# Calendar No. _____

111TH CONGRESS
1ST SESSION

# S. _____

**[Report No. 111–_____]**

To make quality, affordable health care available to all Americans, reduce costs, improve health care quality, enhance disease prevention, and strengthen the health care workforce.

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IN THE SENATE OF THE UNITED STATES

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Mr. KENNEDY, from the Committee on Health, Education, Labor, and Pensions reported the following original bill; which was read twice and placed on the calendar

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# A BILL

To make quality, affordable health care available to all Americans, reduce costs, improve health care quality, enhance disease prevention, and strengthen the health care workforce.

*Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,*

**SECTION 1. SHORT TITLE; TABLE OF CONTENTS.**

(a) SHORT TITLE.—This Act may be cited as the ''Affordable Health Choices Act''.

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

Sec. 1. Short title; table of contents.

TITLE I—QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS

Subtitle A—Effective Coverage for All Americans

PART I—PROVISIONS APPLICABLE TO THE INDIVIDUAL AND GROUP MARKETS

Sec. 101. Amendment to the Public Health Service Act.

"PART A—INDIVIDUAL AND GROUP MARKET REFORMS

"SUBPART 1—GENERAL REFORM

"Sec. 2705. Prohibition of preexisting condition exclusions or other discrimination based on health status.
"Sec. 2701. Fair insurance coverage.
"Sec. 2702. Guaranteed availability of coverage.
"Sec. 2703. Guaranteed renewability of coverage.
"Sec. 2704. Increasing the Transparency of Health Care Costs and Regulatory Fees.
"Sec. 2706. Prohibiting discrimination against individual participants and beneficiaries based on health status.
"Sec. 2707. Ensuring the quality of care.
"Sec. 2708. Coverage of preventive health services.
"Sec. 2709. Coverage of Preventive Women's Health Services.
"Sec. 2710. Extension of dependent coverage.
"Sec. 2711. No lifetime or annual limits.
"Sec. 2712. Notification by plans not providing minimum qualifying coverage.
"Sec. 2713. Non-discrimination in health care.

PART II—PROVISION APPLICABLE TO THE GROUP MARKET

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"Sec. 2720A. Prohibition of discrimination based on salary.

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Sec. 131. No changes to existing coverage.
Sec. 132. Applicability.
Sec. 133. Conforming amendments.
Sec. 134. Savings.
Sec. 135. Effective dates.

Subtitle B—Available Coverage for All Americans

Sec. 141. Building on the success of the Federal Employees Health Benefits Program and the health benefits program of most large employers so all Americans have affordable health benefit choices.
Sec. 142. Affordable health choices for all Americans.

"TITLE XXXI—AFFORDABLE HEALTH CHOICES FOR ALL AMERICANS

"Subtitle A—Affordable Choices

"Sec. 3101. Affordable choices of health benefit plans.
"Sec. 3102. Financial integrity.
"Sec. 3103. Program design.
"Sec. 3104. Allowing State flexibility.
"Sec. 3105. Navigators.
"Sec. 3106. Community health insurance option.
"Sec. 3107. Application of same laws to private plans and the community health insurance option.
"Sec. 3108. Participation of professionals on certain health-related commissions.
"Sec. 3109. Health insurance consumer assistance grants.
Sec. 143. Freedom not to participate in Federal health insurance programs.

Subtitle C—Affordable Coverage for All Americans

Sec. 151. Support for affordable health coverage.

"Subtitle B—Making Coverage Affordable

"Sec. 3111. Support for affordable health coverage.
"Sec. 3112. Small business health options program credit.
Sec. 152. Program integrity.

Subtitle D—Shared Responsibility for Health Care

Sec. 161. Individual responsibility.
Sec. 162. Notification on the availability of affordable health choices.
Sec. 163. Shared responsibility of employers.
"Sec. 3115. Shared responsibility of employers.
"Sec. 3116. Definitions.

Subtitle E—Improving Access to Health Care Services

Sec. 171. Spending for Federally Qualified Health Centers (FQHCs).
Sec. 172. Other provisions.
Sec. 173. Negotiated rulemaking for development of methodology and criteria for designating medically underserved populations and health professions shortage areas.
Sec. 174. Equity for certain eligible survivors.
Sec. 175. Reauthorization of the Wakefield Emergency Medical Services for Children Program.
Sec. 176. Co-locating primary and specialty care in community-based mental health settings.

Subtitle F—Making Health Care More Affordable for Retirees

Sec. 181. Reinsurance for retirees.

Subtitle G—Improving the Use of Health Information Technology for Enrollment; Miscellaneous Provisions

Sec. 185. Health information technology enrollment standards and protocols.
Sec. 186. Rule of construction regarding Hawaii's Prepaid Health Care Act.

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Sec. 203. Quality measure development.
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# TITLE I—QUALITY, AFFORDABLE HEALTH CARE FOR ALL AMERICANS

## Subtitle A—Effective Coverage for All Americans

### PART I—PROVISIONS APPLICABLE TO THE INDIVIDUAL AND GROUP MARKETS

#### SEC. 101. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

Part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg et seq.) is amended—

(1) by striking the part heading and heading for subpart 1 and inserting the following:

**"PART A—INDIVIDUAL AND GROUP MARKET REFORMS**

**"Subpart 1—General Reform";**

(2) in section 2701 (42 U.S.C. 300gg)—

(A) by striking the section heading and subsection (a) and inserting the following:

**"SEC. 2705. PROHIBITION OF PREEXISTING CONDITION EXCLUSIONS OR OTHER DISCRIMINATION BASED ON HEALTH STATUS.**

"(a) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage may not impose any preexisting condition exclusion with respect to such plan or coverage."; and

(B) by transferring the remainder of section so as to appear after the section 2704 as added by paragraph (5);

(3) in section 2702 (42 U.S.C. 300gg-1)—

(A) by striking the section heading and all that follows through subsection (a)—

(B) in subsection (b)—

(i) by striking "health insurance issuer offering health insurance coverage in connection with a group health plan" each place that such appears and inserting "health insurance issuer offering group or individual health insurance coverage"; and

(ii) in paragraph (2)(A)—

(I) by inserting "or individual" after "employer"; and

(II) by inserting "or individual health coverage, as the case may be" before the semicolon;

(C) by redesignating subsections (b) through (f) as subsections (e) through (i), respectively; and

(D) by transferring the remainder of such section to appear at the end of section 2706 (as added by paragraph (5));

(4) by redesignating existing sections 2704 through 2707 and sections 2711 through 2713 as sections 2717 through 2720 and sections 2714 through 2716, respectively; and

(5) by inserting after the subpart heading (as added by paragraph (1)) the following:

**"SEC. 2701. FAIR INSURANCE COVERAGE.**

"(a) IN GENERAL.—With respect to the premium rate charged by a health insurance issuer for health insurance coverage offered in the individual or group market—

"(1) such rate shall vary with respect to the particular plan or coverage involved only by—

"(A) family structure;

"(B) community rating area;

"(C) the actuarial value of the benefit;

"(D) age, except that such rate shall not vary by more than 2 to 1;

"(E) tobacco use, except that such rate shall not vary by more than 1.5 to 1; and

"(F) adherence to or participation in a reasonably designed program of health promotion and disease prevention, if such a program is offered by the employer that is the sponsor of the coverage involved; and

"(2) such rate shall not vary with respect to the particular plan or coverage involved by health status-related factors, gender, class of business, claims experience, industry, or any other factor not described in paragraph (1), except that group health plans and health insurance issuers offering group health insurance coverage may establish premium discounts or rebates for modifying otherwise applicable copayments or deductibles in return for adherence to or participation in reasonably designed programs of health promotion or disease prevention.

"(b) COMMUNITY RATING AREA.—Taking into account the applicable recommendations of the National Association of Insurance Commissioners, the Secretary shall by regulation establish a minimum size for community rating areas for purposes of this section, which, for areas con-

tained in a Metropolitan Statistical Area, shall not be smaller than such area.

**"SEC. 2702. GUARANTEED AVAILABILITY OF COVERAGE.**

"(a) ISSUANCE OF COVERAGE IN THE INDIVIDUAL AND GROUP MARKET.—Subject to subsections (b) through (e), each health insurance issuer that offers health insurance coverage in the individual or group market in a State must accept every employer and individual in the State that applies for such coverage.

"(b) ENROLLMENT.—

"(1) RESTRICTION.—A health insurance issuer described in subsection (a) may restrict enrollment in coverage described in such subsection to open or special enrollment periods.

"(2) ESTABLISHMENT.—A health insurance issuer described in subsection (a) shall, in accordance with the regulations promulgated under paragraph (3), establish special enrollment periods for qualifying events (under section 603 of the Employee Retirement Income Security Act of 1974).

"(3) REGULATIONS.—Not later than 1 year after the date of enactment of this section, the Secretary shall promulgate regulations with respect to enrollment periods under paragraphs (1) and (2).

**"SEC. 2703. GUARANTEED RENEWABILITY OF COVERAGE.**

"(a) IN GENERAL.—Except as provided in this section, if a health insurance issuer offers health insurance coverage in the individual or group market, the issuer must renew or continue in force such coverage at the option of the plan sponsor or the individual, as applicable.

"(b) PROHIBITION ON RESCISSIONS.—A group health plan and a health insurance issuer offering group or individual health insurance coverage shall not rescind such coverage once the plan involved has been issued, except that this subsection shall not apply to a covered individual who has performed an act or practice that constitutes fraud or makes an intentional misrepresentation of material fact as prohibited by the terms of the coverage. Coverage may not be cancelled except with prior notice to the enrollee, and only as permitted under section 2702(c) or 2742(b).

**"SEC. 2704. INCREASING THE TRANSPARENCY OF HEALTH CARE COSTS AND REGULATORY FEES.**

"(a) CLEAR ACCOUNTING FOR COSTS.—A health insurance issuer offering group or individual health insurance coverage shall publicly report (in a manner to be established by the Secretary through regulation) the percentage of total premium revenue that such coverage expends—

"(1) on reimbursement for clinical services provided to enrollees under such plan or coverage;

"(2) for activities that improve health care quality;

"(3) on taxes, license, or regulatory fee costs, and the cost of any surcharge imposed by the Gateway under title XXXI; and

"(4) on all other non-claims costs, including an explanation of the nature of such costs and an itemized list of costs associated with compliance with the Affordable Health Choices Act.

"(b) DEFINITION.—In this section, the term 'activities to improve health care quality' means activities described in section 2707.

"(c) PROCESSES AND METHODS.—The Secretary shall develop a methodology for calculating the percentages described in subsection (a). Such methodology may provide for a requirement that a report described in subsection (a) include an actuarial certification of the information included in such report.

**"SEC. 2706. PROHIBITING DISCRIMINATION AGAINST INDIVIDUAL PARTICIPANTS AND BENEFICIARIES BASED ON HEALTH STATUS.**

"(a) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insur-

ance coverage may not establish rules for eligibility (including continued eligibility) of any individual to enroll under the terms of the plan or coverage based on any of the following health status-related factors in relation to the individual or a dependent of the individual:

"(1) Health status.

"(2) Medical condition (including both physical and mental illnesses).

"(3) Claims experience.

"(4) Receipt of health care.

"(5) Medical history.

"(6) Genetic information.

"(7) Evidence of insurability (including conditions arising out of acts of domestic violence).

"(8) Disability.

"(9) Any other health status-related factor determined appropriate by the Secretary.

"(b) PROGRAMS OF HEALTH PROMOTION OR DISEASE PREVENTION.—

"(1) GENERAL PROVISIONS.—

"(A) GENERAL RULE.—For purposes of paragraph (2)(B), a program of health promotion or disease prevention (referred to in this subsection as a 'wellness program') shall be a program offered by an employer that is de-

signed to promote health or prevent disease that meets the applicable requirements of this subsection.

"(B) NO CONDITIONS BASED ON HEALTH STATUS FACTOR.—If none of the conditions for obtaining a premium discount or rebate or other reward for participation in a wellness program is based on an individual satisfying a standard that is related to a health status factor, such wellness program shall not violate this section if participation in the program is made available to all similarly situated individuals and the requirements of paragraph (2) are complied with.

"(C) CONDITIONS BASED ON HEALTH STATUS FACTOR.—If any of the conditions for obtaining a premium discount or rebate or other reward for participation in a wellness program is based on an individual satisfying a standard that is related to a health status factor, such wellness program shall not violate this section if the requirements of paragraph (3) are complied with.

"(2) WELLNESS PROGRAMS NOT SUBJECT TO REQUIREMENTS.—If none of the conditions for ob-

taining a premium discount or rebate or other reward under a wellness program as described in paragraph (1)(B) are based on an individual satisfying a standard that is related to a health status factor (or if such a wellness program does not provide such a reward), the wellness program shall not violate this section if participation in the program is made available to all similarly situated individuals. The following programs shall not have to comply with the requirements of paragraph (3) if participation in the program is made available to all similarly situated individuals:

"(A) A program that reimburses all or part of the cost for memberships in a fitness center.

"(B) A diagnostic testing program that provides a reward for participation and does not base any part of the reward on outcomes.

"(C) A program that encourages preventive care related to a health condition through the waiver of the copayment or deductible requirement under an individual or group health plan for the costs of certain items or services related to a health condition (such as prenatal care or well-baby visits).

"(D) A program that reimburses individuals for the costs of smoking cessation programs without regard to whether the individual quits smoking.

"(E) A program that provides a reward to individuals for attending a periodic health education seminar.

"(3) WELLNESS PROGRAMS SUBJECT TO REQUIREMENTS.—If any of the conditions for obtaining a premium discount, rebate, or reward under a wellness program as described in paragraph (1)(C) is based on an individual satisfying a standard that is related to a health status factor, the wellness program shall not violate this section if the following requirements are complied with:

"(A) The reward for the wellness program, together with the reward for other wellness programs with respect to the plan that requires satisfaction of a standard related to a health status factor, shall not exceed 30 percent of the cost of employee-only coverage under the plan. If, in addition to employees or individuals, any class of dependents (such as spouses or spouses and dependent children) may participate fully in the wellness program, such reward shall not

exceed 30 percent of the cost of the coverage in which an employee or individual and any dependents are enrolled. For purposes of this paragraph, the cost of coverage shall be determined based on the total amount of employer and employee contributions for the benefit package under which the employee is (or the employee and any dependents are) receiving coverage. A reward may be in the form of a discount or rebate of a premium or contribution, a waiver of all or part of a cost-sharing mechanism (such as deductibles, copayments, or coinsurance), the absence of a surcharge, or the value of a benefit that would otherwise not be provided under the plan. The Secretaries of Labor, Health and Human Services, and the Treasury may increase the reward available under this subparagraph to up to 50 percent of the cost of coverage if the Secretaries determine that such an increase is appropriate.

"(B) The wellness program shall be reasonably designed to promote health or prevent disease. A program complies with the preceding sentence if the program has a reasonable chance of improving the health of, or preventing

disease in, participating individuals and it is not overly burdensome, is not a subterfuge for discriminating based on a health status factor, and is not highly suspect in the method chosen to promote health or prevent disease. The plan or issuer shall evaluate the program's reasonableness at least once per year.

"(C) The plan shall give individuals eligible for the program the opportunity to qualify for the reward under the program at least once each year.

"(D) The full reward under the wellness program shall be made available to all similarly situated individuals. For such purpose, among other things:

"(i) The reward is not available to all similarly situated individuals for a period unless the wellness program allows—

"(I) for a reasonable alternative standard (or waiver of the otherwise applicable standard) for obtaining the reward for any individual for whom, for that period, it is unreasonably difficult due to a medical condition to

1 satisfy the otherwise applicable stand-
2 ard; and
3 ''(II) for a reasonable alternative
4 standard (or waiver of the otherwise
5 applicable standard) for obtaining the
6 reward for any individual for whom,
7 for that period, it is medically inadvis-
8 able to attempt to satisfy the other-
9 wise applicable standard.
10 ''(ii) If reasonable under the cir-
11 cumstances, the plan or issuer may seek
12 verification, such as a statement from an
13 individual's physician, that a health status
14 factor makes it unreasonably difficult or
15 medically inadvisable for the individual to
16 satisfy or attempt to satisfy the otherwise
17 applicable standard.
18 ''(E) The plan or issuer involved shall dis-
19 close in all plan materials describing the terms
20 of the wellness program the availability of a
21 reasonable alternative standard (or the possi-
22 bility of waiver of the otherwise applicable
23 standard) required under subparagraph (D). If
24 plan materials disclose that such a program is
25 available, without describing its terms, the dis-

closure under this subparagraph shall not be required.

"(c) EXISTING PROGRAMS.—Nothing in this section shall prohibit a program of health promotion or disease prevention that was established prior to the date of enactment of this section and applied with all applicable regulations, and that is operating on such date, from continuing to be carried out for as long as such regulations remain in effect.

"(d) REGULATIONS.—Nothing in this section shall be construed as prohibiting the Secretaries of Labor, Health and Human Services, or the Treasury from promulgating regulations in connection with this section.

**"SEC. 2707. ENSURING THE QUALITY OF CARE.**

"(a) IN GENERAL.—Except as provided in subsection (c), a group health plan and a health insurance issuer offering group or individual health insurance coverage shall develop and implement a reimbursement structure for making payments to health care providers that provides incentives for—

"(1) the provision of high quality health care under the plan or coverage in a manner that includes—

"(A) the implementation of case management, care coordination, chronic disease man-

agement, and medication and care compliance activities that includes the use of the medical home model as defined in section 212 of the Affordable Health Choices Act for treatment or services under the plan or coverage;

"(B) the implementation of activities to prevent hospital readmissions through a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post-discharge reinforcement by an appropriate health care professional;

"(C) the implementation of activities to improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence based medicine, and health information technology under the plan or coverage;

"(D) the implementation of wellness and health promotion activities;

"(E) child health measures under section 1139A of the Social Security Act; and

"(F) culturally and linguistically appropriate care, as defined by the Secretary; and

"(2) payment policies that substantially reflects the payment policy of the Medicare program under title XVIII of the Social Security Act and the Children's Health Insurance Program under title XXI of such Act with respect to any generally implemented incentive policy to promote high quality health care, except that in order that no plan or issuer be forced to deny patients medical care needed to prevent their deaths or preserve or restore their health, no plan or issuer shall be prohibited from providing payment for a treatment or diagnostic procedure it chooses to cover, unless such treatment or procedure has been determined to be unsafe or dangerous or capable of neither preventing the patient's death nor preserving or restoring the patient's health.

"(b) WELLNESS AND PREVENTION PROGRAMS.—For purposes of subsection (a)(1)(D), wellness and health promotion activities may include personalized wellness and prevention services, which are coordinated, maintained or delivered by a health care provider, a wellness and prevention plan manager, or a health, wellness or prevention services organization that conducts health risk assessments or offer ongoing face-to-face, telephonic or web-based intervention efforts for each of the program's par-

1 ticipants, and which may include the following wellness
2 and prevention efforts:
3 "(1) Smoking cessation.
4 "(2) Weight management.
5 "(3) Stress management.
6 "(4) Physical fitness.
7 "(5) Nutrition.
8 "(6) Heart disease prevention.
9 "(7) Healthy lifestyle support.
10 "(8) Diabetes prevention.
11 "(c) EXCEPTIONS.—In promulgating regulations
12 under subsection (d), the Secretary may provide for excep-
13 tions to the requirements of subsection (a) for insurers
14 that substantially meet the goals of this section.
15 "(d) REGULATIONS.—Not later than 180 days after
16 the date of enactment of the Affordable Health Choices
17 Act, the Secretary shall promulgate regulations—
18 "(1) that define the term 'generally imple-
19 mented' for purposes of subsection (a)(2);
20 "(2) that require the expiration of a minimum
21 period of time between the date on which a policy
22 is generally implemented for purposes of subsection
23 (a)(2) and the date on which such policy shall apply
24 with respect to health insurance coverage offered in
25 the individual or group market; and

"(3) that provide criteria for determining whether a payment policy is described in subsection (a).

"(e) STUDY AND REPORT.—Not later than 180 days after the date of enactment of the Affordable Health Choices Act, the Government Accountability Office shall conduct a study and submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report regarding the impact the activities under this section have had on the quality and cost of health care.

**"SEC. 2708. COVERAGE OF PREVENTIVE HEALTH SERVICES.**

"(a) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage shall provide coverage for and shall not impose any cost sharing requirements (other than minimal cost sharing in accordance with guidelines developed by the Secretary) for—

"(1) evidence-based items or services that have in effect a rating of 'A' or 'B' in the current recommendations of the United States Preventive Services Task Force;

"(2) immunizations that have in effect a recommendation from the Advisory Committee on Im-

1 munization Practices of the Centers for Disease
2 Control and Prevention with respect to the indi-
3 vidual involved; and
4 ''(3) with respect to infants, children, and ado-
5 lescents, evidence-informed preventive care and
6 screenings provided for in the comprehensive guide-
7 lines supported by the Health Resources and Serv-
8 ices Administration.
9 ''(b) INTERVAL.—
10 ''(1) IN GENERAL.—The Secretary shall estab-
11 lish a minimum interval between the date on which
12 a recommendation described in subsection (a)(1) or
13 (a)(2) or a guideline under subsection (a)(3) is
14 issued and the plan year with respect to which the
15 requirement described in subsection (a) is effective
16 with respect to the service described in such rec-
17 ommendation or guideline.
18 ''(2) MINIMUM.—The interval described in
19 paragraph (1) shall not be less than 1 year.
20 **''SEC. 2709. COVERAGE OF PREVENTIVE WOMEN'S HEALTH**
21 **SERVICES.**
22 ''A group health plan and a health insurance issuer
23 offering group or individual health insurance coverage
24 shall provide coverage for, and shall not impose any cost
25 sharing requirements (other than minimal cost sharing in

accordance with guidelines developed by the Secretary) for, with respect to women (including pregnant women and individuals of child bearing age), such additional preventive care and screenings not covered under section 2708 as provided for in guidelines supported by the Health Resources and Services Administration.

**"SEC. 2710. EXTENSION OF DEPENDENT COVERAGE.**

"(a) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage that provides dependent coverage of children shall continue to make such coverage available for an adult child until the child turns 26 years of age. Nothing in this section shall require a health plan or a health insurance issuer described in the preceding sentence to make coverage available for a child of a child receiving dependent coverage.

"(b) REGULATIONS.—The Secretary shall promulgate regulations to define the dependents to which coverage shall be made available under subsection (a).

**"SEC. 2711. NO LIFETIME OR ANNUAL LIMITS.**

"(a) IN GENERAL.—A group health plan and a health insurance issuer offering group or individual health insurance coverage may not establish lifetime or annual limits on the dollar value of benefits for any participant or beneficiary.

"(b) PREVENTING FRAUD AND ABUSE.—This section shall not apply until the date on which the Secretary certifies that enacting this section will not result in undue proliferation of fraud and abuse, especially with regard to durable medical equipment.

**"SEC. 2712. NOTIFICATION BY PLANS NOT PROVIDING MINIMUM QUALIFYING COVERAGE.**

"(a) IN GENERAL.—Not later than 1 year after the date on which the Secretary establishes criteria with respect to minimum qualifying coverage under section 3103, a group health plan and a health insurance issuer offering group or individual health insurance coverage that fails to provide such minimum qualifying coverage shall notify, in such manner as may be required by the Secretary, enrollees and prospective enrollees in such plan or coverage of such failure prior to enrollment or re-enrollment.

"(b) MODIFICATIONS.—If the Secretary modifies the criteria with respect to minimum qualifying coverage under section 3103, a group health plan or health insurance issuer that fails to provide such modified minimum qualifying coverage shall provide the notice required under subsection (a) within 60 days of the date of such modification.

**"SEC. 2713. NON-DISCRIMINATION IN HEALTH CARE.**

"A group health plan and a health insurance issuer offering group or individual health insurance coverage shall not discriminate with respect to participation under the plan or coverage against any health care provider who is acting within the scope of that provider's license or certification under applicable State law. This section shall not require that a group health plan or health insurance issuer contract with any health care provider willing to abide by the terms and conditions for participation established by the plan or issuer. Nothing in this section shall be construed as preventing a group health plan, a health insurance issuer, or the Secretary from establishing varying reimbursement rates based on quality or performance measures.".

## PART II—PROVISION APPLICABLE TO THE GROUP MARKET

**SEC. 121. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.**

Subpart 2 of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg-4 et seq.) is amended by adding at the end the following:

**"SEC. 2720A. PROHIBITION OF DISCRIMINATION BASED ON SALARY.**

"(a) IN GENERAL.—A group health plan and a health insurance issuer offering group health insurance coverage

may not establish rules relating to the health insurance coverage eligibility (including continued eligibility) of any full-time employee under the terms of the plan that are based on the total hourly or annual salary of the employee.

"(b) LIMITATION.—Subsection (a) shall not be construed to prohibit a group health plan or health insurance issuer from establishing contribution requirements for enrollment in the plan or coverage that provide for the payment by employees with lower hourly or annual compensation of a lower dollar or percentage contribution than the payment required of a similarly situated employees with a higher hourly or annual compensation.".

## PART III—OTHER PROVISIONS

### SEC. 131. NO CHANGES TO EXISTING COVERAGE.

(a) OPTION TO RETAIN CURRENT INSURANCE COVERAGE.—

(1) IN GENERAL.—Nothing in this Act (or an amendment made by this Act) shall be construed to require that an individual terminate coverage under a group health plan or health insurance coverage in which such individual was enrolled prior to the date of enactment of this title.

(2) CONTINUATION OF COVERAGE.—With respect to a group health plan or health insurance coverage in which an individual was enrolled prior to

the date of enactment of this title, this subtitle (and the amendments made by this subtitle) shall not apply to such plan or coverage, regardless of whether the individual renews such coverage after such date of enactment.

(b) ALLOWANCE FOR FAMILY MEMBERS TO JOIN CURRENT COVERAGE.—With respect to a group health plan or health insurance coverage in which an individual was enrolled prior to the date of enactment of this title and which is renewed after such date, family members of such individual shall be permitted to enroll in such plan or coverage if such enrollment is permitted under the terms of the plan in effect as of such date of enactment.

(c) ALLOWANCE FOR NEW EMPLOYEES TO JOIN CURRENT PLAN.—A group health plan that provides coverage on the date of enactment of this Act may provide for the enrolling of new employees (and their families) in such plan, and this subtitle (and the amendments made by this subtitle) shall not apply with respect to such plan and such new employees (and their families).

(d) NO ADDITIONAL BENEFIT.—Subsections (b) and (c) shall only apply to individuals described in such subsections and the family members of such individuals (as provided for in such subsections).

(e) LIMITATION.—Subsections (a) through (d) shall not apply to any group health plan or health insurance coverage that has been modified to a significant extent with respect to covered benefits or cost sharing requirements after the date of enactment of this Act. The Secretary shall by regulation establish criteria to determine whether a plan or health insurance coverage has been modified to a significant extent under the preceding sentence, except that any coverage amendment made pursuant to an agreement between an employer or an individual and a health insurance issuer relating to the coverage which amends the coverage solely to conform to any requirement added by this Act (or amendments to this Act) shall not be treated as a significant modification.

(f) EFFECT ON COLLECTIVE BARGAINING AGREEMENTS.—In the case of health insurance coverage maintained pursuant to one or more collective bargaining agreements between employee representatives and one or more employers that was ratified before the date of enactment of this title, the provisions of this subtitle (and the amendments made by this subtitle) shall not apply until the date on which the last of the collective bargaining agreements relating to the coverage terminates. Any coverage amendment made pursuant to a collective bargaining agreement relating to the coverage which amends

the coverage solely to conform to any requirement added by this subtitle (or amendments) shall not be treated as a termination of such collective bargaining agreement.

(g) RISK ADJUSTMENT.—The provisions of section 3101(c)(6) of the Public Health Service Act (as added by section 142) shall not apply to a group health plan or health insurance coverage to which this section applies.

**SEC. 132. APPLICABILITY.**

Section 2721 of the Public Health Service Act (42 U.S.C. 300gg-21) is amended—

(1) by striking subsection (a);

(2) in subsection (b)—

(A) in paragraph (1), by striking ''1 through 3'' and inserting ''1 and 2''; and

(B) in paragraph (2)—

(i) in subparagraph (A), by striking ''subparagraph (D)'' and inserting ''subparagraph (D) or (E)'';

(ii) by striking ''1 through 3'' and inserting ''1 and 2''; and

(iii) by adding at the end the following:

''(E) ELECTION NOT APPLICABLE.—The election described in subparagraph (A) shall not

be available with respect to the provisions of subpart 1.";

(3) in subsection (c), by striking "1 through 3 shall not apply to any group" and inserting "1 and 2 shall not apply to any individual coverage or any group"; and

(4) in subsection (d)—

(A) in paragraph (1), by striking "1 through 3 shall not apply to any group" and inserting "1 and 2 shall not apply to any individual coverage or any group";

(B) in paragraph (2)—

(i) in the matter preceding subparagraph (A), by striking "1 through 3 shall not apply to any group" and inserting "1 and 2 shall not apply to any individual coverage or any group"; and

(ii) in subparagraph (C), by inserting "or, with respect to individual coverage, under any health insurance coverage maintained by the same health insurance issuer"; and

(C) in paragraph (3), by striking "any group" and inserting "any individual coverage or any group".

**SEC. 133. CONFORMING AMENDMENTS.**

(a) PUBLIC HEALTH SERVICE ACT.—Title XXVII of the Public Health Service Act (42 U.S.C. 300gg et seq.) is amended—

(1) in section 2705 (42 U.S.C. 300gg), as so redesignated by section 101(2)—

(A) in subsection (c)—

(i) in paragraph (2), by striking ''group health plan'' each place that such appears and inserting ''group or individual health plan''; and

(ii) in paragraph (3)—

(I) by striking ''group health insurance'' each place that such appears and inserting ''group or individual health insurance''; and

(II) in subparagraph (D), by striking ''small or large'' and inserting ''individual or group'';

(B) in subsection (d), by striking ''group health insurance'' each place that such appears and inserting ''group or individual health insurance''; and

(C) in subsection (e)(1)(A), by striking ''group health insurance'' and inserting ''group or individual health insurance'';

(2) by striking the heading for subpart 2 of part A;

(3) in section 2717 (42 U.S.C. 300gg-4), as so redesignated—

(A) in subsection (a), by striking ''health insurance issuer offering group health insurance coverage'' and inserting ''health insurance issuer offering group or individual health insurance coverage'';

(B) in subsection (b)—

(i) by striking ''health insurance issuer offering group health insurance coverage in connection with a group health plan'' in the matter preceding paragraph (1) and inserting ''health insurance issuer offering group or individual health insurance coverage''; and

(ii) in paragraph (1), by striking ''plan'' and inserting ''plan or coverage'';

(C) in subsection (c)—

(i) in paragraph (2), by striking ''group health insurance coverage offered by a health insurance issuer'' and inserting ''health insurance issuer offering group or individual health insurance coverage''; and

(ii) in paragraph (3), by striking ''issuer'' and inserting ''health insurance issuer''; and

(D) in subsection (e), by striking ''health insurance issuer offering group health insurance coverage'' and inserting ''health insurance issuer offering group or individual health insurance coverage'';

(4) in section 2718 (42 U.S.C. 300gg-5), as so redesignated—

(A) in subsection (a), by striking ''(or health insurance coverage offered in connection with such a plan)'' each place that such appears and inserting ''or a health insurance issuer offering group or individual health insurance coverage'';

(B) in subsection (b), by striking ''(or health insurance coverage offered in connection with such a plan)'' each place that such appears and inserting ''or a health insurance issuer offering group or individual health insurance coverage''; and

(C) in subsection (c)—

(i) in paragraph (1), by striking ''(and group health insurance coverage offered in

connection with a group health plan)'' and inserting ''and a health insurance issuer offering group or individual health insurance coverage'';

(ii) in paragraph (2), by striking ''(or health insurance coverage offered in connection with such a plan)'' each place that such appears and inserting ''or a health insurance issuer offering group or individual health insurance coverage'';

(5) in section 2719 (42 U.S.C. 300gg-6), as so redesignated, by striking ''health insurance issuers providing health insurance coverage in connection with group health plans'' and inserting ''and health insurance issuers offering group or individual health insurance coverage'';

(6) in section 2720 (42 U.S.C. 300gg-7), as so redesignated—

(A) in subsection (a), by striking ''health insurance coverage offered in connection with such plan'' and inserting ''individual health insurance coverage'';

(B) in subsection (b)—

(i) in paragraph (1), by striking ''or a health insurance issuer that provides

health insurance coverage in connection with a group health plan'' and inserting ''or a health insurance issuer that offers group or individual health insurance coverage'';

(ii) in paragraph (2), by striking ''health insurance coverage offered in connection with the plan'' and inserting ''individual health insurance coverage''; and

(iii) in paragraph (3), by striking ''health insurance coverage offered by an issuer in connection with such plan'' and inserting ''individual health insurance coverage'';

(C) in subsection (c), by striking ''health insurance issuer providing health insurance coverage in connection with a group health plan'' and inserting ''health insurance issuer that offers group or individual health insurance coverage''; and

(D) in subsection (e)(1), by striking ''health insurance coverage offered in connection with such a plan'' and inserting ''individual health insurance coverage'';

(7) by striking the heading for subpart 3;

(8) in section 2714 (42 U.S.C. 300gg-11), as so redesignated—

(A) by striking the section heading and all that follows through subsection (b);

(B) in subsection (c)—

(i) in paragraph (1)—

(I) in the matter preceding subparagraph (A), by striking ''small group'' and inserting ''group and individual''; and

(II) in subparagraph (B)—

(aa) in the matter preceding clause (i), by inserting ''and individuals'' after ''employers'';

(bb) in clause (i), by inserting ''or any additional individuals'' after ''additional groups''; and

(cc) in clause (ii), by striking ''without regard to the claims experience of those employers and their employees (and their dependents) or any health status-related factor relating to such'' and inserting ''and individuals

without regard to the claims experience of those individuals, employers and their employees (and their dependents) or any health status-related factor relating to such individuals''; and

(ii) in paragraph (2), by striking ''small group'' and inserting ''group or individual'';

(C) in subsection (d)—

(i) by striking ''small group'' each place that such appears and inserting ''group or individual''; and

(ii) in paragraph (1)(B)—

(I) by striking ''all employers'' and inserting ''all employers and individuals'';

(II) by striking ''those employers'' and inserting ''those individuals, employers''; and

(III) by striking ''such employees'' and inserting ''such individuals, employees'';

(D) by striking subsection (e);

(E) by striking subsection (f); and

(F) by transferring the remainder of such section to appear at the end of section 2702 (as added by section 101(5));

(9) in section 2715 (42 U.S.C. 300gg-12), as so redesignated—

(A) by striking the section heading and all that follows through subsection (a);

(B) in subsection (b)—

(i) in the matter preceding paragraph (1), by striking ''group health plan in the small or large group market'' and inserting ''health insurance coverage offered in the group or individual market'';

(ii) in paragraph (1), by inserting '', or individual, as applicable,'' after ''plan sponsor'';

(iii) in paragraph (2), by inserting '', or individual, as applicable,'' after ''plan sponsor''; and

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

''(3) VIOLATION OF PARTICIPATION OR CONTRIBUTION RATES.—In the case of a group health plan, the plan sponsor has failed to comply with a material plan provision relating to employer con-

tribution or group participation rules, pursuant to applicable State law.''; 

(C) in subsection (c)—

(i) in paragraph (1)—

(I) in the matter preceding subparagraph (A), by striking ''group health insurance coverage offered in the small or large group market'' and inserting ''group or individual health insurance coverage'';

(II) in subparagraph (A), by inserting ''or individual, as applicable,'' after ''plan sponsor'';

(III) in subparagraph (B)—

(aa) by inserting ''or individual, as applicable,'' after ''plan sponsor''; and

(bb) by inserting ''or individual health insurance coverage''; and

(IV) in subparagraph (C), by inserting ''or individuals, as applicable,'' after ''those sponsors''; and

(ii) in paragraph (2)(A)—

(I) in the matter preceding clause (i), by striking ''small group market or the large group market, or both markets,'' and inserting ''individual or group market, or all markets,''; and

(II) in clause (i), by inserting ''or individual, as applicable,'' after ''plan sponsor''; and

(D) by transferring the remainder of such section to appear at the end of section 2703 (as added by section 101(5));

(10) in section 2716 (42 U.S.C. 300gg-13), as so redesignated—

(A) in subsection (a)—

(i) in the matter preceding paragraph (1), by striking ''small employer'' and inserting ''small employer or an individual'';

(ii) in paragraph (1), by inserting '', or individual, as applicable,'' after ''employer'' each place that such appears; and

(iii) in paragraph (2), by striking ''small employer'' and inserting ''employer, or individual, as applicable,'';

(B) in subsection (b)—

(i) in paragraph (1)—

(I) in the matter preceding subparagraph (A), by striking ''small employer'' and inserting ''employer, or individual, as applicable,'';

(II) in subparagraph (A), by adding ''and'' at the end;

(III) by striking subparagraphs (B) and (C); and

(IV) in subparagraph (D)—

(aa) by inserting '', or individual, as applicable,'' after ''employer''; and

(bb) by redesignating such subparagraph as subparagraph (B);

(ii) in paragraph (2)—

(I) by striking ''small employers'' each place that such appears and inserting ''employers, or individuals, as applicable,''; and

(II) by striking ''small employer'' and inserting ''employer, or individual, as applicable,''; and

(C) by redesignating such section as section 2712 and transferring such section to ap-

pear after section 2711 (as added by section 101(5));

(11) by redesignating subpart 4 as subpart 2;

(12) in section 2721 (42 U.S.C. 300gg-21)—

(A) by striking subsection (a);

(B) by striking ''subparts 1 through 3'' each place that such appears and inserting ''subpart 1''; and

(C) by redesignating subsections (b) through (e) as subsections (a) through (d), respectively;

(13) in section 2722 (42 U.S.C. 300gg-22)—

(A) in subsection (a)—

(i) in paragraph (1), by striking ''small or large group markets'' and inserting ''individual or group market''; and

(ii) in paragraph (2), by inserting ''or individual health insurance coverage'' after ''group health plans''; and

(B) in subsection (b)(1)(B), by inserting ''individual health insurance coverage or'' after ''respect to''; and

(14) in section 2723(a)(1) (42 U.S.C. 300gg-23), by inserting ''individual or'' before ''group health insurance''.

(b) APPLICABILITY.—Notwithstanding any other provision of the Affordable Health Choices Act, nothing in such Act (or an amendment made by such Act) shall be construed to—

(1) authorize the Secretary of Health and Human Services to promulgate regulations that prohibit a group health plan or health insurance issuer from carrying out utilization management techniques that are commonly used as of the date of enactment of this section; or

(2) restrict the application of the amendments made by this subtitle.

(c) TECHNICAL AMENDMENT TO THE EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.—Subpart B of part 7 of subtitle A of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1181 et. seq.) is amended, by adding at the end the following:

**"SEC. 715. ADDITIONAL MARKET REFORMS.**

"(a) GENERAL RULE.—Except as provided in subsection (b)—

"(1) the provisions of subpart 1 of part A of title XXVII of the Public Health Service Act (as amended by the Affordable Health Choices Act) shall apply to group health plans, and health insurance issuers providing health insurance coverage in

connection with group health plans, as if included in this subpart; and

"(2) to the extent that any provision of this part conflicts with a provision of such subpart 1 with respect to group health plans, or health insurance issuers providing health insurance coverage in connection with group health plans, the provisions of such subpart 1 shall apply.

"(b) EXCEPTION.—Notwithstanding subsection (a), the provisions of sections 2701, 2702, and 2704 of title XXVII of the Public Health Service Act (as amended by the Affordable Health Choices Act) shall not apply with respect to self-insured group health plans, and the provisions of this part shall continue to apply to such plans as if such sections of the Public Health Service Act (as so amended) had not been enacted.".

(d) TECHNICAL AMENDMENT TO THE INTERNAL REVENUE CODE OF 1986.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended by adding at the end the following:

**"SEC. 9815. ADDITIONAL MARKET REFORMS.**

"(a) GENERAL RULE.—Except as provided in subsection (b)—

"(1) the provisions of subpart 1 of part A of title XXVII of the Public Health Service Act (as

amended by the Affordable Health Choices Act) shall apply to group health plans, and health insurance issuers providing health insurance coverage in connection with group health plans, as if included in this subchapter; and

"(2) to the extent that any provision of this subchapter conflicts with a provision of such subpart 1 with respect to group health plans, or health insurance issuers providing health insurance coverage in connection with group health plans, the provisions of such subpart 1 shall apply.

"(b) EXCEPTION.—Notwithstanding subsection (a), the provisions of sections 2701, 2702, and 2704 of title XXVII of the Public Health Service Act (as amended by the Affordable Health Choices Act) shall not apply with respect to self-insured group health plans, and the provisions of this subchapter shall continue to apply to such plans as if such sections of the Public Health Service Act (as so amended) had not been enacted.".

**SEC. 134. 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.

**SEC. 135. EFFECTIVE DATES.**

(a) APPLICABILITY.—Except as otherwise provided in subsection (b), this subtitle (and the amendments made by this subtitle) shall become effective for plan years beginning on or after the date that is 1 year after the date of enactment of this Act.

(b) DELAYED APPLICABILITY.—Sections 2701, 2702, 2705, and 2706 of the Public Health Service Act (as added by section 101) shall become effective with respect to group health plans or health insurance coverage offered in a State on the date on which such State becomes a participating or establishing State under section 3104 of the Public Health Service Act (as added by section 142).

# Subtitle B—Available Coverage for All Americans

**SEC. 141. BUILDING ON THE SUCCESS OF THE FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM AND THE HEALTH BENEFITS PROGRAM OF MOST LARGE EMPLOYERS SO ALL AMERICANS HAVE AFFORDABLE HEALTH BENEFIT CHOICES.**

(a) FINDINGS.—The Senate finds that—

(1) the Federal employees health benefits program under chapter 89 of title 5, United States Code, allows Members of Congress, and section 514 of the Employee Retirement Income Security Act of 1974 allows large employers, to have affordable choices among competing health benefit plans;

(2) the Federal employees health benefits program ensures that the health benefit plans available to Members of Congress meet minimum standards of quality and effectiveness;

(3) millions of Americans have no meaningful choice in health benefits, because health benefit plans are either unavailable or unaffordable; and

(4) all Americans should have the same kinds of meaningful choices of health benefit plans that Members of Congress, as Federal employees, enjoy

through the Federal employees health benefits program.

(b) SENSE OF THE SENATE.—It is the sense of the Senate that Congress should establish a means for all Americans to enjoy affordable choices in health benefit plans, in the same manner that Members of Congress have such choices through the Federal employees health benefits program.

**SEC. 142. AFFORDABLE HEALTH CHOICES FOR ALL AMERICANS.**

(a) PURPOSE.—It is the purpose of this section to facilitate the establishment of Affordable Health Benefit Gateways in each State, with appropriate flexibility for States in establishing and administering the Gateways.

(b) AMERICAN HEALTH BENEFIT GATEWAYS.—The Public Health Service Act ( 42 U.S.C. 201 et seq.) is amended by adding at the end the following:

# "TITLE XXXI—AFFORDABLE HEALTH CHOICES FOR ALL AMERICANS

## "Subtitle A—Affordable Choices

**"SEC. 3101. AFFORDABLE CHOICES OF HEALTH BENEFIT PLANS.**

"(a) ASSISTANCE TO STATES TO ESTABLISH AMERICAN HEALTH BENEFIT GATEWAYS.—

"(1) PLANNING AND ESTABLISHMENT GRANTS.—Not later than 60 days after the date of enactment of this section (or as soon as practicable thereafter), the Secretary shall make awards, from amounts appropriated under paragraph (5), to States in the amount specified in paragraph (2) for the uses described in paragraph (3).

"(2) AMOUNT SPECIFIED.—

"(A) TOTAL DETERMINED.—For each fiscal year, the Secretary shall determine the total amount that the Secretary will make available for grants under this subsection.

"(B) STATE AMOUNT.—For each State that is awarded a grant under paragraph (1), the amount of such grants shall be based on a formula established by the Secretary under which each State shall receive an award in an amount that is based on the following two components:

"(i) A minimum amount for each State.

"(ii) An additional amount based on population.

The Secretary shall ensure that the aggregate amount awarded to all States under clause (i)

is not less than 60 percent of the aggregate amount awarded to all States under this subparagraph.

"(3) USE OF FUNDS.—A State shall use amounts awarded under this subsection for activities (including planning activities) related to establishing an American Health Benefit Gateway, as described in subsection (b).

"(4) RENEWABILITY OF GRANT.—

"(A) IN GENERAL.—The Secretary may renew a grant awarded under paragraph (1) if the State recipient of such grant—

"(i) is making progress, as determined by the Secretary, toward—

"(I) establishing a Gateway; and

"(II) implementing the reforms described in subtitle A of title I of the Affordable Health Choices Act; and

"(ii) is meeting such other benchmarks as the Secretary may establish.

"(B) LIMITATION.—If a State is an establishing State or a participating State (as defined in section 3104), such State shall not be eligible for a grant renewal under subparagraph (A) as of the second fiscal year following the

date on which such State was deemed to be an establishing State or a participating State.

"(5) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary to carry out this subsection in each of fiscal years 2009 through 2014.

"(b) AMERICAN HEALTH BENEFIT GATEWAYS.—An American Health Benefit Gateway (referred to in this title as a 'Gateway') means a mechanism that—

"(1) facilitates the purchase of health insurance coverage and related insurance products through the Gateway at an affordable price by qualified individuals and qualified employers and reduces the cost of health care; and

"(2) meets the requirements of subsection (c).

"(c) REQUIREMENTS.—

"(1) ESTABLISHMENT.—A Gateway shall be a governmental agency or nonprofit entity that is established by—

"(A) a State, in the case of an establishing State (as described in section 3104); or

"(B) the Secretary, in the case of a participating State (as described in section 3104).

"(2) OFFERING OF COVERAGE.—

"(A) IN GENERAL.—A Gateway shall make available qualified health plans to qualified individuals and qualified employers.

"(B) INCLUSION.—In making available coverage pursuant to subparagraph (A), a Gateway shall include a community health insurance option (as described in section 3106).

"(C) LIMITATION.—A Gateway may not make available any health plan or other health insurance coverage that is not a qualified health plan.

"(D) ALLOWANCE TO OFFER.—A Gateway may make available a qualified health plan notwithstanding any provision of law that may require benefits other than the essential health benefits specified under section 3103(a).

"(E) STATES MAY REQUIRE ADDITIONAL BENEFITS.—Subject to the requirements of subparagraph (F), a State may require that a qualified health plan offered in such State offer benefits in addition to the essential health benefits described in section 3103(a).

"(F) ADDITIONAL BENEFITS.—

"(i) NO ADDITIONAL FEDERAL COST.—A requirement by a State under

subparagraph (E) that a qualified health plan cover benefits in addition to the essential health benefits required shall not affect the amount of a credit provided under section 3111 with respect to such plan.

"(ii) STATE MUST ASSUME COST.—A State shall make payments to or on behalf of an eligible individual to defray the cost of any additional benefits described in subparagraph (E).

"(3) FUNCTIONS.—A Gateway shall, at a minimum—

"(A) establish procedures for the certification, recertification, and decertification, consistent with guidelines developed by the Secretary under subsection (m), of health plans as qualified health plans;

"(B) develop and make available tools to allow consumers to receive accurate and culturally and linguistically appropriate information on—

"(i) expected premiums and out of pocket expenses (taking into account any

1 credits for which such individual is eligible
2 under section 3111);
3 ''(ii) the availability of in-network and
4 out-of-network providers;
5 ''(iii) the costs of any surcharge as-
6 sessed under paragraph (4);
7 ''(iv) data, by plan, that reflects the
8 frequency with which preventive services
9 rated 'A' or 'B' by the U.S. Preventive
10 Services Task Force or recommended by
11 the Advisory Committee on Immunization
12 Practices are utilized by enrollees, a com-
13 parison of such data to the average fre-
14 quency with which such preventive services
15 are utilized by enrollees across all qualified
16 health plans, and whether such preventive
17 services are utilized by enrollees as fre-
18 quently as recommended;
19 ''(v) medical loss ratios, as reported
20 under section 2704(a);
21 ''(vi) any quality measures for health
22 plan performance endorsed under section
23 399JJ; and
24 ''(vii) such other matters relating to
25 consumer costs and expected experience

under the plan as a Gateway may determine necessary;

"(C) utilize the administrative simplification measures and standards developed under section 222 of the Affordable Health Choices Act;

"(D) enter into agreements, to the extent determined appropriate by the Gateway, with navigators, as described in section 3105;

"(E) facilitate the purchase of coverage for long-term services and supports;

"(F) collect, analyze, and respond to complaints and concerns from enrollees regarding coverage provided through the Gateway;

"(G) provide for the operation of a toll-free telephone hotline to respond to requests for assistance; and

"(H) maintain an Internet website through which enrollees and prospective enrollees of qualified health plans may obtain standardized comparative information on such plans.

"(4) SURCHARGES.—

"(A) IN GENERAL.—A Gateway may assess a surcharge on all health insurance issuers offering qualified health plans through the

Gateway to pay for the administrative and operational expenses of the Gateway.

"(B) LIMITATION.—A surcharge described in subparagraph (A) may not exceed 4 percent of the premiums collected by a qualified health plan.

"(C) FURTHER LIMITATION.—No funds collected through a Gateway surcharge for administrative and operational expenses may be used for staff retreats, promotional giveaways, excessive executive compensation, or promotion of Federal or State legislative and regulatory modifications.

"(5) RISK ADJUSTMENT PAYMENT.—

"(A) ESTABLISHING AND PARTICIPATING STATES.—

"(i) LOW ACTUARIAL RISK PLANS.—Using the criteria and methods developed under subparagraph (B), each establishing State or participating State (as defined in section 3104) shall assess a charge on health plans and health insurance issuers (with respect to health insurance coverage) described in subparagraph (C) if the actuarial risk of the enrollees of such plans or

coverage for a year is less than the average actuarial risk of all enrollees in all plans or coverage in such State for such year that are not self-insured group health plans (which are subject to the provisions of the Employee Retirement Income Security Act of 1974).

"(ii) HIGH ACTUARIAL RISK PLANS.—Using the criteria and methods developed under subparagraph (B), each establishing State or participating State (as defined in section 3104) shall provide a payment to health plans and health insurance issuers (with respect to health insurance coverage) described in subparagraph (C) if the actuarial risk of the enrollees of such plans or coverage for a year is greater than the average actuarial risk of all enrollees in all plans and coverage in such State for such year that are not self-insured group health plans (which are subject to the provisions of the Employee Retirement Income Security Act of 1974).

"(B) CRITERIA AND METHODS.—The Secretary, in consultation with States, shall estab-

lish criteria and methods to be used in carrying out the risk adjustment activities under this paragraph. The Secretary may utilize criteria and methods similar to the criteria and methods utilized under part C or D of title XVIII of the Social Security Act.

"(C) SCOPE.—A health plan or a health insurance issuer is described in this subparagraph if such health plan or health insurance issuer provides coverage for an individual or for an employer group the size of which does not exceed—

"(i) in the case of an employer with its primary place of business located in an establishing State, the criteria relating to the size of employers established by such State as described in section 3116(a)(2)(A)(ii)(I); or

"(ii) in the case of an employer with its primary place of business located in a participating State, the criteria relating to the size of employers established by the Secretary as described in section 3116(a)(2)(A)(ii)(II).

"(6) FACILITATING ENROLLMENT.—

"(A) IN GENERAL.—A Gateway shall (through, to the extent practicable, the use of information technology) implement policies and procedures to—

"(i) facilitate the identification of individuals who lack qualifying coverage; and

"(ii) assist such individuals in enrolling in—

"(I) a qualified health plan that is affordable and available to such individual, if such individual is a qualified individual;

"(II) the medicaid program under title XIX of the Social Security Act, if such individual is eligible for such program;

"(III) the CHIP program under title XXI of the Social Security Act, if such individual is eligible for such program; or

"(IV) other Federal programs in which such individual is eligible to participate.

"(B) CHOICE FOR INDIVIDUALS ELIGIBLE FOR CHIP.—A qualified individual who is eligi-

ble for the Children's Health Insurance Program under title XXI of the Social Security Act may elect to enroll in such program or in a qualified health plan. Where such individual is a minor child, such election shall be made by the parent or guardian of such child.

"(C) OVERSIGHT.—The Secretary shall oversee the implementation of subparagraph (A)(ii) to ensure that individuals are assisted to enroll in the program most appropriate under such subparagraph for each such individual.

"(D) ACCESSIBILITY OF MATERIALS.—Any materials used by a Gateway to carry out this paragraph shall be provided in a form and manner calculated to be understood by individuals who may apply to be enrollees in a qualified health plan, taking into account potential language barriers and disabilities of individuals.

"(7) CONSULTATION.—A Gateway shall consult with stakeholders relevant to carrying out the activities under this subsection, including—

"(A) educated health care consumers who are enrollees in qualified health plans;

"(B) individuals and entities with experience in facilitating enrollment in qualified health plans;

"(C) representatives of small businesses and self-employed individuals;

"(D) State Medicaid offices; and

"(E) advocates for enrolling hard to reach populations.

"(8) STANDARDS AND PROTOCOLS.—

"(A) IN GENERAL.—The Secretary, in consultation with the Office of the National Coordinator for Health Information Technology, shall develop interoperable, secure, scalable, and reusable standards and protocols that facilitate enrollment of individuals in Federal and State health and human services programs.

"(B) COORDINATION.—The Secretary shall facilitate enrollment of individuals in programs described in subparagraph (A) through methods which shall include—

"(i) electronic matching against existing Federal and State data to serve as evidence of eligibility and digital documentation in lieu of paper-based documentation;

"(ii) capability for individuals to apply, recertify, and manage eligibility information online, including conducting real-time queries against databases for existing eligibility prior to submitting applications; and

"(iii) other functionalities necessary to provide eligible individuals with a streamlined enrollment process.

"(C) ASSISTANCE.—The Secretary shall award grants to enhance community-based enrollment to—

"(i) States to assist such States in—

"(I) contracting with qualified technology vendors to develop or acquire electronic enrollment software systems;

"(II) contracting with community and consumer focused nonprofit organizations with experience working with consumers, including the uninsured and the underinsured, to establish Statewide helplines for enrollment assistance and referrals; and

"(III) establishing public education campaigns through grants to qualifying organizations for the design and implementation of public education campaigns targeting uninsured and traditionally underserved communities; and

"(ii) community-based organizations for infrastructure and training to establish electronic assistance programs.

"(9) NOTIFICATION.—With respect to the standards and protocols developed under paragraph (8), the Secretary—

"(A) shall notify States of such standards and protocols; and

"(B) may require, as a condition of receiving Federal funds, that States or other entities incorporate such standards and protocols into such investments.

"(10) PUBLICATION OF COSTS.—A Gateway shall publish the average costs of income or other taxes, licensing or regulatory fees, and any surcharges imposed by the Gateway, and the administrative costs of such Gateway, on an Internet website to educate consumers on such costs. Such

information shall also include monies lost to waste, fraud, and abuse.

"(d) CERTIFICATION.—A Gateway may certify a health plan as a qualified health plan if—

"(1) such health plan meets the requirements of subsection (m);

"(2) the Gateway determines that making available such health plan through such Gateway is in the interests of qualified individuals and qualified employers in the States or States in which such Gateway operates, except that the Gateway may not exclude a health plan—

"(A) on the basis that such plan is a fee-for-service plan;

"(B) through the imposition of premium price controls; or

"(C) on the basis that the plan provides treatments necessary to prevent patients' deaths in circumstances the Gateway determines are inappropriate or to costly; and

"(3) the Gateway determines that the plan has not established a pattern or practice under which benefits covered by the plan are denied to covered individuals on the basis of the individuals' age or expected length of life or of the individuals' present or

predicted disability, degree of medical dependency, or quality of life.

"(e) GUIDANCE.—The Secretary shall develop guidance that may be used by a Gateway to carry out the activities described in this section.

"(f) FLEXIBILITY.—

"(1) REGIONAL OR OTHER INTERSTATE GATEWAYS.—A Gateway may operate in more than one State, provided that each State in which such Gateway operates permits such operation.

"(2) SUBSIDIARY GATEWAYS.—A State may establish one or more subsidiary Gateway, provided that—

"(A) each such Gateway serves a geographically distinct area; and

"(B) the area served by each such Gateway is at least as large as a community rating area described in section 2701.

"(g) NO LIMITATION ON CONTRACTING BASED ON ABORTION.—No individual health care provider or health care facility may be excluded from contracting with a health insurance issuer participating in the Gateway on the basis that the provider or facility performs abortions or the provider or facility refuses to perform abortions, except in an emergency, if performing abortions is con-

1 trary to the religious or moral beliefs of the provider or
2 facility.

3 "(h) PORTALS TO STATE GATEWAY.—The Secretary
4 shall establish a mechanism, including an Internet
5 website, through which a resident of any State may iden-
6 tify any Gateway operating in such State.

7 "(i) CHOICE.—

8 "(1) QUALIFIED INDIVIDUALS.—A qualified in-
9 dividual may enroll in any qualified health plan
10 available to such individual.

11 "(2) QUALIFIED EMPLOYERS.—

12 "(A) EMPLOYER MAY SPECIFY TIER.—A
13 qualified employer may provide support for cov-
14 erage of employees under a qualified health
15 plan by selecting any tier of cost sharing de-
16 scribed in section 3111(a)(1).

17 "(B) EMPLOYEE MAY CHOOSE PLANS
18 WITHIN A TIER.—Each employee of a qualified
19 employer may choose to enroll in a qualified
20 health plan that offers coverage at the tier of
21 cost sharing selected by an employer, as de-
22 scribed in subparagraph (A).

23 "(3) SELF-EMPLOYED INDIVIDUALS.—

24 "(A) DEEMING.—An individual who is self-
25 employed (as defined in section 401(c)(1) of the

Internal Revenue Code of 1986) shall be deemed to be a qualified employer unless such individual notifies the applicable Gateway that such individual elects to be considered a qualified individual.

"(B) ELIGIBILITY.—In the case of a self-employed individual making the election described in subparagraph (A)—

"(i) the income of such individual for purposes of section 3111 shall be deemed to be the total business income of such individual;

"(ii) premium payments made by such individual to a qualified health plan shall not be treated as employer-provided coverage under section 106(a) of the Internal Revenue Code of 1986; and

"(iii) the individual shall not be eligible for a credit under section 3112.

"(j) PAYMENT OF PREMIUMS BY QUALIFIED INDIVIDUALS.—A qualified individual enrolled in any qualified health plan may pay any applicable premium owed by such individual to the health insurance issuer issuing such qualified health plan.

"(k) SINGLE RISK POOL.—

"(1) INDIVIDUAL MARKET.—A health insurance issuer shall consider all enrollees in an individual plan, including individuals who do not purchase such a plan through the Gateway, to be members of a single risk pool.

"(2) GROUP HEALTH INSURANCE POLICIES.—A health insurance issuer shall consider all enrollees in a small group health plan, other than a self-insured group health plan, including individuals who do not purchase such a plan through the Gateway, to be members of a single risk pool.

"(l) EMPOWERING CONSUMER CHOICE.—

"(1) CONTINUED OPERATION OF MARKET OUTSIDE GATEWAYS.—Nothing in this title shall be construed to prohibit a health insurance issuer from offering a health insurance policy or providing coverage under such policy to a qualified individual where such policy is not a qualified health plan. Nothing in this title shall be construed to prohibit a qualified individual from enrolling in a health insurance plan where such plan is not a qualified health plan.

"(2) CONTINUED OPERATION OF STATE BENEFIT REQUIREMENTS.—Nothing in this title shall be construed to terminate, abridge, or limit the oper-

ation of any requirement under State law with respect to any policy or plan that is not a qualified health plan to offer benefits required under State law.

"(3) VOLUNTARY NATURE OF A GATEWAY.—

"(A) CHOICE TO ENROLL OR NOT TO ENROLL.—Nothing in this title shall be construed to restrict the choice of a qualified individual to enroll or not to enroll in a qualified health plan or to participate in a Gateway.

"(B) PROHIBITION AGAINST COMPELLED ENROLLMENT.—Nothing in this title shall be construed to compel an individual to enroll in a qualified health plan or to participate in a Gateway.

"(m) CRITERIA FOR CERTIFICATION.—

"(1) IN GENERAL.—The Secretary shall, by regulation, establish criteria for certification of health plans as qualified health plans. Such criteria shall require that, to be certified, a plan—

"(A) not employ marketing practices that have the effect of discouraging the enrollment in such plan by individuals with significant health needs;

"(B) employ methods to ensure that insurance products are simple, comparable, and structured for ease of consumer choice;

"(C) ensure a wide choice of providers (in a manner consistent with applicable network adequacy provisions under section 2702(c));

"(D) include within health insurance plan networks those essential community providers, where available, that serve predominately low-income, medically-underserved individuals, such as health care providers defined in section 340B(a)(4) of the Public Health Service Act and providers described in section 1927(c)(1)(D)(i)(IV) of the Social Security Act as set forth by section 221 of Public Law 111-8;

"(E) make available to individuals enrolled in, or seeking to enroll in, such plan a detailed description of—

"(i) benefits offered, including maximums, limitations (including differential cost-sharing for out of network services), exclusions and other benefit limitations;

"(ii) the service area;

"(iii) required premiums;

1 "(iv) cost-sharing requirements;
2 "(v) the manner in which enrollees ac-
3 cess providers; and
4 "(vi) the grievance and appeals proce-
5 dures;
6 "(F) provide coverage for at least the es-
7 sential health care benefits established under
8 section 3103(a);
9 "(G)(i) is accredited by the National Com-
10 mittee for Quality Assurance or by any other
11 entity recognized by the Secretary for the ac-
12 creditation of health insurance issuers or plans;
13 or
14 "(ii) receives such accreditation within a
15 period established by a Gateway for such ac-
16 creditation that is applicable to all qualified
17 health plans;
18 "(H) implement a quality improvement
19 strategy described in subsection (n)(1);
20 "(I) have adequate procedures in place for
21 appeals of coverage determinations;
22 "(J) may not establish a benefit design
23 that is likely to substantially discourage enroll-
24 ment by certain qualified individuals in such
25 plan; and

"(K) report to the applicable Gateway data on any quality measures for health plan performance endorsed under section 399JJ.

"(2) REQUEST TO NATIONAL ASSOCIATION OF INSURANCE COMMISSIONERS.—The Secretary shall request the National Association of Insurance Commissioners to develop and submit to the Secretary model criteria for the certification of qualified health plans, that address the elements described in subparagraphs (A) through (K) of paragraph (1). In developing such criteria, the National Association of Insurance Commissioners shall consult with appropriate Federal agencies, consumer representatives, insurance carriers, and other stakeholders.

"(3) REQUIRED CONSIDERATION.—If the model criteria described in paragraph (2) are submitted to the Secretary by the date that is 9 months after the date on which a request is made under such paragraph, the Secretary shall consider such model criteria in promulgating the regulations under paragraph (1).

"(4) RULE OF CONSTRUCTION.—Nothing in paragraph (1)(D) shall be construed to require a qualified health plan to contract with a provider described in such paragraph if such provider refuses to

accept the generally applicable payment rates of such plan.

"(n) REWARDING QUALITY THROUGH MARKET-BASED INCENTIVES.—

"(1) STRATEGY DESCRIBED.—A strategy described in this paragraph is a payment structure that provides increased reimbursement or other incentives for—

"(A) improving health outcomes through the implementation of activities that shall include quality reporting, effective case management, care coordination, chronic disease management, medication and care compliance initiatives, including through the use of the medical home model as defined in section 212 of the Affordable Health Choices Act, for treatment or services under the plan or coverage;

"(B) the implementation of activities to prevent hospital readmissions through a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post discharge reinforcement by an appropriate health care professional;

"(C) the implementation of activities to improve patient safety and reduce medical errors through the appropriate use of best clinical practices, evidence based medicine, and health information technology under the plan or coverage; and

"(D) the implementation of wellness and health promotion activities.

"(2) GUIDELINES.—The Secretary, in consultation with experts in health care quality and stakeholders, shall develop guidelines concerning the matters described in paragraph (1).

"(3) REQUIREMENTS.—The guidelines developed under paragraph (2) shall require the periodic reporting to the applicable Gateway of the activities that a qualified health plan has conducted to implement a strategy described in paragraph (1).

"(o) NO INTERFERENCE WITH STATE REGULATORY AUTHORITY.—Nothing in this title shall be construed to preempt any State law that does not prevent the application of the provisions of this title.

"(p) QUALITY IMPROVEMENT.—

"(1) ENHANCING PATIENT SAFETY.—Beginning on January 1, 2012 a qualified health plan may contract with—

"(A) a hospital with greater than 50 beds only if such hospital—

"(i) utilizes a patient safety evaluation system as described in part C of title IX; and

"(ii) implements a mechanism to ensure that each patient receives a comprehensive program for hospital discharge that includes patient-centered education and counseling, comprehensive discharge planning, and post discharge reinforcement by an appropriate health care professional; or

"(B) a health care provider if such provider implements such mechanisms to improve health care quality as the Secretary may by regulation require.

"(2) EXCEPTIONS.—The Secretary may establish reasonable exceptions to the requirements described in paragraph (1).

"(3) ADJUSTMENT.—The Secretary may by regulation adjust the number of beds described in paragraph (1)(A).

"(q) CONTINUED APPLICABILITY OF MENTAL HEALTH PARITY.—Section 2716 shall apply to qualified

1 health plans in the same manner and to the same extent
2 as such section applies to health insurance issuers and
3 group health plans.

4 "(r) PROMOTION OF INFORMED CHOICE OF HEALTH
5 INSURANCE COVERAGE.—

6 "(1) IN GENERAL.—The Secretary shall develop
7 standards for use by health insurance issuers offer-
8 ing health insurance coverage through the Gateway
9 in the individual or group market in compiling and
10 providing to enrollees a summary of benefits expla-
11 nation that accurately represents the benefits and
12 coverage provided by the issuer under each of its ap-
13 plicable health insurance products. In developing
14 such standards, the Secretary shall consult with the
15 National Association of Insurance Commissioners, a
16 working group composed of representatives of health
17 insurance-related consumer advocacy organizations,
18 health insurance issuers, health care professionals,
19 patient advocates including those representing indi-
20 viduals with limited English proficiency, and other
21 qualified individuals.

22 "(2) REQUIREMENTS.—The standards for the
23 summary of benefits explanation developed under
24 paragraph (1) shall provide for the following:

"(A) APPEARANCE.—The standards shall ensure that the summary is presented in a uniform format.

"(B) LANGUAGE.—The standards shall ensure that the language used in the summary is presented in a manner determined to be understandable by the average health plan enrollee.

"(C) CONTENTS.—The standards shall ensure that the summary includes the following:

"(i) Information determined to be essential to a consumer's understanding of the applicable health insurance plan benefits.

"(ii) Uniform definitions of standard insurance terms including premium, deductible, co-insurance, co-payment, out-of-pocket limit, preferred provider, non-preferred provider, out-of-network co-payments, usual, customary and reasonable fees, excluded services, grievance and appeals, prior authorization, precertification, and such other terms as determined by the Secretary so that consumers may compare health insurance coverage and understand the terms of coverage.

"(iii) Uniform definitions of medical terms including hospitalization, hospital outpatient care, emergency room care, physician services, prescription drug coverage, durable medical equipment, home health care, skilled nursing care, rehabilitation services, hospice services, emergency medical transportation, and such other terms as determined by the Secretary so that consumers may compare the medical benefits and understand the extent of those medical benefits (or exceptions to those benefits).

"(iv) A statement of whether the plan meets minimum qualifying coverage (when effective under section 3103.)

"(v) Examples to illustrate common benefits scenarios, including scenarios that illustrate the health care needs of pregnancy and of at least several serious or chronic medical conditions.

"(vi) Illustrations that enhance consumer understanding of the explanation.

"(3) REQUIREMENT TO PROVIDE.—Not later than 12 months after the Secretary develops stand-

ards under paragraph (1), each health insurance issuer offering health insurance coverage through the Gateway shall, prior to any enrollment restriction, provide annually to enrollees and potential enrollees a summary of benefits explanation pursuant to the standards developed by the Secretary under paragraph (1)

"(4) PREEMPTION.—The standards developed under paragraph (1) shall preempt any related State standards that require summary of benefits health plan explanations that provide less information to consumers, as determined by the Secretary.

"(5) FAILURE TO PROVIDE.—A health insurance issuer that willfully fails to provide the information required under this subsection shall be subject to a fine of not more than $1,000 for each such failure. Such failure with respect to each enrollee shall constitute a separate offense for purposes of this paragraph.

"(6) APPLICATION.—The provisions of this subsection shall apply to health insurance coverage offered through the Gateway. The Secretary shall evaluate the impact on consumers of expanding the application of the provisions of this subsection to additional health insurance issuers.

"(s) DISCLOSURE OF INFORMATION.—

"(1) IN GENERAL.—In connection with the offering of any health insurance coverage in the individual or group market through a Gateway, a health insurance issuer—

"(A) shall disclose to such individual or employer as part of its solicitation and sales materials, the information described in paragraph (2);

"(B) shall disclose to such individual or employer enrolled in such plan any change and an explanation of such change with respect to the information described in paragraph (2) with reasonable and timely advance notice with respect to such change;

"(C) upon the request of such individual or employer, shall provide the information described in paragraph (2); and

"(D) shall disclose such information as the Secretary may require in order to ensure compliance with consumer protection provisions under this title.

"(2) INFORMATION DESCRIBED.—

"(A) IN GENERAL.—Subject to subparagraph (C), with respect to a health insurance

issuer offering health insurance coverage in the individual or group market through a Gateway, information disclosed under this paragraph shall include—

"(i) the provisions of such coverage concerning the issuer's right to change premium rates, co-payments, in- and out-of-provider networks, or any other information as determined by the Secretary; and

"(ii) the benefits and premiums available under all health insurance coverage for which an individual or employers is qualified.

"(B) FORM OF INFORMATION.—Information shall be provided under this paragraph in a manner determined to be understandable by the average employer or individual and shall be sufficient to reasonably inform such employer or individual of their rights and obligations under the health insurance coverage involved.

"(C) EXCEPTION.—Information described under this paragraph shall not include information that is proprietary or trade secret information.

**"SEC. 3102. FINANCIAL INTEGRITY.**

"(a) ACCOUNTING FOR EXPENDITURES.—

"(1) IN GENERAL.—A Gateway shall keep an accurate accounting of all activities, receipts, and expenditures and shall annually submit to the Secretary a report concerning such accountings.

"(2) INVESTIGATIONS.—The Secretary may investigate the affairs of a Gateway, may examine the properties and records of a Gateway, and may require periodical reports in relation to activities undertaken by a Gateway. A Gateway shall fully cooperate in any investigation conducted under this paragraph.

"(3) AUDITS.—A Gateway shall be subject to annual audits by the Secretary.

"(4) PATTERN OF ABUSE.—If the Secretary determines that a Gateway or a State has engaged in serious misconduct with respect to compliance with the requirements of, or carrying out activities required under, this title, the Secretary may rescind from payments otherwise due to such State involved under this or any other Act administered by the Secretary an amount not to exceed 1 percent of such payments per year until corrective actions are taken by the State that are determined to be adequate by the Secretary.

"(5) PROTECTIONS AGAINST FRAUD AND ABUSE.—With respect to activities carried out under this title, the Secretary shall provide for the efficient and non-discriminatory administration of Gateway activities and implement any measure or procedure that—

"(A) the Secretary determines is appropriate to reduce fraud and abuse in the administration of this title; and

"(B) the Secretary has authority to implement under this title or any other Act;

"(6) APPLICATION OF THE FALSE CLAIMS ACT.—

"(A) IN GENERAL.—Payments made by, through, or in connection with a Gateway are subject to the False Claims Act (31 U.S.C. 3729 et seq.) if those payments include any Federal funds. Compliance with the requirements of this Act concerning eligibility for a health insurance issuer to participate in the Gateway shall be a material condition of an issuer's entitlement to receive payments, including subsidy payments, through the Gateway.

"(B) DAMAGES.—Notwithstanding paragraph (1) of section 3729(a) of title 31, United

States Code, and subject to paragraph (2) of such section, the civil penalty assessed under the False Claims Act on any person found liable under such Act as described in subparagraph (A) shall be increased by not less than 3 times and not more than 6 times the amount of damages which the Government sustains because of the act of that person.

''(b) GAO OVERSIGHT.—Not later than 5 years after the date of enactment of this section, the Comptroller General shall conduct an ongoing study of Gateway activities and the enrollees in qualified health plans offered through Gateways. Such study shall review—

''(1) the operations and administration of Gateways, including surveys and reports of qualified health plans offered through Gateways and on the experience of such plans (including data on enrollees in Gateways and individuals purchasing health insurance coverage outside of Gateways), the expenses of Gateways, claims statistics relating to qualified health plans, complaints data relating to such plans, and the manner in which Gateways meets their goals;

''(2) any significant observations regarding the utilization and adoption of Gateways;

"(3) where appropriate, recommendations for improvements in the operations or policies of Gateways; and

"(4) how many physicians, by area and specialty, are not taking or accepting new patients enrolled in Federal Government health care programs, and the adequacy of provider networks of Federal Government health care programs.

**"SEC. 3103. PROGRAM DESIGN.**

"(a) PROGRAM DESIGN.—

"(1) IN GENERAL.—The Secretary shall establish the following:

"(A) Subject to paragraph (2), the essential health care benefits eligible for credits under section 3111, where such benefits shall include at least the following general categories:

"(i) Ambulatory patient services.

"(ii) Emergency services.

"(iii) Hospitalization.

"(iv) Maternity and newborn care.

"(v) Mental health and substance abuse services.

"(vi) Prescription drugs.

"(vii) Rehabilitative and habilitative services and devices.

1 "(viii) Laboratory services.
2 "(ix) Preventive and wellness services.
3 "(x) Pediatric services, including oral
4 and vision care.
5 "(B) The criteria that coverage must meet
6 to be considered minimum qualifying coverage.
7 "(C) The conditions under which coverage
8 shall be considered affordable and available cov-
9 erage for individuals and families at different
10 income levels.
11 "(D) The essential benefits provided for in
12 subparagraph (A) shall include a requirement
13 that there be non-discrimination in health care
14 in a manner that, with respect to an individual
15 who is eligible for medical or surgical care
16 under a qualified health plan offered through a
17 Gateway, prohibits the Administrator of the
18 Gateway, or a qualified health plan offered
19 through the Gateway, from denying such indi-
20 vidual benefits for religious or spiritual health
21 care, except that such religious or spiritual
22 health care shall be an expense eligible for de-
23 duction as a medical care expense as deter-
24 mined by Internal Revenue Service Rulings in-

terpreting section 213(d) of the Internal Revenue Code of 1986 as of January 1, 2009.

"(2) LIMITATION.—The Secretary shall ensure that the scope of the essential health benefits under paragraph (1)(A) is equal to the scope of benefits provided under a typical employer plan, as determined by the Secretary.

"(3) CERTIFICATION.—In establishing the essential health benefits described in paragraph (1)(A), the Secretary shall submit a report to the appropriate committees of Congress containing a certification from the Chief Actuary of the Centers for Medicare & Medicaid Services that such essential health benefits meet the limitation described in paragraph (2).

"(b) NATIONAL INDEPENDENT COMMISSION ON ESSENTIAL HEALTH CARE BENEFITS.—

"(1) ESTABLISHMENT.—There is established a temporary advisory commission to be known as the National Independent Commission on Essential Health Care Benefits (in this section referred to as the 'Commission').

"(2) DUTIES.—The Commission shall:

"(A) Review and analyze the benefits offered under typical employer-sponsored health

1 plans, and State laws requiring coverage of
2 specified items and services in the individual
3 and group insurance markets.
4 "(B) Hold public hearings, meetings, or
5 other public listening sessions not less than 3
6 times to take testimony and receive such evi-
7 dence as the Commission considers advisable to
8 carry out activities under this section.
9 "(C) Make recommendations to the Sec-
10 retary regarding the specific items and services
11 that should be included in the essential heath
12 care benefits package eligible for credits under
13 section 3111.
14 "(3) CONSIDERATIONS.—The Commission shall
15 consider—
16 "(A) the clinical appropriateness and effec-
17 tiveness of the benefits covered;
18 "(B) the affordability of the benefits cov-
19 ered;
20 "(C) the financial protection of enrollees
21 against high healthcare expenses;
22 "(D) access to necessary healthcare serv-
23 ices, including primary and preventive health
24 services;

"(E) existing State laws that require coverage of health care items or services in the individual and group markets; and

"(F) the potential of additional or expanded benefits to increase costs and the interactions between the addition or expansion of benefits and reductions in existing benefits to meet the actuarial limitations described in subsection (a)(2).

"(4) MEMBERSHIP.—

"(A) NUMBER AND APPOINTMENT.—The Commission shall be composed of 17 members to be appointed by the Secretary.

"(B) QUALIFICATIONS.—

"(i) IN GENERAL.—The membership of the Commission shall include individuals with national recognition for their expertise in clinical medicine, primary and preventive health care, integrative medicine, and actuarial science and health plan benefit design.

"(ii) INCLUSION.—The membership of the Commission shall include an expert in actuarial science and health plan benefit design, a health care provider, a patient or

consumer advocate, a representative of labor organizations representing workers, an employer, a third-party payer, a health services researcher, an individual skilled in the conduct and interpretation of the biomedical and health sciences, an individual with expertise in pediatric health care, and an individual with expertise in outcomes and effectiveness research and technology assessment.

"(C) CHAIRMAN.—The Secretary shall designate a member of the Commission who is an expert in actuarial science and health plan benefit design, at the time of appointment of such member, as Chairman.

"(D) MEETINGS.—The Commission shall meet at the call of the Chairman. Advance notice of such meetings shall be published in the Federal Register and the meetings shall be open to the public.

"(E) ETHICAL DISCLOSURES.—The Secretary shall establish a system for public disclosure by members of the Commission of financial and other potential conflicts of interest relating to such members.

"(F) DEADLINE FOR APPOINTMENT.—Members of the Commission shall be appointed by not later than 45 days after the date of enactment of this title.

"(G) TERMS OF APPOINTMENT.—The term of any appointment under subparagraph (A) to the Commission shall be for the life of the Commission.

"(H) COMPENSATION.—Members of the Commission shall receive no additional pay, allowances, or benefits by reason of their service on the Commission.

"(I) EXPENSES.—Each member of the Commission shall receive travel expenses and per diem in lieu of subsistence in accordance with sections 5702 and 5703 of title 5, United States Code.

"(5) STAFF AND SUPPORT SERVICES.—

"(A) EXECUTIVE DIRECTOR.—

"(i) APPOINTMENT.—The Secretary shall appoint an executive director of the Commission.

"(ii) COMPENSATION.—The executive director of the Commission shall be paid

the rate of basic pay for level V of the Executive Schedule.

"(iii) STAFF.—With the approval of the Commission, the executive director may appoint such personnel as the executive director considers appropriate.

"(iv) APPLICABILITY OF CIVIL SERVICE LAWS.—The staff of the Commission shall be appointed without regard to the provisions of title 5, United States Code, governing appointments in the competitive service, and shall be paid without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title (relating to classification and General Schedule pay rates).

"(v) EXPERTS AND CONSULTANTS.—With the approval of the Commission, the executive director may procure temporary and intermittent services under section 3109(b) of title 5, United States Code.

"(6) POWERS.—

"(A) COST ESTIMATES BY OFFICE OF MANAGEMENT AND BUDGET AND OFFICE OF THE CHIEF ACTUARY OF THE CENTERS FOR MEDI-

CARE & MEDICARE SERVICES.—The Director of the Office of Management and Budget or the Chief Actuary of the Centers for Medicare & Medicaid Services, or both, shall provide to the Commission, upon the request of the Commission, such cost estimates as the Commission determines to be necessary to carry out its duties under this section.

"(B) TECHNICAL ASSISTANCE.—Upon the request of the Commission, the head of a Federal agency or its representatives, including representatives of the Office of Personnel Management, shall provide such technical assistance to the Commission as the Commission determines to be necessary to carry out its duties under this section.

"(C) OBTAINING INFORMATION.—The Commission may secure directly from any Federal agency information necessary to enable it to carry out its duties, if the information may be disclosed under section 552 of title 5, United States Code.

"(D) PUBLIC INPUT.—The Commission shall adopt procedures allowing any interested party to submit information for the Commis-

sion's use in making reports and recommendations.

"(7) REPORT.—Not later than 6 months after the date of enactment of this title, the Commission shall submit a report to the Secretary and Congress which shall contain a detailed statement of only those recommendations, findings, and conclusions of the Commission that receive the approval of at least 12 members of the Commission. The Secretary shall provide for publication in the Federal Register and the posting on an appropriate Internet website of the report and recommendations of the Commission.

"(8) TERMINATION.—The Commission shall terminate on the date that is 30 days after the date on which the report is submitted under subsection (7).

"(9) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this subsection, $1,500,000.

"(c) REQUIRED ELEMENTS FOR CONSIDERATION.—

"(1) ESSENTIAL HEALTH CARE BENEFITS.—In establishing the essential health benefits under subsection (a)(1)(A), the Secretary shall—

"(A) consider the report and recommendations of the Commission established under subsection (b);

"(B) ensure that such essential health benefits reflect an appropriate balance among the categories described in such subsection, so that benefits are not unduly weighted toward any category;

"(C) not make coverage decisions, determine reimbursement rates, establish incentive programs, or design benefits in ways that discriminate against individuals because of their age, disability, or expected length of life;

"(D) take into account the health care needs of diverse segments of the population, including women, children, persons with disabilities, and other groups;

"(E) ensure that health benefits established as essential not be subject to denial to individuals against their wishes on the basis of the individuals' age or expected length of life or of the individuals' present or predicted disability, degree of medical dependency, or quality of life; and

"(F) review the essential health benefits under subsection (a)(1)(A) not less than annually, and provide a report to Congress and the public that contains—

"(i) an assessment of whether enrollees are facing any difficulty accessing needed services for reasons of coverage or cost;

"(ii) an assessment of whether the essential benefits package needs to be modified or updated to account for changes in medical evidence or scientific advancement;

"(iii) information on how the benefit package will be modified to address any such gaps in access or changes in the evidence base; and

"(iv) an assessment of the potential of additional or expanded benefits to increase costs and the interactions between the addition or expansion of benefits and reductions in existing benefits to meet actuarial limitations described in subsection (a)(2).

"(2) MINIMUM QUALIFYING COVERAGE.—In establishing the criteria described in subsection (a)(1)(B), the Secretary—

1 "(A) shall—
2 "(i) exclude from meeting such cri-
3 teria any coverage that—
4 "(I) provides reimbursement for
5 the treatment or mitigation of—
6 "(aa) a single disease or
7 condition; or
8 "(bb) an unreasonably lim-
9 ited set of diseases or conditions;
10 or
11 "(II) has an out of pocket limit
12 that exceeds the amount described in
13 section 223(c)(2) of the Internal Rev-
14 enue Code of 1986 for the year in-
15 volved; and
16 "(ii) establish such criteria (taking
17 into account the requirements established
18 under clause (i)) in a manner that results
19 in the least practicable disruption of the
20 health care marketplace, consistent with
21 the goals and activities under this title;
22 and
23 "(B) may provide for the application of
24 different criteria (except with respect to the

limitation described in subparagraph (A)(i)(II)) with respect to young adults.

"(3) AFFORDABLE COVERAGE.—The Secretary shall establish a standard under which coverage is defined to be unaffordable only if the premium paid by the individual is greater than 12.5 percent of the adjusted gross income of the individual involved. Beginning with calendar years after 2013, the Secretary shall adjust the percentage described in this paragraph by an amount that is equal to the percentage increase or decrease in the medical care component of the Consumer Price Index for all urban consumers (U.S. city average) during the preceding calendar year.

**"SEC. 3104. ALLOWING STATE FLEXIBILITY.**

"(a) OPTIONAL STATE ESTABLISHMENT OF GATEWAY.—During the 4-year period following the date of enactment of this section, a State may—

"(1)(A) establish a Gateway;

"(B) adopt the insurance reform provisions as provided for in subtitle A of title I of the Affordable Health Choices Act (and the amendments made by such title); and

"(C) agree to make employers that are State or local governments subject to sections 162 and 163 of the Affordable Health Choices Act.

"(2)(A) request that the Secretary operate (for a minimum period of 5 years) a Gateway in such State;

"(B) adopt the insurance reform provisions as provided for in subtitle A of title I of the Affordable Health Choices Act (and the amendments made by such subtitle); and

"(C) agree to make employers that are State or local governments subject to sections 162 and 163 of the Affordable Health Choices Act; or

"(3) elect not to take the actions described in paragraph (1) or (2).

"(b) ESTABLISHING STATES.—

"(1) IN GENERAL.—If the Secretary determines that a State has taken the actions described in subsection (a)(1), any resident of that State who is an eligible individual shall be eligible for credits under section 3111 beginning on the date that is 60 days after the date of such determination.

"(2) CONTINUED REVIEW.—The Secretary shall establish procedures to ensure continued review by the Secretary of the compliance of a State with the

requirements of subsection (a). If the Secretary determines that a State has failed to maintain compliance with such requirements, the Secretary may revoke the determination under paragraph (1).

"(3) DEEMING.—A State that is the subject of a positive determination by the Secretary under paragraph (1) (unless such determination is revoked under paragraph (2)) shall be deemed to be an 'establishing State' beginning on the date that is 60 days after the date of such determination.

"(c) REQUEST FOR THE SECRETARY TO ESTABLISH A GATEWAY.—

"(1) IN GENERAL.—In the case of a State that makes the request described in subsection (a)(2), the Secretary shall determine whether the State has enacted and has in effect the insurance reforms provided for in subtitle A of title I of the Affordable Health Choices Act.

"(2) OPERATION OF GATEWAY.—

"(A) POSITIVE DETERMINATION.—If the Secretary determines that the State has enacted and has in effect the insurance reforms described in paragraph (1), the Secretary shall establish a Gateway in such State as soon as practicable after making such determination.

"(B) NEGATIVE DETERMINATION.—If the Secretary determines that the State has not enacted or does not have in effect the insurance reforms described in paragraph (1), the Secretary shall establish a Gateway in such State as soon as practicable after the Secretary determines that such State has enacted and has in effect such reforms.

"(3) PARTICIPATING STATE.—The State shall be deemed to be a 'participating State' on the date on which the Gateway established by the Secretary is in effect in such State.

"(4) ELIGIBILITY.—Any resident of a State described in paragraph (3) who is an eligible individual shall be eligible for credits under section 3111 beginning on the date that is 60 days after the date on which such Gateway is established in such State.

"(d) FEDERAL FALLBACK IN THE CASE OF STATES THAT REFUSE TO IMPROVE HEALTH CARE COVERAGE.—

"(1) IN GENERAL.—Upon the expiration of the 4-year period following the date of enactment of this section, in the case of a State that is not otherwise a participating State or an establishing State—

"(A) the Secretary shall establish and operate a Gateway in such State;

"(B) the insurance reform provisions provided for in subtitle A of title I of the Affordable Health Choices Act shall become effective in such State, notwithstanding any contrary provision of State law;

"(C) the State shall be deemed to be a 'participating State'; and

"(D) the residents of that State who are eligible individuals shall be eligible for credits under section 3111 beginning on the date that is 60 days after the date on which such Gateway is established, if the State agrees to make employers that are State or local governments subject to sections 162 and 163 of the Affordable Health Choices Act.

"(2) ELIGIBILITY OF INDIVIDUALS FOR CREDITS.—With respect to a State that makes the election described in subsection (a)(3), the residents of such State shall not be eligible for credits under section 3111 until such State becomes a participating State under paragraph (1).

**"SEC. 3105. NAVIGATORS.**

"(a) IN GENERAL.—The Secretary shall award grants to establishing or participating States to enable such States (or the Gateways operating in such States)

to enter into agreements with private and public entities under which such entities will serve as navigators in accordance with this section.

"(b) ELIGIBILITY.—

"(1) IN GENERAL.—To be eligible to enter into an agreement under subsection (a), an entity shall demonstrate that the entity has existing relationships with, or could readily establish relationships with, employers and employees, consumers (including the uninsured and the underinsured), or self-employed individuals, likely to be qualified to enroll in a qualified health plan.

"(2) TYPES.—Entities described in paragraph (1) may include trade, industry and professional associations, commercial fishing industry organizations, ranching and farming organizations, community and consumer-focused nonprofit groups, chambers of commerce, unions, small business development centers, other licensed insurance agents and brokers, and other entities that the Secretary determines to be capable of carrying out the duties described in subsection (c).

"(c) DUTIES.—An entity that serves as a navigator under an agreement under subsection (a) shall—

"(1) conduct public education activities to raise awareness of the program under this title;

"(2) distribute fair and impartial information concerning enrollment in qualified health plans, and the availability of credits under section 3111;

"(3) facilitate enrollment in a qualified health plan;

"(4) provide referrals to the appropriate State agency or agencies for any enrollee with a grievance, complaint, or question regarding their health plan, coverage, or a determination under such plan or coverage; and

"(5) provide information in a manner determined by the Secretary to be culturally and linguistically appropriate to the needs of the population served by the Gateway.

"(d) STANDARDS.—

"(1) IN GENERAL.—The Secretary shall establish standards for navigators under this section, including provisions to ensure that any private or public entity that is selected as a navigator is qualified, and licensed if appropriate, to engage in the navigator activities described in this section and to avoid conflicts of interest. Under such standards, a navigator shall not—

"(A) be a health insurance issuer; or

"(B) receive any consideration directly or indirectly from any health insurance issuer in connection with the participation of any employer in the program under this title or the enrollment of any qualified individual or qualified employer in a qualified health plan.

"(2) FAIR AND IMPARTIAL INFORMATION AND SERVICES.—The Secretary, in collaboration with States, shall develop guidelines regarding the duties described in subsection (c).

**"SEC. 3106. COMMUNITY HEALTH INSURANCE OPTION.**

"(a) VOLUNTARY NATURE.—

"(1) NO REQUIREMENT FOR HEALTH CARE PROVIDERS TO PARTICIPATE.—Nothing in this section shall be construed to require a health care provider to participate in a community health insurance option, or to impose any penalty for non-participation.

"(2) NO REQUIREMENT FOR INDIVIDUALS TO JOIN.—Nothing in this section shall be construed to require an individual to participate in a community health insurance option, or to impose any penalty for non-participation.

1 "(b) ESTABLISHMENT OF COMMUNITY HEALTH IN-
2 SURANCE OPTION.—
3 "(1) ESTABLISHMENT.—The Secretary shall es-
4 tablish a community health insurance option to
5 offer, through each Gateway established under this
6 title, health care coverage that provides value,
7 choice, competition, and stability of affordable, high
8 quality coverage throughout the United States.
9 "(2) COMMUNITY HEALTH INSURANCE OP-
10 TION.—In this section, the term 'community health
11 insurance option' means health insurance coverage
12 that—
13 "(A) except as specifically provided for in
14 this section, complies with the requirements for
15 being a qualified health plan;
16 "(B) provides high value for the premium
17 charged;
18 "(C) reduces administrative costs and pro-
19 motes administrative simplification for bene-
20 ficiaries;
21 "(D) promotes high quality clinical care;
22 "(E) provides high quality customer service
23 to beneficiaries;
24 "(F) offers a wide choice of providers; and

"(G) complies with State laws (if any), except as otherwise provided for in this title, relating to—

"(i) guaranteed renewal;

"(ii) rating;

"(iii) preexisting conditions;

"(iv) non-discrimination;

"(v) quality improvement and reporting;

"(vi) fraud and abuse;

"(vii) solvency and financial requirements;

"(viii) market conduct;

"(ix) prompt payment;

"(x) appeals and grievances;

"(xi) privacy and confidentiality;

"(xii) licensure; and

"(xiii) benefit plan material or information.

"(3) ESSENTIAL HEALTH BENEFITS.—

"(A) GENERAL RULE.—Except as provided in subparagraph (B), a community health insurance option offered under this section shall provide coverage only for the essential health benefits described in section 3103.

"(B) STATES MAY OFFER ADDITIONAL BENEFITS.—A State may require that a community health insurance option offered in such State offer benefits in addition to the essential health benefits required under subparagraph (A).

"(C) CREDITS.—

"(i) IN GENERAL.—An individual enrolled in a community health insurance option under this section shall be eligible for credits under section 3111 in the same manner as an individual who is enrolled in a qualified health plan.

"(ii) NO ADDITIONAL FEDERAL COST.—A requirement by a State under subparagraph (B) that a community health insurance option cover benefits in addition to the essential health benefits required under subparagraph (A) shall not affect the amount of a credit provided under section 3111 with respect to such plan.

"(D) STATE MUST ASSUME COST.—A State shall make payments to or on behalf of an eligible individual to defray the cost of any

additional benefits described in subparagraph (B).

"(E) ENSURING ACCESS TO ALL SERVICES.—Nothing in this Act shall prohibit an individual enrolled in a community health insurance option from paying out-of-pocket the full cost of any item or service not included as an essential health benefit or otherwise covered as a benefit by a health plan. Nothing in this Act shall prohibit any type of medical provider from accepting an out-of-pocket payment from an individual enrolled in a community health insurance option for a service otherwise not included as an essential health benefit.

"(F) PROTECTING ACCESS TO END OF LIFE CARE.—A community health insurance option offered under this section shall be prohibited from limiting access to end of life care.

"(4) COST SHARING.—A community health insurance option shall offer coverage at each of the cost sharing tiers described in section 3111(a).

"(5) PREMIUMS.—

"(A) PREMIUMS SUFFICIENT TO COVER COSTS.—The Secretary shall set premium rates in an amount sufficient to cover expected costs

(including claims and administrative costs) using methods in general use by qualified health plans.

"(B) APPLICABLE RULES.—The provisions of title XXVII relating to premiums shall apply to community health insurance options under this section, including modified community rating provisions under section 2701.

"(C) COLLECTION OF DATA.—The Secretary shall collect data as necessary to set premium rates under subparagraph (A).

"(D) CONTINGENCY MARGIN.—In establishing premium rates under subparagraph (A), the Secretary shall include an appropriate amount for a contingency margin.

"(6) REIMBURSEMENT RATES.—

"(A) NEGOTIATED RATES.—The Secretary shall negotiate rates for the reimbursement of health care providers for benefits covered under a community health insurance option.

"(B) LIMITATION.—The rates described in subparagraph (A) shall not be higher, in aggregate, than the average reimbursement rates paid by health insurance issuers offering qualified health plans through the Gateway.

"(C) INNOVATION.—Subject to the limits contained in subparagraph (A), a State Advisory Council established or designated under subsection (d) may develop or encourage the use of innovative payment policies that promote quality, efficiency and savings to consumers.

"(D) PHYSICIAN NEGOTIATED RATES.—Nothing in this paragraph shall prohibit the application of a State law that permits physicians to jointly negotiate with health plans. In such State, physicians may jointly negotiate with a community health insurance option concerning rates paid by the option.

"(7) SOLVENCY AND CONSUMER PROTECTION.—

"(A) SOLVENCY.—The Secretary shall establish a Federal solvency standard to be applied with respect to a community health insurance option. A community health insurance option shall also be subject to the solvency standard of each State in which such community health insurance option is offered.

"(B) MINIMUM REQUIRED.—In establishing the standard described under subparagraph (A), the Secretary shall require a reserve

fund that shall be equal to at least the dollar value of the incurred but not reported claims of a community health insurance option.

"(C) CONSUMER PROTECTIONS.—The consumer protection laws of a State shall apply to a community health insurance option.

"(8) REQUIREMENTS ESTABLISHED IN PARTNERSHIP WITH INSURANCE COMMISSIONERS.—

"(A) IN GENERAL.—The Secretary, in collaboration with the National Association of Insurance Commissioners (in this paragraph referred to as the 'NAIC'), may promulgate regulations to establish additional requirements for a community health insurance option.

"(B) APPLICABILITY.—Any requirement promulgated under subparagraph (A) shall be applicable to such option beginning 90 days after the date on which the regulation involved becomes final.

"(9) OMBUDSMAN.—In establishing community health insurance options, the Secretary shall establish an ombudsman or similar mechanism to provide assistance to consumers with respect to disputes, grievances, or appeals.

"(c) START-UP FUND.—

"(1) ESTABLISHMENT OF FUND.—

"(A) IN GENERAL.—There is established in the Treasury of the United States a trust fund to be known as the 'Health Benefit Plan Start-Up Fund' (referred to in this section as the 'Start-Up Fund'), that shall consist of such amounts as may be appropriated or credited to the Start-Up Fund as provided for in this subsection to provide loans for the initial operations of a community health insurance option. Such amounts shall remain available until expended.

"(B) FUNDING.—There is hereby appropriated to the Start-Up Fund, out of any moneys in the Treasury not otherwise appropriated an amount requested by the Secretary of Health and Human Services as necessary to—

"(i) pay the start-up costs associated with the initial operations of a community health insurance option;

"(ii) pay the costs of making payments on claims submitted during the period that is not more than 90 days from the date on which such option is offered; and

"(iii) make payments under paragraph (3).

"(2) USE OF START-UP FUND.—The Secretary shall use amounts contained in the Start-Up Fund to make payments (subject to the repayment requirements in paragraph (5)) for the purposes described in paragraph (1)(B).

"(3) RISK CORRIDOR PAYMENTS.—

"(A) IN GENERAL.—In any case in which the Secretary has entered into a contract with a contracting administrator, the Secretary shall use amounts contained in the Start-Up Fund to make risk corridor payments to such administrator during the 2-year period beginning on the date on which such administrator enters into a contract under subsection (e). Such payments shall be based on the risk corridors in effect during fiscal years 2006 and 2007 for making payments under section 1860D-15(e) of the Social Security Act.

"(B) SUBSEQUENT YEAR.—In years after the expiration of the period referred to in subparagraph (A), the Secretary may extend or increase the risk corridors and payments provided for under subparagraph (A).

"(C) AMOUNT USED TO REDUCE COSTS.—The Secretary shall deposit any payments received from a contracting administrator under subparagraph (A) into the Start-Up Fund.

"(4) PASS THROUGH OF REBATES.—The Secretary may establish procedures for reducing the amount of payments to a contracting administrator to take into account any rebates or price concessions.

"(5) REPAYMENT.—

"(A) IN GENERAL.—A community health insurance option shall be required to repay the Secretary of the Treasury (on such terms as the Secretary may require) for any payments made under paragraph (1)(B) by the date that is not later than 10 years after the date on which the payment is made. The Secretary may require the payment of interest with respect to such repayments at rates that do not exceed the market interest rate (as determined by the Secretary).

"(B) SANCTIONS IN CASE OF FOR-PROFIT CONVERSION.—In any case in which the Secretary enters into a contract with a qualified entity for the offering of a community health

insurance option and such entity is determined to be a for-profit entity by the Secretary, such entity shall be—

"(i) immediately liable to the Secretary for any payments received by such entity from the Start-Up Fund; and

"(ii) permanently ineligible to offer a qualified health plan.

"(d) STATE ADVISORY COUNCIL.—

"(1) ESTABLISHMENT.—A State shall establish or designate a public or non-profit private entity to serve as the State Advisory Council to provide recommendations to the Secretary on the operations and policies of a community health insurance option in the State. Such Council shall provide recommendations on at least the following:

"(A) policies and procedures to integrate quality improvement and cost containment mechanisms into the health care delivery system;

"(B) mechanisms to facilitate public awareness of the availability of a community health insurance option; and

"(C) alternative payment structures under a community health insurance option for health

1 care providers that encourage quality improve-
2 ment and cost control.
3 ''(2) MEMBERS.—The members of the State
4 Advisory Council shall be representatives of the pub-
5 lic and shall include educated health care consumers
6 and providers.
7 ''(3) APPLICABILITY OF RECOMMENDATIONS.—
8 The Secretary may apply the recommendations of a
9 State Advisory Council to a community health insur-
10 ance option that State, in any other State, or in all
11 States.
12 ''(e) AUTHORITY TO CONTRACT; TERMS OF CON-
13 TRACT.—
14 ''(1) AUTHORITY.—
15 ''(A) IN GENERAL.—The Secretary may
16 enter into a contract or contracts with one or
17 more qualified entities for the purpose of per-
18 forming administrative functions (including
19 functions described in subsection (a)(4) of sec-
20 tion 1874A of the Social Security Act) with re-
21 spect to a community health insurance option in
22 the same manner as the Secretary may enter
23 into contracts under subsection (a)(1) of such
24 section. The Secretary shall have the same au-
25 thority with respect to a community health in-

surance option under this section as the Secretary has under subsections (a)(1) and (b) of section 1874A of the Social Security Act with respect to title XVIII of such Act.

"(B) REQUIREMENTS APPLY.—If the Secretary enters into a contract with a qualified entity to offer a community health insurance option, under such contract such entity—

"(i) shall meet the criteria established under paragraph (2); and

"(ii) shall receive an administrative fee under paragraph (7).

"(C) LIMITATION.—Contracts under this subsection shall not involve the transfer of insurance risk to the contracting administrator.

"(D) REFERENCE.—An entity with which the Secretary has entered into a contract under this paragraph shall be referred to as a 'contracting administrator'.

"(2) QUALIFIED ENTITY.—To be qualified to be selected by the Secretary to offer a community health insurance option, an entity shall—

"(A) meet the criteria established under section 1874A(a)(2) of the Social Security Act;

"(B) be a nonprofit entity for purposes of offering such option;

"(C) meet the solvency standards applicable under subsection (b)(7);

"(D) be eligible to offer health insurance or health benefits coverage;

"(E) meet quality standards specified by the Secretary;

"(F) have in place effective procedures to control fraud, abuse, and waste; and

"(G) meet such other requirements as the Secretary may impose.

"Procedures described under subparagraph (F) shall include the implementation of procedures to use beneficiary identifiers to identify individuals entitled to benefits so that such an individual's social security account number is not used, and shall also include procedures for the use of technology (including front-end, prepayment intelligent data-matching technology similar to that used by hedge funds, investment funds, and banks) to provide real-time data analysis of claims for payment under this title to identify and investigate unusual billing or order practices under this title that could indicate fraud or abuse.

"(3) TERM.—A contract provided for under paragraph (1) shall be for a term of at least 5 years but not more than 10 years, as determined by the Secretary. At the end of each such term, the Secretary shall conduct a competitive bidding process for the purposes of renewing existing contracts or selecting new qualified entities with which to enter into contracts under such paragraph.

"(4) LIMITATION.—A contract may not be renewed under this subsection unless the Secretary determines that the contracting administrator has met performance requirements established by the Secretary in the areas described in paragraph (7)(B).

"(5) AUDITS.—The Inspector General shall conduct periodic audits with respect to contracting administrators under this subsection to ensure that the administrator involved is in compliance with this section.

"(6) REVOCATION.—A contract awarded under this subsection shall be revoked by the Secretary or the Inspector General only after notice to the contracting administrator involved and an opportunity for a hearing. The Secretary may revoke such contract if the Secretary determines that such administrator has engaged in fraud, deception, waste, abuse

of power, negligence, mismanagement of taxpayer dollars, or gross mismanagement. An entity that has had a contract revoked under this paragraph shall not be qualified to enter into a subsequent contract under this subsection.

"(7) FEE FOR ADMINISTRATION.—

"(A) IN GENERAL.—The Secretary shall pay the contracting administrator a fee for the management, administration, and delivery of the benefits under this section.

"(B) REQUIREMENT FOR HIGH QUALITY ADMINISTRATION.—The Secretary may increase the fee described in subparagraph (A) by not more than 10 percent, or reduce the fee described in subparagraph (A) by not more than 50 percent, based on the extent to which the contracting administrator, in the determination of the Secretary, meets performance requirements established by the Secretary, in at least the following areas:

"(i) Maintaining low premium costs and low cost sharing requirements, provided that such requirements are consistent with section 3111(a).

"(ii) Reducing administrative costs and promoting administrative simplification for beneficiaries.

"(iii) Promoting high quality clinical care.

"(iv) Providing high quality customer service to beneficiaries.

"(C) NON-RENEWAL.—The Secretary may not renew a contract to offer a community health insurance option under this section with any contracting entity that has been assessed more than one reduction under subparagraph (B) during the contract period.

"(8) LIMITATION.—Notwithstanding the terms of a contract under this subsection, the Secretary shall negotiate the reimbursement rates for purposes of subsection (b)(6).

"(f) REPORT BY HHS AND INSOLVENCY WARNINGS.—

"(1) IN GENERAL.—On an annual basis, the Secretary shall conduct a study on the solvency of a community health insurance option and submit to Congress a report describing the results of such study.

"(2) RESULT.—If, in any year, the result of the study under paragraph (1) is that a community health insurance option is insolvent, such result shall be treated as a community health insurance option solvency warning.

"(3) SUBMISSION OF PLAN AND PROCEDURE.—

"(A) IN GENERAL.—If there is a community health insurance option solvency warning under paragraph (2) made in a year, the President shall submit to Congress, within the 15-day period beginning on the date of the budget submission to Congress under section 1105(a) of title 31, United States Code, for the succeeding year, proposed legislation to respond to such warning.

"(B) PROCEDURE.—In the case of a legislative proposal submitted by the President pursuant to subparagraph (A), such proposal shall be considered by Congress using the same procedures described under sections 803 and 804 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 that shall be used for a medicare funding warning.

"(g) MARKETING PARITY.—In a facility controlled by the Federal Government, or by a State, where marketing

or promotional materials related to a community health insurance option are made available to the public, making available marketing or promotional materials relating to private health insurance plans shall not be prohibited. Such materials include informational pamphlets, guidebooks, enrollment forms, or other materials determined reasonable for display.

''(h) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated, such sums as may be necessary to carry out this section.

**"SEC. 3107. APPLICATION OF SAME LAWS TO PRIVATE PLANS AND THE COMMUNITY HEALTH INSURANCE OPTION.**

''(a) IN GENERAL.—Notwithstanding any other provision of law, any health insurance coverage offered by a private health insurance issuer shall not be subject to any Federal or State law described in subsection (b) if a community health insurance option under section 3106 is not subject to such law.

''(b) LAWS DESCRIBED.—The Federal and State laws described in this subsection are those Federal and State laws relating to—

''(1) guaranteed renewal;

''(2) rating;

''(3) preexisting conditions;

1 ''(4) non-discrimination;
2 ''(5) quality improvement and reporting;
3 ''(6) fraud and abuse;
4 ''(7) solvency and financial requirements;
5 ''(8) market conduct;
6 ''(9) prompt payment;
7 ''(10) appeals and grievances;
8 ''(11) privacy and confidentiality;
9 ''(12) licensure; and
10 ''(13) benefit plan material or information.

11 **''SEC. 3108. PARTICIPATION OF PROFESSIONALS ON CER-**
12 **TAIN HEALTH-RELATED COMMISSIONS.**

13 ''The membership of any council, committee, or other
14 advisory body which the Secretary uses to inform official
15 decision-making related to coverage of, or payment for,
16 medical procedures, conditions, or care, shall have as its
17 participants professionals who hold medical degrees from
18 accredited American universities or colleges and have ac-
19 tive clinical practice. Such advisory entities shall be com-
20 posed of not less than one-third of such professionals.

21 **''SEC. 3109. HEALTH INSURANCE CONSUMER ASSISTANCE**
22 **GRANTS.**

23 ''(a) IN GENERAL.—The Secretary shall award
24 grants to establishing or participating States to enable
25 such States (or the Gateways operating in such States)

to establish, expand, or provide support for offices of health insurance consumer assistance.

"(b) ELIGIBILITY.—

"(1) IN GENERAL.—To be eligible to receive a grant, a State shall designate an office of health insurance consumer assistance that, directly or in coordination with State health insurance regulators and consumer assistance organizations, receives and responds to inquiries and complaints concerning health insurance coverage with respect to Federal health insurance requirements and under State law.

"(2) CRITERIA.—A State that receives a grant under this section shall comply with criteria established by the Secretary for carrying out activities under such grant.

"(c) DUTIES.—The State-designated office of health insurance consumer assistance shall—

"(1) assist with the filing of complaints and appeals, including filing appeals with a qualified health plan's internal appeal or grievance process and providing information about the external appeal process;

"(2) track consumer complaints, quantify such complaints, and regularly report such complaints to the State Gateway or the Secretary, as necessary;

"(3) educate consumers on their rights and responsibilities with respect to qualified health plans; and

"(4) assist consumers with enrollment in a qualified health plan by providing information, referral, and assistance, in collaboration with navigators under section 3105.

"(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $20,000,000 for fiscal year 2010, and such sums as may be necessary for each fiscal year thereafter.".

**SEC. 143. FREEDOM NOT TO PARTICIPATE IN FEDERAL HEALTH INSURANCE PROGRAMS.**

(a) REQUIREMENT.—Notwithstanding any other provision of law, on the date of enactment of this Act, all Members of Congress and congressional staff shall enroll in a Federal health insurance program—

(1) created under this Act (or an amendment made by this Act); or

(2) offered through a Gateway established under this Act (or an amendment made by this Act).

(b) DEFINITIONS.—In this section:

(1) MEMBER OF CONGRESS.—The term "Member of Congress" means any member of the House of Representatives or the Senate.

(2) CONGRESSIONAL STAFF.—The term ''congressional staff'' means all full-time and part-time employees employed by the official office of a Member of Congress, whether in Washington, DC or outside of Washington, DC.

# Subtitle C—Affordable Coverage for All Americans

**SEC. 151. SUPPORT FOR AFFORDABLE HEALTH COVERAGE.**

(a) IN GENERAL.—Title XXXI of the Public Health Service Act, as added by section 142(a), is amended by inserting after subtitle A the following:

# "Subtitle B—Making Coverage Affordable

**"SEC. 3111. SUPPORT FOR AFFORDABLE HEALTH COVERAGE.**

''(a) COST SHARING FOR A BASIC PLAN.—

''(1) BASIC PLAN.—The Secretary shall establish at least the following tiers of cost sharing for eligible individuals:

''(A) A tier for a basic plan in which—

''(i) a qualified health plan shall, on average, provide reimbursement for 76 percent of the total allowed costs of the benefit provided; and

"(ii) the out of pocket limitation for the plan shall not be greater than the out of pocket limitation applicable under section 223(c)(2) of the Internal Revenue Code of 1986.

"(B) A tier in which—

"(i) the average reimbursement percentage is equal to the reimbursement percentage of the basic plan increased by 8 percentage points; and

"(ii) the dollar value of the out of pocket limitation shall not be greater than 50 percent of the dollar value of the out of pocket limitation of the basic plan.

"(C) A tier in which—

"(i) the average reimbursement percentage is equal to the reimbursement percentage of the basic plan increased by 17 percentage points; and

"(ii) the dollar value of the out of pocket limitation shall not be greater than 20 percent of the dollar value of the out of pocket limitation of the basic plan.

"(2) OUT OF POCKET.—For purposes of this section, the term 'out of pocket' shall include all ex-

1 penditures for covered qualified medical expenses (as
2 provided for with respect to high deductible health
3 plans under section 223(d)(2) of the Internal Rev-
4 enue Code of 1986).
5 "(b) PAYMENT OF CREDITS.—
6 "(1) IN GENERAL.—The Secretary shall, with
7 respect to an eligible individual (as defined in section
8 3116(a)(1)) and on behalf of such individual, pay a
9 premium credit to the Gateway through which the
10 individual is enrolled in the qualified health plan in-
11 volved. Such Gateway shall remit an amount equal
12 to such credit to the qualified health plan in which
13 such individual is enrolled.
14 "(2) AMOUNT.—
15 "(A) IN GENERAL.—Subject to the index-
16 ing provision described in paragraph (6), and
17 the limitation described in paragraph (4), the
18 amount of an annual credit with respect to an
19 eligible individual under paragraph (1) shall be
20 an amount determined by the Secretary so that
21 the eligible individual involved is not required to
22 pay in the case of an individual with an ad-
23 justed gross income equal to 400 percent of the
24 poverty line for a family of the size involved, an

amount that exceeds 12.5 percent of such individual's income for the year involved.

"(B) REDUCTIONS BASED ON INCOME.—The amount that an eligible individual is required to pay under subparagraph (A) shall be ratably reduced to 1 percent of income in the case of an eligible individual with an adjusted gross income equal to 150 percent of the poverty line for a family of the size involved for the year.

"(3) SIMPLIFIED SCHEDULE.—The Secretary may establish a schedule of premium credits under this subsection in dollar amounts to simplify the administration of this section so long as any such schedule does not significantly change the value of the premium credits described in paragraph (2).

"(4) LIMITATION OF CREDITS.—

"(A) IN GENERAL.—A credit under paragraph (1) may not exceed the lesser of the amount of the reference premium for the individual involved or the premium of the qualified health plan in which such individual is enrolled.

"(B) REFERENCE PREMIUM.—In this section, the term 'reference premium' means—

"(i) with respect to an individual enrolling in coverage whose adjusted gross income does not exceed 200 percent of the poverty line for a family of the size involved for the year, the weighted average annual premium of the 3 lowest cost qualified health plans that—

"(I) meet the criteria for cost sharing and out of pocket limits described in subsection (a)(1)(C); and

"(II) are offered in the community rating area in which the individual resides;

"(ii) with respect to an individual enrolling in coverage whose adjusted gross income exceeds 200, but does not exceed 300, percent of the poverty line for a family of the size involved for the year, the weighted average annual premium of the 3 lowest cost qualified health plans that—

"(I) meet the criteria for cost sharing and out of pocket limits described in subsection (a)(1)(B); and

"(II) are offered in the community rating area in which the individual resides; and

"(iii) with respect to an individual enrolling in coverage whose adjusted gross income exceeds 300, but does not exceed 400, percent of the poverty line for a family of the size involved for the year, the weighted average annual premium of the 3 lowest cost qualified health plans that—

"(I) meet the criteria for cost sharing and out of pocket limits described in subsection (a)(1)(A); and

"(II) are offered in the community rating area in which the individual resides.

"(C) INDIVIDUALS ALLOWED TO ENROLL IN ANY PLAN.—Nothing in this section shall be construed to prohibit a qualified individual from enrolling in any qualified health plan.

"(D) LIMITATION.—In determining the 3 lowest cost health plans for purposes of this paragraph, the community health insurance option shall not be considered.

"(5) METHOD OF CALCULATION.—

"(A) CALCULATION OF CREDIT BASED ON ESSENTIAL HEALTH CARE BENEFITS.—In the case of a qualified health plan that provides reimbursement for benefits that are not included in the essential health benefits established by the Secretary under section 3103(a)(1)(A), the reference premium shall be determined for purposes of paragraph (2) without regard to such reimbursement.

"(B) RISK ADJUSTMENT.—The reference premium shall be adjusted to account for premium differences based on age, family size, and geographic variation.

"(C) RULE IN CASE OF FEWER PLANS.—In any case in which there are less than 3 qualified health plans offered in the community rating area in which the individual resides, the determinations made under paragraph (2) shall be based on the number of such qualified plans that are actually offered in the area.

"(6) INDEXING.—Beginning with calendar years after 2013, the percentages described in paragraph (2) that specify the portion of the reference premium that an individual or family is responsible for paying shall be annually adjusted by a percent-

1 age that is equal to the percentage increase or de-
2 crease in the medical care component of the Con-
3 sumer Price Index for all urban consumers (U.S.
4 city average) during the preceding calendar year.
5 "(c) STATE FLEXIBILITY.—A State may make pay-
6 ments to or on behalf of an eligible individual that are
7 greater than the amounts required under this section.
8 "(d) ELIGIBILITY DETERMINATIONS.—
9 "(1) RULE FOR ELIGIBILITY DETERMINA-
10 TIONS.—The Secretary shall, by regulation, establish
11 rules and procedures for—
12 "(A) the submission of applications during
13 the fourth quarter of the calendar year involved
14 for payments under this section, including the
15 electronic submission of documents necessary
16 for application and enrollment;
17 "(B) making determinations with respect
18 to the eligibility of individuals submitting appli-
19 cations under subparagraph (A) for payments
20 under this section and informing individuals of
21 such determinations, including verifying income
22 through the use of data contained in the tax re-
23 turns of applicants for such credits;
24 "(C) making determinations of adjusted
25 gross income in cases where the individual ap-

plicant was not required to file a tax return for the taxable year involved;

"(D) resolving appeals of such determinations;

"(E) redetermining eligibility on a periodic basis; and

"(F) making payments under this section.

"(2) DETERMINATION OF ELIGIBILITY.—For purposes of paragraph (1), the Secretary shall establish rules that permit eligibility to be determined based on—

"(A) the applicant's adjusted gross income for the second preceding taxable year; or

"(B) in the case of an individual who is seeking payment under this section based on claiming a significant decrease in adjusted gross income—

"(i) the applicant's adjusted gross income for the most recent period otherwise practicable; or

"(ii) the applicant's declaration of estimated annual adjusted gross income for the year involved.

"(3) DETERMINING ELIGIBILITY.—

"(A) AUTHORITY OF THE SECRETARY.—

"(i) IN GENERAL.—The Secretary shall have the authority to make determinations (including redeterminations) with respect to the eligibility of individuals submitting applications for credits under this section. The Secretary shall verify, through the Internal Revenue Service or using the income and eligibility verification system utilized for purposes of the Medicaid program under section 1137 of the Social Security Act, the income data received from individuals submitting applications for credits under this section.

"(ii) AUTHORITY TO USE TAX RETURNS.—To be eligible to receive a credit under this section, an individual shall—

"(I) authorize the disclosure of the tax return information of the individual as provided for in section 6103(l)(21) of the Internal Revenue Code; or

"(II) with respect to individuals who do not file a tax return for the year involved—

"(aa) provide satisfactory documentation of adjusted gross income, as determined by the Secretary, which may include a prior year Federal income tax return; and

"(bb) authorize the disclosure to the Secretary of such information as may be required from the Internal Revenue Service to verify that such individual has not filed a tax return for the year involved.

"(iii) STRINGENCY.—The verification requirements with respect to individuals described in clause (ii)(II) shall be at least as stringent as those required under section 1137 of the Social Security Act.

"(B) DELEGATION OF AUTHORITY.—Except under the conditions described in subparagraph (D), the Secretary shall delegate to a Gateway (and, upon request from such State or States, to the State or States in which such Gateway operates) the authority to carry out the activities described in subparagraph (A).

The Gateway may consult with the Internal Revenue Service to verify income data received from individuals submitting applications for credits under this section.

"(C) REQUIREMENT FOR CONSISTENCY.—A Gateway (and, as applicable, the State or States in which such Gateway operates) shall carry out the activities described in subparagraph (B) in a manner that is consistent with the regulations promulgated under paragraph (1).

"(D) REVOCATION OF AUTHORITY.—If the Secretary determines that a Gateway (or the State or States in which such Gateway operates) is carrying out the activities described in subparagraph (A) in a manner that is substantially inconsistent with the regulations promulgated under paragraph (1), the Secretary may, after notice and opportunity for a hearing, revoke the delegation of authority under subparagraph (A). If the Secretary revokes the delegation of authority, the references to a Gateway in subparagraph (E) and (F) shall be deemed to be references to the Secretary.

"(E) REQUIREMENT TO REPORT CHANGE IN STATUS.—

"(i) IN GENERAL.—An individual who has been determined to be eligible for credits under this section shall notify the Gateway of any changes that may affect such eligibility in a manner specified by the Secretary.

"(ii) REDETERMINATION.—If the Gateway receives a notice from an individual under clause (i), the Gateway shall promptly redetermine the individual's eligibility for payments.

"(F) TERMINATION OF PAYMENTS.—The Gateway shall terminate payments on behalf of an individual (after providing notice to the individual) if—

"(i) the individual fails to provide information for purposes of subparagraph (E)(i) on a timely basis; or

"(ii) the Gateway determines that the individual is no longer eligible for such payments.

"(G) TERRITORIAL TAX AUTHORITIES.—With respect to determinations of eligibility for,

or payment of, credits under this section that require the use of information maintained by a tax authority of a United States territory, the Secretary shall make such determination in coordination with such authority under rules and procedures that are similar to the rules and procedures applied to determinations made where such information is obtained from the Internal Revenue Service.

"(4) APPLICATION.—

"(A) METHODS.—The process established under paragraph (1)(A) shall permit applications in person, by mail, telephone, or the Internet.

"(B) FORM AND CONTENTS.—An application under paragraph (1)(A) shall be in such form and manner as specified by the Secretary, and may require documentation.

"(C) SUBMISSION.—An application under paragraph (1)(A) may be submitted to the Gateway, or to a State agency for a determination under this section.

"(D) ASSISTANCE.—A Gateway, or a State agency under this section, shall assist individ-

uals in the filing of applications under paragraph (1)(A).

"(5) RECONCILIATION.—

"(A) FILING OF STATEMENT.—In the case of an individual who has received payments under this section for a year and who is claiming a significant decrease (as determined by the Secretary) in adjusted gross income from such year, such individual shall file with the Secretary an income reconciliation statement, at such time, in such manner, and containing such information as the Secretary may require.

"(B) RECONCILIATION.—

"(i) IN GENERAL.—Based on and using the adjusted gross income reported in the statement filed by an individual under subparagraph (A), the Secretary shall compute the amount of payments that should have been provided on behalf of the individual for the year involved.

"(ii) OVERPAYMENT OF PAYMENTS.—

"(I) IN GENERAL.—Subject to the limitation in subclause (II), if the amount of payments provided on behalf of an individual for a year under

this section was significantly greater (as determined by the Secretary) than the amount computed under clause (i), the individual shall be liable to the Secretary for such excess amount. The Secretary may establish methods under which such liability may be assessed through a reduction in the amount of any credit otherwise applicable under this section with respect to such individual.

"(II) LIMITATION.—With respect to any individual described in subclause (I) who had a verified adjusted gross income that did not exceed 400 percent of the poverty line for a family of the size involved for such year, the amount of any repayment under such subclause (I) shall not exceed—

"(aa) $250 for an individual who filed an individual tax return for such year; or

"(bb) $400 for an individual who filed a joint tax return for such year.

Any such individual with a adjusted gross income that exceeds 400 percent of the poverty line for a family of the size involved for such year shall repay the entire amount so received.

"(iii) UNDERPAYMENT OF PAYMENTS.—If the amount of payments provided to an individual for a year under this section was less than the amount computed under clause (i), the Secretary shall pay to the individual the amount of such deficit. The Secretary may establish methods under which such payments may be provided through an increase in the amount of any credit otherwise applicable under this section with respect to such individual.

"(iv) COORDINATION WITH IRS.—The Secretary shall coordinate with the Secretary of the Treasury to develop procedures to enable the Internal Revenue Service to administer this subparagraph with respect to the collection of overpayments.

"(C) FAILURE TO FILE.—In the case of an individual who fails to file a statement for a year as required under subparagraph (A), the

individual shall not be eligible for further payments until such statement is filed. The Secretary shall waive the application of this subparagraph if the individual establishes, to the satisfaction of the Secretary, good cause for the failure to file the statement on a timely basis.

"(D) DETERMINATIONS.—The Secretary shall make determinations with respect to statements submitted under this paragraph based on income data from the most recent tax return filed by the individual.

"(6) DETERMINATIONS MADE WITH RESPECT TO SAME TAXABLE YEARS.—In making determinations under this section with respect to adjusted gross income as compared to the poverty line, the Secretary shall ensure that the poverty line data used relates to the same taxable year for which the adjusted gross income is determined.

"(7) OUTREACH.—The Gateway shall conduct culturally and linguistically appropriate outreach activities to provide information to individuals that may potentially be eligible for payments under this section. Such activities shall include information on the application process with respect to such payments.

"(e) EXCLUSION FROM INCOME.—Amounts received by an individual under this section shall not be considered as income, and shall not be taken into account in determining assets or resources for purposes of determining the eligibility of such individual, or any other individual, for benefits or assistance, or the amount or extent of benefits or assistance, under any Federal program or under any State or local program financed in whole or in part with Federal funds.

"(f) CONFLICT.—A Gateway may not establish rules that conflict with or prevent the application of regulations promulgated by the Secretary under this title.

"(g) NO FEDERAL FUNDING.—Nothing in this title shall allow Federal payments for individuals who are not lawfully present in the United States.

"(h) APPROPRIATION.—Out of any funds in the Treasury of the United States not otherwise appropriated, there are appropriated such sums as may be necessary to carry out this section for each fiscal year.

**"SEC. 3112. SMALL BUSINESS HEALTH OPTIONS PROGRAM CREDIT.**

"(a) CALCULATION OF CREDIT.—For each calendar year beginning in calendar year 2010, in the case of an employer that is a qualified small employer, out of any funds in the Treasury of the United States not otherwise

appropriated, the Secretary shall make a payment to such qualified small employer in the amount described in subsection (b).

"(b) GENERAL CREDIT AMOUNT.—For purposes of this section:

"(1) IN GENERAL.—The credit amount described in this subsection shall be the product of—

"(A) the applicable amount specified in paragraph (2);

"(B) the employer size factor specified in paragraph (3); and

"(C) the percentage of year factor specified in paragraph (4).

"(2) APPLICABLE AMOUNT.—For purposes of paragraph (1):

"(A) IN GENERAL.—The applicable amount shall be equal to—

"(i) $1,000 for each employee of the employer who receives self-only health insurance coverage through the employer;

"(ii) $2,000 for each employee of the employer who receives family health insurance coverage through the employer; and

"(iii) $1,500 for each employee of the employer who receives health insurance

coverage for two adults or one adult and one or more children through the employer.

"(B) BONUS FOR PAYMENT OF GREATER PERCENTAGE OF PREMIUMS.—The applicable amount specified in subparagraph (A) shall be increased by $200 in the case of subparagraph (A)(i), $400 in the case of subparagraph (A)(ii), and $300 in the case of subparagraph (A)(iii), for each additional 10 percent of the qualified employee health insurance expenses exceeding 60 percent which are paid by the qualified small employer.

"(3) EMPLOYER SIZE FACTOR.—For purposes of paragraph (1), the employer size factor shall be the percentage determined in accordance with the following:

"(A) With respect to an employer with 10 or fewer employees, the percentage shall be 100 percent.

"(B) With respect to an employer with more than 10, but not more than 20, full-time employees, the percentage shall be 80 percent.

"(C) With respect to an employer with more than 20, but not more than 30, full-time employees, the percentage shall be 50 percent.

"(D) With respect to an employer with more than 30, but not more than 40, full-time employees, the percentage shall be 40 percent.

"(E) With respect to an employer with more than 40, but not more than 50, full-time employees, the percentage shall be 20 percent.

"(F) With respect to an employer with more than 50 full-time employees, the percentage shall be 0 percent.

"(4) PERCENTAGE OF YEAR FACTOR.—For purposes of paragraph (1), the percentage of year factor shall be equal to the ratio of—

"(A) the number of months during the year for which the employer paid or incurred at least 60 percent of the qualified employee health insurance expenses of such employer; and

"(B) 12.

"(c) DEFINITIONS AND SPECIAL RULES.—For purposes of this section:

"(1) QUALIFIED SMALL EMPLOYER.—

"(A) IN GENERAL.—The term 'qualified small employer' means an employer (as defined in section 3(d) of the Fair Labor Standards Act

of 1938 and including self-employed individuals) that—

"(i) pays or incurs at least 60 percent of the qualified employee health insurance expenses of such employer, or who is self-employed; and

"(ii) was—

"(I) an employer that—

"(aa) employed an average of 50 or fewer full-time employees during the preceding taxable year; and

"(bb) had an average wage of less than $50,000 for full time employees in the preceding taxable year; or

"(II) a self-employed individual that—

"(aa) had not less than $5,000 in net earnings;

"(bb) had not greater than $50,000 in net earnings; and

"(cc) has elected not to receive a credit under section 3111.

"(B) LIMITATION.—An employer may not receive a credit under this section for more than 1 period of not more than 3 consecutive years.

"(2) QUALIFIED EMPLOYEE HEALTH INSURANCE EXPENSES.—

"(A) IN GENERAL.—The term 'qualified employee health insurance expenses' means any amount paid by an employer or an employee of such employer for health insurance coverage to the extent such amount is for coverage—

"(i) provided to any employee (as defined in section 3(e) of the Fair Labor Standards Act of 1938), or

"(ii) for a self-employed individual.

"(B) EXCEPTION FOR AMOUNTS PAID UNDER SALARY REDUCTION ARRANGEMENTS.—No amount paid or incurred for health insurance coverage pursuant to a salary reduction arrangement shall be taken into account for purposes of subparagraph (A).

"(3) FULL-TIME EMPLOYEE.—The term 'full time employee' means, with respect to any period, an employee (as defined in section 3(e) of the Fair Labor Standards Act of 1938) of an employer if the average number of hours worked by such employee

in the preceding taxable year for such employer was at least 40 hours per week.

"(d) INFLATION ADJUSTMENT.—

"(1) IN GENERAL.—For each calendar year after 2010, the dollar amounts specified in subsections (b)(2)(A), (b)(2)(B), and (c)(1)(A)(ii) (after the application of this paragraph) shall be the amounts in effect in the preceding calendar year or, if greater, the product of—

"(A) the corresponding dollar amount specified in such subsection; and

"(B) the ratio of the index of wage inflation (as determined by the Bureau of Labor Statistics) for August of the preceding calendar year to such index of wage inflation for August of 2008.

"(2) ROUNDING.—If any amount determined under paragraph (1) is not a multiple of $100, such amount shall be rounded to the next lowest multiple of $100.

"(e) APPLICATION OF CERTAIN RULES IN DETERMINATION OF EMPLOYER SIZE.—For purposes of this section:

"(1) APPLICATION OF AGGREGATION RULE FOR EMPLOYERS.—All persons treated as a single em-

ployer under subsection (b), (c), (m), or (o) of section 414 of the Internal Revenue Code of 1986 shall be treated as 1 employer.

"(2) EMPLOYERS NOT IN EXISTENCE IN PRECEDING YEAR.—In the case of an employer which was not in existence for the full preceding taxable year, the determination of whether such employer meets the requirements of this section shall be based on the average number of full-time employees that it is reasonably expected such employer will employ on business days in the employer's first full taxable year.

"(3) PREDECESSORS.—Any reference in this subsection to an employer shall include a reference to any predecessor of such employer.".

**SEC. 152. PROGRAM INTEGRITY.**

(a) IN GENERAL.—Subsection (l) of section 6103 of the Internal Revenue Code of 1986 is amended by adding at the end the following new paragraph:

"(21) VOLUNTARY AUTHORIZATION FOR INCOME VERIFICATION.—

"(A) VOLUNTARY AUTHORIZATION.—The Secretary shall provide a mechanism for each taxpayer to indicate whether such taxpayer authorizes the Secretary to disclose to the Sec-

retary of Health and Human Services (or, pursuant to a delegation described in subsection (d)(4)(B), to a State or a Gateway (as defined in section 3101 of the Public Health Service Act) return information of a taxpayer who may be eligible for credits under section 3111 of the Public Health Service Act.

"(B) PROVISION OF INFORMATION.—If a taxpayer authorizes the disclosure described in subparagraph (A), the Secretary shall disclose to the Secretary of Health and Human Services (or, pursuant to a delegation described in subsection (d)(4)(B), to a State or a Gateway) the minimum necessary amount of information necessary to establish whether such individual is eligible for credits under section 3111 of the Public Health Service Act.

"(C) RESTRICTION ON USE OF DISCLOSED INFORMATION.—Return information disclosed under subparagraph (A) may be used by the Secretary (or, pursuant to a delegation described in subsection (d)(4)(B), a State or a Gateway) only for the purposes of, and to the extent necessary in, establishing the appropriate

amount of any payments under section 3111 of the Public Health Service Act.''.

(b) COLLECTION OF AMOUNTS.—Section 6305(a) of the Internal Revenue Code of 1986 is amended by inserting ''or under section 3111 of the Public Health Service Act'' after ''Social Security Act''.

(c) CONFORMING AMENDMENTS.—

(1) Paragraph (3) of section 6103(a) of such Code is amended by striking ''or (20)'' and inserting ''(20), or (21)''.

(2) Paragraph (4) of section 6103(p) of such Code is amended by striking ''(l)(10), (16), (18), (19), or (20)'' each place it appears and inserting ''(l)(10), (16), (18), (19), (20), or (21)''.

(3) Paragraph (2) of section 7213(a) of such Code is amended by striking ''or (20)'' and inserting ''(20), or (21)''.

# Subtitle D—Shared Responsibility for Health Care

**SEC. 161. INDIVIDUAL RESPONSIBILITY.**

(a) PAYMENTS.—

(1) IN GENERAL.—Subchapter A of chapter 1 of the Internal Revenue Code of 1986 (relating to determination of tax liability) is amended by adding at the end the following new part:

## "PART VIII—SHARED RESPONSIBILITY PAYMENTS

"Sec. 59B. Shared responsibility payments.

**"SEC. 59B. SHARED RESPONSIBILITY PAYMENTS.**

"(a) REQUIREMENT.—Every individual shall ensure that such individual, and each dependent of such individual, is covered under qualifying coverage at all times during the taxable year.

"(b) PAYMENT.—

"(1) IN GENERAL.—

"(A) IN GENERAL.—In the case of any individual who did not have in effect qualifying coverage (as defined in section 3116 of the Public Health Service Act) for any month during the taxable year, there is hereby imposed for the taxable year, in addition to any other amount imposed by this subtitle, an amount equal to the amount established under paragraph (2).

"(B) RULE FOR DEPENDENTS.—Any amount to be imposed under this subsection with respect to an individual described in subparagraph (A) that is a dependent (as defined in section 152) of another taxpayer shall be imposed—

"(i) except in any case described in clause (ii), upon the taxpayer on whom such individual is a dependent; or

"(ii) in any case in which the taxpayer with respect to whom such individual is a dependent files a joint return, jointly upon the taxpayer and the spouse of the taxpayer.

"(C) LIMITATION.—The maximum amount imposed under this paragraph with respect to any taxpayer shall not exceed 4 times the amount determined under paragraph (2)(D).

"(2) AMOUNT ESTABLISHED.—

"(A) REQUIREMENT TO ESTABLISH.—Not later than June 30 of each calendar year, the Secretary, in consultation with the Secretary of Health and Human Services and with the States, shall establish an amount for purposes of paragraph (1).

"(B) EFFECTIVE DATE.—The amount established under subparagraph (A) shall be effective with respect to the taxable year following the date on which the amount under subparagraph (A) is established.

"(C) REQUIRED CONSIDERATION.—Subject to the limitation described in subparagraph (D), in establishing the amount under subparagraph (A), the Secretary shall seek to establish the minimum practicable amount that can accomplish the goal of enhancing participation in qualifying coverage (as so defined).

"(D) LIMITATION.—

"(i) IN GENERAL.—Subject to an adjustment under clause (ii), the amount established under this subparagraph is $750.

"(ii) INFLATION ADJUSTMENT.—Beginning with taxable years after 2011, the amount described in clause (i) shall be adjusted by the Secretary by notice, published in the Federal Register, for each fiscal year to reflect the total percentage change that occurred in the medical care component of the Consumer Price Index for all urban consumers (all items; U.S. city average) during the preceding calendar year.

"(c) EXEMPTIONS.—Subsection (b) shall not apply to any individual—

"(1) with respect to any month if such month occurs during any period in which such individual did not have qualifying coverage (as so defined) for a period of less than 90 days,

"(2) who is a resident of a State that is not a participating State or an establishing State (as such terms are defined in section 3104 of the Public Health Service Act),

"(3) who is an Indian as defined in section 4 of the Indian Health Care Improvement Act,

"(4) for whom affordable health care coverage is not available (as such terms are defined by the Secretary of Health and Human Services under section 3103 of the Public Health Service Act), or

"(5) described in section 3116(a)(4)(C) of the Public Health Service Act.

"(d) COORDINATION WITH OTHER PROVISIONS.—

"(1) NOT TREATED AS TAX FOR CERTAIN PURPOSES.—The amount imposed by this section shall not be treated as a tax imposed by this chapter for purposes of determining—

"(A) the amount of any credit allowable under this chapter, or

"(B) the amount of the minimum tax imposed by section 55.

"(2) TREATMENT UNDER SUBTITLE F.—For purposes of subtitle F, the amount imposed by this section shall be treated as if it were a tax imposed by section 1.

"(3) SECTION 15 NOT TO APPLY.—Section 15 shall not apply to the amount imposed by this section.

"(4) SECTION NOT TO AFFECT LIABILITY OF POSSESSIONS, ETC.—This section shall not apply for purposes of determining liability to any possession of the United States. For purposes of section 932 and 7654, the amount imposed under this section shall not be treated as a tax imposed by this chapter.

"(e) USES.—Amounts collected under this section shall be dedicated to premium credits established under section 3111 of the Public Health Service Act.

"(f) REGULATIONS.—The Secretary may prescribe such regulations as may be appropriate to carry out the purposes of this section.".

(2) CLERICAL AMENDMENT.—The table of parts for subchapter A of chapter 1 of such Code is amended by adding at the end the following new item:

"PART VIII—SHARED RESPONSIBILITY PAYMENTS".

(3) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 2011.

(b) REPORTING OF HEALTH INSURANCE COVERAGE.—

(1) IN GENERAL.—Part III of subchapter A of chapter 61 of the Internal Revenue Code of 1986 is amended by inserting after subpart B the following new subpart:

**"Subpart D—Information Regarding Health Insurance Coverage**

"Sec. 6055. Reporting of health insurance coverage.

**"SEC. 6055. REPORTING OF HEALTH INSURANCE COVERAGE.**

"(a) IN GENERAL.—Every person who provides health insurance that is qualifying coverage shall make a return described in subsection (b).

"(b) FORM AND MANNER OF RETURN.—A return is described in this subsection if such return—

"(1) is in such form as the Secretary prescribes,

"(2) contains—

"(A) the name, address, and taxpayer identification number of each individual who is

1 covered under health insurance that is quali-
2 fying coverage provided by such person, and
3 "(B) the number of months during the cal-
4 endar year during which each such individual
5 was covered under such health insurance, and
6 "(3) such other information as the Secretary
7 may prescribe.
8 "(c) STATEMENTS TO BE FURNISHED TO INDIVID-
9 UALS WITH RESPECT TO WHOM INFORMATION IS RE-
10 PORTED.—
11 "(1) IN GENERAL.—Every person required to
12 make a return under subsection (a) shall furnish to
13 each individual whose name is required to be set
14 forth in such return a written statement showing—
15 "(A) the name, address, and phone num-
16 ber of the information contact of the person re-
17 quired to make such return, and
18 "(B) the number of months during the cal-
19 endar year during which such individual was
20 covered under health insurance that is quali-
21 fying coverage provided by such person.
22 "(2) TIME FOR FURNISHING STATEMENTS.—
23 The written statement required under paragraph (1)
24 shall be furnished on or before January 31 of the

1 year following the calendar year for which the return
2 under subsection (a) was required to be made.
3 "(d) QUALIFYING COVERAGE.—For purposes of this
4 section, the term 'qualifying coverage' has the meaning
5 given such term under section 3116 of the Public Health
6 Service Act.".
7 (2) CONFORMING AMENDMENTS.—The table of
8 subparts for part III of subchapter A of chapter 61
9 of such Code is amended by inserting after the item
10 relating to subpart C the following new item:

"SUBPART D—HEALTH INSURANCE COVERAGE".

11 (3) EFFECTIVE DATE.—The amendments made
12 by this section shall apply to taxable years beginning
13 after December 31, 2011.
14 (c) NOTIFICATION OF NONENROLLMENT.—Not later
15 than June 30 of each year, the Secretary of the Treasury,
16 acting through the Internal Revenue Service and in con-
17 sultation with the Secretary of Health and Human Serv-
18 ices, shall send a notification each individual who files an
19 individual income tax return and who is not enrolled in
20 qualifying coverage (as defined in section 3116 of the Pub-
21 lic Health Service Act). Such notification shall contain in-
22 formation on the services available through the Gateway
23 (if any) operating in the State in which such individual
24 resides.

**SEC. 162. NOTIFICATION ON THE AVAILABILITY OF AFFORDABLE HEALTH CHOICES.**

The Fair Labor Standards Act of 1938 is amended by inserting after section 18 (29 U.S.C. 218) the following:

**"SEC. 18A. NOTICE TO EMPLOYEES.**

"(a) IN GENERAL.—In accordance with regulations promulgated by the Secretary, an employer to which this Act applies, shall provide to each employee at the time of hiring (or with respect to current employees, within 90 days of the date on which a State becomes an establishing or participating State under section 3104 of the Public Health Service Act), written notice informing the employee of the existence of the American Health Benefits Gateway, including a description of the services provided by such Gateway and the manner in which the employee may contact the Gateway to request assistance.

"(b) EFFECTIVE DATE.—Subsection (a) shall take effect with respect to employers in a State beginning 90 days after the date on which the State becomes an establishing or participating State under section 3104 of the Public Health Service. Act.".

**SEC. 163. SHARED RESPONSIBILITY OF EMPLOYERS.**

Subtitle B of title XXXI of the Public Health Service Act, as amended by section 151, is further amended by adding at the end the following:

**"SEC. 3115. SHARED RESPONSIBILITY OF EMPLOYERS.**

"(a) EMPLOYEES NOT OFFERED COVERAGE.—An employer shall make a payment to the Secretary in the amount described in subsection (b) with respect to each employee—

"(1) who is not offered qualifying coverage by such employer during each month where such employee is not offered qualifying coverage; or

"(2) on behalf of whom such employer is not contributing at least 60 percent of the monthly premiums for such coverage for each such month.

"(b) AMOUNT.—

"(1) IN GENERAL.—The annual amount described in this subsection shall be equal to $750 for each full-time employee described in subsection (a). Such amount shall be pro-rated with respect to each month in which subsection (a) applies with respect to an employee.

"(2) PRO RATA APPLICATION FOR PART-TIME EMPLOYEES.—The provisions of paragraph (1) shall apply with respect to part-time employees employed by the employer, except that the annual payment amount described in such paragraph shall be reduced to $375 for each part-time employee.

"(3) APPLICATION.—The provisions of this subsection shall only apply with respect to the number

of employees employed by the employer in excess of 25 employees.

"(c) PROCEDURES.—The Secretary shall develop procedures for making determinations with respect to qualifying coverage and for making the payments required under subsection (a). Such procedures shall provide for the making of payments on a quarterly basis.

"(d) USE OF FUNDS.—Amounts shall be collected under subsection (a) and be available for obligation only to the extent and in the amount provided in advance in appropriations Acts. Such amounts are authorized to remain available until expended.

"(e) INFLATION ADJUSTMENT.—Beginning with calendar years after 2013, the amounts described in subsection (b) shall be adjusted by the Secretary by notice, published in the Federal Register, for each fiscal year to reflect the total percentage change that occurred in the medical care component of the Consumer Price Index for all urban consumers (all items; U.S. city average) during the preceding calendar year.

"(f) EXEMPTION FOR SMALL EMPLOYERS.—

"(1) IN GENERAL.—For purposes of this section, the term 'employer' means an employer that employs more than 25 employees on business days during the preceding calendar year. An employer

shall not be considered to employ more than 25 employees if—

"(A) the employer's workforce exceeds 25 employees for 120 days or fewer during the calendar year; and

"(B) the employees employed during such 120-day period were seasonal workers.

"(2) DEFINITION OF SEASONAL WORKERS.—In this subsection, the term 'seasonal worker' means an individual who performs labor or services on a seasonal basis where, ordinarily, the employment pertains to or is of the kind exclusively performed at certain seasons or periods of the year and which, from its nature, may not be continuous or carried on throughout the year.

"(3) APPLICATION OF AGGREGATION RULE FOR EMPLOYERS.—All persons treated as a single employer under subsection (b), (c), (m), or (o) of section 414 of the Internal Revenue Code of 1986 shall be treated as 1 employer.

"(4) EMPLOYERS NOT IN EXISTENCE IN PRECEDING YEAR.—In the case of an employer which was not in existence throughout the preceding calendar year, the determination of whether such employer is a small or large employer shall be based on

the average number of employees that it is reasonably expected such employer will employ on business days in the current calendar year.

"(5) PREDECESSORS.—Any reference in this subsection to an employer shall include a reference to any predecessor of such employer.

"(g) AUTHORITY TO CERTIFY.—The Secretary, in collaboration with the Secretary of the Treasury and the Secretary of Labor, shall establish procedures for determining the number of employees of employers who are not offered qualifying coverage.

"(h) INDEPENDENT CONTRACTORS.—For purposes of determining whether an employer is subject to this section, any individual who qualifies as an independent contractor under Federal law and who is retained by such employer shall not be counted when determining the number of employees employed by the employer.

"(i) REGULATIONS.—The Secretary, in consultation with the Secretary of Labor, shall promulgate such regulations as may be appropriate to carry out activities under this section.

"(j) EFFECTIVE DATE.—This section shall apply with respect to an employer beginning in the calendar year in which the State in which the employer is located becomes an establishing State or a participating State.

**"SEC. 3116. DEFINITIONS.**

"(a) IN GENERAL.—In this title:

"(1) ELIGIBLE INDIVIDUAL.—The term 'eligible individual' means an individual who is—

"(A) a citizen or national of the United States or an alien lawfully admitted to the United States for permanent residence or an alien lawfully present in the United States;

"(B) a qualified individual;

"(C) enrolled in a qualified health plan; and

"(D) not receiving full benefits coverage under a State child health plan under title XXI of the Social Security Act (42 U.S.C. 1397aa et seq.) (or full benefits coverage under a demonstration project funded through such title XXI).

"(2) QUALIFIED EMPLOYER.—

"(A) IN GENERAL.—The term 'qualified employer' means an employer that—

"(i) elects to make all full-time employees of such employer eligible for a qualified health plan; and

"(ii)(I) in the case of an employer that elects to make its employees eligible

for qualified health plans in an establishing State—

"(aa) employs fewer than the number of employees specified in subparagraph (B); and

"(bb) meets criteria established by the State; or

"(II) in the case of an employer that elects to make its employees eligible for qualified health plans in a participating State—

"(aa) employs fewer than the number of employees specified in subparagraph (B); and

"(bb) meets criteria established by the Secretary.

"(B) NUMBER OF EMPLOYEES.—

"(i) ESTABLISHMENT.—

"(I) BY STATE.—In the case of an establishing State, such State may by regulation establish the number of employees described in subparagraph (A)(ii)(I)(aa) but such number may not be less than 50.

"(II) BY THE SECRETARY.—In the case of a participating State, the Secretary may by regulation establish the number of employees described in subparagraph (A)(ii)(II)(aa) but such number may not be less than 50.

"(ii) DEFAULT.—If a State or the Secretary does not establish the number described in subclause (I) or (II), respectively, of clause (i), such number shall be 50.

"(C) CONTINUATION OF PARTICIPATION.—A qualified employer that is enrolled in a qualified health plan and that experiences an increase in the number of employees of such employer such that the number of employees of such employer exceeds the number specified in subparagraph (B)(i) or subparagraph (B)(ii), as applicable, shall, notwithstanding such increase, continue to be considered a qualified employer for purposes of this title, provided that such employer remains enrolled in a qualified health plan.

"(3) QUALIFIED HEALTH PLAN.—

"(A) IN GENERAL.—The term 'qualified health plan' means health plan that—

"(i) has in effect a certification (which may include a seal or other indication of approval) that such plan meets the criteria for certification described in section 3101(m) issued or recognized by each Gateway through which such plan is offered; and

"(ii) is offered by a health insurance issuer that—

"(I) is licensed and in good standing to offer health insurance coverage in each State in which such issuer offers health insurance coverage under this title;

"(II) agrees to offer at least one qualified health plan in the tier described in section 3111(a)(1)(A) and at least one plan in the tier described in section 3111(a)(1)(B);

"(III) complies with the regulations developed by the Secretary under section 3101(m) and such other

requirements as an applicable Gateway may establish; and

"(IV) agrees to pay any surcharge assessed under section 3101(c)(4).

"(B) INCLUSION OF COMMUNITY HEALTH INSURANCE OPTION.—Any reference in this title to a qualified health plan shall be deemed to include a community health insurance option, unless specifically provided for otherwise.

"(4) QUALIFIED INDIVIDUAL.—

"(A) IN GENERAL.—The term 'qualified individual' means an individual who is—

"(i) residing in a participating State or an establishing State (as defined in section 3104);

"(ii) not incarcerated, except an individual in custody pending the disposition of charges;

"(iii) not entitled to coverage under the Medicare program under part A of title XVIII of the Social Security Act;

"(iv) not enrolled in coverage under the Medicare program under part B of title

XVIII of the Social Security Act or under part C of such title; and

"(v) not eligible for coverage under—

"(I) the Medicaid program under a State plan under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.), or under a waiver under section 1115 of such Act;

"(II) the TRICARE program under chapter 55 of title 10, United States Code (as defined in section 1072(7) of such title);

"(III) the Federal employees health benefits program under chapter 89 of title 5, United States Code; or

"(IV) employer-sponsored coverage (except as provided under subparagraph (B)).

"(B) EMPLOYEES WITHOUT AFFORDABLE COVERAGE.—An individual who is eligible for employer-sponsored coverage shall be deemed to be a qualified individual under subparagraph (A) only if such coverage—

"(i) does not meet the criteria established under section 3103 for minimum qualifying coverage; or

"(ii) is not affordable (as such term is defined by the Secretary under section 3103) for such employee.

"(C) INDIVIDUALS AT LESS THAN 150 PERCENT OF POVERTY.—An individual with an adjusted gross income that does not exceed 150 percent of the poverty line for a family of the size involved shall not be considered a qualified individual for purposes of this title.

"(5) QUALIFYING COVERAGE.—The term 'qualifying coverage' means—

"(A) a group health plan or health insurance coverage—

"(i) that an individual is enrolled in on the date of enactment of this title; or

"(ii) that is described in clause (i) and that is renewed by an enrollee as provided for in section 131 of the Affordable Health Choices Act;

"(B) a group health plan or health insurance coverage that—

"(i) is not described in subparagraph (A); and

"(ii) meets or exceeds the criteria for minimum qualifying coverage (as defined in section 3103);

"(C) Medicare coverage under parts A and B of title XVIII of the Social Security Act or under part C of such title;

"(D) Medicaid coverage under a State plan under title XIX of the Social Security Act (or under a waiver under section 1115 of such Act), other than coverage consisting solely of benefits under section 1928 of such Act;

"(E) coverage under title XXI of the Social Security Act;

"(F) coverage under the TRICARE program under chapter 55 of title 10, United States Code;

"(G) coverage under the veteran's health care program under chapter 17 of title 38, United States Code, but only if the coverage for the individual involved is determined by the Secretary to be not less than the coverage provided under a qualified health plan, based on

the individual's priority for services as provided under section 1705(a) of such title;

"(H) coverage under the Federal employees health benefits program under chapter 89 of title 5, United States Code;

"(I) a State health benefits high risk pool;

"(J) a health benefit plan under section 2504(e) of title 22, United States Code; or

"(K) coverage under a qualified health plan.

For purposes of this paragraph, an individual shall be deemed to have qualifying coverage if such individual is an individual described in section 1402(e) or (g) of the Internal Revenue Code of 1986.

"(6) ADJUSTED GROSS INCOME.—The term 'adjusted gross income' with respect to an individual has the meaning given such term for purposes of section 62(a) of the Internal Revenue Code of 1986.

"(7) EDUCATED HEALTH CARE CONSUMER.—The term 'educated health care consumer' means an individual who is knowledgeable about the health care system, and has background or experience in making informed decisions regarding health, medical, and scientific matters.

"(b) INCORPORATION OF ADDITIONAL DEFINITIONS.—Unless specifically provided for otherwise, the definitions contained in section 2791 shall apply with respect to this title.".

# Subtitle E—Improving Access to Health Care Services

**SEC. 171. 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. 172. OTHER PROVISIONS.**

(a) SETTINGS FOR SERVICE DELIVERY.—Section 330(a)(1) of the Public Health Service Act (42 U.S.C. 254b(a)(1)) is amended by adding at the end the fol-

lowing: "Required primary health services and additional health services may be provided either at facilities directly operated by the center or at any other inpatient or outpatient settings determined appropriate by the center to meet the needs of its patents.".

(b) LOCATION OF SERVICE DELIVERY SITES.—Section 330(a) of the Public Health Service Act (42 U.S.C. 254b(a)) is amended by adding at the end the following:

"(3) CONSIDERATIONS.—

"(A) LOCATION OF SITES.—Subject to subparagraph (B), a center shall not be required to locate its service facility or facilities within a designated medically underserved area in order to serve either the residents of its catchment area or a special medically underserved population comprised of migratory and seasonal agricultural workers, the homeless, or residents of public housing, if that location is determined by the center to be reasonably accessible to and appropriate to meet the needs of the medically underserved residents of the center's catchment area or the special medically underserved population, in accordance with subparagraphs (A) and (J) of subsection (k)(3).

"(B) LOCATION WITHIN ANOTHER CENTER'S AREA.—The Secretary may permit applicants for grants under this section to propose the location of a service delivery site within another center's catchment area if the applicant demonstrates sufficient unmet need in such area and can otherwise justify the need for additional Federal resources in the catchment area. In determining whether to approve such a proposal, the Secretary shall take into consideration whether collaboration between the two centers exists, or whether the applicant has made reasonable attempts to establish such collaboration, and shall consider any comments timely submitted by the affected center concerning the potential impact of the proposal on the availability or accessibility of services the affected center currently provides or the financial viability of the affected center.".

(c) AFFILIATION AGREEMENTS.—Section 330(k)(3)(B) of the Public Health Service Act (42 U.S.C. 254b(k)(3)(B)) is amended by inserting before the semicolon the following: ", including contractual arrangements as appropriate, while maintaining full compliance with the requirements of this section, including the requirements

of subparagraph (H) concerning the composition and authorities of the center's governing board, and, except as otherwise provided in clause (ii) of such subparagraph, ensuring full autonomy of the center over policies, direction, and operations related to health care delivery, personnel, finances, and quality assurance''.

(d) GOVERNANCE REQUIREMENTS.—Section 330(k)(3) of the Public Health Service Act (42 U.S.C. 254b(k)(3)) is amended—

(1) in subparagraph (H)—

(A) in clause (ii), strike ''; and'' and inserting '', except that in the case of a public center (as defined in the second sentence of this paragraph), the public entity may retain authority to establish financial and personnel policies for the center; and'';

(B) in clause (iii), by adding ''and'' at the end; and

(C) by inserting after clause (iii) the following:

''(iv) in the case of a co-applicant with a public entity, meets the requirements of clauses (i) and (ii);''; and

(2) in the second sentence, by inserting before the period the following: ''that is governed by a

board that satisfies the requirements of subparagraph (H) or that jointly applies (or has applied) for funding with a co-applicant board that meets such requirements''.

(e) ADJUSTMENT IN CENTER'S OPERATING PLAN AND BUDGET.—Section 330(k)(3)(I)(i) of the Public Health Service Act (42 U.S.C. 254b(k)(3)(I)(i)) is amended by adding before the semicolon the following: '', which may be modified by the center at any time during the fiscal year involved if such modifications do not require additional grant funds, do not compromise the availability or accessibility of services currently provided by the center, and otherwise meet the conditions of subsection (a)(3)(B), except that any such modifications that do not comply with this clause, as determined by the health center, shall be submitted to the Secretary for approval''.

(f) JOINT PURCHASING ARRANGEMENTS FOR REDUCED COST.—Section 330(l) of the Public Health Service Act (42 U.S.C. 254b(l)) is amended—

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

''(1) IN GENERAL.—The Secretary''; and

(2) by adding at the end the following:

''(2) ASSISTANCE WITH SUPPLIES AND SERVICES COSTS.—The Secretary, directly or through

grants or contracts, may carry out projects to establish and administer arrangements under which the costs of providing the supplies and services needed for the operation of federally qualified health centers are reduced through collaborative efforts of the centers, through making purchases that apply to multiple centers, or through such other methods as the Secretary determines to be appropriate.''.

(g) OPPORTUNITY TO CORRECT MATERIAL FAILURE REGARDING GRANT CONDITIONS.—Section 330(e) of the Public Health Service Act (42 U.S.C. 254b(e)) is amended by adding at the end the following:

''(6) OPPORTUNITY TO CORRECT MATERIAL FAILURE REGARDING GRANT CONDITIONS.—If the Secretary finds that a center materially fails to meet any requirement (except for any requirements waived by the Secretary) necessary to qualify for its grant under this subsection, the Secretary shall provide the center with an opportunity to achieve compliance (over a period of up to 1 year from making such finding) before terminating the center's grant. A center may appeal and obtain an impartial review of any Secretarial determination made with respect to a grant under this subsection, or may appeal and receive a fair hearing on any Secretarial determina-

tion involving termination of the center's grant entitlement, modification of the center's service area, termination of a medically underserved population designation within the center's service area, disallowance of any grant expenditures, or a significant reduction in a center's grant amount.''.

**SEC. 173. 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 Sates 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 re-

view 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. 174. EQUITY FOR CERTAIN ELIGIBLE SURVIVORS.**

(a) REBUTTABLE PRESUMPTION.—Section 411(c)(4) of the Black Lung Benefits Act (30 U.S.C. 921(c)(4)) is amended by striking the last sentence.

(b) CONTINUATION OF BENEFITS.—Section 422(l) of the Black Lung Benefits Act (30 U.S.C. 932(l)) is amended by striking ", except with respect to a claim filed under this part on or after the effective date of the Black Lung Benefits Amendments of 1981".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to claims filed under part B or part C of the Black Lung Benefits Act (30 U.S.C. 921 et seq., 931 et seq.) after January 1, 2005, that are pending on or after the date of enactment of this Act.

**SEC. 175. 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. 176. 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. GRANTS 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' refers to the following 3 groups:

"(A) Children and adolescents with mental and emotional disturbances who have co-occurring primary care conditions and chronic diseases.

"(B) Adults with mental illnesses who have co-occurring primary care conditions and chronic diseases.

"(C) Older adults with mental illnesses who have co-occurring primary care conditions and chronic diseases.

"(b) PROGRAM AUTHORIZED.—The Secretary, acting through the Administrator of the Substance Abuse and Mental Health Services Administration and in coordination with the Director of the Health Resources and Services Administration, shall award grants 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.

1 "(c) APPLICATION.—To be eligible to receive a grant
2 under this section, an eligible entity shall submit an appli-
3 cation to the Administrator at such time, in such manner,
4 and accompanied by such information as the Adminis-
5 trator may require. Each such application shall include—
6 "(1) an assessment of the primary care needs
7 of the patients served by the eligible entity and a de-
8 scription of how the eligible entity will address such
9 needs; and
10 "(2) a description of partnerships, cooperative
11 agreements, or other arrangements with local pri-
12 mary care providers, including community health
13 centers, to provide services to special populations.
14 "(d) USE OF FUNDS.—
15 "(1) IN GENERAL.—For the benefit of special
16 populations, an eligible entity shall use funds award-
17 ed under this section for—
18 "(A) the provision, by qualified primary
19 care professionals on a reasonable cost basis,
20 of—
21 "(i) primary care services on site at
22 the eligible entity;
23 "(ii) diagnostic and laboratory serv-
24 ices; or

"(iii) adult and pediatric eye, ear, and dental screenings;

"(B) reasonable costs associated with medically necessary referrals to qualified specialty care professionals as well as to other coordinators of care or, if permitted by the terms of the grant, for the provision, 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 improvements or modifications needed to bring primary and specialty care professionals on site at the eligible entity.

"(2) LIMITATION.—Not to exceed 15 percent of grant funds may be used for activities described in subparagraphs (C) and (D) of paragraph (1).

"(e) GEOGRAPHIC DISTRIBUTION.—The Secretary shall ensure that grants awarded under this section are equitably distributed among the geographical regions of the United States and between urban and rural populations.

"(f) EVALUATION.—Not later than 3 months 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.

"(g) REPORT.—Not later than 5 years after the date of enactment of this section, the Secretary shall prepare and submit to the appropriate committees of Congress a report that shall evaluate the activities funded under this section. The report shall include an evaluation of the impact of co-locating primary and specialty care in community mental and behavioral health settings on overall patient health status and recommendations on whether or not the demonstration program under this section should be made permanent.

"(h) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, $50,000,0000 for fiscal year 2010 and such sums as may be necessary for each of fiscal years 2011 through 2014.".

# Subtitle F—Making Health Care More Affordable for Retirees

**SEC. 181. REINSURANCE FOR RETIREES.**

(a) ADMINISTRATION.—

(1) IN GENERAL.—Not later than 90 days after the date of enactment of this section, the Secretary shall establish a temporary reinsurance program to

provide reimbursement to participating employment-based plans for a portion of the cost of providing health benefits to retirees whose primary residence is located in any State that is not a participating State or an establishing State (as described in section 3104) for a portion of the cost of providing health insurance coverage to retirees (and to the eligible spouses, surviving spouses, and dependents of such retirees) during the period beginning on the date on which such program is established and ending on the date on which such State becomes a participating State or an establishing State.

(2) REFERENCE.—In this section:

(A) HEALTH BENEFITS.—The term ''health benefits'' means medical, surgical, hospital, prescription drug, and such other benefits as shall be determined by the Secretary, whether self-funded, or delivered through the purchase of insurance or otherwise.

(B) EMPLOYMENT-BASED PLAN.—The term ''employment-based plan'' means a group health benefits plan that—

(i) is—

(I) maintained by one or more current or former employers (includ-

ing without limitation any State or local government or political subdivision thereof), employee organization, a voluntary employees' beneficiary association, or a committee or board of individuals appointed to administer such plan; or

(II) a multiemployer plan (as defined in section 3(37) of the Employee Retirement Income Security Act of 1974); and

(ii) provides health benefits to retirees.

(C) RETIREES.—The term ''retirees'' means individuals who are age 55 and older but are not eligible for coverage under title XVIII of the Social Security Act, and who are not active employees of an employer maintaining , or currently contributing to, the employment-based plan or of any employer that has made substantial contributions to fund such plan.

(b) PARTICIPATION.—

(1) EMPLOYMENT-BASED PLAN ELIGIBILITY.—To be eligible to participate in the program established under this section, an employment-based plan

(as defined in subsection (a)(2) and referred to in this section as a ''participating employment-based plan'' shall—

(A) provide employment-based health plan benefits; and

(B) submit to the Secretary an application for participation in the program, at such time, in such manner, and containing such information as the Secretary shall require.

(2) APPROPRIATE EMPLOYMENT-BASED HEALTH BENEFITS.—Appropriate employment-based health benefits described in this paragraph shall—

(A) meet the requirements established under section 3103(a)(1)(B);

(B) implement programs and procedures to generate cost-savings with respect to participants with chronic and high-cost conditions;

(C) provide documentation of the actual cost of medical claims involved; and

(D) be certified as appropriate by the Secretary.

(c) PAYMENTS.—

(1) SUBMISSION OF CLAIMS.—

(A) IN GENERAL.—A participating employment-based plan shall submit claims for reim-

bursement to the Secretary which shall contain documentation of the actual costs of the items and services for which each claim is being submitted.

(B) BASIS FOR CLAIMS.—Claims submitted under paragraph (1) shall be based on the actual amount expended by the participating employment-based plan involved within the plan year for the appropriate employment-based health benefits provided to a retiree or the spouse, surviving spouse, or dependent of such retiree. In determining the amount of a claim for purposes of this subsection, the participating employment-based plan shall take into account any negotiated price concessions (such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations) obtained by such plan with respect to such health benefit. For purposes of determining the amount of any such claim, the costs paid by the retiree or the retiree's spouse, surviving spouse, or dependent in the form of deductibles, co-payments, or co-insurance shall be included in the amounts paid by the participating employment-based plan.

(2) PROGRAM PAYMENTS.—If the Secretary determines that a participating employment-based plan has submitted a valid claim under paragraph (1), the Secretary shall reimburse such plan for 80 percent of that portion of the costs attributable to such claim that exceed $15,000, subject to the limits contained in paragraph (3).

(3) LIMIT.—To be eligible for reimbursement under the program, a claim submitted by a participating employment-based plan shall not be less than $15,000 nor greater than $90,000. Such amounts shall be adjusted each fiscal year based on the percentage increase in the Medical Care Component of the Consumer Price Index for all urban consumers (rounded to the nearest multiple of $1,000) for the year involved.

(4) USE OF PAYMENTS.—Amounts paid to a participating employment-based plan under this subsection shall be used to lower costs for the plan. Such payments may be used to reduce premium costs for an entity described in subsection (a)(2)(B)(i) or to reduce premium contributions, co-payments, deductibles, co-insurance, or other out-of-pocket costs for plan participants. Such payments shall not be used as general revenues for an entity

described in subsection (a)(2)(B)(i). The Secretary shall develop a mechanism to monitor the appropriate use of such payments by such entities.

(5) PAYMENTS NOT TREATED AS INCOME.—Payments received under this subsection shall not be included in determining the gross income of an entity described in subsection (a)(2)(B)(i) that is maintaining or currently contributing to a participating employment-based plan.

(6) APPEALS.—The Secretary shall establish—

(A) an appeals process to permit participating employment-based plans to appeal a determination of the Secretary with respect to claims submitted under this section; and

(B) procedures to protect against fraud, waste, and abuse under the program.

(d) AUDITS.—The Secretary shall conduct annual audits of claims data submitted by participating employment-based plans under this section to ensure that such plans are in compliance with the requirements of this section.

(e) RETIREE RESERVE TRUST FUND.—

(1) ESTABLISHMENT OF TRUST FUND.—

(A) IN GENERAL.—There is established in the Treasury of the United States a trust fund

to be known as the ''Retiree Reserve Trust Fund'' (referred to in this section as the ''Trust Fund''), that shall consist of such amounts as may be appropriated or credited to the Trust Fund as provided for in this subsection to enable the Secretary to carry out the program under this section. Such amounts shall remain available until expended.

(B) FUNDING.—There are hereby appropriated to the Trust Fund, out of any moneys in the Treasury not otherwise appropriated an amount requested by the Secretary of Health and Human Services as necessary to carry out this section, except that the total of all such amounts requested shall not exceed $10,000,000,000.

(C) APPROPRIATIONS FROM THE TRUST FUND.—Amounts in the Trust Fund may be appropriated to provide funding to carry out this program under this section

(2) USE OF TRUST FUND.—The Secretary shall use amounts contained in the Trust Fund to carry out the program under this section.

(3) LIMITATIONS.—The Secretary has the authority to stop taking applications for participation

in the program to comply with the funding limit provided for in paragraph (1)(B).

# Subtitle G—Improving the Use of Health Information Technology for Enrollment; Miscellaneous Provisions

**SEC. 185. HEALTH INFORMATION TECHNOLOGY ENROLLMENT STANDARDS AND PROTOCOLS.**

Title XXX of the Public Health Service Act (42 U.S.C. 300jj et seq.) is amended by adding at the end the following:

## "Subtitle C—Other Provisions

**"SEC. 3021. HEALTH INFORMATION TECHNOLOGY ENROLLMENT STANDARDS AND PROTOCOLS.**

"(a) IN GENERAL.—

"(1) STANDARDS AND PROTOCOLS.—Not later than 180 days after the date of enactment of this title, the Secretary, in consultation with the HIT Policy Committee and the HIT Standards Committee, shall develop interoperable and secure standards and protocols that facilitate enrollment of individuals in Federal and State health and human services programs, as determined by the Secretary.

"(2) METHODS.—The Secretary shall facilitate enrollment in such programs through methods deter-

mined appropriate by the Secretary, which shall include providing individuals and third parties authorized by such individuals and their designees notification of eligibility and verification of eligibility required under such programs.

"(b) CONTENT.—The standards and protocols for electronic enrollment in the Federal and State programs described in subsection (a) shall allow for the following:

"(1) Electronic matching against existing Federal and State data, including vital records, employment history, enrollment systems, tax records, and other data determined appropriate by the Secretary to serve as evidence of eligibility and in lieu of paper-based documentation.

"(2) Simplification and submission of electronic documentation, digitization of documents, and systems verification of eligibility.

"(3) Reuse of stored eligibility information (including documentation) to assist with retention of eligible individuals.

"(4) Capability for individuals to apply, recertify and manage their eligibility information online, including at home, at points of service, and other community-based locations.

"(5) Ability to expand the enrollment system to integrate new programs, rules, and functionalities, to operate at increased volume, and to apply streamlined verification and eligibility processes to other Federal and State programs, as appropriate.

"(6) Notification of eligibility, recertification, and other needed communication regarding eligibility, which may include communication via email and cellular phones.

"(7) Other functionalities necessary to provide eligibles with streamlined enrollment process.

"(c) APPROVAL AND NOTIFICATION.—With respect to any standard or protocol developed under subsection (a) that has been approved by the HIT Policy Committee and the HIT Standards Committee, the Secretary—

"(1) shall notify States of such standards or protocols; and

"(2) may require, as a condition of receiving Federal funds for the health information technology investments, that States or other entities incorporate such standards and protocols into such investments.

"(d) GRANTS FOR IMPLEMENTATION OF APPROPRIATE ENROLLMENT HIT.—

"(1) IN GENERAL.—The Secretary shall award grant to eligible entities to develop new, and adapt

existing, technology systems to implement the HIT enrollment standards and protocols developed under subsection (a) (referred to in this subsection as 'appropriate HIT technology').

"(2) ELIGIBLE ENTITIES.—To be eligible for a grant under this subsection, an entity shall—

"(A) be a State, political subdivision of a State, or a local governmental entity; and

"(B) submit to the Secretary an application at such time, in such manner, and containing—

"(i) a plan to adopt and implement appropriate enrollment technology that includes—

"(I) proposed reduction in maintenance costs of technology systems;

"(II) elimination or updating of legacy systems; and

"(III) demonstrated collaboration with other entities that may receive a grant under this section that are located in the same State, political subdivision, or locality;

"(ii) an assurance that the entity will share such appropriate enrollment tech-

nology in accordance with paragraph (4); and

"(iii) such other information as the Secretary may require.

"(3) SHARING.—

"(A) IN GENERAL.—The Secretary shall ensure that appropriate enrollment HIT adopted under grants under this subsection is made available to other qualified State, qualified political subdivisions of a State, or other appropriate qualified entities (as described in subparagraph (B)) at no cost.

"(B) QUALIFIED ENTITIES.—The Secretary shall determine what entities are qualified to receive enrollment HIT under subparagraph (A), taking into consideration the recommendations of the HIT Policy Committee and the HIT Standards Committee.".

**SEC. 186. RULE OF CONSTRUCTION REGARDING HAWAII'S PREPAID HEALTH CARE ACT.**

Nothing in this title (or an amendment made by this title) shall be construed to modify or limit the application of the exemption for Hawaii's Prepaid Health Care Act (Haw. Rev. Stat. §§ 393-1 et seq.) as provided for under

section 514(b)(5) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1144(b)(5)).

**SEC. 187. 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 Mem-

bers 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 In-

stitute, 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 es-

tablishment 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.

**SEC. 188. STUDY AND REPORT ON RATES OF PREVENTABLE DISEASES IN NEW MEDICARE ENROLLEES.**

(a) STUDY.—

(1) IN GENERAL.—The Comptroller General of the United States (in this section referred to as the ''Comptroller General'') shall conduct a study on—

(A) whether applicable new Medicare enrollees exhibit higher than expected rates of preventable disease when compared to the entire population of new Medicare enrollees or another appropriate statistical baseline; and

(B) if applicable new Medicare enrollees exhibit such a higher than expected rate of preventable disease, whether such rate is related to the failure of the enrollee's previous private health insurance issuer to promote, cover, or adequately pay for preventive health benefits.

(2) APPLICABLE NEW MEDICARE ENROLLEE.—In this section, the term ''applicable new Medicare enrollee'' means an individual—

(A) who is entitled to, or enrolled for, benefits under part A of title XVII of the Social Security Act (42 U.S.C. 1395 et seq.) or enrolled for benefits under part B of such title on or after the date of enactment of this Act; and

(B) who was covered by private health insurance or Medicaid or other Federal Government health programs (as of the day before the date of such entitlement or enrollment).

(b) REPORT.—Not later than 3 years after the date on which at least 5 Gateways under title XXXI of the

Public Health Service Act, as added by section 142, are operating in the United States, 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.

**SEC. 189. TRANSPARENCY IN GOVERNMENT.**

Not later than 30 days after the date of enactment of this Act, the Secretary of Health and Human Services shall publish on the Internet website of the Department of Health and Human Services, a list of all of the authorities provided to the Secretary under this Act (and the amendments made by this Act).

**SEC. 189A. PRESERVING THE SOLVENCY OF MEDICARE AND SOCIAL SECURITY.**

Nothing in this Act (or an amendment made by this Act) shall be carried out in a manner that threatens the solvency of Medicare or Social Security programs.

**SEC. 189B. PROHIBITION AGAINST DISCRIMINATION ON ASSISTED SUICIDE.**

(a) IN GENERAL.—The Federal Government, and any State or local government or health care provider that receives Federal financial assistance under this Act (or under an amendment made by this Act) or any health plan created under this Act (or under an amendment made by

this Act), may not subject an individual or institutional health care entity to discrimination on the basis that the entity does not provide any health care item or service furnished for the purpose of causing, or for the purpose of assisting in causing, the death of any individual, such as by assisted suicide, euthanasia, or mercy killing.

(b) DEFINITION.—In this section, the term ''health care entity'' includes an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan.

(c) CONSTRUCTION AND TREATMENT OF CERTAIN SERVICES.—Nothing in subsection (a) shall be construed to apply to or to affect any limitation relating to—

(1) the withholding or withdrawing of medical treatment or medical care;

(2) the withholding or withdrawing of nutrition or hydration;

(3) abortion; or

(4) the use of an item, good, benefit, or service furnished for the purpose of alleviating pain or discomfort, even if such use may increase the risk of death, so long as such item, good, benefit, or service is not also furnished for the purpose of causing, or

the purpose of assisting in causing, death, for any reason.

(d) ADMINISTRATION.—The Office for Civil Rights of the Department of Health and Human Services is designated to receive complaints of discrimination based on this section.

**SEC. 189C. ACCESS TO THERAPIES.**

Notwithstanding any other provision of the Affordable Health Choices Act, the Secretary of Health and Human Services shall not promulgate any regulation that—

(1) creates any unreasonable barriers to the ability of individuals to obtain appropriate medical care;

(2) impedes timely access to health care services;

(3) interferes with communications regarding a full range of treatment options between the patient and the provider;

(4) restricts the ability of health care providers to provide full disclosure of all relevant information to patients making health care decisions;

(5) violates the principles of informed consent and the ethical standards of health care professionals; or

(6) limits the availability of health care treatment for the full duration of a patient's medical needs.

**SEC. 189D. FREEDOM NOT TO PARTICIPATE IN FEDERAL HEALTH INSURANCE PROGRAMS.**

No individual, company, business, nonprofit entity, or health insurer offering group or individual health insurance shall be required to participate in any Federal health insurance program created under this Act (or any amendments made by this Act), or in any Federal health insurance program expanded by this Act (or any such amendments), and there shall be no penalty or fine imposed upon any such insurer for choosing not to participate in such programs.

# Subtitle H—CLASS Act

**SEC. 190. SHORT TITLE OF SUBTITLE.**

This subtitle may be cited as the ''Community Living Assistance Services and Supports Act'' or the ''CLASS Act''.

**SEC. 191. 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 143, 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) DISABILITY DETERMINATION SERVICE.—The term 'Disability Determination Service' means, with respect to each State, the entity that has an agreement with the Commissioner of Social Security to make disability determinations for purposes of title II or XVI of the Social Security Act (42 U.S.C. 401 et seq., 1381 et seq.).

"(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, for each calendar year that occurs 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 that 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) 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.—Beginning with the first year of the CLASS program, and for each year thereafter, 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.

"(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 a Gateway established under section 3101.

"(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 in-

dividuals enrolled in the CLASS program as necessary.

"(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) PENALTY FOR REENOLLMENT 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 reenollment 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, in coordination with the Commissioner of Social Security, may factor in costs for administering the program, not to exceed—

"(A) in the case of the first 5 years in which the program is in effect under this title, an amount equal to 3 percent of all premiums paid during each such year; and

"(B) in the case of subsequent years, an amount equal to 5 percent of the total amount of all expenditures (including benefits paid) under this title with respect to that year.

"(3) NO UNDERWRITING REQUIREMENTS.—No underwriting (other than on the basis of age in accordance with paragraph (2)) 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.

**"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) shall 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 para-

graph (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;

"(C) whose employer does not elect to participate in the automatic enrollment process established by the Secretary; or

"(D) who is a spouse described in subsection (c)(2) of who is not subject to automatic enrollment.

"(3) ADMINISTRATION.—

"(A) IN GENERAL.—The Secretary and the Secretary of the Treasury shall, by regulation, establish procedures to—

"(i) ensure that an individual is not automatically enrolled in the CLASS program by more than 1 employer; and

"(ii) allow for an individual's employer to deduct a premium for a spouse described in subsection (c)(1)(B) who is not subject to automatic enrollment.

"(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—

"(1) an individual—

"(A) who has attained age 18;

"(B) who—

"(i) receives wages on which there is imposed a tax under section 3201(a) of the Internal Revenue Code of 1986; or

"(ii) derives self-employment income on which there is imposed a tax under section 1401(a) of the Internal Revenue Code of 1986;

"(C) who is actively employed; and

"(D) who is not—

"(i) 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

"(ii) 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)); or

"(2) the spouse of an individual described in paragraph (1) and who would be an individual so described but for subparagraph (B) or (C) of that paragraph.

"(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 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, in coordination with the Commissioner of Social Security, 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 enter into agreements with—

"(i) the Disability Determination Service for each State to provide for eligibility assessments of active enrollees who apply for receipt of benefits;

"(ii) the Protection and Advocacy System for each State to provide advocacy services in accordance with subsection (d); and

"(iii) public and private entities to provide advice and assistance counseling in accordance with subsection (e).

"(B) REGULATIONS.—The Secretary, in coordination with the Commissioner of Social Security, shall promulgate regulations to de-

velop an expedited 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 applicant 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 being 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 con-

sumer 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 advise 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

1 care, and Medicaid shall provide secondary
2 coverage for such care.
3 "(ii) BENEFICIARIES RECEIVING
4 HOME AND COMMUNITY-BASED SERV-
5 ICES.—
6 "(I) 50 PERCENT OF BENEFIT
7 RETAINED BY BENEFICIARY.—Subject
8 to subclause (II), if a beneficiary is
9 receiving medical assistance under
10 Medicaid for home and community
11 based services, the beneficiary shall
12 retain an amount equal to 50 percent
13 of the beneficiary's daily or weekly
14 cash benefit (as applicable), and the
15 remainder of the daily or weekly cash
16 benefit shall be applied toward the
17 cost to the State of providing such as-
18 sistance (and shall not be used to
19 claim Federal matching funds under
20 Medicaid), and Medicaid shall provide
21 secondary coverage for the remainder
22 of any costs incurred in providing
23 such assistance.
24 "(II) REQUIREMENT FOR STATE
25 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 Fed-

eral 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, in coordination with the Commissioner of Social Security—

"(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).

1 "(e) ADVICE AND ASSISTANCE COUNSELING.—An
2 agreement entered into under subsection (a)(2)(A)(iii)
3 shall require the entity to assign, as requested by an eligi-
4 ble beneficiary that is covered by such agreement, an ad-
5 vice and assistance counselor who shall provide an eligible
6 beneficiary with information regarding—
7 "(1) accessing and coordinating long-term serv-
8 ices and supports in the most integrated setting;
9 "(2) possible eligibility for other benefits and
10 services;
11 "(3) development of a service and support plan;
12 "(4) information about programs established
13 under the Assistive Technology Act of 1998 and the
14 services offered under such programs;
15 "(5) available assistance with decision making
16 concerning medical care, including the right to ac-
17 cept or refuse medical or surgical treatment and the
18 right to formulate advance directives or other writ-
19 ten instructions recognized under State law, such as
20 a living will or durable power of attorney for health
21 care, in the case that an injury or illness causes the
22 individual to be unable to make health care deci-
23 sions; and
24 "(6) such other services as the Secretary, by
25 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 Disability Determination Service and Protection and Advocacy System for a State, advocacy counselors for eligible beneficiaries, and any other entities that provide

1 services to active enrollees and eligible beneficiaries under
2 the CLASS program comply with the following:
3 ''(1) If the entity provides counseling or plan-
4 ning services, such services are provided in a manner
5 that fosters the best interests of the active enrollee
6 or beneficiary.
7 ''(2) The entity has established operating proce-
8 dures that are designed to avoid or minimize con-
9 flicts of interest between the entity and an active en-
10 rollee or beneficiary.
11 ''(3) The entity provides information about all
12 services and options available to the active enrollee
13 or beneficiary, to the best of its knowledge, including
14 services available through other entities or providers.
15 ''(4) The entity assists the active enrollee or
16 beneficiary to access desired services, regardless of
17 the provider.
18 ''(5) The entity reports the number of active
19 enrollees and beneficiaries provided with assistance
20 by age, disability, and whether such enrollees and
21 beneficiaries received services from the entity or an-
22 other entity.
23 ''(6) If the entity provides counseling or plan-
24 ning services, the entity ensures that an active en-

rollee 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.

The Secretary shall establish the procedures under this subsection that apply to the Disability Determination Service in coordination with the Commissioner of Social Security.

**"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) LOCK-BOX PROTECTION.—

"(1) IN GENERAL.—Notwithstanding any other provision of law, it shall not be in order in the Senate or the House of Representatives to consider any measure that would authorize the payment or use of amounts in the Fund for any purpose other than a purpose authorized under this title.

"(2) 60-VOTE WAIVER REQUIRED IN THE SENATE.—

"(A) IN GENERAL.—Paragraph (1) may be waived or suspended in the Senate only by the

affirmative vote of 3/5 of the Members, duly chosen and sworn.

"(B) APPEALS.—

"(i) PROCEDURE.—Appeals in the Senate from the decisions of the Chair relating to subparagraph (A) shall be limited to 1 hour, to be equally divided between, and controlled by, the mover and the manager of the measure that would authorize the payment or use of amounts in the Fund for a purpose other than a purpose authorized under this title.

"(ii) 60-VOTES REQUIRED.—An affirmative vote of 3/5 of the Members, duly chosen and sworn, shall be required in the Senate to sustain an appeal of the ruling of the Chair on a point of order raised in relation to subparagraph (A).

"(3) RULES OF THE SENATE AND HOUSE OF REPRESENTATIVES.—This subsection is enacted by Congress—

"(A) as an exercise of the rulemaking power of the Senate and House of Representatives, respectively, and is deemed to be part of the rules of each House, respectively, but appli-

cable only with respect to the procedure to be followed in that House in the case of a measure described in paragraph (1), and it supersedes other rules only to the extent that it is inconsistent with such rules; and

"(B) with full recognition of the constitutional right of either House to change the rules (so far as they relate to the procedure of that House) at any time, in the same manner, and to the same extent as in the case of any other rule of that House.

"(d) 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 Commissioner of Social Security, 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 projections under section 3203(b)(2)(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;

"(IV) an actuarial opinion by the Chief Actuary of the Social Security Administration 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

"(V) an opinion by the Commissioner of Social Security that the Disability Determination Service personnel are not over burdened by the additional requirements of the CLASS program; 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 projections under section 3203(b)(2)(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 indi-

vidual 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; and

"(2) the determination of monthly premiums under such plan.

"(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. REGULATIONS; ANNUAL REPORT.**

"(a) 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.

"(b) 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 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

5006(e)(2)(A) of division B of Public Law 111–5, is amended—

(A) in paragraph (72), by striking ''and'' at the end;

(B) in paragraph (73)(B), by striking the period and inserting ''; and''; and

(C) by inserting after paragraph (73) the following:

''(74) 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.''.

(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—

(1) in paragraph (73)(B), by striking ''and'' at the end;

(2) in paragraph (74), by striking the period at the end and inserting ''; and''; and

(3) by inserting after paragraph (74), the following:

"(75) 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 work-

ers, 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 Gateway established under section 3101 of such Act that is supplemental coverage to the benefits provided under a CLASS Independence Benefit Plan under that program.''; 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.

# TITLE II—IMPROVING THE QUALITY AND EFFICIENCY OF HEALTH CARE

## Subtitle A—National Strategy to Improve Health Care Quality

**SEC. 201. NATIONAL STRATEGY.**

(a) IN GENERAL.—Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by adding at the end the following:

**"PART S—HEALTH CARE QUALITY PROGRAMS**

**"Subpart I—National Strategy for Quality Improvement in Health Care**

**"SEC. 399HH. NATIONAL STRATEGY FOR QUALITY IMPROVEMENT IN HEALTH CARE.**

"(a) ESTABLISHMENT OF NATIONAL STRATEGY AND PRIORITIES.—

"(1) NATIONAL STRATEGY.—The Secretary, through a transparent collaborative process, shall establish a national strategy to improve the delivery of health care services, patient health outcomes, and population health.

"(2) IDENTIFICATION OF PRIORITIES.—

"(A) IN GENERAL.—The Secretary shall identify national priorities for improvement in developing the strategy under paragraph (1).

"(B) REQUIREMENTS.—The Secretary shall ensure that priorities identified under subparagraph (A) will—

"(i) address the health care provided to patients with high-cost chronic diseases;

"(ii) improve the design, development, demonstration, dissemination, and adoption of infrastructure and innovative methodologies and strategies for quality improvement in the delivery of health care services that represent best practices to improve patient safety and reduce medical errors, preventable admissions and readmissions, and health care-associated infections;

"(iii) have the greatest potential for improving the health outcomes, efficiency, and patient-centeredness of health care;

"(iv) reduce health disparities across health disparity populations (as defined by section 485E) and geographic areas;

"(v) address gaps in quality and health outcomes measures, comparative effectiveness information, and data aggrega-

tion techniques, including the use of data registries;

"(vi) identify areas in the delivery of health care services that have the potential for rapid improvement in the quality of patient care;

"(vii) improve Federal payment policy to emphasize quality;

"(viii) enhance the use of health care data to improve quality, transparency, and outcomes; and

"(ix) address other areas as determined appropriate by the Secretary.

"(C) CONSIDERATIONS.—In identifying priorities under subparagraph (A), the Secretary shall take into consideration—

"(i) the recommendations submitted by qualified consensus-based entities as required under section 399JJ; and

"(ii) the recommendations of the Interagency Working Group on Health Care Quality established under section 202 of the Affordable Health Choices Act.

"(b) STRATEGIC PLAN.—

"(1) IN GENERAL.—The national strategy shall include a comprehensive strategic plan to achieve the priorities described in subsection (a).

"(2) REQUIREMENTS.—The strategic plan shall include provisions for addressing, at a minimum, the following:

"(A) Coordination among agencies within the Department, which shall include steps to minimize duplication of efforts and utilization of common quality measures, where available. Such common quality measures shall be measures endorsed under section 399JJ.

"(B) Agency-specific strategic plans to achieve national priorities.

"(C) Establishment of annual benchmarks for each relevant agency to achieve national priorities.

"(D) A process for regular reporting by the agencies to the Secretary on the implementation of the strategic plan.

"(E) Use of common incentives among public and private payers with regard to quality and patient safety efforts.

"(F) Incorporating quality improvement and measurement in the strategic plan for

health information technology required by the American Recovery and Reinvestment Act of 2009 (Public Law 111–5).

"(c) PERIODIC UPDATE OF NATIONAL STRATEGY.—The Secretary shall update the national strategy not less than triennially. Any such update shall include a review of short- and long-term goals.

"(d) SUBMISSION AND AVAILABILITY OF NATIONAL STRATEGY.—The Secretary shall transmit to the relevant Committees of Congress the national strategy and updates to such strategy.

"(e) PUBLIC REPORTING.—

"(1) ANNUAL NATIONAL HEALTH CARE QUALITY REPORT CARD.—Not later than January 31, 2011, and annually thereafter, the Secretary shall publish a national health care quality report card, which shall include—

"(A) the considerations for national priorities described in subsection (a)(2);

"(B) an analysis of the progress of the strategic plans under subsection (b)(2)(B) in achieving the national priorities under subsection (a)(2), and any gaps in such strategic plans;

"(C) the extent to which private sector strategies have informed Federal quality improvement efforts; and

"(D) a summary of consumer and provider feedback regarding quality improvement practices.

"(2) WEBSITE.—Not later than July 1, 2010, the Director shall create an Internet website to make public information regarding—

"(A) the national priorities for health care quality improvement established under subsection (a)(2);

"(B) the agency-specific strategic plans for health care quality described in subsection (b)(2)(B);

"(C) the annual national health care quality report card described in paragraph (1); and

"(D) other information, as the Secretary determines to be appropriate.".

(b) AGENCY QUALITY REVIEW.—

(1) IN GENERAL.—Each relevant agency within the Department of Health and Human Services shall review the statutory authority, regulations, policies, and procedures of such agency, as in effect on the date of enactment of this title, for purposes of deter-

mining whether there are any deficiencies or inconsistencies that prohibit full compliance with the intent, purposes, and provisions of this title (and the amendments made by this title).

(2) PROPOSALS.—Each agency described in paragraph (1) shall, not later than July 1, 2010, submit to the Secretary of Health and Human Services a proposal of the measures as may be necessary to bring the authority, regulations, policies, and procedures of such agency into conformity with the intent, purposes, and provisions of the this title (and the amendments made by this title).

**SEC. 202. INTERAGENCY WORKING GROUP ON HEALTH CARE QUALITY.**

(a) IN GENERAL.—The President shall convene a working group to be known as the Interagency Working Group on Health Care Quality (referred to in this section as the ''Working Group'').

(b) GOALS.—The goals of the Working Group shall be to achieve the following:

(1) Collaboration, cooperation, and consultation between Federal departments and agencies with respect to developing and disseminating strategies, goals, models, and timetables that are consistent with the national priorities identified under section

1 399HH(a)(2) of the Public Health Service Act (as
2 added by section 201).
3 (2) Avoidance of inefficient duplication of qual-
4 ity improvement efforts and resources, where prac-
5 ticable, and a streamlined process for quality report-
6 ing and compliance requirements.
7 (c) COMPOSITION.—
8 (1) IN GENERAL.—The Working Group shall be
9 composed of senior level representatives of—
10 (A) the Department of Health and Human
11 Services;
12 (B) the Department of Labor;
13 (C) the United States Office of Personnel
14 Management;
15 (D) the Department of Defense;
16 (E) the Department of Education;
17 (F) the Department of Veterans Affairs;
18 and
19 (G) any other Federal agencies and depart-
20 ments with activities relating to improving
21 health care quality and safety, as determined by
22 the President.
23 (2) CHAIR AND VICE-CHAIR.—

(A) CHAIR.—The Working Group shall be chaired by the Secretary of Health and Human Services.

(B) VICE-CHAIR.—Members of the Working Group, other than the Secretary of Health and Human Services, shall serve as Vice Chair of the Group on a rotating basis, as determined by the Group.

(d) REPORT TO CONGRESS.—Not later than December 31, 2010, and annually thereafter, the Working Group shall submit to the relevant Committees of Congress, and make public on an Internet website, a report describing the progress and recommendations of the Working Group in meeting the goals described in subsection (b).

**SEC. 203. QUALITY MEASURE DEVELOPMENT.**

Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) is amended—

(1) by redesignating part D as part E;

(2) by redesignating sections 931 through 938 as sections 941 through 948, respectively;

(3) in section 948(1), as so redesignated, by striking "931" and inserting "941"; and

(4) by inserting after section 926 the following:

## "PART D—HEALTH CARE QUALITY IMPROVEMENT

### "Subpart I—Quality Measure Development

**"SEC. 931. QUALITY MEASURE DEVELOPMENT.**

''(a) QUALITY MEASURE.—In this subpart, the term 'quality measure' means a standard for measuring the performance and improvement of population health or of health plans, providers of services, and other clinicians in the delivery of health care services.

''(b) IDENTIFICATION OF QUALITY MEASURES.—

''(1) IDENTIFICATION.—The Director shall identify, not less often than biennially, gaps where no quality measures exist, or where existing quality measures need improvement, updating, or expansion, consistent with the national strategy under section 399HH, for use in programs authorized under this Act. In identifying such gaps, the Director shall take into consideration the gaps identified by a qualified consensus-based entity under section 399JJ.

''(2) PUBLICATION.—The Director shall make available to the public on an Internet website a report on any gaps identified under paragraph (1) and the process used to make such identification.

''(c) GRANTS OR CONTRACTS FOR QUALITY MEASURE DEVELOPMENT.—

"(1) IN GENERAL.—The Director shall award grants, contracts, or intergovernmental agreements to eligible entities for purposes of developing, improving, updating, or expanding quality measures identified under subsection (b).

"(2) PRIORITIZATION IN THE DEVELOPMENT OF QUALITY MEASURES.—In awarding grants, contracts, or agreements under this subsection, the Director shall give priority to the development of quality measures that allow the assessment of—

"(A) health outcomes and functional status of patients;

"(B) the continuity, management, and coordination of health care and care transitions, including episodes of care, for patients across the continuum of providers, health care settings, and health plans;

"(C) patient, caregiver, and authorized representative experience, quality and relevance of information provided to patients, caregivers, and authorized representatives, and use of information by patients, caregivers, and authorized representatives to inform decisionmaking about treatment options and, where appropriate, palliative care;

1 "(D) the safety, effectiveness, and timeli-
2 ness of care;
3 "(E) health disparities across health dis-
4 parity populations (as defined in section 485E)
5 and geographic areas;
6 "(F) the appropriate use of health care re-
7 sources and services; or
8 "(G) use of innovative strategies and meth-
9 odologies identified under section 933.
10 "(3) ELIGIBLE ENTITIES.—To be eligible for a
11 grant or contract under this subsection, an entity
12 shall—
13 "(A) have demonstrated expertise and ca-
14 pacity in the development and evaluation of
15 quality measures;
16 "(B) have adopted procedures to include in
17 the quality measure development process—
18 "(i) the views of those providers or
19 payers whose performance will be assessed
20 by the measure; and
21 "(ii) the views of other parties who
22 also will use the quality measures (such as
23 patients, consumers, and health care pur-
24 chasers);

"(C) collaborate with a qualified consensus-based entity (as defined in section 399JJ), as practicable, and the Secretary so that quality measures developed by the eligible entity will meet the requirements to be considered for endorsement by such qualified consensus-based entity;

"(D) have transparent policies regarding conflicts of interest; and

"(E) submit an application to the Director at such time and in such manner, as the Director may require.

"(4) USE OF FUNDS.—An entity that receives a grant, contract, or agreement under this subsection shall use such award to develop quality measures that meet the following requirements:

"(A) Such measures build upon measures developed under section 1139A of Social Security Act, where applicable.

"(B) To the extent practicable, data on such quality measures is able to be collected using health information technologies.

"(C) Each quality measure is free of charge to users of such measure.

"(D) Each quality measure is publicly available on an Internet website.

"(d) OTHER ACTIVITIES BY THE DIRECTOR.—The Director may use amounts available under this section to update and test, where applicable, quality measures endorsed by a qualified consensus-based entity (as defined in section 399JJ) or adopted by the Secretary.

"(e) FUNDING.—There are authorized to be appropriated to carry out this section, $75,000,000 for each of fiscal years 2010 through 2014.".

**SEC. 204. QUALITY MEASURE ENDORSEMENT; PUBLIC REPORTING; DATA COLLECTION.**

Title III of the Public Health Service Act (42 U.S.C. 241 et seq.), as amended by section 201, is further amended by adding at the end the following:

**"Subpart II—Health Care Quality Programs**

**"SEC. 399JJ. QUALITY MEASURE ENDORSEMENT.**

"(a) DEFINITIONS.—In this subpart:

"(1) QUALIFIED CONSENSUS-BASED ENTITY.—The term 'qualified consensus-based entity' means an entity with a contract with the Secretary under section 1890 of the Social Security Act.

"(2) QUALITY MEASURE.—The term 'quality measure' means a standard for measuring the performance and improvement of population health or

of health plans, providers of services, and other clinicians in the delivery of health care services.

"(3) MULTI-STAKEHOLDER GROUP.—The term 'multi-stakeholder group' means, with respect to a quality measure, a voluntary collaborative of organizations representing a broad group of stakeholders interested in or affected by the use of such quality measure.

"(b) GRANTS AND CONTRACTS.—A qualified consensus-based entity may receive a grant or contract under this subsection to—

"(1) make recommendations to the Secretary for national priorities for performance improvement in population health and in the delivery of health care services;

"(2) identify gaps in endorsed quality measures, which shall include measures that—

"(A) are within priority areas identified by the Secretary under the national strategy established under section 399HH;

"(B) assess common care episodes, patient health outcomes, processes, efficiency, cost, and appropriate use of health care services and resources and address health disparities across

health disparity populations (as defined in section 485E) and geographic areas; or

"(C) assess use of innovative methodologies and strategies for quality improvement practices in the delivery of health care services that represent best practices for such quality improvement identified in section 933;

"(3) identify and endorse quality measures, including measures that address gaps identified in paragraph (2);

"(4) update endorsed quality measures at least every 3 years;

"(5) make endorsed quality measures publicly available and have a plan for broad-based dissemination of endorsed measures; and

"(6) transmit endorsed quality measures to the Secretary.

"(c) ANNUAL REPORTS.—

"(1) IN GENERAL.—A qualified consensus-based entity that receives a grant or contract under this section shall provide a report to the Secretary not less than annually—

"(A) of where gaps (as described in subsection (b)(2)) exist and where quality measures

are unavailable or inadequate to identify or address such gaps; and

"(B) regarding areas in which evidence is insufficient to support endorsement of quality measures in priority areas identified by the Secretary under the national strategy established under section 399HH and where targeted research may address such gaps.

"(2) IMPACT OF QUALITY MEASURES.—A qualified consensus-based entity that receives a grant or contract under this section shall provide a report to the Secretary not less than annually regarding the economic and quality impact of the use of endorsed measures.

"(d) PRIORITIES FOR PERFORMANCE IMPROVEMENT.—

"(1) RECOMMENDATION FOR NATIONAL PRIORITIES.—A qualified consensus-based entity that receives a grant or contract under this section shall evaluate evidence and convene multi-stakeholder groups to make recommendations to the Secretary for national priorities for performance improvement in population health and in the delivery of health care services for consideration under the national strategy established under section 399HH. The

qualified consensus-based entity shall make such recommendations not less frequently than triennially.

"(2) REQUIREMENTS FOR TRANSPARENCY IN PROCESS.—

"(A) IN GENERAL.—In convening multi-stakeholder groups under paragraph (1) with respect to recommendations for national priorities, the qualified consensus-based entity shall provide for an open and transparent process for the activities conducted pursuant to such convening.

"(B) SELECTION OF ORGANIZATIONS PARTICIPATING IN MULTI-STAKEHOLDER GROUPS.—The process under subparagraph (A) shall ensure that the selection of representatives comprising such groups provides for public nominations for, and the opportunity for public comment on, such selection.

"(3) CONSIDERATIONS IN RECOMMENDING PRIORITIES.—In making recommendations under paragraph (1), the qualified consensus-based entity shall ensure that priority is given to areas in the delivery of health care services for all populations including children, and other vulnerable populations that—

"(A) address the health care provided to patients with prevalent, high-cost chronic diseases;

"(B) improve the design, development, demonstration, and adoption of infrastructure and innovative methodologies and strategies for quality improvement practices in the delivery of health care services, including those that improve patient safety and reduce medical errors, readmissions, and health care-associated infections;

"(C) have the greatest potential for improving the health outcomes, efficiency, and patient-centeredness of health care;

"(D) reduce health disparities across populations (as defined in section 485E) and geographic areas;

"(E) address gaps in quality and health outcomes measures, comparative effectiveness information, and data aggregation techniques, including the use of data registries;

"(F) identify areas in the delivery of health care services that have the potential for rapid improvement in the quality of patient care; and

"(G) address the appropriate use of health care technology, resources and services.

"(e) PROCESS FOR CONSULTATION OF STAKEHOLDER GROUPS.—

"(1) CONSULTATION OF SELECTION OF ENDORSED QUALITY MEASURES.—A qualified consensus-based entity that receives a grant or contract under this section shall convene multi-stakeholder groups to provide guidance on the selection of individual or composite quality measures, for use in reporting performance information to the public or for use in Federal health programs, from among—

"(A) such measures that have been endorsed by the qualified consensus-based entity (under section 1890(b) of the Social Security Act or otherwise); and

"(B) such measures that have not been considered for endorsement by the qualified consensus-based entity but are used or proposed to be used by the Secretary under subsection (f)(2) under laws under the jurisdiction of the Secretary that require the collection or reporting of quality measures.

"(2) TRANSMISSION OF MULTI-STAKEHOLDER GUIDANCE.—The qualified consensus-based entity

shall transmit to the Secretary the guidance of multi-stakeholder groups provided under paragraph (1).

"(3) REQUIREMENT FOR TRANSPARENCY IN PROCESS.—

"(A) IN GENERAL.—In convening multi-stakeholder groups under paragraph (1) with respect to the selection of quality measures, the qualified consensus-based entity shall provide for an open and transparent process for the activities conducted pursuant to such convening.

"(B) SELECTION OF ORGANIZATIONS PARTICIPATING IN MULTI-STAKEHOLDER GROUPS.—The process under subparagraph (A) shall ensure that the selection of representatives comprising such groups provides for public nominations for, and the opportunity for public comment on, such selection.

"(f) COORDINATION OF USE OF QUALITY MEASURES.—

"(1) ENDORSED QUALITY MEASURES.—The Secretary may make a determination under regulation or otherwise to use a quality measure described in subsection (e)(1)(A) only after taking into ac-

count the guidance of multi-stakeholder groups under subsection (e)(2).

"(2) USE OF INTERIM MEASURES.—

"(A) IN GENERAL.—The Secretary may make a determination, by regulation or otherwise, to use a quality measure that has not been endorsed as described in subsection (e)(1)(A), provided that the Secretary—

"(i) in a timely manner, transmits the measure to the qualified consensus-based entity for consideration for endorsement and for the multi-stakeholder consultation process under subsection (e)(1);

"(ii) publishes in the Federal Register the rationale for the use of the measure; and

"(iii) phases out use of the measure upon a decision of the qualified consensus-based entity not to endorse the measure, contingent on availability of an adequate alternative endorsed measure (as determined by the Secretary), taking into account guidance from multi-stakeholder consultation process under subsection (e)(1).

"(B) NO ADEQUATE ALTERNATIVE.—If an adequate alternative endorsed measure is not available, the Secretary shall support the development of such an alternative endorsed measure, as described in section 931.

"(3) REQUIREMENT OF COORDINATION WITH ENTITY.—

"(A) REQUIREMENT FOR NOTIFICATION OF ENTITY OF DEADLINE FOR RECOMMENDATIONS FOR QUALITY MEASURES IN PROPOSED REGULATIONS.—For each notice of proposed rulemaking to implement the collection or reporting of data on quality measures as described in section 399LL, the Secretary shall establish a process for the regular provision of advance notice to the qualified consensus-based entity of the date certain by which recommendations of the entity with respect to quality measures must be submitted to the Secretary for consideration in the development of such specified regulation.

"(B) TIMELY NOTICE.—Under the process established under subparagraph (A), notice shall be given to the qualified consensus-based

entity not less than 120 days before the date certain referred to in subparagraph (A).

"(C) PUBLICATION OF DESCRIPTION OF ENTITY RECOMMENDATIONS AND RESPONSES.—In publishing a specified regulation, the Secretary shall include a description of each recommendation of the qualified consensus-based entity with respect to quality measures and shall include responses of the Secretary to each such recommendation.

"(D) DEFINITION.—In this paragraph, the term 'specified regulation' means a notice of proposed rulemaking to implement the collection or reporting of data on quality measures as described in section 399LL.

"(4) EFFECTIVE DATE.—This subsection shall apply with respect to determinations or requirements by the Secretary for the use of quality measures made on or after the date of enactment of the Affordable Health Choices Act.

"(g) REVIEW OF QUALITY MEASURES USED BY THE SECRETARY.—

"(1) IN GENERAL.—Not less than once every 3 years, the Secretary shall review quality measures

used by the Secretary and, with respect to each such measure, shall determine whether to—

"(A) maintain the use of such measure; or

"(B) phase out such measure.

"(2) CONSIDERATIONS.—In conducting the review under paragraph (1), the Secretary shall—

"(A) seek to avoid duplication of measures used; and

"(B) take into consideration current innovative methodologies and strategies for quality improvement practices in the delivery of health care services that represent best practices for such quality improvement and measures endorsed by a qualified consensus-based entity since the previous review by the Secretary.

"(h) PROCESS FOR DISSEMINATION OF MEASURES USED BY THE SECRETARY.—The Secretary shall establish a process for disseminating quality measures used by the Secretary. Such process shall include the incorporation of such measures, where applicable, in workforce programs, training curricula, payment programs, and any other means of dissemination determined by the Secretary. The Secretary shall establish a process to disseminate such quality measures through the Interagency Working Group

1 established under section 202 of the Affordable Health
2 Choices Act.
3 "(i) FUNDING.—To carry out this section there are
4 authorized to be appropriated $50,000,000 for each of fis-
5 cal years for 2010 through 2014.

6 **"SEC. 399KK. PUBLIC REPORTING OF PERFORMANCE IN-**
7 **FORMATION.**

8 "(a) REPORTING OF QUALITY MEASURES.—
9 "(1) IN GENERAL.—
10 "(A) REPORTING SYSTEM.—Not later than
11 5 years after the date of enactment of the Af-
12 fordable Health Choices Act, and after notice
13 and opportunity for public comment, the Sec-
14 retary shall implement a system for the report-
15 ing on quality measures that protect patient
16 privacy and, where appropriate—
17 "(i) assess health outcomes and func-
18 tional status of patients;
19 "(ii) assess the continuity and coordi-
20 nation of care and care transitions, includ-
21 ing episodes of care, for patients across the
22 continuum of providers and health care
23 settings;
24 "(iii) assess patient experience and
25 patient, caregiver, and family engagement;

"(iv) assess the safety, effectiveness, and timeliness of care; and

"(v) assess health disparities (as defined by section 485E) across populations and geographic areas.

"(2) FORM AND MANNER.—The data submitted under the system implemented under paragraph (1) shall be in a form and manner specified by the Secretary.

"(3) MEASURES DESCRIBED.—The quality measures described in paragraph (1) shall—

"(A) be risk adjusted, taking into account differences in patient health status, patient characteristics, and geographic location, as appropriate;

"(B) be valid, reliable, evidence-based, feasible to collect, and actionable by providers, payers and consumers, as appropriate;

"(C) minimize the burden of collection and reporting such measures; and

"(D) be consistent with the national strategy established by the Secretary under section 399HH.

"(b) DEVELOPMENT OF PERFORMANCE WEBSITES.—The Secretary shall make available to the

public performance information summarizing data on quality measures collected in subsection (a) through a series of standardized Internet websites tailored to respond to the differing needs of hospitals and other institutional providers and services, physicians and other clinicians, patients, consumers, researchers, policymakers, States, and such other stakeholders as the Secretary may specify.

"(c) DESIGN.—Each standardized Internet website made available under subsection (b) shall be designed to make the use and navigation of that website readily available to individuals accessing it. The Secretary shall develop a flexible format to meet the differing needs of the various stakeholders and shall modify the website to permit a user to easily customize queries.

"(d) INFORMATION ON CONDITIONS.—Performance information made publicly available on a standardized Internet website under subsection (b) shall be presented by, but not limited to, clinical condition to the extent such information is available, and the information presented shall, where appropriate, be provider-specific and sufficiently disaggregated and specific to meet the needs of patients with different clinical conditions.

"(e) CONSULTATION.—The Secretary shall carry out this section in collaboration with a qualified consensus-based entity under section 399JJ to determine the type

of information that is useful to stakeholders and the format that best facilitates use of the reports and of performance reporting Internet websites. The qualified consensus-based entity shall convene multi-stakeholder groups as provided in section 399JJ to review the design and format of each Internet website made available under subsection (b) and shall transmit to the Secretary the views of such multi-stakeholder groups with respect to each such design and format.

**"SEC. 399LL. EVALUATION OF DATA COLLECTION PROCESS FOR QUALITY MEASUREMENT.**

''(a) GAO EVALUATIONS.—The Comptroller General of the United States shall conduct periodic evaluations of the implementation of the data collection processes for quality measures used by the Secretary.

''(b) CONSIDERATIONS.—In carrying out the evaluation under subsection (a), the Comptroller General shall determine—

''(1) whether the system for the collection of data for quality measures provides for validation of data as relevant, fair, and scientifically credible;

''(2) whether data collection efforts under the system use the most efficient and cost-effective means in a manner that minimizes administrative burden on persons required to collect data and that

adequately protects the privacy of patients' personal health information and provides data security;

"(3) whether standards under the system provide for an opportunity for physicians and other clinicians and institutional providers of services to review and correct findings; and

"(4) the extent to which quality measures—

"(A) assess health outcomes and functional status of patients;

"(B) assess the continuity and coordination of care and care transitions, including episodes of care, for patients across the continuum of providers, age, and health care settings;

"(C) assess patient experience and patient, caregiver, and family engagement;

"(D) assess the safety, effectiveness, and timeliness of care;

"(E) assess health disparities across health disparity populations (as defined by section 485E) and geographic areas;

"(F) address the appropriate use of health care resources and services;

"(G) are designed to be collected as part of health information technologies supporting better delivery of health care services;

"(H) result in direct or indirect costs to users of such measures; and

"(I) provide utility to both the care of individuals and the management of population health.

"(c) REPORT.—The Comptroller General shall submit reports to Congress and to the Secretary containing a description of the findings and conclusions of the results of each such evaluation.".

**SEC. 205. COLLECTION AND ANALYSIS OF DATA FOR QUALITY AND RESOURCE USE MEASURES.**

(a) IN GENERAL.—Part S of title III of the Public Health Service Act, as amended by section 204, is further amended by adding at the end the following:

**"SEC. 399MM. COLLECTION AND ANALYSIS OF DATA FOR QUALITY AND RESOURCE USE MEASURES.**

"(a) PURPOSE.—The purpose of this section is to provide for the development of reports based on Federal health care data and private data that is publicly available or is provided by the entity making the request for the report in order to—

"(1) improve the quality and efficiency of health care and advance health care research;

"(2) enhance the education and awareness of consumers for evaluating health care services; and

"(3) provide the public with reports on national, regional, and provider- and supplier-specific performance, which may be in a provider- or supplier-identifiable format.

"(b) ESTABLISHMENT OF PROCESS.—The Secretary shall establish a process to collect, and validate, aggregate data on quality measures described in section 399JJ to facilitate public reporting described in section 399KK. Such process shall—

"(1) be developed based on guidance of a broad-based, public-private collaboration;

"(2) employ methods that are scientifically sound and feasible to implement nationwide through the use of consistent methods for the collection, analysis, and reporting of quality and resource use measures;

"(3) over time, where feasible, build on expanding availability of health information technology and other data systems that are directly used to improve and coordinate patient care;

"(4) allow for the integration of data on quality of care and resource use from a range of data sources used by providers and patients to coordinate and improve care, including public sources, private sources, and public-private collaborations;

"(5) be implemented in accordance with an aggressive timeline to be established by the Secretary based on the technical and practical feasibility of measures and related data systems; and

"(6) utilize clinical and claims data to evaluate the quality and efficiency of health care.

"(c) DATA COLLECTION, AGGREGATION, AND ANALYSIS.—The Secretary shall ensure the collection and aggregation of consistent data on quality and resource use measures from information systems used to support health care delivery to implement the public reporting of performance information as described in section 399KK. The Secretary shall ensure that such collection, aggregation, and analysis systems span an increasingly broad range of patient populations, providers, and geographic areas over time.

"(d) GRANTS AND CONTRACTS FOR DATA COLLECTION.—

"(1) IN GENERAL.—The Secretary shall award grants or contracts to eligible entities to support the collection and aggregation of quality and resource use measures described under subsection (c).

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

"(A)(i) be a multi-stakeholder entity that coordinates the development of methods and implementation plans for the consistent reporting of summary quality and cost information;

"(ii) be an entity capable of submitting such summary data for a particular population and providers, such as a disease registry, regional collaboration, health plan collaboration, or other population-wide source; or

"(iii) be a Federal Indian Health Service program or a health program operated by an Indian Tribe (as defined in section 4 of the Indian Health Care Improvement Act);

"(B) promote the use of the systems that provide data to improve and coordinate patient care;

"(C) support the provision of timely, consistent quality and resource use information to health care providers, and other groups and organizations as appropriate, with an opportunity for providers to correct inaccurate measures; and

"(D) support the provision of consistent measures on quality and resource use to the

public in accordance with the process established by the Secretary under subsection (b).

"(3) CONSISTENT DATA AGGREGATION.—The Secretary shall award funding under this subsection only to entities enabling summary data that can be integrated and compared across multiple sources. The Secretary shall also provide standards for the protection of the security and privacy of patient data.

"(e) PILOT PROGRAMS TO DEVELOP, VALIDATE, AND IMPROVE METHODS USED TO SUPPORT THE NATIONWIDE QUALITY MEASUREMENT AND REPORTING STRATEGY.—

"(1) IN GENERAL.—

"(A) DEVELOPMENT, VALIDATION, AND IMPROVEMENT METHODS.—The Secretary shall support the development, validation, implementation, and refinement of nationally consistent methods used to support quality measurement and reporting under section 399KK.

"(B) GRANTS AND CONTRACTS.—The Secretary may award grants or contracts to eligible quality data entities to carry out subparagraph (A).

"(2) ELIGIBLE QUALITY DATA ENTITIES.—To be eligible for a grant or contract under this subsection, a quality data entity shall—

"(A) be a public or private organization with expertise and experience in large-scale health care data aggregation, integration, analysis, or reporting; and

"(B) support the implementation of quality measurement and reporting under section 399KK, including the production of data that can be combined and compared with equivalent information from other entities involved in supporting the delivery of care.

"(f) GRANTS AND CONTRACTS FOR DATA ANALYSIS.—

"(1) FEDERAL HEALTH CARE DATA.—In this subsection:

"(A) IN GENERAL.—Subject to subparagraph (B), the term 'Federal health care data' means—

"(i) deidentified enrollment data and deidentified claims data maintained by the Secretary or entities under programs, contracts, grants, or memoranda of under-

standing administered by the Secretary; and

"(ii) where feasible, other deidentified enrollment data and deidentified claims data maintained by the Federal Government or entities under contract with the Federal Government.

"(B) EXCEPTION.—The term 'Federal health care data' includes data relating to programs administered by the Secretary under the Social Security Act only to the extent that the disclosure of such data is authorized or required under such Act.

"(2) AWARDS.—The Secretary shall award contracts to eligible entities to support the analysis of quality and resource use measures described under subsection (c).

"(3) ELIGIBLE ENTITIES.—

"(A) QUALIFICATIONS.—The Secretary shall enter into a contract with an entity under paragraph (2) only if the Secretary determines that the entity—

"(i) has the research capability to conduct and complete reports under this subsection;

1 "(ii) has in place—
2 "(I) an information technology
3 infrastructure to support the database
4 of Federal health care data that is to
5 be disclosed to the entity; and
6 "(II) operational standards to
7 provide security for such database;
8 "(iii) has experience with, and exper-
9 tise on, the development of reports on
10 health care quality and efficiency; and
11 "(iv) has a significant business pres-
12 ence in the United States.
13 "(B) CONTRACT REQUIREMENTS.—Each
14 contract with an entity under paragraph (2)
15 shall contain the following requirements:
16 "(i) ENSURING BENEFICIARY PRI-
17 VACY.—
18 "(I) HIPAA.—The entity shall
19 meet the requirements imposed on a
20 covered entity for purposes of apply-
21 ing part C of title XI and all regu-
22 latory provisions promulgated there-
23 under, including regulations (relating
24 to privacy) adopted pursuant to the
25 authority of the Secretary under sec-

tion 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

"(II) OTHER STATUTORY PROTECTIONS.—The entity shall be required to refrain from disclosing data that could be withheld by the Secretary under section 552 of title 5, United States Code, or whose disclosure by the Secretary would violate section 552a of such title.

"(ii) PROPRIETARY INFORMATION.—The entity shall provide assurances that the entity will not disclose any negotiated price concessions, such as discounts, direct or indirect subsidies, rebates, and direct or indirect remunerations, obtained by health care providers or suppliers or health care plans, or any other proprietary cost information.

"(iii) DISCLOSURE.—The entity shall disclose—

"(I) any financial, reporting, or contractual relationship between the

entity and any health care provider or supplier or health care plan; and

"(II) if applicable, the fact that the entity is managed, controlled, or operated by any health care provider or supplier or health care plan.

"(iv) COMPONENT OF ANOTHER ORGANIZATION.—If the entity is a component of another organization—

"(I) the entity shall maintain Federal health care data and reports separately from the rest of the organization and establish appropriate security measures to maintain the confidentiality and privacy of the Federal health care data and reports; and

"(II) the entity shall not make an unauthorized disclosure to the rest of the organization of Federal health care data or reports in breach of such confidentiality and privacy requirement.

"(v) TERMINATION OR NONRENEWAL.—If a contract under this sub-

1 section is terminated or not renewed, the
2 following requirements shall apply:
3 "(I) CONFIDENTIALITY AND PRI-
4 VACY PROTECTIONS.—The entity shall
5 continue to comply with the confiden-
6 tiality and privacy requirements under
7 this subsection with respect to all
8 Federal health care data disclosed to
9 the entity and each report developed
10 by the entity.
11 "(II) DISPOSITION OF DATA AND
12 REPORTS.—The entity shall—
13 "(aa) return to the Sec-
14 retary all Federal health care
15 data disclosed to the entity and
16 each report developed by the enti-
17 ty; or
18 "(bb) if returning the Fed-
19 eral health care data and reports
20 is not practicable, destroy the re-
21 ports and Federal health care
22 data.
23 "(vi) RISK ADJUSTMENT.—The entity
24 shall ensure that the methodology used to
25 develop a report under paragraph (4) shall

include acceptable risk adjustment and case-mix adjustment developed in consultation with providers.

"(C) COMPETITIVE PROCEDURES.—Competitive procedures (as defined in section 4(5) of the Federal Procurement Policy Act) shall be used to enter into contracts under paragraph (2).

"(D) REVIEW OF CONTRACT IN EVENT OF A MERGER OR ACQUISITION.—The Secretary shall review the contract with an entity receiving a contract under this subsection in the event of a merger or acquisition of the entity in order to ensure that the requirements under this subsection will continue to be met.

"(4) PROCEDURES FOR THE DEVELOPMENT OF REPORTS.—Notwithstanding section 552(b)(6) or 552a(b) of title 5, United States Code, subject to paragraph (1)(B), not later than 12 months after the date of enactment of this section, the Secretary, in accordance with the purpose described in subsection (a), shall establish and implement procedures under which an entity may submit a request to an entity with a contract under this subsection to develop a report based on—

"(A) Federal health care data disclosed to the entity under paragraph (5); and

"(B) private data that is publicly available or is provided to the entity by the entity making the request for the report.

"(5) ACCESS TO FEDERAL HEALTH CARE DATA.—

"(A) IN GENERAL.—The procedures established under paragraph (4) shall provide for the secure disclosure of Federal health care data to each entity with a contract under paragraph (2).

"(B) UPDATE INFORMATION.—Not less than every 6 months, the Secretary shall update the information disclosed under subparagraph (A) to each such entity.

"(g) PUBLIC REPORTING OF QUALITY RESOURCE USE MEASURES AT THE PROVIDER, GROUP, SYSTEM, REGIONAL, AND OTHER LEVELS.—The Secretary shall make aggregated data, and reports developed under subsection (f), on quality and resource use measures collected under this section available to health care providers and the public through the process described in 399KK.

"(h) RESEARCH ACCESS TO HEALTH CARE DATA AND REPORTING ON PERFORMANCE.—The Secretary

shall permit researchers that meet criteria used to evaluate the appropriateness of the release data for research purposes (as established by the Secretary) to—

"(1) have access to Federal health care data (as defined in subsection (f)); and

"(2) report on the performance of health care providers and suppliers, including reporting in a provider- or supplier-identifiable format.

"(i) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $90,000,000 for each of fiscal years 2010 through 2014.".

(b) HIT POLICY COMMITTEE.—Section 3002(b)(2)(B) of the Public Health Service Act (42 U.S.C. 300jj–12(b)(2)(B)) is amended by adding at the end the following:

"(ix) The use of certified electronic health records to collect and report quality measures accepted by the Secretary.".

# Subtitle B—Health Care Quality Improvements

**SEC. 211. HEALTH CARE DELIVERY SYSTEM RESEARCH; QUALITY IMPROVEMENT TECHNICAL ASSISTANCE.**

Part D of title IX of the Public Health Service Act, as amended by section 203, is further amended by adding at the end the following:

**"Subpart II—Health Care Quality Improvement Programs**

**"SEC. 933. HEALTH CARE DELIVERY SYSTEM RESEARCH.**

''(a) PURPOSE.—The purposes of this section are to—

''(1) enable the Director to identify, develop, evaluate, disseminate, and provide training in innovative methodologies and strategies for quality improvement practices in the delivery of health care services that represent best practices (referred to as 'best practices') in health care quality, safety, and value; and

''(2) ensure that the Director is accountable for implementing a model to pursue such research in a collaborative manner with other related Federal agencies.

"(b) ESTABLISHMENT OF CENTER.—There is established within the Agency the Patient Safety Research Center (referred to in this section as the 'Center').

"(c) GENERAL FUNCTIONS OF CENTER.—The Center shall—

"(1) carry out its functions using research from a variety of disciplines, which may include epidemiology, health services, sociology, psychology, human factors engineering, biostatistics, health economics, clinical research, and health informatics;

"(2) conduct or support activities for activities identified in subsection (a), and for—

"(A) best practices for quality improvement practices in the delivery of health care services; and

"(B) that include changes in processes of care and the redesign of systems used by providers that will reliably result in intended health outcomes, improve patient safety, and reduce medical errors (such as skill development for health care providers in team-based health care delivery and rapid cycle process improvement) and facilitate adoption of improved workflow;

"(3) identify health care providers, including health care systems, single institutions, and individual providers, that—

"(A) deliver consistently high-quality, efficient health care services (as determined by the Secretary); and

"(B) employ best practices that are adaptable and scalable to diverse health care settings or effective in improving care across diverse settings;

"(4) assess research, evidence, and knowledge about what strategies and methodologies are most effective in improving health care delivery;

"(5) find ways to translate such information rapidly and effectively into practice, and document the sustainability of those improvements;

"(6) create strategies for quality improvement through the development of tools, methodologies, and interventions that can successfully reduce variations in the delivery of health care;

"(7) identify, measure, and improve organizational, human, or other causative factors, including those related to the culture and system design of a health care organization, that contribute to the suc-

1 cess and sustainability of specific quality improve-
2 ment and patient safety strategies;
3 ''(8) provide for the development of best prac-
4 tices in the delivery of health care services that—
5 ''(A) have a high likelihood of success,
6 based on structured review of empirical evi-
7 dence;
8 ''(B) are specified with sufficient detail of
9 the individual processes, steps, training, skills,
10 and knowledge required for implementation and
11 incorporation into workflow of health care prac-
12 titioners in a variety of settings;
13 ''(C) are designed to be readily adapted by
14 health care providers in a variety of settings;
15 and
16 ''(D) where applicable, assist health care
17 providers in working with other health care pro-
18 viders across the continuum of care and in en-
19 gaging patients and their families in improving
20 the care and patient health outcomes;
21 ''(9) provide for the funding of the activities of
22 organizations with recognized expertise and excel-
23 lence in improving the delivery of health care serv-
24 ices, including children's health care, by involving
25 multiple disciplines, managers of health care entities,

broad development and training, patients, caregivers and families, and frontline health care workers, including activities for the examination of strategies to share best quality improvement practices and to promote excellence in the delivery of health care services; and

"(10) build capacity at the State and community level to lead quality and safety efforts through education, training, and mentoring programs to carry out the activities under paragraphs (1) through (9).

"(d) RESEARCH FUNCTIONS OF CENTER.—

"(1) IN GENERAL.—The Center shall support, such as through a contract or other mechanism, research on health care delivery system improvement and the development of tools to facilitate adoption of best practices that improve the quality, safety, and efficiency of health care delivery services. Such support may include establishing a Quality Improvement Network Research Program for the purpose of testing, scaling, and disseminating of interventions to improve quality and efficiency in health care. Recipients of funding under the Program may include national, State, multi-State, or multi-site quality improvement networks.

"(2) RESEARCH REQUIREMENTS.—The research conducted pursuant to paragraph (1) shall—

"(A) address the priorities identified by the Secretary in the national strategic plan established under section 399HH;

"(B) identify areas in which evidence is insufficient to identify strategies and methodologies, taking into consideration areas of insufficient evidence identified by a qualified consensus-based entity in the report required under section 399JJ;

"(C) address concerns identified by health care institutions and providers and communicated through the Center pursuant to subsection (e);

"(D) reduce preventable morbidity, mortality, and associated costs of morbidity and mortality by building capacity for patient safety research;

"(E) support the discovery of processes for the reliable, safe, efficient, and responsive delivery of health care, taking into account discoveries from clinical research and comparative effectiveness research;

"(F) be designed to help improve health care quality and is tested in practice-based settings;

"(G) allow communication of research findings and translate evidence into practice recommendations that are adaptable to a variety of settings, and which, as soon as practicable after the establishment of the Center, shall include—

"(i) the implementation of a national application of Intensive Care Unit improvement projects relating to the adult (including geriatric), pediatric, and neonatal patient populations;

"(ii) practical methods for addressing health care associated infections, including Methicillin–Resistant Staphylococcus Aureus and Vancomycin–Resistant Entercoccus infections and other emerging infections; and

"(iii) practical methods for reducing preventable hospital admissions and readmissions;

"(H) expand demonstration projects for improving the quality of children's health care

and the use of health information technology, such as through Pediatric Quality Improvement Collaboratives and Learning Networks, consistent with provisions of section 1139A of the Social Security Act for assessing and improving quality, where applicable;

"(I) identify and mitigate hazards by—

"(i) analyzing events reported to patient safety reporting systems and patient safety organizations; and

"(ii) using the results of such analyses to develop scientific methods of response to such events;

"(J) include the conduct of systematic reviews of existing practices that improve the quality, safety, and efficiency of health care delivery, as well as new research on improving such practices; and

"(K) include the examination of how to measure and evaluate the progress of quality and patient safety activities.

"(e) DISSEMINATION OF RESEARCH FINDINGS.—

"(1) PUBLIC AVAILABILITY.—The Director shall make the research findings of the Center available to the public through multiple media and appro-

priate formats to reflect the varying needs of health care providers and consumers and diverse levels of health literacy.

"(2) LINKAGE TO HEALTH INFORMATION TECHNOLOGY.—The Secretary shall ensure that research findings and results generated by the Center are shared with the Office of the National Coordinator of Health Information Technology and used to inform the activities of the health information technology extension program under section 3012, as well as any relevant standards, certification criteria, or implementation specifications.

"(f) PRIORITIZATION.—The Director shall identify and regularly update a list of processes or systems on which to focus research and dissemination activities of the Center, taking into account—

"(1) cost to Federal health programs;

"(2) consumer assessment of health care experience;

"(3) provider assessment of such processes or systems and opportunities to minimize distress and injury to the health care workforce;

"(4) potential impact of such processes or systems on health status and function of patients, including vulnerable populations including children;

"(5) areas of insufficient evidence identified under subsection (d)(2)(B); and

"(6) the evolution of meaningful use of health information technology, as defined in section 3000.

"(g) FUNDING.—There is authorized to be appropriated to carry out this section $20,000,000 for fiscal years 2010 through 2014.

**"SEC. 934. QUALITY IMPROVEMENT TECHNICAL ASSISTANCE AND IMPLEMENTATION.**

"(a) IN GENERAL.—The Director, through the Patient Safety Research Center established in section 933 (referred to in this section as the 'Center'), shall award—

"(1) technical assistance grants or contracts to eligible entities to provide technical support to institutions that deliver health care and health care providers so that such institutions and providers understand, adapt, and implement the models and practices identified in the research conducted by the Center, including the Quality Improvement Networks Research Program; and

"(2) implementation grants or contracts to eligible entities to implement the models and practices described under paragraph (1).

"(b) ELIGIBLE ENTITIES.—

"(1) TECHNICAL ASSISTANCE AWARD.—To be eligible to receive a technical assistance grant or contract under subsection (a)(1), an entity—

"(A) may be a health care provider, health care provider association, professional society, health care worker organization, Indian health organization, quality improvement organization, patient safety organization, local quality improvement collaborative, the Joint Commission, academic health center, university, physician-based research network, primary care extension program established under section 399V, a Federal Indian Health Service program or a health program operated by an Indian Tribe (as defined in section 4 of the Indian Health Care Improvement Act), or any other entity identified by the Secretary; and

"(B) shall have demonstrated expertise in providing information and technical support and assistance to health care providers regarding quality improvement.

"(2) IMPLEMENTATION AWARD.—To be eligible to receive an implementation grant or contract under subsection (a)(2), an entity—

"(A) may be a hospital or other health care provider or consortium or providers, as determined by the Secretary; and

"(B) shall have demonstrated expertise in providing information and technical support and assistance to health care providers regarding quality improvement.

"(c) APPLICATION.—

"(1) TECHNICAL ASSISTANCE AWARD.—To receive a technical assistance grant or contract under subsection (a)(1), an eligible entity shall submit an application to the Secretary at such time, in such manner, and containing—

"(A) a plan for a sustainable business model that may include a system of—

"(i) charging fees to institutions and providers that receive technical support from the entity; and

"(ii) reducing or eliminating such fees for such institutions and providers that serve low-income populations; and

"(B) such other information as the Director may require.

"(2) IMPLEMENTATION AWARD.—To receive a grant or contract under subsection (a)(2), an eligible

entity shall submit an application to the Secretary at such time, in such manner, and containing—

"(A) a plan for implementation of a model or practice identified in the research conducted by the Center including—

"(i) financial cost, staffing requirements, and timeline for implementation; and

"(ii) pre- and projected post-implementation quality measure performance data in targeted improvement areas identified by the Secretary; and

"(B) such other information as the Director may require.

"(d) MATCHING FUNDS.—The Director may not award a grant or contract under this section to an entity unless the entity agrees that it will make available (directly or through contributions from other public or private entities) non-Federal contributions toward the activities to be carried out under the grant or contract in an amount equal to $1 for each $5 of Federal funds provided under the grant or contract. Such non-Federal matching funds may be provided directly or through donations from public or private entities and may be in cash or in-kind, fairly evaluated, including plant, equipment, or services.

1 "(e) EVALUATION.—
2 "(1) IN GENERAL.—The Director shall evaluate
3 the performance of each entity that receives a grant
4 or contract under this section. The evaluation of an
5 entity shall include a study of—
6 "(A) the success of such entity in achiev-
7 ing the implementation, by the health care in-
8 stitutions and providers assisted by such entity,
9 of the models and practices identified in the re-
10 search conducted by the Center under section
11 933;
12 "(B) the perception of the health care in-
13 stitutions and providers assisted by such entity
14 regarding the value of the entity; and
15 "(C) where practicable, better patient
16 health outcomes and lower cost resulting from
17 the assistance provided by such entity.
18 "(2) EFFECT OF EVALUATION.—Based on the
19 outcome of the evaluation of the entity under para-
20 graph (1), the Director shall determine whether to
21 renew a grant or contract with such entity under
22 this section.
23 "(f) COORDINATION.—The entities that receive a
24 grant or contract under this section shall coordinate with
25 health information technology regional extension centers

under section 3012(c) and the primary care extension program established under section 399V regarding the dissemination of quality improvement, system delivery reform, and best practices information.''.

**SEC. 212. GRANTS TO ESTABLISH COMMUNITY HEALTH TEAMS TO SUPPORT THE PATIENT-CENTERED MEDICAL HOME.**

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary'') shall establish a program to provide grants to eligible entities to establish community-based interdisciplinary, interprofessional teams (referred to in this section as ''health teams'') to support primary care practices, including obstetrics and gynecology practices, within the hospital service areas served by the eligible entities. Grants shall be used to—

(1) establish health teams to provide support services to primary care providers; and

(2) provide capitated payments to primary care providers as determined by the Secretary.

(b) ELIGIBLE ENTITIES.—To be eligible to receive a grant under subsection (a), an entity shall—

(1)(A) be a State or State-designated entity; or

1 ⟦(B) be an Indian Tribe or tribal organization,
2 as defined in section 4 of the Indian Health Care
3 Improvement Act;⟧
4 (2) submit a plan for achieving long-term finan-
5 cial sustainability within 3 years;
6 (3) submit a plan for incorporating prevention
7 initiatives and patient education and care manage-
8 ment resources into the delivery of health care that
9 is integrated with community-based prevention and
10 treatment resources, where available;
11 (4) ensure that the health team established by
12 the entity includes an interdisciplinary, interprofes-
13 sional team of health care providers, as determined
14 by the Secretary; such team may include medical
15 specialists, nurses, nutritionists, dieticians, social
16 workers, behavioral and mental health providers (in-
17 cluding substance use disorder prevention and treat-
18 ment providers), doctors of chiropractic, licensed
19 complementary and alternative medicine practi-
20 tioners, and physicians' assistants; and
21 (5) submit to the Secretary an application at
22 such time, in such manner, and containing such in-
23 formation as the Secretary may require.

(c) REQUIREMENTS FOR HEALTH TEAMS.—A health team established pursuant to a grant under subsection (a) shall—

(1) establish contractual agreements with primary care providers to provide support services;

(2) support patient-centered medical homes, defined as mode of care that includes—

(A) personal physicians;

(B) whole person orientation;

(C) coordinated and integrated care;

(D) safe and high quality care though evidence-informed medicine, appropriate use of health information technology, and continuous quality improvements;

(E) expanded access to care; and

(F) payment that recognizes added value from additional components of patient-centered care;

(3) collaborate with local primary care providers and existing State and community based resources to coordinate disease prevention, chronic disease management, transitioning between health care providers and settings and case management for patients, including children, with priority given to

1 those amenable to prevention and with chronic dis-
2 eases or conditions identified by the Secretary;
3 (4) in collaboration with local health care pro-
4 viders, develop and implement interdisciplinary,
5 interprofessional care plans that integrate clinical
6 and community preventive and health promotion
7 services for patients, including children, with a pri-
8 ority given to those amenable to prevention and with
9 chronic diseases or conditions identified by the Sec-
10 retary;
11 (5) incorporate health care providers, patients,
12 caregivers, and authorized representatives in pro-
13 gram design and oversight;
14 (6) provide support necessary for local primary
15 care providers to—
16 (A) coordinate and provide access to high-
17 quality health care services;
18 (B) coordinate and provide access to pre-
19 ventive and health promotion services;
20 (C) provide access to appropriate specialty
21 care and inpatient services;
22 (D) provide quality-driven, cost-effective,
23 culturally appropriate, and patient- and family-
24 centered health care;

(E) provide access to pharmacist-delivered medication management services, including medication reconciliation;

(F) provide coordination of the appropriate use of complementary and alternative (CAM) services to those who request such services;

(G) promote effective strategies for treatment planning, monitoring health outcomes and resource use, sharing information, treatment decision support, and organizing care to avoid duplication of service and other medical management approaches intended to improve quality and value of health care services;

(H) provide local access to the continuum of health care services in the most appropriate setting, including access to individuals that implement the care plans of patients and coordinate care, such as integrative health care practitioners;

(I) collect and report data that permits evaluation of the success of the collaborative effort on patient outcomes, including collection of data on patient experience of care, and identification of areas for improvement; and

(J) establish a coordinated system of early identification and referral for children at risk for developmental or behavioral problems such as through the use of infolines, health information technology, or other means as determined by the Secretary;

(7) provide 24-hour care management and support during transitions in care settings including—

(A) a transitional care program that provides onsite visits from the care coordinator, assists with the development of discharge plans and medication reconciliation upon admission to and discharge from the hospitals, nursing home, or other institution setting;

(B) discharge planning and counseling support to providers, patients, caregivers, and authorized representatives;

(C) assuring that post-discharge care plans include medication management, as appropriate;

(D) referrals for mental and behavioral health services, which may include the use of infolines; and

(E) transitional health care needs from adolescence to adulthood;

(8) serve as a liaison to community prevention and treatment programs;

(9) demonstrate a capacity to implement and maintain health information technology that meets the requirements of certified EHR technology (as defined in section 3000 of the Public Health Service Act (42 U.S.C. 300jj)) to facilitate coordination among members of the applicable care team and affiliated primary care practices; and

(10) where applicable, report to the Secretary information on quality measures used under section 399JJ of the Public Health Service Act.

(d) REQUIREMENT FOR PRIMARY CARE PROVIDERS.—A provider who contracts with a care team shall—

(1) provide a care plan to the care team for each patient participant;

(2) provide access to participant health records; and

(3) meet regularly with the care team to ensure integration of care.

(e) REPORTING TO SECRETARY.—An entity that receives a grant under subsection (a) shall submit to the Secretary a report that describes and evaluates, as re-

1 quested by the Secretary, the activities carried out by the
2 entity under subsection (c).

3 (f) DEFINITION OF PRIMARY CARE.—In this section,
4 the term ''primary care'' means the provision of inte-
5 grated, accessible health care services by clinicians who
6 are accountable for addressing a large majority of personal
7 health care needs, developing a sustained partnership with
8 patients, and practicing in the context of family and com-
9 munity.

10 **SEC. 213. GRANTS TO IMPLEMENT MEDICATION MANAGE-**
11 **MENT SERVICES IN TREATMENT OF CHRONIC**
12 **DISEASE.**

13 Title IX of the Public Health Service Act (42 U.S.C.
14 299 et seq.), as amended by section 211, is further amend-
15 ed by inserting after section 934 the following:

16 **''SEC. 935. GRANTS TO IMPLEMENT MEDICATION MANAGE-**
17 **MENT SERVICES IN TREATMENT OF CHRONIC**
18 **DISEASES.**

19 ''(a) IN GENERAL.—The Secretary, acting through
20 the Patient Safety Research Center established in section
21 933 (referred to in this section as the 'Center'), shall es-
22 tablish a program to provide grants to eligible entities to
23 implement medication management (referred to in this
24 section as 'MTM') services provided by licensed phar-
25 macists, as a collaborative, multidisciplinary, inter-profes-

1 sional approach to the treatment of chronic diseases for
2 targeted individuals, to improve the quality of care and
3 reduce overall cost in the treatment of such diseases. The
4 Secretary shall commence the grant program not later
5 than May 1, 2010.

6 "(b) ELIGIBLE ENTITIES.—To be eligible to receive
7 a grant under subsection (a), an entity shall—

8 "(1) provide a setting appropriate for MTM
9 services, as recommended by the experts described in
10 subsection (e);

11 "(2) submit to the Secretary a plan for achiev-
12 ing long-term financial sustainability;

13 "(3) where applicable, submit a plan for coordi-
14 nating MTM services through local community
15 health teams established in section 212 of the Af-
16 fordable Health Choices Act or in collaboration with
17 primary care extension programs established in sec-
18 tion 399V;

19 "(4) submit a plan for meeting the require-
20 ments under subsection (c); and

21 "(5) submit to the Secretary such other infor-
22 mation as the Secretary may require.

23 "(c) MTM SERVICES TO TARGETED INDIVIDUALS.—
24 The MTM services provided with the assistance of a grant
25 awarded under subsection (a) shall, as allowed by State

law including applicable collaborative pharmacy practice agreements, include—

"(1) performing or obtaining necessary assessments of the health and functional status of each patient receiving such MTM services;

"(2) formulating a medication treatment plan according to therapeutic goals agreed upon by the prescriber and the patient or caregiver or authorized representative of the patient;

"(3) selecting, initiating, modifying, recommending changes to, or administering medication therapy;

"(4) monitoring, which may include access to, ordering, or performing laboratory assessments, and evaluating the response of the patient to therapy, including safety and effectiveness;

"(5) performing an initial comprehensive medication review to identify, resolve, and prevent medication-related problems, including adverse drug events, quarterly targeted medication reviews for ongoing monitoring, and additional followup interventions on a schedule developed collaboratively with the prescriber;

"(6) documenting the care delivered and communicating essential information about such care,

including a summary of the medication review, and the recommendations of the pharmacist to other appropriate health care providers of the patient in a timely fashion;

"(7) providing education and training designed to enhance the understanding and appropriate use of the medications by the patient, caregiver, and other authorized representative;

"(8) providing information, support services, and resources and strategies designed to enhance patient adherence with therapeutic regimens;

"(9) coordinating and integrating MTM services within the broader health care management services provided to the patient; and

"(10) such other patient care services allowed under pharmacist scopes of practice in use in other Federal programs that have implemented MTM services.

"(d) TARGETED INDIVIDUALS.—MTM services provided by licensed pharmacists under a grant awarded under subsection (a) shall be offered to targeted individuals who—

"(1) take 4 or more prescribed medications (including over-the-counter medications and dietary supplements);

1 ''(2) take any 'high risk' medications;
2 ''(3) have 2 or more chronic diseases, as identi-
3 fied by the Secretary; or
4 ''(4) have undergone a transition of care, or
5 other factors, as determined by the Secretary, that
6 are likely to create a high risk of medication-related
7 problems.
8 ''(e) CONSULTATION WITH EXPERTS.—In designing
9 and implementing MTM services provided under grants
10 awarded under subsection (a), the Secretary shall consult
11 with Federal, State, private, public-private, and academic
12 entities, pharmacy and pharmacist organizations, health
13 care organizations, consumer advocates, chronic disease
14 groups, and other stakeholders involved with the research,
15 dissemination, and implementation of pharmacist-deliv-
16 ered MTM services, as the Secretary determines appro-
17 priate. The Secretary, in collaboration with this group,
18 shall determine whether it is possible to incorporate rapid
19 cycle process improvement concepts in use in other Fed-
20 eral programs that have implemented MTM services.
21 ''(f) REPORTING TO THE SECRETARY.—An entity
22 that receives a grant under subsection (a) shall submit to
23 the Secretary a report that describes and evaluates, as re-
24 quested by the Secretary, the activities carried out under

subsection (c), including quality measures endorsed under 399JJ, as determined by the Secretary.

"(g) EVALUATION AND REPORT.—The Secretary shall submit to the relevant committees of Congress a report which shall—

"(1) assess the clinical effectiveness of pharmacist-provided services under the MTM services program, as compared to usual care, including an evaluation of whether enrollees maintained better health with fewer hospitalizations and emergency room visits than similar patients not enrolled in the program;

"(2) assess changes in overall health care resource use by targeted individuals;

"(3) assess patient and prescriber satisfaction with MTM services;

"(4) assess the impact of patient-cost sharing requirements on medication adherence and recommendations for modifications;

"(5) identify and evaluate other factors that may impact clinical and economic outcomes, including demographic characteristics, clinical characteristics, and health services use of the patient, as well as characteristics of the regimen, pharmacy benefit, and MTM services provided; and

"(6) evaluate the extent to which participating pharmacists who maintain a dispensing role have a conflict of interest in the provision of MTM services, and if such conflict is found, provide recommendations on how such a conflict might be appropriately addressed.

"(h) GRANT TO FUND DEVELOPMENT OF PERFORMANCE MEASURES.—Secretary may, through the quality measure development program under section 931 of the Public Health Service Act, award grants or contracts to eligible entities for the purpose of funding the development of performance measures that assess the use and effectiveness of medication therapy management services.".

**SEC. 214. DESIGN AND IMPLEMENTATION OF REGIONALIZED SYSTEMS FOR EMERGENCY CARE.**

(a) IN GENERAL.—Title XII of the Public Health Service Act (42 U.S.C. 300d et seq.) is amended—

(1) in section 1203—

(A) in the section heading, by inserting "**FOR TRAUMA SYSTEMS**" after "**GRANTS**"; and

(B) in subsection (a), by striking "Administrator of the Health Resources and Services Administration" and inserting "Assistant Secretary for Preparedness and Response";

(2) by inserting after section 1203 the following:

**"SEC. 1204. COMPETITIVE GRANTS FOR REGIONALIZED SYSTEMS FOR EMERGENCY CARE RESPONSE.**

"(a) IN GENERAL.—The Secretary, acting through the Assistant Secretary for Preparedness and Response, shall award not fewer than 4 multiyear contracts or competitive grants to eligible entities to support pilot projects that design, implement, and evaluate innovative models of regionalized, comprehensive, and accountable emergency care and trauma systems.

"(b) ELIGIBLE ENTITY; REGION.—In this section:

"(1) ELIGIBLE ENTITY.—The term 'eligible entity' means—

"(A) a State or a partnership of 1 or more States and 1 or more local governments; or

"(B) an Indian Tribe (as defined in section 4 of the Indian Health Care Improvement Act) or a partnership of 1 or more Indian Tribes.

"(2) REGION.—The term 'region' means an area within a State, an area that lies within multiple States, or a similar area (such as a multicounty area), as determined by the Secretary.

"(3) EMERGENCY SERVICES.—The term 'emergency services' includes acute, prehospital, and trauma care.

"(c) PILOT PROJECTS.—The Secretary shall award a contract or grant under subsection (a) to an eligible entity that proposes a pilot project to design, implement, and evaluate an emergency medical and trauma system that—

"(1) coordinates with public health and safety services, emergency medical services, medical facilities, trauma centers, and other entities in a region to develop an approach to emergency medical and trauma system access throughout the region, including 9–1–1 Public Safety Answering Points and emergency medical dispatch;

"(2) includes a mechanism, such as a regional medical direction or transport communications system, that operates throughout the region to ensure that the patient is taken to the medically appropriate facility (whether an initial facility or a higher-level facility) in a timely fashion;

"(3) allows for the tracking of prehospital and hospital resources, including inpatient bed capacity, emergency department capacity, trauma center capacity, on-call specialist coverage, ambulance diversion status, and the coordination of such tracking

with regional communications and hospital destination decisions; and

"(4) includes a consistent region-wide prehospital, hospital, and interfacility data management system that—

"(A) submits data to the National EMS Information System, the National Trauma Data Bank, and others;

"(B) reports data to appropriate Federal and State databanks and registries; and

"(C) contains information sufficient to evaluate key elements of prehospital care, hospital destination decisions, including initial hospital and interfacility decisions, and relevant health outcomes of hospital care.

"(d) APPLICATION.—

"(1) IN GENERAL.—An eligible entity that seeks a contract or grant described in subsection (a) shall submit to the Secretary an application at such time and in such manner as the Secretary may require.

"(2) APPLICATION INFORMATION.—Each application shall include—

"(A) an assurance from the eligible entity that the proposed system—

"(i) has been coordinated with the applicable State Office of Emergency Medical Services (or equivalent State office);

"(ii) includes consistent indirect and direct medical oversight of prehospital, hospital, and interfacility transport throughout the region;

"(iii) coordinates prehospital treatment and triage, hospital destination, and interfacility transport throughout the region;

"(iv) includes a categorization or designation system for special medical facilities throughout the region that is integrated with transport and destination protocols;

"(v) includes a regional medical direction, patient tracking, and resource allocation system that supports day-to-day emergency care and surge capacity and is integrated with other components of the national and State emergency preparedness system; and

"(vi) addresses pediatric concerns related to integration, planning, prepared-

ness, and coordination of emergency medical services for infants, children and adolescents; and

"(B) such other information as the Secretary may require.

"(e) REQUIREMENT OF MATCHING FUNDS.—

"(1) IN GENERAL.—The Secretary may not make a grant under this section unless the State (or consortia of States) involved agrees, with respect to the costs to be incurred by the State (or consortia) in carrying out the purpose for which such grant was made, to make available non-Federal contributions (in cash or in kind under paragraph (2)) toward such costs in an amount equal to not less than $1 for each $3 of Federal funds provided in the grant. Such contributions may be made directly or through donations from public or private entities.

"(2) NON-FEDERAL CONTRIBUTIONS.—Non-Federal contributions required in paragraph (1) may be in cash or in kind, fairly evaluated, including equipment or services (and excluding indirect or overhead costs). Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government,

may not be included in determining the amount of such non-Federal contributions.

"(f) PRIORITY.—The Secretary shall give priority for the award of the contracts or grants described in subsection (a) to any eligible entity that serves a population in a medically underserved area (as defined in section 330(b)(3)).

"(g) REPORT.—Not later than 90 days after the completion of a pilot project under subsection (a), the recipient of such contract or grant described in shall submit to the Secretary a report containing the results of an evaluation of the program, including an identification of—

"(1) the impact of the regional, accountable emergency care and trauma system on patient health outcomes for various critical care categories, such as trauma, stroke, cardiac emergencies, neurological emergencies, and pediatric emergencies;

"(2) the system characteristics that contribute to the effectiveness and efficiency of the program (or lack thereof);

"(3) methods of assuring the long-term financial sustainability of the emergency care and trauma system;

"(4) the State and local legislation necessary to implement and to maintain the system;

"(5) the barriers to developing regionalized, accountable emergency care and trauma systems, as well as the methods to overcome such barriers; and

"(6) recommendations on the utilization of available funding for future regionalization efforts.

"(h) DISSEMINATION OF FINDINGS.—The Secretary shall, as appropriate, disseminate to the public and to the appropriate Committees of the Congress, the information contained in a report made under subsection (g)."; and

(3) in section 1232—

(A) in subsection (a), by striking "appropriated" and all that follows through the period at the end and inserting "appropriated $24,000,000 for each of fiscal years 2010 through 2014."; and

(B) by inserting after subsection (c) the following:

"(d) AUTHORITY.—For the purpose of carrying out parts A through C, beginning on the date of enactment of the Affordable Health Choices Act, the Secretary shall transfer authority in administering grants and related authorities under such parts from the Administrator of the Health Resources and Services Administration to the Assistant Secretary for Preparedness and Response.".

(b) SUPPORT FOR EMERGENCY MEDICINE RESEARCH.—Part H of title IV of the Public Health Service Act (42 U.S.C. 289 et seq.) is amended by inserting after the section 498C the following:

**"SEC. 498D. SUPPORT FOR EMERGENCY MEDICINE RESEARCH.**

"(a) EMERGENCY MEDICAL RESEARCH.—The Secretary shall support Federal programs administered by the National Institutes of Health, the Agency for Healthcare Research and Quality, the Health Resources and Services Administration, the Centers for Disease Control and Prevention, and other agencies involved in improving the emergency care system to expand and accelerate research in emergency medical care systems and emergency medicine, including—

"(1) the basic science of emergency medicine;

"(2) the model of service delivery and the components of such models that contribute to enhanced patient health outcomes;

"(3) the translation of basic scientific research into improved practice; and

"(4) the development of timely and efficient delivery of health services.

"(b) PEDIATRIC EMERGENCY MEDICAL RESEARCH.—The Secretary shall support Federal programs

1 administered by the National Institutes of Health, the
2 Agency for Healthcare Research and Quality, the Health
3 Resources and Services Administration, the Centers for
4 Disease Control and Prevention, and other agencies to co-
5 ordinate and expand research in pediatric emergency med-
6 ical care systems and pediatric emergency medicine, in-
7 cluding—

8 ''(1) an examination of the gaps and opportuni-
9 ties in pediatric emergency care research and a
10 strategy for the optimal organization and funding of
11 such research;

12 ''(2) the role of pediatric emergency services as
13 an integrated component of the overall health sys-
14 tem;

15 ''(3) system-wide pediatric emergency care plan-
16 ning, preparedness, coordination, and funding;

17 ''(4) pediatric training in professional edu-
18 cation; and

19 ''(5) research in pediatric emergency care, spe-
20 cifically on the efficacy, safety, and health outcomes
21 of medications used for infants, children, and adoles-
22 cents in emergency care settings in order to improve
23 patient safety.

24 ''(c) IMPACT RESEARCH.—The Secretary shall sup-
25 port research to determine the estimated economic impact

of, and savings that result from, the implementation of coordinated emergency care systems.

"(d) 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. 215. TRAUMA CARE CENTERS AND SERVICE AVAILABILITY.**

(a) TRAUMA CARE CENTERS.—

(1) GRANTS FOR TRAUMA CARE CENTERS.—Section 1241 of the Public Health Service Act (42 U.S.C. 300d–41) is amended by striking subsections (a) and (b) and inserting the following:

"(a) IN GENERAL.—The Secretary shall establish 3 programs to award grants to qualified public, nonprofit, Indian Health Service, Indian tribal, and urban Indian trauma centers—

"(1) to assist in defraying substantial uncompensated care costs;

"(2) to further the core missions of such trauma centers, including by addressing costs associated with patient stabilization and transfer, trauma education and outreach, coordination with local and regional trauma systems, essential personnel and other

fixed costs, and expenses associated with employee and non-employee physician services; and

"(3) to provide emergency relief to ensure the continued and future availability of trauma services.

"(b) MINIMUM QUALIFICATIONS OF TRAUMA CENTERS.—

"(1) PARTICIPATION IN TRAUMA CARE SYSTEM OPERATING UNDER CERTAIN PROFESSIONAL GUIDELINES.—Except as provided in paragraph (2), the Secretary may not award a grant to a trauma center under subsection (a) unless the trauma center is a participant in a trauma system that substantially complies with section 1213.

"(2) EXEMPTION.—Paragraph (1) shall not apply to trauma centers that are located in States with no existing trauma care system.

"(3) QUALIFICATION FOR SUBSTANTIAL UNCOMPENSATED CARE COSTS.—The Secretary shall award substantial uncompensated care grants under subsection (a)(1) only to trauma centers meeting at least 1 of the criteria in 1 of the following 3 categories:

"(A) CATEGORY A.—The criteria for category A are as follows:

"(i) At least 40 percent of the visits in the emergency department of the hospital in which the trauma center is located were charity or self-pay patients.

"(ii) At least 50 percent of the visits in such emergency department were Medicaid (under title XIX of the Social Security Act (42 U.S.C. 1396 et seq.)) and charity and self-pay patients combined.

"(B) CATEGORY B.—The criteria for category B are as follows:

"(i) At least 35 percent of the visits in the emergency department were charity or self-pay patients.

"(ii) At least 50 percent of the visits in the emergency department were Medicaid and charity and self-pay patients combined.

"(C) CATEGORY C.—The criteria for category C are as follows:

"(i) At least 20 percent of the visits in the emergency department were charity or self-pay patients.

"(ii) At least 30 percent of the visits in the emergency department were Med-

icaid and charity and self-pay patients combined.

"(4) TRAUMA CENTERS IN 1115 WAIVER STATES.—Notwithstanding paragraph (3), the Secretary may award a substantial uncompensated care grant to a trauma center under subsection (a)(1) if the trauma center qualifies for funds under a Low Income Pool or Safety Net Care Pool established through a waiver approved under section 1115 of the Social Security Act (42 U.S.C. 1315).

"(5) DESIGNATION.—The Secretary may not award a grant to a trauma center unless such trauma center is verified by the American College of Surgeons or designated by an equivalent State or local agency.

"(c) ADDITIONAL REQUIREMENTS.—The Secretary may not award a grant to a trauma center under subsection (a)(1) unless such trauma center—

"(1) submits to the Secretary a plan satisfactory to the Secretary that demonstrates a continued commitment to serving trauma patients regardless of their ability to pay; and

"(2) has policies in place to assist patients who cannot pay for part or all of the care they receive,

including a sliding fee scale, and to ensure fair billing and collection practices.''.

(2) CONSIDERATIONS IN MAKING GRANTS.—Section 1242 of the Public Health Service Act (42 U.S.C. 300d–42) is amended by striking subsections (a) and (b) and inserting the following:

''(a) SUBSTANTIAL UNCOMPENSATED CARE AWARDS.—

''(1) IN GENERAL.—The Secretary shall establish an award basis for each eligible trauma center for grants under section 1241(a)(1) according to the percentage described in paragraph (2), subject to the requirements of section 1241(b)(3).

''(2) PERCENTAGES.—The applicable percentages are as follows:

''(A) With respect to a category A trauma center, 100 percent of the uncompensated care costs.

''(B) With respect to a category B trauma center, not more than 75 percent of the uncompensated care costs.

''(C) With respect to a category C trauma center, not more than 50 percent of the uncompensated care costs.

''(b) CORE MISSION AWARDS.—

"(1) IN GENERAL.—In awarding grants under section 1241(a)(2), the Secretary shall—

"(A) reserve 25 percent of the amount allocated for core mission awards for Level III and Level IV trauma centers; and

"(B) reserve 25 percent of the amount allocated for core mission awards for large urban Level I and II trauma centers—

"(i) that have at least 1 graduate medical education fellowship in trauma or trauma related specialties for which demand is exceeding supply;

"(ii) for which—

"(I) annual uncompensated care costs exceed $10,000,000; or

"(II) at least 20 percent of emergency department visits are charity or self-pay or Medicaid patients; and

"(iii) that are not eligible for substantial uncompensated care awards under section 1241(a)(1).

"(c) EMERGENCY AWARDS.—In awarding grants under section 1241(a)(3), the Secretary shall—

"(1) give preference to any application submitted by a trauma center that provides trauma care

in a geographic area in which the availability of trauma care has significantly decreased or will significantly decrease if the center is forced to close or downgrade service or growth in demand for trauma services exceeds capacity; and

"(2) reallocate any emergency awards funds not obligated due to insufficient, or a lack of qualified, applications to the significant uncompensated care award program.".

(3) CERTAIN AGREEMENTS.—Section 1243 of the Public Health Service Act (42 U.S.C. 300d–43) is amended by striking subsections (a), (b), and (c) and inserting the following:

"(a) MAINTENANCE OF FINANCIAL SUPPORT.—The Secretary may require a trauma center receiving a grant under section 1241(a) to maintain access to trauma services at comparable levels to the prior year during the grant period .

"(b) TRAUMA CARE REGISTRY.—The Secretary may require the trauma center receiving a grant under section 1241(a) to provide data to a national and centralized registry of trauma cases, in accordance with guidelines developed by the American College of Surgeons, and as the Secretary may otherwise require.".

(4) GENERAL PROVISIONS.—Section 1244 of the Public Health Service Act (42 U.S.C. 300d–44) is amended by striking subsections (a), (b), and (c) and inserting the following:

"(a) APPLICATION.—The Secretary may not award a grant to a trauma center under section 1241(a) unless such center submits an application for the grant to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and information as the Secretary determines to be necessary to carry out this part.

"(b) LIMITATION ON DURATION OF SUPPORT.—The period during which a trauma center receives payments under a grant under section 1241(a)(3) shall be for 3 fiscal years, except that the Secretary may waive such requirement for a center and authorize such center to receive such payments for 1 additional fiscal year.

"(c) LIMITATION ON AMOUNT OF GRANT.—Notwithstanding section 1242(a), a grant under section 1241 may not be made in an amount exceeding $2,000,000 for each fiscal year.

"(d) ELIGIBILITY.—Except as provided in section 1242(b)(1)(B)(iii), acquisition of, or eligibility for, a grant under section 1241(a) shall not preclude a trauma center

from being eligible for other grants described in such section.

"(e) FUNDING DISTRIBUTION.—Of the total amount appropriated for a fiscal year under section 1245, 70 percent shall be used for substantial uncompensated care awards under section 1241(a)(1), 20 percent shall be used for core mission awards under section 1241(a)(2), and 10 percent shall be used for emergency awards under section 1241(a)(3).

"(f) MINIMUM ALLOWANCE.—Notwithstanding subsection (e), if the amount appropriated for a fiscal year under section 1245 is less than $25,000,000, all available funding for such fiscal year shall be used for substantial uncompensated care awards under section 1241(a)(1).

"(g) SUBSTANTIAL UNCOMPENSATED CARE AWARD DISTRIBUTION AND PROPORTIONAL SHARE.—Notwithstanding section 1242(a), of the amount appropriated for substantial uncompensated care grants for a fiscal year, the Secretary shall—

"(1) make available—

"(A) 50 percent of such funds for category A trauma center grantees;

"(B) 35 percent of such funds for category B trauma center grantees; and

"(C) 15 percent of such funds for category C trauma center grantees; and

"(2) provide available funds within each category in a manner proportional to the award basis specified in section 1242(a)(2) to each eligible trauma center.

"(h) REPORT.—Beginning 2 years after the date of enactment of the Affordable Health Choices Act, and every 2 years thereafter, the Secretary shall biennially report to Congress regarding the status of the grants made under section 1241 and on the overall financial stability of trauma centers.".

(5) AUTHORIZATION OF APPROPRIATIONS.—Section 1245 of the Public Health Service Act (42 U.S.C. 300d–45) is amended to read as follows:

**"SEC. 1245. AUTHORIZATION OF APPROPRIATIONS.**

"For the purpose of carrying out this part, there are authorized to be appropriated $100,000,000 for fiscal year 2009, and such sums as may be necessary for each of fiscal years 2010 through 2015. Such authorization of appropriations is in addition to any other authorization of appropriations or amounts that are available for such purpose.".

(6) DEFINITION.—Part D of title XII of the Public Health Service Act (42 U.S.C. 300d–41 et seq.) is amended by adding at the end the following:

**"SEC. 1246. DEFINITION.**

''In this part, the term 'uncompensated care costs' means unreimbursed costs from serving self-pay, charity, or Medicaid patients, without regard to payment under section 1923 of the Social Security Act, all of which are attributable to emergency care and trauma care, including costs related to subsequent inpatient admissions to the hospital.''.

(b) TRAUMA SERVICE AVAILABILITY.—Title XII of the Public Health Service Act (42 U.S.C. 300d et seq.) is amended by adding at the end the following:

**"PART H—TRAUMA SERVICE AVAILABILITY**

**"SEC. 1281. GRANTS TO STATES.**

''(a) ESTABLISHMENT.—To promote universal access to trauma care services provided by trauma centers and trauma-related physician specialties, the Secretary shall provide funding to States to enable such States to award grants to eligible entities for the purposes described in this section.

''(b) AWARDING OF GRANTS BY STATES.—Each State may award grants to eligible entities within the State for the purposes described in subparagraph (d).

"(c) ELIGIBILITY.—

"(1) IN GENERAL.—To be eligible to receive a grant under subsection (b) an entity shall—

"(A) be—

"(i) a public or nonprofit trauma center or consortium thereof that meets that requirements of paragraphs (1), (2), and (5) of section 1241(b);

"(ii) a safety net public or nonprofit trauma center that meets the requirements of paragraphs (1) through (5) of section 1241(b); or

"(iii) a hospital in an underserved area (as defined by the State) that seeks to establish new trauma services; and

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

"(2) LIMITATION.—A State shall use at least 40 percent of the amount available to the State under this part for a fiscal year to award grants to safety net trauma centers described in paragraph (1)(A)(ii).

1 "(d) USE OF FUNDS.—The recipient of a grant under
2 subsection (b) shall carry out 1 or more of the following
3 activities consistent with subsection (b):
4 "(1) Providing trauma centers with funding to
5 support physician compensation in trauma-related
6 physician specialties where shortages exist in the re-
7 gion involved, with priority provided to safety net
8 trauma centers described in subsection (c)(1)(A)(ii).
9 "(2) Providing for individual safety net trauma
10 center fiscal stability and costs related to having
11 service that is available 24 hours a day, 7 days a
12 week, with priority provided to safety net trauma
13 centers described in subsection (c)(1)(A)(ii) located
14 in urban, border, and rural areas.
15 "(3) Reducing trauma center overcrowding at
16 specific trauma centers related to throughput of
17 trauma patients.
18 "(4) Establishing new trauma services in un-
19 derserved areas as defined by the State.
20 "(5) Enhancing collaboration between trauma
21 centers and other hospitals and emergency medical
22 services personnel related to trauma service avail-
23 ability.

"(6) Making capital improvements to enhance access and expedite trauma care, including providing helipads and associated safety infrastructure.

"(7) Enhancing trauma surge capacity at specific trauma centers.

"(8) Ensuring expedient receipt of trauma patients transported by ground or air to the appropriate trauma center.

"(9) Enhancing interstate trauma center collaboration.

"(e) LIMITATION.—

"(1) IN GENERAL.—A State may use not more than 20 percent of the amount available to the State under this part for a fiscal year for administrative costs associated with awarding grants and related costs.

"(2) MAINTENANCE OF EFFORT.—The Secretary may not provide funding to a State under this part unless the State agrees that such funds will be used to supplement and not supplant State funding otherwise available for the activities and costs described in this part.

"(f) DISTRIBUTION OF FUNDS.—The following shall apply with respect to grants provided in this part:

"(1) LESS THAN $10,000,000.—If the amount of appropriations for this part in a fiscal year is less than $10,000,000, the Secretary shall divide such funding evenly among only those States that have 1 or more trauma centers eligible for funding under section 1241(b)(3)(A).

"(2) LESS THAN $20,000,000.—If the amount of appropriations in a fiscal year is less than $20,000,000, the Secretary shall divide such funding evenly among only those States that have 1 or more trauma centers eligible for funding under subparagraphs (A) and (B) of section 1241(b)(3).

"(3) LESS THAN $30,000,000.—If the amount of appropriations for this part in a fiscal year is less than $30,000,000, the Secretary shall divide such funding evenly among only those States that have 1 or more trauma centers eligible for funding under section 1241(b)(3).

"(4) $30,000,000 OR MORE.—If the amount of appropriations for this part in a fiscal year is $30,000,000 or more, the Secretary shall divide such funding evenly among all States.

**"SEC. 1282. AUTHORIZATION OF APPROPRIATIONS.**

''For the purpose of carrying out this part, there is authorized to be appropriated $100,000,000 for each of fiscal years 2010 through 2015.''.

**SEC. 216. REDUCING AND REPORTING HOSPITAL READMISSIONS.**

(a) IN GENERAL.—Part S of title III of the Public Health Service Act, as amended by section 205, is further amended by adding at the end the following:

**"SEC. 399NN. READMISSIONS.**

''(a) PURPOSE.—The purpose of this section is to improve the quality and value of inpatient hospital services in order to—

''(1) improve the coordination of care; and

''(2) appropriately reduce inefficiency and waste, such as unnecessary hospital readmissions, in the care furnished.

''(b) INFORMATION GATHERING AND ANALYSIS.—Beginning 2010, the Secretary shall analyze and calculate hospital-specific and national applicable readmissions rates based on subsection (e). In developing criteria and carrying out this section, the Secretary shall consider the unique characters of rural and low-volume hospitals (including critical access hospitals).

''(c) DISCLOSURE.—

"(1) IN GENERAL.—Beginning in 2011, the Secretary shall establish procedures to provide for the confidential disclosure to hospitals receiving funds under this Act of information on hospital-specific and national applicable readmission rates described in subsection (b).

"(2) PUBLIC DISCLOSURE OF INFORMATION.—Not later than 2 years after the date of enactment of this section, the Secretary shall make the information on the rates of applicable readmission rates and other statistical information of hospital receiving funds under this Act disclosed under paragraph (1) publicly available in a form and manner determined appropriate by the Secretary.

"(3) REPORT.—Not later than 180 days after the date of enactment of this section, the Secretary shall submit to Congress a report that contains—

"(A) a summary of the implementation of the procedures under paragraph (1);

"(B) a plan for the public disclosure of information under paragraph (2); and

"(C) recommendations for such legislation or administrative action as the Secretary determines appropriate.

"(d) APPLICABLE READMISSION DEFINED.—

"(1) IN GENERAL.—In this section, the term 'applicable readmission' means a readmission—

"(A) selected by the Secretary under subsection (e));

"(B) that occurs within a time interval (as specified under subsection (f)) following a discharge from a hospital; and

"(C) which is for a condition or procedure selected under subsection (g).

"(2) DETERMINATION OF APPLICABILITY TO READMISSIONS TO CERTAIN HOSPITALS.—The Secretary shall determine whether the term 'applicable readmission' includes readmissions to the same hospital as the prior discharge or readmissions to any hospital.

"(e) SELECTION OF READMISSIONS.—Not later 6 months after the date of enactment of this section, the Secretary, in consultation with appropriate representatives of the Centers for Medicare & Medicaid Services and the Agency for Healthcare Research and Quality, shall, for each of the conditions or procedures selected under subsection (g), select readmissions that meet each of the following requirements:

"(1) The readmission could reasonably have been prevented by the provision of care consistent

with evidence-based guidelines during the prior admission or the post discharge follow-up period.

"(2) The readmission is for a condition or procedure related to the care provided during the prior admission or post discharge follow-up period, which includes a readmission for the following:

"(A) The same condition or procedure as the prior discharge.

"(B) An infection or other complication of care.

"(C) A condition or procedure indicative of a failed surgical intervention.

"(D) Other conditions or procedures as determined appropriate by the Secretary.

"(f) SPECIFICATION OF TIME INTERVAL.—The Secretary shall specify a time interval, of not less than 7 days and not more than 30 days, between the prior discharge and applicable readmission for purposes of this section.

"(g) SELECTION OF CONDITIONS OR PROCEDURES.—

"(1) IN GENERAL.—Not later than 6 months after the date of enactment of this section, the Secretary shall select at least 2 conditions or procedures which meet each of the following requirements:

"(A) Such conditions or procedures have a high volume.

"(B) For the time interval specified under subsection (f), such conditions or procedures have a relatively high rate of occurrence of subsequent readmissions described in subsection (f), as compared to all other conditions or procedures.

"(2) EXPANSION OF CONDITIONS OR PROCEDURES SELECTED.—The Secretary shall expand the list of readmission conditions analyzed under this section to include at least 8 conditions with the highest volume and highest rate of readmissions. At least one of the conditions selected shall be a condition prevalent in geriatric patients.

"(h) QUALITY IMPROVEMENT PROGRAM FOR HOSPITALS WITH A HIGH SEVERITY ADJUSTED READMISSION RATE.—

"(1) ESTABLISHMENT.—

"(A) IN GENERAL.—Not later than 2 years after the date of enactment of this section, the Secretary shall establish a program for eligible hospitals to improve their readmission rates through the use of patient safety organizations (as defined in section 921(4)).

"(B) ELIGIBLE HOSPITAL DEFINED.—In this subsection, the term 'eligible hospital' means a hospital which the Secretary determines (based on the most recent available historical data) has a severity adjusted readmission rate for the conditions described in subsection (g) among the highest 25 percent of all hospitals nationally.

"(C) RISK ADJUSTMENT.—The Secretary shall utilize appropriate risk adjustment measures to determine eligible hospitals.

"(2) REPORT TO THE SECRETARY.—Eligible hospitals and patient safety organizations working with those hospitals shall report to the Secretary on the processes employed by the hospital to improve readmission rates and the impact of such processes on readmission rates.".

(b) GAO STUDY AND REPORT.—

(1) STUDY.—The Comptroller General of the United States shall conduct a study on the impact of section 399NN of the Public Health Service Act, as added by subsection (a), on—

(A) care furnished to consumers;

(B) expenditures under Federal health programs; and

(C) the cost and quality of care furnished by hospitals.

(2) REPORT.—Not later than January 1, 2013, the Comptroller General of the United States shall submit to Congress a report on the study conducted under paragraph (1), together with recommendations for such legislation and administrative action as the Comptroller General determines appropriate.

(c) STUDY BY IOM.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall seek to enter into an agreement with the Institute of Medicine to submit to Congress, not later than 1 year after the date of enactment of this Act, a report on recommendations on how to reduce unnecessary hospital readmissions. Such report shall also include recommendations on how to develop a coordinated care plan for patients being discharged from the hospital.

(2) AUTHORIZATION.—For the purpose of carrying out this subsection, there is authorized to be appropriated such sums as may be necessary for fiscal year 2010.

**SEC. 217. PROGRAM TO FACILITATE SHARED DECISION-MAKING.**

Part D of title IX of the Public Health Service Act, as amended by section 213, is further amended by adding at the end the following:

**"SEC. 936. PROGRAM TO FACILITATE SHARED DECISION-MAKING.**

"(a) PURPOSE.—The purpose of this section is to facilitate collaborative processes between patients, caregivers or authorized representatives, and clinicians that engages the patient, caregiver or authorized representative in decisionmaking, provides patients, caregivers or authorized representatives with information about trade-offs among treatment options, and facilitates the incorporation of patient preferences and values into the medical plan.

"(b) DEFINITIONS.—In this section:

"(1) PATIENT DECISION AID.—The term 'patient decision aid' means an educational tool that helps patients, caregivers or authorized representatives understand and communicate their beliefs and preferences related to their treatment options, and to decide with their health care provider what treatments are best for them based on their treatment options, scientific evidence, circumstances, beliefs, and preferences.

"(2) PREFERENCE SENSITIVE CARE.—The term 'preference sensitive care' means medical care for which the clinical evidence does not clearly support one treatment option such that the appropriate course of treatment depends on the values of the patient or the preferences of the patient, caregivers or authorized representatives regarding the benefits, harms and scientific evidence for each treatment option, the use of such care should depend on the informed patient choice among clinically appropriate treatment options.

"(c) ESTABLISHMENT OF INDEPENDENT STANDARDS FOR PATIENT DECISION AIDS FOR PREFERENCE SENSITIVE CARE.—

"(1) CONTRACT WITH ENTITY TO ESTABLISH STANDARDS AND CERTIFY PATIENT DECISION AIDS.—

"(A) IN GENERAL.—For purposes of supporting consensus-based standards for patient decision aids for preference sensitive care and a certification process for patient decision aids for use in the Federal health programs and by other interested parties, the Secretary shall have in effect a contract with the qualified consensus-based entity identified in section 399JJ.

Such contract shall provide that the entity perform the duties described in paragraph (2).

"(B) TIMING FOR FIRST CONTRACT.—As soon as practicable after the date of the enactment of this section, the Secretary shall enter into the first contract under subparagraph (A).

"(C) PERIOD OF CONTRACT.—A contract under subparagraph (A) shall be for a period of 18 months (except such contract may be renewed after a subsequent bidding process).

"(2) DUTIES.—The following duties are described in this paragraph:

"(A) DEVELOP AND IDENTIFY STANDARDS FOR PATIENT DECISION AIDS.—The entity shall synthesize evidence and convene a broad range of experts and key stakeholders to develop and identify consensus-based standards to evaluate patient decision aids for preference sensitive care.

"(B) ENDORSE PATIENT DECISION AIDS.—The entity shall review patient decision aids and develop a certification process whether patient decision aids meet the standards developed and identified under subparagraph (A). The entity shall give priority to the review and certifi-

cation of patient decision aids for preference sensitive care.

"(d) PROGRAM TO DEVELOP, UPDATE AND PATIENT DECISION AIDS TO ASSIST HEALTH CARE PROVIDERS AND PATIENTS.—

"(1) IN GENERAL.—The Secretary, acting through the Director, and in coordination with heads of other relevant agencies, such as the Director of the Centers for Disease Control and Prevention and the Director of the National Institutes of Health, shall establish a program to award grants or contracts—

"(A) to develop, update, and produce patient decision aids for preference sensitive care to assist health care providers in educating patients, caregivers, and authorized representatives concerning the relative safety, relative effectiveness (including possible health outcomes and impact on functional status), and relative cost of treatment or, where appropriate, palliative care options;

"(B) to test such materials to ensure such materials are balanced and evidence based in aiding health care providers and patients, caregivers, and authorized representatives to make

1 informed decisions about patient care and can
2 be easily incorporated into a broad array of
3 practice settings; and
4 "(C) to educate providers on the use of
5 such materials, including through academic cur-
6 ricula.
7 "(2) REQUIREMENTS FOR PATIENT DECISION
8 AIDS.—Patient decision aids developed and produced
9 pursuant to a grant or contract under paragraph
10 (1)—
11 "(A) shall be designed to engage patients,
12 caregivers, and authorized representatives in in-
13 formed decisionmaking with health care pro-
14 viders;
15 "(B) shall present up-to-date clinical evi-
16 dence about the risks and benefits of treatment
17 options in a form and manner that is age-ap-
18 propriate and can be adapted for patients, care-
19 givers, and authorized representatives from a
20 variety of cultural and educational backgrounds
21 to reflect the varying needs of consumers and
22 diverse levels of health literacy;
23 "(C) shall, where appropriate, explain why
24 there is a lack of evidence to support one treat-
25 ment option over another; and

"(D) shall address health care decisions across the age span, including those affecting vulnerable populations including children.

"(3) DISTRIBUTION.—The Director shall ensure that patient decision aids produced with grants or contracts under this section are available to the public.

"(4) NONDUPLICATION OF EFFORTS.—The Director shall ensure that the activities under this section of the Agency and other agencies, including the Centers for Disease Control and Prevention and the National Institutes of Health, are free of unnecessary duplication of effort.

"(e) GRANTS TO SUPPORT SHARED DECISION MAKING IMPLEMENTATION.—

"(1) IN GENERAL.—The Secretary shall establish a program to provide for the phased-in development, implementation, and evaluation of shared decisionmaking using patient decision aids to meet the objective of improving the understanding of patients of their medical treatment options.

"(2) SHARED DECISIONMAKING RESOURCE CENTERS.—

"(A) IN GENERAL.—The Secretary shall provide grants for the establishment and sup-

port of Shared Decision Making Resource Centers (referred to in this subsection as 'Centers') to provide technical assistance to providers and to develop and disseminate best practices and other information to support and accelerate adoption, implementation, and effective use of patient decision aids and shared decision making by providers.

"(B) OBJECTIVES.—The objective of a Center is to enhance and promote the adoption of patient decision aids and shared decision-making through—

"(i) providing assistance to eligible providers with the implementation and effective use of, and training on, patient decision aids; and

"(ii) the dissemination of best practices and research on the implementation and effective use of patient decision aids.

"(3) SHARED DECISIONMAKING PARTICIPATION GRANTS.—

"(A) IN GENERAL.—The Secretary shall provide grants to health care providers for the development and implementation of shared decisionmaking techniques.

"(B) PREFERENCE.—In order to facilitate the use of best practices, the Secretary shall provide a preference in making grants under this subsection to health care providers who participate in training by Shared Decision Making Resource Centers or comparable training.

"(C) LIMITATION.—Funds under this paragraph shall not be used to purchase or implement use of patient decision aids other than those certified under the process identified in subsection (c).

"(4) GUIDANCE.—The Secretary may issue guidance to eligible grantees under this subsection on the use of patient decision aids.

"(5) QUALITY MEASURES.—

"(A) IN GENERAL.—The Secretary shall measure the quality of shared decisionmaking. For purposes of making such measurements, the Secretary shall select quality measures as described in section 399JJ.

"(B) REPORTING DATA ON MEASURES.—A provider receiving a grant under this subsection shall report to the Secretary data on quality measures selected under subparagraph (A) in

accordance with procedures established by the Secretary.

"(C) FEEDBACK ON MEASURES.—The Secretary shall provide confidential reports to eligible providers receiving a grant under this section on the performance of the eligible provider on quality measures selected by the Secretary under subparagraph (A), the aggregate performance of all eligible providers participating in the program, and any improvements in such performance. Such reports shall be made publicly available not less than 3 years after the date of enactment of this section.

"(D) GRANT TO FUND DEVELOPMENT OF PERFORMANCE MEASURES.—The Director may, through the quality measure development program under section 931, award grants or contracts to eligible entities to fund development of performance measures which assess the use by health care providers of shared decisionmaking processes or patient decision aids.

"(E) CONTENTS OF REPORT.—Each report submitted under this paragraph shall—

"(i) include an assessment of—

1 "(I) quality measures selected
2 under subparagraph (A);
3 "(II) patient and health care pro-
4 vider satisfaction with regard to ac-
5 tivities carried out under this para-
6 graph;
7 "(III) utilization of medical serv-
8 ices for patients of providers receiving
9 a grant under this paragraph and
10 other patients as determined appro-
11 priate by the Secretary;
12 "(IV) appropriate utilization of
13 shared decisionmaking by providers
14 receiving a grant under this para-
15 graph; and
16 "(V) the costs to providers par-
17 ticipating of selecting, purchasing,
18 and incorporating approved patient
19 decision aids and meeting reporting
20 requirements under this paragraph;
21 and
22 "(ii) identify the characteristics of in-
23 dividual eligible providers that are most ef-
24 fective in implementing shared decision-

making under the applicable phase of the program.

"(f) FUNDING.—For purposes of carrying out this section there are authorized to be appropriated such sums as may be necessary for fiscal year 2010 and each subsequent fiscal year.".

**SEC. 218. PRESENTATION OF PRESCRIPTION DRUG BENEFIT AND RISK INFORMATION.**

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary"), acting through the Commissioner of Food and Drugs, shall determine whether the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format (such as a table or drug facts box) to the promotional labeling or print advertising of such drugs would improve health care decisionmaking by clinicians and patients and consumers.

(b) REVIEW AND CONSULTATION.—In making the determination under subsection (a), the Secretary shall review all available scientific evidence and research on decisionmaking and social and cognitive psychology and consult with drug manufacturers, clinicians, patients and consumers, experts in health literacy, representatives of racial and ethnic minorities, and experts in women's and pediatric health.

(c) REPORT.—Not later than 1 year after the date of enactment of this Act, the Secretary shall submit to Congress a report that provides—

(1) the determination by the Secretary under subsection (a); and

(2) the reasoning and analysis underlying that determination.

(d) AUTHORITY.—If the Secretary determines under subsection (a) that the addition of quantitative summaries of the benefits and risks of prescription drugs in a standardized format (such as a table or drug facts box) to the promotional labeling or print advertising of such drugs would improve health care decision-making by clinicians and patients and consumers, then the Secretary, not later than 3 years after the date of submission of the report under subsection (c), shall promulgate proposed regulations as necessary to implement such format.

(e) CLARIFICATION.—Nothing in this section shall be construed to restrict the existing authorities of the Secretary with respect to benefit and risk information.

**SEC. 219. CENTER FOR HEALTH OUTCOMES RESEARCH AND EVALUATION.**

Part D of title IX of the Public Health Service Act, as amended by section 217, is further amended by adding at the end the following:

**"SEC. 937. CENTER FOR HEALTH OUTCOMES RESEARCH AND EVALUATION.**

''(a) ESTABLISHMENT.—The Secretary shall establish within the Agency the Center for Health Outcomes Research and Evaluation (referred to in this section as the 'Center') to collect, conduct, support, and synthesize research with respect to comparing health outcomes, effectiveness, and appropriateness of health care services and procedures in order to identify the manner in which diseases, disorders, and other health conditions can most effectively and appropriately be prevented, diagnosed, treated, and managed clinically.

''(b) DUTIES.—The Center shall—

''(1) coordinate, conduct, support, and synthesize research relevant to the comparative health outcomes and effectiveness of the full spectrum of health care treatments, including pharmaceuticals, medical devices, medical and surgical procedures, screening and diagnostics, behavioral health care, oral health, and other health interventions;

''(2) coordinate, conduct, and support systematic reviews of clinical research, including original research conducted subsequent to the date of the enactment of this section;

''(3) coordinate, conduct, support, and synthesize research that—

"(A) identifies which treatment is most effective and least toxic for each individual given each individual's genetic makeup and coexisting conditions; and

"(B) reduces treatment disparities, among ethnic and racial minorities, children, and vulnerable populations;

"(4) use a broad range of methodologies, including randomized controlled clinical trials, observational studies and other approaches;

"(5) create informational tools that organize, synthesize, and disseminate research findings to providers, patients, and public and private payers;

"(6) develop a publicly available resource database that collects and contains high-quality, independent evidence to inform healthcare decision-making, which shall include reliable evidence from government and non-government sources;

"(7) submit to the Secretary, and Congress appropriate relevant reports described in subsection (h);

"(8) encourage, as appropriate, the development and use of clinical registries and the development of health outcomes research data networks from electronic health records, post marketing drug and med-

ical device surveillance efforts, and other forms of electronic health data; and

"(9) not later than one year after the date of the enactment of this section, develop minimum methodological standards to be used when conducting studies of comparative health outcomes and value (and procedures for use of such standards) in order to help ensure accurate and effective comparisons and assessments of treatment options, and update such standards at least biennially.

"(c) POWERS.—

"(1) OBTAINING OFFICIAL DATA.—The Center may secure directly from any department or agency of the United States information necessary to enable the Center to carry out this section. Upon request of the Center, the head of that department or agency shall furnish that information to the Center on an agreed upon schedule.

"(2) DATA COLLECTION.—In order to carry out its functions, the Center shall—

"(A) utilize existing information, both published and unpublished, where possible, collected and assessed either by the staff of the Center or under other arrangements made in accordance with this section;

"(B) carry out, or award grants or contracts for, original research and experimentation, where existing information is inadequate;

"(C) adopt procedures allowing any interested party to submit information for use by the Center or the Advisory Counsel under subsection (d) in making reports and recommendations; and

"(D) comply with any existing data privacy standards applicable to the Center.

"(3) PERIODIC AUDIT.—The Center shall be subject to periodic audit by the Comptroller General.

"(d) ADVISORY COUNCIL.—

"(1) IN GENERAL.—To ensure transparency, the Secretary shall establish through the Agency's National Advisory Council, an advisory council (referred to in this section as the 'Council') that includes representatives from the scientific research, patient, provider, and health industry communities.

"(2) COMPOSITION OF COUNCIL.—

"(A) IN GENERAL.—The members of the Council shall consist of—

"(i) 2 ex officio members who shall be—

"(I) the Director; and

"(II) the Chief Medical Officer of the Centers for Medicare & Medicaid Services; and

"(ii) 19 additional members who shall represent broad constituencies of stakeholders.

"(B) QUALIFICATIONS.—

"(i) DIVERSE REPRESENTATION OF PERSPECTIVES.—The members of the Council shall represent a broad range of perspectives and shall collectively have experience in the following areas:

"(I) Epidemiology.

"(II) Health services research.

"(III) Bioethics.

"(IV) Communication and decision sciences.

"(V) Health economics.

"(VI) Safe use of medical products.

"(VII) The practice of medicine.

"(ii) DIVERSE REPRESENTATION OF HEALTH CARE COMMUNITY.—At least one

member shall represent each of the following health care communities:

"(I) Consumers.

"(II) Practicing physicians, including surgeons.

"(III) Nurses.

"(IV) State licensed practitioners and other health care professionals.

"(V) Employers.

"(VI) Public payers.

"(VII) Insurance plans.

"(VIII) Clinical researchers who conduct research on behalf of pharmaceutical or device manufacturers.

"(IX) Clinical researchers who conduct research related to personalized medicine.

"(X) Clinical researchers who conduct research related to reducing health disparities.

"(3) APPOINTMENT.—The Secretary or the Secretary's designee shall appoint the members of the Council.

"(4) TERMS.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), each member of the Council shall be appointed for a term of 4 years.

"(B) TERMS OF INITIAL APPOINTEES.—Of the members first appointed—

"(i) 10 shall be appointed for a term of 4 years; and

"(ii) 9 shall be appointed for a term of 2 years.

"(5) CONFLICTS OF INTEREST.—In appointing the members of the Council, the Secretary shall take into consideration any financial conflicts of interest.

"(e) RARE DISEASE RESEARCH.—In the case of a research study of a rare disease, the Secretary shall appoint a clinical expert advisory panel for purposes of assisting in the design of such research study and determining the feasibility of recruiting for and conducting such research study.

"(f) EXPERT ADVISORY PANELS.—The Center may appoint expert advisory panels to advise the Center and the agency, instrumentality, or entity conducting the research regarding the research question involved and the research design or protocol, including important patient subgroups and other parameters of the research. Such ex-

pert advisory panels may include individuals with experience in the relevant topic, project, or category for which the panel is established, including practicing and research clinicians and relevant specialists and subspecialists.

"(g) RESEARCH REQUIREMENTS.—Any research conducted, supported, or synthesized under this section shall meet the following requirements:

"(1) ENSURING TRANSPARENCY, CREDIBILITY, AND ACCESS.—The establishment of the agenda and conduct of the research shall be insulated from undue political or stakeholder influence, in accordance with the following:

"(A) Methods of conducting such research shall be scientifically based and take into account scientific advances in personalized medicine and reduces treatment disparities that include ethnic and racial minorities and children.

"(B) All aspects of the prioritization of research, conduct of the research, and development of conclusions based on the research shall be transparent to all stakeholders.

"(C) The process and methods for conducting such research shall be publicly documented and available to all stakeholders.

"(D) The Center shall establish a process for stakeholders involved to review and provide comment on the methods and findings of such research.

"(2) STAKEHOLDER INPUT.—The priorities of the research, the research, and the dissemination of the research shall involve the consultation of patients, health care providers, experts in wellness and health promotion, and health care consumer representatives through transparent mechanisms recommended by the Council.

"(h) PUBLIC ACCESS TO HEALTH OUTCOMES INFORMATION.—

"(1) IN GENERAL.—To the extent practicable, not later than 180 days after receipt by the Center of a relevant report described in paragraph (2), appropriate information contained in such report shall be posted on the official public Internet site of the Center, as applicable.

"(2) RELEVANT REPORTS DESCRIBED.—For purposes of this section, a relevant report is each of the following submitted by a grantee or contractor of the Center:

"(A) An interim progress report.

"(B) A draft final report that is available to stakeholders for review.

"(C) Stakeholder comments and response to same.

"(D) A final progress report on new research submitted for publication by a peer review journal.

"(E) A final report.

"(3) BENEFIT TO SUBPOPULATIONS.—All reports described in paragraph (2) shall assess whether the research demonstrates a benefit of the therapy with respect to a specific subpopulation of individuals, even if the outcome of the research demonstrates that, on average, with respect to the general population, the clinical benefits of the treatment do not exceed the harm.

"(i) ACCESS BY CONGRESS AND THE COUNSEL TO CENTER INFORMATION.—The Secretary shall establish a process for the Center to share with Congress reports and non-proprietary data of the Center.

"(j) DISSEMINATION, INCORPORATION, AND FEEDBACK OF INFORMATION.—

"(1) DISSEMINATION.—The Center shall provide for the dissemination of findings produced by research supported, conducted, or synthesized under

this section to health care providers, patients, vendors of health information technology focused on clinical decision support, appropriate professional associations, and Federal and private health plans. Center reports and recommendations shall not be construed as mandates for payment, coverage, or treatment.

"(2) INCORPORATION.—The Center shall assist users of health information technology focused on clinical decision support to promote the timely incorporation of the findings described in paragraph (1) into clinical practices and to promote the ease of use of such incorporation.

"(3) FEEDBACK.—The Center shall establish a process to receive feedback from providers, patients, 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 under this section.

"(k) REPORTS TO CONGRESS.—

"(1) ANNUAL REPORTS.—Beginning not later than one year after the date of enactment of this section, the Director shall submit to Congress an annual report on the activities of the Center and the

Council, and the research conducted, under this section.

"(2) ANALYSIS AND REVIEW.—Not later than December 31, 2011, the Secretary, shall submit to Congress a report on all activities conducted or supported under this section as of such date. Such report shall—

"(A) include an evaluation of the impact from such activities, the overall costs of such activities, and an analysis of the backlog of any research proposals approved but not funded; and

"(B) address whether Congress should expand the responsibilities of the Center to include studies of the effectiveness of various aspects of the health care delivery system, including health plans and delivery models, such as health plan features, benefit designs and performance, and the ways in which health services are organized, managed, and delivered.".

**SEC. 220. DEMONSTRATION PROGRAM TO INTEGRATE QUALITY IMPROVEMENT AND PATIENT SAFETY TRAINING INTO CLINICAL EDUCATION OF HEALTH PROFESSIONALS.**

(a) IN GENERAL.—The Secretary may award grants to eligible entities or consortia under this section to carry out demonstration projects to develop and implement academic curricula that integrates quality improvement and patient safety in the clinical education of health professionals. Such awards shall be made on a competitive basis and pursuant to peer review.

(b) ELIGIBILITY.—To be eligible to receive a grant under subsection (a), an entity or consortium shall—

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

(2) be or include—

(A) a health professions school;

(B) a school of public health;

(C) a school of social work;

(D) a school of nursing;

(E) a school of pharmacy;

(F) an institution with a graduate medical education program; or

(G) a school of health care administration;

(3) collaborate in the development of curricula described in subsection (a) with an organization that accredits such school or institution;

(4) provide for the collection of data regarding the effectiveness of the demonstration project; and

(5) provide matching funds in accordance with subsection (c).

(c) MATCHING FUNDS.—

(1) IN GENERAL.—The Secretary may award a grant to an entity or consortium under this section only if the entity or consortium agrees to make available non-Federal contributions toward the costs of the program to be funded under the grant in an amount that is not less than $1 for each $5 of Federal funds provided under the grant.

(2) DETERMINATION OF AMOUNT CONTRIBUTED.—Non-Federal contributions under paragraph (1) may be in cash or in kind, fairly evaluated, including equipment or services. Amounts provided by the Federal Government, or services assisted or subsidized to any significant extent by the Federal Government, may not be included in determining the amount of such contributions.

(d) EVALUATION.—The Secretary shall take such action as may be necessary to evaluate the projects funded

under this section and publish, make publicly available, and disseminate the results of such evaluations on as wide a basis as is practicable.

(e) REPORTS.—Not later than 2 years after the date of enactment of this section, and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate and the Committee on Energy and Commerce and the Committee on Ways and Means of the House of Representatives a report that—

(1) describes the specific projects supported under this section; and

(2) contains recommendations for Congress based on the evaluation conducted under subsection (d).

**SEC. 221. OFFICE OF WOMEN'S HEALTH.**

(a) HEALTH AND HUMAN SERVICES OFFICE ON WOMEN'S HEALTH.—

(1) ESTABLISHMENT.—Part A of title II of the Public Health Service Act (42 U.S.C. 202 et seq.) is amended by adding at the end the following:

**"SEC. 229. HEALTH AND HUMAN SERVICES OFFICE ON WOMEN'S HEALTH.**

''(a) ESTABLISHMENT OF OFFICE.—There is established within the Office of the Secretary, an Office on

Women's Health (referred to in this section as the 'Office'). The Office shall be headed by a Deputy Assistant Secretary for Women's Health who may report to the Secretary.

"(b) DUTIES.—The Secretary, acting through the Office, with respect to the health concerns of women, shall—

"(1) establish short-range and long-range goals and objectives within the Department of Health and Human Services and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Department that relate to disease prevention, health promotion, service delivery, research, and public and health care professional education, for issues of particular concern to women throughout their lifespan;

"(2) provide expert advice and consultation to the Secretary concerning scientific, legal, ethical, and policy issues relating to women's health;

"(3) monitor the Department of Health and Human Services' offices, agencies, and regional activities regarding women's health and identify needs regarding the coordination of activities, including intramural and extramural multidisciplinary activities;

"(4) establish a Department of Health and Human Services Coordinating Committee on Wom-

en's Health, which shall be chaired by the Deputy Assistant Secretary for Women's Health and composed of senior level representatives from each of the agencies and offices of the Department of Health and Human Services;

"(5) establish a National Women's Health Information Center to—

"(A) facilitate the exchange of information regarding matters relating to health information, health promotion, preventive health services, research advances, and education in the appropriate use of health care;

"(B) facilitate access to such information;

"(C) assist in the analysis of issues and problems relating to the matters described in this paragraph; and

"(D) provide technical assistance with respect to the exchange of information (including facilitating the development of materials for such technical assistance);

"(6) coordinate efforts to promote women's health programs and policies with the private sector; and

"(7) through publications and any other means appropriate, provide for the exchange of information

between the Office and recipients of grants, contracts, and agreements under subsection (c), and between the Office and health professionals and the general public.

"(c) GRANTS AND CONTRACTS REGARDING DUTIES.—

"(1) AUTHORITY.—In carrying out subsection (b), the Secretary may make grants to, and enter into cooperative agreements, contracts, and interagency agreements with, public and private entities, agencies, and organizations.

"(2) EVALUATION AND DISSEMINATION.—The Secretary shall directly or through contracts with public and private entities, agencies, and organizations, provide for evaluations of projects carried out with financial assistance provided under paragraph (1) and for the dissemination of information developed as a result of such projects.

"(d) REPORTS.—Not later than 1 year after the date of enactment of this section, and every second year thereafter, the Secretary shall prepare and submit to the appropriate committees of Congress a report describing the activities carried out under this section during the period for which the report is being prepared.

"(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2010 through 2014.".

(2) TRANSFER OF FUNCTIONS.—There are transferred to the Office on Women's Health (established under section 229 of the Public Health Service Act, as added by this section), all functions exercised by the Office on Women's Health of the Public Health Service prior to the date of enactment of this section, including all personnel and compensation authority, all delegation and assignment authority, and all remaining appropriations. All orders, determinations, rules, regulations, permits, agreements, grants, contracts, certificates, licenses, registrations, privileges, and other administrative actions that—

(A) have been issued, made, granted, or allowed to become effective by the President, any Federal agency or official thereof, or by a court of competent jurisdiction, in the performance of functions transferred under this paragraph; and

(B) are in effect at the time this section takes effect, or were final before the date of enactment of this section and are to become effective on or after such date,

shall continue in effect according to their terms until modified, terminated, superseded, set aside, or revoked in accordance with law by the President, the Secretary, or other authorized official, a court of competent jurisdiction, or by operation of law.

(b) CENTERS FOR DISEASE CONTROL AND PREVENTION OFFICE OF WOMEN'S HEALTH.—Part A of title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by adding at the end the following:

**"SEC. 310A. CENTERS FOR DISEASE CONTROL AND PREVENTION OFFICE OF WOMEN'S HEALTH.**

"(a) ESTABLISHMENT.—There is established within the Office of the Director of the Centers for Disease Control and Prevention, an office to be known as the Office of Women's Health (referred to in this section as the 'Office'). The Office shall be headed by a director who shall be appointed by the Director of such Centers.

"(b) PURPOSE.—The Director of the Office shall—

"(1) report to the Director of the Centers for Disease Control and Prevention on the current level of the Centers' activity regarding women's health conditions across, where appropriate, age, biological, and sociocultural contexts, in all aspects of the Centers' work, including prevention programs, public and professional education, services, and treatment;

"(2) establish short-range and long-range goals and objectives within the Centers for women's health and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Centers that relate to prevention, research, education and training, service delivery, and policy development, for issues of particular concern to women;

"(3) identify projects in women's health that should be conducted or supported by the Centers;

"(4) consult with health professionals, nongovernmental organizations, consumer organizations, women's health professionals, and other individuals and groups, as appropriate, on the policy of the Centers with regard to women; and

"(5) serve as a member of the Department of Health and Human Services Coordinating Committee on Women's Health (established under section 229(b)(4)).

"(c) DEFINITION.—As used in this section, the term 'women's health conditions', with respect to women of all age, ethnic, and racial groups, means diseases, disorders, and conditions—

"(1) unique to, significantly more serious for, or significantly more prevalent in women; and

"(2) for which the factors of medical risk or type of medical intervention are different for women, or for which there is reasonable evidence that indicates that such factors or types may be different for women.

"(d) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2010 through 2014.".

(c) OFFICE OF WOMEN'S HEALTH RESEARCH.—Section 486(a) of the Public Health Service Act (42 U.S.C. 287d(a)) is amended by inserting "and who shall report directly to the Director" before the period at the end thereof .

(d) SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION.—Section 501(f) of the Public Health Service Act (42 U.S.C. 290aa(f)) is amended—

(1) in paragraph (1), by inserting "who shall report directly to the Administrator" before the period;

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

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

"(4) OFFICE.—Nothing in this subsection shall be construed to preclude the Secretary from establishing within the Substance Abuse and Mental Health Administration an Office of Women's Health.".

(e) AGENCY FOR HEALTHCARE RESEARCH AND QUALITY ACTIVITIES REGARDING WOMEN'S HEALTH..—Part C of title IX of the Public Health Service Act (42 U.S.C. 299c et seq.) is amended—

(1) by redesignating sections 925 and 926 as sections 926 and 927, respectively; and

(2) by inserting after section 924 the following:

**"SEC. 925. ACTIVITIES REGARDING WOMEN'S HEALTH.**

"(a) ESTABLISHMENT.—There is established within the Office of the Director, an Office of Women's Health and Gender-Based Research (referred to in this section as the 'Office'). The Office shall be headed by a director who shall be appointed by the Director of Healthcare and Research Quality.

"(b) PURPOSE.—The official designated under subsection (a) shall—

"(1) report to the Director on the current Agency level of activity regarding women's health, across, where appropriate, age, biological, and sociocultural contexts, in all aspects of Agency work,

including the development of evidence reports and clinical practice protocols and the conduct of research into patient outcomes, delivery of health care services, quality of care, and access to health care;

''(2) establish short-range and long-range goals and objectives within the Agency for research important to women's health and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Agency that relate to health services and medical effectiveness research, for issues of particular concern to women;

''(3) identify projects in women's health that should be conducted or supported by the Agency;

''(4) consult with health professionals, nongovernmental organizations, consumer organizations, women's health professionals, and other individuals and groups, as appropriate, on Agency policy with regard to women; and

''(5) serve as a member of the Department of Health and Human Services Coordinating Committee on Women's Health (established under section 229(b)(4)).''.

''(c) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized

to be appropriated such sums as may be necessary for each of the fiscal years 2010 through 2014.''.

(f) HEALTH RESOURCES AND SERVICES ADMINISTRATION OFFICE OF WOMEN'S HEALTH.—Title VII of the Social Security Act (42 U.S.C. 901 et seq.) is amended by adding at the end the following:

**"SEC. 713. OFFICE OF WOMEN'S HEALTH.**

''(a) ESTABLISHMENT.—The Secretary shall establish within the Office of the Administrator of the Health Resources and Services Administration, an office to be known as the Office of Women's Health. The Office shall be headed by a director who shall be appointed by the Administrator.

''(b) PURPOSE.—The Director of the Office shall—

''(1) report to the Administrator on the current Administration level of activity regarding women's health across, where appropriate, age, biological, and sociocultural contexts;

''(2) establish short-range and long-range goals and objectives within the Health Resources and Services Administration for women's health and, as relevant and appropriate, coordinate with other appropriate offices on activities within the Administration that relate to health care provider training,

1 health service delivery, research, and demonstration
2 projects, for issues of particular concern to women;
3 ''(3) identify projects in women's health that
4 should be conducted or supported by the bureaus of
5 the Administration;
6 ''(4) consult with health professionals, non-
7 governmental organizations, consumer organizations,
8 women's health professionals, and other individuals
9 and groups, as appropriate, on Administration policy
10 with regard to women; and
11 ''(5) serve as a member of the Department of
12 Health and Human Services Coordinating Com-
13 mittee on Women's Health (established under sec-
14 tion 229(b)(4) of the Public Health Service Act).
15 ''(c) CONTINUED ADMINISTRATION OF EXISTING
16 PROGRAMS.—The Director of the Office shall assume the
17 authority for the development, implementation, adminis-
18 tration, and evaluation any projects carried out through
19 the Health Resources and Services Administration relat-
20 ing to women's health on the date of enactment of this
21 section.
22 ''(d) DEFINITIONS.—For purposes of this section:
23 ''(1) ADMINISTRATION.—The term 'Administra-
24 tion' means the Health Resources and Services Ad-
25 ministration.

"(2) ADMINISTRATOR.—The term 'Administrator' means the Administrator of the Health Resources and Services Administration.

"(3) OFFICE.—The term 'Office' means the Office of Women's Health established under this section in the Administration.

"(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2010 through 2014.".

(g) FOOD AND DRUG ADMINISTRATION OFFICE OF WOMEN'S HEALTH.—Chapter X of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amended by adding at the end the following:

**"SEC. 1011. OFFICE OF WOMEN'S HEALTH.**

"(a) ESTABLISHMENT.—There is established within the Office of the Commissioner, an office to be known as the Office of Women's Health (referred to in this section as the 'Office'). The Office shall be headed by a director who shall be appointed by the Commissioner of Food and Drugs.

"(b) PURPOSE.—The Director of the Office shall—

"(1) report to the Commissioner of Food and Drugs on current Food and Drug Administration (referred to in this section as the 'Administration')

levels of activity regarding women's participation in clinical trials and the analysis of data by sex in the testing of drugs, medical devices, and biological products across, where appropriate, age, biological, and sociocultural contexts;

''(2) establish short-range and long-range goals and objectives within the Administration for issues of particular concern to women's health within the jurisdiction of the Administration, including, where relevant and appropriate, adequate inclusion of women and analysis of data by sex in Administration protocols and policies;

''(3) provide information to women and health care providers on those areas in which differences between men and women exist;

''(4) consult with pharmaceutical, biologics, and device manufacturers, health professionals with expertise in women's issues, consumer organizations, and women's health professionals on Administration policy with regard to women;

''(5) make annual estimates of funds needed to monitor clinical trials and analysis of data by sex in accordance with needs that are identified; and

''(6) serve as a member of the Department of Health and Human Services Coordinating Com-

1 mittee on Women's Health (established under sec-
2 tion 229(b)(4) of the Public Health Service Act).
3 ''(c) AUTHORIZATION OF APPROPRIATIONS.—For the
4 purpose of carrying out this section, there are authorized
5 to be appropriated such sums as may be necessary for
6 each of the fiscal years 2010 through 2014.''.
7 (h) NO NEW REGULATORY AUTHORITY.—Nothing in
8 this section and the amendments made by this section may
9 be construed as establishing regulatory authority or modi-
10 fying any existing regulatory authority.
11 (i) LIMITATION ON TERMINATION.—Notwithstanding
12 any other provision of law, a Federal office of women's
13 health (including the Office of Research on Women's
14 Health of the National Institutes of Health) or Federal
15 appointive position with primary responsibility over wom-
16 en's health issues (including the Associate Administrator
17 for Women's Services under the Substance Abuse and
18 Mental Health Services Administration) that is in exist-
19 ence on the date of enactment of this section shall not
20 be terminated, reorganized, or have any of it's powers or
21 duties transferred unless such termination, reorganization,
22 or transfer is approved by Congress through the adoption
23 of a concurrent resolution of approval.
24 (j) RULE OF CONSTRUCTION.—Nothing in this sec-
25 tion (or the amendments made by this section) shall be

construed to limit the authority of the Secretary of Health and Human Services with respect to women's health, or with respect to activities carried out through the Department of Health and Human Services on the date of enactment of this section.

**SEC. 222. ADMINISTRATIVE SIMPLIFICATION.**

(a) STANDARDS FOR FINANCIAL AND ADMINISTRATIVE TRANSACTIONS.—

(1) IN GENERAL.—The Secretary shall adopt and regularly update standards, implementation specifications, and operating rules for the electronic exchange and use of health information for purposes of financial and administrative transactions (as provided for in paragraph (2)).

(2) ADDITIONAL REQUIREMENTS FOR FINANCIAL AND ADMINISTRATIVE TRANSACTIONS.—The standards, implementation specifications, and operating rules provided for in paragraph (1) shall—

(A) be unique with no conflicting or redundant standards;

(B) be authoritative, requiring no additional standards or companion guides;

(C) be comprehensive and robust, requiring minimal augmentation by paper transactions or clarification by phone calls;

(D) enable the real time determination of a patient's financial responsibility at the point of service and, to the extent possible, prior to service, including whether a patient is eligible for a specific service with a specific physician at a specific facility, which may include a machine-readable health plan identification card;

(E) provide for timely acknowledgment; and

(F) require that all data elements within a standard or specification (such as reason and remark codes) be described in unambiguous terms (with no optional fields permitted and a requirement that data elements be either required or conditioned upon set values in other fields) with additional conditions being prohibited.

(3) TIME FOR ADOPTION.—Not later than 2 years after the date of enactment of this section, the Secretary shall adopt standards, implementation specifications, and operating rules under this section.

(4) REQUIREMENTS FOR INITIAL STANDARDS.—The initial set of standards, implementation

specifications, and operating rules under paragraph (1) shall include—

(A) requirements to clarify, refine, and expand, as needed, standards required under section 1173 of the Social Security Act;

(B) requirements for acknowledgments, such as those for receipt of a claim;

(C) requirements to permit electronic funds transfers (to allow automated reconciliation with the related health care payment and remittance advice);

(D) the requirements of timely and transparent claim and denial management processes, including tracking, adjudication, and appeal processing (for all participants, including health insurance issuers, health care providers, and patients); and

(E) other requirements relating to administrative simplification as identified by the Secretary, in consultation with stakeholders.

(5) BUILDING ON EXISTING STANDARDS.—In developing the standards, implementation specifications, and operating rules under paragraph (1), the Secretary shall build upon existing and planned

standards, implementation specifications, and operating rules.

(6) EXPEDITED PROCEDURES FOR ADOPTION OF ADDITIONS AND MODIFICATIONS TO STANDARDS.—Notwithstanding any other provision of law, the Secretary may use the following expedited procedures for purposes of paragraph (1):

(A) EXPEDITED UPGRADE PROGRAM.—The Secretary shall provide for an expedited upgrade program (in this paragraph referred to as the ''upgrade program''), in accordance with this paragraph, to develop and approve additions and modifications to the standards described in paragraph (4) to improve the quality of such standards or to extend the functionality of such standards to meet evolving requirements in health care.

(B) PUBLICATION OF NOTICES.—Under the upgrade program:

(i) VOLUNTARY NOTICE OF INITIATION OF PROCESS.—Not later than 30 days after the date the Secretary receives a notice from a standard setting organization that the organization is initiating a process to develop an addition or modifica-

tion to a standard described in paragraph (4), the Secretary shall publish a notice in the Federal Register that—

(I) identifies the subject matter of the addition or modification;

(II) provides a description of how persons may participate in the development process; and

(III) invites public participation in such process.

(ii) VOLUNTARY NOTICE OF PRELIMINARY DRAFT OF ADDITIONS OR MODIFICATIONS TO STANDARDS.—Not later than 30 days after the date the Secretary receives a notice from a standard setting organization that the organization has prepared a preliminary draft of an addition or modification to a standard described in paragraph (4), the Secretary shall publish a notice in the Federal Register that—

(I) identifies the subject matter of (and summarizes) the addition or modification;

(II) specifies the procedure for obtaining the draft;

(III) provides a description of how persons may submit comments in writing and at any public hearing or meeting held by the organization on the addition or modification; and

(IV) invites submission of such comments and participation in such hearing or meeting without requiring the public to pay a fee to participate.

(iii) NOTICE OF PROPOSED ADDITION OR MODIFICATION TO STANDARDS.—Not later than 30 days after the date the Secretary receives a notice from a standard setting organization that the organization has a proposed addition or modification to a standard described in paragraph (4) that the organization intends to submit under subparagraph (D)(iii), the Secretary shall publish a notice in the Federal Register that contains, with respect to the proposed addition or modification, the information required in the notice under clause (ii) with respect to the addition or modification.

(iv) CONSTRUCTION.—Nothing in this paragraph shall be construed as requiring a standard setting organization to request the notices described in clauses (i) and (ii) with respect to an addition or modification to a standard in order to qualify for an expedited determination under subparagraph (C) with respect to a proposal submitted to the Secretary for adoption of such addition or modification.

(C) PROVISION OF EXPEDITED DETERMINATION.—Under the upgrade program and with respect to a proposal by a standard setting organization for an addition or modification to a standard described in paragraph (4), if the Secretary determines that the standard setting organization developed such addition or modification in accordance with the requirements of subparagraph (D) and the National Committee on Vital and Health Statistics recommends approval of such addition or modification under subparagraph (E), the Secretary shall provide for expedited treatment of such proposal in accordance with subparagraph (F).

(D) REQUIREMENTS.—The requirements under this subparagraph with respect to a proposed addition or modification to a standard by a standard setting organization are the following:

(i) REQUEST FOR PUBLICATION OF NOTICE.—The standard setting organization submits to the Secretary a request for publication in the Federal Register of a notice described in subparagraph (B)(iii) for the proposed addition or modification.

(ii) PROCESS FOR RECEIPT AND CONSIDERATION OF PUBLIC COMMENT.—The standard setting organization provides for a process through which, after the publication of the notice referred to under clause (i), the organization—

(I) receives and responds to public comments submitted on a timely basis on the proposed addition or modification before submitting such proposed addition or modification to the National Committee on Vital and Health Statistics under clause (iii);

(II) makes publicly available a written explanation for its response in the proposed addition or modification to comments submitted on a timely basis; and

(III) makes public comments received under clause (I) available, or provides access to such comments, to the Secretary.

(iii) SUBMITTAL OF FINAL PROPOSED ADDITION OR MODIFICATION TO NCVHS.—After completion of the process under clause (ii), the standard setting organization submits the proposed addition or modification to the National Committee on Vital and Health Statistics for review and consideration under subparagraph (E). Such submission shall include information on the organization's compliance with the notice and comment requirements (and responses to those comments) under clause (ii).

(E) HEARINGS AND RECOMMENDATIONS BY NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS.—Under the upgrade pro-

gram, upon receipt of a proposal submitted by a standard setting organization under subparagraph (D)(iii) for the adoption of an addition or modification to a standard, the National Committee on Vital and Health Statistics shall provide notice to the public and a reasonable opportunity for public testimony at a hearing on such addition or modification. The Secretary may participate in such hearing in such capacity (including presiding ex officio) as the Secretary shall determine appropriate. Not later than 120 days after the date of receipt of the proposal, the Committee shall submit to the Secretary its recommendation to adopt (or not adopt) the proposed addition or modification.

(F) DETERMINATION BY SECRETARY TO ACCEPT OR REJECT NATIONAL COMMITTEE ON VITAL AND HEALTH STATISTICS RECOMMENDATION.—

(i) TIMELY DETERMINATION.—Under the upgrade program, if the National Committee on Vital and Health Statistics submits to the Secretary a recommendation under subparagraph (E) to adopt a proposed addition or modification, not later

than 90 days after the date of receipt of such recommendation the Secretary shall make a determination to accept or reject the recommendation and shall publish notice of such determination in the Federal Register not later than 90 days after the date of the determination.

(ii) CONTENTS OF NOTICE.—If the determination is to reject the recommendation, such notice shall include the reasons for the rejection. If the determination is to accept the recommendation, as part of such notice the Secretary shall promulgate the modified standard (including the accepted proposed addition or modification accepted) as a final rule under this subsection without any further notice or public comment period.

(iii) LIMITATION ON CONSIDERATION.—The Secretary shall not consider a proposal under this subparagraph unless the Secretary determines that the requirements of subparagraph (D) (including publication of notice and opportunity for pub-

lic comment) have been met with respect to the proposal.

(G) EXEMPTION FROM PAPERWORK REDUCTION ACT.—Chapter 35 of title 44, United States Code, shall not apply to a final rule promulgated under subparagraph (F).

(H) TREATMENT AS SATISFYING REQUIREMENTS FOR NOTICE AND COMMENT.—Any requirements under section 553 of title 5, United States Code, relating to notice and an opportunity for public comment with respect to a final rule promulgated under subparagraph (F) shall be treated as having been met by meeting the requirements of the notice and opportunity for public comment provided under provisions of subparagraphs (B)(iii), (D), and (E).

(I) MODIFICATION DEFINED.—For purposes of this section, the term ''modification'' includes a new version or a version upgrade.

(7) IMPLEMENTATION AND ENFORCEMENT.—Not later than 2 years after the date of enactment of this section, the Secretary shall submit to the appropriate committees of Congress a plan for the implementation and enforcement, by not later than 5 years after such date of enactment, of the standards,

implementation specifications, and operating rules provided for under paragraph (1).

(b) HEALTH PLAN IDENTIFIER.—Not later than 1 year after the date of enactment of this section, the Secretary shall promulgate a final rule to establish a National Health Plan Identifier system.

**SEC. 223. PATIENT NAVIGATOR PROGRAM.**

Section 340A of the Public Health Service Act (42 U.S.C. 256a) is amended—

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

"(3) MINIMUM CORE PROFICIENCIES.—The Secretary shall not award a grant to an entity under this section unless such entity provides assurances that patient navigators recruited, assigned, trained, or employed using grant funds meet minimum core proficiencies, as defined by the entity that submits the application, that are tailored for the main focus or intervention of the navigator involved."; and

(2) in subsection (m)—

(A) in paragraph (1), by striking "and $3,500,000 for fiscal year 2010." and inserting "$3,500,000 for fiscal year 2010, and such sums as may be necessary for each of fiscal years 2011 through 2015."; and

(B) in paragraph (2), by striking ''2010'' and inserting ''2015''.

**SEC. 224. AUTHORIZATION OF APPROPRIATIONS.**

Except where otherwise provided in this subtitle (or an amendment made by this subtitle), there is authorized to be appropriated such sums as may be necessary to carry out this subtitle (and such amendments made by this subtitle).

# Subtitle C—Civil and Criminal Penalties for Acts Involving Federal Health Care Programs; Exception to Limitation on Certain Physician Referrals

**SEC. 231. SAFE HARBORS TO ANTIKICKBACK CIVIL PENALTIES AND CRIMINAL PENALTIES FOR PROVISION OF HEALTH INFORMATION TECHNOLOGY AND TRAINING SERVICES.**

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

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

''(4) For purposes of this subsection, inducements to reduce or limit services described in paragraph (1) shall not include the practical or other advantages resulting

from health information technology or related installation, maintenance, support, or training services.''; and

(2) in subsection (i), by adding at the end the following new paragraph:

''(8) The term 'health information technology' means hardware, software, license, right, intellectual property, equipment, or other information technology (including new versions, upgrades, and connectivity) designed or provided primarily for the electronic creation, maintenance, or exchange of health information to better coordinate care or improve health care quality, efficiency, or research.''.

(b) FOR CRIMINAL PENALTIES.—Section 1128B of such Act (42 U.S.C. 1320a–7b) is amended—

(1) in subsection (b)(3)—

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

(B) in the subparagraph (H) added by section 237(d) of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (Public Law 108–173; 117 Stat. 2213)—

(i) by moving such subparagraph 2 ems to the left; and

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

(C) in the subparagraph (H) added by section 431(a) of such Act (117 Stat. 2287)—

(i) by redesignating such subparagraph as subparagraph (I);

(ii) by moving such subparagraph 2 ems to the left; and

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

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

"(J) any nonmonetary remuneration (in the form of health information technology, as defined in section 1128A(i)(8), or related installation, maintenance, support or training services) made to a person by a specified entity (as defined in subsection (g)) if—

"(i) the provision of such remuneration is without an agreement between the parties or legal condition that—

"(I) limits or restricts the use of the health information technology to services provided by the physician to individuals receiving services at the specified entity;

"(II) limits or restricts the use of the health information technology in conjunc-

tion with other health information technology; or

"(III) conditions the provision of such remuneration on the referral of patients or business to the specified entity;

"(ii) such remuneration is arranged for in a written agreement that is signed by the parties involved (or their representatives) and that specifies the remuneration solicited or received (or offered or paid) and states that the provision of such remuneration is made for the primary purpose of better coordination of care or improvement of health quality, efficiency, or research; and

"(iii) the specified entity providing the remuneration (or a representative of such entity) has not taken any action to disable any basic feature of any hardware or software component of such remuneration that would permit interoperability."; and

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

"(g) SPECIFIED ENTITY DEFINED.—For purposes of subsection (b)(3)(J), the term 'specified entity' means an entity that is a hospital, group practice, prescription drug

1 plan sponsor, a Medicare Advantage organization, or any
2 other such entity specified by the Secretary, considering
3 the goals and objectives of this section, as well as the goals
4 to better coordinate the delivery of health care and to pro-
5 mote the adoption and use of health information tech-
6 nology.''.

7 (c) EFFECTIVE DATE AND EFFECT ON STATE
8 LAWS.—

9 (1) EFFECTIVE DATE.—The amendments made
10 by subsections (a) and (b) shall take effect on the
11 date that is 120 days after the date of the enact-
12 ment of this Act.

13 (2) PREEMPTION OF STATE LAWS.—No State
14 (as defined in section 1101(a) of the Social Security
15 Act (42 U.S.C. 1301(a)) for purposes of title XI of
16 such Act) shall have in effect a State law that im-
17 poses a criminal or civil penalty for a transaction de-
18 scribed in section 1128A(b)(4) or section
19 1128B(b)(3)(J) of such Act, as added by subsections
20 (a)(1) and (b), respectively, if the conditions de-
21 scribed in the respective provision, with respect to
22 such transaction, are met.

23 (d) STUDY AND REPORT TO ASSESS EFFECT OF
24 SAFE HARBORS ON HEALTH SYSTEM.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall conduct a study to determine the impact of each of the safe harbors described in paragraph (3). In particular, the study shall examine the following:

(A) The effectiveness of each safe harbor in increasing the adoption of health information technology.

(B) The types of health information technology provided under each safe harbor.

(C) The extent to which the financial or other business relationships between providers under each safe harbor have changed as a result of the safe harbor in a way that adversely affects or benefits the health care system or choices available to consumers.

(D) The impact of the adoption of health information technology on health care quality, cost, and access under each safe harbor.

(2) REPORT.—Not later than 3 years after the effective date described in subsection (c)(1), the Secretary of Health and Human Services shall submit to Congress a report on the study under paragraph (1).

(3) SAFE HARBORS DESCRIBED.—For purposes of paragraphs (1) and (2), the safe harbors described in this paragraph are—

(A) the safe harbor under section 1128A(b)(4) of such Act (42 U.S.C. 1320a–7a(b)(4)), as added by subsection (a)(1); and

(B) the safe harbor under section 1128B(b)(3)(J) of such Act (42 U.S.C. 1320a–7b(b)(3)(J)), as added by subsection (b).

**SEC. 232. EXCEPTION TO LIMITATION ON CERTAIN PHYSICIAN REFERRALS (UNDER STARK) FOR PROVISION OF HEALTH INFORMATION TECHNOLOGY AND TRAINING SERVICES TO HEALTH CARE PROFESSIONALS.**

(a) IN GENERAL.—Section 1877(b) of the Social Security Act (42 U.S.C. 1395nn(b)) is amended by adding at the end the following new paragraph:

''(6) INFORMATION TECHNOLOGY AND TRAINING SERVICES.—

''(A) IN GENERAL.—Any nonmonetary remuneration (in the form of health information technology or related installation, maintenance, support or training services) made by a specified entity to a physician if—

"(i) the provision of such remuneration is without an agreement between the parties or legal condition that—

"(I) limits or restricts the use of the health information technology to services provided by the physician to individuals receiving services at the specified entity;

"(II) limits or restricts the use of the health information technology in conjunction with other health information technology; or

"(III) conditions the provision of such remuneration on the referral of patients or business to the specified entity;

"(ii) such remuneration is arranged for in a written agreement that is signed by the parties involved (or their representatives) and that specifies the remuneration made and states that the provision of such remuneration is made for the primary purpose of better coordination of care or improvement of health quality, efficiency, or research; and

"(iii) the specified entity (or a representative of such entity) has not taken any action to disable any basic feature of any hardware or software component of such remuneration that would permit interoperability.

"(B) HEALTH INFORMATION TECHNOLOGY DEFINED.—For purposes of this paragraph, the term 'health information technology' means hardware, software, license, right, intellectual property, equipment, or other information technology (including new versions, upgrades, and connectivity) designed or provided primarily for the electronic creation, maintenance, or exchange of health information to better coordinate care or improve health care quality, efficiency, or research.

"(C) SPECIFIED ENTITY DEFINED.—For purposes of this paragraph, the term 'specified entity' means an entity that is a hospital, group practice, prescription drug plan sponsor, a Medicare Advantage organization, or any other such entity specified by the Secretary, considering the goals and objectives of this section, as well as the goals to better coordinate the deliv-

ery of health care and to promote the adoption and use of health information technology.''.

(b) EFFECTIVE DATE; EFFECT ON STATE LAWS.—

(1) EFFECTIVE DATE.—The amendment made by subsection (a) shall take effect on the date that is 120 days after the date of the enactment of this Act.

(2) PREEMPTION OF STATE LAWS.—No State (as defined in section 1101(a) of the Social Security Act (42 U.S.C. 1301(a)) for purposes of title XI of such Act) shall have in effect a State law that imposes a criminal or civil penalty for a transaction described in section 1877(b)(6) of such Act, as added by subsection (a), if the conditions described in such section, with respect to such transaction, are met.

(c) STUDY AND REPORT TO ASSESS EFFECT OF EXCEPTION ON HEALTH SYSTEM.—

(1) IN GENERAL.—The Secretary of Health and Human Services shall conduct a study to determine the impact of the exception under section 1877(b)(6) of such Act (42 U.S.C. 1395nn(b)(6)), as added by subsection (a). In particular, the study shall examine the following:

(A) The effectiveness of the exception in increasing the adoption of health information technology.

(B) The types of health information technology provided under the exception.

(C) The extent to which the financial or other business relationships between providers under the exception have changed as a result of the exception in a way that adversely affects or benefits the health care system or choices available to consumers.

(D) The impact of the adoption of health information technology on health care quality, cost, and access under the exception.

(2) REPORT.—Not later than 3 years after the effective date described in subsection (b)(1), the Secretary of Health and Human Services shall submit to Congress a report on the study under paragraph (1).

**SEC. 233. RULES OF CONSTRUCTION REGARDING USE OF CONSORTIA.**

(a) APPLICATION TO SAFE HARBOR FROM CRIMINAL PENALTIES.—Section 1128B(b)(3) of the Social Security Act (42 U.S.C. 1320a–7b(b)(3)) is amended by adding after and below subparagraph (J), as added by section

231(b)(1), the following: ''For purposes of subparagraph (J), nothing in such subparagraph shall be construed as preventing a specified entity, consistent with the specific requirements of such subparagraph, from forming a consortium composed of health care providers, payers, employers, and other interested entities to collectively purchase and donate health information technology, or from offering health care providers a choice of health information technology products in order to take into account the varying needs of such providers receiving such products.''.

(b) APPLICATION TO STARK EXCEPTION.—Paragraph (6) of section 1877(b) of the Social Security Act (42 U.S.C. 1395nn(b)), as added by section 232(a), is amended by adding at the end the following new subparagraph:

''(D) RULE OF CONSTRUCTION.—For purposes of subparagraph (A), nothing in such subparagraph shall be construed as preventing a specified entity, consistent with the specific requirements of such subparagraph, from—

''(i) forming a consortium composed of health care providers, payers, employers, and other interested entities to collectively purchase and donate health information technology; or

"(ii) offering health care providers a choice of health information technology products in order to take into account the varying needs of such providers receiving such products.".

# TITLE III—IMPROVING THE HEALTH OF THE AMERICAN PEOPLE

## Subtitle A—Modernizing Disease Prevention and Public Health Systems

### SEC. 301. NATIONAL PREVENTION, HEALTH PROMOTION AND PUBLIC HEALTH COUNCIL.

(a) ESTABLISHMENT.—The President shall establish a council to be known as the "National Prevention, Health Promotion and Public Health Council" (referred to in this section as the "Council").

(b) CHAIRPERSON.—The President shall appoint an individual to serve as the chairperson of the Council.

(c) COMPOSITION.—The Council shall be composed of—

(1) the Secretary of Health and Human Services;

(2) the Secretary of Agriculture;

(3) the Secretary of Education;

(4) the Chairman of the Federal Trade Commission;

(5) the Chairman of the Federal Communications Commission;

(6) the Secretary of Transportation;

(7) the Secretary of Defense;

(8) the Secretary of Veterans Affairs;

(9) the Secretary of the Interior;

(10) the Secretary of Labor;

(11) the Secretary of Homeland Security;

(12) the Secretary of Housing and Urban Development;

(13) the Director of the United States Patent and Trademark Office;

(14) the Administrator of the Environmental Protection Agency;

(15) the Director of the Domestic Policy Council;

(16) the Director of the Office of Personnel Management;

(17) the Director of the Office of National Drug Control Policy;

(18) the Chairman of the Corporation for National and Community Service; and

(19) the head of any other Federal agency that the chairperson determines is appropriate.

(d) PURPOSES AND DUTIES.—The Council shall—

(1) provide coordination and leadership at the Federal level, and among all Federal departments and agencies, with respect to prevention, wellness and health promotion practices, the public health system, and integrative health care in the United States;

(2) after obtaining input from relevant stakeholders, develop a national prevention, health promotion, public health, and integrative health care strategy that incorporates the most effective and achievable means of improving the health status of Americans and reducing the incidence of preventable illness and disability in the United States;

(3) provide recommendations to the President and Congress concerning the most pressing health issues confronting the United States and changes in Federal policy to achieve national wellness, health promotion, and public health goals, including the reduction of tobacco use, sedentary behavior, and poor nutrition;

(4) consider and propose evidence-based models, policies, and innovative approaches for the pro-

motion of transformative models of prevention, integrative health, and public health on individual and community levels across the United States;

(5) establish processes for continual public input, including input from State, regional, and local leadership communities and other relevant stakeholders, including Indian tribes and tribal organizations;

(6) submit the reports required under subsection (g); and

(7) carry out other activities determined appropriate by the President.

(e) MEETINGS.—The Council shall meet at the call of the Chairperson.

(f) NATIONAL PREVENTION AND HEALTH PROMOTION STRATEGY.—Not later than 1 year after the date of enactment of this Act, the Chairperson, in consultation with the Council, shall develop and make public a national prevention, health promotion and public health strategy, and shall review and revise such strategy periodically. Such strategy shall—

(1) set specific goals and objectives for improving the health of the United States through federally-supported prevention, health promotion, and

public health programs, consistent with ongoing goal setting efforts conducted by specific agencies;

(2) establish specific and measurable actions and timelines to carry out the strategy, and determine accountability for meeting those timelines, within and across Federal departments and agencies; and

(3) make recommendations to improve Federal efforts relating to prevention, health promotion, public health, and integrative health care practices to ensure Federal efforts are consistent with available standards and evidence.

(g) REPORT.—Not later than July 1, 2010, and annually thereafter through January 1, 2015, the Council shall submit to the President and the relevant committees of Congress, a report that—

(1) describes the activities and efforts on prevention, health promotion, and public health and activities to develop a national strategy conducted by the Council during the period for which the report is prepared;

(2) describes the national progress in meeting specific prevention, health promotion, and public health goals defined in the strategy and further describes corrective actions recommended by the Coun-

cil and taken by relevant agencies and organizations to meet these goals;

(3) contains a list of national priorities on health promotion and disease prevention to address lifestyle behavior modification (smoking cessation, proper nutrition, and appropriate exercise) and the prevention measures for the 5 leading disease killers in the United States;

(4) contains specific science-based initiatives to achieve the measurable goals of Healthy People 2010 regarding nutrition, exercise, and smoking cessation, and targeting the 5 leading disease killers in the United States;

(5) contains specific plans for consolidating Federal health programs and Centers that exist to promote healthy behavior and reduce disease risk (including eliminating programs and offices determined to be ineffective in meeting the priority goals of Healthy People 2010);

(6) contains specific plans to ensure that all Federal health care programs are fully coordinated with science-based prevention recommendations by the Director of the Centers for Disease Control and Prevention;

(7) contains specific plans to ensure that all non-Department of Health and Human Services prevention programs are based on the science-based guidelines developed by the Centers for Disease Control and Prevention under paragraph (4); and

(8) contains a list of new non-Federal and non-government partners identified by the council to build Federal capacity in health promotion and disease prevention efforts.

(h) PERIODIC REVIEWS.—The Secretary and the Comptroller General of the United States shall jointly conduct periodic reviews, not less than every 5 years, and evaluations of every Federal disease prevention and health promotion initiative, program, and agency. Such reviews shall be evaluated based on effectiveness in meeting metrics-based goals with an analysis posted on such agencies' public Internet websites.

(i) ANNUAL REQUEST TO GIVE TESTIMONY.—The Chairperson shall annually request an opportunity to testify before Congress concerning—

(1) the progress made by the United States in meeting the prevention, health promotion, and public health goals defined in the strategy and the effectiveness of Federal programs related to these goals; and

(2) the amount and sources of Federal funds that are targeted to prevention, health promotion, and public health initiatives and results of program evaluations.

**SEC. 302. PREVENTION AND PUBLIC HEALTH FUND.**

(a) PURPOSE.—It is the purpose of this section to establish a Prevention and Public Health Fund (referred to in this section as the ''Fund''), to be administered through the Department of Health and Human Services, Office of the Secretary, to provide for expanded and sustained national investment in prevention and public health programs to improve health and help restrain the rate of growth in private and public sector health care costs.

(b) FUNDING.—There are hereby authorized to be appropriated, and appropriated, to the Fund, out of any monies in the Treasury not otherwise appropriated—

(1) for fiscal year 2010, $2,000,000,000;

(2) for fiscal year 2011, $4,000,000,000;

(3) for fiscal year 2012, $6,000,000,000;

(4) for fiscal year 2013, $8,000,000,000;

(5) for fiscal year 2014, $10,000,000,000;

(6) for fiscal year 2015, $ 10,000,000,000;

(7) for fiscal year 2016, $10,000,000,000;

(8) for fiscal year 2017, $10,000,000,000;

(9) for fiscal year 2018, $10,000,000,000; and

(10) for fiscal year 2019, and each fiscal year thereafter, $10,000,000,000.

(c) USE OF FUND.—The Secretary shall transfer amounts in the Fund to accounts within the Department of Health and Human Services to increase funding, over the fiscal year 2008 level, for programs authorized by the Public Health Service Act, for prevention, wellness and public health activities including prevention research and health screenings. Such transfers shall be subject to the transfer authority provided for in the annual appropriations Act for the fiscal year in which the funds become available.

(d) TRANSFER AUTHORITY .—The Committee on Appropriations of the Senate and the Committee on Appropriations of the House of Representatives may provide for the transfer of funds in the Fund to eligible activities under this section, subject to subsection (c).

**SEC. 303. CLINICAL AND COMMUNITY PREVENTIVE SERVICES.**

(a) PREVENTIVE SERVICES TASK FORCE.—Section 915 of the Public Health Service Act (42 U.S.C. 299b-4) is amended by striking subsection (a) and inserting the following:

''(a) PREVENTIVE SERVICES TASK FORCE.—

1 "(1) ESTABLISHMENT AND PURPOSE.—The Di-
2 rector shall convene an independent Preventive Serv-
3 ices Task Force (referred to in this subsection as the
4 'Task Force') to be composed of individuals with ap-
5 propriate expertise. Such Task Force shall review
6 the scientific evidence related to the effectiveness,
7 appropriateness, and cost-effectiveness of clinical
8 preventive services for the purpose of developing rec-
9 ommendations for the health care community, and
10 updating previous clinical preventive recommenda-
11 tions, to be published in the Guide to Clinical Pre-
12 ventive Services (referred to in this section as the
13 'Guide'), for individuals and organizations delivering
14 clinical services, including primary care profes-
15 sionals, health care systems, professional societies,
16 employers, community organizations, non-profit or-
17 ganizations, Congress and other policy-makers, gov-
18 ernmental public health agencies, health care quality
19 organizations, and organizations developing national
20 health objectives. Such recommendations shall con-
21 sider clinical preventive best practice recommenda-
22 tions from the Agency for Healthcare Research and
23 Quality, the National Institutes of Health, the Cen-
24 ters for Disease Control and Prevention, the Insti-

tute of Medicine, specialty medical associations, patient groups, and scientific societies.

"(2) DUTIES.—The duties of the Task Force shall include—

"(A) the development of additional topic areas for new recommendations and interventions related to those topic areas, including those related to specific sub-populations and age groups;

"(B) at least once during every 5-year period, review interventions and update recommendations related to existing topic areas, including new or improved techniques to assess the health effects of interventions;

"(C) improved integration with Federal Government health objectives and related target setting for health improvement;

"(D) the enhanced dissemination of recommendations;

"(E) the provision of technical assistance to those health care professionals, agencies and organizations that request help in implementing the Guide recommendations; and

"(F) the submission of yearly reports to Congress and related agencies identifying gaps

in research, such as preventive services that receive an insufficient evidence statement, and recommending priority areas that deserve further examination, including areas related to populations and age groups not adequately addressed by current recommendations.

"(3) ROLE OF AGENCY.—The Agency shall provide ongoing administrative, research, and technical support for the operations of the Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force, ensuring adequate staff resources, and assistance to those organizations requesting it for implementation of the Guide's recommendations.

"(4) COORDINATION WITH COMMUNITY PREVENTIVE SERVICES TASK FORCE.—The Task Force shall take appropriate steps to coordinate its work with the Community Preventive Services Task Force and the Advisory Committee on Immunization Practices, including the examination of how each task force's recommendations interact at the nexus of clinic and community.

"(5) OPERATION.—Operation. In carrying out the duties under paragraph (2), the Task Force is

not subject to the provisions of Appendix 2 of title 5, United States Code.

"(6) INDEPENDENCE.—All members of the Task Force convened under this subsection, and any recommendations made by such members, shall be independent and, to the extent practicable, not subject to political pressure.

"(7) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for each fiscal year to carry out the activities of the Task Force.".

(b) COMMUNITY PREVENTIVE SERVICES TASK FORCE.—Part P of title III of the Public Health Service Act is amended by adding at the end the following:

**"SEC. 399S. COMMUNITY PREVENTIVE SERVICES TASK FORCE.**

"(a) ESTABLISHMENT AND PURPOSE.—The Director of the Centers for Disease Control and Prevention shall convene an independent Community Preventive Services Task Force (referred to in this subsection as the 'Task Force') to be composed of individuals with appropriate expertise. Such Task Force shall review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of community preventive interventions for the purpose of developing recommendations, to be pub-

lished in the Guide to Community Preventive Services (referred to in this section as the 'Guide'), for individuals and organizations delivering population-based services, including primary care professionals, health care systems, professional societies, employers, community organizations, non-profit organizations, schools, governmental public health agencies, Indian tribes, tribal organizations and urban Indian organizations, medical groups, Congress and other policy-makers. Community preventive services include any policies, programs, processes or activities designed to affect or otherwise affecting health at the population level.

"(b) DUTIES.—The duties of the Task Force shall include—

"(1) the development of additional topic areas for new recommendations and interventions related to those topic areas, including those related to specific populations and age groups, as well as the social, economic and physical environments that can have broad effects on the health and disease of populations and health disparities among sub-populations and age groups;

"(2) at least once during every 5-year period, review interventions and update recommendations related to existing topic areas, including new or im-

proved techniques to assess the health effects of interventions, including health impact assessment and population health modeling;

"(3) improved integration with Federal Government health objectives and related target setting for health improvement;

"(4) the enhanced dissemination of recommendations;

"(5) the provision of technical assistance to those health care professionals, agencies, and organizations that request help in implementing the Guide recommendations; and

"(6) providing yearly reports to Congress and related agencies identifying gaps in research and recommending priority areas that deserve further examination, including areas related to populations and age groups not adequately addressed by current recommendations.

"(c) ROLE OF AGENCY.—The Director shall provide ongoing administrative, research, and technical support for the operations of the Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force, ensuring adequate staff resources, and assistance to those organizations requesting it for implementation of Guide recommendations.

"(d) COORDINATION WITH PREVENTIVE SERVICES TASK FORCE.—The Task Force shall take appropriate steps to coordinate its work with the U.S. Preventive Services Task Force and the Advisory Committee on Immunization Practices, including the examination of how each task force's recommendations interact at the nexus of clinic and community.

"(e) OPERATION.—In carrying out the duties under subsection (b), the Task Force shall not be subject to the provisions of Appendix 2 of title 5, United States Code.

"(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated such sums as may be necessary for each fiscal year to carry out the activities of the Task Force.".

**SEC. 304. EDUCATION AND OUTREACH CAMPAIGN REGARDING PREVENTIVE BENEFITS.**

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall provide for the planning and implementation of a national public–private partnership for a prevention and health promotion outreach and education campaign to raise public awareness of health improvement across the life span. Such campaign shall include the dissemination of information that—

(1) describes the importance of utilizing preventive services to promote wellness, reduce health disparities, and mitigate chronic disease;

(2) promotes the use of preventive services recommended by the United States Preventive Services Task Force and the Community Preventive Services Task Force;

(3) encourages healthy behaviors linked to the prevention of chronic diseases;

(4) explains the preventive services covered under health plans offered through a Gateway;

(5) describes additional preventive care supported by the Centers for Disease Control and Prevention, the Health Resources and Services Administration, the Substance Abuse and Mental Health Services Administration, the Advisory Committee on Immunization Practices, and other appropriate agencies; and

(6) includes general health promotion information.

(b) CONSULTATION.—In coordinating the campaign under subsection (a), the Secretary shall consult with the Institute of Medicine to provide ongoing advice on evidence-based scientific information for policy, program development, and evaluation.

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

# Subtitle B—Increasing Access to Clinical Preventive Services

**SEC. 311. RIGHT CHOICES PROGRAM.**

(a) IN GENERAL.—Beginning on the date of enactment of this Act, the Secretary shall award an annual grant to each State for the establishment of ''Right Choices Programs''.

(b) ADMINISTRATION.—A State shall use amounts received under a grant under subsection (a) to establish and implement a Right Choices Program. A State may administer the program through the State Medicaid program or through a comparable program. Under such program the State shall—

(1) conduct outreach activities through State health and human services programs, through safety net facilities, or through other mechanisms determined appropriate by the State and the Secretary, to identify uninsured individuals; and

(2) provide individuals identified under paragraph (1), who are eligible individuals, with a Right Choices Card to be used to access the services described in subsection (d).

(c) ELIGIBLE INDIVIDUALS.—To be eligible to participate in a Right Choices program under this section, an individual shall—

(1) be a citizen or national of the United States or an alien lawfully admitted to the United States for permanent residence or otherwise residing in the United States under color of law;

(2) not be covered under any health insurance coverage during the 6-month period immediately preceding the date of the determination of eligibility;

(3) have a family income that does not exceed 350 percent of the Federal poverty level for a family of the size involved; and

(4) not be eligible for health care benefits provided through Medicare, Medicaid, the State Children's Health Insurance Program, the armed services, or the Department of Veterans Affairs.

(d) SERVICES.—Services described in this subsection include the following:

(1) RISK-STRATIFIED CARE PLAN.—

(A) IN GENERAL.—An eligible individual participating in the Right Choices Program shall receive—

(i) a one-time health risk appraisal; and

(ii) a risk-stratified care plan provided by a primary care professional who may be affiliated with the Medicare or Medicaid programs under title XVIII or XIX of the Social Security Act, or with a Federal or State safety net provider (such as a community care team, community health center, or rural health clinic, as identified by the State).

(B) REFERRALS.—A care plan under subparagraph (A)—

(i) shall include recommendations for behavioral changes, referrals to community-based resources, and referrals for age and gender appropriate immunizations and screenings to prevent chronic diseases (as identified by the Secretary, in consultation with the Director of the Centers for Disease Control and Prevention, the Administrator of the Agency for Healthcare Research and Quality, the Administrator of the Health Resources and Services Administration, the Administrator of the Substance Abuse and Mental Health Services

Administration, and other appropriate sources); and

(ii) to the extent feasible, shall include referrals by the State of individuals to State and Federal programs for which they may be eligible.

(2) TREATMENT.—An eligible individual participating in the Right Choices Program who has been diagnosed with an illnesses shall be referred for treatment to existing Federal or State safety net providers or facilities, as appropriate (such as public hospitals, community health centers, and rural health clinics).

(e) PAYMENT OF PROVIDERS.—

(1) IN GENERAL.—The State shall be required to reimburse health care providers that provide services to individuals under the Right Choices Program. Such reimbursement shall be approved by the Secretary and determined based on the amount paid by the State for similar services under the Medicaid program in the State. Such reimbursement shall not exceed the reimbursement provided for similar services under the Medicare program.

(2) COST SHARING.—A State shall require that an eligible individual with a family income that ex-

ceeds 200 percent of the Federal poverty level for a family of the size involved that is participating in the State's Right Choices Program, contribute a portion of the cost of care under such Program on a sliding scale as determined by the Secretary.

(f) AMOUNT OF GRANT.—The amount of a grant to a State under this section for a year shall be determined by the Secretary based on the rates of uninsured per capita of adults and children in the State (as compared to all States) and the prevalence of the most common costly chronic diseases in the State (as compared to all States). The Secretary shall determine what amount of the grant can be used for State administration of the program. The Secretary may also set aside not more than 20 percent of the funds appropriated to carry out this section to allocate to programs that fund the treatment of individuals participating in a Right Choices Program.

(g) PAYMENTS.—The Secretary shall determine the manner in which payments shall be made to States under this section on a prospective basis to enable the State to provide individuals with access to items and services until the Federal or State Gateways are available.

(h) LIMITATION ON FUNDS.—The Secretary shall not obligate in excess of $5,000,000,000 for any fiscal year under this section.

(i) DEFINITION.—In this section, the term ''State'' means each of the several States, the District of Columbia, and each of the territories of the United States, and shall include Indian tribes and tribal organizations (as such terms are defined in section 4(b) and section 4(c) of the Indian Self-Determination and Education Assistance Act).

(j) EVALUATION.—The Secretary shall conduct an annual evaluation of the effectiveness of the pilot program under this section.

(k) LIMITATION.—Nothing in this title (or an amendment made by this title) shall require that a State use State revenue to fund programs under this section.

(l) SUNSET.—The program under this section shall terminate with respect to a State, on the date on which the Federal or State Gateways are available.

**SEC. 312. SCHOOL-BASED HEALTH CLINICS.**

Part Q of title III of the Public Health Service Act (42 U.S.C. 280h et seq.) is amended by adding at the end the following:

**''SEC. 399Z–1. SCHOOL-BASED HEALTH CLINICS.**

''(a) DEFINITIONS; ESTABLISHMENT OF CRITERIA.—In this section:

''(1) COMPREHENSIVE PRIMARY HEALTH SERVICES.—The term 'comprehensive primary health services' means the core services offered by school-

1 based health clinics, which shall include the fol-
2 lowing:
3 "(A) PHYSICAL.—Comprehensive health
4 assessments, diagnosis, and treatment of minor,
5 acute, and chronic medical conditions, and re-
6 ferrals to, and follow-up for, specialty care and
7 oral health services.
8 "(B) MENTAL HEALTH.—Mental health
9 and substance use disorder assessments, crisis
10 intervention, counseling, treatment, and referral
11 to a continuum of services including emergency
12 psychiatric care, community support programs,
13 inpatient care, and outpatient programs.
14 "(2) MEDICALLY UNDERSERVED CHILDREN
15 AND ADOLESCENTS.—
16 "(A) IN GENERAL.—The term 'medically
17 underserved children and adolescents' means a
18 population of children and adolescents who are
19 residents of an area designated as a medically
20 underserved area or a health professional short-
21 age area by the Secretary.
22 "(B) CRITERIA.—The Secretary shall pre-
23 scribe criteria for determining the specific
24 shortages of personal health services for medi-

cally underserved children and adolescents under subparagraph (A) that shall—

"(i) take into account any comments received by the Secretary from the chief executive officer of a State and local officials in a State; and

"(ii) include factors indicative of the health status of such children and adolescents of an area, including the ability of the residents of such area to pay for health services, the accessibility of such services, the availability of health professionals to such children and adolescents, and other factors as determined appropriate by the Secretary.

"(3) SCHOOL-BASED HEALTH CLINIC.—The term 'school-based health clinic' means a health clinic that—

"(A) is located in or near a school facility of a school district or board;

"(B) is organized through school, community, and health provider relationships;

"(C) is administered by a sponsoring facility; and

"(D) provides, at a minimum, comprehensive primary health services during school hours to children and adolescents by health professionals in accordance with established standards, community practice, reporting laws, and other State laws, including parental consent and notification laws that are not inconsistent with Federal law.

"(4) SPONSORING FACILITY.—The term 'sponsoring facility' is a community-based organization, which may include—

"(A) a hospital;

"(B) a public health department;

"(C) a community health center;

"(D) a nonprofit health care agency;

"(E) a local education agency;

"(F) a faith-based organization; or

"(G) any other entity determined appropriate by the Secretary.

"(b) AUTHORITY TO AWARD GRANTS.—The Secretary shall award grants for the costs of the operation of school-based health clinics (referred to in this section as 'SBHCs') 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 SBHC (as defined in subsection (a)(4)); and

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

"(A) evidence that the applicant meets all criteria necessary to be designated an SBHC;

"(B) evidence of local need for the services to be provided by the SBHC;

"(C) an assurance that—

"(i) SBHC services will be provided to those children and adolescents for whom parental or guardian consent has been obtained in cooperation with Federal, State, and local laws governing health care service provision to children and adolescents;

"(ii) the SBHC has made and will continue to make every reasonable effort to establish and maintain collaborative relationships with other health care providers in the catchment area of the SBHC;

"(iii) the SBHC will provide on-site access during the academic day when school is in session and 24-hour coverage through an on-call system and through its backup health providers to ensure access to

services on a year-round basis when the school or the SBHC is closed;

"(iv) the SBHC will be integrated into the school environment and will coordinate health services with school personnel, such as administrators, teachers, nurses, counselors, and support personnel, as well as with other community providers co-located at the school;

"(v) the SBHC sponsoring facility assumes all responsibility for the SBHC administration, operations, and oversight; and

"(vi) the SBHC will comply with Federal, State, and local laws concerning patient privacy and student records, including regulations promulgated under the Health Insurance Portability and Accountability Act of 1996 and section 444 of the General Education Provisions Act; and

"(D) such other information as the Secretary may require.

"(d) PREFERENCES.—In reviewing applications, the Secretary may give preference to applicants who demonstrate an ability to serve the following:

"(1) Communities that have evidenced barriers to primary health care and mental health and substance use disorder prevention services for children and adolescents.

"(2) Communities with high per capita numbers of children and adolescents who are uninsured, underinsured, or enrolled in public health insurance programs.

"(3) Populations of children and adolescents that have historically demonstrated difficulty in accessing health and mental health and substance use disorder prevention services.

"(e) WAIVER OF REQUIREMENTS.—The Secretary may—

"(1) under appropriate circumstances, waive the application of all or part of the requirements of this subsection with respect to an SBHC for not to exceed 2 years; and

"(2) upon a showing of good cause, waive the requirement that the SBHC provide all required comprehensive primary health services for a designated period of time to be determined by the Secretary.

"(f) USE OF FUNDS.—

"(1) FUNDS.—Funds awarded under a grant under this section may be used for

"(A) acquiring and leasing equipment (including the costs of amortizing the principle of, and paying interest on, loans for such equipment);

"(B) providing training related to the provision of required comprehensive primary health services and additional health services;

"(C) the management and operation of health center programs; and

"(D) the payment of salaries for physicians, nurses, and other personnel of the SBHC.

"(2) CONSTRUCTION.—The Secretary may award grants which may be used to pay the costs associated with expanding and modernizing existing buildings for use as an SBHC, including the purchase of trailers or manufactured buildings to install on the school property.

"(3) AMOUNT.—The amount of any grant made in any fiscal year to an SBHC shall be determined by the Secretary, taking into account—

"(A) the financial need of the SBHC;

"(B) State, local, or other operation funding provided to the SBHC; and

"(C) other factors as determined appropriate by the Secretary.

"(4) LIMITATION.—Any provider of services that is determined by a State to be in violation of a State law described in subsection (a)(4)(D) with respect to activities carried out at a SBHC shall not be eligible to receive additional funding under this section.

"(g) MATCHING REQUIREMENT.—

"(1) IN GENERAL.—Each eligible entity that receives a grant under this section shall provide, from non-Federal sources, an amount equal to 20 percent of the amount of the grant (which may be provided in cash or in-kind) to carry out the activities supported by the grant.

"(2) WAIVER.—The Secretary may waive all or part of the matching requirement described in paragraph (1) for any fiscal year for the SBHC if the Secretary determines that applying the matching requirement to the SBHC would result in serious hardship or an inability to carry out the purposes of this section.

1 "(h) SUPPLEMENT, NOT SUPPLANT.—Grant funds
2 provided under this section shall be used to supplement,
3 not supplant, other Federal or State funds.
4 "(i) TECHNICAL ASSISTANCE.—The Secretary shall
5 establish a program through which the Secretary shall
6 provide (either through the Department of Health and
7 Human Services or by grant or contract) technical and
8 other assistance to SBHCs to assist such SBHCs to meet
9 the requirements of subsection (c)(2)(C). Services pro-
10 vided through the program may include necessary tech-
11 nical and nonfinancial assistance, including fiscal and pro-
12 gram management assistance, training in fiscal and pro-
13 gram management, operational and administrative sup-
14 port, and the provision of information to the entities of
15 the variety of resources available under this title and how
16 those resources can be best used to meet the health needs
17 of the communities served by the entities.
18 "(j) EVALUATION.—The Secretary shall develop and
19 implement a plan for evaluating SBHCs and monitoring
20 quality performance under the awards made under this
21 section.
22 "(k) AGE APPROPRIATE SERVICES.—An eligible enti-
23 ty receiving funds under this section shall only provide age
24 appropriate services through a SBHC funded under this
25 section to an individual.

"(l) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this section, there are authorized to be appropriated such sums as may be necessary for each of the fiscal years 2010 through 2014.".

**SEC. 313. ORAL HEALTHCARE PREVENTION ACTIVITIES.**

(a) IN GENERAL.—Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by adding at the end the following:

## "PART S—ORAL HEALTHCARE PREVENTION ACTIVITIES

**"SEC. 399GG. ORAL HEALTHCARE PREVENTION EDUCATION CAMPAIGN.**

"(a) ESTABLISHMENT.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention and in consultation with professional oral health organizations, shall, subject to the availability of appropriations, establish a 5-year national, public education campaign (referred to in this section as the 'campaign') that is focused on oral healthcare prevention and education, including prevention of oral disease such as early childhood and other caries, periodontal disease, and oral cancer.

"(b) REQUIREMENTS.—In establishing the campaign, the Secretary shall—

"(1) ensure that activities are targeted towards specific populations such as children, pregnant women, parents, the elderly, individuals with disabilities, and ethnic and racial minority populations, including Indians, Alaska Natives and Native Hawaiians (as defined in section 4(c) of the Indian Health Care Improvement Act) in a culturally and linguistically appropriate manner; and

"(2) utilize science-based strategies to convey oral health prevention messages that include, but are not limited to, community water fluoridation and dental sealants.

"(c) PLANNING AND IMPLEMENTATION.—Not later than 2 years after the date of enactment of this section, the Secretary shall begin implementing the 5-year campaign. During the 2-year period referred to in the previous sentence, the Secretary shall conduct planning activities with respect to the campaign.

**"SEC. 399GG-1. RESEARCH-BASED DENTAL CARIES DISEASE MANAGEMENT.**

"(a) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall award demonstration grants to eligible entities to demonstrate the effectiveness of research-based dental caries disease management activities.

1 "(b) ELIGIBILITY.—To be eligible for a grant under
2 this section, an entity shall—
3 "(1) be a community-based provider of dental
4 services (as defined by the Secretary), including a
5 Federally-qualified health center, a clinic of a hos-
6 pital owned or operated by a State (or by an instru-
7 mentality or a unit of government within a State),
8 a State or local department of health, a dental pro-
9 gram of the Indian Health Service, an Indian tribe
10 or tribal organization, or an urban Indian organiza-
11 tion (as such terms are defined in section 4 of the
12 Indian Health Care Improvement Act), a health sys-
13 tem provider, a private provider of dental services,
14 medical, dental, public health, nursing, nutrition
15 educational institutions, or national organizations in-
16 volved in improving children's oral health; and
17 "(2) submit to the Secretary an application at
18 such time, in such manner, and containing such in-
19 formation as the Secretary may require.
20 "(c) USE OF FUNDS.—A grantee shall use amounts
21 received under a grant under this section to demonstrate
22 the effectiveness of research-based dental caries disease
23 management activities.
24 "(d) USE OF INFORMATION.—The Secretary shall
25 utilize information generated from grantees under this

section in planning and implementing the public education campaign under section 399GG.

**"SEC. 399GG-2. AUTHORIZATION OF APPROPRIATIONS.**

"There is authorized to be appropriated to carry out this part, such sums as may be necessary.".

**SEC. 314. ORAL HEALTH IMPROVEMENT.**

(a) SCHOOL-BASED SEALANT PROGRAMS.—Section 317M(c)(1) of the Public Health Service Act (42 U.S.C. 247b-14(c)(1)) is amended by striking "may award grants to States and Indian tribes" and inserting "shall award a grant to each of the 50 States and territories and to Indians, Indian tribes, tribal organizations and urban Indian organizations (as such terms are defined in section 4 of the Indian Health Care Improvement Act)".

(b) ORAL HEALTH INFRASTRUCTURE.—Section 317M of the Public Health Service Act (42 U.S.C. 247b-14) is amended—

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

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

"(d) ORAL HEALTH INFRASTRUCTURE.—

"(1) COOPERATIVE AGREEMENTS.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall enter into

cooperative agreements with State, territorial, and Indian tribes or tribal organizations (as those terms are defined in section 4 of the Indian Health Care Improvement Act) to establish oral health leadership and program guidance, oral health data collection and interpretation, (including determinants of poor oral health among vulnerable populations), a multi-dimensional delivery system for oral health, and to implement science-based programs (including dental sealants and community water fluoridation) to improve oral health.

"(2) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated such sums as necessary to carry out this subsection for fiscal years 2010 through 2014.".

(c) UPDATING NATIONAL ORAL HEALTHCARE SURVEILLANCE ACTIVITIES.—

(1) PRAMS.—

(A) IN GENERAL.—The Secretary of Health and Human Services (referred to in this subsection as the "Secretary") shall carry out activities to update and improve the Pregnancy Risk Assessment Monitoring System (referred to in this section as "PRAMS") as it relates to oral healthcare.

(B) STATE REPORTS AND MANDATORY MEASUREMENTS.—

(i) IN GENERAL.—Not later than 5 years after the date of enactment of this Act, and every 5 years thereafter, a State shall submit to the Secretary a report concerning activities conducted within the State under PRAMS.

(ii) MEASUREMENTS.—The oral healthcare measurements developed by the Secretary for use under PRAMS shall be mandatory with respect to States for purposes of the State reports under clause (i).

(C) FUNDING.—There is authorized to be appropriated to carry out this paragraph, such sums as may be necessary.

(2) NATIONAL HEALTH AND NUTRITION EXAMINATION SURVEY.—The Secretary shall develop oral healthcare components that shall include tooth-level surveillance for inclusion in the National Health and Nutrition Examination Survey. Such components shall be updated by the Secretary at least every 6 years. For purposes of this paragraph, the term ''tooth-level surveillance'' means a clinical examination where an examiner looks at each dental surface,

on each tooth in the mouth and as expanded by the Division of Oral Health of the Centers for Disease Control and Prevention.

(3) MEDICAL EXPENDITURES PANEL SURVEY.—The Secretary shall ensure that the Medical Expenditures Panel Survey by the Agency for Healthcare Research and Quality includes the verification of dental utilization, expenditure, and coverage findings through conduct of a look-back analysis.

(4) NATIONAL ORAL HEALTH SURVEILLANCE SYSTEM.—

(A) APPROPRIATIONS.—There is authorized to be appropriated, such sums as may be necessary for each of fiscal years 2010 through 2014 to increase the participation of States in the National Oral Health Surveillance System from 16 States to all 50 States, territories, and District of Columbia.

(B) REQUIREMENTS.—The Secretary shall ensure that the National Oral Health Surveillance System include the measurement of early childhood caries.

# Subtitle C—Creating Healthier Communities

**SEC. 321. COMMUNITY TRANSFORMATION GRANTS.**

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Director of the Centers for Disease Control and Prevention (referred to in this section as the ''Director''), shall award competitive grants to State and local governmental agencies and community-based organizations for the implementation, evaluation, and dissemination of evidence-based community preventive health activities in order to reduce chronic disease rates, address health disparities, and develop a stronger evidence-base of effective prevention programming.

(b) ELIGIBILITY.—To be eligible to receive a grant under subsection (a), an entity shall—

(1) be a—

(A) State governmental agency;

(B) local governmental agency;

(C) national network of community-based organizations; or

(D) Indian tribe; and

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

1 description of the program to be carried out under
2 the grant; and
3 (3) demonstrate a history or capacity, if fund-
4 ed, to develop relationships necessary to engage key
5 stakeholders from multiple sectors across a commu-
6 nity, such as healthy futures corps.
7 (c) USE OF FUNDS.—
8 (1) IN GENERAL.—An eligible entity shall use
9 amounts received under a grant under this section to
10 carry out programs described in this subsection.
11 (2) COMMUNITY TRANSFORMATION PLAN.—
12 (A) IN GENERAL.—An eligible entity that
13 receives a grant under this section shall submit
14 to the Director (for approval) a detailed plan
15 that includes the policy, environmental, pro-
16 grammatic, and as appropriate infrastructure
17 changes needed to promote healthy living and
18 reduce disparities.
19 (B) ACTIVITIES.—Activities within the
20 plan may focus on (but not be limited to)—
21 (i) creating healthier school environ-
22 ments, including increasing healthy food
23 options, physical activity opportunities,
24 promotion of healthy lifestyle and preven-

tion curricula, and activities to prevent chronic diseases;

(ii) creating the infrastructure to support active living and access to nutritious foods in a safe environment;

(iii) developing and promoting programs targeting a variety of age levels to increase access to nutrition, physical activity and smoking cessation, enhance safety in a community, or address any other chronic disease priority area identified by the grantee;

(iv) assessing and implementing worksite wellness programming and incentives;

(v) working to highlight healthy options at restaurants and other food venues;

(vi) prioritizing strategies to reduce racial and ethnic disparities, including social determinants of health; and

(vii) addressing the needs of special populations, including all age groups and individuals with disabilities.

(3) COMMUNITY-BASED PREVENTION HEALTH ACTIVITIES.—

(A) IN GENERAL.—An eligible entity shall use amounts received under a grant under this section to implement a variety of programs, policies, and infrastructure improvements to promote healthier lifestyles.

(B) ACTIVITIES.—An eligible entity shall implement activities detailed in the community transformation plan under paragraph (2).

(C) IN-KIND SUPPORT.—An eligible entity shall provide in-kind resources such as staff, equipment, or office space in carrying out activities under this section.

(4) EVALUATION.—

(A) IN GENERAL.—An eligible entity shall use amounts provided under a grant under this section to conduct activities to measure changes in the prevalence of chronic disease risk factors among community members participating in preventive health activities

(B) TYPES OF MEASURES.—In carrying out subparagraph (A), the eligible entity shall, with respect to residents in the community, measure—

(i) changes in weight;

(ii) changes in proper nutrition;

(iii) changes in physical activity;

(iv) changes in tobacco use prevalence;

(v) other factors using community-specific data from the Behavioral Risk Factor Surveillance Survey; and

(vi) other factors as determined by the Secretary.

(C) REPORTING.—An eligible entity shall annually submit to the Director a report containing an evaluation of activities carried out under the grant.

(5) DISSEMINATION.—A grantee under this section shall—

(A) meet at least annually in regional or national meetings to discuss challenges, best practices, and lessons learned with respect to activities carried out under the grant; and

(B) develop models for the replication of successful programs and activities and the mentoring of other eligible entities.

(d) TRAINING.—

(1) IN GENERAL.—The Director shall develop a program to provide training for eligible entities on effective strategies for the prevention and control of chronic disease

(2) COMMUNITY TRANSFORMATION PLAN.—The Director shall provide appropriate feedback and technical assistance to grantees to establish community transformation plans

(3) EVALUATION.—The Director shall provide a literature review and framework for the evaluation of programs conducted as part of the grant program under this section, in addition to working with academic institutions or other entities with expertise in outcome evaluation.

(e) PROHIBITION.—A grantee shall not use funds provided under a grant under this section to create video games or to carry out any other activities that may lead to higher rates of obesity or inactivity.

(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section, such sums as may be necessary for each fiscal years 2010 through 2014.

**SEC. 322. HEALTHY AGING, LIVING WELL.**

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Director of the Centers for Disease Control and Prevention, shall award grants to State or local health departments and Indian tribes to carry out 5-year pilot programs to provide public health

1 community interventions, screenings, and where nec-
2 essary, clinical referrals for individuals who are between
3 55 and 64 years of age.

4 (b) ELIGIBILITY.—To be eligible to receive a grant
5 under subsection (a), an entity shall—

6 (1) be—

7 (A) a State health department;

8 (B) a local health department; or

9 (C) an Indian tribe;

10 (2) submit to the Secretary an application at
11 such time, in such manner, and containing such in-
12 formation as the Secretary may require including a
13 description of the program to be carried out under
14 the grant;

15 (3) design a strategy for improving the health
16 of the 55-to-64 year-old population through commu-
17 nity-based public health interventions; and

18 (4) demonstrate the capacity, if funded, to de-
19 velop the relationships necessary with relevant health
20 agencies, health care providers, community-based or-
21 ganizations, and insurers to carry out the activities
22 described in subsection (c), such relationships to in-
23 clude the identification of a community-based clinical
24 partner, such as a community health center or rural
25 health clinic.

(c) USE OF FUNDS.—

(1) IN GENERAL.—A State or local health department shall use amounts received under a grant under this section to carry out a program to provide the services described in this subsection to individuals who are between 55 and 64 years of age.

(2) PUBLIC HEALTH INTERVENTIONS.—

(A) IN GENERAL.—In developing and implementing such activities, a grantee shall collaborate with the Centers for Disease Control and Prevention and the Administration on Aging, and relevant local agencies and organizations.

(B) TYPES OF INTERVENTION ACTIVITIES.—Intervention activities conducted under this paragraph may include efforts to improve nutrition, increase physical activity, reduce tobacco use and substance abuse, improve mental health, and promote healthy lifestyles among the target population.

(3) COMMUNITY PREVENTIVE SCREENINGS.—

(A) IN GENERAL.—In addition to community-wide public health interventions, a State or local health department shall use amounts received under a grant under this section to con-

duct ongoing health screening to identify risk factors for cardiovascular disease, stroke, and diabetes among individuals who are between 55 and 64 years of age.

(B) TYPES OF SCREENING ACTIVITIES.—Screening activities conducted under this paragraph may include—

(i) mental health/behavioral health and substance use disorders;

(ii) physical activity, smoking, and nutrition; and

(iii) any other measures deemed appropriate by the Secretary.

(C) MONITORING.—Grantees under this section shall maintain records of screening results under this paragraph to establish the baseline data for monitoring the targeted population

(4) CLINICAL REFERRAL/TREATMENT FOR CHRONIC DISEASES.—

(A) IN GENERAL.—A State or local health department shall use amounts received under a grant under this section to ensure that individuals between 55 and 64 years of age who are found to have chronic disease risk factors

through the screening activities described in paragraph (3)(B), receive clinical referral/treatment for follow-up services to reduce such risk.

(B) MECHANISM.—

(i) IDENTIFICATION AND DETERMINATION OF STATUS.—With respect to each individual with risk factors for or having heart disease, stroke, diabetes, or any other condition for which such individual was screened under paragraph (3), a grantee under this section shall determine whether or not such individual is covered under any public or private health insurance program.

(ii) INSURED INDIVIDUALS.—An individual determined to be covered under a health insurance program under clause (i) shall be referred by the grantee to the existing providers under such program or, if such individual does not have a current provider, to a provider who is in-network with respect to the program involved.

(iii) UNINSURED INDIVIDUALS.—With respect to an individual determined to be uninsured under clause (i), the grantee's

community-based clinical partner described in subsection (b)(4) shall assist the individual in determining eligibility for available public coverage options and identify other appropriate community health care resources and assistance programs.

(C) PUBLIC HEALTH INTERVENTION PROGRAM.—A State or local health department shall use amounts received under a grant under this section to enter into contracts with community health centers or rural health clinics and mental health and substance use disorder service providers to assist in the referral/treatment of at risk patients to community resources for clinical follow-up and help determine eligibility for other public programs.

(5) GRANTEE EVALUATION.—An eligible entity shall use amounts provided under a grant under this section to conduct activities to measure changes in the prevalence of chronic disease risk factors among participants.

(d) PILOT PROGRAM EVALUATION.—The Secretary shall conduct an annual evaluation of the effectiveness of the pilot program under this section. In determining such effectiveness, the Secretary shall consider changes in the

1 prevalence of uncontrolled chronic disease risk factors
2 among new Medicare enrollees (or individuals nearing en-
3 rollment, including those who are 63 and 64 years of age)
4 who reside in States or localities receiving grants under
5 this section as compared with national and historical data
6 for those States and localities for the same population.

7 (e) AUTHORIZATION OF APPROPRIATIONS.—There
8 are authorized to be appropriated to carry out this section,
9 such sums as may be necessary for each of fiscal years
10 2010 through 2014.

11 **SEC. 323. WELLNESS FOR INDIVIDUALS WITH DISABILITIES.**

12 Title V of the Rehabilitation Act of 1973 (29 U.S.C.
13 791 et seq.) is amended by adding at the end of the fol-
14 lowing:

15 **"SEC. 510. ESTABLISHMENT OF STANDARDS FOR ACCES-**
16 **SIBLE MEDICAL DIAGNOSTIC EQUIPMENT.**

17 "(a) STANDARDS.—Not later than 24 months after
18 the date of enactment of the Affordable Health Choices
19 Act, the Architectural and Transportation Barriers Com-
20 pliance Board shall, in consultation with the Commis-
21 sioner of the Food and Drug Administration, promulgate
22 regulatory standards in accordance with the Administra-
23 tive Procedure Act (2 U.S.C. 551 et seq.) setting forth
24 the minimum technical criteria for medical diagnostic
25 equipment used in (or in conjunction with) physician's of-

fices, clinics, emergency rooms, hospitals, and other medical settings. The standards shall ensure that such equipment is accessible to, and usable by, individuals with accessibility needs, and shall allow independent entry to, use of, and exit from the equipment by such individuals to the maximum extent possible.

"(b) MEDICAL DIAGNOSTIC EQUIPMENT COVERED.—The standards issued under subsection (a) for medical diagnostic equipment shall apply to equipment that includes examination tables, examination chairs (including chairs used for eye examinations or procedures, and dental examinations or procedures), weight scales, mammography equipment, x-ray machines, and other radiological equipment commonly used for diagnostic purposes by health professionals.

"(c) REVIEW AND AMENDMENT.—The Architectural and Transportation Barriers Compliance Board, in consultation with the Commissioner of the Food and Drug Administration, shall periodically review and, as appropriate, amend the standards in accordance with the Administrative Procedure Act (2 U.S.C. 551 et seq.).".

**SEC. 324. IMMUNIZATIONS.**

(a) STATE AUTHORITY TO PURCHASE RECOMMENDED VACCINES FOR ADULTS.—Section 317 of the

Public Health Service Act (42 U.S.C. 247b) is amended by adding at the end the following:

"(l) AUTHORITY TO PURCHASE RECOMMENDED VACCINES FOR ADULTS.—

"(1) IN GENERAL.—The Secretary may negotiate and enter into contracts with manufacturers of vaccines for the purchase and delivery of vaccines for adults as provided for under subsection (e).

"(2) STATE PURCHASE.—A State may obtain additional quantities of such adult vaccines (subject to amounts specified to the Secretary by the State in advance of negotiations) through the purchase of vaccines from manufacturers at the applicable price negotiated by the Secretary under this subsection.".

(b) DEMONSTRATION PROGRAM TO IMPROVE IMMUNIZATION COVERAGE.—Section 317 of the Public Health Service Act (42 U.S.C. 247b), as amended by subsection (a), is further amended by adding at the end the following:

"(m) DEMONSTRATION PROGRAM TO IMPROVE IMMUNIZATION COVERAGE.—

"(1) IN GENERAL.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish a demonstration program to award grants to States to improve the provision of recommended immunizations for

1 children, adolescents, and adults through the use of
2 evidence-based, population-based interventions for
3 high-risk populations.

4 "(2) STATE PLAN.—To be eligible for a grant
5 under paragraph (1), a State shall submit to the
6 Secretary an application at such time, in such man-
7 ner, and containing such information as the Sec-
8 retary may require, including a State plan that de-
9 scribes the interventions to be implemented under
10 the grant and how such interventions match with
11 local needs and capabilities, as determined through
12 consultation with local authorities.

13 "(3) USE OF FUNDS.—Funds received under a
14 grant under this subsection shall be used to imple-
15 ment interventions that are recommended by the
16 Task Force on Community Preventive Services (as
17 established by the Secretary, acting through the Di-
18 rector of the Centers for Disease Control and Pre-
19 vention) or other evidence-based interventions, in-
20 cluding—

21 "(A) providing immunization reminders or
22 recalls for target populations of clients, pa-
23 tients, and consumers;

24 "(B) educating targeted populations and
25 health care providers concerning immunizations

in combination with one or more other interventions;

"(C) reducing out-of-pocket costs for families for vaccines and their administration;

"(D) carrying out immunization-promoting strategies for participants or clients of public programs, including assessments of immunization status, referrals to health care providers, education, provision of on-site immunizations, or incentives for immunization;

"(E) providing for home visits that promote immunization through education, assessments of need, referrals, provision of immunizations, or other services;

"(F) providing reminders or recalls for immunization providers;

"(G) conducting assessments of, and providing feedback to, immunization providers;

"(H) any combination of one or more interventions described in this paragraph; or

"(I) immunization information systems to allow all States to have electronic databases for immunization records.

"(4) CONSIDERATION.—In awarding grants under this subsection, the Secretary shall consider

any reviews or recommendations of the Task Force on Community Preventive Services.

"(5) EVALUATION.—Not later than 3 years after the date on which a State receives a grant under this subsection, the State shall submit to the Secretary an evaluation of progress made toward improving immunization coverage rates among high-risk populations within the State.

"(6) REPORT TO CONGRESS.—Not later than 4 years after the date of enactment of the Affordable Health Choices Act, the Secretary shall submit to Congress a report concerning the effectiveness of the demonstration program established under this subsection together with recommendations on whether to continue and expand such program.

"(7) 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 2014.".

(c) REAUTHORIZATION OF IMMUNIZATION PROGRAM.—Section 317(j) of the Public Health Service Act (42 U.S.C. 247b(j)) is amended—

(1) in paragraph (1), by striking "for each of the fiscal years 1998 through 2005"; and

(2) in paragraph (2), by striking ''after October 1, 1997,''.

(d) RULE OF CONSTRUCTION REGARDING ACCESS TO IMMUNIZATIONS.—Nothing in this section (including the amendments made by this section), or any other provision of this Act (including any amendments made by this Act) shall be construed to decrease children's access to immunizations.

**SEC. 325. NUTRITION LABELING OF STANDARD MENU ITEMS AT CHAIN RESTAURANTS AND OF ARTICLES OF FOOD SOLD FROM VENDING MACHINES.**

(a) TECHNICAL AMENDMENTS.—Section 403(q)(5)(A) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)(A)) is amended—

(1) in subitem (i), by inserting at the beginning ''except as provided in clause (H)(ii)(III),''; and

(2) in subitem (ii), by inserting at the beginning ''except as provided in clause (H)(ii)(III),''.

(b) LABELING REQUIREMENTS.—Section 403(q)(5) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343(q)(5)) is amended by adding at the end the following:

''(H) RESTAURANTS, RETAIL FOOD ESTABLISHMENTS, AND VENDING MACHINES.—

"(i) GENERAL REQUIREMENTS FOR RESTAURANTS AND SIMILAR RETAIL FOOD ESTABLISHMENTS.—Except for food described in subclause (vii), in the case of food that is a standard menu item that is offered for sale in a restaurant or similar retail food establishment that is part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items, the restaurant or similar retail food establishment shall disclose the information described in subclauses (ii) and (iii).

"(ii) INFORMATION REQUIRED TO BE DISCLOSED BY RESTAURANTS AND RETAIL FOOD ESTABLISHMENTS.—Except as provided in subclause (vii), the restaurant or similar retail food establishment shall disclose in a clear and conspicuous manner—

"(I)(aa) in a nutrient content disclosure statement adjacent to the name of the standard menu item, so as to be clearly associated with the standard menu item, on the menu listing the item for sale, the number of calories contained in the standard menu item, as usually prepared and offered for sale; and

"(bb) a succinct statement concerning suggested daily caloric intake, as specified by the Secretary by regulation and posted prominently on the menu and designed to enable the public to understand, in the context of a total daily diet, the significance of the caloric information that is provided on the menu;

"(II)(aa) in a nutrient content disclosure statement adjacent to the name of the standard menu item, so as to be clearly associated with the standard menu item, on the menu board, including a drive-through menu board, the number of calories contained in the standard menu item, as usually prepared and offered for sale; and

"(bb) a succinct statement concerning suggested daily caloric intake, as specified by the Secretary by regulation and posted prominently on the menu board, designed to enable the public to understand, in the context of a total daily diet, the significance of the nutrition information that is provided on the menu board;

"(III) in a written form, available on the premises of the restaurant or similar retail establishment and to the consumer upon request, the nutrition in-

formation required under clauses (C) and (D) of subparagraph (1); and

"(IV) on the menu or menu board, a prominent, clear, and conspicuous statement regarding the availability of the information described in item (III).

"(iii) SELF-SERVICE FOOD AND FOOD ON DISPLAY.—Except as provided in subclause (vii), in the case of food sold at a salad bar, buffet line, cafeteria line, or similar self-service facility, and for self-service beverages or food that is on display and that is visible to customers, a restaurant or similar retail food establishment shall place adjacent to each food offered a sign that lists calories per displayed food item or per serving.

"(iv) REASONABLE BASIS.—For the purposes of this clause, a restaurant or similar retail food establishment shall have a reasonable basis for its nutrient content disclosures, including nutrient databases, cookbooks, laboratory analyses, and other reasonable means, as described in section 101.10 of title 21, Code of Federal Regulations (or any successor regulation) or in a related guidance of the Food and Drug Administration.

"(v) MENU VARIABILITY AND COMBINATION MEALS.—The Secretary shall establish by regulation standards for determining and disclosing the nutrient content for standard menu items that come in different flavors, varieties, or combinations, but which are listed as a single menu item, such as soft drinks, ice cream, pizza, doughnuts, or children's combination meals, through means determined by the Secretary, including ranges, averages, or other methods.

"(vi) ADDITIONAL INFORMATION.—If the Secretary determines that a nutrient, other than a nutrient required under subclause (ii)(III), should be disclosed for the purpose of providing information to assist consumers in maintaining healthy dietary practices, the Secretary may require, by regulation, disclosure of such nutrient in the written form required under subclause (ii)(III).

"(vii) NONAPPLICABILITY TO CERTAIN FOOD.—

"(I) IN GENERAL.—Subclauses (i) through (vi) do not apply to—

"(aa) items that are not listed on a menu or menu board (such as condiments and other items placed on the table or counter for general use);

"(bb) daily specials, temporary menu items appearing on the menu for less than 60 days per calendar year, or custom orders; or

"(cc) such other food that is part of a customary market test appearing on the menu for less than 90 days, under terms and conditions established by the Secretary.

"(II) WRITTEN FORMS.—Subparagraph (5)(C) shall apply to any regulations promulgated under subclauses (ii)(III) and (vi).

"(viii) VENDING MACHINES.—

"(I) IN GENERAL.—In the case of an article of food sold from a vending machine that—

"(aa) does not permit a prospective purchaser to examine the Nutrition Facts Panel before purchasing the article or does not otherwise provide visible nutrition information at the point of purchase; and

"(bb) is operated by a person who is engaged in the business of owning or operating 20 or more vending machines,

the vending machine operator shall provide a sign in close proximity to each article of food or

the selection button that includes a clear and conspicuous statement disclosing the number of calories contained in the article.

"(ix) VOLUNTARY PROVISION OF NUTRITION INFORMATION.—

"(I) IN GENERAL.—An authorized official of any restaurant or similar retail food establishment or vending machine operator not subject to the requirements of this clause may elect to be subject to the requirements of such clause, by registering biannually the name and address of such restaurant or similar retail food establishment or vending machine operator with the Secretary, as specified by the Secretary by regulation.

"(II) REGISTRATION.—Within 120 days of enactment of this clause, the Secretary shall publish a notice in the Federal Register specifying the terms and conditions for implementation of item (I), pending promulgation of regulations.

"(III) RULE OF CONSTRUCTION.—Nothing in this subclause shall be construed to authorize the Secretary to require an application, review,

or licensing process for any entity to register with the Secretary, as described in such item.

"(x) REGULATIONS.—

"(I) PROPOSED REGULATION.—Not later than 1 year after the date of enactment of this clause, the Secretary shall promulgate proposed regulations to carry out this clause.

"(II) CONTENTS.—In promulgating regulations, the Secretary shall—

"(aa) consider standardization of recipes and methods of preparation, reasonable variation in serving size and formulation of menu items, space on menus and menu boards, inadvertent human error, training of food service workers, variations in ingredients, and other factors, as the Secretary determines; and

"(bb) specify the format and manner of the nutrient content disclosure requirements under this subclause.

"(III) REPORTING.—The Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a quarterly report

that describes the Secretary's progress toward promulgating final regulations under this subparagraph.

''(xi) DEFINITION.—In this clause, the term 'menu' or 'menu board' means the primary writing of the restaurant or other similar retail food establishment from which a consumer makes an order selection.''

(c) NATIONAL UNIFORMITY.—Section 403A(a)(4) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343-1(a)(4)) is amended by striking ''except a requirement for nutrition labeling of food which is exempt under subclause (i) or (ii) of section 403(q)(5)(A)'' and inserting ''except that this paragraph does not apply to food that is offered for sale in a restaurant or similar retail food establishment that is not part of a chain with 20 or more locations doing business under the same name (regardless of the type of ownership of the locations) and offering for sale substantially the same menu items unless such restaurant or similar retail food establishment complies with the voluntary provision of nutrition information requirements under section 403(q)(5)(H)(ix)''.

(d) RULE OF CONSTRUCTION.—Nothing in the amendments made by this section shall be construed—

(1) to preempt any provision of State or local law, unless such provision establishes or continues into effect nutrient content disclosures of the type required under section 403(q)(5)(H) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (b)) and is expressly preempted under subsection (a)(4) of such section;

(2) to apply to any State or local requirement respecting a statement in the labeling of food that provides for a warning concerning the safety of the food or component of the food; or

(3) except as provided in section 403(q)(5)(H)(ix) of the Federal Food, Drug, and Cosmetic Act (as added by subsection (b)), to apply to any restaurant or similar retail food establishment other than a restaurant or similar retail food establishment described in section 403(q)(5)(H)(i) of such Act.

**SEC. 326. ENCOURAGING EMPLOYER-SPONSORED WELLNESS PROGRAMS.**

A group health plan and a health insurance issuer offering health insurance coverage in connection with a group health plan may offer incentives to an individual who voluntarily participates in a wellness program that is reasonably-designed to promote health or prevent disease.

Nothing in this Act (or an amendment made by this Act) shall be construed to limit the ability of a group health plan or health insurance issuer, under regulations in effect on the date of enactment of this Act, to offer participants variations in employee contributions towards the cost of coverage for participation in wellness programs.

**SEC. 327. DEMONSTRATION PROJECT CONCERNING INDIVIDUALIZED WELLNESS PLAN.**

Section 330 of the Public Health Service Act (42 U.S.C. 245b) is amended by adding at the end the following:

"(s) PILOT PROGRAM FOR INDIVIDUALIZED WELLNESS PLANS.—

"(1) IN GENERAL.—The Secretary shall establish a pilot program to test the impact of providing at-risk populations who utilize community health centers funded under this section an individualized wellness plan that is designed to reduce risk factors for preventable conditions as identified by a comprehensive risk-factor assessment.

"(2) AGREEMENTS.—The Secretary shall enter into agreements with not more than 10 community health centers funded under this section to conduct activities under the pilot program under paragraph (1).

"(3) WELLNESS PLANS.—

"(A) IN GENERAL.—An individualized wellness plan prepared under the pilot program under this subsection may include one or more of the following as appropriate to the individual's identified risk factors:

"(i) Nutritional counseling.

"(ii) A physical activity plan.

"(iii) Alcohol and smoking cessation counseling and services.

"(iv) Stress management.

"(v) Dietary supplements that have health claims approved by the Secretary.

"(vi) Compliance assistance provided by a community health center employee.

"(B) RISK FACTORS.—Wellness plan risk factors shall include—

"(i) weight;

"(ii) tobacco and alcohol use;

"(iii) exercise rates;

"(iv) nutritional status; and

"(v) blood pressure.

"(C) COMPARISONS.—Individualized wellness plans shall make comparisons between the individual involved and a control group of

individuals with respect to the risk factors described in subparagraph (B).

"(4) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection, such sums as may be necessary.".

**SEC. 328. REASONABLE BREAK TIME FOR NURSING MOTHERS.**

Section 7 of the Fair Labor Standards Act of 1938 (29 U.S.C. 207) is amended by adding at the end the following:

"(r)(1) An employer shall provide—

"(A) a reasonable break time for an employee to express breast milk for her nursing child for 1 year after the child's birth each time such employee has need to express the milk; and

"(B) a place, other than a bathroom, that is shielded from view and free from intrusion from coworkers and the public, which may be used by an employee to express breast milk.

"(2) An employer shall not be required to compensate an employee receiving reasonable break time under paragraph (1) for any work time spent for such purpose.

"(3) An employer that employs less than 50 employees shall not be subject to the requirements of this subsection, if such requirements would impose an undue hard-

ship by causing the employer significant difficulty or expense when considered in relation to the size, financial resources, nature, or structure of the employer's business.''.

# Subtitle D—Support for Prevention and Public Health Innovation

## SEC. 331. RESEARCH ON OPTIMIZING THE DELIVERY OF PUBLIC HEALTH SERVICES.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Director of the Centers for Disease Control and Prevention, shall provide funding for research in the area of public health services and systems.

(b) REQUIREMENTS OF RESEARCH.—Research supported under this section shall include—

(1) examining evidence-based practices relating to prevention, with a particular focus on high priority areas as identified by the Secretary in the National Prevention Strategy or Healthy People 2020, and including comparing community-based public health interventions in terms of effectiveness and cost;

(2) analyzing the translation of interventions from academic settings to real world settings; and

(3) identifying effective strategies for organizing, financing, or delivering public health services

in real world community settings, including comparing State and local health department structures and systems in terms of effectiveness and cost.

(c) EXISTING PARTNERSHIPS.—Research supported under this section shall be coordinated with the Community Preventive Services Task Force and carried out by building on existing partnerships within the Federal Government while also considering initiatives at the State and local levels and in the private sector.

(d) ANNUAL REPORT.—The Secretary shall, on an annual basis, submit to Congress a report concerning the activities and findings with respect to research supported under this section.

**SEC. 332. UNDERSTANDING HEALTH DISPARITIES: DATA COLLECTION AND ANALYSIS.**

The Public Health Service Act (42 U.S.C. 201 et seq.) as amended by section 172, is further amended by adding at the end the following:

# "TITLE XXXIII—DATA COLLECTION, ANALYSIS, AND QUALITY

**"SEC. 3301. DATA COLLECTION, ANALYSIS, AND QUALITY.**

"(a) DATA COLLECTION.—

"(1) IN GENERAL.—The Secretary shall ensure that, by not later than 1 year after the date of en-

actment of this title, any ongoing or federally conducted or supported health care or public health program, activity or survey collects and reports—

"(A) data on race and ethnicity for applicants, recipients, or beneficiaries;

"(B) data on gender, geographic location, socioeconomic status (including education, employment or income), primary language, and, disability status data for applicants, recipients, or beneficiaries;

"(C) data at the smallest geographic level such as State, local, or institutional levels if such data can be aggregated;

"(D) if practicable, data by racial and ethnic subgroups for applicants, recipients or beneficiaries using, if needed, statistical oversamples of these subpopulations; and

"(E) any other demographic data as deemed appropriate by the Secretary regarding health disparities.

"(2) COLLECTION STANDARDS.—In collecting data described in paragraph (1), the Secretary or designee shall—

"(A) use Office of Management and Budget standards, at a minimum, for race and ethnicity measures;

"(B) develop standards for the measurement of gender, geographic location, socioeconomic status, primary language and disability measures; and

"(C) develop standards for the collection of data described in paragraph (1) that, at a minimum—

"(i) collects self-reported data by the applicant, recipient, or beneficiary; and

"(ii) collects data from a parent or legal guardian if the applicant, recipient, or beneficiary is a minor or legally incapacitated.

"(3) DATA MANAGEMENT.—In collecting data described in paragraph (1), the Secretary, acting through the National Coordinator for Health Information Technology shall—

"(A) develop national standards for the management of data collected; and

"(B) develop interoperability and security systems for data management.

"(b) DATA ANALYSIS.—

"(1) IN GENERAL.—For each federally conducted or supported health care or public health program or activity, the Secretary shall analyze data collected under paragraph (a) to detect and monitor trends in health disparities (as defined in section 485E) at the Federal and State levels.

"(c) DATA REPORTING AND DISSEMINATION.—

"(1) IN GENERAL.—The Secretary shall make the analyses described in (b) available to—

"(A) the Office of Minority Health;

"(B) the National Center on Minority Health and Health Disparities;

"(C) the Agency for Healthcare Research and Quality;

"(D) the Centers for Disease Control and Prevention;

"(E) the Centers for Medicare & Medicaid Services;

"(F) the Indian Health Service and epidemiology centers funded under the Indian Health Care Improvement Act;

"(G) other agencies within the Department of Health and Human Services; and

"(H) other entities as determined appropriate by the Secretary.

"(2) REPORTING OF DATA.—The Secretary shall report data and analyses described in (a) and (b) through—

"(A) public postings on the Internet websites of the Department of Health and Human Services; and

"(B) any other reporting or dissemination mechanisms determined appropriate by the Secretary.

"(3) AVAILABILITY OF DATA.—The Secretary may make data described in (a) and (b) available for additional research, analyses, and dissemination to other Federal agencies, non-governmental entities, and the public.

"(d) LIMITATIONS ON USE OF DATA.—Nothing in this section shall be construed to permit the use of information collected under this section in a manner that would adversely affect any individual.

"(e) PROTECTION OF DATA.—The Secretary shall ensure (through the promulgation of regulations or otherwise) that all data collected pursuant to subsection (a) is protected—

"(1) under the same privacy protections that are at least as broad as those that the Secretary applies to other health data under the regulations pro-

1 mulgated under section 264(c) of the Health Insur-
2 ance Portability and Accountability Act of 1996
3 (Public Law 104-191; 110 Stat. 2033); and
4 ''(2) from all inappropriate internal use by any
5 entity that collects, stores, or receives the data, in-
6 cluding use of such data in determinations of eligi-
7 bility (or continued eligibility) in health plans, and
8 from other inappropriate uses, as defined by the
9 Secretary.
10 ''(f) DATA ON RURAL UNDERSERVED POPU-
11 LATIONS.—The Secretary shall ensure that any data col-
12 lected in accordance with this section regarding racial and
13 ethnic minority groups is also collected regarding under-
14 served rural and frontier populations.
15 ''(g) AUTHORIZATION OF APPROPRIATIONS.—For the
16 purpose of carrying out this section, there are authorized
17 to be appropriated such sums as may be necessary for
18 each of fiscal years 2010 through 2014.
19 ''(h) REQUIREMENT FOR IMPLEMENTATION.—Not-
20 withstanding any other provision of this section, data may
21 not be collected under this section unless funds are di-
22 rectly appropriated for such purpose in an appropriations
23 Act.''.

**SEC. 333. HEALTH IMPACT ASSESSMENTS.**

(a) PURPOSE.—It is the purpose of this section to determine if the built environment has an impact on health.

(b) DEFINITION.—In this section:

(1) ADMINISTRATOR.—The term ''Administrator'' means the Administrator of the Environmental Protection Agency.

(2) BUILT ENVIRONMENT.—The term ''built environment'' means an environment consisting of building, spaces, and products that are created or modified by individuals and entities, including homes, schools, workplaces, greenways, business areas, transportation systems, and parks and recreation areas, electrical transmission lines, waste disposal sites, and land-use planning and policies that impact urban, rural and suburban communities.

(3) DIRECTOR.—The term ''Director'' means the Director of the Centers for Disease Control and Prevention.

(4) ENVIRONMENTAL HEALTH.—The term ''environmental health'' means the health and wellbeing of a population as affected by the direct pathological effects of chemicals, radiation or biological agents, and the effects, including the indirect effects, of the

broad physical, psychological, social and aesthetic environment.

(5) HEALTH IMPACT ASSESSMENT.—The term ''health impact assessment'' means a combination of procedures, methods, and tools by which a regulation, program, or other project is assessed as to its potential effects on the health of a population, and the distribution of those effects within the population.

(6) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(c) FOSTERING HEALTH IMPACT ASSESSMENT.—

(1) ESTABLISHMENT.—The Secretary, acting through the Director and in coordination with the Administrator, shall establish a program at the National Center of Environmental Health at the Centers for Disease Control and Prevention to foster advances and provide technical support in the field of health impact assessments.

(2) ACTIVITIES.—Through the program under paragraph (1), the Secretary shall—

(A) collect and disseminate evidence-based practices relating to health impact assessments;

(B) manage capacity building grants, technical assistance, and training on the use of health impact assessments; and

(C) provide guidance on health impact assessments including similar international efforts, known associations between the built environment and health outcomes, forecasting of potential health effects of the built environment, and best practices relating to the inclusion of the public in planning processes.

**SEC. 334. CDC AND EMPLOYER-BASED WELLNESS PROGRAMS.**

Title III of the Public Health Service Act (42 U.S.C. 241 et seq.), as amended by section 314) is further amended by adding at the end the following:

**"PART T—EMPLOYER-BASED WELLNESS PROGRAM**

**"SEC. 399HH. WORKPLACE WELLNESS MARKETING CAMPAIGN.**

''Subject to appropriations Acts, the Director of the Centers for Disease Control and Prevention (referred to in this section as the 'Director'), in coordination with relevant worksite health promotion organizations, State and local health departments, the Indian Health Service, In-

dian tribes and tribal organizations, and academic institutions, shall conduct targeted educational campaigns to—

"(1) make employers, employer groups, and other interested parties aware of the benefits of employer-based wellness programs;

"(2) establish a culture of health by emphasizing health promotion and disease prevention;

"(3) emphasize an integrated and coordinated approach to workplace wellness; and

"(4) ensure informed decisions through high quality information to organizational leaders.

**"SEC. 399HH-1. TECHNICAL ASSISTANCE FOR EMPLOYER-BASED WELLNESS PROGRAMS.**

"In order to expand the utilization of evidence-based prevention and health promotion approaches in the workplace, the Director shall—

"(1) provide employers (including small, medium, and large employers, as determined by the Director) with technical assistance, consultation, tools, and other resources in evaluating such employers' employer-based wellness programs, including—

"(A) measuring the participation and methods to increase participation of employees in such programs;

"(B) developing standardized measures that assess policy, environmental and systems changes necessary to have a positive health impact on employees' health behaviors, health outcomes, and health care expenditures; and

"(C) evaluating such programs as they relate to changes in the health status of employees, the absenteeism of employees, the productivity of employees, the rate of workplace injury, and the medical costs incurred by employees; and

"(2) build evaluation capacity among workplace staff by training employers on how to evaluate employer-based wellness programs by ensuring evaluation resources, technical assistance, and consultation are available to workplace staff as needed through such mechanisms as web portals, call centers, or other means.

**"SEC. 399HH-2. NATIONAL WORKSITE HEALTH POLICIES AND PROGRAMS STUDY.**

"(a) IN GENERAL.—In order to assess, analyze, and monitor over time data about workplace policies and programs, and to develop instruments to assess and evaluate comprehensive workplace chronic disease prevention and health promotion programs, policies and practices, not

later than 2 years after the date of enactment of this part, and at regular intervals (to be determined by the Director) thereafter, the Director shall conduct a national worksite health policies and programs survey to assess employer-based health policies and programs.

"(b) REPORT.—Upon the completion of each study under subsection (a), the Director shall submit to Congress a report that includes the recommendations of the Director for the implementation of effective employer-based health policies and programs.

**"SEC. 399HH-3. RESEARCH IN WORKPLACE WELLNESS.**

"(a) WORKPLACE DEMONSTRATION STUDIES.—To expand the science base for effective prevention and health promotion approaches in the workplace, the Director, in collaboration with academic institutions and employers, shall institute workplace demonstration projects across small, medium, and large employers. Such demonstration projects shall be designed to determine how best to transform the work environment for health, safety, and wellness, how to create a strong, sustainable, coordinated, and integrated workplace health promotion and wellness program, and how to create innovative and sustainable policy and environmental strategies to improve employee health and wellness.

"(b) REPORT.—Upon the completion of the study under subsection (b), the Director shall submit to Congress a report that includes the recommendations of the Director for the implementation of effective employer-based health policies and programs.

**"SEC. 399HH–4. PRIORITIZATION OF EVALUATION BY SECRETARY.**

"The Secretary shall evaluate, in accordance with this part, all programs funded through the Centers for Disease Control and Prevention before conducting such an evaluation of privately funded programs unless an entity with a privately funded wellness program requests such an evaluation.

**"SEC. 399HH–5. PROHIBITION OF FEDERAL WORKPLACE WELLNESS REQUIREMENTS.**

"Notwithstanding any other provision of this part, any recommendations, data, or assessments carried out under this part shall not be used to mandate requirements for workplace wellness programs.".

**SEC. 335. EPIDEMIOLOGY-LABORATORY CAPACITY GRANTS.**

Title XXVIII of the Public Health Service Act (42 U.S.C. 300hh et seq.) is amended by adding at the end the following:

# "Subtitle C—Strengthening Public Health Surveillance Systems

**"SEC. 2821. EPIDEMIOLOGY-LABORATORY CAPACITY GRANTS.**

"(a) IN GENERAL.—Subject to the availability of appropriations, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall establish an Epidemiology and Laboratory Capacity Grant Program to award grants to eligible entities to assist public health agencies in improving surveillance for, and response to, infectious diseases and other conditions of public health importance by—

"(1) strengthening epidemiologic capacity;

"(2) enhancing laboratory practice;

"(3) improving information systems; and

"(4) developing and implementing prevention and control strategies.

"(b) ELIGIBLE ENTITIES.—In this section, the term 'eligible entity' means an entity that—

"(1) is—

"(A) a State health department;

"(B) a local health department that meets such criteria as the Director of the Centers for Diseases Control and Prevention determines for purposes of this section;

"(C) a tribal jurisdiction that meets such criteria as the Director of the Centers for Disease Control and Prevention determines for purposes of this section; or

"(D) a partnership established for purposes of this section between one or more eligible entities described in subparagraph (A), (B), or (C) and an academic center; and

"(2) submits 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) IN GENERAL.—An eligible entity shall use amounts received under a grant under this section for core functions described in this subsection including—

"(A) building public health capacity to identify and monitor the occurrence of infectious diseases and other conditions of public health importance;

"(B) detecting new and emerging infectious disease threats, including laboratory capacity to detect antimicrobial resistant infections;

"(C) identifying and responding to disease outbreaks;

"(D) hiring necessary staff;

"(E) conducting needed staff training and educational development; and

"(F) other activities that improve surveillance as determined by the Director of the Centers for Disease Control and Prevention.

"(2) DEVELOPMENT AND MAINTENANCE OF INFORMATION EXCHANGE.—

"(A) NATIONAL STANDARDS.—Not later than 180 days after the date of the enactment of this subtitle, the Secretary, acting through the Director of the Centers for Disease Control and Prevention, and in consultation with the National Coordinator for Health Information Technology, shall issue guidelines for public health entities that—

"(i) are designed to ensure that all State and local health departments and public health laboratories have access to information systems to receive, monitor, and report infectious diseases and other urgent conditions of public health importance; and

"(ii) are consistent with standards and recommendations for health information technology by the National Coordinator for Health Information Technology, and by the American Health Information Community (AHIC) and its successors.

"(B) SECURE INFORMATION SYSTEMS.—An eligible entity shall use amounts received through a grant under this section to ensure that the entity has access to a web-based, secure information system that complies with the guidelines developed under subparagraph (A). Such a system shall be designed—

"(i) to receive automated case reports of State and national reportable conditions from clinical systems and health care offices that use electronic health records and from clinical and public health laboratories, and to submit reports of nationally reportable conditions to the Director of the Centers for Disease Control and Prevention;

"(ii) to receive and analyze, within 24 hours, de-identified electronic clinical data for situational awareness and to forward

such reports immediately to the Centers for Disease Control and Prevention at the time of receipt;

''(iii) to manage, link, and process different types of data, including information on newly reported cases, exposed contacts, laboratory results, number of people vaccinated or given prophylactic medications, adverse events monitoring and follow-up, in an integrated outbreak management system;

''(iv) to geocode analyze, display, report, and map, using Geographic Information System technology, accumulated data and to share data with other local health departments, State health departments, and the Centers for Disease Control and Prevention;

''(v) to receive, manage, and disseminate alerts, protocols, and other information, including Health Alert Network and Epi-X information, as appropriate, for public health workers, health care providers, and public health partners in emergency response within each health depart-

ment's jurisdiction and to automate the exchange and cascading of such information with external partners using national standards;

"(vi) to have information technology security and critical infrastructure protection as appropriate to protect public health information;

"(vii) to have the technical infrastructure needed to ensure availability, backup, and disaster recovery of data, application services, and communications systems during natural disasters such as floods, tornados, hurricanes, and power outages; and

"(viii) to provide for other capabilities as the Secretary determines appropriate.

"(C) LABORATORY SYSTEMS.—An eligible entity shall use amounts received under a grant under this section to ensure that State or local public health laboratories are utilizing web-based, secure systems that are in compliance with the guidelines developed by the Secretary under subparagraph (A) and that—

"(i) are fully integrated laboratory information systems;

"(ii) provide for the reporting of electronic test results to the appropriate local and State health departments using currently existing national format and coding standards;

"(iii) have information technology security and critical infrastructure protection to protect public health information (as determined by the Secretary);

"(iv) have the technical infrastructure needed to ensure availability, backup, and disaster recovery of data, application services, and communications systems during natural disasters including floods, tornadoes, hurricanes, and power outages; and

"(v) address other capabilities as the Secretary determines appropriate.

"(D) OTHER USES.—In addition to the activities described in subparagraphs (B) and (C), an eligible entity (including the entity's public health laboratory) may use amounts received under a grant under this section for systems development and maintenance, hiring necessary staff, and staff technical training. Grantees under this section may elect to develop their

own systems or use federally developed systems in carrying out activities under this paragraph.

"(d) PRIORITY.—In allocating funds under subsection (f)(2) for activities under subsection (c)(2)(B) (relating to secure information systems), the Secretary shall give priority to eligible entities that demonstrate need.

"(e) REPORTS.—Not later than September 30, 2011, and each September 30 thereafter, the Secretary shall submit to Congress an annual report on the activities carried out under this section by recipients of assistance under this section.

"(f) AUTHORIZATION OF APPROPRIATIONS.—There are authorized to be appropriated to carry out this section $190,000,000 for each of fiscal years 2010 through 2013, of which—

"(1) not less than $95,000,000 shall be made available each such fiscal year for activities under subsection (c)(1);

"(2) not less than $60,000,000 shall be made available each such fiscal year for activities under subsection (c)(2)(B); and

"(3) not less than $32,000,000 shall be made available each such fiscal year for activities under subsection (c)(2)(C).".

**SEC. 336. FEDERAL MESSAGING ON HEALTH PROMOTION AND DISEASE PREVENTION.**

(a) MEDIA CAMPAIGN.—

(1) IN GENERAL.—Not later than 1 year after the date of enactment of this Act, the Secretary of Health and Human Services (referred to in this section as the ''Secretary''), acting through the Director of the Centers for Disease Control and Prevention, shall establish and implement a national science-based media campaign on health promotion and disease prevention.

(2) REQUIREMENTS OF CAMPAIGN.—The campaign implemented under paragraph (1)—

(A) shall be designed to address proper nutrition, regular exercise, smoking cessation, obesity reduction, the 5 leading disease killers in the United States, and secondary prevention through disease screening promotion;

(B) shall be carried out through competitively bid contracts awarded to entities providing for the professional production and design of such campaign;

(C) may include the use of television, radio, Internet, and other commercial marketing venues and may be targeted to specific

1 age groups based on peer-reviewed social re-
2 search;
3 (D) shall not be duplicative of any other
4 Federal efforts relating to health promotion and
5 disease prevention; and
6 (E) may include the use of humor and na-
7 tionally recognized positive role models.
8 (3) EVALUATION.—The Secretary shall ensure
9 that the campaign implemented under paragraph (1)
10 is subject to an independent evaluation every 2 years
11 and shall report every 2 years to Congress on the ef-
12 fectiveness of such campaigns towards meeting
13 science-based metrics.
14 (b) WEBSITE.—The Secretary, in consultation with
15 private-sector experts, shall maintain or enter into a con-
16 tract to maintain an Internet website to provide science-
17 based information on guidelines for nutrition, regular ex-
18 ercise, obesity reduction, smoking cessation, and specific
19 chronic disease prevention. Such website shall be designed
20 to provide information to health care providers and con-
21 sumers.
22 (c) DISSEMINATION OF INFORMATION THROUGH
23 PROVIDERS.—The Secretary, acting through the Centers
24 for Disease Control and Prevention, shall develop and im-
25 plement a plan for the dissemination of health promotion

and disease prevention information consistent with national priorities, to health care providers who participate in Federal programs, including programs administered by the Indian Health Service, the Department of Veterans Affairs, the Department of Defense, and the Health Resources and Services Administration, and the Medicare and Medicaid Programs.

(d) PERSONALIZED PREVENTION PLANS.—

(1) CONTRACT.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall enter into a contract with a qualified entity for the development and operation of a Federal Internet website personalized prevention plan tool.

(2) USE.—The website developed under paragraph (1) shall be designed to be used as a source of the most up-to-date scientific evidence relating to disease prevention for use by individuals. Such website shall contain a component that enables an individual to determine their disease risk (based on personal health and family history, BMI, and other relevant information) relating to the 5 leading diseases in the United States, and obtain personalized suggestions for preventing such diseases.

(e) INTERNET PORTAL.—The Secretary shall establish an Internet portal for accessing risk-assessment tools developed and maintained by private and academic entities.

(f) PRIORITY FUNDING.—Funding for the activities authorized under this section shall take priority over funding provided through the Centers for Disease Control and Prevention for grants to States and other entities for similar purposes and goals as provided for in this section. Not to exceed $500,000,000 shall be expended on the campaigns and activities required under this section.

# Subtitle E—Advancing Research and Treatment for Pain Care Management

**SEC. 341. INSTITUTE OF MEDICINE CONFERENCE ON PAIN.**

(a) CONVENING.—Not later than June 30, 2010, the Secretary of Health and Human Services shall seek to enter into an agreement with the Institute of Medicine of the National Academies to convene a Conference on Pain (in this section referred to as ''the Conference'').

(b) PURPOSES.—The purposes of the Conference shall be to—

(1) increase the recognition of pain as a significant public health problem in the United States;

(2) evaluate the adequacy of assessment, diagnosis, treatment, and management of acute and chronic pain in the general population, and in identified racial, ethnic, gender, age, and other demographic groups that may be disproportionately affected by inadequacies in the assessment, diagnosis, treatment, and management of pain;

(3) identify barriers to appropriate pain care, including—

(A) lack of understanding and education among employers, patients, health care providers, regulators, and third-party payors;

(B) barriers to access to care at the primary, specialty, and tertiary care levels, including barriers—

(i) specific to those populations that are disproportionately undertreated for pain;

(ii) related to physician concerns over regulatory and law enforcement policies applicable to some pain therapies; and

(iii) attributable to benefit, coverage, and payment policies in both the public and private sectors; and

(C) gaps in basic and clinical research on the symptoms and causes of pain, and potential assessment methods and new treatments to improve pain care; and

(4) establish an agenda for action in both the public and private sectors that will reduce such barriers and significantly improve the state of pain care research, education, and clinical care in the United States.

(c) OTHER APPROPRIATE ENTITY.—If the Institute of Medicine declines to enter into an agreement under subsection (a), the Secretary of Health and Human Services may enter into such agreement with another appropriate entity.

(d) REPORT.—A report summarizing the Conference's findings and recommendations shall be submitted to the Congress not later than June 30, 2011.

(e) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this section, there is authorized to be appropriated $500,000 for each of fiscal years 2010 and 2011.

**SEC. 342. PAIN RESEARCH AT NATIONAL INSTITUTES OF HEALTH.**

Part B of title IV of the Public Health Service Act (42 U.S.C. 284 et seq.) is amended by adding at the end the following:

**"SEC. 409J. PAIN RESEARCH.**

"(a) RESEARCH INITIATIVES.—

"(1) IN GENERAL.—The Director of NIH is encouraged to continue and expand, through the Pain Consortium, an aggressive program of basic and clinical research on the causes of and potential treatments for pain.

"(2) ANNUAL RECOMMENDATIONS.—Not less than annually, the Pain Consortium, in consultation with the Division of Program Coordination, Planning, and Strategic Initiatives, shall develop and submit to the Director of NIH recommendations on appropriate pain research initiatives that could be undertaken with funds reserved under section 402A(c)(1) for the Common Fund or otherwise available for such initiatives.

"(3) DEFINITION.—In this subsection, the term 'Pain Consortium' means the Pain Consortium of the National Institutes of Health or a similar trans-National Institutes of Health coordinating entity

designated by the Secretary for purposes of this subsection.

"(b) INTERAGENCY PAIN RESEARCH COORDINATING COMMITTEE.—

"(1) ESTABLISHMENT.—The Secretary shall establish not later than 1 year after the date of the enactment of this section and as necessary maintain a committee, to be known as the Interagency Pain Research Coordinating Committee (in this section referred to as the 'Committee'), to coordinate all efforts within the Department of Health and Human Services and other Federal agencies that relate to pain research.

"(2) MEMBERSHIP.—

"(A) IN GENERAL.—The Committee shall be composed of the following voting members:

"(i) Not more than 7 voting Federal representatives as follows:

"(I) The Director of the Centers for Disease Control and Prevention.

"(II) The Director of the National Institutes of Health and the directors of such national research institutes and national centers as the Secretary determines appropriate.

"(III) The heads of such other agencies of the Department of Health and Human Services as the Secretary determines appropriate.

"(IV) Representatives of other Federal agencies that conduct or support pain care research and treatment, including the Department of Defense and the Department of Veterans Affairs.

"(ii) 12 additional voting members appointed under subparagraph (B).

"(B) ADDITIONAL MEMBERS.—The Committee shall include additional voting members appointed by the Secretary as follows:

"(i) 6 members shall be appointed from among scientists, physicians, and other health professionals, who—

"(I) are not officers or employees of the United States;

"(II) represent multiple disciplines, including clinical, basic, and public health sciences;

"(III) represent different geographical regions of the United States; and

"(IV) are from practice settings, academia, manufacturers or other research settings; and

"(ii) 6 members shall be appointed from members of the general public, who are representatives of leading research, advocacy, and service organizations for individuals with pain-related conditions.

"(C) NONVOTING MEMBERS.—The Committee shall include such nonvoting members as the Secretary determines to be appropriate.

"(3) CHAIRPERSON.—The voting members of the Committee shall select a chairperson from among such members. The selection of a chairperson shall be subject to the approval of the Director of NIH.

"(4) MEETINGS.—The Committee shall meet at the call of the chairperson of the Committee or upon the request of the Director of NIH, but in no case less often than once each year.

"(5) DUTIES.—The Committee shall—

"(A) develop a summary of advances in pain care research supported or conducted by the Federal agencies relevant to the diagnosis, prevention, and treatment of pain and diseases and disorders associated with pain;

"(B) identify critical gaps in basic and clinical research on the symptoms and causes of pain;

"(C) make recommendations to ensure that the activities of the National Institutes of Health and other Federal agencies, including the Department of Defense and the Department of Veteran Affairs, are free of unnecessary duplication of effort;

"(D) make recommendations on how best to disseminate information on pain care; and

"(E) make recommendations on how to expand partnerships between public entities, including Federal agencies, and private entities to expand collaborative, cross-cutting research.

"(6) REVIEW.—The Secretary shall review the necessity of the Committee at least once every 2 years.".

**SEC. 343. PAIN CARE EDUCATION AND TRAINING.**

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

**"SEC. 759. PROGRAM FOR EDUCATION AND TRAINING IN PAIN CARE.**

''(a) IN GENERAL.—The Secretary may make awards of grants, cooperative agreements, and contracts to health professions schools, hospices, and other public and private entities for the development and implementation of programs to provide education and training to health care professionals in pain care.

''(b) PRIORITIES.—In making awards under subsection (a), the Secretary shall give priority to awards for the implementation of programs under such subsection.

''(c) CERTAIN TOPICS.—An award may be made under subsection (a) only if the applicant for the award agrees that the program carried out with the award will include information and education on—

''(1) recognized means for assessing, diagnosing, treating, and managing pain and related signs and symptoms, including the medically appropriate use of controlled substances;

''(2) applicable laws, regulations, rules, and policies on controlled substances, including the degree to which misconceptions and concerns regarding

such laws, regulations, rules, and policies, or the enforcement thereof, may create barriers to patient access to appropriate and effective pain care;

"(3) interdisciplinary approaches to the delivery of pain care, including delivery through specialized centers providing comprehensive pain care treatment expertise;

"(4) cultural, linguistic, literacy, geographic, and other barriers to care in underserved populations; and

"(5) recent findings, developments, and improvements in the provision of pain care.

"(d) PROGRAM SITES.—Education and training under subsection (a) may be provided at or through health professions schools, residency training programs, and other graduate programs in the health professions; entities that provide continuing education in medicine, pain management, dentistry, psychology, social work, nursing, and pharmacy; hospices; and such other programs or sites as the Secretary determines to be appropriate.

"(e) EVALUATION OF PROGRAMS.—The Secretary shall (directly or through grants or contracts) provide for the evaluation of programs implemented under subsection (a) in order to determine the effect of such programs on knowledge and practice of pain care.

"(f) PEER REVIEW GROUPS.—In carrying out section 799(f) with respect to this section, the Secretary shall ensure that the membership of each peer review group involved includes individuals with expertise and experience in pain care.

"(g) PAIN CARE DEFINED.—For purposes of this section the term 'pain care' means the assessment, diagnosis, treatment, or management of acute or chronic pain regardless of causation or body location.

"(h) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $5,000,000 for each of the fiscal years 2010 through 2012. Amounts appropriated under this subsection shall remain available until expended.".

**SEC. 344. PUBLIC AWARENESS CAMPAIGN ON PAIN MANAGEMENT.**

Part B of title II of the Public Health Service Act (42 U.S.C. 238 et seq.) is amended by adding at the end the following:

**"SEC. 249. NATIONAL EDUCATION OUTREACH AND AWARENESS CAMPAIGN ON PAIN MANAGEMENT.**

"(a) ESTABLISHMENT.—Not later than June 30, 2010, the Secretary shall establish and implement a national pain care education outreach and awareness campaign described in subsection (b).

1 "(b) REQUIREMENTS.—The Secretary shall design
2 the public awareness campaign under this section to edu-
3 cate consumers, patients, their families, and other care-
4 givers with respect to—
5 "(1) the incidence and importance of pain as a
6 national public health problem;
7 "(2) the adverse physical, psychological, emo-
8 tional, societal, and financial consequences that can
9 result if pain is not appropriately assessed, diag-
10 nosed, treated, or managed;
11 "(3) the availability, benefits, and risks of all
12 pain treatment and management options;
13 "(4) having pain promptly assessed, appro-
14 priately diagnosed, treated, and managed, and regu-
15 larly reassessed with treatment adjusted as needed;
16 "(5) the role of credentialed pain management
17 specialists and subspecialists, and of comprehensive
18 interdisciplinary centers of treatment expertise;
19 "(6) the availability in the public, nonprofit,
20 and private sectors of pain management-related in-
21 formation, services, and resources for consumers,
22 employers, third-party payors, patients, their fami-
23 lies, and caregivers, including information on—

"(A) appropriate assessment, diagnosis, treatment, and management options for all types of pain and pain-related symptoms; and

"(B) conditions for which no treatment options are yet recognized; and

"(7) other issues the Secretary deems appropriate.

"(c) CONSULTATION.—In designing and implementing the public awareness campaign required by this section, the Secretary shall consult with organizations representing patients in pain and other consumers, employers, physicians including physicians specializing in pain care, other pain management professionals, medical device manufacturers, and pharmaceutical companies.

"(d) COORDINATION.—

"(1) LEAD OFFICIAL.—The Secretary shall designate one official in the Department of Health and Human Services to oversee the campaign established under this section.

"(2) AGENCY COORDINATION.—The Secretary shall ensure the involvement in the public awareness campaign under this section of the Surgeon General of the Public Health Service, the Director of the Centers for Disease Control and Prevention, and such other representatives of offices and agencies of

the Department of Health and Human Services as the Secretary determines appropriate.

"(e) UNDERSERVED AREAS AND POPULATIONS.—In designing the public awareness campaign under this section, the Secretary shall—

"(1) take into account the special needs of geographic areas and racial, ethnic, gender, age, and other demographic groups that are currently underserved; and

"(2) provide resources that will reduce disparities in access to appropriate diagnosis, assessment, and treatment.

"(f) GRANTS AND CONTRACTS.—The Secretary may make awards of grants, cooperative agreements, and contracts to public agencies and private nonprofit organizations to assist with the development and implementation of the public awareness campaign under this section.

"(g) EVALUATION AND REPORT.—Not later than the end of fiscal year 2012, the Secretary shall prepare and submit to the Congress a report evaluating the effectiveness of the public awareness campaign under this section in educating the general public with respect to the matters described in subsection (b).

"(h) AUTHORIZATION OF APPROPRIATIONS.—For purposes of carrying out this section, there are authorized

to be appropriated $2,000,000 for fiscal year 2010 and $4,000,000 for each of fiscal years 2011 through 2012.''.

## Subtitle F—Coordinated Environmental Public Health Network

### SEC. 351. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

The Public Health Service Act (42 U.S.C. 201 et seq.), as amended by section 332, is further amended by adding at the end the following:

## ''TITLE XXXIV—COORDINATED ENVIRONMENTAL PUBLIC HEALTH NETWORK

### ''SEC. 3400. DEFINITIONS.

''In this title:

''(1) ADMINISTRATOR.—The term 'Administrator' means the Administrator of the Environmental Protection Agency.

''(2) COORDINATED NETWORK.—The term 'Coordinated Network' means the Coordinated Environmental Public Health Network established under section 3401(a).

''(3) DIRECTOR.—The term 'Director' means the Director of the Centers for Disease Control and Prevention.

"(4) DIRECTOR OF CENTER.—The term 'Director of Center' means the Director of the National Center for Environmental Health at the Centers for Disease Control and Prevention.

"(5) MEDICAL PRIVACY REGULATIONS.—The term 'medical privacy regulations' means the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996.

"(6) PRIORITY CHRONIC CONDITIONS AND HEALTH EFFECTS.—The term 'priority chronic conditions and health effects' means the conditions, as specified by the Secretary, to be tracked in the Coordinated Network and the State Networks.

"(7) STATE NETWORK.—The term 'State Network' means a State Environmental Public Health Network established under section 3401(b).

"(8) STATE.—The term 'State' means a State, local government, territory, or Indian tribe that is eligible to receive a health tracking grant under section 3401(b).

**"SEC. 3401. ESTABLISHMENT OF COORDINATED AND STATE ENVIRONMENTAL PUBLIC HEALTH NETWORKS.**

"(a) COORDINATED ENVIRONMENTAL PUBLIC HEALTH NETWORK.—Not later than 36 months after the date of the enactment of this title, the Secretary, acting through the Director, in consultation with the Administrator and the Director of Center, and with the involvement of other Federal agencies, and State and local health departments, shall establish and operate a Coordinated Environmental Public Health Network. In establishing and operating the Coordinated Network, the Secretary shall, as practicable—

"(1) identify, build upon, expand, and coordinate among existing data and surveillance systems, surveys, registries, and other Federal public health and environmental infrastructure as practicable;

"(2) provide for public access to an electronic national database that accepts data from the State Networks on the incidence and prevalence of priority chronic conditions and health effects and relevant environmental and other factors, in a manner which protects personal privacy consistent with the medical privacy regulations;

"(3) prepare, publish, and submit to Congress—

"(A) not later than 12 months after the date of enactment of this title, and annually thereafter, a Coordinated Network Status Report, including a statement of the activities carried out under this title, the identification of gaps in the data of the coordinated Network, including diseases of concern and environmental exposures not tracked, and identification of key milestones achieved in the preceding year, with such report to be made available to the public on the websites of the Centers for Disease Control and Prevention and the Environmental Protection Agency; and

"(B) not later than 2 years after the date of enactment of this title, and biennially thereafter, a Coordinated Network Health and Environment Report, including a statement of the activities carried out under this title, an analysis of the most currently available incidence, prevalence, and trends of priority chronic conditions and health effects, and potentially relevant environmental and other factors, by State and, as practicable by local areas, and recommendations regarding high risk populations, public health concerns, response and prevention strate-

gies, and additional tracking needs, in order to allow the public to access and understand information about environmental health at the Federal, State, and, where practicable, local level;

''(4) provide for the establishment of State Networks, and coordinate the State Networks as provided for under subsection (b);

''(5) provide technical assistance to support the State Networks;

''(6) not later than 12 months after the date of the enactment of this title, develop minimum standards and procedures for data collection and reporting for the State Networks, to be updated not less than annually thereafter; and

''(7) in developing the minimum standards and procedures under subparagraph (F), include mechanisms for allowing the States to set priorities, and allocate resources accordingly.

''(b) STATE ENVIRONMENTAL PUBLIC HEALTH NETWORKS.—

''(1) GRANTS.—Not later than 12 months after the date of the enactment of this title, the Secretary, acting through the Director, in consultation with the Administrator and the Director of Center shall award grants to States for the establishment, main-

tenance, and operation of State Networks in accordance with the minimum standards and procedures established by the Secretary under subsection (a)(3).

"(2) SPECIALIZED ASSISTANCE.—The Coordinated Network shall provide specialized assistance to grantees in the establishment, maintenance, and operation of State Networks.

"(3) REQUIREMENTS.—A State receiving a grant under this subsection shall use the grant—

"(A) to establish an environmental public health network that will provide—

"(i) for the tracking of the incidence, prevalence, and trends of priority chronic conditions and health effects, as well as any additional priority chronic conditions and health effects and potentially related environmental exposures of concern to that State;

"(ii) for identification of priority chronic conditions and health effects and potentially relevant environmental and other factors that disproportionately impact low income and minority communities;

"(iii) for the protection of the confidentiality of all personal data reported, in

accordance with the medical privacy regulations;

"(iv) a means by which confidential data may, in accordance with Federal and State law, be disclosed to researchers for the purposes of public health research;

"(v) the fullest possible public access to data collected by the State Network or through the Coordinated Network, while ensuring that individual privacy is protected in accordance with subsection (a)(1)(B); and

"(vi) for the collection of exposure data through biomonitoring and other methods, which may include the entering into of cooperative agreements as described in section 3404;

"(B) to develop a publicly available plan for establishing the State Network in order to meet minimum standards and procedures as developed by the Secretary under subsection (a)(1)(F);

"(C) to appoint a lead public health department or agency that will be responsible for the development, operation, and maintenance of

the State Network, and ensure the appropriate coordination among State and local agencies, including environmental agencies, regarding the development, operation, and maintenance of the State Network; and

"(D) to recruit and train public health officials to continue to expand the State Network.

"(4) LIMITATION.—A State that receives a grant under this section may not use more than 10 percent of the funds made available through the grant for administrative costs.

"(5) APPLICATION.—To seek a grant under this section, a State shall submit to the Secretary an application at such time, in such form and manner, and accompanied by such information as the Secretary may specify.

"(c) PILOT PROJECTS.—

"(1) IN GENERAL.—A State may apply for a grant under this subsection to implement a pilot project that is approved by the Secretary, acting through the Director and in consultation with the Administrator, and the Director of Center.

"(2) ACTIVITIES.—A State shall use amounts received under a grant under this subsection to carry out a pilot project designed to develop State

Network enhancements and to develop programs to address specific local and regional concerns.

"(3) RESULTS.—The Secretary may consider the results of the pilot projects under this subsection for inclusion into the Coordinated Network.

"(d) PRIVACY.—In establishing and operating the Coordinated Network under subsection (a), and in making grants under subsections (b) and (c), the Secretary shall ensure the protection of privacy of individually identifiable health information, including ensuring protection consistent with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

"(e) 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 2014.

**"SEC. 3402. INCREASING PUBLIC HEALTH PERSONNEL CAPACITY.**

"(a) IN GENERAL.—Beginning in fiscal year 2010, the Secretary, acting through the Director, shall enter into a cooperative agreement with the Council of State and Territorial Epidemiologists to train and place, in State and local health departments, applied epidemiology fellows to enhance State and local public health capacity in the

areas of environmental health, chronic and other noninfectious diseases and conditions, and public health surveillance.

"(b) 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 2014.

**"SEC. 3403. GENERAL PROVISION.**

"The Secretary shall integrate the enactment of this title with all environmental health tracking programs funded prior to the date of enactment of this title, including by integrating the programs, in existence on the date of enactment of this title, to develop State Network enhancements and to develop programs to address specific local and regional concerns.

**"SEC. 3404. EXPANSION OF BIOMONITORING CAPABILITIES AND DATA COLLECTION.**

"(a) PURPOSE.—It is the purpose of this section to expand the scope and amount of biomonitoring data collected and analyzed by the Centers for Disease Control and Prevention, State laboratories, and consortia of State laboratories, in order to obtain robust information, including information by geographically defined areas and subpopulations, about a range of environmental exposures.

"(b) IN GENERAL.—In meeting the purpose of this section, the Secretary shall ensure that biomonitoring data are collected intramurally through appropriate sources, including the National Health and Nutrition Examination Survey, and extramurally shall enter into collaboration or partnerships with other entities to obtain additional information regarding vulnerable subpopulations or other subpopulations.

"(c) COOPERATIVE AGREEMENTS.—

"(1) IN GENERAL.—The Secretary, acting through the Director, shall enter into cooperative agreements with States or consortia of States to support the purposes of this title.

"(2) APPLICATIONS.—Applications for such cooperative agreements by consortia of States shall address the manner in which such States will coordinate activities with other States in the region, and shall designate a lead State for administrative purposes.

"(3) TRAINING AND QUALITY ASSURANCE.—The Secretary, acting through the Director, shall through the cooperative agreements with States or a consortia of States provide laboratory training and quality assurance.

"(d) PRIVACY.—In carrying out this section, the Secretary shall ensure the protection of privacy of individually identifiable health information, including ensuring protection consistent with the regulations promulgated under section 264(c) of the Health Insurance Portability and Accountability Act of 1996 (42 U.S.C. 1320d–2 note).

"(e) 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 2014.".

# Subtitle G—Miscellaneous Provisions

**SEC. 361. SENSE OF THE SENATE CONCERNING CBO SCORING.**

(a) FINDING.—The Senate finds that the costs of prevention programs are difficult to estimate due in part because prevention initiatives are hard to measure and results may occur outside the 5 and 10 year budget windows.

(b) SENSE OF CONGRESS.—It is the sense of the Senate that Congress should work with the Congressional Budget Office to develop better methodologies for scoring progress to be made in prevention and wellness programs.

**SEC. 362. EFFECTIVENESS OF FEDERAL HEALTH AND WELLNESS INITIATIVES.**

To determine whether existing Federal health and wellness initiatives are effective in achieving their stated goals, the Secretary of Health and Human Services shall—

(1) conduct an evaluation of such programs as they relate to changes in health status of the American public and specifically on the health status of the Federal workforce, including absenteeism of employees, the productivity of employees, the rate of workplace injury, and the medical costs incurred by employees, and health conditions, including workplace fitness, healthy food and beverages, and incentives in the Federal Employee Health Benefits Program; and

(2) submit to Congress a report concerning such evaluation, which shall include conclusions concerning the reasons that such existing programs have proven successful or not successful and what factors contributed to such conclusions.

# TITLE IV—HEALTH CARE WORKFORCE

## Subtitle A—Purpose and Definitions

**SEC. 401. 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. 402. DEFINITIONS.**

(a) THIS TITLE.—In this title:

(1) 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.

(2) 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).

(3) LOW INCOME INDIVIDUAL, STATE WORKFORCE INVESTMENT BOARD, AND LOCAL WORKFORCE INVESTMENT BOARD.—The terms ''low-income individual'', ''State workforce investment board'', and ''local workforce investment board'', have the meanings given the terms in section 101 of the Workforce investment Act of 1998 (29 U.S.C. 2801).

(4) 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.

(5) 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 (b) or (c) 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 pro-

gram' means cooperative program consisting of an entity that has received an award under subsection (b) or (c) 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 subsection (b)(4) or (c)(4) of section 751, 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

1 understand health information and services in order
2 to make appropriate health decisions.

3 ''(22) MENTAL HEALTH SERVICE PROFES-
4 SIONAL.—The term 'mental health service profes-
5 sional' means an individual with a graduate or post-
6 graduate degree from an accredited institution of
7 higher education in psychiatry, psychology, school
8 psychology, behavioral pediatrics, psychiatric nurs-
9 ing, social work, school social work, substance abuse
10 disorder prevention and treatment, marriage and
11 family counseling, school counseling, or professional
12 counseling.

13 ''(23) ONE-STOP DELIVERY SYSTEM CENTER.—
14 The term 'one-stop delivery system' means a one-
15 stop delivery system described in section 134(c) of
16 the Workforce Investment Act of 1998 (29 U.S.C.
17 2864(c)).

18 ''(24) PARAPROFESSIONAL CHILD AND ADOLES-
19 CENT MENTAL HEALTH WORKER.—The term 'para-
20 professional child and adolescent mental health
21 worker' means an individual who is not a mental or
22 behavioral health service professional, but who works
23 at the first stage of contact with children and fami-
24 lies 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. 411. 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 by—

(A) disseminating information on current and projected health care workforce supply and demand;

(B) disseminating information on health care workforce education and training capacity and instruction or delivery models and best practices;

(C) recognizing efforts of Federal, State, and local partnerships to develop and offer health care career pathways of proven effectiveness;

(D) disseminating information on promising retention practices for health care professionals;

(E) communicating information on important policies and practices that affect the re-

cruitment, education and training, and retention of the health care workforce; and

(F) disseminating recommendations on the development of a fiscally sustainable integrated workforce that supports a high-quality health care delivery system that meets the needs of patients and populations;

(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 appro-

priate 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 members 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 tile 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) 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 (2);

(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 (3).

(2) 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, and including identified models of education and training delivery and best practices;

(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 scholar-

ship programs to require low-income, minority medical students to serve in their home communities, if designated as medical underserved community.

(3) HIGH PRIORITY AREAS.—

(A) IN GENERAL.—The initial high priority topics described in this paragraph include—

(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) Medicare and Medicaid graduate medical education policies and recommendations, including increasing direct payments to community based training sites and medical training programs, for aligning with national workforce goals;

(iv) nursing workforce capacity at all levels, including education and training ca-

pacity, projected demands, and integration within the health care delivery system;

(v) oral health care workforce capacity, including education and training capacity, projected demands, and integration within the health care delivery system;

(vi) mental and behavioral health care workforce capacity, including education and training capacity, projected demands, and integration within the health care delivery system;

(vii) allied health and public health care workforce capacity, including education and training capacity, projected demands, and integration within the health care delivery system;

(viii) the geographic distribution of health care providers as compared to the identified health care workforce needs of States and regions; and

(ix) emergency medical service workforce capacity, including training and the retention and recruitment of the volunteer workforce.

(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.

(4) GRANT PROGRAM.—The Commission shall review implementation progress reports on, and report to Congress about, the State Health Care Workforce Development Grants program established in section 412.

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

(6) 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.

(7) ASSESSMENT.—The Commission shall assess and receive reports from the National Center

for Health Care Workforce Analysis established under title VII of the Public Service Health Act.

(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 reim-

bursement. 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 unre-

1 stricted access to all deliberations, records, and data
2 of the Commission, immediately upon request.
3 (3) PERIODIC AUDIT.—The Commission shall
4 be subject to periodic audit by an independent public
5 accountant under contract to the Commission.
6 (h) AUTHORIZATION OF APPROPRIATIONS.—
7 (1) REQUEST FOR APPROPRIATIONS.—The
8 Commission shall submit requests for appropriations
9 in the same manner as the Comptroller General of
10 the United States submits requests for appropria-
11 tions. Amounts so appropriated for the Commission
12 shall be separate from amounts appropriated for the
13 Comptroller General.
14 (2) AUTHORIZATION.—There are authorized to
15 be appropriated such sums as may be necessary to
16 carry out this section.
17 (3) GIFTS.—The Commission is authorized to
18 accept and gifts for purposing of carrying out this
19 section.
20 (i) DEFINITIONS.—In this section:
21 (1) HEALTH CARE WORKFORCE.—The term
22 ''health care workforce'' includes all health care pro-
23 viders with direct patient care and support respon-
24 sibilities, such as physicians, nurses, nurse practi-
25 tioners, primary care providers, preventive medicine

1 physicians, optometrists, ophthalmologists, physician
2 assistants, pharmacists, dentists, dental hygienists,
3 and other oral healthcare professionals, allied health
4 professionals, doctors of chiropractic, community
5 health workers, health care paraprofessionals, direct
6 care workers, psychologists and other behavioral and
7 mental health professionals (including substance
8 abuse prevention and treatment providers), social
9 workers, physical and occupational therapists, cer-
10 tified nurse midwives, podiatrists, the EMS work-
11 force (including professional and volunteer ambu-
12 lance personnel and firefighters who perform emer-
13 gency medical services), licensed complementary and
14 alternative medicine providers, integrative health
15 practitioners, public health professionals, and any
16 other health professional that the Comptroller Gen-
17 eral of the United States determines appropriate.
18 (2) HEALTH PROFESSIONALS.—The term
19 ''health professionals'' includes—
20 (A) dentists, dental hygienists, primary
21 care providers, specialty physicians, nurses,
22 nurse practitioners, physician assistants, psy-
23 chologists and other behavioral and mental
24 health professionals (including substance abuse
25 prevention and treatment providers), social

workers, physical 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 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.

(j) REIMBURSEMENT OF COSTS.—The Commission shall reimburse the Government Accountability Office for the full cost of carrying out its activities under this section as billed therefore by the Comptroller General of the United States. Such reimbursements shall be credited to the appropriation account ''Salaries and Expenses, Government Accountability Office'' current when the payment is received and remain available until expended.

**SEC. 412. 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) ASSESSMENT AND REPORTING.—

(1) DUTIES OF COMMISSION.—The National Health Care Workforce Commission established in section 411 (referred to in this section as the ''Commission'') shall—

(A) 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 paragraph (2) for grant recipients;

(B) assess the implementation of the grants; and

(C) collect performance and report information, including identified models and best practices, on grants from the fiscal and administrative agent and distribute this information to Congress, relevant Federal agencies, and to the public.

(2) 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 Commission, which shall review reports on the development, implementation, and evaluation activities of the grant program, including—

(A) administering the grants;

(B) providing technical assistance to grantees; and

(C) 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 individ-

uals 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.

(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 that 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 potential use of grants to be competitively awarded by the State partnership to encourage innovative approaches to improving the supply, diversity, distribution, and development of regional health care workforces, including the alignment of curricula (and prerequisites) for health care careers, the ex-

pansion of and access to quality and timely career information and guidance, and education and training programs;

(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 State and regional levels and career planning information, and as appropriate, requests for Federal program or administrative waivers;

(iii) develop and disseminate a preliminary statewide strategy that addresses short- and long-term health care workforce development supply versus demand, including the solicitation of comments or feedback from key stakeholders and the general public, and refine accordingly;

(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 the provision of technical assistance and capacity building activities such as the dissemination of best practices and tools within the State;

(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. 413. HEALTH CARE WORKFORCE PROGRAM 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 purposes of the National Center are to—

''(A) provide for the development of information describing the health care workforce and

the analysis of health care workforce related issues;

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

"(C) collect, analyze, and report data related to programs under this title in coordination with the State and Regional Centers for Health Workforce Analysis described in subsection (c) (referred to in this section as the 'State and Regional Centers') and with the State agency responsible for the statewide employment statistics system under section 15(e) of the Wagner-Peyser Act (29 U.S.C. 49l–2).

"(3) FUNCTIONS.—The National Center shall, in coordination with the Commission established in section 411 of the Affordable Health Choices Act—

"(A) annually evaluate the effectiveness of programs under this title;

"(B) develop and publish benchmarks for performance for programs under this title;

"(C) establish, maintain, and make publicly available through the Internet a national health workforce database to collect data from—

"(i) 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)); and

"(ii) the State and Regional Centers described in subsection (c); and

"(D) and establish and maintain a registry of each grant awarded under this title.

"(4) COLLABORATION AND DATA SHARING.—

"(A) IN GENERAL.—The National Center shall collaborate with Federal agencies, health professions education organizations, health professions organizations, and professional medical societies for the purpose of linking data regarding grants awarded under this title with 1 or more of the following:

"(i) Data maintained by the Department of Health and Human Services and its various agencies.

"(ii) Data maintained by the Bureau of Labor Statistics.

"(iii) Data maintained by the Census Bureau.

"(iv) Data maintained by the Departments of Defense and Veterans Affairs.

"(v) Data sets maintained by health professions education organizations, health professions organizations, or professional medical societies.

"(vi) Other data sets, as the Secretary determines appropriate.

"(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 health professions education organizations, health professions organizations, or professional medical 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 to the National Center data regarding programs under this title;

"(B) conducting and broadly disseminating research and reports on State, regional, and national health workforce issues;

"(C) evaluating the effectiveness of programs under this title; and

"(D) providing technical assistance to local and regional entities on the collection, analysis, and reporting of data related to health workforce issues.

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

"(A) be a State (including a State Office of Rural Health), a State workforce investment board, a public health or health professions school, an academic health center (including an area health education center program), or an appropriate public or private nonprofit entity or a partnership of such entities, such as a community college system; 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 of a grant or contract awarded to an eligible entity under this title for the establishment and maintenance of a longitudinal evaluation of students, residents, fellows, interns, or faculty who have received education, training, or financial assistance from programs under this title.

"(2) CAPABILITY.—A longitudinal evaluation shall be capable of—

"(A) studying participation in the National Health Service Corps, practice in federally qualified health centers, practice in health professional shortage areas and medically underserved areas, and practice in primary care; 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 have not previously received an increase under this section.''; and

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

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

''(1) IN GENERAL.—

''(A) NATIONAL CENTER FOR HEALTH WORKFORCE ANALYSIS.—To carry out subsection (b), there are authorized to be appropriated $5,000,000 for each of fiscal years 2010 and 2011, $10,000,000 for each of fiscal years 2012 through 2014, and such sums as may be necessary for each subsequent fiscal year.

''(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, and such sums as may be necessary for each subsequent fiscal year.

''(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.

"(D) 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."; and

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

(b) TRANSFER OF FUNCTIONS.—Not later than 180 days after the date of enactment of this Act, all of the functions, authorities, and resources of the National Center for Health Workforce Analysis of the Health Resources and Services Administration, as in effect on the date before the date of enactment of this Act, shall be transferred to the National Center for Health Workforce Analysis established under section 761 of the Public Health Service Act, as amended by subsection (a).

(c) PRIORITY FOR 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)(3)(D)).".

(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) not later than 3 years after the date of enactment of the Affordable Health Choices Act, develop, publish, and implement performance measures, which shall be quantitative to the extent possible, 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) not later than 3 years after the date of enactment of the Affordable Health Choices Act, develop, publish, and implement performance measures, which shall be quantitative to the extent possible, 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) not later than 3 years after the date of enactment of the Affordable Health Choices Act develop, publish, and implement performance measures, which shall be quantitative to the extent possible, 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. 421. 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. 422. 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. 423. 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, pedi-

atric 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. 424. 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 423, 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 insti-

tution 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 ⅓ of the eligi-

ble 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. 425. 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 Heath 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. 426. 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 424, 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 de-

gree 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. 427. 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.".

[NOTE: this section is the same as section 173 of title I.]

**SEC. 428. NURSE-MANAGED HEALTH CLINICS.**

(a) PURPOSE.—The purpose of this section is to fund the development and operation of nurse-managed health clinics in order to provide comprehensive primary health care and wellness services to vulnerable populations living in the Nation's medically underserved communities, and to reduce the level of health disparities experienced by vulnerable populations.

(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. 429. 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. 430. 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 pur-

poses 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 Affordable Health Choices 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. 431. 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 411 of the Affordable Health Choices 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 (which may be departments, divisions, or other 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 411 of the Affordable Health Choices 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. 432. 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 431, 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 serv-

ices 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. 433. 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 413 of this Act, as section 749; and

(2) inserting after section 747A, as added by section 432, 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 heath 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 devel-

opment 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 sub-

stance-related disorders, individuals with disabilities, and individuals with HIV/AIDS.

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

"(7) Qualified applicants that provide instruction regarding the oral health status, dental care needs, and risk-based clinical disease management of all populations, with an emphasis on underserved children.

"(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) PREFERENCE IN MAKING AWARDS.—In making awards of grants or contracts under this section, the Secretary shall give preference to any qualified applicant that—

"(1) has a high rate for placing graduates in practice settings having the principal focus of serv-

ing in underserved areas or health disparity populations (including serving patients eligible for Medicaid or the Children's Health Insurance Program, or those with special health care needs); or

"(2) during the 2-year period before the fiscal year for which such an award is sought, has achieved a significant increase in the rate of placing graduates in such settings or graduating practitioners who serve health disparity populations in their practices.

"(e) 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.

"(f) 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.

"(g) 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.

''(h) 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. 434. 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. 340H. 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.—

"(1) IN GENERAL.—The Secretary shall contract with the Director of the Institute of Medicine (referred to in this subsection as the 'Director') 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.

"(2) DATA COLLECTION.—

"(A) BASELINE DATA.—The Director shall gather data from each demonstration project not later than 24 months after the commencement of the project, which shall serve as baseline data for the study.

"(B) COMPARISON DATA.—The Director shall begin collecting data from each demonstration project 1 year after such project concludes, and shall conclude such data collection not later than 18 months after the conclusion of the project.

"(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. 435. 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 con-

taining 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, including guidelines for the content of the fellowships.

"(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; 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 transfer funds awarded to an individual under this section to the institution where such individual will carry out the award, in order to facilitate financial management of the reward pursuant to guidelines of the Health Resources and Services Administration.''.

(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. 436. 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 413) 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 professional training programs in child and adolescent mental health under subsection (a)(3), 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;

"(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 paraprofessionals serving high-priority populations and to applicants who come from high-priority communities and plan to serve in Health Professional Shortage Areas, Medically Underserved Areas, or Medically Underserved Populations; and

"(D) offer curriculum taught collaboratively with a family on the consumer and family lived experience or the importance of family-professional partnership.

"(4) In selecting the grant recipients to offer preservice or in-service training of paraprofessional child and adolescent mental health workers under subsection (a)(4), the Secretary shall give priority to applicants that—

"(A) have demonstrated the ability to collect data on the number of paraprofessional child and adolescent mental health workers trained by the applicant and the populations served by these workers after the completion of the training;

"(B) have demonstrated familiarity with evidence-based methods in child and adolescent mental health services;

"(C) have programs designed to increase the number of professionals serving high-priority populations, or who come from high-priority communities and plan to serve medically underserved populations or in health professional shortage areas or medically underserved areas;

"(D) offer curriculum taught collaboratively with a family on the consumer and family lived experience or the importance of family-paraprofessional partnership; 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), 753(b), and 755(b)".

**SEC. 437. CULTURAL COMPETENCY, PREVENTION AND PUBLIC HEALTH AND INDIVIDUALS WITH DISABILITIES TRAINING.**

Part B of title VII of the Public Health Service Act (42 U.S.C. 293 et seq.) is amended by adding at the end the following:

**"SEC. 742. CULTURAL COMPETENCY, PREVENTION AND PUBLIC HEALTH AND INDIVIDUALS WITH DISABILITIES TRAINING.**

"(a) IN GENERAL.—The Secretary shall support the development, evaluation, and dissemination of model curricula for cultural competency, prevention, and public health proficiency and aptitude for working with individuals with disabilities training for use in health professions schools and continuing education programs, and for other purposes determined appropriate by the Secretary.

"(b) CURRICULA.—

"(1) 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.

"(2) FOCUS.—Curricula developed under this section shall include a focus on cultural competency measures, prevention and public health competency measures, and working with individuals with disabilities competency measures. In addition, cultural competency, prevention and public health proficiency, and working with individuals with disabilities aptitude self-assessment methodology for health providers, systems, and institutions.

"(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 necessary for each of the fiscal years 2010 through 2015.''.

**SEC. 438. 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, who will upon completion of their studies in such programs, be qualified to effectively provide primary health care services to women at locations where women might require health care services, in-

cluding acute care facilities, ambulatory care facilities, birth centers, personal residences, and other settings as authorized by State or Federal law; and

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

**SEC. 439. 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, such as by providing career counseling and mentoring.

"(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. 440. 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 435, as section 865; and

(B) by redesignating part I as part H.

**SEC. 441. 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. 442. 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 440, 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. 443. 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.), as amended by subsection (b), is amended by adding at the end the following:

**''SEC. 399U. 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, guide, and provide experiential learning opportunities that target behavioral risk factors;

"(3) to educate and provide guidance regarding effective strategies to promote positive health behaviors within the family;

"(4) to educate and provide outreach regarding enrollment in health insurance including the State 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;

"(5) to educate and refer 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

"(6) 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

1 receiving funding under this section to implement a proc-
2 ess or an outcome-based payment system that rewards
3 community health workers for connecting underserved
4 populations with the most appropriate services at the most
5 appropriate time. Nothing in this section shall be con-
6 strued to require such a payment.

7 ''(g) QUALITY ASSURANCE AND COST EFFECTIVE-
8 NESS.—The Secretary shall establish guidelines for assur-
9 ing the quality of the training and supervision of commu-
10 nity health workers under the programs funded under this
11 section and for assuring the cost-effectiveness of such pro-
12 grams.

13 ''(h) MONITORING.—The Secretary shall monitor
14 community health worker programs identified in approved
15 applications under this section and shall determine wheth-
16 er such programs are in compliance with the guidelines
17 established under subsection (g).

18 ''(i) TECHNICAL ASSISTANCE.—The Secretary may
19 provide technical assistance to community health worker
20 programs identified in approved applications under this
21 section with respect to planning, developing, and operating
22 programs under the grant.

23 ''(j) AUTHORIZATION OF APPROPRIATIONS.—There
24 are authorized to be appropriated, such sums as may be

1 necessary to carry out this section for each of fiscal years
2 2010 through 2014.
3 ''(k) DEFINITIONS.—In this section:
4 ''(1) COMMUNITY HEALTH WORKER.—The term
5 'community health worker', as defined by the De-
6 partment of Labor as Standard Occupational Classi-
7 fication [21–1094] means an individual who pro-
8 motes health or nutrition within the community in
9 which the individual resides—
10 ''(A) by serving as a liaison between com-
11 munities and healthcare agencies;
12 ''(B) by providing guidance and social as-
13 sistance to community residents;
14 ''(C) by enhancing community residents'
15 ability to effectively communicate with
16 healthcare providers;
17 ''(D) by providing culturally and linguis-
18 tically appropriate health or nutrition edu-
19 cation;
20 ''(E) by advocating for individual and com-
21 munity health; and
22 ''(F) by providing referral and follow-up
23 services or otherwise coordinating care.
24 ''(2) COMMUNITY SETTING.—The term 'commu-
25 nity setting' means a home or a community organi-

zation 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.".

(b) TECHNICAL AMENDMENTS.—

(1) Section 399R of the Public Health Service Act (as added by section 2 of the ALS Registry Act (Public Law 110-373; 122 Stat. 4047)) is redesignated as section 399S.

(2) Section 399R of such Act (as added by section 3 of the Prenatally and Postnatally Diagnosed Conditions Awareness Act (Public Law 110–374; 122 Stat. 4051)) is redesignated as section 399T.

**SEC. 444. YOUTH PUBLIC HEALTH PROGRAM.**

Section 751(b)(4)(A) of the Public Health Service Act, as amended by section 453, is further amended by adding at the end the following:

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

**SEC. 445. 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 426, 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

1 laboratory science and informatics and may expand the
2 Epidemic Intelligence Service.
3 "(b) SPECIFIC USES.—In carrying out subsection
4 (a), the Secretary shall provide for the expansion of exist-
5 ing fellowship programs operated through the Centers for
6 Disease Control and Prevention in a manner that is de-
7 signed to alleviate shortages of the type described in sub-
8 section (a).
9 "(c) OTHER PROGRAMS.—The Secretary may provide
10 for the expansion of other applied epidemiology training
11 programs that meet objectives similar to the objectives of
12 the programs described in subsection (b).
13 "(d) WORK OBLIGATION.—Participation in fellow-
14 ship training programs under this section shall be deemed
15 to be service for purposes of satisfying work obligations
16 stipulated in contracts under section 338I(j).
17 "(e) GENERAL SUPPORT.—Amounts may be used
18 from grants awarded under this section to expand the
19 Public Health Informatics Fellowship Program at the
20 Centers for Disease Control and Prevention to better sup-
21 port all public health systems at all levels of government.
22 "(f) AUTHORIZATION OF APPROPRIATIONS.—There
23 are authorized to be appropriated to carry out this section
24 $39,500,000 for each of fiscal years 2010 through 2013,
25 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. 446. 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.

"(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 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 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 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 Com-

missioned 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 Workforce Commission established under section 411 of the Affordable Health Choices Act, 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 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 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. 451. 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 sub-

section (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 pro-

fessions 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 pro-

fessions 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. 452. 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. 453. 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 awards in accordance with this section.

"(b) INFRASTRUCTURE DEVELOPMENT AWARD.—

"(1) IN GENERAL.—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 of an area health education center program.

"(2) ELIGIBLE ENTITY.—For purposes of this subsection, an '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 paragraph (1) to a school of nursing.

"(3) APPLICATION.—An eligible entity desiring to receive an award under this subsection shall sub-

mit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

"(4) USE OF FUNDS.—

"(A) REQUIRED ACTIVITIES.—An eligible entity shall use amounts awarded under a grant under paragraph (1) to carry out the following activities:

"(i) 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.

"(ii) 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 pri-

mary 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.

''(iii) 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.

''(iv) 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.

"(v) 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.

"(vi) Propose and implement effective program and outcomes measurement and evaluation strategies.

"(B) INNOVATIVE OPPORTUNITIES.—An eligible entity may use amounts awarded under a grant under paragraph (1) to carry out any of the following activities:

"(i) 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.

"(ii) 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.

"(iii) 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.

"(c) POINT OF SERVICE MAINTENANCE AND ENHANCEMENT AWARD.—

"(1) IN GENERAL.—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 program.

"(2) ELIGIBLE ENTITY.—For purposes of this subsection, the term 'eligible entity' means an entity

that has received funds under this section (as this section was in effect on the day before the date of enactment of the Affordable Health Choices Act), is operating an area health education center program, including area health education centers, and has a center or centers that are no longer eligible to receive financial assistance under subsection (b).

"(3) APPLICATION.—An eligible entity desiring to receive an award under this subsection shall submit to the Secretary an application at such time, in such manner, and containing such information as the Secretary may require.

"(4) USE OF FUNDS.—

"(A) REQUIRED ACTIVITIES.—An eligible entity shall use amounts awarded under a grant under paragraph (1) to carry out the following activities:

"(i) 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 groups, underserved areas, or with rural backgrounds into

health care careers, and support such individuals in attaining such careers.

"(ii) 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 and to health disparity populations, in collaboration with other Federal and State health care workforce development programs, and in health care safety net sites.

"(iii) Prepare individuals to more effectively provide health services to underserved areas or 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, behavioral and mental health facili-

ties, public health departments, or other appropriate facilities.

"(iv) 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.

"(v) 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.

"(vi) Propose and implement effective program and outcomes measurement and evaluation strategies.

"(B) INNOVATIVE OPPORTUNITIES.—An eligible entity shall use amounts awarded under a grant under paragraph (1) to carry out at least 1 of the following activities:

"(i) Develop innovative curricula in collaboration with community-based ac-

1 credited primary care residency training
2 programs, Federally qualified health cen-
3 ters, rural health clinics, behavioral and
4 mental health facilities, public health de-
5 partments, or other appropriate facilities,
6 with the goal of increasing the number of
7 primary care physicians and other primary
8 care providers prepared to serve in under-
9 served areas and health disparity popu-
10 lations.

11 ''(ii) Coordinate community-based
12 participatory research with academic
13 health centers, and facilitate rapid flow
14 and dissemination of evidence-based health
15 care information, research results, and best
16 practices to improve quality, efficiency, and
17 effectiveness of health care and health care
18 systems within community settings.

19 ''(iii) Develop and implement other
20 strategies to address identified workforce
21 needs and increase and enhance the health
22 care workforce in the area served by the
23 area health education center program.

24 ''(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 places at least 10 percent of its students in training sites affiliated with an area health education center that is 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 at least 10 percent of students from that school in training sites in the area health education center program area.

"(B) An entity receiving funds under subsection (c) does not distribute such funding to a center that is eligible to receive funding under subsection (b).

"(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 geo-

graphic 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 (b).

"(f) LIMITATION.—Not less than 75 percent of the total amount provided to an area health education center program under subsection (b) or (c) 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 (b).

"(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 (k)(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 (b) 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 (c) 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 (b);

"(B) not less than 60 percent shall be used for awards under subsection (c);

"(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. 454. 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 associa-

tions 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. 455. 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 443, is further amended by adding at the end the following:

**''SEC. 399V. 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;

"(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 212 of the Affordable Health Choices 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.".

**SEC. 456. DEFINITION OF ECONOMIC HARDSHIP.**

Section 435(o) of the Higher Education Act of 1965 (20 U.S.C. 1085(o)) is amended—

(1) in paragraph (1)—

(A) in subparagraph (A)(ii), by striking "or" after the semicolon;

(B) by redesignating subparagraph (B) as subparagraph (C); and

(C) by inserting after subparagraph (A) the following:

"(B) such borrower is working full-time and has a Federal educational debt burden that equals or exceeds 20 percent of such borrower's adjusted gross income, and the difference between such borrower's adjusted gross income

minus such burden is less than 220 percent of the greater of—

"(i) the annual earnings of an individual earning the minimum wage under section 6 of the Fair Labor Standards Act of 1938; or

"(ii) 150 percent of the poverty line, as defined under section 673(2) of the Community Services Block Grant Act, applicable to such borrower's family size; or"; and

(2) in paragraph (2), by striking "(1)(B)" and inserting "(1)(C)".

# Subtitle F—General Provisions

**SEC. 461. 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 V—PREVENTING FRAUD AND ABUSE

## Subtitle A—Establishment of New Health and Human Services and Department of Justice Health Care Fraud Positions

**SEC. 501. HEALTH AND HUMAN SERVICES SENIOR ADVISOR.**

Part C of title XXVII of the Public Health Service Act (42 U.S.C. 300gg-91 et seq.) is amended—

(1) by redesignating section 2792 as section 2796; and

(2) by inserting after section 2791, the following:

**"SEC. 2792. SENIOR ADVISOR FOR HEALTH CARE FRAUD.**

"(a) ESTABLISHMENT.—The Secretary shall appoint an individual to serve as the Senior Advisor for Health Care Fraud (referred to in this section as the 'Senior Advisor') within the Office of the Deputy Secretary. The Senior Advisory shall be the principal advisor on policy and program development and oversight with respect to—

"(1) the detection and prevention of health care fraud, waste, and abuse involving public health in-

1 surance coverage and private health insurance cov-
2 erage; and
3 ''(2) the coordination of anti-fraud efforts with-
4 in the Department of Health and Human Services
5 and with the Inspector General, the Department of
6 Justice, other Federal agencies as appropriate, State
7 and local law enforcement, State regulatory agen-
8 cies, and private health insurance coverage.
9 ''(b) REQUIREMENTS.—The Senior Advisor shall—
10 ''(1) be an officer or employee of the Depart-
11 ment of Health and Human Services designated by
12 the Secretary for purposes of this section from
13 among the career officers and employees of the De-
14 partment who have the experience and expertise nec-
15 essary to carry out the duties specified in subsection
16 (a); or
17 ''(2) be an individual hired by the Secretary
18 from the private sector from among individuals in
19 the private sector who have the experience and ex-
20 pertise necessary to carry out the duties specified in
21 subsection (a).
22 ''(c) DEFINITION.—In this section, the term 'public
23 health insurance coverage' means coverage—
24 ''(1) provided under title XVIII, XIX, or XXI
25 of the Social Security Act;

"(2) provided under the veteran's health care program under chapter 17 of title 38, United States Code;

"(3) provided through the Indian Health Service;

"(4) under the TRICARE program under chapter 55 of title 10, United States Code; and

"(5) under the Federal Employees Health Benefits Program under chapter 89 of title 5, United States Code.".

**SEC. 502. DEPARTMENT OF JUSTICE POSITION.**

Chapter 41 of title 28, United States Code, is amended by adding at the end the following:

**"§ 614. Senior Counsel for Health Care Fraud Enforcement**

"The Attorney General shall appoint an individual to serve as the Senior Counsel for Health Care Fraud Enforcement (referred to in this section as the 'Senior Counsel') within the Office of the Deputy Attorney General to serve as the principal advisor to the Attorney General on policy and program development and oversight with respect to—

"(1) the investigation and prosecution of health care fraud and abuse involving public and private

health insurance coverage (as defined in section 2791 of the Public Health Service Act); and

''(2) the coordination of such efforts within the Department of Justice and with the Inspector General, the Department of Health and Human Services, other Federal agencies as appropriate, State and local law enforcement, State regulatory agencies, and private health insurance coverage.''.

**SEC. 503. REPORTS TO CONGRESS.**

(a) REPORTS.—The Senior Advisor for Health Care Fraud appointed under section 2792 of the Public Health Service Act and the Senior Counsel for Health Care Fraud Enforcement appointed under section 614 of title 28, United States Code, shall annually report to the Committee On Health, Education, Labor, and Pensions and the Committee on Finance of the Senate and the Committee on Ways and Means of the House of Representatives regarding the detection and prevention of health care fraud, waste, and abuse involving public health insurance and private health insurance coverage.

(b) DEFINITION.—In this section, the term ''public health insurance coverage'' means coverage—

(1) provided under title XVIII, XIX, or XXI of the Social Security Act;

(2) provided under the veteran's health care program under chapter 17 of title 38, United States Code;

(3) provided through the Indian Health Service;

(4) under the TRICARE program under chapter 55 of title 10, United States Code; and

(5) under the Federal Employees Health Benefits Program under chapter 89 of title 5, United States Code.

**SEC. 504. FRAUD, WASTE, AND ABUSE COMMISSION.**

(a) ESTABLISHMENT.—Not later than 180 days after the date of enactment of this Act, the President shall establish a commission to be composed of representatives appointed by the President from insurers, employers, health care providers, anti-fraud organizations, consumers and patient groups, and Federal officials to review Federal health care programs and private health insurance with respect to policies and procedures to eliminate fraud, waste, and abuse under such programs and to more effectively align public and private sector efforts to combat fraud, waste, and abuse.

(b) PERIOD OF REVIEW.—The commission under subsection (a) shall review the programs involved for a period of 2 years following the date on which such commission is established.

(c) REPORT.—Not later than 3 years after the date on which the commission under subsection (a) is established, the commission shall submit to the Committee on Health, Education, Labor, and Pensions and 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 concerning the review conducted under such subsection. Such report shall include recommendations for modify such programs and other recommendations to better coordinate public and private efforts to combat fraud and abuse.

(d) COOPERATION.—The President shall direct Federal officials to cooperate in the activities of the commission under this section. Commissioners shall have experience in fighting waste, fraud or abuse in the public and private sectors.

(e) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section, $5,000,000.

## Subtitle B—Health Care Program Integrity Coordinating Council

**SEC. 511. ESTABLISHMENT.**

Part C of title XXVII of the Public Health Service Act (42 U.S.C. 300gg-91 et seq.), as amended by section

501, is further amended by inserting after section 2793, the following:

**"SEC. 2794. HEALTH CARE PROGRAM INTEGRITY COORDINATING COUNCIL.**

"(a) ESTABLISHMENT.—There is established a council to be known as the 'Health Care Program Integrity Coordinating Council' (referred to in this section as the 'Council').

"(b) MEMBERSHIP.—The Council shall be composed of—

"(1) the Secretary of Health and Human Services;

"(2) the Attorney General;

"(3) the Inspector General for the Department of Health and Human Services;

"(4) the Secretary of Labor;

"(5) the Secretary of Defense;

"(6) the Director of the Office of Personnel Management;

"(7) the Under Secretary for Health for the Veterans Health Administration of the Department of Veterans Affairs;

"(8) the Commissioner of the Social Security Administration;

"(9) the President of the National Association of Insurance Commissioners;

"(10) the President of the National Association of Medicaid Fraud Control Units;

"(11) the Comptroller General of the United States;

"(12) the Inspector General of the Department of Labor;

"(13) the Inspector General of the Department of Defense;

"(14) the Inspector General of the Department of Veterans Affairs;

"(15) the Inspector General of the Department of Justice;

"(16) the chairperson and ranking member of relevant committees of jurisdiction of the Senate and the House of Representatives; and

"(17) any other member, the appointment of whom a majority of the members of the Council determines is necessary to carry out this title, except that an individual who is a representative of an entity subject to regulation under such Act shall not be appointed under this subparagraph.

"(c) DUTIES.—The Council shall—

"(1) not later than 6 months after the date of enactment of this section, develop a strategic plan for improving the coordination and information sharing among Federal agencies, State agencies, and private health insurance coverage with respect to the prevention, detection, and control of fraud, waste, and abuse, including fraud and abuse of consumers of the health care program or private health insurance issuers;

"(2) annually submit to Congress a report on actions taken to implement the strategic plan required under paragraph (1);

"(3) in carrying out the responsibilities identified under paragraph (1), evaluate ways to ensure that private health insurance coverage is included in investigative and data sharing programs, to the maximum extent feasible, with adequate protection provided for law enforcement-related data that is sensitive because of concerns for the identities of criminal subjects or targets, and that recognizes that private coverage may be responsible for fraud, waste, and abuse of public and policyholder funds;

"(4) not later than 12 months after the date of enactment of this section, develop and issue guidelines for purposes of carrying out the strategic plan

under paragraph (1), recognizing that fraudulent activity in the health care system can affect both public and private sector health insurance coverage, and that the prevention, detection, investigation, and prosecution of fraud against private health insurance coverage is integral to the overall effort to combat health care fraud;

''(5) at least once during every 5-year period, update the strategic plan issued pursuant to paragraph (1) and the guidelines issued pursuant to paragraph (4);

''(6) develop recommendations, in consultation with the Office of Management and Budget, for measures to estimate the amount of fraud, waste, and abuse in connection with public and private health insurance coverage, and the annual savings resulting from specific program integrity measures;

''(7) identify improvements needed for purposes of information-sharing systems and activities used in implementing the strategic plan under paragraph (1); and

''(8) establish a consultative panel composed of representatives of the private sector health insurance industry and consult with this panel in the formulation of Council recommendations.

"(d) EXEMPTIONS.—The Council shall be exempt from—

"(1) sections 553, 556, and 557 of title 5, United States Code, in the issuance of guidelines pursuant to subsection (c)(4); and

"(2) the Federal Advisory Committee Act (5 U.S.C. app.) in order to protect against the release of information which might undermine Federal, State, or local health care fraud control efforts.

"(e) PUBLIC PARTICIPATION.—The Council shall provide for reasonable public participation in matters before the Council to the extent that such participation would not compromise the Council's, or any other Federal, State, or local government entity's, efforts to control health care fraud and abuse.".

# Subtitle C—False Statements and Representations

## SEC. 521. 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.''.

# Subtitle D—Federal Health Care Offense

**SEC. 531. 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''.

# Subtitle E—Uniformity in Fraud and Abuse Reporting

**SEC. 541. 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.), as amended by section

511, is further amended by inserting after section 2794, the following:

**"SEC. 2795. 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.".

# Subtitle F—Applicability of State Law to Combat Fraud and Abuse

**SEC. 551. 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 521, 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 regu-

1 latory standards establishing, or issue an order relating
2 to a specific person establishing, that a person engaged
3 in the business of providing insurance through a multiple
4 employer welfare arrangement described in section 3(40)
5 is subject to the laws of the States in which such person
6 operates which regulate insurance in such State, notwith-
7 standing section 514(b)(6) of this Act or the Liability Risk
8 Retention Act of 1986, and regardless of whether the law
9 of the State is otherwise preempted under any of such pro-
10 visions. This section shall not apply to any plan or ar-
11 rangement that does not fall within the meaning of the
12 term 'multiple employer welfare arrangement' under sec-
13 tion 3(40(A).''.

14 (b) CONFORMING AMENDMENT.—The table of sec-
15 tions for part 5 of subtitle B of title I of the Employee
16 Retirement Income Security Act of 1974, as amended by
17 section 521, is further amended by adding at the end the
18 following:

''Sec. 520. Applicability of State law to combat fraud and abuse.''.

# Subtitle G—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

**SEC. 561. 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 551, 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 551, 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.".

# Subtitle H—Requiring Multiple Employer Welfare Arrangement (MEWA) Plans to File a Registration Form With the Department of Labor Prior to Enrolling Anyone in the Plan

**SEC. 571. 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''.

# Subtitle I—Permitting Evidentiary Privilege and Confidential Communications

## SEC. 581. 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.".

# TITLE VI—IMPROVING ACCESS TO INNOVATIVE MEDICAL THERAPIES

## Subtitle A—Biologics Price Competition and Innovation

**SEC. 601. 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. 602. 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 ap-

proved 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.

"(l) 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 ref-

erence 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 prod-

uct 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 in-

junctive 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 reason-

ably 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 spon-

sor 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 spon-

sor 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 sec-

tion 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

1 considered to have a new active ingredient under
2 this section.''.
3 (e) PRODUCTS PREVIOUSLY APPROVED UNDER SEC-
4 TION 505.—
5 (1) REQUIREMENT TO FOLLOW SECTION 351.—
6 Except as provided in paragraph (2), an application
7 for a biological product shall be submitted under
8 section 351 of the Public Health Service Act (42
9 U.S.C. 262) (as amended by this Act).
10 (2) EXCEPTION.—An application for a biologi-
11 cal product may be submitted under section 505 of
12 the Federal Food, Drug, and Cosmetic Act (21
13 U.S.C. 355) if—
14 (A) such biological product is in a product
15 class for which a biological product in such
16 product class is the subject of an application
17 approved under such section 505 not later than
18 the date of enactment of this Act; and
19 (B) such application—
20 (i) has been submitted to the Sec-
21 retary of Health and Human Services (re-
22 ferred to in this subtitle as the ''Sec-
23 retary'') before the date of enactment of
24 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) ALLOCATION OF SAVINGS; SPECIAL RESERVE FUND.—

(1) DETERMINATION OF SAVINGS.—The Secretary of the Treasury, in consultation with the Secretary, shall for each fiscal year determine the amount of the savings to the Federal Government as a result of the enactment of this subtitle and shall transfer such amount to the Fund established under paragraph (2) pursuant to a relevant appropriations Act.

(2) SPECIAL RESERVE FUND.—

(A) IN GENERAL.—There is established in the Treasury of the United States a fund to be designated as the ''Biological Product Savings Fund'' to be made available to the Secretary without fiscal year limitation.

(B) USE OF FUND.—The amounts made available to the Secretary through the Fund under subparagraph (A) shall be expended on activities authorized under the Public Health Service Act.

(3) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated for each fiscal year to the Fund established under paragraph

(2), the amount of the savings determined for such fiscal year under paragraph (1).

(h) GOVERNMENT ACCOUNTABILITY OFFICE STUDY.—

(1) IN GENERAL.—Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States shall study and report to Congress regarding—

(A) the extent to which pediatric studies of biological products are being required under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); and

(B) any pediatric needs not being met under existing authority.

(2) CONTENT OF STUDY.—The study under paragraph (1) shall review and assess—

(A) the extent to which pediatric studies of biological products are required under subsections (a) and (b) of section 505B of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355c);

(B) the extent to which pediatric studies of biological products are required as part of risk evaluation and mitigation strategies under such Act;

(C) the number, importance, and prioritization of any biological products that are not being tested for pediatric use; and

(D) recommendations for ensuring pediatric testing of products identified in subparagraph (C), including the consideration of any incentives, such as those provided under the Best Pharmaceuticals for Children Act.

(i) 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. 603. 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. 611. 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 non-compliance, 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 612 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 612 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. 612. 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 in-

tentional 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 Affordable Health Choices 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 ex-

ceeds 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 subparagraph (a)(5)(E), through one or more of the following actions:

"(I) Where a covered entity knowingly and intentionally violates subparagraph (a)(5)(B), the covered entity shall be required to pay a mon-

etary penalty to a manufacturer or manufacturers in the form of interest on sums for which the covered entity is found liable under paragraph (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 subparagraph (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 Serv-

ices, 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 Affordable Health Choices 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 manufac-

turer 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 611(c), by inserting ''after audit as described in subparagraph (D) and'' after ''finds,''.

**SEC. 613. 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 en-

actment 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.