his or her agreement to be subject to the confidentiality provisions set forth in this paragraph, including those under clause (ii).

`(C) LIMITATION ON DISCLOSURE- No person that receives confidential information pursuant to subparagraph (B) shall disclose any confidential information to any other person or entity, including the reference product sponsor employees, outside scientific consultants, or other outside counsel retained by the reference product sponsor, without the prior written consent of the subsection (k) applicant, which shall not be unreasonably withheld.

`(D) USE OF CONFIDENTIAL INFORMATION- Confidential information shall be used for the sole and exclusive purpose of determining, with respect to each patent assigned to or exclusively licensed by the reference product sponsor, whether a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k).

`(E) OWNERSHIP OF CONFIDENTIAL INFORMATION- The confidential information disclosed under this paragraph is, and shall remain, the property of the subsection (k) applicant. By providing the confidential information pursuant to this paragraph, the subsection (k) applicant does not provide the reference product sponsor or the outside counsel any interest in or license to use the confidential information, for purposes other than those specified in subparagraph (D).

`(F) EFFECT OF INFRINGEMENT ACTION- In the event that the reference product sponsor files a patent infringement suit, the use of confidential information shall continue to be governed by the terms of this paragraph until such time as a court enters a protective order regarding the information. Upon entry of such order, the subsection (k) applicant may redesignate confidential information in accordance with the terms of that order. No confidential information shall be included in any publicly-available complaint or other pleading. In the event that the reference product sponsor does not file an infringement action by the date

specified in paragraph (6), the reference product sponsor shall return or destroy all confidential information received under this paragraph, provided that if the reference product sponsor opts to destroy such information, it will confirm destruction in writing to the subsection (k) applicant.

`(G) RULE OF CONSTRUCTION- Nothing in this paragraph shall be construed--

`(i) as an admission by the subsection (k) applicant regarding the validity, enforceability, or infringement of any patent; or

`(ii) as an agreement or admission by the subsection (k) applicant with respect to the competency, relevance, or materiality of any confidential information.

`(H) EFFECT OF VIOLATION- The disclosure of any confidential information in violation of this paragraph shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider immediate injunctive relief to be an appropriate and necessary remedy for any violation or threatened violation of this paragraph.

`(2) SUBSECTION (k) APPLICATION INFORMATION- Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant--

`(A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and

`(B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

`(3) LIST AND DESCRIPTION OF PATENTS-

`(A) LIST BY REFERENCE PRODUCT SPONSOR- Not later than 60 days after the receipt of the application and information under paragraph (2), the reference product sponsor shall provide to the subsection (k) applicant--

`(i) a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor, or by a patent owner that has granted an exclusive license to the reference product sponsor with respect to the reference product, if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application; and

`(ii) an identification of the patents on such list that the reference product sponsor would be prepared to license to the subsection (k) applicant.

`(B) LIST AND DESCRIPTION BY SUBSECTION (k) APPLICANT- Not later than 60 days after receipt of the list under subparagraph (A), the subsection (k) applicant--

`(i) may provide to the reference product sponsor a list of patents to which the subsection (k) applicant believes a claim of patent infringement could reasonably be asserted by the reference product

sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application;

`(ii) shall provide to the reference product sponsor, with respect to each patent listed by the reference product sponsor under subparagraph (A) or listed by the subsection (k) applicant under clause (i)--

`(I) a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application; or

`(II) a statement that the subsection (k) applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires; and

`(iii) shall provide to the reference product sponsor a response regarding each patent identified by the reference product sponsor under subparagraph (A)(ii).

`(C) DESCRIPTION BY REFERENCE PRODUCT SPONSOR- Not later than 60 days after receipt of the list and statement under subparagraph (B), the reference product sponsor shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I).

`(4) PATENT RESOLUTION NEGOTIATIONS-

`(A) IN GENERAL- After receipt by the subsection (k) applicant of the statement under paragraph (3)(C), the reference product sponsor and the subsection (k) applicant shall engage in good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6).

`(B) FAILURE TO REACH AGREEMENT- If, within 15 days of beginning negotiations under subparagraph (A), the subsection (k) applicant and the reference product sponsor fail to agree on a final and complete list of which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6), the provisions of paragraph (5) shall apply to the parties.

`(5) PATENT RESOLUTION IF NO AGREEMENT-

`(A) NUMBER OF PATENTS- The subsection (k) applicant shall notify the reference product sponsor of the number of patents that such applicant will provide to the reference product sponsor under subparagraph (B)(i)(I).

`(B) EXCHANGE OF PATENT LISTS-

`(i) IN GENERAL- On a date agreed to by the subsection (k) applicant and the reference product sponsor, but in no case later than 5 days after the subsection (k) applicant notifies the reference product sponsor under subparagraph (A), the subsection (k) applicant and the reference product sponsor shall simultaneously exchange--

`(I) the list of patents that the subsection (k) applicant believes should be the subject of an action for patent infringement under paragraph (6); and

`(II) the list of patents, in accordance with clause (ii), that the reference product sponsor believes should be the subject of an action for patent infringement under paragraph (6).

`(ii) NUMBER OF PATENTS LISTED BY REFERENCE PRODUCT SPONSOR-

`(I) IN GENERAL- Subject to subclause (II), the number of patents listed by the reference product sponsor under clause (i)(II) may not exceed the number of patents listed by the subsection (k) applicant under clause (i)(I).

`(II) EXCEPTION- If a subsection (k) applicant does not list any patent under clause (i)(I), the reference product sponsor may list 1 patent under clause (i)(II).

`(6) IMMEDIATE PATENT INFRINGEMENT ACTION-

`(A) ACTION IF AGREEMENT ON PATENT LIST- If the subsection (k) applicant and the reference product sponsor agree on patents as described in paragraph (4), not later than 30 days after such agreement, the reference product sponsor shall bring an action for patent infringement with respect to each such patent.

`(B) ACTION IF NO AGREEMENT ON PATENT LIST- If the provisions of paragraph (5) apply to the parties as described in paragraph (4)(B), not later than 30 days after the exchange of lists under paragraph (5)(B), the reference product sponsor shall bring an action for patent infringement with respect to each patent that is included on such lists.

`(C) NOTIFICATION AND PUBLICATION OF COMPLAINT-

`(i) NOTIFICATION TO SECRETARY- Not later than 30 days after a complaint is served to a subsection (k) applicant in an action for patent infringement described under this paragraph, the subsection (k) applicant shall provide the Secretary with notice and a copy of such complaint.

`(ii) PUBLICATION BY SECRETARY- The Secretary shall publish in the Federal Register notice of a complaint received under clause (i).

`(7) NEWLY ISSUED OR LICENSED PATENTS- In the case of a patent that--

`(A) is issued to, or exclusively licensed by, the reference product sponsor after the date that the reference product sponsor provided the list to the subsection (k) applicant under paragraph (3)(A); and

`(B) the reference product sponsor reasonably believes that, due to the issuance of such patent, a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application,

not later than 30 days after such issuance or licensing, the reference product sponsor shall provide to the subsection (k) applicant a supplement to the list provided by the reference product sponsor under paragraph (3)(A) that includes such patent, not later than 30 days after such supplement is provided, the subsection (k) applicant shall provide a statement to the reference product sponsor in accordance with paragraph (3)(B), and such patent shall be subject to paragraph (8).

`(8) NOTICE OF COMMERCIAL MARKETING AND PRELIMINARY INJUNCTION-

`(A) NOTICE OF COMMERCIAL MARKETING- The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

`(B) PRELIMINARY INJUNCTION- After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is--

`(i) included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by the subsection (k) applicant under paragraph (3)(B); and

`(ii) not included, as applicable, on--

`(I) the list of patents described in paragraph (4); or

`(II) the lists of patents described in paragraph (5)(B).

`(C) REASONABLE COOPERATION- If the reference product sponsor has sought a preliminary injunction under subparagraph (B), the reference product sponsor and the subsection (k) applicant shall reasonably cooperate to expedite such further discovery as is needed in connection with the preliminary injunction motion.

`(9) LIMITATION ON DECLARATORY JUDGMENT ACTION-

`(A) SUBSECTION (k) APPLICATION PROVIDED- If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).

`(B) SUBSEQUENT FAILURE TO ACT BY SUBSECTION (k) APPLICANT- If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

`(C) SUBSECTION (k) APPLICATION NOT PROVIDED- If a subsection (k)

applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent that claims the biological product or a use of the biological product.'

(b) Definitions- Section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)) is amended--

(1) by striking 'In this section, the term 'biological product' means' and inserting the following: 'In this section:

'(1) The term 'biological product' means';

(2) in paragraph (1), as so designated, by inserting 'protein (except any chemically synthesized polypeptide),' after 'allergenic product,'; and

(3) by adding at the end the following:

'(2) The term 'biosimilar' or 'biosimilarity', in reference to a biological product that is the subject of an application under subsection (k), means--

'(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and

'(B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

'(3) The term 'interchangeable' or 'interchangeability', in reference to a biological product that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

'(4) The term 'reference product' means the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k).'

(c) Conforming Amendments Relating to Patents-

(1) PATENTS- Section 271(e) of title 35, United States Code, is amended--

(A) in paragraph (2)--

(i) in subparagraph (A), by striking 'or' at the end;

(ii) in subparagraph (B), by adding 'or' at the end; and

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

'(C)(i) with respect to a patent that is identified in the list of patents described in section 351(l)(3) of the Public Health Service Act (including as provided under section 351(l)(7) of such Act), an application seeking approval of a biological product, or

'(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,'; and

(iv) in the matter following subparagraph (C) (as added by clause (iii)), by striking 'or veterinary biological product' and inserting ', veterinary biological product, or biological product';

(B) in paragraph (4)--

(i) in subparagraph (B), by--
(I) striking `or veterinary biological product' and inserting `, veterinary biological product, or biological product'; and
(II) striking `and' at the end;

(ii) in subparagraph (C), by--
(I) striking `or veterinary biological product' and inserting `, veterinary biological product, or biological product'; and
(II) striking the period and inserting `, and';
(iii) by inserting after subparagraph (C) the following:
`D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(l)(6) of such Act, and the biological product has not yet been approved because of section 351(k)(7) of such Act.'; and
(iv) in the matter following subparagraph (D) (as added by clause (iii)), by striking `and (C)' and inserting `(C), and (D)'; and
(C) by adding at the end the following:
`6)(A) Subparagraph (B) applies, in lieu of paragraph (4), in the case of a patent--
(i) that is identified, as applicable, in the list of patents described in section 351(l)(4) of the Public Health Service Act or the lists of patents described in section 351(l)(5)(B) of such Act with respect to a biological product; and
(ii) for which an action for infringement of the patent with respect to the biological product--
(I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(l)(6) of such Act; or
(II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.
(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.
(C) The owner of a patent that should have been included in the list described in section 351(l)(3)(A) of the Public Health Service Act, including as provided under section 351(l)(7) of such Act for a biological product, but was not timely included in such list, may not bring an action under this section for infringement of the patent with respect to the biological product.'

(2) CONFORMING AMENDMENT UNDER TITLE 28- Section 2201(b) of title 28, United States Code, is amended by inserting before the period the following: `, or

section 351 of the Public Health Service Act'.

(d) Conforming Amendments Under the Federal Food, Drug, and Cosmetic Act-

(1) CONTENT AND REVIEW OF APPLICATIONS- Section 505(b)(5)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(5)(B)) is amended by inserting before the period at the end of the first sentence the following: `or, with respect to an applicant for approval of a biological product under section 351(k) of the Public Health Service Act, any necessary clinical study or studies'.

(2) NEW ACTIVE INGREDIENT- Section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amended by adding at the end the following:

`(n) New Active Ingredient-

`(1) NON-INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT- A biological product that is biosimilar to a reference product under section 351 of the Public Health Service Act, and that the Secretary has not determined to meet the standards described in subsection (k)(4) of such section for interchangeability with the reference product, shall be considered to have a new active ingredient under this section.

`(2) INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT- A biological product that is interchangeable with a reference product under section 351 of the Public Health Service Act shall not be considered to have a new active ingredient under this section.'.

(e) Products Previously Approved Under Section 505-

(1) REQUIREMENT TO FOLLOW SECTION 351- Except as provided in paragraph (2), an application for a biological product shall be submitted under section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act).

(2) EXCEPTION- An application for a biological product may be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) if--

(A) such biological product is in a product class for which a biological product in such product class is the subject of an application approved under such section 505 not later than the date of enactment of this Act; and

(B) such application--

(i) has been submitted to the Secretary of Health and Human Services (referred to in this subtitle as the `Secretary') before the date of enactment of this Act; or

(ii) is submitted to the Secretary not later than the date that is 10 years after the date of enactment of this Act.

(3) LIMITATION- Notwithstanding paragraph (2), an application for a biological product may not be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) if there is another biological product approved under subsection (a) of section 351 of the Public Health Service Act that could be a reference product with respect to such application (within the meaning of such section 351) if such application were submitted under subsection (k) of such section 351.

(4) DEEMED APPROVED UNDER SECTION 351- An approved application for a biological product under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) shall be deemed to be a license for the biological

product under such section 351 on the date that is 10 years after the date of enactment of this Act.

(5) DEFINITIONS- For purposes of this subsection, the term 'biological product' has the meaning given such term under section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act).

(f) Follow-on Biologics User Fees-

(1) DEVELOPMENT OF USER FEES FOR BIOSIMILAR BIOLOGICAL PRODUCTS-

(A) IN GENERAL- Beginning not later than October 1, 2010, the Secretary shall develop recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of biosimilar biological product applications submitted under section 351(k) of the Public Health Service Act (as added by this Act) for the first 5 fiscal years after fiscal year 2012. In developing such recommendations, the Secretary shall consult with--

- (i) the Committee on Health, Education, Labor, and Pensions of the Senate;
- (ii) the Committee on Energy and Commerce of the House of Representatives;
- (iii) scientific and academic experts;
- (iv) health care professionals;
- (v) representatives of patient and consumer advocacy groups; and
- (vi) the regulated industry.

(B) PUBLIC REVIEW OF RECOMMENDATIONS- After negotiations with the regulated industry, the Secretary shall--

- (i) present the recommendations developed under subparagraph (A) to the Congressional committees specified in such subparagraph;
- (ii) publish such recommendations in the Federal Register;
- (iii) provide for a period of 30 days for the public to provide written comments on such recommendations;
- (iv) hold a meeting at which the public may present its views on such recommendations; and
- (v) after consideration of such public views and comments, revise such recommendations as necessary.

(C) TRANSMITTAL OF RECOMMENDATIONS- Not later than January 15, 2012, the Secretary shall transmit to Congress the revised recommendations under subparagraph (B), a summary of the views and comments received under such subparagraph, and any changes made to the recommendations in response to such views and comments.

(2) ESTABLISHMENT OF USER FEE PROGRAM- It is the sense of the Senate that, based on the recommendations transmitted to Congress by the Secretary pursuant to paragraph (1)(C), Congress should authorize a program, effective on October 1, 2012, for the collection of user fees relating to the submission of biosimilar biological product applications under section 351(k) of the Public Health Service Act (as added by this Act).

(3) TRANSITIONAL PROVISIONS FOR USER FEES FOR BIOSIMILAR BIOLOGICAL PRODUCTS-

(A) APPLICATION OF THE PRESCRIPTION DRUG USER FEE PROVISIONS- Section 735(1)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.

379g(1)(B)) is amended by striking `section 351' and inserting `subsection (a) or (k) of section 351'.

(B) EVALUATION OF COSTS OF REVIEWING BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS- During the period beginning on the date of enactment of this Act and ending on October 1, 2010, the Secretary shall collect and evaluate data regarding the costs of reviewing applications for biological products submitted under section 351(k) of the Public Health Service Act (as added by this Act) during such period.

(C) AUDIT-

(i) IN GENERAL- On the date that is 2 years after first receiving a user fee applicable to an application for a biological product under section 351(k) of the Public Health Service Act (as added by this Act), and on a biennial basis thereafter until October 1, 2013, the Secretary shall perform an audit of the costs of reviewing such applications under such section 351(k). Such an audit shall compare--

(I) the costs of reviewing such applications under such section 351(k) to the amount of the user fee applicable to such applications; and

(II)(aa) such ratio determined under subclause (I); to

(bb) the ratio of the costs of reviewing applications for biological products under section 351(a) of such Act (as amended by this Act) to the amount of the user fee applicable to such applications under such section 351(a).

(ii) ALTERATION OF USER FEE- If the audit performed under clause (i) indicates that the ratios compared under subclause (II) of such clause differ by more than 5 percent, then the Secretary shall alter the user fee applicable to applications submitted under such section 351(k) to more appropriately account for the costs of reviewing such applications.

(iii) ACCOUNTING STANDARDS- The Secretary shall perform an audit under clause (i) in conformance with the accounting principles, standards, and requirements prescribed by the Comptroller General of the United States under section 3511 of title 31, United State Code, to ensure the validity of any potential variability.

(4) AUTHORIZATION OF APPROPRIATIONS- There is authorized to be appropriated to carry out this subsection such sums as may be necessary for each of fiscal years 2010 through 2012.

(g) Pediatric Studies of Biological Products-

(1) IN GENERAL- Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended by adding at the end the following:

`(m) Pediatric Studies-

`(1) APPLICATION OF CERTAIN PROVISIONS- The provisions of subsections (a), (d), (e), (f), (i), (j), (k), (l), (p), and (q) of section 505A of the Federal Food, Drug, and Cosmetic Act shall apply with respect to the extension of a period under paragraphs (2) and (3) to the same extent and in the same manner as such provisions apply with respect to the extension of a period under subsection (b) or (c) of section 505A of the Federal Food, Drug, and Cosmetic Act.

`(2) MARKET EXCLUSIVITY FOR NEW BIOLOGICAL PRODUCTS- If, prior to approval of an application that is submitted under subsection (a), the Secretary

determines that information relating to the use of a new biological product in the pediatric population may produce health benefits in that population, the Secretary makes a written request for pediatric studies (which shall include a timeframe for completing such studies), the applicant agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act--

`(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

`(B) if the biological product is designated under section 526 for a rare disease or condition, the period for such biological product referred to in section 527(a) is deemed to be 7 years and 6 months rather than 7

years.

`(3) MARKET EXCLUSIVITY FOR ALREADY-MARKETED BIOLOGICAL PRODUCTS- If the Secretary determines that information relating to the use of a licensed biological product in the pediatric population may produce health benefits in that population and makes a written request to the holder of an approved application under subsection (a) for pediatric studies (which shall include a timeframe for completing such studies), the holder agrees to the request, such studies are completed using appropriate formulations for each age group for which the study is requested within any such timeframe, and the reports thereof are submitted and accepted in accordance with section 505A(d)(3) of the Federal Food, Drug, and Cosmetic Act--

`(A) the periods for such biological product referred to in subsection (k)(7) are deemed to be 4 years and 6 months rather than 4 years and 12 years and 6 months rather than 12 years; and

`(B) if the biological product is designated under section 526 for a rare disease or condition, the period for such biological product referred to in section 527(a) is deemed to be 7 years and 6 months rather than 7

years.

`(4) EXCEPTION- The Secretary shall not extend a period referred to in paragraph (2)(A), (2)(B), (3)(A), or (3)(B) if the determination under section 505A(d)(3) is made later than 9 months prior to the expiration of such period.'

(2) STUDIES REGARDING PEDIATRIC RESEARCH-

(A) PROGRAM FOR PEDIATRIC STUDY OF DRUGS- Subsection (a)(1) of section 409I of the Public Health Service Act (42 U.S.C. 284m) is amended by inserting ', biological products,' after 'including drugs'.

(B) INSTITUTE OF MEDICINE STUDY- Section 505A(p) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355b(p)) is amended by striking paragraphs (4) and (5) and inserting the following:

`(4) review and assess the number and importance of biological products for children that are being tested as a result of the amendments made by the Biologics Price Competition and Innovation Act of 2009 and the importance for children, health care providers, parents, and others of labeling changes made as a result of such testing;

`(5) review and assess the number, importance, and prioritization of any biological products that are not being tested for pediatric use; and
` (6) offer recommendations for ensuring pediatric testing of biological products, including consideration of any incentives, such as those provided under this section or section 351(m) of the Public Health Service Act.'.

(h) Orphan Products- If a reference product, as defined in section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act) has been designated under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) for a rare disease or condition, a biological product seeking approval for such disease or condition under subsection (k) of such section 351 as biosimilar to, or interchangeable with, such reference product may be licensed by the Secretary only after the expiration for such reference product of the later of--

(1) the 7-year period described in section 527(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc(a)); and

(2) the 12-year period described in subsection (k)(7) of such section 351.

SEC. 7003. SAVINGS.

(a) Determination- The Secretary of the Treasury, in consultation with the Secretary of Health and Human Services, shall for each fiscal year determine the amount of savings to the Federal Government as a result of the enactment of this subtitle.

(b) Use- Notwithstanding any other provision of this subtitle (or an amendment made by this subtitle), the savings to the Federal Government generated as a result of the enactment of this subtitle shall be used for deficit reduction.

Subtitle B--More Affordable Medicines for Children and Underserved Communities

SEC. 7101. EXPANDED PARTICIPATION IN 340B PROGRAM.

(a) Expansion of Covered Entities Receiving Discounted Prices- Section 340B(a)(4) of the Public Health Service Act (42 U.S.C. 256b(a)(4)) is amended by adding at the end the following:

`(M) A children's hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(iii) of the Social Security Act, or a free-standing cancer hospital excluded from the Medicare prospective payment system pursuant to section 1886(d)(1)(B)(v) of the Social Security Act, that would meet the requirements of subparagraph (L), including the disproportionate share adjustment percentage requirement under clause (ii) of such subparagraph, if the hospital were a subsection (d) hospital as defined by section 1886(d)(1)(B) of the Social Security Act.

`(N) An entity that is a critical access hospital (as determined under section 1820(c)(2) of the Social Security Act), and that meets the requirements of subparagraph (L)(i).

`(O) An entity that is a rural referral center, as defined by section 1886(d)(5)(C)(i) of the Social Security Act, or a sole community hospital, as defined by section 1886(d)(5)(C)(iii) of such Act, and that both meets the requirements of subparagraph (L)(i) and has a disproportionate share adjustment percentage equal to or greater than 8 percent.'.

(b) Extension of Discount to Inpatient Drugs- Section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended--

(1) in paragraphs (2), (5), (7), and (9) of subsection (a), by striking

'outpatient' each place it appears; and

(2) in subsection (b)--

(A) by striking 'Other Definition' and all that follows through 'In this section' and inserting the following: 'Other Definitions-

'(1) IN GENERAL- In this section'; and

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

'(2) COVERED DRUG- In this section, the term 'covered drug'--

'(A) means a covered outpatient drug (as defined in section 1927(k)(2) of the Social Security Act); and

'(B) includes, notwithstanding paragraph (3)(A) of section 1927(k) of such Act, a drug used in connection with an inpatient or outpatient service provided by a hospital described in subparagraph (L), (M), (N), or (O) of subsection (a)(4) that is enrolled to participate in the drug discount program under this section.'

(c) Prohibition on Group Purchasing Arrangements- Section 340B(a) of the Public Health Service Act (42 U.S.C. 256b(a)) is amended--

(1) in paragraph (4)(L)--

(A) in clause (i), by adding 'and' at the end;

(B) in clause (ii), by striking '; and' and inserting a period; and

(C) by striking clause (iii); and

(2) in paragraph (5), as amended by subsection (b)--

(A) by redesignating subparagraphs (C) and (D) as subparagraphs (D) and (E); respectively; and

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

'(C) PROHIBITION ON GROUP PURCHASING ARRANGEMENTS-

'(i) IN GENERAL- A hospital described in subparagraph (L), (M), (N), or (O) of paragraph (4) shall not obtain covered outpatient drugs through a group purchasing organization or other group purchasing arrangement, except as permitted or provided for pursuant to clauses (ii) or (iii).

'(ii) INPATIENT DRUGS- Clause (i) shall not apply to drugs purchased for inpatient use.

'(iii) EXCEPTIONS- The Secretary shall establish reasonable exceptions to clause (i)--

'(I) with respect to a covered outpatient drug that is unavailable to be purchased through the program under this section due to a drug shortage problem, manufacturer noncompliance, or any other circumstance beyond the hospital's control;

'(II) to facilitate generic substitution when a generic covered outpatient drug is available at a lower price; or

'(III) to reduce in other ways the administrative burdens of managing both inventories of drugs subject to this section and inventories of drugs that are not subject to this section, so long as the exceptions do not create a duplicate discount problem in violation of subparagraph (A) or a diversion problem in violation of subparagraph (B).

'(iv) PURCHASING ARRANGEMENTS FOR INPATIENT DRUGS- The Secretary shall ensure that a hospital described in subparagraph (L), (M), (N), or (O) of subsection (a)(4) that is enrolled to participate in the drug

discount program under this section shall have multiple options for purchasing covered drugs for inpatients, including by utilizing a group purchasing organization or other group purchasing arrangement, establishing and utilizing its own group purchasing program, purchasing directly from a manufacturer, and any other purchasing arrangements that the Secretary determines is appropriate to ensure access to drug discount pricing under this section for inpatient drugs taking into account the particular needs of small and rural hospitals.'

(d) Medicaid Credits on Inpatient Drugs- Section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended by striking subsection (c) and inserting the following:

`(c) Medicaid Credit- Not later than 90 days after the date of filing of the hospital's most recently filed Medicare cost report, the hospital shall issue a credit as determined by the Secretary to the State Medicaid program for inpatient covered drugs provided to Medicaid recipients.'

(e) Effective Dates-

(1) IN GENERAL- The amendments made by this section and section 7102 shall take effect on January 1, 2010, and shall apply to drugs purchased on or after January 1, 2010.

(2) EFFECTIVENESS- The amendments made by this section and section 7102 shall be effective and shall be taken into account in determining whether a manufacturer is deemed to meet the requirements of section 340B(a) of the Public Health Service Act (42 U.S.C. 256b(a)), notwithstanding any other provision of law.

SEC. 7102. IMPROVEMENTS TO 340B PROGRAM INTEGRITY.

(a) Integrity Improvements- Subsection (d) of section 340B of the Public Health Service Act (42 U.S.C. 256b) is amended to read as follows:

`(d) Improvements in Program Integrity-

`(1) MANUFACTURER COMPLIANCE-

`(A) IN GENERAL- From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by manufacturers with the requirements of this section in order to prevent overcharges and other violations of the discounted pricing requirements specified in this section.

`(B) IMPROVEMENTS- The improvements described in subparagraph (A) shall include the following:

`(i) The development of a system to enable the Secretary to verify the accuracy of ceiling prices calculated by manufacturers under subsection (a)(1) and charged to covered entities, which shall include the following:

`(I) Developing and publishing through an appropriate policy or regulatory issuance, precisely defined standards and methodology for the calculation of ceiling prices under such subsection.

`(II) Comparing regularly the ceiling prices calculated by the Secretary with the quarterly pricing data that is reported by manufacturers to the Secretary.

`(III) Performing spot checks of sales transactions by covered entities.

`(IV) Inquiring into the cause of any pricing discrepancies that may be identified and either taking, or requiring manufacturers to take, such corrective action as is appropriate in response to such price discrepancies.

`(ii) The establishment of procedures for manufacturers to issue refunds to covered entities in the event that there is an overcharge by the manufacturers, including the following:

`(I) Providing the Secretary with an explanation of why and how the overcharge occurred, how the refunds will be calculated, and to whom the refunds will be issued.

`(II) Oversight by the Secretary to ensure that the refunds are issued accurately and within a reasonable period of time, both in routine instances of retroactive adjustment to relevant pricing data and exceptional circumstances such as erroneous or intentional overcharging for covered drugs.

`(iii) The provision of access through the Internet website of the Department of Health and Human Services to the applicable ceiling prices for covered drugs as calculated and verified by the Secretary in accordance with this section, in a manner (such as through the use of password protection) that limits such access to covered entities and adequately assures security and protection of privileged pricing data from unauthorized re-disclosure.

`(iv) The development of a mechanism by which--

`(I) rebates and other discounts provided by manufacturers to other purchasers subsequent to the sale of covered drugs to covered entities are reported to the Secretary; and

`(II) appropriate credits and refunds are issued to covered entities if such discounts or rebates have the effect of lowering the applicable ceiling price for the relevant quarter for the drugs involved.

`(v) Selective auditing of manufacturers and wholesalers to ensure the integrity of the drug discount program under this section.

`(vi) The imposition of sanctions in the form of civil monetary penalties, which--

`(I) shall be assessed according to standards established in regulations to be promulgated by the Secretary not later than 180 days after the date of enactment of the Patient Protection and Affordable Care Act;

`(II) shall not exceed \$5,000 for each instance of overcharging a covered entity that may have occurred; and

`(III) shall apply to any manufacturer with an agreement under this section that knowingly and intentionally charges a covered entity a price for purchase of a drug that exceeds the maximum applicable price under subsection (a)(1).

`(2) COVERED ENTITY COMPLIANCE-

`(A) IN GENERAL- From amounts appropriated under paragraph (4), the Secretary shall provide for improvements in compliance by covered entities with the requirements of this section in order to prevent diversion and

violations of the duplicate discount provision and other requirements specified under subsection (a)(5).

`(B) IMPROVEMENTS- The improvements described in subparagraph (A) shall include the following:

`(i) The development of procedures to enable and require covered entities to regularly update (at least annually) the information on the Internet website of the Department of Health and Human Services relating to this section.

`(ii) The development of a system for the Secretary to verify the accuracy of information regarding covered entities that is listed on the website described in clause (i).

`(iii) The development of more detailed guidance describing methodologies and options available to covered entities for billing covered drugs to State Medicaid agencies in a manner that avoids duplicate discounts pursuant to subsection (a)(5)(A).

`(iv) The establishment of a single, universal, and standardized identification system by which each covered entity site can be identified by manufacturers, distributors, covered entities, and the Secretary for purposes of facilitating the ordering, purchasing, and delivery of covered drugs under this section, including the processing of chargebacks for such drugs.

`(v) The imposition of sanctions, in appropriate cases as determined by the Secretary, additional to those to which covered entities are subject under subsection (a)(5)(E), through one or more of the following

actions:

`(I) Where a covered entity knowingly and intentionally violates subsection (a)(5)(B), the covered entity shall be required to pay a monetary penalty to a manufacturer or manufacturers in the form of interest on sums for which the covered entity is found liable under subsection (a)(5)(E), such interest to be compounded monthly and equal to the current short term interest rate as determined by the Federal Reserve for the time period for which the covered entity is liable.

`(II) Where the Secretary determines a violation of subsection (a)(5)(B) was systematic and egregious as well as knowing and intentional, removing the covered entity from the drug discount program under this section and disqualifying the entity from re-entry into such program for a reasonable period of time to be determined by the Secretary.

`(III) Referring matters to appropriate Federal authorities within the Food and Drug Administration, the Office of Inspector General of Department of Health and Human Services, or other Federal agencies for consideration of appropriate action under other Federal statutes, such as the Prescription Drug Marketing Act (21 U.S.C. 353).

`(3) ADMINISTRATIVE DISPUTE RESOLUTION PROCESS-

`(A) IN GENERAL- Not later than 180 days after the date of enactment of the Patient Protection and Affordable Care Act, the Secretary shall promulgate regulations to establish and implement an administrative process for the resolution of claims by covered entities that they have

been overcharged for drugs purchased under this section, and claims by manufacturers, after the conduct of audits as authorized by subsection (a)(5)(D), of violations of subsections (a)(5)(A) or (a)(5)(B), including appropriate procedures for the provision of remedies and enforcement of determinations made pursuant to such process through mechanisms and sanctions described in paragraphs (1)(B) and (2)(B).

`(B) DEADLINES AND PROCEDURES- Regulations promulgated by the Secretary under subparagraph (A) shall--

`(i) designate or establish a decision-making official or decision-making body within the Department of Health and Human Services to be responsible for reviewing and finally resolving claims by covered entities that they have been charged prices for covered drugs in excess of the ceiling price described in subsection (a)(1), and claims by manufacturers that violations of subsection (a)(5)(A) or (a)(5)(B) have occurred;

`(ii) establish such deadlines and procedures as may be necessary to ensure that claims shall be resolved fairly, efficiently, and expeditiously;

`(iii) establish procedures by which a covered entity may discover and obtain such information and documents from manufacturers and third parties as may be relevant to demonstrate the merits of a claim that charges for a manufacturer's product have exceeded the applicable ceiling price under this section, and may submit such documents and information to the administrative official or body responsible for adjudicating such claim;

`(iv) require that a manufacturer conduct an audit of a covered entity pursuant to subsection (a)(5)(D) as a prerequisite to initiating administrative dispute resolution proceedings against a covered entity;

`(v) permit the official or body designated under clause (i), at the request of a manufacturer or manufacturers, to consolidate claims brought by more than one manufacturer against the same covered entity where, in the judgment of such official or body, consolidation is appropriate and consistent with the goals of fairness and economy of resources; and

`(vi) include provisions and procedures to permit multiple covered entities to jointly assert claims of overcharges by the same manufacturer for the same drug or drugs in one administrative proceeding, and permit such claims to be asserted on behalf of covered entities by associations or organizations representing the interests of such covered entities and of which the covered entities are members.

`(C) FINALITY OF ADMINISTRATIVE RESOLUTION- The administrative resolution of a claim or claims under the regulations promulgated under subparagraph (A) shall be a final agency decision and shall be binding upon the parties involved, unless invalidated by an order of a court of competent jurisdiction.

`(4) AUTHORIZATION OF APPROPRIATIONS- There are authorized to be appropriated to carry out this subsection, such sums as may be necessary for fiscal year 2010 and each succeeding fiscal year.'.

(b) Conforming Amendments- Section 340B(a) of the Public Health Service Act (42 U.S.C. 256b(a)) is amended--

(1) in subsection (a)(1), by adding at the end the following: 'Each such agreement shall require that the manufacturer furnish the Secretary with reports, on a quarterly basis, of the price for each covered drug subject to the agreement that, according to the manufacturer, represents the maximum price that covered entities may permissibly be required to pay for the drug (referred to in this section as the 'ceiling price'), and shall require that the manufacturer offer each covered entity covered drugs for purchase at or below the applicable ceiling price if such drug is made available to any other purchaser at any price.'; and

(2) in the first sentence of subsection (a)(5)(E), as redesignated by section 7101(c), by inserting 'after audit as described in subparagraph (D) and' after 'finds,'.

SEC. 7103. GAO STUDY TO MAKE RECOMMENDATIONS ON IMPROVING THE 340B PROGRAM.

(a) Report- Not later than 18 months after the date of enactment of this Act, the Comptroller General of the United States shall submit to Congress a report that examines whether those individuals served by the covered entities under the program under section 340B of the Public Health Service Act (42 U.S.C. 256b) (referred to in this section as the '340B program') are receiving optimal health care services.

(b) Recommendations- The report under subsection (a) shall include recommendations on the following:

(1) Whether the 340B program should be expanded since it is anticipated that the 47,000,000 individuals who are uninsured as of the date of enactment of this Act will have health care coverage once this Act is implemented.

(2) Whether mandatory sales of certain products by the 340B program could hinder patients access to those therapies through any provider.

(3) Whether income from the 340B program is being used by the covered entities under the program to further the program objectives.

TITLE VIII--CLASS ACT

SEC. 8001. SHORT TITLE OF TITLE.

This title may be cited as the 'Community Living Assistance Services and Supports Act' or the 'CLASS Act'.

SEC. 8002. ESTABLISHMENT OF NATIONAL VOLUNTARY INSURANCE PROGRAM FOR PURCHASING COMMUNITY LIVING ASSISTANCE SERVICES AND SUPPORT.

(a) Establishment of CLASS Program-

(1) IN GENERAL- The Public Health Service Act (42 U.S.C. 201 et seq.), as amended by section 4302(a), is amended by adding at the end the following:

'TITLE XXXII--COMMUNITY LIVING ASSISTANCE SERVICES AND SUPPORTS

'SEC. 3201. PURPOSE.

'The purpose of this title is to establish a national voluntary insurance program for purchasing community living assistance services and supports in order to--

'(1) provide individuals with functional limitations with tools that will allow them to maintain their personal and financial independence and live in the community through a new financing strategy for community living assistance services and supports;

- `(2) establish an infrastructure that will help address the Nation's community living assistance services and supports needs;
- `(3) alleviate burdens on family caregivers; and
- `(4) address institutional bias by providing a financing mechanism that supports personal choice and independence to live in the community.

`SEC. 3202. DEFINITIONS.

`In this title:

`(1) ACTIVE ENROLLEE- The term `active enrollee' means an individual who is enrolled in the CLASS program in accordance with section 3204 and who has paid any premiums due to maintain such enrollment.

`(2) ACTIVELY EMPLOYED- The term `actively employed' means an individual who--

`(A) is reporting for work at the individual's usual place of employment or at another location to which the individual is required to travel because of the individual's employment (or in the case of an individual who is a member of the uniformed services, is on active duty and is physically able to perform the duties of the individual's position); and

`(B) is able to perform all the usual and customary duties of the individual's employment on the individual's regular work schedule.

`(3) ACTIVITIES OF DAILY LIVING- The term `activities of daily living' means each of the following activities specified in section 7702B(c)(2)(B) of the Internal Revenue Code of 1986:

`(A) Eating.

`(B) Toileting.

`(C) Transferring.

`(D) Bathing.

`(E) Dressing.

`(F) Continence.

`(4) CLASS PROGRAM- The term `CLASS program' means the program established under this title.

`(5) ELIGIBILITY ASSESSMENT SYSTEM- The term `Eligibility Assessment System' means the entity established by the Secretary under section 3205(a)(2) to make functional eligibility determinations for the CLASS program.

`(6) ELIGIBLE BENEFICIARY-

`(A) IN GENERAL- The term `eligible beneficiary' means any individual who is an active enrollee in the CLASS program and, as of the date described in subparagraph (B)--

`(i) has paid premiums for enrollment in such program for at least 60 months;

`(ii) has earned, with respect to at least 3 calendar years that occur during the first 60 months for which the individual has paid premiums for enrollment in the program, at least an amount equal to the amount of wages and self-employment income which an individual must have in order to be credited with a quarter of coverage under section 213(d) of the Social Security Act for the year; and

`(iii) has paid premiums for enrollment in such program for at least 24 consecutive months, if a lapse in premium payments of more than 3 months has occurred during the period that begins on the date of the

individual's enrollment and ends on the date of such determination.

`(B) DATE DESCRIBED- For purposes of subparagraph (A), the date described in this subparagraph is the date on which the individual is determined to have a functional limitation described in section 3203(a)(1)(C) that is expected to last for a continuous period of more than 90 days.

`(C) REGULATIONS- The Secretary shall promulgate regulations specifying exceptions to the minimum earnings requirements under subparagraph (A)(ii) for purposes of being considered an eligible beneficiary for certain populations.

`(7) HOSPITAL; NURSING FACILITY; INTERMEDIATE CARE FACILITY FOR THE MENTALLY RETARDED; INSTITUTION FOR MENTAL DISEASES- The terms `hospital', `nursing facility', `intermediate care facility for the mentally retarded', and `institution for mental diseases' have the meanings given such terms for purposes of Medicaid.

`(8) CLASS INDEPENDENCE ADVISORY COUNCIL- The term `CLASS Independence Advisory Council' or `Council' means the Advisory Council established under section 3207 to advise the Secretary.

`(9) CLASS INDEPENDENCE BENEFIT PLAN- The term `CLASS Independence Benefit Plan' means the benefit plan developed and designated by the Secretary in accordance with section 3203.

`(10) CLASS INDEPENDENCE FUND- The term `CLASS Independence Fund' or `Fund' means the fund established under section 3206.

`(11) MEDICAID- The term `Medicaid' means the program established under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.).

`(12) POVERTY LINE- The term `poverty line' has the meaning given that term in section 2110(c)(5) of the Social Security Act (42 U.S.C. 1397jj(c)(5)).

`(13) PROTECTION AND ADVOCACY SYSTEM- The term `Protection and Advocacy System' means the system for each State established under section 143 of the Developmental Disabilities Assistance and Bill of Rights Act of 2000 (42 U.S.C. 15043).

`SEC. 3203. CLASS INDEPENDENCE BENEFIT PLAN.

`(a) Process for Development-

`(1) IN GENERAL- The Secretary, in consultation with appropriate actuaries and other experts, shall develop at least 3 actuarially sound benefit plans as alternatives for consideration for designation by the Secretary as the CLASS Independence Benefit Plan under which eligible beneficiaries shall receive benefits under this title. Each of the plan alternatives developed shall be designed to provide eligible beneficiaries with the benefits described in section 3205 consistent with the following requirements:

`(A) PREMIUMS-

`(i) IN GENERAL- Beginning with the first year of the CLASS program, and for each year thereafter, subject to clauses (ii) and (iii), the Secretary shall establish all premiums to be paid by enrollees for the year based on an actuarial analysis of the 75-year costs of the program that ensures solvency throughout such 75-year period.

`(ii) NOMINAL PREMIUM FOR POOREST INDIVIDUALS AND FULL-TIME STUDENTS-

`(I) IN GENERAL- The monthly premium for enrollment in the CLASS program shall not exceed the applicable dollar amount per month

determined under subclause (II) for--

`(aa) any individual whose income does not exceed the poverty line; and
`(bb) any individual who has not attained age 22, and is actively employed during any period in which the individual is a full-time student (as determined by the Secretary).

`(II) APPLICABLE DOLLAR AMOUNT- The applicable dollar amount described in this subclause is the amount equal to \$5, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) for each year occurring after 2009 and before such year.

`(iii) CLASS INDEPENDENCE FUND RESERVES- At such time as the CLASS program has been in operation for 10 years, the Secretary shall establish all premiums to be paid by enrollees for the year based on an actuarial analysis that accumulated reserves in the CLASS Independence Fund would not decrease in that year. At such time as the Secretary determines the CLASS program demonstrates a sustained ability to finance expected yearly expenses with expected yearly premiums and interest credited to the CLASS Independence Fund, the Secretary may decrease the required amount of CLASS Independence Fund reserves.

`(B) VESTING PERIOD- A 5-year vesting period for eligibility for benefits.

`(C) BENEFIT TRIGGERS- A benefit trigger for provision of benefits that requires a determination that an individual has a functional limitation, as certified by a licensed health care practitioner, described in any of the following clauses that is expected to last for a continuous period of more than 90 days:

`(i) The individual is determined to be unable to perform at least the minimum number (which may be 2 or 3) of activities of daily living as are required under the plan for the provision of benefits without substantial assistance (as defined by the Secretary) from another individual.

`(ii) The individual requires substantial supervision to protect the individual from threats to health and safety due to substantial cognitive impairment.

`(iii) The individual has a level of functional limitation similar (as determined under regulations prescribed by the Secretary) to the level of functional limitation described in clause (i) or (ii).

`(D) CASH BENEFIT- Payment of a cash benefit that satisfies the following requirements:

`(i) MINIMUM REQUIRED AMOUNT- The benefit amount provides an eligible beneficiary with not less than an average of \$50 per day (as determined based on the reasonably expected distribution of beneficiaries receiving benefits at various benefit levels).

`(ii) AMOUNT SCALED TO FUNCTIONAL ABILITY- The benefit amount is varied based on a scale of functional ability, with not less than 2, and not more than 6, benefit level amounts.

`(iii) DAILY OR WEEKLY- The benefit is paid on a daily or weekly basis.

`(iv) NO LIFETIME OR AGGREGATE LIMIT- The benefit is not subject to any lifetime or aggregate limit.

`(E) COORDINATION WITH SUPPLEMENTAL COVERAGE OBTAINED THROUGH THE EXCHANGE- The benefits allow for coordination with any supplemental coverage purchased through an Exchange established under section 1311 of the Patient Protection and Affordable Care Act.

`(2) REVIEW AND RECOMMENDATION BY THE CLASS INDEPENDENCE ADVISORY COUNCIL- The CLASS Independence Advisory Council shall--

`(A) evaluate the alternative benefit plans developed under paragraph (1); and

`(B) recommend for designation as the CLASS Independence Benefit Plan for offering to the public the plan that the Council determines best balances price and benefits to meet enrollees' needs in an actuarially sound manner, while optimizing the probability of the long-term sustainability of the CLASS program.

`(3) DESIGNATION BY THE SECRETARY- Not later than October 1, 2012, the Secretary, taking into consideration the recommendation of the CLASS Independence Advisory Council under paragraph (2)(B), shall designate a benefit plan as the CLASS Independence Benefit Plan. The Secretary shall publish such designation, along with details of the plan and the reasons for the selection by the Secretary, in a final rule that allows for a period of public comment.

`(b) Additional Premium Requirements-

`(1) ADJUSTMENT OF PREMIUMS-

`(A) IN GENERAL- Except as provided in subparagraphs (B), (C), (D), and (E), the amount of the monthly premium determined for an individual upon such individual's enrollment in the CLASS program shall remain the same for as long as the individual is an active enrollee in the program.

`(B) RECALCULATED PREMIUM IF REQUIRED FOR PROGRAM SOLVENCY-

`(i) IN GENERAL- Subject to clause (ii), if the Secretary determines, based on the most recent report of the Board of Trustees of the CLASS Independence Fund, the advice of the CLASS Independence Advisory Council, and the annual report of the Inspector General of the Department of Health and Human Services, and waste, fraud, and abuse, or such other information as the Secretary determines appropriate, that the monthly premiums and income to the CLASS Independence Fund for a year are projected to be insufficient with respect to the 20-year period that begins with that year, the Secretary shall adjust the monthly premiums for individuals enrolled in the CLASS program as necessary (but maintaining a nominal premium for enrollees whose income is below the poverty line or who are full-time students actively employed).

`(ii) EXEMPTION FROM INCREASE- Any increase in a monthly premium imposed as result of a determination described in clause (i) shall not apply with respect to the monthly premium of any active enrollee who--

`(I) has attained age 65;

`(II) has paid premiums for enrollment in the program for at least 20 years; and

`(III) is not actively employed.

`(C) RECALCULATED PREMIUM IF REENROLLMENT AFTER MORE THAN A 3-MONTH LAPSE-

`(i) IN GENERAL- The reenrollment of an individual after a 90-day period

during which the individual failed to pay the monthly premium required to maintain the individual's enrollment in the CLASS program shall be treated as an initial enrollment for purposes of age-adjusting the premium for enrollment in the program.

`(ii) CREDIT FOR PRIOR MONTHS IF REENROLLED WITHIN 5 YEARS- An individual who reenrolls in the CLASS program after such a 90-day period and before the end of the 5-year period that begins with the first month for which the individual failed to pay the monthly premium required to maintain the individual's enrollment in the program shall be--

`(I) credited with any months of paid premiums that accrued prior to the individual's lapse in enrollment; and

`(II) notwithstanding the total amount of any such credited months, required to satisfy section 3202(6)(A)(ii) before being eligible to receive benefits.

`(D) NO LONGER STATUS AS A FULL-TIME STUDENT- An individual subject to a nominal premium on the basis of being described in subsection (a)(1)(A)(ii)(I)(bb) who ceases to be described in that subsection, beginning with the first month following the month in which the individual ceases to be so described, shall be subject to the same monthly premium as the monthly premium that applies to an individual of the same age who first enrolls in the program under the most similar circumstances as the individual (such as the first year of eligibility for enrollment in the program or in a subsequent year).

`(E) PENALTY FOR REENROLLMENT AFTER 5-YEAR LAPSE- In the case of an individual who reenrolls in the CLASS program after the end of the 5-year period described in subparagraph (C)(ii), the monthly premium required for the individual shall be the age-adjusted premium that would be applicable to an initially enrolling individual who is the same age as the reenrolling individual, increased by the greater of--

`(i) an amount that the Secretary determines is actuarially sound for each month that occurs during the period that begins with the first month for which the individual failed to pay the monthly premium required to maintain the individual's enrollment in the CLASS program and ends with the month preceding the month in which the reenrollment is effective; or

`(ii) 1 percent of the applicable age-adjusted premium for each such month occurring in such period.

`(2) ADMINISTRATIVE EXPENSES- In determining the monthly premiums for the CLASS program the Secretary may factor in costs for administering the program, not to exceed for any year in which the program is in effect under this title, an amount equal to 3 percent of all premiums paid during the year.

`(3) NO UNDERWRITING REQUIREMENTS- No underwriting (other than on the basis of age in accordance with subparagraphs (D) and (E) of paragraph (1)) shall be used to--

`(A) determine the monthly premium for enrollment in the CLASS program; or

`(B) prevent an individual from enrolling in the program.

`(c) Self-attestation and Verification of Income- The Secretary shall

establish procedures to--

- `(1) permit an individual who is eligible for the nominal premium required under subsection (a)(1)(A)(ii), as part of their automatic enrollment in the CLASS program, to self-attest that their income does not exceed the poverty line or that their status as a full-time student who is actively employed;
- `(2) verify, using procedures similar to the procedures used by the Commissioner of Social Security under section 1631(e)(1)(B)(ii) of the Social Security Act and consistent with the requirements applicable to the conveyance of data and information under section 1942 of such Act, the validity of such self-attestation; and
- `(3) require an individual to confirm, on at least an annual basis, that their income does not exceed the poverty line or that they continue to maintain such status.

`SEC. 3204. ENROLLMENT AND DISENROLLMENT REQUIREMENTS.

`(a) Automatic Enrollment-

- `(1) IN GENERAL- Subject to paragraph (2), the Secretary, in coordination with the Secretary of the Treasury, shall establish procedures under which each individual described in subsection (c) may be automatically enrolled in the CLASS program by an employer of such individual in the same manner as an employer may elect to automatically enroll employees in a plan under section 401(k), 403(b), or 457 of the Internal Revenue Code of 1986.
- `(2) ALTERNATIVE ENROLLMENT PROCEDURES- The procedures established under paragraph (1) shall provide for an alternative enrollment process for an individual described in subsection (c) in the case of such an individual--
 - `(A) who is self-employed;
 - `(B) who has more than 1 employer; or
 - `(C) whose employer does not elect to participate in the automatic enrollment process established by the Secretary.

`(3) ADMINISTRATION-

- `(A) IN GENERAL- The Secretary and the Secretary of the Treasury shall, by regulation, establish procedures to ensure that an individual is not automatically enrolled in the CLASS program by more than 1 employer.
- `(B) FORM- Enrollment in the CLASS program shall be made in such manner as the Secretary may prescribe in order to ensure ease of administration.

`(b) Election to Opt-Out- An individual described in subsection (c) may elect to waive enrollment in the CLASS program at any time in such form and manner as the Secretary and the Secretary of the Treasury shall prescribe.

`(c) Individual Described- For purposes of enrolling in the CLASS program, an individual described in this paragraph is an individual--

- `(1) who has attained age 18;
- `(2) who--
 - `(A) receives wages on which there is imposed a tax under section 3201(a) of the Internal Revenue Code of 1986; or
 - `(B) derives self-employment income on which there is imposed a tax under section 1401(a) of the Internal Revenue Code of 1986;
- `(3) who is actively employed; and
- `(4) who is not--
 - `(A) a patient in a hospital or nursing facility, an intermediate care

facility for the mentally retarded, or an institution for mental diseases and receiving medical assistance under Medicaid; or

`(B) confined in a jail, prison, other penal institution or correctional facility, or by court order pursuant to conviction of a criminal offense or in connection with a verdict or finding described in section 202(x)(1)(A)(ii) of the Social Security Act (42 U.S.C. 402(x)(1)(A)(ii)).

`(d) Rule of Construction- Nothing in this title shall be construed as requiring an active enrollee to continue to satisfy subparagraph (B) or (C) of subsection (c)(1) in order to maintain enrollment in the CLASS program.

`(e) Payment-

`(1) PAYROLL DEDUCTION- An amount equal to the monthly premium for the enrollment in the CLASS program of an individual shall be deducted from the wages or self-employment income of such individual in accordance with such procedures as the Secretary, in coordination with the Secretary of the Treasury, shall establish for employers who elect to deduct and withhold such premiums on behalf of enrolled employees.

`(2) ALTERNATIVE PAYMENT MECHANISM- The Secretary, in coordination with the Secretary of the Treasury, shall establish alternative procedures for the payment of monthly premiums by an individual enrolled in the CLASS program--

`(A) who does not have an employer who elects to deduct and withhold premiums in accordance with subparagraph (A); or

`(B) who does not earn wages or derive self-employment income.

`(f) Transfer of Premiums Collected-

`(1) IN GENERAL- During each calendar year the Secretary of the Treasury shall deposit into the CLASS Independence Fund a total amount equal, in the aggregate, to 100 percent of the premiums collected during that year.

`(2) TRANSFERS BASED ON ESTIMATES- The amount deposited pursuant to paragraph (1) shall be transferred in at least monthly payments to the CLASS Independence Fund on the basis of estimates by the Secretary and certified to the Secretary of the Treasury of the amounts collected in accordance with subparagraphs (A) and (B) of paragraph (5). Proper adjustments shall be made in amounts subsequently transferred to the Fund to the extent prior estimates were in excess of, or were less than, actual amounts collected.

`(g) Other Enrollment and Disenrollment Opportunities- The Secretary, in coordination with the Secretary of the Treasury, shall establish procedures under which--

`(1) an individual who, in the year of the individual's initial eligibility to enroll in the CLASS program, has elected to waive enrollment in the program, is eligible to elect to enroll in the program, in such form and manner as the Secretaries shall establish, only during an open enrollment period established by the Secretaries that is specific to the individual and that may not occur more frequently than biennially after the date on which the individual first elected to waive enrollment in the program; and

`(2) an individual shall only be permitted to disenroll from the program (other than for nonpayment of premiums) during an annual disenrollment period established by the Secretaries and in such form and manner as the Secretaries shall establish.

`SEC. 3205. BENEFITS.

`(a) Determination of Eligibility-

`(1) APPLICATION FOR RECEIPT OF BENEFITS- The Secretary shall establish procedures under which an active enrollee shall apply for receipt of benefits under the CLASS Independence Benefit Plan.

`(2) ELIGIBILITY ASSESSMENTS-

`(A) IN GENERAL- Not later than January 1, 2012, the Secretary shall--

`(i) establish an Eligibility Assessment System (other than a service with which the Commissioner of Social Security has entered into an agreement, with respect to any State, to make disability determinations for purposes of title II or XVI of the Social Security Act) to provide for eligibility assessments of active enrollees who apply for receipt of benefits;

`(ii) enter into an agreement with the Protection and Advocacy System for each State to provide advocacy services in accordance with subsection (d); and

`(iii) enter into an agreement with public and private entities to provide advice and assistance counseling in accordance with subsection (e).

`(B) REGULATIONS- The Secretary shall promulgate regulations to develop an expedited nationally equitable eligibility determination process, as certified by a licensed health care practitioner, an appeals process, and a redetermination process, as certified by a licensed health care practitioner, including whether an active enrollee is eligible for a cash benefit under the program and if so, the amount of the cash benefit (in accordance the sliding scale established under the plan).

`(C) PRESUMPTIVE ELIGIBILITY FOR CERTAIN INSTITUTIONALIZED ENROLLEES PLANNING TO DISCHARGE- An active enrollee shall be deemed presumptively eligible if the enrollee--

`(i) has applied for, and attests is eligible for, the maximum cash benefit available under the sliding scale established under the CLASS Independence Benefit Plan;

`(ii) is a patient in a hospital (but only if the hospitalization is for long-term care), nursing facility, intermediate care facility for the mentally retarded, or an institution for mental diseases; and

`(iii) is in the process of, or about to begin the process of, planning to discharge from the hospital, facility, or institution, or within 60 days from the date of discharge from the hospital, facility, or institution.

`(D) APPEALS- The Secretary shall establish procedures under which an applicant for benefits under the CLASS Independence Benefit Plan shall be guaranteed the right to appeal an adverse determination.

`(b) Benefits- An eligible beneficiary shall receive the following benefits under the CLASS Independence Benefit Plan:

`(1) CASH BENEFIT- A cash benefit established by the Secretary in accordance with the requirements of section 3203(a)(1)(D) that--

`(A) the first year in which beneficiaries receive the benefits under the plan, is not less than the average dollar amount specified in clause (i) of such section; and

`(B) for any subsequent year, is not less than the average per day dollar limit applicable under this subparagraph for the preceding year, increased by the percentage increase in the consumer price index for all urban consumers (U.S. city average) over the previous year.

`(2) ADVOCACY SERVICES- Advocacy services in accordance with subsection (d).

`(3) ADVICE AND ASSISTANCE COUNSELING- Advice and assistance counseling in accordance with subsection (e).

`(4) ADMINISTRATIVE EXPENSES- Advocacy services and advice and assistance counseling services under paragraphs (2) and (3) of this subsection shall be included as administrative expenses under section 3203(b)(3).

`(c) Payment of Benefits-

`(1) LIFE INDEPENDENCE ACCOUNT-

`(A) IN GENERAL- The Secretary shall establish procedures for administering the provision of benefits to eligible beneficiaries under the CLASS Independence Benefit Plan, including the payment of the cash benefit for the beneficiary into a Life Independence Account established by the Secretary on behalf of each eligible beneficiary.

`(B) USE OF CASH BENEFITS- Cash benefits paid into a Life Independence Account of an eligible beneficiary shall be used to purchase nonmedical services and supports that the beneficiary needs to maintain his or her independence at home or in another residential setting of their choice in the community, including (but not limited to) home modifications, assistive technology, accessible transportation, homemaker services, respite care, personal assistance services, home care aides, and nursing support. Nothing in the preceding sentence shall prevent an eligible beneficiary from using cash benefits paid into a Life Independence Account for obtaining assistance with decision making concerning medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advance directives or other written instructions recognized under State law, such as a living will or durable power of attorney for health care, in the case that an injury or illness causes the individual to be unable to make health care decisions.

`(C) ELECTRONIC MANAGEMENT OF FUNDS- The Secretary shall establish procedures for--

`(i) crediting an account established on behalf of a beneficiary with the beneficiary's cash daily benefit;

`(ii) allowing the beneficiary to access such account through debit cards; and

`(iii) accounting for withdrawals by the beneficiary from such account.

`(D) PRIMARY PAYOR RULES FOR BENEFICIARIES WHO ARE ENROLLED IN MEDICAID-

In the case of an eligible beneficiary who is enrolled in Medicaid, the following payment rules shall apply:

`(i) INSTITUTIONALIZED BENEFICIARY- If the beneficiary is a patient in a hospital, nursing facility, intermediate care facility for the mentally retarded, or an institution for mental diseases, the beneficiary shall retain an amount equal to 5 percent of the beneficiary's daily or weekly cash benefit (as applicable) (which shall be in addition to the amount of the beneficiary's personal needs allowance provided under Medicaid),

and the remainder of such benefit shall be applied toward the facility's cost of providing the beneficiary's care, and Medicaid shall provide secondary coverage for such care.

`(ii) BENEFICIARIES RECEIVING HOME AND COMMUNITY-BASED SERVICES-

`(I) 50 PERCENT OF BENEFIT RETAINED BY BENEFICIARY- Subject to subclause (II), if a beneficiary is receiving medical assistance under Medicaid for home and community based services, the beneficiary shall retain an amount equal to 50 percent of the beneficiary's daily or weekly cash benefit (as applicable), and the remainder of the daily or weekly cash benefit shall be applied toward the cost to the State of providing such assistance (and shall not be used to claim Federal matching funds under Medicaid), and Medicaid shall provide secondary coverage for the remainder of any costs incurred in providing such assistance.

`(II) REQUIREMENT FOR STATE OFFSET- A State shall be paid the remainder of a beneficiary's daily or weekly cash benefit under subclause (I) only if the State home and community-based waiver under section 1115 of the Social Security Act (42 U.S.C. 1315) or subsection (c) or (d) of section 1915 of such Act (42 U.S.C. 1396n), or the State plan amendment under subsection (i) of such section does not include a waiver of the requirements of section 1902(a)(1) of the Social Security Act (relating to statewideness) or of section 1902(a)(10)(B) of such Act (relating to comparability) and the State offers at a minimum case management services, personal care services, habilitation services, and respite care under such a waiver or State plan amendment.

`(III) DEFINITION OF HOME AND COMMUNITY-BASED SERVICES- In this clause, the term 'home and community-based services' means any services which may be offered under a home and community-based waiver authorized for a State under section 1115 of the Social Security Act (42 U.S.C. 1315) or subsection (c) or (d) of section 1915 of such Act (42 U.S.C. 1396n) or under a State plan amendment under subsection (i) of such section.

`(iii) BENEFICIARIES ENROLLED IN PROGRAMS OF ALL-INCLUSIVE CARE FOR THE ELDERLY (PACE)-

`(I) IN GENERAL- Subject to subclause (II), if a beneficiary is receiving medical assistance under Medicaid for PACE program services under section 1934 of the Social Security Act (42 U.S.C. 1396u-4), the beneficiary shall retain an amount equal to 50 percent of the beneficiary's daily or weekly cash benefit (as applicable), and the remainder of the daily or weekly cash benefit shall be applied toward the cost to the State of providing such assistance (and shall not be used to claim Federal matching funds under Medicaid), and Medicaid shall provide secondary coverage for the remainder of any costs incurred in providing such assistance.

`(II) INSTITUTIONALIZED RECIPIENTS OF PACE PROGRAM SERVICES- If a beneficiary receiving assistance under Medicaid for PACE program services is a patient in a hospital, nursing facility, intermediate

care facility for the mentally retarded, or an institution for mental diseases, the beneficiary shall be treated as in institutionalized beneficiary under clause (i).

`(2) AUTHORIZED REPRESENTATIVES-

`(A) IN GENERAL- The Secretary shall establish procedures to allow access to a beneficiary's cash benefits by an authorized representative of the eligible beneficiary on whose behalf such benefits are paid.

`(B) QUALITY ASSURANCE AND PROTECTION AGAINST FRAUD AND ABUSE- The procedures established under subparagraph (A) shall ensure that authorized representatives of eligible beneficiaries comply with standards of conduct established by the Secretary, including standards requiring that such representatives provide quality services on behalf of such beneficiaries, do not have conflicts of interest, and do not misuse benefits paid on behalf of such beneficiaries or otherwise engage in fraud or abuse.

`(3) COMMENCEMENT OF BENEFITS- Benefits shall be paid to, or on behalf of, an eligible beneficiary beginning with the first month in which an application for such benefits is approved.

`(4) ROLLOVER OPTION FOR LUMP-SUM PAYMENT- An eligible beneficiary may elect to--

`(A) defer payment of their daily or weekly benefit and to rollover any such deferred benefits from month-to-month, but not from year-to-year; and

`(B) receive a lump-sum payment of such deferred benefits in an amount that may not exceed the lesser of--

`(i) the total amount of the accrued deferred benefits; or

`(ii) the applicable annual benefit.

`(5) PERIOD FOR DETERMINATION OF ANNUAL BENEFITS-

`(A) IN GENERAL- The applicable period for determining with respect to an eligible beneficiary the applicable annual benefit and the amount of any accrued deferred benefits is the 12-month period that commences with the first month in which the beneficiary began to receive such benefits, and each 12-month period thereafter.

`(B) INCLUSION OF INCREASED BENEFITS- The Secretary shall establish procedures under which cash benefits paid to an eligible beneficiary that increase or decrease as a result of a change in the functional status of the beneficiary before the end of a 12-month benefit period shall be included in the determination of the applicable annual benefit paid to the eligible beneficiary.

`(C) RECOUPMENT OF UNPAID, ACCRUED BENEFITS-

`(i) IN GENERAL- The Secretary, in coordination with the Secretary of the Treasury, shall recoup any accrued benefits in the event of--

`(I) the death of a beneficiary; or

`(II) the failure of a beneficiary to elect under paragraph (4)(B) to receive such benefits as a lump-sum payment before the end of the 12-month period in which such benefits accrued.

`(ii) PAYMENT INTO CLASS INDEPENDENCE FUND- Any benefits recouped in accordance with clause (i) shall be paid into the CLASS Independence Fund and used in accordance with section 3206.

`(6) REQUIREMENT TO RECERTIFY ELIGIBILITY FOR RECEIPT OF BENEFITS- An

eligible beneficiary shall periodically, as determined by the Secretary--

`(A) recertify by submission of medical evidence the beneficiary's continued eligibility for receipt of benefits; and

`(B) submit records of expenditures attributable to the aggregate cash benefit received by the beneficiary during the preceding year.

`(7) SUPPLEMENT, NOT SUPPLANT OTHER HEALTH CARE BENEFITS- Subject to the Medicaid payment rules under paragraph (1)(D), benefits received by an eligible beneficiary shall supplement, but not supplant, other health care benefits for which the beneficiary is eligible under Medicaid or any other Federally funded program that provides health care benefits or assistance.

`(d) Advocacy Services- An agreement entered into under subsection (a)(2)(A)(ii) shall require the Protection and Advocacy System for the State to--

`(1) assign, as needed, an advocacy counselor to each eligible beneficiary that is covered by such agreement and who shall provide an eligible beneficiary with--

`(A) information regarding how to access the appeals process established for the program;

`(B) assistance with respect to the annual recertification and notification required under subsection (c)(6); and

`(C) such other assistance with obtaining services as the Secretary, by regulation, shall require; and

`(2) ensure that the System and such counselors comply with the requirements of subsection (h).

`(e) Advice and Assistance Counseling- An agreement entered into under subsection (a)(2)(A)(iii) shall require the entity to assign, as requested by an eligible beneficiary that is covered by such agreement, an advice and assistance counselor who shall provide an eligible beneficiary with information regarding--

`(1) accessing and coordinating long-term services and supports in the most integrated setting;

`(2) possible eligibility for other benefits and services;

`(3) development of a service and support plan;

`(4) information about programs established under the Assistive Technology Act of 1998 and the services offered under such programs;

`(5) available assistance with decision making concerning medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advance directives or other written instructions recognized under State law, such as a living will or durable power of attorney for health care, in the case that an injury or illness causes the individual to be unable to make health care decisions; and

`(6) such other services as the Secretary, by regulation, may require.

`(f) No Effect on Eligibility for Other Benefits- Benefits paid to an eligible beneficiary under the CLASS program shall be disregarded for purposes of determining or continuing the beneficiary's eligibility for receipt of benefits under any other Federal, State, or locally funded assistance program, including benefits paid under titles II, XVI, XVIII, XIX, or XXI of the Social Security Act (42 U.S.C. 401 et seq., 1381 et seq., 1395 et seq., 1396 et seq.,

1397aa et seq.), under the laws administered by the Secretary of Veterans Affairs, under low-income housing assistance programs, or under the supplemental nutrition assistance program established under the Food and Nutrition Act of 2008 (7 U.S.C. 2011 et seq.).

`(g) Rule of Construction- Nothing in this title shall be construed as prohibiting benefits paid under the CLASS Independence Benefit Plan from being used to compensate a family caregiver for providing community living assistance services and supports to an eligible beneficiary.

`(h) Protection Against Conflict of Interests- The Secretary shall establish procedures to ensure that the Eligibility Assessment System, the Protection and Advocacy System for a State, advocacy counselors for eligible beneficiaries, and any other entities that provide services to active enrollees and eligible beneficiaries under the CLASS program comply with the following:

`(1) If the entity provides counseling or planning services, such services are provided in a manner that fosters the best interests of the active enrollee or beneficiary.

`(2) The entity has established operating procedures that are designed to avoid or minimize conflicts of interest between the entity and an active enrollee or beneficiary.

`(3) The entity provides information about all services and options available to the active enrollee or beneficiary, to the best of its knowledge, including services available through other entities or providers.

`(4) The entity assists the active enrollee or beneficiary to access desired services, regardless of the provider.

`(5) The entity reports the number of active enrollees and beneficiaries provided with assistance by age, disability, and whether such enrollees and beneficiaries received services from the entity or another entity.

`(6) If the entity provides counseling or planning services, the entity ensures that an active enrollee or beneficiary is informed of any financial interest that the entity has in a service provider.

`(7) The entity provides an active enrollee or beneficiary with a list of available service providers that can meet the needs of the active enrollee or beneficiary.

`SEC. 3206. CLASS INDEPENDENCE FUND.

`(a) Establishment of CLASS Independence Fund- There is established in the Treasury of the United States a trust fund to be known as the 'CLASS Independence Fund'. The Secretary of the Treasury shall serve as Managing Trustee of such Fund. The Fund shall consist of all amounts derived from payments into the Fund under sections 3204(f) and 3205(c)(5)(C)(ii), and remaining after investment of such amounts under subsection (b), including additional amounts derived as income from such investments. The amounts held in the Fund are appropriated and shall remain available without fiscal year limitation--

`(1) to be held for investment on behalf of individuals enrolled in the CLASS program;

`(2) to pay the administrative expenses related to the Fund and to investment under subsection (b); and

`(3) to pay cash benefits to eligible beneficiaries under the CLASS Independence Benefit Plan.

`(b) Investment of Fund Balance- The Secretary of the Treasury shall invest and manage the CLASS Independence Fund in the same manner, and to the same extent, as the Federal Supplementary Medical Insurance Trust Fund may be invested and managed under subsections (c), (d), and (e) of section 1841(d) of the Social Security Act (42 U.S.C. 1395t).

`(c) Board of Trustees-

`(1) IN GENERAL- With respect to the CLASS Independence Fund, there is hereby created a body to be known as the Board of Trustees of the CLASS Independence Fund (hereinafter in this section referred to as the `Board of Trustees') composed of the Secretary of the Treasury, the Secretary of Labor, and the Secretary of Health and Human Services, all ex officio, and of two members of the public (both of whom may not be from the same political party), who shall be nominated by the President for a term of 4 years and subject to confirmation by the Senate. A member of the Board of Trustees serving as a member of the public and nominated and confirmed to fill a vacancy occurring during a term shall be nominated and confirmed only for the remainder of such term. An individual nominated and confirmed as a member of the public may serve in such position after the expiration of such member's term until the earlier of the time at which the member's successor takes office or the time at which a report of the Board is first issued under paragraph (2) after the expiration of the member's term. The Secretary of the Treasury shall be the Managing Trustee of the Board of Trustees. The Board of Trustees shall meet not less frequently than once each calendar year. A person serving on the Board of Trustees shall not be considered to be a fiduciary and shall not be personally liable for actions taken in such capacity with respect to the Trust Fund.

`(2) DUTIES-

`(A) IN GENERAL- It shall be the duty of the Board of Trustees to do the following:

`(i) Hold the CLASS Independence Fund.

`(ii) Report to the Congress not later than the first day of April of each year on the operation and status of the CLASS Independence Fund during the preceding fiscal year and on its expected operation and status during the current fiscal year and the next 2 fiscal years.

`(iii) Report immediately to the Congress whenever the Board is of the opinion that the amount of the CLASS Independence Fund is not actuarially sound in regards to the projection under section 3203(b)(1)(B)(i).

`(iv) Review the general policies followed in managing the CLASS Independence Fund, and recommend changes in such policies, including necessary changes in the provisions of law which govern the way in which the CLASS Independence Fund is to be managed.

`(B) REPORT- The report provided for in subparagraph (A)(ii) shall--

`(i) include--

`(I) a statement of the assets of, and the disbursements made from, the CLASS Independence Fund during the preceding fiscal year;

`(II) an estimate of the expected income to, and disbursements to be made from, the CLASS Independence Fund during the current fiscal year and each of the next 2 fiscal years;

`(III) a statement of the actuarial status of the CLASS Independence Fund for the current fiscal year, each of the next 2 fiscal years, and as projected over the 75-year period beginning with the current fiscal year; and

`(IV) an actuarial opinion by the Chief Actuary of the Centers for Medicare & Medicaid Services certifying that the techniques and methodologies used are generally accepted within the actuarial profession and that the assumptions and cost estimates used are reasonable; and

`(ii) be printed as a House document of the session of the Congress to which the report is made.

`(C) RECOMMENDATIONS- If the Board of Trustees determines that enrollment trends and expected future benefit claims on the CLASS Independence Fund are not actuarially sound in regards to the projection under section 3203(b)(1)(B)(i) and are unlikely to be resolved with reasonable premium increases or through other means, the Board of Trustees shall include in the report provided for in subparagraph (A)(ii) recommendations for such legislative action as the Board of Trustees determine to be appropriate, including whether to adjust monthly premiums or impose a temporary moratorium on new enrollments.

`SEC. 3207. CLASS INDEPENDENCE ADVISORY COUNCIL.

`(a) Establishment- There is hereby created an Advisory Committee to be known as the `CLASS Independence Advisory Council'.

`(b) Membership-

`(1) IN GENERAL- The CLASS Independence Advisory Council shall be composed of not more than 15 individuals, not otherwise in the employ of the United States--

`(A) who shall be appointed by the President without regard to the civil service laws and regulations; and

`(B) a majority of whom shall be representatives of individuals who participate or are likely to participate in the CLASS program, and shall include representatives of older and younger workers, individuals with disabilities, family caregivers of individuals who require services and supports to maintain their independence at home or in another residential setting of their choice in the community, individuals with expertise in long-term care or disability insurance, actuarial science, economics, and other relevant disciplines, as determined by the Secretary.

`(2) TERMS-

`(A) IN GENERAL- The members of the CLASS Independence Advisory Council shall serve overlapping terms of 3 years (unless appointed to fill a vacancy occurring prior to the expiration of a term, in which case the individual shall serve for the remainder of the term).

`(B) LIMITATION- A member shall not be eligible to serve for more than 2 consecutive terms.

`(3) CHAIR- The President shall, from time to time, appoint one of the

members of the CLASS Independence Advisory Council to serve as the Chair.

`(c) Duties- The CLASS Independence Advisory Council shall advise the Secretary on matters of general policy in the administration of the CLASS program established under this title and in the formulation of regulations under this title including with respect to--

`(1) the development of the CLASS Independence Benefit Plan under section 3203;

`(2) the determination of monthly premiums under such plan; and

`(3) the financial solvency of the program.

`(d) Application of FACA- The Federal Advisory Committee Act (5 U.S.C. App.), other than section 14 of that Act, shall apply to the CLASS Independence Advisory Council.

`(e) Authorization of Appropriations-

`(1) IN GENERAL- There are authorized to be appropriated to the CLASS Independence Advisory Council to carry out its duties under this section, such sums as may be necessary for fiscal year 2011 and for each fiscal year thereafter.

`(2) AVAILABILITY- Any sums appropriated under the authorization contained in this section shall remain available, without fiscal year limitation, until expended.

SEC. 3208. SOLVENCY AND FISCAL INDEPENDENCE; REGULATIONS; ANNUAL REPORT.

`(a) Solvency- The Secretary shall regularly consult with the Board of Trustees of the CLASS Independence Fund and the CLASS Independence Advisory Council, for purposes of ensuring that enrollees premiums are adequate to ensure the financial solvency of the CLASS program, both with respect to fiscal years occurring in the near-term and fiscal years occurring over 20- and 75-year periods, taking into account the projections required for such periods under subsections (a)(1)(A)(i) and (b)(1)(B)(i) of section 3202.

`(b) No Taxpayer Funds Used To Pay Benefits- No taxpayer funds shall be used for payment of benefits under a CLASS Independent Benefit Plan. For purposes of this subsection, the term 'taxpayer funds' means any Federal funds from a source other than premiums deposited by CLASS program participants in the CLASS Independence Fund and any associated interest earnings.

`(c) Regulations- The Secretary shall promulgate such regulations as are necessary to carry out the CLASS program in accordance with this title. Such regulations shall include provisions to prevent fraud and abuse under the program.

`(d) Annual Report- Beginning January 1, 2014, the Secretary shall submit an annual report to Congress on the CLASS program. Each report shall include the following:

`(1) The total number of enrollees in the program.

`(2) The total number of eligible beneficiaries during the fiscal year.

`(3) The total amount of cash benefits provided during the fiscal year.

`(4) A description of instances of fraud or abuse identified during the fiscal year.

`(5) Recommendations for such administrative or legislative action as the Secretary determines is necessary to improve the program, ensure the solvency of the program, or to prevent the occurrence of fraud or abuse.

`SEC. 3209. INSPECTOR GENERAL'S REPORT.

`The Inspector General of the Department of Health and Human Services shall submit an annual report to the Secretary and Congress relating to the overall progress of the CLASS program and of the existence of waste, fraud, and abuse in the CLASS program. Each such report shall include findings in the following areas:

- `(1) The eligibility determination process.
- `(2) The provision of cash benefits.
- `(3) Quality assurance and protection against waste, fraud, and abuse.
- `(4) Recouping of unpaid and accrued benefits.

`SEC. 3210. TAX TREATMENT OF PROGRAM.

`The CLASS program shall be treated for purposes of the Internal Revenue Code of 1986 in the same manner as a qualified long-term care insurance contract for qualified long-term care services.'

(2) CONFORMING AMENDMENTS TO MEDICAID- Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)), as amended by section 6505, is amended by inserting after paragraph (80) the following:

`(81) provide that the State will comply with such regulations regarding the application of primary and secondary payor rules with respect to individuals who are eligible for medical assistance under this title and are eligible beneficiaries under the CLASS program established under title XXXII of the Public Health Service Act as the Secretary shall establish; and'

(b) Assurance of Adequate Infrastructure for the Provision of Personal Care Attendant Workers- Section 1902(a) of the Social Security Act (42 U.S.C. 1396a(a)), as amended by subsection (a)(2), is amended by inserting after paragraph (81) the following:

`(82) provide that, not later than 2 years after the date of enactment of the Community Living Assistance Services and Supports Act, each State shall--

`(A) assess the extent to which entities such as providers of home care, home health services, home and community service providers, public authorities created to provide personal care services to individuals eligible for medical assistance under the State plan, and nonprofit organizations, are serving or have the capacity to serve as fiscal agents for, employers of, and providers of employment-related benefits for, personal care attendant workers who provide personal care services to individuals receiving benefits under the CLASS program established under title XXXII of the Public Health Service Act, including in rural and underserved areas;

`(B) designate or create such entities to serve as fiscal agents for, employers of, and providers of employment-related benefits for, such workers to ensure an adequate supply of the workers for individuals receiving benefits under the CLASS program, including in rural and underserved areas; and

`(C) ensure that the designation or creation of such entities will not negatively alter or impede existing programs, models, methods, or administration of service delivery that provide for consumer controlled or self-directed home and community services and further ensure that such

entities will not impede the ability of individuals to direct and control their home and community services, including the ability to select, manage, dismiss, co-employ, or employ such workers or inhibit such individuals from relying on family members for the provision of personal care services.'.

(c) Personal Care Attendants Workforce Advisory Panel-

(1) ESTABLISHMENT- Not later than 90 days after the date of enactment of this Act, the Secretary of Health and Human Services shall establish a Personal Care Attendants Workforce Advisory Panel for the purpose of examining and advising the Secretary and Congress on workforce issues related to personal care attendant workers, including with respect to the adequacy of the number of such workers, the salaries, wages, and benefits of such workers, and access to the services provided by such workers.

(2) MEMBERSHIP- In appointing members to the Personal Care Attendants Workforce Advisory Panel, the Secretary shall ensure that such members include the following:

- (A) Individuals with disabilities of all ages.
- (B) Senior individuals.
- (C) Representatives of individuals with disabilities.
- (D) Representatives of senior individuals.
- (E) Representatives of workforce and labor organizations.
- (F) Representatives of home and community-based service providers.
- (G) Representatives of assisted living providers.

(d) Inclusion of Information on Supplemental Coverage in the National Clearinghouse for Long-term Care Information; Extension of Funding- Section 6021(d) of the Deficit Reduction Act of 2005 (42 U.S.C. 1396p note) is amended--

(1) in paragraph (2)(A)--

- (A) in clause (ii), by striking `and' at the end;
- (B) in clause (iii), by striking the period at the end and inserting `; and'; and
- (C) by adding at the end the following:

`(iv) include information regarding the CLASS program established under title XXXII of the Public Health Service Act and coverage available for purchase through a Exchange established under section 1311 of the Patient Protection and Affordable Care Act that is supplemental coverage to the benefits provided under a CLASS Independence Benefit Plan under that program, and information regarding how benefits provided under a CLASS Independence Benefit Plan differ from disability insurance benefits.'; and

(2) in paragraph (3), by striking `2010' and inserting `2015'.

(e) Effective Date- The amendments made by subsections (a), (b), and (d) take effect on January 1, 2011.

(f) Rule of Construction- Nothing in this title or the amendments made by this title are intended to replace or displace public or private disability insurance benefits, including such benefits that are for income replacement.

TITLE IX--REVENUE PROVISIONS

Subtitle A--Revenue Offset Provisions

SEC. 9001. EXCISE TAX ON HIGH COST EMPLOYER-SPONSORED HEALTH COVERAGE.

(a) In General- Chapter 43 of the Internal Revenue Code of 1986, as amended by section 1513, is amended by adding at the end the following:

SEC. 4980I. EXCISE TAX ON HIGH COST EMPLOYER-SPONSORED HEALTH COVERAGE.

(a) Imposition of Tax- If--

- (1) an employee is covered under any applicable employer-sponsored coverage of an employer at any time during a taxable period, and
 - (2) there is any excess benefit with respect to the coverage,
- there is hereby imposed a tax equal to 40 percent of the excess benefit.

(b) Excess Benefit- For purposes of this section--

(1) IN GENERAL- The term 'excess benefit' means, with respect to any applicable employer-sponsored coverage made available by an employer to an employee during any taxable period, the sum of the excess amounts determined under paragraph (2) for months during the taxable period.

(2) MONTHLY EXCESS AMOUNT- The excess amount determined under this paragraph for any month is the excess (if any) of--

- (A) the aggregate cost of the applicable employer-sponsored coverage of the employee for the month, over
- (B) an amount equal to 1/12 of the annual limitation under paragraph (3) for the calendar year in which the month occurs.

(3) ANNUAL LIMITATION- For purposes of this subsection--

(A) IN GENERAL- The annual limitation under this paragraph for any calendar year is the dollar limit determined under subparagraph (C) for the calendar year.

(B) APPLICABLE ANNUAL LIMITATION- The annual limitation which applies for any month shall be determined on the basis of the type of coverage (as determined under subsection (f)(1)) provided to the employee by the employer as of the beginning of the month.

(C) APPLICABLE DOLLAR LIMIT- Except as provided in subparagraph (D)--

(i) 2013- In the case of 2013, the dollar limit under this subparagraph is--

- (I) in the case of an employee with self-only coverage, \$8,500, and
- (II) in the case of an employee with coverage other than self-only coverage, \$23,000.

(ii) EXCEPTION FOR CERTAIN INDIVIDUALS- In the case of an individual who is a qualified retiree or who participates in a plan sponsored by an employer the majority of whose employees are engaged in a high-risk profession or employed to repair or install electrical or telecommunications lines--

- (I) the dollar amount in clause (i)(I) (determined after the application of subparagraph (D)) shall be increased by \$1,350, and
- (II) the dollar amount in clause (i)(II) (determined after the application of subparagraph (D)) shall be increased by \$3,000.

(iii) SUBSEQUENT YEARS- In the case of any calendar year after 2013, each of the dollar amounts under clauses (i) and (ii) shall be increased to the amount equal to such amount as in effect for the calendar year preceding such year, increased by an amount equal to the product of--

- (I) such amount as so in effect, multiplied by

`(II) the cost-of-living adjustment determined under section 1(f)(3) for such year (determined by substituting the calendar year that is 2 years before such year for `1992' in subparagraph (B) thereof), increased by 1 percentage point.

If any amount determined under this clause is not a multiple of \$50, such amount shall be rounded to the nearest multiple of \$50.

`(D) TRANSITION RULE FOR STATES WITH HIGHEST COVERAGE COSTS-

`(i) IN GENERAL- If an employee is a resident of a high cost State on the first day of any month beginning in 2013, 2014, or 2015, the annual limitation under this paragraph for such month with respect to such employee shall be an amount equal to the applicable percentage of the annual limitation (determined without regard to this subparagraph or subparagraph (C)(ii)).

`(ii) APPLICABLE PERCENTAGE- The applicable percentage is 120 percent for 2013, 110 percent for 2014, and 105 percent for 2015.

`(iii) HIGH COST STATE- The term `high cost State' means each of the 17 States which the Secretary of Health and Human Services, in consultation with the Secretary, estimates had the highest average cost during 2012 for employer-sponsored coverage under health plans. The Secretary's estimate shall be made on the basis of aggregate premiums paid in the State for such health plans, determined using the most recent data available as of August 31, 2012.

`(c) Liability To Pay Tax-

`(1) IN GENERAL- Each coverage provider shall pay the tax imposed by subsection (a) on its applicable share of the excess benefit with respect to an employee for any taxable period.

`(2) COVERAGE PROVIDER- For purposes of this subsection, the term `coverage provider' means each of the following:

`(A) HEALTH INSURANCE COVERAGE- If the applicable employer-sponsored coverage consists of coverage under a group health plan which provides health insurance coverage, the health insurance issuer.

`(B) HSA AND MSA CONTRIBUTIONS- If the applicable employer-sponsored coverage consists of coverage under an arrangement under which the employer makes contributions described in subsection (b) or (d) of section 106, the employer.

`(C) OTHER COVERAGE- In the case of any other applicable employer-sponsored coverage, the person that administers the plan benefits.

`(3) APPLICABLE SHARE- For purposes of this subsection, a coverage provider's applicable share of an excess benefit for any taxable period is the amount which bears the same ratio to the amount of such excess benefit as--

`(A) the cost of the applicable employer-sponsored coverage provided by the provider to the employee during such period, bears to

`(B) the aggregate cost of all applicable employer-sponsored coverage provided to the employee by all coverage providers during such period.

`(4) RESPONSIBILITY TO CALCULATE TAX AND APPLICABLE SHARES-

`(A) IN GENERAL- Each employer shall--

`(i) calculate for each taxable period the amount of the excess benefit subject to the tax imposed by subsection (a) and the applicable share of such excess benefit for each coverage provider, and

`(ii) notify, at such time and in such manner as the Secretary may prescribe, the Secretary and each coverage provider of the amount so determined for the provider.

`(B) SPECIAL RULE FOR MULTIEMPLOYER PLANS- In the case of applicable employer-sponsored coverage made available to employees through a multiemployer plan (as defined in section 414(f)), the plan sponsor shall make the calculations, and provide the notice, required under subparagraph (A).

`(d) Applicable Employer-Sponsored Coverage; Cost- For purposes of this section--

`(1) APPLICABLE EMPLOYER-SPONSORED COVERAGE-

`(A) IN GENERAL- The term `applicable employer-sponsored coverage' means, with respect to any employee, coverage under any group health plan made available to the employee by an employer which is excludable from the employee's gross income under section 106, or would be so excludable if it were employer-provided coverage (within the meaning of such section 106).

`(B) EXCEPTIONS- The term `applicable employer-sponsored coverage' shall not include--

`(i) any coverage (whether through insurance or otherwise) described in section 9832(c)(1)(A) or for long-term care, or

`(ii) any coverage described in section 9832(c)(3) the payment for which is not excludable from gross income and for which a deduction under section 162(l) is not allowable.

`(C) COVERAGE INCLUDES EMPLOYEE PAID PORTION- Coverage shall be treated as applicable employer-sponsored coverage without regard to whether the employer or employee pays for the coverage.

`(D) SELF-EMPLOYED INDIVIDUAL- In the case of an individual who is an employee within the meaning of section 401(c)(1), coverage under any group health plan providing health insurance coverage shall be treated as applicable employer-sponsored coverage if a deduction is allowable under section 162(l) with respect to all or any portion of the cost of the coverage.

`(E) GOVERNMENTAL PLANS INCLUDED- Applicable employer-sponsored coverage shall include coverage under any group health plan established and maintained primarily for its civilian employees by the Government of the United States, by the government of any State or political subdivision thereof, or by any agency or instrumentality of any such government.

`(2) DETERMINATION OF COST-

`(A) IN GENERAL- The cost of applicable employer-sponsored coverage shall be determined under rules similar to the rules of section 4980B(f)(4), except that in determining such cost, any portion of the cost of such coverage which is attributable to the tax imposed under this section shall not be taken into account and the amount of such cost shall be calculated separately for self-only coverage and other coverage. In the case of applicable employer-sponsored coverage which provides coverage to retired

employees, the plan may elect to treat a retired employee who has not attained the age of 65 and a retired employee who has attained the age of 65 as similarly situated beneficiaries.

`(B) HEALTH FSAS- In the case of applicable employer-sponsored coverage consisting of coverage under a flexible spending arrangement (as defined in section 106(c)(2)), the cost of the coverage shall be equal to the sum of--

`(i) the amount of employer contributions under any salary reduction election under the arrangement, plus

`(ii) the amount determined under subparagraph (A) with respect to any reimbursement under the arrangement in excess of the contributions described in clause (i).

`(C) ARCHER MSAS AND HSAS- In the case of applicable employer-sponsored coverage consisting of coverage under an arrangement under which the employer makes contributions described in subsection (b) or (d) of section 106, the cost of the coverage shall be equal to the amount of employer contributions under the arrangement.

`(D) ALLOCATION ON A MONTHLY BASIS- If cost is determined on other than a monthly basis, the cost shall be allocated to months in a taxable period on such basis as the Secretary may prescribe.

`(e) Penalty for Failure To Properly Calculate Excess Benefit-

`(1) IN GENERAL- If, for any taxable period, the tax imposed by subsection (a) exceeds the tax determined under such subsection with respect to the total excess benefit calculated by the employer or plan sponsor under subsection (c)(4)--

`(A) each coverage provider shall pay the tax on its applicable share (determined in the same manner as under subsection (c)(4)) of the excess, but no penalty shall be imposed on the provider with respect to such amount, and

`(B) the employer or plan sponsor shall, in addition to any tax imposed by subsection (a), pay a penalty in an amount equal to such excess, plus interest at the underpayment rate determined under section 6621 for the period beginning on the due date for the payment of tax imposed by subsection (a) to which the excess relates and ending on the date of payment of the penalty.

`(2) LIMITATIONS ON PENALTY-

`(A) PENALTY NOT TO APPLY WHERE FAILURE NOT DISCOVERED EXERCISING REASONABLE DILIGENCE- No penalty shall be imposed by paragraph (1)(B) on any failure to properly calculate the excess benefit during any period for which it is established to the satisfaction of the Secretary that the employer or plan sponsor neither knew, nor exercising reasonable diligence would have known, that such failure existed.

`(B) PENALTY NOT TO APPLY TO FAILURES CORRECTED WITHIN 30 DAYS- No penalty shall be imposed by paragraph (1)(B) on any such failure if--

`(i) such failure was due to reasonable cause and not to willful neglect, and

`(ii) such failure is corrected during the 30-day period beginning on the 1st date that the employer knew, or exercising reasonable diligence

would have known, that such failure existed.

`(C) WAIVER BY SECRETARY- In the case of any such failure which is due to reasonable cause and not to willful neglect, the Secretary may waive part or all of the penalty imposed by paragraph (1), to the extent that the payment of such penalty would be excessive or otherwise inequitable relative to the failure involved.

`(f) Other Definitions and Special Rules- For purposes of this section--

`(1) COVERAGE DETERMINATIONS-

`(A) IN GENERAL- Except as provided in subparagraph (B), an employee shall be treated as having self-only coverage with respect to any applicable employer-sponsored coverage of an employer.

`(B) MINIMUM ESSENTIAL COVERAGE- An employee shall be treated as having coverage other than self-only coverage only if the employee is enrolled in coverage other than self-only coverage in a group health plan which provides minimum essential coverage (as defined in section 5000A(f)) to the employee and at least one other beneficiary, and the benefits provided under such minimum essential coverage do not vary based on whether any individual covered under such coverage is the employee or another beneficiary.

`(2) QUALIFIED RETIREE- The term `qualified retiree' means any individual who--

`(A) is receiving coverage by reason of being a retiree,

`(B) has attained age 55, and

`(C) is not entitled to benefits or eligible for enrollment under the Medicare program under title XVIII of the Social Security Act.

`(3) EMPLOYEES ENGAGED IN HIGH-RISK PROFESSION- The term `employees engaged in a high-risk profession' means law enforcement officers (as such term is defined in section 1204 of the Omnibus Crime Control and Safe Streets Act of 1968), employees in fire protection activities (as such term is defined in section 3(y) of the Fair Labor Standards Act of 1938), individuals who provide out-of-hospital emergency medical care (including emergency medical technicians, paramedics, and first-responders), and individuals engaged in the construction, mining, agriculture (not including food processing), forestry, and fishing industries. Such term includes an employee who is retired from a high-risk profession described in the preceding sentence, if such employee satisfied the requirements of such sentence for a period of not less than 20 years during the employee's employment.

`(4) GROUP HEALTH PLAN- The term `group health plan' has the meaning given such term by section 5000(b)(1).

`(5) HEALTH INSURANCE COVERAGE; HEALTH INSURANCE ISSUER-

`(A) HEALTH INSURANCE COVERAGE- The term `health insurance coverage' has the meaning given such term by section 9832(b)(1) (applied without regard to subparagraph (B) thereof, except as provided by the Secretary in regulations).

`(B) HEALTH INSURANCE ISSUER- The term `health insurance issuer' has the meaning given such term by section 9832(b)(2).

`(6) PERSON THAT ADMINISTERS THE PLAN BENEFITS- The term `person that administers the plan benefits' shall include the plan sponsor if the plan

sponsor administers benefits under the plan.

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

`(8) TAXABLE PERIOD- The term `taxable period' means the calendar year or such shorter period as the Secretary may prescribe. The Secretary may have different taxable periods for employers of varying sizes.

`(9) AGGREGATION RULES- All employers treated as a single employer under subsection (b), (c), (m), or (o) of section 414 shall be treated as a single employer.

`(10) DENIAL OF DEDUCTION- For denial of a deduction for the tax imposed by this section, see section 275(a)(6).

`(g) Regulations- The Secretary shall prescribe such regulations as may be necessary to carry out this section.'

(b) Clerical Amendment- The table of sections for chapter 43 of such Code, as amended by section 1513, is amended by adding at the end the following new item:

`Sec. 4980I. Excise tax on high cost employer-sponsored health coverage.'

(c) Effective Date- The amendments made by this section shall apply to taxable years beginning after December 31, 2012.

SEC. 9002. INCLUSION OF COST OF EMPLOYER-SPONSORED HEALTH COVERAGE ON W-2.

(a) In General- Section 6051(a) of the Internal Revenue Code of 1986 (relating to receipts for employees) is amended by striking `and' at the end of paragraph (12), by striking the period at the end of paragraph (13) and inserting `, and', and by adding after paragraph (13) the following new paragraph:

`(14) the aggregate cost (determined under rules similar to the rules of section 4980B(f)(4)) of applicable employer-sponsored coverage (as defined in section 4980I(d)(1)), except that this paragraph shall not apply to--

`(A) coverage to which paragraphs (11) and (12) apply, or

`(B) the amount of any salary reduction contributions to a flexible spending arrangement (within the meaning of section 125).'

(b) Effective Date- The amendments made by this section shall apply to taxable years beginning after December 31, 2010.

SEC. 9003. DISTRIBUTIONS FOR MEDICINE QUALIFIED ONLY IF FOR PRESCRIBED DRUG OR INSULIN.

(a) HSAs- Subparagraph (A) of section 223(d)(2) of the Internal Revenue Code of 1986 is amended by adding at the end the following: `Such term shall include an amount paid for medicine or a drug only if such medicine or drug is a prescribed drug (determined without regard to whether such drug is available without a prescription) or is insulin.'

(b) Archer MSAs- Subparagraph (A) of section 220(d)(2) of the Internal Revenue Code of 1986 is amended by adding at the end the following: `Such term shall include an amount paid for medicine or a drug only if such medicine or drug is a prescribed drug (determined without regard to whether such drug is available without a prescription) or is insulin.'

(c) Health Flexible Spending Arrangements and Health Reimbursement Arrangements- Section 106 of the Internal Revenue Code of 1986 is amended by adding at the end the following new subsection:

`f) Reimbursements for Medicine Restricted to Prescribed Drugs and Insulin- For purposes of this section and section 105, reimbursement for expenses incurred for a medicine or a drug shall be treated as a reimbursement for medical expenses only if such medicine or drug is a prescribed drug (determined without regard to whether such drug is available without a prescription) or is insulin.'.

(d) Effective Dates-

(1) DISTRIBUTIONS FROM SAVINGS ACCOUNTS- The amendments made by subsections (a) and (b) shall apply to amounts paid with respect to taxable years beginning after December 31, 2010.

(2) REIMBURSEMENTS- The amendment made by subsection (c) shall apply to expenses incurred with respect to taxable years beginning after December 31, 2010.

SEC. 9004. INCREASE IN ADDITIONAL TAX ON DISTRIBUTIONS FROM HSAS AND ARCHER MSAS NOT USED FOR QUALIFIED MEDICAL EXPENSES.

(a) HSAs- Section 223(f)(4)(A) of the Internal Revenue Code of 1986 is amended by striking `10 percent' and inserting `20 percent'.

(b) Archer MSAs- Section 220(f)(4)(A) of the Internal Revenue Code of 1986 is amended by striking `15 percent' and inserting `20 percent'.

(c) Effective Date- The amendments made by this section shall apply to distributions made after December 31, 2010.

SEC. 9005. LIMITATION ON HEALTH FLEXIBLE SPENDING ARRANGEMENTS UNDER CAFETERIA PLANS.

(a) In General- Section 125 of the Internal Revenue Code of 1986 is amended--

(1) by redesignating subsections (i) and (j) as subsections (j) and (k), respectively, and

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

`i) Limitation on Health Flexible Spending Arrangements- For purposes of this section, if a benefit is provided under a cafeteria plan through employer contributions to a health flexible spending arrangement, such benefit shall not be treated as a qualified benefit unless the cafeteria plan provides that an employee may not elect for any taxable year to have salary reduction contributions in excess of \$2,500 made to such arrangement.'.

(b) Effective Date- The amendments made by this section shall apply to taxable years beginning after December 31, 2010.

SEC. 9006. EXPANSION OF INFORMATION REPORTING REQUIREMENTS.

(a) In General- Section 6041 of the Internal Revenue Code of 1986 is amended by adding at the end the following new subsections:

`h) Application to Corporations- Notwithstanding any regulation prescribed by the Secretary before the date of the enactment of this subsection, for purposes of this section the term `person' includes any corporation that is not an organization exempt from tax under section 501(a).

`i) Regulations- The Secretary may prescribe such regulations and other guidance as may be appropriate or necessary to carry out the purposes of this section, including rules to prevent duplicative reporting of transactions.'.

(b) Payments for Property and Other Gross Proceeds- Subsection (a) of section 6041 of the Internal Revenue Code of 1986 is amended--

(1) by inserting `amounts in consideration for property,' after `wages,'

- (2) by inserting 'gross proceeds,' after 'emoluments, or other', and
- (3) by inserting 'gross proceeds,' after 'setting forth the amount of such'.

(c) Effective Date- The amendments made by this section shall apply to payments made after December 31, 2011.

SEC. 9007. ADDITIONAL REQUIREMENTS FOR CHARITABLE HOSPITALS.

(a) Requirements To Qualify as Section 501(c)(3) Charitable Hospital Organization- Section 501 of the Internal Revenue Code of 1986 (relating to exemption from tax on corporations, certain trusts, etc.) is amended by redesignating subsection (r) as subsection (s) and by inserting after subsection (q) the following new subsection:

`(r) Additional Requirements for Certain Hospitals-

`(1) IN GENERAL- A hospital organization to which this subsection applies shall not be treated as described in subsection (c)(3) unless the organization--

`(A) meets the community health needs assessment requirements described in paragraph (3),

`(B) meets the financial assistance policy requirements described in paragraph (4),

`(C) meets the requirements on charges described in paragraph (5), and

`(D) meets the billing and collection requirement described in paragraph (6).

`(2) HOSPITAL ORGANIZATIONS TO WHICH SUBSECTION APPLIES-

`(A) IN GENERAL- This subsection shall apply to--

`(i) an organization which operates a facility which is required by a State to be licensed, registered, or similarly recognized as a hospital, and

`(ii) any other organization which the Secretary determines has the provision of hospital care as its principal function or purpose constituting the basis for its exemption under subsection (c)(3) (determined without regard to this subsection).

`(B) ORGANIZATIONS WITH MORE THAN 1 HOSPITAL FACILITY- If a hospital organization operates more than 1 hospital facility--

`(i) the organization shall meet the requirements of this subsection separately with respect to each such facility, and

`(ii) the organization shall not be treated as described in subsection (c)(3) with respect to any such facility for which such requirements are not separately met.

`(3) COMMUNITY HEALTH NEEDS ASSESSMENTS-

`(A) IN GENERAL- An organization meets the requirements of this paragraph with respect to any taxable year only if the organization--

`(i) has conducted a community health needs assessment which meets the requirements of subparagraph (B) in such taxable year or in either of the 2 taxable years immediately preceding such taxable year, and

`(ii) has adopted an implementation strategy to meet the community health needs identified through such assessment.

`(B) COMMUNITY HEALTH NEEDS ASSESSMENT- A community health needs assessment meets the requirements of this paragraph if such community health needs assessment--

`(i) takes into account input from persons who represent the broad interests of the community served by the hospital facility, including those with special knowledge of or expertise in public health, and
` (ii) is made widely available to the public.

`(4) FINANCIAL ASSISTANCE POLICY- An organization meets the requirements of this paragraph if the organization establishes the following policies:

`(A) FINANCIAL ASSISTANCE POLICY- A written financial assistance policy which includes--

`(i) eligibility criteria for financial assistance, and whether such assistance includes free or discounted care,

`(ii) the basis for calculating amounts charged to patients,

`(iii) the method for applying for financial assistance,

`(iv) in the case of an organization which does not have a separate billing and collections policy, the actions the organization may take in the event of non-payment, including collections action and reporting to credit agencies, and

`(v) measures to widely publicize the policy within the community to be served by the organization.

`(B) POLICY RELATING TO EMERGENCY MEDICAL CARE- A written policy requiring the organization to provide, without discrimination, care for emergency medical conditions (within the meaning of section 1867 of the Social Security Act (42 U.S.C. 1395dd)) to individuals regardless of their eligibility under the financial assistance policy described in subparagraph (A).

`(5) LIMITATION ON CHARGES- An organization meets the requirements of this paragraph if the organization--

`(A) limits amounts charged for emergency or other medically necessary care provided to individuals eligible for assistance under the financial assistance policy described in paragraph (4)(A) to not more than the lowest amounts charged to individuals who have insurance covering such care, and

`(B) prohibits the use of gross charges.

`(6) BILLING AND COLLECTION REQUIREMENTS- An organization meets the requirement of this paragraph only if the organization does not engage in extraordinary collection actions before the organization has made reasonable efforts to determine whether the individual is eligible for assistance under the financial assistance policy described in paragraph (4)(A).

`(7) REGULATORY AUTHORITY- The Secretary shall issue such regulations and guidance as may be necessary to carry out the provisions of this subsection, including guidance relating to what constitutes reasonable efforts to determine the eligibility of a patient under a financial assistance policy for purposes of paragraph (6).'

(b) Excise Tax for Failures To Meet Hospital Exemption Requirements-

(1) IN GENERAL- Subchapter D of chapter 42 of the Internal Revenue Code of 1986 (relating to failure by certain charitable organizations to meet certain qualification requirements) is amended by adding at the end the following new section:

`SEC. 4959. TAXES ON FAILURES BY HOSPITAL ORGANIZATIONS.

`If a hospital organization to which section 501(r) applies fails to meet the requirement of section 501(r)(3) for any taxable year, there is imposed on the organization a tax equal to \$50,000.'.

(2) CONFORMING AMENDMENT- The table of sections for subchapter D of chapter 42 of such Code is amended by adding at the end the following new item:
`Sec. 4959. Taxes on failures by hospital organizations.'.

(c) Mandatory Review of Tax Exemption for Hospitals- The Secretary of the Treasury or the Secretary's delegate shall review at least once every 3 years the community benefit activities of each hospital organization to which section 501(r) of the Internal Revenue Code of 1986 (as added by this section) applies.

(d) Additional Reporting Requirements-

(1) COMMUNITY HEALTH NEEDS ASSESSMENTS AND AUDITED FINANCIAL STATEMENTS-

Section 6033(b) of the Internal Revenue Code of 1986 (relating to certain organizations described in section 501(c)(3)) is amended by striking `and' at the end of paragraph (14), by redesignating paragraph (15) as paragraph (16), and by inserting after paragraph (14) the following new paragraph:

`(15) in the case of an organization to which the requirements of section 501(r) apply for the taxable year--

`(A) a description of how the organization is addressing the needs identified in each community health needs assessment conducted under section 501(r)(3) and a description of any such needs that are not being addressed together with the reasons why such needs are not being addressed, and

`(B) the audited financial statements of such organization (or, in the case of an organization the financial statements of which are included in a consolidated financial statement with other organizations, such consolidated financial statement).'

(2) TAXES- Section 6033(b)(10) of such Code is amended by striking `and' at the end of subparagraph (B), by inserting `and' at the end of subparagraph (C), and by adding at the end the following new subparagraph:

`(D) section 4959 (relating to taxes on failures by hospital organizations),'

(e) Reports-

(1) REPORT ON LEVELS OF CHARITY CARE- The Secretary of the Treasury, in consultation with the Secretary of Health and Human Services, shall submit to the Committees on Ways and Means, Education and Labor, and Energy and Commerce of the House of Representatives and to the Committees on Finance and Health, Education, Labor, and Pensions of the Senate an annual report on the following:

(A) Information with respect to private tax-exempt, taxable, and government-owned hospitals regarding--

(i) levels of charity care provided,

(ii) bad debt expenses,

(iii) unreimbursed costs for services provided with respect to means-tested government programs, and

(iv) unreimbursed costs for services provided with respect to non-means tested government programs.

(B) Information with respect to private tax-exempt hospitals regarding costs incurred for community benefit activities.

(2) REPORT ON TRENDS-

(A) STUDY- The Secretary of the Treasury, in consultation with the Secretary of Health and Human Services, shall conduct a study on trends in the information required to be reported under paragraph (1).

(B) REPORT- Not later than 5 years after the date of the enactment of this Act, the Secretary of the Treasury, in consultation with the Secretary of Health and Human Services, shall submit a report on the study conducted under subparagraph (A) to the Committees on Ways and Means, Education and Labor, and Energy and Commerce of the House of Representatives and to the Committees on Finance and Health, Education, Labor, and Pensions of the Senate.

(f) Effective Dates-

(1) IN GENERAL- Except as provided in paragraphs (2) and (3), the amendments made by this section shall apply to taxable years beginning after the date of the enactment of this Act.

(2) COMMUNITY HEALTH NEEDS ASSESSMENT- The requirements of section 501(r)(3) of the Internal Revenue Code of 1986, as added by subsection (a), shall apply to taxable years beginning after the date which is 2 years after the date of the enactment of this Act.

(3) EXCISE TAX- The amendments made by subsection (b) shall apply to failures occurring after the date of the enactment of this Act.

SEC. 9008. IMPOSITION OF ANNUAL FEE ON BRANDED PRESCRIPTION PHARMACEUTICAL MANUFACTURERS AND IMPORTERS.

(a) Imposition of Fee-

(1) IN GENERAL- Each covered entity engaged in the business of manufacturing or importing branded prescription drugs shall pay to the Secretary of the Treasury not later than the annual payment date of each calendar year beginning after 2009 a fee in an amount determined under subsection (b).

(2) ANNUAL PAYMENT DATE- For purposes of this section, the term 'annual payment date' means with respect to any calendar year the date determined by the Secretary, but in no event later than September 30 of such calendar

year.

(b) Determination of Fee Amount-

(1) IN GENERAL- With respect to each covered entity, the fee under this section for any calendar year shall be equal to an amount that bears the same ratio to \$2,300,000,000 as--

(A) the covered entity's branded prescription drug sales taken into account during the preceding calendar year, bear to

(B) the aggregate branded prescription drug sales of all covered entities taken into account during such preceding calendar year.

(2) SALES TAKEN INTO ACCOUNT- For purposes of paragraph (1), the branded prescription drug sales taken into account during any calendar year with respect to any covered entity shall be determined in accordance with the following table:

[THIS SEARCH](#) [THIS DOCUMENT](#) [GO TO](#)
[Next Hit](#) [Forward](#) [New Bills Search](#)
[Prev Hit](#) [Back](#) [HomePage](#)
[Hit List](#) [Best Sections](#) [Help](#)
[Contents Display](#)

[THOMAS Home](#) | [Contact](#) | [Accessibility](#) | [Legal](#) | [USA.gov](#)