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111TH CONGRESS
1ST SESSION

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[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.

IN THE SENATE OF THE UNITED STATES

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

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.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*

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

4 (a) SHORT TITLE.—This Act may be cited as the
5 “Affordable Health Choices Act”.

2

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

Sec. 121. Amendment to the Public Health Service Act.

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

PART III—OTHER PROVISIONS

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.

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“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. 187. Key National indicators.
- Sec. 188. Study and report on rates of preventable diseases in new Medicare enrollees.
- Sec. 189. Transparency in government.
- Sec. 189A. Preserving the solvency of Medicare and Social Security.
- Sec. 189B. Prohibition against discrimination on assisted suicide.
- Sec. 189C. Access to therapies.
- Sec. 189D. Freedom not to participate in Federal health insurance programs.

Subtitle H—CLASS Act

- Sec. 190. Short title of subtitle.
- Sec. 191. Establishment of national voluntary insurance program for purchasing community living assistance services and support.

“TITLE XXXII—COMMUNITY LIVING ASSISTANCE SERVICES AND SUPPORTS

- “Sec. 3201. Purpose.
- “Sec. 3202. Definitions.
- “Sec. 3203. CLASS Independence Benefit Plan.
- “Sec. 3204. Enrollment and disenrollment requirements.
- “Sec. 3205. Benefits.
- “Sec. 3206. CLASS Independence Fund.
- “Sec. 3207. CLASS Independence Advisory Council.
- “Sec. 3208. Regulations; annual report.
- “Sec. 3209. Inspector General’s report.
- “Sec. 3210. Tax treatment of program.

TITLE II—IMPROVING THE QUALITY AND EFFICIENCY OF HEALTH CARE

Subtitle A—National Strategy to Improve Health Care Quality

- Sec. 201. National strategy.
- Sec. 202. Interagency Working Group on Health Care Quality.
- Sec. 203. Quality measure development.
- Sec. 204. Quality measure endorsement; public reporting; data collection.
- Sec. 205. Collection and analysis of data for quality and resource use measures.

Subtitle B—Health Care Quality Improvements

- Sec. 211. Health care delivery system research; Quality improvement technical assistance.
- Sec. 212. Grants to establish community health teams to support the patient-centered medical home.
- Sec. 213. Grants to implement medication management services in treatment of chronic disease.
- Sec. 214. Design and implementation of regionalized systems for emergency care.
- Sec. 215. Trauma care centers and service availability.
- Sec. 216. Reducing and reporting hospital readmissions.
- Sec. 217. Program to facilitate shared decisionmaking.
- Sec. 218. Presentation of prescription drug benefit and risk information.
- Sec. 219. Center for health outcomes research and evaluation.
- Sec. 220. Demonstration program to integrate quality improvement and patient safety training into clinical education of health professionals.

- Sec. 221. Office of women's health.
- Sec. 222. Administrative simplification.
- Sec. 223. Patient navigator program.
- Sec. 224. Authorization of appropriations.

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.
- Sec. 232. Exception to limitation on certain physician referrals (under Stark) for provision of health information technology and training services to health care professionals.
- Sec. 233. Rules of construction regarding use of consortia.

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.
- Sec. 302. Prevention and Public Health Fund.
- Sec. 303. Clinical and Community Preventive Services.
- Sec. 304. Education and outreach campaign regarding preventive benefits.

Subtitle B—Increasing Access to Clinical Preventive Services

- Sec. 311. Right choices program.
- Sec. 312. School-based health clinics.
- Sec. 313. Oral healthcare prevention activities.
- Sec. 314. Oral health improvement.

Subtitle C—Creating Healthier Communities

- Sec. 321. Community transformation grants.
- Sec. 322. Healthy aging, living well.
- Sec. 323. Wellness for individuals with disabilities.
- Sec. 324. Immunizations.
- Sec. 325. Nutrition labeling of standard menu items at chain restaurants and of articles of food sold from vending machines.
- Sec. 326. Encouraging employer-sponsored wellness programs.
- Sec. 327. Demonstration project concerning individualized wellness plan.
- Sec. 328. Reasonable break time for nursing mothers.

Subtitle D—Support for Prevention and Public Health Innovation

- Sec. 331. Research on optimizing the delivery of public health services.
- Sec. 332. Understanding health disparities: data collection and analysis.
- Sec. 333. Health impact assessments.
- Sec. 334. CDC and employer-based wellness programs.
- Sec. 335. Epidemiology-Laboratory Capacity Grants.
- Sec. 336. Federal messaging on health promotion and disease prevention.

Subtitle E—Advancing Research and Treatment for Pain Care Management

- Sec. 341. Institute of Medicine Conference on Pain.
- Sec. 342. Pain research at National Institutes of Health.
- Sec. 343. Pain care education and training.

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Sec. 344. Public awareness campaign on pain management.

Subtitle F—Coordinated Environmental Public Health Network

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TITLE IV—HEALTH CARE WORKFORCE

Subtitle A—Purpose and Definitions

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Sec. 402. Definitions.

Subtitle B—Innovations in the Health Care Workforce

Sec. 411. National health care workforce commission.

Sec. 412. State health care workforce development grants.

Sec. 413. Health care workforce program assessment.

Subtitle C—Increasing the Supply of the Health Care Workforce

Sec. 421. Federally supported student loan funds.

Sec. 422. Nursing student loan program.

Sec. 423. Health care workforce loan repayment programs.

Sec. 424. Public health workforce recruitment and retention programs.

Sec. 425. Allied health workforce recruitment and retention programs.

Sec. 426. Grants for State and local programs.

Sec. 427. Funding for National Health Service Corps.

Sec. 428. Nurse-managed health clinics.

Sec. 429. Elimination of cap on commissioned corps.

Sec. 430. Establishing a 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.

Sec. 432. Training opportunities for direct care workers.

Sec. 433. Training in general, pediatric, and public health dentistry.

Sec. 434. Alternative dental health care providers demonstration project.

Sec. 435. Geriatric education and training; career awards; comprehensive geriatric education.

Sec. 436. Mental and behavioral health education and training grants.

Sec. 437. Cultural competency, prevention and public health and individuals with disabilities training.

Sec. 438. Advanced nursing education grants.

Sec. 439. Nurse education, practice, and retention grants.

Sec. 440. Loan repayment and scholarship program.

Sec. 441. Nurse faculty loan program.

Sec. 442. Authorization of appropriations for parts B through D of title VIII.

Sec. 443. Grants to promote the community health workforce.

Sec. 444. Youth public health program.

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Sec. 446. United States Public Health Sciences Track.

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Subtitle E—Supporting the Existing Health Care Workforce

- Sec. 451. Centers of excellence.
- Sec. 452. Health care professionals training for diversity.
- Sec. 453. Interdisciplinary, community-based linkages.
- Sec. 454. Workforce diversity grants.
- Sec. 455. Primary care extension program.
- Sec. 456. Definition of economic hardship.

Subtitle F—General Provisions

- Sec. 461. Reports.

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.
- Sec. 502. Department of Justice Position.
- Sec. 503. Reports to Congress.
- Sec. 504. Fraud, waste, and abuse commission.

Subtitle B—Health Care Program Integrity Coordinating Council

- Sec. 511. Establishment.

Subtitle C—False Statements and Representations

- Sec. 521. Prohibition on false statements and representations.

Subtitle D—Federal Health Care Offense

- Sec. 531. Clarifying definition.

Subtitle E—Uniformity in Fraud and Abuse Reporting

- Sec. 541. Development of model uniform report form.

Subtitle F—Applicability of State Law to Combat Fraud and Abuse

- Sec. 551. Applicability of State law to combat fraud and abuse.

Subtitle G—Enabling the Department of Labor to Issue Administrative Sum-
mary Cease and Desist Orders and Summary Seizures Orders Against
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- 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.

Subtitle H—Requiring Multiple Employer Welfare Arrangement (MEWA)
Plans to File a Registration Form With the Department of Labor Prior to
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- Sec. 571. MEWA plan registration with Department of Labor.

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- Sec. 581. Permitting evidentiary privilege and confidential communications.

TITLE VI—IMPROVING ACCESS TO INNOVATIVE MEDICAL
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Subtitle A—Biologics Price Competition and Innovation

Sec. 601. Short title.

Sec. 602. Approval pathway for biosimilar biological products.

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Sec. 611. Expanded participation in 340B program.

Sec. 612. Improvements to 340B program integrity.

Sec. 613. GAO study to make recommendations on improving the 340B pro-
gram.

1 **TITLE I—QUALITY, AFFORDABLE**
2 **HEALTH CARE FOR ALL**
3 **AMERICANS**

4 **Subtitle A—Effective Coverage for**
5 **All Americans**

6 **PART I—PROVISIONS APPLICABLE TO THE**
7 **INDIVIDUAL AND GROUP MARKETS**

8 **SEC. 101. AMENDMENT TO THE PUBLIC HEALTH SERVICE**
9 **ACT.**

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

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

14 **“PART A—INDIVIDUAL AND GROUP MARKET**
15 **REFORMS**

16 **“Subpart 1—General Reform”;**

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

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

3 **“SEC. 2705. PROHIBITION OF PREEXISTING CONDITION EX-**
4 **CLUSIONS OR OTHER DISCRIMINATION**
5 **BASED ON HEALTH STATUS.**

6 “(a) IN GENERAL.—A group health plan and a health
7 insurance issuer offering group or individual health insur-
8 ance coverage may not impose any preexisting condition
9 exclusion with respect to such plan or coverage.”; and

10 (B) by transferring the remainder of sec-
11 tion so as to appear after the section 2704 as
12 added by paragraph (5);

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

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

16 (B) in subsection (b)—

17 (i) by striking “health insurance
18 issuer offering health insurance coverage in
19 connection with a group health plan” each
20 place that such appears and inserting
21 “health insurance issuer offering group or
22 individual health insurance coverage”; and

23 (ii) in paragraph (2)(A)—

24 (I) by inserting “or individual”
25 after “employer”; and

1 (II) by inserting “or individual
2 health coverage, as the case may be”
3 before the semicolon;

4 (C) by redesignating subsections (b)
5 through (f) as subsections (e) through (i), re-
6 spectively; and

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

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

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

16 **“SEC. 2701. FAIR INSURANCE COVERAGE.**

17 “(a) IN GENERAL.—With respect to the premium
18 rate charged by a health insurance issuer for health insur-
19 ance coverage offered in the individual or small group
20 market—

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

23 “(A) family structure;

24 “(B) community rating area;

25 “(C) the actuarial value of the benefit;

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

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

5 “(F) adherence to or participation in a
6 reasonably designed program of health pro-
7 motion and disease prevention, if such a pro-
8 gram is offered by the employer that is the
9 sponsor of the coverage involved; and

10 “(2) such rate shall not vary with respect to the
11 particular plan or coverage involved by health sta-
12 tus-related factors, gender, class of business, claims
13 experience, industry, or any other factor not de-
14 scribed in paragraph (1), except that group health
15 plans and health insurance issuers offering group
16 health insurance coverage may establish premium
17 discounts or rebates for modifying otherwise applica-
18 ble copayments or deductibles in return for adher-
19 ence to or participation in reasonably designed pro-
20 grams of health promotion or disease prevention.

21 “(b) COMMUNITY RATING AREA.—Taking into ac-
22 count the applicable recommendations of the National As-
23 sociation of Insurance Commissioners, the Secretary shall
24 by regulation establish a minimum size for community rat-
25 ing areas for purposes of this section, which, for areas con-

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

3 **“SEC. 2702. GUARANTEED AVAILABILITY OF COVERAGE.**

4 “(a) ISSUANCE OF COVERAGE IN THE INDIVIDUAL
5 AND GROUP MARKET.—Subject to subsections (b)
6 through (e), each health insurance issuer that offers
7 health insurance coverage in the individual or group mar-
8 ket in a State must accept every employer and individual
9 in the State that applies for such coverage.

10 “(b) ENROLLMENT.—

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

15 “(2) ESTABLISHMENT.—A health insurance
16 issuer described in subsection (a) shall, in accord-
17 ance with the regulations promulgated under para-
18 graph (3), establish special enrollment periods for
19 qualifying events (under section 603 of the Em-
20 ployee Retirement Income Security Act of 1974).

21 “(3) REGULATIONS.—Not later than 1 year
22 after the date of enactment of this section, the Sec-
23 retary shall promulgate regulations with respect to
24 enrollment periods under paragraphs (1) and (2).

1 **“SEC. 2703. GUARANTEED RENEWABILITY OF COVERAGE.**

2 “(a) IN GENERAL.—Except as provided in this sec-
3 tion, if a health insurance issuer offers health insurance
4 coverage in the individual or group market, the issuer
5 must renew or continue in force such coverage at the op-
6 tion of the plan sponsor or the individual, as applicable.

7 “(b) PROHIBITION ON RESCISSIONS.—A group
8 health plan and a health insurance issuer offering group
9 or individual health insurance coverage shall not rescind
10 such coverage once the plan involved has been issued, ex-
11 cept that this subsection shall not apply to a covered indi-
12 vidual who has performed an act or practice that con-
13 stitutes fraud or makes an intentional misrepresentation
14 of material fact as prohibited by the terms of the coverage.
15 Coverage may not be cancelled except with prior notice
16 to the enrollee, and only as permitted under section
17 2702(c) or 2742(b).

18 **“SEC. 2704. INCREASING THE TRANSPARENCY OF HEALTH**
19 **CARE COSTS AND REGULATORY FEES.**

20 “(a) CLEAR ACCOUNTING FOR COSTS.—A health in-
21 surance issuer offering group or individual health insur-
22 ance coverage shall publicly report (in a manner to be es-
23 tablished by the Secretary through regulation) the per-
24 centage of total premium revenue that such coverage ex-
25 pends—

1 “(1) on reimbursement for clinical services pro-
2 vided to enrollees under such plan or coverage;

3 “(2) for activities that improve health care
4 quality;

5 “(3) on taxes, license, or regulatory fee costs,
6 and the cost of any surcharge imposed by the Gate-
7 way under title XXXI; and

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

12 “(b) DEFINITION.—In this section, the term ‘activi-
13 ties to improve health care quality’ means activities de-
14 scribed in section 2707.

15 “(c) PROCESSES AND METHODS.—The Secretary
16 shall develop a methodology for calculating the percent-
17 ages described in subsection (a). Such methodology may
18 provide for a requirement that a report described in sub-
19 section (a) include an actuarial certification of the infor-
20 mation included in such report.

21 **“SEC. 2706. PROHIBITING DISCRIMINATION AGAINST INDIVIDUAL PARTICIPANTS AND BENEFICIARIES**
22 **BASED ON HEALTH STATUS.**
23

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

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

6 “(1) Health status.

7 “(2) Medical condition (including both physical
8 and mental illnesses).

9 “(3) Claims experience.

10 “(4) Receipt of health care.

11 “(5) Medical history.

12 “(6) Genetic information.

13 “(7) Evidence of insurability (including condi-
14 tions arising out of acts of domestic violence).

15 “(8) Disability.

16 “(9) Any other health status-related factor de-
17 termined appropriate by the Secretary.

18 “(b) PROGRAMS OF HEALTH PROMOTION OR DIS-
19 EASE PREVENTION.—

20 “(1) GENERAL PROVISIONS.—

21 “(A) GENERAL RULE.—For purposes of
22 paragraph (2)(B), a program of health pro-
23 motion or disease prevention (referred to in this
24 subsection as a ‘wellness program’) shall be a
25 program offered by an employer that is de-

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

4 “(B) NO CONDITIONS BASED ON HEALTH
5 STATUS FACTOR.—If none of the conditions for
6 obtaining a premium discount or rebate or
7 other reward for participation in a wellness pro-
8 gram is based on an individual satisfying a
9 standard that is related to a health status fac-
10 tor, such wellness program shall not violate this
11 section if participation in the program is made
12 available to all similarly situated individuals
13 and the requirements of paragraph (2) are com-
14 plied with.

15 “(C) CONDITIONS BASED ON HEALTH STA-
16 TUS FACTOR.—If any of the conditions for ob-
17 taining a premium discount or rebate or other
18 reward for participation in a wellness program
19 is based on an individual satisfying a standard
20 that is related to a health status factor, such
21 wellness program shall not violate this section if
22 the requirements of paragraph (3) are complied
23 with.

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

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

13 “(A) A program that reimburses all or
14 part of the cost for memberships in a fitness
15 center.

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

19 “(C) A program that encourages preven-
20 tive care related to a health condition through
21 the waiver of the copayment or deductible re-
22 quirement under an individual or group health
23 plan for the costs of certain items or services
24 related to a health condition (such as prenatal
25 care or well-baby visits).

1 “(D) A program that reimburses individ-
2 uals for the costs of smoking cessation pro-
3 grams without regard to whether the individual
4 quits smoking.

5 “(E) A program that provides a reward to
6 individuals for attending a periodic health edu-
7 cation seminar.

8 “(3) WELLNESS PROGRAMS SUBJECT TO RE-
9 QUIREMENTS.—If any of the conditions for obtaining
10 a premium discount, rebate, or reward under a
11 wellness program as described in paragraph (1)(C)
12 is based on an individual satisfying a standard that
13 is related to a health status factor, the wellness pro-
14 gram shall not violate this section if the following re-
15 quirements are complied with:

16 “(A) The reward for the wellness program,
17 together with the reward for other wellness pro-
18 grams with respect to the plan that requires
19 satisfaction of a standard related to a health
20 status factor, shall not exceed 30 percent of the
21 cost of employee-only coverage under the plan.
22 If, in addition to employees or individuals, any
23 class of dependents (such as spouses or spouses
24 and dependent children) may participate fully
25 in the wellness program, such reward shall not

1 exceed 30 percent of the cost of the coverage in
2 which an employee or individual and any de-
3 pendents are enrolled. For purposes of this
4 paragraph, the cost of coverage shall be deter-
5 mined based on the total amount of employer
6 and employee contributions for the benefit
7 package under which the employee is (or the
8 employee and any dependents are) receiving
9 coverage. A reward may be in the form of a dis-
10 count or rebate of a premium or contribution,
11 a waiver of all or part of a cost-sharing mecha-
12 nism (such as deductibles, copayments, or coin-
13 surance), the absence of a surcharge, or the
14 value of a benefit that would otherwise not be
15 provided under the plan. The Secretaries of
16 Labor, Health and Human Services, and the
17 Treasury may increase the reward available
18 under this subparagraph to up to 50 percent of
19 the cost of coverage if the Secretaries determine
20 that such an increase is appropriate.

21 “(B) The wellness program shall be rea-
22 sonably designed to promote health or prevent
23 disease. A program complies with the preceding
24 sentence if the program has a reasonable
25 chance of improving the health of, or preventing

1 disease in, participating individuals and it is
2 not overly burdensome, is not a subterfuge for
3 discriminating based on a health status factor,
4 and is not highly suspect in the method chosen
5 to promote health or prevent disease. The plan
6 or issuer shall evaluate the program's reason-
7 ableness at least once per year.

8 “(C) The plan shall give individuals eligible
9 for the program the opportunity to qualify for
10 the reward under the program at least once
11 each year.

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

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

19 “(I) for a reasonable alternative
20 standard (or waiver of the otherwise
21 applicable standard) for obtaining the
22 reward for any individual for whom,
23 for that period, it is unreasonably dif-
24 ficult 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-

1 closure under this subparagraph shall not be re-
2 quired.

3 “(c) EXISTING PROGRAMS.—Nothing in this section
4 shall prohibit a program of health promotion or disease
5 prevention that was established prior to the date of enact-
6 ment of this section and applied with all applicable regula-
7 tions, and that is operating on such date, from continuing
8 to be carried out for as long as such regulations remain
9 in effect.

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

14 **“SEC. 2707. ENSURING THE QUALITY OF CARE.**

15 “(a) IN GENERAL.—Except as provided in subsection
16 (c), a group health plan and a health insurance issuer of-
17 fering group or individual health insurance coverage shall
18 develop and implement a reimbursement structure for
19 making payments to health care providers that provides
20 incentives for—

21 “(1) the provision of high quality health care
22 under the plan or coverage in a manner that in-
23 cludes—

24 “(A) the implementation of case manage-
25 ment, care coordination, chronic disease man-

1 agement, and medication and care compliance
2 activities that includes the use of the medical
3 home model as defined in section 212 of the Af-
4 fordable Health Choices Act for treatment or
5 services under the plan or coverage;

6 “(B) the implementation of activities to
7 prevent hospital readmissions through a com-
8 prehensive program for hospital discharge that
9 includes patient-centered education and coun-
10 seling, comprehensive discharge planning, and
11 post-discharge reinforcement by an appropriate
12 health care professional;

13 “(C) the implementation of activities to
14 improve patient safety and reduce medical er-
15 rors through the appropriate use of best clinical
16 practices, evidence based medicine, and health
17 information technology under the plan or cov-
18 erage;

19 “(D) the implementation of wellness and
20 health promotion activities;

21 “(E) child health measures under section
22 1139A of the Social Security Act; and

23 “(F) culturally and linguistically appro-
24 priate care, as defined by the Secretary; and

1 “(2) payment policies that substantially reflects
2 the payment policy of the Medicare program under
3 title XVIII of the Social Security Act and the Chil-
4 dren’s Health Insurance Program under title XXI of
5 such Act with respect to any generally implemented
6 incentive policy to promote high quality health care,
7 except that in order that no plan or issuer be forced
8 to deny patients medical care needed to prevent
9 their deaths or preserve or restore their health, no
10 plan or issuer shall be prohibited from providing
11 payment for a treatment or diagnostic procedure it
12 chooses to cover, unless such treatment or procedure
13 has been determined to be unsafe or dangerous or
14 capable of neither preventing the patient’s death nor
15 preserving or restoring the patient’s health.

16 “(b) WELLNESS AND PREVENTION PROGRAMS.—For
17 purposes of subsection (a)(1)(D), wellness and health pro-
18 motion activities may include personalized wellness and
19 prevention services, which are coordinated, maintained or
20 delivered by a health care provider, a wellness and preven-
21 tion plan manager, or a health, wellness or prevention
22 services organization that conducts health risk assess-
23 ments or offer ongoing face-to-face, telephonic or web-
24 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

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

4 “(e) STUDY AND REPORT.—Not later than 180 days
5 after the date of enactment of the Affordable Health
6 Choices Act, the Government Accountability Office shall
7 conduct a study and submit to the Committee on Health,
8 Education, Labor, and Pensions of the Senate and the
9 Committee on Energy and Commerce of the House of
10 Representatives a report regarding the impact the activi-
11 ties under this section have had on the quality and cost
12 of health care.

13 **“SEC. 2708. COVERAGE OF PREVENTIVE HEALTH SERVICES.**

14 “(a) IN GENERAL.—A group health plan and a health
15 insurance issuer offering group or individual health insur-
16 ance coverage shall provide coverage for and shall not im-
17 pose any cost sharing requirements (other than minimal
18 cost sharing in accordance with guidelines developed by
19 the Secretary) for—

20 “(1) evidence-based items or services that have
21 in effect a rating of ‘A’ or ‘B’ in the current rec-
22 ommendations of the United States Preventive Serv-
23 ices Task Force;

24 “(2) immunizations that have in effect a rec-
25 ommendation 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

1 accordance with guidelines developed by the Secretary)
2 for, with respect to women (including pregnant women
3 and individuals of child bearing age), such additional pre-
4 ventive care and screenings not covered under section
5 2708 as provided for in guidelines supported by the
6 Health Resources and Services Administration.

7 **“SEC. 2710. EXTENSION OF DEPENDENT COVERAGE.**

8 “(a) IN GENERAL.—A group health plan and a health
9 insurance issuer offering group or individual health insur-
10 ance coverage that provides dependent coverage of chil-
11 dren shall continue to make such coverage available for
12 an adult child until the child turns 26 years of age. Noth-
13 ing in this section shall require a health plan or a health
14 insurance issuer described in the preceding sentence to
15 make coverage available for a child of a child receiving
16 dependent coverage.

17 “(b) REGULATIONS.—The Secretary shall promul-
18 gate regulations to define the dependents to which cov-
19 erage shall be made available under subsection (a).

20 **“SEC. 2711. NO LIFETIME OR ANNUAL LIMITS.**

21 “(a) IN GENERAL.—A group health plan and a health
22 insurance issuer offering group or individual health insur-
23 ance coverage may not establish lifetime or annual limits
24 on the dollar value of benefits for any participant or bene-
25 ficiary.

1 “(b) PREVENTING FRAUD AND ABUSE.—This section
2 shall not apply until the date on which the Secretary cer-
3 tifies that enacting this section will not result in undue
4 proliferation of fraud and abuse, especially with regard to
5 durable medical equipment.

6 **“SEC. 2712. NOTIFICATION BY PLANS NOT PROVIDING MIN-**
7 **IMUM QUALIFYING COVERAGE.**

8 “(a) IN GENERAL.—Not later than 1 year after the
9 date on which the Secretary establishes criteria with re-
10 spect to minimum qualifying coverage under section 3103,
11 a group health plan and a health insurance issuer offering
12 group or individual health insurance coverage that fails
13 to provide such minimum qualifying coverage shall notify,
14 in such manner as may be required by the Secretary, en-
15 rollees and prospective enrollees in such plan or coverage
16 of such failure prior to enrollment or re-enrollment.

17 “(b) MODIFICATIONS.—If the Secretary modifies the
18 criteria with respect to minimum qualifying coverage
19 under section 3103, a group health plan or health insur-
20 ance issuer that fails to provide such modified minimum
21 qualifying coverage shall provide the notice required under
22 subsection (a) within 60 days of the date of such modifica-
23 tion.

1 **“SEC. 2713. NON-DISCRIMINATION IN HEALTH CARE.**

2 “A group health plan and a health insurance issuer
3 offering group or individual health insurance coverage
4 shall not discriminate with respect to participation under
5 the plan or coverage against any health care provider who
6 is acting within the scope of that provider’s license or cer-
7 tification under applicable State law. This section shall not
8 require that a group health plan or health insurance issuer
9 contract with any health care provider willing to abide by
10 the terms and conditions for participation established by
11 the plan or issuer. Nothing in this section shall be con-
12 strued as preventing a group health plan, a health insur-
13 ance issuer, or the Secretary from establishing varying re-
14 imbursement rates based on quality or performance meas-
15 ures.”.

16 **PART II—PROVISION APPLICABLE TO THE**
17 **GROUP MARKET**

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

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

23 **“SEC. 2720A. PROHIBITION OF DISCRIMINATION BASED ON**
24 **SALARY.**

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

1 may not establish rules relating to the health insurance
2 coverage eligibility (including continued eligibility) of any
3 full-time employee under the terms of the plan that are
4 based on the total hourly or annual salary of the employee.
5 “(b) LIMITATION.—Subsection (a) shall not be con-
6 strued to prohibit a group health plan or health insurance
7 issuer from establishing contribution requirements for en-
8 rollment in the plan or coverage that provide for the pay-
9 ment by employees with lower hourly or annual compensa-
10 tion of a lower dollar or percentage contribution than the
11 payment required of a similarly situated employees with
12 a higher hourly or annual compensation.”.

13 **PART III—OTHER PROVISIONS**

14 **SEC. 131. NO CHANGES TO EXISTING COVERAGE.**

15 (a) OPTION TO RETAIN CURRENT INSURANCE COV-
16 ERAGE.—

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

23 (2) CONTINUATION OF COVERAGE.—With re-
24 spect to a group health plan or health insurance cov-
25 erage in which an individual was enrolled prior to

1 the date of enactment of this title, this subtitle (and
2 the amendments made by this subtitle) shall not
3 apply to such plan or coverage, regardless of wheth-
4 er the individual renews such coverage after such
5 date of enactment.

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

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

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

1 (e) LIMITATION.—Subsections (a) through (d) shall
2 not apply to any group health plan or health insurance
3 coverage that has been modified to a significant extent
4 with respect to covered benefits or cost sharing require-
5 ments after the date of enactment of this Act. The Sec-
6 retary shall by regulation establish criteria to determine
7 whether a plan or health insurance coverage has been
8 modified to a significant extent under the preceding sen-
9 tence, except that any coverage amendment made pursu-
10 ant to an agreement between an employer or an individual
11 and a health insurance issuer relating to the coverage
12 which amends the coverage solely to conform to any re-
13 quirement added by this Act (or amendments to this Act)
14 shall not be treated as a significant modification.

15 (f) EFFECT ON COLLECTIVE BARGAINING AGREE-
16 MENTS.—In the case of health insurance coverage main-
17 tained pursuant to one or more collective bargaining
18 agreements between employee representatives and one or
19 more employers that was ratified before the date of enact-
20 ment of this title, the provisions of this subtitle (and the
21 amendments made by this subtitle) shall not apply until
22 the date on which the last of the collective bargaining
23 agreements relating to the coverage terminates. Any cov-
24 erage amendment made pursuant to a collective bar-
25 gaining agreement relating to the coverage which amends

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

4 (g) RISK ADJUSTMENT.—The provisions of section
5 3101(c)(6) of the Public Health Service Act (as added by
6 section 142) shall not apply to a group health plan or
7 health insurance coverage to which this section applies.

8 **SEC. 132. APPLICABILITY.**

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

11 (1) by striking subsection (a);

12 (2) in subsection (b)—

13 (A) in paragraph (1), by striking “1
14 through 3” and inserting “1 and 2”; and

15 (B) in paragraph (2)—

16 (i) in subparagraph (A), by striking
17 “subparagraph (D)” and inserting “sub-
18 paragraph (D) or (E)”;
19

20 (ii) by striking “1 through 3” and in-
serting “1 and 2”; and

21 (iii) by adding at the end the fol-
22 lowing:

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

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

3 (3) in subsection (c), by striking “1 through 3
4 shall not apply to any group” and inserting “1 and
5 2 shall not apply to any individual coverage or any
6 group”; and

7 (4) in subsection (d)—

8 (A) in paragraph (1), by striking “1
9 through 3 shall not apply to any group” and in-
10 sserting “1 and 2 shall not apply to any indi-
11 vidual coverage or any group”;

12 (B) in paragraph (2)—

13 (i) in the matter preceding subpara-
14 graph (A), by striking “1 through 3 shall
15 not apply to any group” and inserting “1
16 and 2 shall not apply to any individual cov-
17 erage or any group”; and

18 (ii) in subparagraph (C), by inserting
19 “or, with respect to individual coverage,
20 under any health insurance coverage main-
21 tained by the same health insurance
22 issuer”; and

23 (C) in paragraph (3), by striking “any
24 group” and inserting “any individual coverage
25 or any group”.

1 **SEC. 133. CONFORMING AMENDMENTS.**

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

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

7 (A) in subsection (c)—

8 (i) in paragraph (2), by striking
9 “group health plan” each place that such
10 appears and inserting “group or individual
11 health plan”; and

12 (ii) in paragraph (3)—

13 (I) by striking “group health in-
14 surance” each place that such appears
15 and inserting “group or individual
16 health insurance”; and

17 (II) in subparagraph (D), by
18 striking “small or large” and insert-
19 ing “individual or group”;

20 (B) in subsection (d), by striking “group
21 health insurance” each place that such appears
22 and inserting “group or individual health insur-
23 ance”; and

24 (C) in subsection (e)(1)(A), by striking
25 “group health insurance” and inserting “group
26 or individual health insurance”;

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

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

5 (A) in subsection (a), by striking “health
6 insurance issuer offering group health insur-
7 ance coverage” and inserting “health insurance
8 issuer offering group or individual health insur-
9 ance coverage”;

10 (B) in subsection (b)—

11 (i) by striking “health insurance
12 issuer offering group health insurance cov-
13 erage in connection with a group health
14 plan” in the matter preceding paragraph
15 (1) and inserting “health insurance issuer
16 offering group or individual health insur-
17 ance coverage”; and

18 (ii) in paragraph (1), by striking
19 “plan” and inserting “plan or coverage”;

20 (C) in subsection (c)—

21 (i) in paragraph (2), by striking
22 “group health insurance coverage offered
23 by a health insurance issuer” and inserting
24 “health insurance issuer offering group or
25 individual health insurance coverage”; and

1 (ii) in paragraph (3), by striking
2 “issuer” and inserting “health insurance
3 issuer”; and

4 (D) in subsection (e), by striking “health
5 insurance issuer offering group health insur-
6 ance coverage” and inserting “health insurance
7 issuer offering group or individual health insur-
8 ance coverage”;

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

11 (A) in subsection (a), by striking “(or
12 health insurance coverage offered in connection
13 with such a plan)” each place that such appears
14 and inserting “or a health insurance issuer of-
15 fering group or individual health insurance cov-
16 erage”;

17 (B) in subsection (b), by striking “(or
18 health insurance coverage offered in connection
19 with such a plan)” each place that such appears
20 and inserting “or a health insurance issuer of-
21 fering group or individual health insurance cov-
22 erage”; and

23 (C) in subsection (c)—

24 (i) in paragraph (1), by striking “(and
25 group health insurance coverage offered in

1 connection with a group health plan)” and
2 inserting “and a health insurance issuer
3 offering group or individual health insur-
4 ance coverage”;

5 (ii) in paragraph (2), by striking “(or
6 health insurance coverage offered in con-
7 nection with such a plan)” each place that
8 such appears and inserting “or a health in-
9 surance issuer offering group or individual
10 health insurance coverage”;

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

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

19 (A) in subsection (a), by striking “health
20 insurance coverage offered in connection with
21 such plan” and inserting “individual health in-
22 surance coverage”;

23 (B) in subsection (b)—

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

1 health insurance coverage in connection
2 with a group health plan” and inserting
3 “or a health insurance issuer that offers
4 group or individual health insurance cov-
5 erage”;

6 (ii) in paragraph (2), by striking
7 “health insurance coverage offered in con-
8 nection with the plan” and inserting “indi-
9 vidual health insurance coverage”; and

10 (iii) in paragraph (3), by striking
11 “health insurance coverage offered by an
12 issuer in connection with such plan” and
13 inserting “individual health insurance cov-
14 erage”;

15 (C) in subsection (c), by striking “health
16 insurance issuer providing health insurance cov-
17 erage in connection with a group health plan”
18 and inserting “health insurance issuer that of-
19 fers group or individual health insurance cov-
20 erage”; and

21 (D) in subsection (e)(1), by striking
22 “health insurance coverage offered in connec-
23 tion with such a plan” and inserting “individual
24 health insurance coverage”;

25 (7) by striking the heading for subpart 3;

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

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

5 (B) in subsection (c)—

6 (i) in paragraph (1)—

7 (I) in the matter preceding sub-
8 paragraph (A), by striking “small
9 group” and inserting “group and indi-
10 vidual”; and

11 (II) in subparagraph (B)—

12 (aa) in the matter preceding
13 clause (i), by inserting “and indi-
14 viduals” after “employers”;

15 (bb) in clause (i), by insert-
16 ing “or any additional individ-
17 uals” after “additional groups”;
18 and

19 (cc) in clause (ii), by strik-
20 ing “without regard to the claims
21 experience of those employers
22 and their employees (and their
23 dependents) or any health status-
24 related factor relating to such”
25 and inserting “and individuals

1 without regard to the claims ex-
2 perience of those individuals, em-
3 ployers and their employees (and
4 their dependents) or any health
5 status-related factor relating to
6 such individuals”; and

7 (ii) in paragraph (2), by striking
8 “small group” and inserting “group or in-
9 dividual”;

10 (C) in subsection (d)—

11 (i) by striking “small group” each
12 place that such appears and inserting
13 “group or individual”; and

14 (ii) in paragraph (1)(B)—

15 (I) by striking “all employers”
16 and inserting “all employers and indi-
17 viduals”;

18 (II) by striking “those employ-
19 ers” and inserting “those individuals,
20 employers”; and

21 (III) by striking “such employ-
22 ees” and inserting “such individuals,
23 employees”;

24 (D) by striking subsection (e);

25 (E) by striking subsection (f); and

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

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

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

8 (B) in subsection (b)—

9 (i) in the matter preceding paragraph
10 (1), by striking “group health plan in the
11 small or large group market” and inserting
12 “health insurance coverage offered in the
13 group or individual market”;

14 (ii) in paragraph (1), by inserting “,
15 or individual, as applicable,” after “plan
16 sponsor”;

17 (iii) in paragraph (2), by inserting “,
18 or individual, as applicable,” after “plan
19 sponsor”; and

20 (iv) by striking paragraph (3) and in-
21 serting the following:

22 “(3) VIOLATION OF PARTICIPATION OR CON-
23 TRIBUTION RATES.—In the case of a group health
24 plan, the plan sponsor has failed to comply with a
25 material plan provision relating to employer con-

1 tribution or group participation rules, pursuant to
2 applicable State law.”;

3 (C) in subsection (c)—

4 (i) in paragraph (1)—

5 (I) in the matter preceding sub-
6 paragraph (A), by striking “group
7 health insurance coverage offered in
8 the small or large group market” and
9 inserting “group or individual health
10 insurance coverage”;

11 (II) in subparagraph (A), by in-
12 serting “or individual, as applicable,”
13 after “plan sponsor”;

14 (III) in subparagraph (B)—

15 (aa) by inserting “or indi-
16 vidual, as applicable,” after “plan
17 sponsor”; and

18 (bb) by inserting “or indi-
19 vidual health insurance cov-
20 erage”; and

21 (IV) in subparagraph (C), by in-
22 serting “or individuals, as applicable,”
23 after “those sponsors”; and

24 (ii) in paragraph (2)(A)—

1 (I) in the matter preceding clause
2 (i), by striking “small group market
3 or the large group market, or both
4 markets,” and inserting “individual or
5 group market, or all markets,”; and

6 (II) in clause (i), by inserting “or
7 individual, as applicable,” after “plan
8 sponsor”; and

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

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

14 (A) in subsection (a)—

15 (i) in the matter preceding paragraph
16 (1), by striking “small employer” and in-
17 serting “small employer or an individual”;

18 (ii) in paragraph (1), by inserting “,
19 or individual, as applicable,” after “em-
20 ployer” each place that such appears; and

21 (iii) in paragraph (2), by striking
22 “small employer” and inserting “employer,
23 or individual, as applicable,”;

24 (B) in subsection (b)—

25 (i) in paragraph (1)—

1 (I) in the matter preceding sub-
2 paragraph (A), by striking “small em-
3 ployer” and inserting “employer, or
4 individual, as applicable,”;

5 (II) in subparagraph (A), by add-
6 ing “and” at the end;

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

9 (IV) in subparagraph (D)—

10 (aa) by inserting “, or indi-
11 vidual, as applicable,” after “em-
12 ployer”; and

13 (bb) by redesignating such
14 subparagraph as subparagraph
15 (B);

16 (ii) in paragraph (2)—

17 (I) by striking “small employers”
18 each place that such appears and in-
19 serting “employers, or individuals, as
20 applicable,”; and

21 (II) by striking “small employer”
22 and inserting “employer, or indi-
23 vidual, as applicable,”; and

24 (C) by redesignating such section as sec-
25 tion 2712 and transferring such section to ap-

1 pear after section 2711 (as added by section
2 101(5));
3 (11) by redesignating subpart 4 as subpart 2;
4 (12) in section 2721 (42 U.S.C. 300gg-21)—
5 (A) by striking subsection (a);
6 (B) by striking “subparts 1 through 3”
7 each place that such appears and inserting
8 “subpart 1”; and
9 (C) by redesignating subsections (b)
10 through (e) as subsections (a) through (d), re-
11 spectively;
12 (13) in section 2722 (42 U.S.C. 300gg-22)—
13 (A) in subsection (a)—
14 (i) in paragraph (1), by striking
15 “small or large group markets” and insert-
16 ing “individual or group market”; and
17 (ii) in paragraph (2), by inserting “or
18 individual health insurance coverage” after
19 “group health plans”; and
20 (B) in subsection (b)(1)(B), by inserting
21 “individual health insurance coverage or” after
22 “respect to”; and
23 (14) in section 2723(a)(1) (42 U.S.C. 300gg-
24 23), by inserting “individual or” before “group
25 health insurance”.

1 (b) APPLICABILITY.—Notwithstanding any other pro-
2 vision of the Affordable Health Choices Act, nothing in
3 such Act (or an amendment made by such Act) shall be
4 construed to—

5 (1) authorize the Secretary of Health and
6 Human Services to promulgate regulations that pro-
7 hibit a group health plan or health insurance issuer
8 from carrying out utilization management techniques
9 that are commonly used as of the date of enactment
10 of this section; or

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

13 (c) TECHNICAL AMENDMENT TO THE EMPLOYEE RE-
14 TIREMENT INCOME SECURITY ACT OF 1974.—Subpart B
15 of part 7 of subtitle A of title I of the Employee Retire-
16 ment Income Security Act of 1974 (29 U.S.C. 1181 et.
17 seq.) is amended, by adding at the end the following:

18 **“SEC. 715. ADDITIONAL MARKET REFORMS.**

19 “(a) GENERAL RULE.—Except as provided in sub-
20 section (b)—

21 “(1) the provisions of subpart 1 of part A of
22 title XXVII of the Public Health Service Act (as
23 amended by the Affordable Health Choices Act)
24 shall apply to group health plans, and health insur-
25 ance issuers providing health insurance coverage in

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

3 “(2) to the extent that any provision of this
4 part conflicts with a provision of such subpart 1
5 with respect to group health plans, or health insur-
6 ance issuers providing health insurance coverage in
7 connection with group health plans, the provisions of
8 such subpart 1 shall apply.

9 “(b) EXCEPTION.—Notwithstanding subsection (a),
10 the provisions of sections 2701, 2702, and 2704 of title
11 XXVII of the Public Health Service Act (as amended by
12 the Affordable Health Choices Act) shall not apply with
13 respect to self-insured group health plans, and the provi-
14 sions of this part shall continue to apply to such plans
15 as if such sections of the Public Health Service Act (as
16 so amended) had not been enacted.”.

17 (d) TECHNICAL AMENDMENT TO THE INTERNAL
18 REVENUE CODE OF 1986.—Subchapter B of chapter 100
19 of the Internal Revenue Code of 1986 is amended by add-
20 ing at the end the following:

21 **“SEC. 9815. ADDITIONAL MARKET REFORMS.**

22 “(a) GENERAL RULE.—Except as provided in sub-
23 section (b)—

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

1 amended by the Affordable Health Choices Act)
2 shall apply to group health plans, and health insur-
3 ance issuers providing health insurance coverage in
4 connection with group health plans, as if included in
5 this subchapter; and

6 “(2) to the extent that any provision of this
7 subchapter conflicts with a provision of such subpart
8 1 with respect to group health plans, or health in-
9 surance issuers providing health insurance coverage
10 in connection with group health plans, the provisions
11 of such subpart 1 shall apply.

12 “(b) EXCEPTION.—Notwithstanding subsection (a),
13 the provisions of sections 2701, 2702, and 2704 of title
14 XXVII of the Public Health Service Act (as amended by
15 the Affordable Health Choices Act) shall not apply with
16 respect to self-insured group health plans, and the provi-
17 sions of this subchapter shall continue to apply to such
18 plans as if such sections of the Public Health Service Act
19 (as so amended) had not been enacted.”.

20 **SEC. 134. SAVINGS.**

21 (a) DETERMINATION.—The Secretary of the Treas-
22 ury, in consultation with the Secretary of Health and
23 Human Services, shall for each fiscal year determine the
24 amount of savings to the Federal Government as a result
25 of the enactment of this subtitle.

1 (b) USE.—Notwithstanding any other provision of
2 this subtitle (or an amendment made by this subtitle), the
3 savings to the Federal Government generated as a result
4 of the enactment of this subtitle shall be used for deficit
5 reduction.

6 **SEC. 135. EFFECTIVE DATES.**

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

12 (b) DELAYED APPLICABILITY.—Sections 2701, 2702,
13 2705, and 2706 of the Public Health Service Act (as
14 added by section 101) shall become effective with respect
15 to group health plans or health insurance coverage offered
16 in a State on the date on which such State becomes a
17 participating or establishing State under section 3104 of
18 the Public Health Service Act (as added by section 142).

1 **Subtitle B—Available Coverage for**
2 **All Americans**

3 **SEC. 141. BUILDING ON THE SUCCESS OF THE FEDERAL**
4 **EMPLOYEES HEALTH BENEFITS PROGRAM**
5 **AND THE HEALTH BENEFITS PROGRAM OF**
6 **MOST LARGE EMPLOYERS SO ALL AMERI-**
7 **CANS HAVE AFFORDABLE HEALTH BENEFIT**
8 **CHOICES.**

9 (a) FINDINGS.—The Senate finds that—

10 (1) the Federal employees health benefits pro-
11 gram under chapter 89 of title 5, United States
12 Code, allows Members of Congress, and section 514
13 of the Employee Retirement Income Security Act of
14 1974 allows large employers, to have affordable
15 choices among competing health benefit plans;

16 (2) the Federal employees health benefits pro-
17 gram ensures that the health benefit plans available
18 to Members of Congress meet minimum standards of
19 quality and effectiveness;

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

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

1 through the Federal employees health benefits pro-
2 gram.

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

9 **SEC. 142. AFFORDABLE HEALTH CHOICES FOR ALL AMERI-**
10 **CANS.**

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

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

18 **“TITLE XXXI—AFFORDABLE**
19 **HEALTH CHOICES FOR ALL**
20 **AMERICANS**

21 **“Subtitle A—Affordable Choices**

22 **“SEC. 3101. AFFORDABLE CHOICES OF HEALTH BENEFIT**
23 **PLANS.**

24 **“(a) ASSISTANCE TO STATES TO ESTABLISH AMER-**
25 **ICAN HEALTH BENEFIT GATEWAYS.—**

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

8 “(2) AMOUNT SPECIFIED.—

9 “(A) TOTAL DETERMINED.—For each fis-
10 cal year, the Secretary shall determine the total
11 amount that the Secretary will make available
12 for grants under this subsection.

13 “(B) STATE AMOUNT.—For each State
14 that is awarded a grant under paragraph (1),
15 the amount of such grants shall be based on a
16 formula established by the Secretary under
17 which each State shall receive an award in an
18 amount that is based on the following two com-
19 ponents:

20 “(i) A minimum amount for each
21 State.

22 “(ii) An additional amount based on
23 population.

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

1 is not less than 60 percent of the aggregate
2 amount awarded to all States under this sub-
3 paragraph.

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

9 “(4) RENEWABILITY OF GRANT.—

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

13 “(i) is making progress, as determined
14 by the Secretary, toward—

15 “(I) establishing a Gateway; and

16 “(II) implementing the reforms
17 described in subtitle A of title I of the
18 Affordable Health Choices Act; and

19 “(ii) is meeting such other bench-
20 marks as the Secretary may establish.

21 “(B) LIMITATION.—If a State is an estab-
22 lishing State or a participating State (as de-
23 fined in section 3104), such State shall not be
24 eligible for a grant renewal under subparagraph
25 (A) as of the second fiscal year following the

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

3 “(5) AUTHORIZATION OF APPROPRIATIONS.—

4 There are authorized to be appropriated such sums
5 as may be necessary to carry out this subsection in
6 each of fiscal years 2009 through 2014.

7 “(b) AMERICAN HEALTH BENEFIT GATEWAYS.—An
8 American Health Benefit Gateway (referred to in this title
9 as a ‘Gateway’) means a mechanism that—

10 “(1) facilitates the purchase of health insurance
11 coverage and related insurance products through the
12 Gateway at an affordable price by qualified individ-
13 uals and qualified employers and reduces the cost of
14 health care; and

15 “(2) meets the requirements of subsection (c).

16 “(c) REQUIREMENTS.—

17 “(1) ESTABLISHMENT.—A Gateway shall be a
18 governmental agency or nonprofit entity that is es-
19 tablished by—

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

22 “(B) the Secretary, in the case of a par-
23 ticipating State (as described in section 3104).

24 “(2) OFFERING OF COVERAGE.—

1 “(A) IN GENERAL.—A Gateway shall make
2 available qualified health plans to qualified indi-
3 viduals and qualified employers.

4 “(B) INCLUSION.—In making available
5 coverage pursuant to subparagraph (A), a Gate-
6 way shall include a community health insurance
7 option (as described in section 3106).

8 “(C) LIMITATION.—A Gateway may not
9 make available any health plan or other health
10 insurance coverage that is not a qualified health
11 plan.

12 “(D) ALLOWANCE TO OFFER.—A Gateway
13 may make available a qualified health plan not-
14 withstanding any provision of law that may re-
15 quire benefits other than the essential health
16 benefits specified under section 3103(a).

17 “(E) STATES MAY REQUIRE ADDITIONAL
18 BENEFITS.—Subject to the requirements of
19 subparagraph (F), a State may require that a
20 qualified health plan offered in such State offer
21 benefits in addition to the essential health bene-
22 fits described in section 3103(a).

23 “(F) ADDITIONAL BENEFITS.—

24 “(i) NO ADDITIONAL FEDERAL
25 COST.—A requirement by a State under

1 subparagraph (E) that a qualified health
2 plan cover benefits in addition to the es-
3 sential health benefits required shall not
4 affect the amount of a credit provided
5 under section 3111 with respect to such
6 plan.

7 “(ii) STATE MUST ASSUME COST.—A
8 State shall make payments to or on behalf
9 of an eligible individual to defray the cost
10 of any additional benefits described in sub-
11 paragraph (E).

12 “(3) FUNCTIONS.—A Gateway shall, at a min-
13 imum—

14 “(A) establish procedures for the certifi-
15 cation, recertification, and decertification, con-
16 sistent with guidelines developed by the Sec-
17 retary under subsection (m), of health plans as
18 qualified health plans;

19 “(B) develop and make available tools to
20 allow consumers to receive accurate and cul-
21 turally and linguistically appropriate informa-
22 tion on—

23 “(i) expected premiums and out of
24 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

1 under the plan as a Gateway may deter-
2 mine necessary;

3 “(C) utilize the administrative simplifica-
4 tion measures and standards developed under
5 section 222 of the Affordable Health Choices
6 Act;

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

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

12 “(F) collect, analyze, and respond to com-
13 plaints and concerns from enrollees regarding
14 coverage provided through the Gateway;

15 “(G) provide for the operation of a toll-free
16 telephone hotline to respond to requests for as-
17 sistance; and

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

22 “(4) SURCHARGES.—

23 “(A) IN GENERAL.—A Gateway may as-
24 sess a surcharge on all health insurance issuers
25 offering qualified health plans through the

1 Gateway to pay for the administrative and oper-
2 ational expenses of the Gateway.

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

7 “(C) FURTHER LIMITATION.—No funds
8 collected through a Gateway surcharge for ad-
9 ministrative and operational expenses may be
10 used for staff retreats, promotional giveaways,
11 excessive executive compensation, or promotion
12 of Federal or State legislative and regulatory
13 modifications.

14 “(5) RISK ADJUSTMENT PAYMENT.—

15 “(A) ESTABLISHING AND PARTICIPATING
16 STATES.—

17 “(i) LOW ACTUARIAL RISK PLANS.—

18 Using the criteria and methods developed
19 under subparagraph (B), each establishing
20 State or participating State (as defined in
21 section 3104) shall assess a charge on
22 health plans and health insurance issuers
23 (with respect to health insurance coverage)
24 described in subparagraph (C) if the actu-
25 arial risk of the enrollees of such plans or

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

8 “(ii) HIGH ACTUARIAL RISK PLANS.—
9 Using the criteria and methods developed
10 under subparagraph (B), each establishing
11 State or participating State (as defined in
12 section 3104) shall provide a payment to
13 health plans and health insurance issuers
14 (with respect to health insurance coverage)
15 described in subparagraph (C) if the actu-
16 arial risk of the enrollees of such plans or
17 coverage for a year is greater than the av-
18 erage actuarial risk of all enrollees in all
19 plans and coverage in such State for such
20 year that are not self-insured group health
21 plans (which are subject to the provisions
22 of the Employee Retirement Income Secu-
23 rity Act of 1974).

24 “(B) CRITERIA AND METHODS.—The Sec-
25 retary, in consultation with States, shall estab-

1 lish criteria and methods to be used in carrying
2 out the risk adjustment activities under this
3 paragraph. The Secretary may utilize criteria
4 and methods similar to the criteria and meth-
5 ods utilized under part C or D of title XVIII
6 of the Social Security Act.

7 “(C) SCOPE.—A health plan or a health
8 insurance issuer is described in this subpara-
9 graph if such health plan or health insurance
10 issuer provides coverage for an individual or for
11 an employer group the size of which does not
12 exceed—

13 “(i) in the case of an employer with
14 its primary place of business located in an
15 establishing State, the criteria relating to
16 the size of employers established by such
17 State as described in section
18 3116(a)(2)(A)(ii)(I); or

19 “(ii) in the case of an employer with
20 its primary place of business located in a
21 participating State, the criteria relating to
22 the size of employers established by the
23 Secretary as described in section
24 3116(a)(2)(A)(ii)(II).

25 “(6) FACILITATING ENROLLMENT.—

1 “(A) IN GENERAL.—A Gateway shall
2 (through, to the extent practicable, the use of
3 information technology) implement policies and
4 procedures to—

5 “(i) facilitate the identification of in-
6 dividuals who lack qualifying coverage; and

7 “(ii) assist such individuals in enroll-
8 ing in—

9 “(I) a qualified health plan that
10 is affordable and available to such in-
11 dividual, if such individual is a quali-
12 fied individual;

13 “(II) the medicaid program
14 under title XIX of the Social Security
15 Act, if such individual is eligible for
16 such program;

17 “(III) the CHIP program under
18 title XXI of the Social Security Act, if
19 such individual is eligible for such
20 program; or

21 “(IV) other Federal programs in
22 which such individual is eligible to
23 participate.

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

1 ble for the Children’s Health Insurance Pro-
2 gram under title XXI of the Social Security Act
3 may elect to enroll in such program or in a
4 qualified health plan. Where such individual is
5 a minor child, such election shall be made by
6 the parent or guardian of such child.

7 “(C) OVERSIGHT.—The Secretary shall
8 oversee the implementation of subparagraph
9 (A)(ii) to ensure that individuals are assisted to
10 enroll in the program most appropriate under
11 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.

19 “(7) CONSULTATION.—A Gateway shall consult
20 with stakeholders relevant to carrying out the activi-
21 ties under this subsection, including—

22 “(A) educated health care consumers who
23 are enrollees in qualified health plans;

1 “(B) individuals and entities with experi-
2 ence in facilitating enrollment in qualified
3 health plans;

4 “(C) representatives of small businesses
5 and self-employed individuals;

6 “(D) State Medicaid offices; and

7 “(E) advocates for enrolling hard to reach
8 populations.

9 “(8) STANDARDS AND PROTOCOLS.—

10 “(A) IN GENERAL.—The Secretary, in con-
11 sultation with the Office of the National Coor-
12 dinator for Health Information Technology,
13 shall develop interoperable, secure, scalable, and
14 reusable standards and protocols that facilitate
15 enrollment of individuals in Federal and State
16 health and human services programs.

17 “(B) COORDINATION.—The Secretary shall
18 facilitate enrollment of individuals in programs
19 described in subparagraph (A) through methods
20 which shall include—

21 “(i) electronic matching against exist-
22 ing Federal and State data to serve as evi-
23 dence of eligibility and digital documenta-
24 tion in lieu of paper-based documentation;

1 “(ii) capability for individuals to
2 apply, recertify, and manage eligibility in-
3 formation online, including conducting
4 real-time queries against databases for ex-
5 isting eligibility prior to submitting appli-
6 cations; and

7 “(iii) other functionalities necessary to
8 provide eligible individuals with a stream-
9 lined enrollment process.

10 “(C) ASSISTANCE.—The Secretary shall
11 award grants to enhance community-based en-
12 rollment to—

13 “(i) States to assist such States in—

14 “(I) contracting with qualified
15 technology vendors to develop or ac-
16 quire electronic enrollment software
17 systems;

18 “(II) contracting with community
19 and consumer focused nonprofit orga-
20 nizations with experience working
21 with consumers, including the unin-
22 sured and the underinsured, to estab-
23 lish Statewide helplines for enrollment
24 assistance and referrals; and

1 “(III) establishing public edu-
2 cation campaigns through grants to
3 qualifying organizations for the design
4 and implementation of public edu-
5 cation campaigns targeting uninsured
6 and traditionally underserved commu-
7 nities; and

8 “(ii) community-based organizations
9 for infrastructure and training to establish
10 electronic assistance programs.

11 “(9) NOTIFICATION.—With respect to the
12 standards and protocols developed under paragraph
13 (8), the Secretary—

14 “(A) shall notify States of such standards
15 and protocols; and

16 “(B) may require, as a condition of receiv-
17 ing Federal funds, that States or other entities
18 incorporate such standards and protocols into
19 such investments.

20 “(10) PUBLICATION OF COSTS.—A Gateway
21 shall publish the average costs of income or other
22 taxes, licensing or regulatory fees, and any sur-
23 charges imposed by the Gateway, and the adminis-
24 trative costs of such Gateway, on an Internet
25 website to educate consumers on such costs. Such

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

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

5 “(1) such health plan meets the requirements of
6 subsection (m);

7 “(2) the Gateway determines that making avail-
8 able such health plan through such Gateway is in
9 the interests of qualified individuals and qualified
10 employers in the States or States in which such
11 Gateway operates, except that the Gateway may not
12 exclude a health plan—

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

15 “(B) through the imposition of premium
16 price controls; or

17 “(C) on the basis that the plan provides
18 treatments necessary to prevent patients’
19 deaths in circumstances the Gateway deter-
20 mines are inappropriate or too costly; and

21 “(3) the Gateway determines that the plan has
22 not established a pattern or practice under which
23 benefits covered by the plan are denied to covered
24 individuals on the basis of the individuals’ age or ex-
25 pected length of life or of the individuals’ present or

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

3 “(e) GUIDANCE.—The Secretary shall develop guid-
4 ance that may be used by a Gateway to carry out the ac-
5 tivities described in this section.

6 “(f) FLEXIBILITY.—

7 “(1) REGIONAL OR OTHER INTERSTATE GATE-
8 WAYS.—A Gateway may operate in more than one
9 State, provided that each State in which such Gate-
10 way operates permits such operation.

11 “(2) SUBSIDIARY GATEWAYS.—A State may es-
12 tablish one or more subsidiary Gateway, provided
13 that—

14 “(A) each such Gateway serves a geo-
15 graphically distinct area; and

16 “(B) the area served by each such Gate-
17 way is at least as large as a community rating
18 area described in section 2701.

19 “(g) NO LIMITATION ON CONTRACTING BASED ON
20 ABORTION.—No individual health care provider or health
21 care facility may be excluded from contracting with a
22 health insurance issuer participating in the Gateway on
23 the basis that the provider or facility performs abortions
24 or the provider or facility refuses to perform abortions,
25 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

1 Internal Revenue Code of 1986) shall be
2 deemed to be a qualified employer unless such
3 individual notifies the applicable Gateway that
4 such individual elects to be considered a quali-
5 fied individual.

6 “(B) ELIGIBILITY.—In the case of a self-
7 employed individual making the election de-
8 scribed in subparagraph (A)—

9 “(i) the income of such individual for
10 purposes of section 3111 shall be deemed
11 to be the total business income of such in-
12 dividual;

13 “(ii) premium payments made by such
14 individual to a qualified health plan shall
15 not be treated as employer-provided cov-
16 erage under section 106(a) of the Internal
17 Revenue Code of 1986; and

18 “(iii) the individual shall not be eligi-
19 ble for a credit under section 3112.

20 “(j) PAYMENT OF PREMIUMS BY QUALIFIED INDI-
21 VIDUALS.—A qualified individual enrolled in any qualified
22 health plan may pay any applicable premium owed by such
23 individual to the health insurance issuer issuing such
24 qualified health plan.

25 “(k) SINGLE RISK POOL.—

1 “(1) INDIVIDUAL MARKET.—A health insurance
2 issuer shall consider all enrollees in an individual
3 plan, including individuals who do not purchase such
4 a plan through the Gateway, to be members of a sin-
5 gle risk pool.

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

12 “(1) EMPOWERING CONSUMER CHOICE.—

13 “(1) CONTINUED OPERATION OF MARKET OUT-
14 SIDE GATEWAYS.—Nothing in this title shall be con-
15 strued to prohibit a health insurance issuer from of-
16 fering a health insurance policy or providing cov-
17 erage under such policy to a qualified individual
18 where such policy is not a qualified health plan.
19 Nothing in this title shall be construed to prohibit
20 a qualified individual from enrolling in a health in-
21 surance plan where such plan is not a qualified
22 health plan.

23 “(2) CONTINUED OPERATION OF STATE BEN-
24 EFIT REQUIREMENTS.—Nothing in this title shall be
25 construed to terminate, abridge, or limit the oper-

1 ation of any requirement under State law with re-
2 spect to any policy or plan that is not a qualified
3 health plan to offer benefits required under State
4 law.

5 “(3) VOLUNTARY NATURE OF A GATEWAY.—

6 “(A) CHOICE TO ENROLL OR NOT TO EN-
7 ROLL.—Nothing in this title shall be construed
8 to restrict the choice of a qualified individual to
9 enroll or not to enroll in a qualified health plan
10 or to participate in a Gateway.

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

16 “(m) CRITERIA FOR CERTIFICATION.—

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

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

1 “(B) employ methods to ensure that insur-
2 ance products are simple, comparable, and
3 structured for ease of consumer choice;

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

7 “(D) include within health insurance plan
8 networks those essential community providers,
9 where available, that serve predominately low-
10 income, medically-underserved individuals, such
11 as health care providers defined in section
12 340B(a)(4) of the Public Health Service Act
13 and providers described in section
14 1927(c)(1)(D)(i)(IV) of the Social Security Act
15 as set forth by section 221 of Public Law 111-
16 8;

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

20 “(i) benefits offered, including maxi-
21 mums, limitations (including differential
22 cost-sharing for out of network services),
23 exclusions and other benefit limitations;

24 “(ii) the service area;

25 “(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

1 “(K) report to the applicable Gateway data
2 on any quality measures for health plan per-
3 formance endorsed under section 399JJ.

4 “(2) REQUEST TO NATIONAL ASSOCIATION OF
5 INSURANCE COMMISSIONERS.—The Secretary shall
6 request the National Association of Insurance Com-
7 missioners to develop and submit to the Secretary
8 model criteria for the certification of qualified health
9 plans, that address the elements described in sub-
10 paragraphs (A) through (K) of paragraph (1). In de-
11 veloping such criteria, the National Association of
12 Insurance Commissioners shall consult with appro-
13 priate Federal agencies, consumer representatives,
14 insurance carriers, and other stakeholders.

15 “(3) REQUIRED CONSIDERATION.—If the model
16 criteria described in paragraph (2) are submitted to
17 the Secretary by the date that is 9 months after the
18 date on which a request is made under such para-
19 graph, the Secretary shall consider such model cri-
20 teria in promulgating the regulations under para-
21 graph (1).

22 “(4) RULE OF CONSTRUCTION.—Nothing in
23 paragraph (1)(D) shall be construed to require a
24 qualified health plan to contract with a provider de-
25 scribed in such paragraph if such provider refuses to

1 accept the generally applicable payment rates of
2 such plan.

3 “(n) REWARDING QUALITY THROUGH MARKET-
4 BASED INCENTIVES.—

5 “(1) STRATEGY DESCRIBED.—A strategy de-
6 scribed in this paragraph is a payment structure
7 that provides increased reimbursement or other in-
8 centives for—

9 “(A) improving health outcomes through
10 the implementation of activities that shall in-
11 clude quality reporting, effective case manage-
12 ment, care coordination, chronic disease man-
13 agement, medication and care compliance initia-
14 tives, including through the use of the medical
15 home model as defined in section 212 of the Af-
16 fordable Health Choices Act, for treatment or
17 services under the plan or coverage;

18 “(B) the implementation of activities to
19 prevent hospital readmissions through a com-
20 prehensive program for hospital discharge that
21 includes patient-centered education and coun-
22 seling, comprehensive discharge planning, and
23 post discharge reinforcement by an appropriate
24 health care professional;

1 “(C) the implementation of activities to
2 improve patient safety and reduce medical er-
3 rors through the appropriate use of best clinical
4 practices, evidence based medicine, and health
5 information technology under the plan or cov-
6 erage; and

7 “(D) the implementation of wellness and
8 health promotion activities.

9 “(2) GUIDELINES.—The Secretary, in consulta-
10 tion with experts in health care quality and stake-
11 holders, shall develop guidelines concerning the mat-
12 ters described in paragraph (1).

13 “(3) REQUIREMENTS.—The guidelines devel-
14 oped under paragraph (2) shall require the periodic
15 reporting to the applicable Gateway of the activities
16 that a qualified health plan has conducted to imple-
17 ment a strategy described in paragraph (1).

18 “(o) NO INTERFERENCE WITH STATE REGULATORY
19 AUTHORITY.—Nothing in this title shall be construed to
20 preempt any State law that does not prevent the applica-
21 tion of the provisions of this title.

22 “(p) QUALITY IMPROVEMENT.—

23 “(1) ENHANCING PATIENT SAFETY.—Beginning
24 on January 1, 2012 a qualified health plan may con-
25 tract with—

1 “(A) a hospital with greater than 50 beds
2 only if such hospital—

3 “(i) utilizes a patient safety evaluation
4 system as described in part C of title IX;
5 and

6 “(ii) implements a mechanism to en-
7 sure that each patient receives a com-
8 prehensive program for hospital discharge
9 that includes patient-centered education
10 and counseling, comprehensive discharge
11 planning, and post discharge reinforcement
12 by an appropriate health care professional;
13 or

14 “(B) a health care provider if such pro-
15 vider implements such mechanisms to improve
16 health care quality as the Secretary may by reg-
17 ulation require.

18 “(2) EXCEPTIONS.—The Secretary may estab-
19 lish reasonable exceptions to the requirements de-
20 scribed in paragraph (1).

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

24 “(q) CONTINUED APPLICABILITY OF MENTAL
25 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:

1 “(A) APPEARANCE.—The standards shall
2 ensure that the summary is presented in a uni-
3 form format.

4 “(B) LANGUAGE.—The standards shall en-
5 sure that the language used in the summary is
6 presented in a manner determined to be under-
7 standable by the average health plan enrollee.

8 “(C) CONTENTS.—The standards shall en-
9 sure that the summary includes the following:

10 “(i) Information determined to be es-
11 sential to a consumer’s understanding of
12 the applicable health insurance plan bene-
13 fits.

14 “(ii) Uniform definitions of standard
15 insurance terms including premium, de-
16 ductible, co-insurance, co-payment, out-of-
17 pocket limit, preferred provider, non-pre-
18 ferred provider, out-of-network co-pay-
19 ments, usual, customary and reasonable
20 fees, excluded services, grievance and ap-
21 peals, prior authorization, precertification,
22 and such other terms as determined by the
23 Secretary so that consumers may compare
24 health insurance coverage and understand
25 the terms of coverage.

1 “(iii) Uniform definitions of medical
2 terms including hospitalization, hospital
3 outpatient care, emergency room care, phy-
4 sician services, prescription drug coverage,
5 durable medical equipment, home health
6 care, skilled nursing care, rehabilitation
7 services, hospice services, emergency med-
8 ical transportation, and such other terms
9 as determined by the Secretary so that
10 consumers may compare the medical bene-
11 fits and understand the extent of those
12 medical benefits (or exceptions to those
13 benefits).

14 “(iv) A statement of whether the plan
15 meets minimum qualifying coverage (when
16 effective under section 3103.)

17 “(v) Examples to illustrate common
18 benefits scenarios, including scenarios that
19 illustrate the health care needs of preg-
20 nancy and of at least several serious or
21 chronic medical conditions.

22 “(vi) Illustrations that enhance con-
23 sumer understanding of the explanation.

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

1 ards under paragraph (1), each health insurance
2 issuer offering health insurance coverage through
3 the Gateway shall, prior to any enrollment restric-
4 tion, provide annually to enrollees and potential en-
5 rollees a summary of benefits explanation pursuant
6 to the standards developed by the Secretary under
7 paragraph (1)

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

13 “(5) FAILURE TO PROVIDE.—A health insur-
14 ance issuer that willfully fails to provide the infor-
15 mation required under this subsection shall be sub-
16 ject to a fine of not more than \$1,000 for each such
17 failure. Such failure with respect to each enrollee
18 shall constitute a separate offense for purposes of
19 this paragraph.

20 “(6) APPLICATION.—The provisions of this sub-
21 section shall apply to health insurance coverage of-
22 fered through the Gateway. The Secretary shall
23 evaluate the impact on consumers of expanding the
24 application of the provisions of this subsection to ad-
25 ditional health insurance issuers.

1 “(s) DISCLOSURE OF INFORMATION.—

2 “(1) IN GENERAL.—In connection with the of-
3 fering of any health insurance coverage in the indi-
4 vidual or group market through a Gateway, a health
5 insurance issuer—

6 “(A) shall disclose to such individual or
7 employer as part of its solicitation and sales
8 materials, the information described in para-
9 graph (2);

10 “(B) shall disclose to such individual or
11 employer enrolled in such plan any change and
12 an explanation of such change with respect to
13 the information described in paragraph (2) with
14 reasonable and timely advance notice with re-
15 spect to such change;

16 “(C) upon the request of such individual or
17 employer, shall provide the information de-
18 scribed in paragraph (2); and

19 “(D) shall disclose such information as the
20 Secretary may require in order to ensure com-
21 pliance with consumer protection provisions
22 under this title.

23 “(2) INFORMATION DESCRIBED.—

24 “(A) IN GENERAL.—Subject to subpara-
25 graph (C), with respect to a health insurance

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

5 “(i) the provisions of such coverage
6 concerning the issuer’s right to change pre-
7 mium rates, co-payments, in- and out-of-
8 provider networks, or any other informa-
9 tion as determined by the Secretary; and

10 “(ii) the benefits and premiums avail-
11 able under all health insurance coverage
12 for which an individual or employers is
13 qualified.

14 “(B) FORM OF INFORMATION.—Informa-
15 tion shall be provided under this paragraph in
16 a manner determined to be understandable by
17 the average employer or individual and shall be
18 sufficient to reasonably inform such employer
19 or individual of their rights and obligations
20 under the health insurance coverage involved.

21 “(C) EXCEPTION.—Information described
22 under this paragraph shall not include informa-
23 tion that is proprietary or trade secret informa-
24 tion.

1 **“SEC. 3102. FINANCIAL INTEGRITY.**

2 “(a) ACCOUNTING FOR EXPENDITURES.—

3 “(1) IN GENERAL.—A Gateway shall keep an
4 accurate accounting of all activities, receipts, and ex-
5 penditures and shall annually submit to the Sec-
6 retary a report concerning such accountings.

7 “(2) INVESTIGATIONS.—The Secretary may in-
8 vestigate the affairs of a Gateway, may examine the
9 properties and records of a Gateway, and may re-
10 quire periodical reports in relation to activities un-
11 dertaken by a Gateway. A Gateway shall fully co-
12 operate in any investigation conducted under this
13 paragraph.

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

16 “(4) PATTERN OF ABUSE.—If the Secretary de-
17 termines that a Gateway or a State has engaged in
18 serious misconduct with respect to compliance with
19 the requirements of, or carrying out activities re-
20 quired under, this title, the Secretary may rescind
21 from payments otherwise due to such State involved
22 under this or any other Act administered by the Sec-
23 retary an amount not to exceed 1 percent of such
24 payments per year until corrective actions are taken
25 by the State that are determined to be adequate by
26 the Secretary.

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

7 “(A) the Secretary determines is appro-
8 priate to reduce fraud and abuse in the admin-
9 istration of this title; and

10 “(B) the Secretary has authority to imple-
11 ment under this title or any other Act;

12 “(6) APPLICATION OF THE FALSE CLAIMS
13 ACT.—

14 “(A) IN GENERAL.—Payments made by,
15 through, or in connection with a Gateway are
16 subject to the False Claims Act (31 U.S.C.
17 3729 et seq.) if those payments include any
18 Federal funds. Compliance with the require-
19 ments of this Act concerning eligibility for a
20 health insurance issuer to participate in the
21 Gateway shall be a material condition of an
22 issuer’s entitlement to receive payments, includ-
23 ing subsidy payments, through the Gateway.

24 “(B) DAMAGES.—Notwithstanding para-
25 graph (1) of section 3729(a) of title 31, United

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

9 “(b) GAO OVERSIGHT.—Not later than 5 years after
10 the date of enactment of this section, the Comptroller
11 General shall conduct an ongoing study of Gateway activi-
12 ties and the enrollees in qualified health plans offered
13 through Gateways. Such study shall review—

14 “(1) the operations and administration of Gate-
15 ways, including surveys and reports of qualified
16 health plans offered through Gateways and on the
17 experience of such plans (including data on enrollees
18 in Gateways and individuals purchasing health in-
19 surance coverage outside of Gateways), the expenses
20 of Gateways, claims statistics relating to qualified
21 health plans, complaints data relating to such plans,
22 and the manner in which Gateways meets their
23 goals;

24 “(2) any significant observations regarding the
25 utilization and adoption of Gateways;

1 “(3) where appropriate, recommendations for
2 improvements in the operations or policies of Gate-
3 ways; and

4 “(4) how many physicians, by area and spe-
5 cialty, are not taking or accepting new patients en-
6 rolled in Federal Government health care programs,
7 and the adequacy of provider networks of Federal
8 Government health care programs.

9 **“SEC. 3103. PROGRAM DESIGN.**

10 “(a) PROGRAM DESIGN.—

11 “(1) IN GENERAL.—The Secretary shall estab-
12 lish the following:

13 “(A) Subject to paragraph (2), the essen-
14 tial health care benefits eligible for credits
15 under section 3111, where such benefits shall
16 include at least the following general categories:

17 “(i) Ambulatory patient services.

18 “(ii) Emergency services.

19 “(iii) Hospitalization.

20 “(iv) Maternity and newborn care.

21 “(v) Mental health and substance
22 abuse services.

23 “(vi) Prescription drugs.

24 “(vii) Rehabilitative and habilitative
25 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-

1 interpreting section 213(d) of the Internal Rev-
2 enue Code of 1986 as of January 1, 2009.

3 “(2) LIMITATION.—The Secretary shall ensure
4 that the scope of the essential health benefits under
5 paragraph (1)(A) is equal to the scope of benefits
6 provided under a typical employer plan, as deter-
7 mined by the Secretary.

8 “(3) CERTIFICATION.—In establishing the es-
9 sential health benefits described in paragraph
10 (1)(A), the Secretary shall submit a report to the
11 appropriate committees of Congress containing a
12 certification from the Chief Actuary of the Centers
13 for Medicare & Medicaid Services that such essential
14 health benefits meet the limitation described in para-
15 graph (2).

16 “(b) NATIONAL INDEPENDENT COMMISSION ON ES-
17 SENTIAL HEALTH CARE BENEFITS.—

18 “(1) ESTABLISHMENT.—There is established a
19 temporary advisory commission to be known as the
20 National Independent Commission on Essential
21 Health Care Benefits (in this section referred to as
22 the ‘Commission’).

23 “(2) DUTIES.—The Commission shall:

24 “(A) Review and analyze the benefits of-
25 fered 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 health
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;

1 “(E) existing State laws that require cov-
2 erage of health care items or services in the in-
3 dividual and group markets; and

4 “(F) the potential of additional or ex-
5 panded benefits to increase costs and the inter-
6 actions between the addition or expansion of
7 benefits and reductions in existing benefits to
8 meet the actuarial limitations described in sub-
9 section (a)(2).

10 “(4) MEMBERSHIP.—

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

14 “(B) QUALIFICATIONS.—

15 “(i) IN GENERAL.—The membership
16 of the Commission shall include individuals
17 with national recognition for their exper-
18 tise in clinical medicine, primary and pre-
19 ventive health care, integrative medicine,
20 and actuarial science and health plan ben-
21 efit design.

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

1 consumer advocate, a representative of
2 labor organizations representing workers,
3 an employer, a third-party payer, a health
4 services researcher, an individual skilled in
5 the conduct and interpretation of the bio-
6 medical and health sciences, an individual
7 with expertise in pediatric health care, and
8 an individual with expertise in outcomes
9 and effectiveness research and technology
10 assessment.

11 “(C) CHAIRMAN.—The Secretary shall des-
12 ignate a member of the Commission who is an
13 expert in actuarial science and health plan ben-
14 efit design, at the time of appointment of such
15 member, as Chairman.

16 “(D) MEETINGS.—The Commission shall
17 meet at the call of the Chairman. Advance no-
18 tice of such meetings shall be published in the
19 Federal Register and the meetings shall be
20 open to the public.

21 “(E) ETHICAL DISCLOSURES.—The Sec-
22 retary shall establish a system for public disclo-
23 sure by members of the Commission of financial
24 and other potential conflicts of interest relating
25 to such members.

1 “(F) DEADLINE FOR APPOINTMENT.—

2 Members of the Commission shall be appointed
3 by not later than 45 days after the date of en-
4 actment of this title.

5 “(G) TERMS OF APPOINTMENT.—The term
6 of any appointment under subparagraph (A) to
7 the Commission shall be for the life of the Com-
8 mission.

9 “(H) COMPENSATION.—Members of the
10 Commission shall receive no additional pay, al-
11 lowances, or benefits by reason of their service
12 on the Commission.

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

18 “(5) STAFF AND SUPPORT SERVICES.—

19 “(A) EXECUTIVE DIRECTOR.—

20 “(i) APPOINTMENT.—The Secretary
21 shall appoint an executive director of the
22 Commission.

23 “(ii) COMPENSATION.—The executive
24 director of the Commission shall be paid

1 the rate of basic pay for level V of the Ex-
2 ecutive Schedule.

3 “(iii) STAFF.—With the approval of
4 the Commission, the executive director may
5 appoint such personnel as the executive di-
6 rector considers appropriate.

7 “(iv) APPLICABILITY OF CIVIL SERV-
8 ICE LAWS.—The staff of the Commission
9 shall be appointed without regard to the
10 provisions of title 5, United States Code,
11 governing appointments in the competitive
12 service, and shall be paid without regard to
13 the provisions of chapter 51 and sub-
14 chapter III of chapter 53 of such title (re-
15 lating to classification and General Sched-
16 ule pay rates).

17 “(v) EXPERTS AND CONSULTANTS.—
18 With the approval of the Commission, the
19 executive director may procure temporary
20 and intermittent services under section
21 3109(b) of title 5, United States Code.

22 “(6) POWERS.—

23 “(A) COST ESTIMATES BY OFFICE OF MAN-
24 AGEMENT AND BUDGET AND OFFICE OF THE
25 CHIEF ACTUARY OF THE CENTERS FOR MEDI-

1 CARE & MEDICARE SERVICES.—The Director of
2 the Office of Management and Budget or the
3 Chief Actuary of the Centers for Medicare &
4 Medicaid Services, or both, shall provide to the
5 Commission, upon the request of the Commis-
6 sion, such cost estimates as the Commission de-
7 termines to be necessary to carry out its duties
8 under this section.

9 “(B) TECHNICAL ASSISTANCE.—Upon the
10 request of the Commission, the head of a Fed-
11 eral agency or its representatives, including rep-
12 resentatives of the Office of Personnel Manage-
13 ment, shall provide such technical assistance to
14 the Commission as the Commission determines
15 to be necessary to carry out its duties under
16 this section.

17 “(C) OBTAINING INFORMATION.—The
18 Commission may secure directly from any Fed-
19 eral agency information necessary to enable it
20 to carry out its duties, if the information may
21 be disclosed under section 552 of title 5, United
22 States Code.

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

1 sion’s use in making reports and recommenda-
2 tions.

3 “(7) REPORT.—Not later than 6 months after
4 the date of enactment of this title, the Commission
5 shall submit a report to the Secretary and Congress
6 which shall contain a detailed statement of only
7 those recommendations, findings, and conclusions of
8 the Commission that receive the approval of at least
9 12 members of the Commission. The Secretary shall
10 provide for publication in the Federal Register and
11 the posting on an appropriate Internet website of
12 the report and recommendations of the Commission.

13 “(8) TERMINATION.—The Commission shall
14 terminate on the date that is 30 days after the date
15 on which the report is submitted under subsection
16 (7).

17 “(9) AUTHORIZATION OF APPROPRIATIONS.—
18 There are authorized to be appropriated to carry out
19 this subsection, \$1,500,000.

20 “(c) REQUIRED ELEMENTS FOR CONSIDERATION.—

21 “(1) ESSENTIAL HEALTH CARE BENEFITS.—In
22 establishing the essential health benefits under sub-
23 section (a)(1)(A), the Secretary shall—

1 “(A) consider the report and recommenda-
2 tions of the Commission established under sub-
3 section (b);

4 “(B) ensure that such essential health ben-
5 efits reflect an appropriate balance among the
6 categories described in such subsection, so that
7 benefits are not unduly weighted toward any
8 category;

9 “(C) not make coverage decisions, deter-
10 mine reimbursement rates, establish incentive
11 programs, or design benefits in ways that dis-
12 criminate against individuals because of their
13 age, disability, or expected length of life;

14 “(D) take into account the health care
15 needs of diverse segments of the population, in-
16 cluding women, children, persons with disabil-
17 ities, and other groups;

18 “(E) ensure that health benefits estab-
19 lished as essential not be subject to denial to in-
20 dividuals against their wishes on the basis of
21 the individuals’ age or expected length of life or
22 of the individuals’ present or predicted dis-
23 ability, degree of medical dependency, or quality
24 of life; and

1 “(F) review the essential health benefits
2 under subsection (a)(1)(A) not less than annu-
3 ally, and provide a report to Congress and the
4 public that contains—

5 “(i) an assessment of whether enroll-
6 ees are facing any difficulty accessing
7 needed services for reasons of coverage or
8 cost;

9 “(ii) an assessment of whether the es-
10 sential benefits package needs to be modi-
11 fied or updated to account for changes in
12 medical evidence or scientific advancement;

13 “(iii) information on how the benefit
14 package will be modified to address any
15 such gaps in access or changes in the evi-
16 dence base; and

17 “(iv) an assessment of the potential of
18 additional or expanded benefits to increase
19 costs and the interactions between the ad-
20 dition or expansion of benefits and reduc-
21 tions in existing benefits to meet actuarial
22 limitations described in subsection (a)(2).

23 “(2) MINIMUM QUALIFYING COVERAGE.—In es-
24 tablishing the criteria described in subsection
25 (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

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

3 “(3) AFFORDABLE COVERAGE.—The Secretary
4 shall establish a standard under which coverage is
5 defined to be unaffordable only if the premium paid
6 by the individual is greater than 12.5 percent of the
7 adjusted gross income of the individual involved. Be-
8 ginning with calendar years after 2013, the Sec-
9 retary shall adjust the percentage described in this
10 paragraph by an amount that is equal to the per-
11 centage increase or decrease in the medical care
12 component of the Consumer Price Index for all
13 urban consumers (U.S. city average) during the pre-
14 ceding calendar year.

15 **“SEC. 3104. ALLOWING STATE FLEXIBILITY.**

16 “(a) OPTIONAL STATE ESTABLISHMENT OF GATE-
17 WAY.—During the 4-year period following the date of en-
18 actment of this section, a State may—

19 “(1)(A) establish a Gateway;

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

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

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

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

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

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

16 “(b) ESTABLISHING STATES.—

17 “(1) IN GENERAL.—If the Secretary determines
18 that a State has taken the actions described in sub-
19 section (a)(1), any resident of that State who is an
20 eligible individual shall be eligible for credits under
21 section 3111 beginning on the date that is 60 days
22 after the date of such determination.

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

1 requirements of subsection (a). If the Secretary de-
2 termines that a State has failed to maintain compli-
3 ance with such requirements, the Secretary may re-
4 voke the determination under paragraph (1).

5 “(3) DEEMING.—A State that is the subject of
6 a positive determination by the Secretary under
7 paragraph (1) (unless such determination is revoked
8 under paragraph (2)) shall be deemed to be an ‘es-
9 tablishing State’ beginning on the date that is 60
10 days after the date of such determination.

11 “(c) REQUEST FOR THE SECRETARY TO ESTABLISH
12 A GATEWAY.—

13 “(1) IN GENERAL.—In the case of a State that
14 makes the request described in subsection (a)(2), the
15 Secretary shall determine whether the State has en-
16 acted and has in effect the insurance reforms pro-
17 vided for in subtitle A of title I of the Affordable
18 Health Choices Act.

19 “(2) OPERATION OF GATEWAY.—

20 “(A) POSITIVE DETERMINATION.—If the
21 Secretary determines that the State has enacted
22 and has in effect the insurance reforms de-
23 scribed in paragraph (1), the Secretary shall es-
24 tablish a Gateway in such State as soon as
25 practicable after making such determination.

1 “(B) NEGATIVE DETERMINATION.—If the
2 Secretary determines that the State has not en-
3 acted or does not have in effect the insurance
4 reforms described in paragraph (1), the Sec-
5 retary shall establish a Gateway in such State
6 as soon as practicable after the Secretary deter-
7 mines that such State has enacted and has in
8 effect such reforms.

9 “(3) PARTICIPATING STATE.—The State shall
10 be deemed to be a ‘participating State’ on the date
11 on which the Gateway established by the Secretary
12 is in effect in such State.

13 “(4) ELIGIBILITY.—Any resident of a State de-
14 scribed in paragraph (3) who is an eligible individual
15 shall be eligible for credits under section 3111 begin-
16 ning on the date that is 60 days after the date on
17 which such Gateway is established in such State.

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

20 “(1) IN GENERAL.—Upon the expiration of the
21 4-year period following the date of enactment of this
22 section, in the case of a State that is not otherwise
23 a participating State or an establishing State—

24 “(A) the Secretary shall establish and op-
25 erate a Gateway in such State;

1 “(B) the insurance reform provisions pro-
2 vided for in subtitle A of title I of the Afford-
3 able Health Choices Act shall become effective
4 in such State, notwithstanding any contrary
5 provision of State law;

6 “(C) the State shall be deemed to be a
7 ‘participating State’; and

8 “(D) the residents of that State who are
9 eligible individuals shall be eligible for credits
10 under section 3111 beginning on the date that
11 is 60 days after the date on which such Gate-
12 way is established, if the State agrees to make
13 employers that are State or local governments
14 subject to sections 162 and 163 of the Afford-
15 able Health Choices Act.

16 “(2) ELIGIBILITY OF INDIVIDUALS FOR CRED-
17 ITS.—With respect to a State that makes the elec-
18 tion described in subsection (a)(3), the residents of
19 such State shall not be eligible for credits under sec-
20 tion 3111 until such State becomes a participating
21 State under paragraph (1).

22 **“SEC. 3105. NAVIGATORS.**

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)

1 to enter into agreements with private and public entities
2 under which such entities will serve as navigators in ac-
3 cordance with this section.

4 “(b) ELIGIBILITY.—

5 “(1) IN GENERAL.—To be eligible to enter into
6 an agreement under subsection (a), an entity shall
7 demonstrate that the entity has existing relation-
8 ships with, or could readily establish relationships
9 with, employers and employees, consumers (includ-
10 ing the uninsured and the underinsured), or self-em-
11 ployed individuals, likely to be qualified to enroll in
12 a qualified health plan.

13 “(2) TYPES.—Entities described in paragraph
14 (1) may include trade, industry and professional as-
15 sociations, commercial fishing industry organiza-
16 tions, ranching and farming organizations, commu-
17 nity and consumer-focused nonprofit groups, cham-
18 bers of commerce, unions, small business develop-
19 ment centers, other licensed insurance agents and
20 brokers, and other entities that the Secretary deter-
21 mines to be capable of carrying out the duties de-
22 scribed in subsection (c).

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

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

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

6 “(3) facilitate enrollment in a qualified health
7 plan;

8 “(4) provide referrals to the appropriate State
9 agency or agencies for any enrollee with a grievance,
10 complaint, or question regarding their health plan,
11 coverage, or a determination under such plan or cov-
12 erage; and

13 “(5) provide information in a manner deter-
14 mined by the Secretary to be culturally and linguis-
15 tically appropriate to the needs of the population
16 served by the Gateway.

17 “(d) STANDARDS.—

18 “(1) IN GENERAL.—The Secretary shall estab-
19 lish standards for navigators under this section, in-
20 cluding provisions to ensure that any private or pub-
21 lic entity that is selected as a navigator is qualified,
22 and licensed if appropriate, to engage in the navi-
23 gator activities described in this section and to avoid
24 conflicts of interest. Under such standards, a navi-
25 gator shall not—

1 “(A) be a health insurance issuer; or

2 “(B) receive any consideration directly or
3 indirectly from any health insurance issuer in
4 connection with the participation of any em-
5 ployer in the program under this title or the en-
6 rollment of any qualified individual or qualified
7 employer in a qualified health plan.

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

12 **“SEC. 3106. COMMUNITY HEALTH INSURANCE OPTION.**

13 “(a) VOLUNTARY NATURE.—

14 “(1) NO REQUIREMENT FOR HEALTH CARE
15 PROVIDERS TO PARTICIPATE.—Nothing in this sec-
16 tion shall be construed to require a health care pro-
17 vider to participate in a community health insurance
18 option, or to impose any penalty for non-participa-
19 tion.

20 “(2) NO REQUIREMENT FOR INDIVIDUALS TO
21 JOIN.—Nothing in this section shall be construed to
22 require an individual to participate in a community
23 health insurance option, or to impose any penalty for
24 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

1 “(G) complies with State laws (if any), ex-
2 cept as otherwise provided for in this title, re-
3 lating to—

4 “(i) guaranteed renewal;

5 “(ii) rating;

6 “(iii) preexisting conditions;

7 “(iv) non-discrimination;

8 “(v) quality improvement and report-
9 ing;

10 “(vi) fraud and abuse;

11 “(vii) solvency and financial require-
12 ments;

13 “(viii) market conduct;

14 “(ix) prompt payment;

15 “(x) appeals and grievances;

16 “(xi) privacy and confidentiality;

17 “(xii) licensure; and

18 “(xiii) benefit plan material or infor-
19 mation.

20 “(3) ESSENTIAL HEALTH BENEFITS.—

21 “(A) GENERAL RULE.—Except as provided
22 in subparagraph (B), a community health in-
23 surance option offered under this section shall
24 provide coverage only for the essential health
25 benefits described in section 3103.

1 “(B) STATES MAY OFFER ADDITIONAL
2 BENEFITS.—A State may require that a com-
3 munity health insurance option offered in such
4 State offer benefits in addition to the essential
5 health benefits required under subparagraph
6 (A).

7 “(C) CREDITS.—

8 “(i) IN GENERAL.—An individual en-
9 rolled in a community health insurance op-
10 tion under this section shall be eligible for
11 credits under section 3111 in the same
12 manner as an individual who is enrolled in
13 a qualified health plan.

14 “(ii) NO ADDITIONAL FEDERAL
15 COST.—A requirement by a State under
16 subparagraph (B) that a community health
17 insurance option cover benefits in addition
18 to the essential health benefits required
19 under subparagraph (A) shall not affect
20 the amount of a credit provided under sec-
21 tion 3111 with respect to such plan.

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

1 additional benefits described in subparagraph
2 (B).

3 “(E) ENSURING ACCESS TO ALL SERV-
4 ICES.—Nothing in this Act shall prohibit an in-
5 dividual enrolled in a community health insur-
6 ance option from paying out-of-pocket the full
7 cost of any item or service not included as an
8 essential health benefit or otherwise covered as
9 a benefit by a health plan. Nothing in this Act
10 shall prohibit any type of medical provider from
11 accepting an out-of-pocket payment from an in-
12 dividual enrolled in a community health insur-
13 ance option for a service otherwise not included
14 as an essential health benefit.

15 “(F) PROTECTING ACCESS TO END OF
16 LIFE CARE.—A community health insurance op-
17 tion offered under this section shall be prohib-
18 ited from limiting access to end of life care.

19 “(4) COST SHARING.—A community health in-
20 surance option shall offer coverage at each of the
21 cost sharing tiers described in section 3111(a).

22 “(5) PREMIUMS.—

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

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

4 “(B) APPLICABLE RULES.—The provisions
5 of title XXVII relating to premiums shall apply
6 to community health insurance options under
7 this section, including modified community rat-
8 ing provisions under section 2701.

9 “(C) COLLECTION OF DATA.—The Sec-
10 retary shall collect data as necessary to set pre-
11 mium rates under subparagraph (A).

12 “(D) CONTINGENCY MARGIN.—In estab-
13 lishing premium rates under subparagraph (A),
14 the Secretary shall include an appropriate
15 amount for a contingency margin.

16 “(6) REIMBURSEMENT RATES.—

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

21 “(B) LIMITATION.—The rates described in
22 subparagraph (A) shall not be higher, in aggre-
23 gate, than the average reimbursement rates
24 paid by health insurance issuers offering quali-
25 fied health plans through the Gateway.

1 “(C) INNOVATION.—Subject to the limits
2 contained in subparagraph (A), a State Advi-
3 sory Council established or designated under
4 subsection (d) may develop or encourage the
5 use of innovative payment policies that promote
6 quality, efficiency and savings to consumers.

7 “(D) PHYSICIAN NEGOTIATED RATES.—
8 Nothing in this paragraph shall prohibit the ap-
9 plication of a State law that permits physicians
10 to jointly negotiate with health plans. In such
11 State, physicians may jointly negotiate with a
12 community health insurance option concerning
13 rates paid by the option.

14 “(7) SOLVENCY AND CONSUMER PROTEC-
15 TION.—

16 “(A) SOLVENCY.—The Secretary shall es-
17 tablish a Federal solvency standard to be ap-
18 plied with respect to a community health insur-
19 ance option. A community health insurance op-
20 tion shall also be subject to the solvency stand-
21 ard of each State in which such community
22 health insurance option is offered.

23 “(B) MINIMUM REQUIRED.—In estab-
24 lishing the standard described under subpara-
25 graph (A), the Secretary shall require a reserve

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

4 “(C) CONSUMER PROTECTIONS.—The con-
5 sumer protection laws of a State shall apply to
6 a community health insurance option.

7 “(8) REQUIREMENTS ESTABLISHED IN PART-
8 NERSHIP WITH INSURANCE COMMISSIONERS.—

9 “(A) IN GENERAL.—The Secretary, in col-
10 laboration with the National Association of In-
11 surance Commissioners (in this paragraph re-
12 ferred to as the ‘NAIC’), may promulgate regu-
13 lations to establish additional requirements for
14 a community health insurance option.

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

20 “(9) OMBUDSMAN.—In establishing community
21 health insurance options, the Secretary shall estab-
22 lish an ombudsman or similar mechanism to provide
23 assistance to consumers with respect to disputes,
24 grievances, or appeals.

25 “(c) START-UP FUND.—

1 “(1) ESTABLISHMENT OF FUND.—

2 “(A) IN GENERAL.—There is established in
3 the Treasury of the United States a trust fund
4 to be known as the ‘Health Benefit Plan Start-
5 Up Fund’ (referred to in this section as the
6 ‘Start-Up Fund’), that shall consist of such
7 amounts as may be appropriated or credited to
8 the Start-Up Fund as provided for in this sub-
9 section to provide loans for the initial oper-
10 ations of a community health insurance option.
11 Such amounts shall remain available until ex-
12 pended.

13 “(B) FUNDING.—There is hereby appro-
14 priated to the Start-Up Fund, out of any mon-
15 eys in the Treasury not otherwise appropriated
16 an amount requested by the Secretary of
17 Health and Human Services as necessary to—

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

21 “(ii) pay the costs of making pay-
22 ments on claims submitted during the pe-
23 riod that is not more than 90 days from
24 the date on which such option is offered;
25 and

1 “(iii) make payments under para-
2 graph (3).

3 “(2) USE OF START-UP FUND.—The Secretary
4 shall use amounts contained in the Start-Up Fund
5 to make payments (subject to the repayment re-
6 quirements in paragraph (5)) for the purposes de-
7 scribed in paragraph (1)(B).

8 “(3) RISK CORRIDOR PAYMENTS.—

9 “(A) IN GENERAL.—In any case in which
10 the Secretary has entered into a contract with
11 a contracting administrator, the Secretary shall
12 use amounts contained in the Start-Up Fund to
13 make risk corridor payments to such adminis-
14 trator during the 2-year period beginning on
15 the date on which such administrator enters
16 into a contract under subsection (e). Such pay-
17 ments shall be based on the risk corridors in ef-
18 fect during fiscal years 2006 and 2007 for
19 making payments under section 1860D-15(e) of
20 the Social Security Act.

21 “(B) SUBSEQUENT YEAR.—In years after
22 the expiration of the period referred to in sub-
23 paragraph (A), the Secretary may extend or in-
24 crease the risk corridors and payments provided
25 for under subparagraph (A).

1 “(C) AMOUNT USED TO REDUCE COSTS.—

2 The Secretary shall deposit any payments re-
3 ceived from a contracting administrator under
4 subparagraph (A) into the Start-Up Fund.

5 “(4) PASS THROUGH OF REBATES.—The Sec-
6 retary may establish procedures for reducing the
7 amount of payments to a contracting administrator
8 to take into account any rebates or price conces-
9 sions.

10 “(5) REPAYMENT.—

11 “(A) IN GENERAL.—A community health
12 insurance option shall be required to repay the
13 Secretary of the Treasury (on such terms as the
14 Secretary may require) for any payments made
15 under paragraph (1)(B) by the date that is not
16 later than 10 years after the date on which the
17 payment is made. The Secretary may require
18 the payment of interest with respect to such re-
19 payments at rates that do not exceed the mar-
20 ket interest rate (as determined by the Sec-
21 retary).

22 “(B) SANCTIONS IN CASE OF FOR-PROFIT
23 CONVERSION.—In any case in which the Sec-
24 retary enters into a contract with a qualified
25 entity for the offering of a community health

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

4 “(i) immediately liable to the Sec-
5 retary for any payments received by such
6 entity from the Start-Up Fund; and

7 “(ii) permanently ineligible to offer a
8 qualified health plan.

9 “(d) STATE ADVISORY COUNCIL.—

10 “(1) ESTABLISHMENT.—A State shall establish
11 or designate a public or non-profit private entity to
12 serve as the State Advisory Council to provide rec-
13 ommendations to the Secretary on the operations
14 and policies of a community health insurance option
15 in the State. Such Council shall provide rec-
16 ommendations on at least the following:

17 “(A) policies and procedures to integrate
18 quality improvement and cost containment
19 mechanisms into the health care delivery sys-
20 tem;

21 “(B) mechanisms to facilitate public
22 awareness of the availability of a community
23 health insurance option; and

24 “(C) alternative payment structures under
25 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-

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

5 “(B) REQUIREMENTS APPLY.—If the Sec-
6 retary enters into a contract with a qualified
7 entity to offer a community health insurance
8 option, under such contract such entity—

9 “(i) shall meet the criteria established
10 under paragraph (2); and

11 “(ii) shall receive an administrative
12 fee under paragraph (7).

13 “(C) LIMITATION.—Contracts under this
14 subsection shall not involve the transfer of in-
15 surance risk to the contracting administrator.

16 “(D) REFERENCE.—An entity with which
17 the Secretary has entered into a contract under
18 this paragraph shall be referred to as a ‘con-
19 tracting administrator’.

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

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

1 “(B) be a nonprofit entity for purposes of
2 offering such option;

3 “(C) meet the solvency standards applica-
4 ble under subsection (b)(7);

5 “(D) be eligible to offer health insurance
6 or health benefits coverage;

7 “(E) meet quality standards specified by
8 the Secretary;

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

11 “(G) meet such other requirements as the
12 Secretary may impose.

13 “Procedures described under subparagraph (F) shall
14 include the implementation of procedures to use ben-
15 eficiary identifiers to identify individuals entitled to
16 benefits so that such an individual’s social security
17 account number is not used, and shall also include
18 procedures for the use of technology (including
19 front-end, prepayment intelligent data-matching
20 technology similar to that used by hedge funds, in-
21 vestment funds, and banks) to provide real-time
22 data analysis of claims for payment under this title
23 to identify and investigate unusual billing or order
24 practices under this title that could indicate fraud or
25 abuse.

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

9 “(4) LIMITATION.—A contract may not be re-
10 newed under this subsection unless the Secretary de-
11 termines that the contracting administrator has met
12 performance requirements established by the Sec-
13 retary in the areas described in paragraph (7)(B).

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

19 “(6) REVOCATION.—A contract awarded under
20 this subsection shall be revoked by the Secretary or
21 the Inspector General only after notice to the con-
22 tracting administrator involved and an opportunity
23 for a hearing. The Secretary may revoke such con-
24 tract if the Secretary determines that such adminis-
25 trator has engaged in fraud, deception, waste, abuse

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

6 “(7) FEE FOR ADMINISTRATION.—

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

11 “(B) REQUIREMENT FOR HIGH QUALITY
12 ADMINISTRATION.—The Secretary may increase
13 the fee described in subparagraph (A) by not
14 more than 10 percent, or reduce the fee de-
15 scribed in subparagraph (A) by not more than
16 50 percent, based on the extent to which the
17 contracting administrator, in the determination
18 of the Secretary, meets performance require-
19 ments established by the Secretary, in at least
20 the following areas:

21 “(i) Maintaining low premium costs
22 and low cost sharing requirements, pro-
23 vided that such requirements are con-
24 sistent with section 3111(a).

1 “(ii) Reducing administrative costs
2 and promoting administrative simplifica-
3 tion for beneficiaries.

4 “(iii) Promoting high quality clinical
5 care.

6 “(iv) Providing high quality customer
7 service to beneficiaries.

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

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

18 “(f) REPORT BY HHS AND INSOLVENCY WARN-
19 INGS.—

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

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

6 “(3) SUBMISSION OF PLAN AND PROCEDURE.—

7 “(A) IN GENERAL.—If there is a commu-
8 nity health insurance option solvency warning
9 under paragraph (2) made in a year, the Presi-
10 dent shall submit to Congress, within the 15-
11 day period beginning on the date of the budget
12 submission to Congress under section 1105(a)
13 of title 31, United States Code, for the suc-
14 ceeding year, proposed legislation to respond to
15 such warning.

16 “(B) PROCEDURE.—In the case of a legis-
17 lative proposal submitted by the President pur-
18 suant to subparagraph (A), such proposal shall
19 be considered by Congress using the same pro-
20 cedures described under sections 803 and 804
21 of the Medicare Prescription Drug, Improve-
22 ment, and Modernization Act of 2003 that shall
23 be used for a medicare funding warning.

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

1 or promotional materials related to a community health
2 insurance option are made available to the public, making
3 available marketing or promotional materials relating to
4 private health insurance plans shall not be prohibited.
5 Such materials include informational pamphlets, guide-
6 books, enrollment forms, or other materials determined
7 reasonable for display.

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

11 **“SEC. 3107. APPLICATION OF SAME LAWS TO PRIVATE**
12 **PLANS AND THE COMMUNITY HEALTH INSUR-**
13 **ANCE OPTION.**

14 “(a) IN GENERAL.—Notwithstanding any other pro-
15 vision of law, any health insurance coverage offered by a
16 private health insurance issuer shall not be subject to any
17 Federal or State law described in subsection (b) if a com-
18 munity health insurance option under section 3106 is not
19 subject to such law.

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

- 23 “(1) guaranteed renewal;
24 “(2) rating;
25 “(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)

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

3 “(b) ELIGIBILITY.—

4 “(1) IN GENERAL.—To be eligible to receive a
5 grant, a State shall designate an office of health in-
6 surance consumer assistance that, directly or in co-
7 ordination with State health insurance regulators
8 and consumer assistance organizations, receives and
9 responds to inquiries and complaints concerning
10 health insurance coverage with respect to Federal
11 health insurance requirements and under State law.

12 “(2) CRITERIA.—A State that receives a grant
13 under this section shall comply with criteria estab-
14 lished by the Secretary for carrying out activities
15 under such grant.

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

18 “(1) assist with the filing of complaints and ap-
19 peals, including filing appeals with a qualified health
20 plan’s internal appeal or grievance process and pro-
21 viding information about the external appeal process;

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

1 “(3) educate consumers on their rights and re-
2 sponsibilities with respect to qualified health plans;
3 and

4 “(4) assist consumers with enrollment in a
5 qualified health plan by providing information, refer-
6 ral, and assistance, in collaboration with navigators
7 under section 3105.

8 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
9 is authorized to be appropriated to carry out this section,
10 \$20,000,000 for fiscal year 2010, and such sums as may
11 be necessary for each fiscal year thereafter.”.

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

14 (a) REQUIREMENT.—Notwithstanding any other pro-
15 vision of law, on the date of enactment of this Act, all
16 Members of Congress and congressional staff shall enroll
17 in a Federal health insurance program—

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

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

22 (b) DEFINITIONS.—In this section:

23 (1) MEMBER OF CONGRESS.—The term “Mem-
24 ber of Congress” means any member of the House
25 of Representatives or the Senate.

1 (2) CONGRESSIONAL STAFF.—The term “con-
2 gressional staff” means all full-time and part-time
3 employees employed by the official office of a Mem-
4 ber of Congress, whether in Washington, DC or out-
5 side of Washington, DC.

6 **Subtitle C—Affordable Coverage**
7 **for All Americans**

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

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

12 **“Subtitle B—Making Coverage**
13 **Affordable**

14 **“SEC. 3111. SUPPORT FOR AFFORDABLE HEALTH COV-**
15 **ERAGE.**

16 “(a) COST SHARING FOR A BASIC PLAN.—

17 “(1) BASIC PLAN.—The Secretary shall estab-
18 lish at least the following tiers of cost sharing for el-
19 igible individuals:

20 “(A) A tier for a basic plan in which—

21 “(i) a qualified health plan shall, on
22 average, provide reimbursement for 76 per-
23 cent of the total allowed costs of the ben-
24 efit provided; and

1 “(ii) the out of pocket limitation for
2 the plan shall not be greater than the out
3 of pocket limitation applicable under sec-
4 tion 223(c)(2) of the Internal Revenue
5 Code of 1986.

6 “(B) A tier in which—

7 “(i) the average reimbursement per-
8 centage is equal to the reimbursement per-
9 centage of the basic plan increased by 8
10 percentage points; and

11 “(ii) the dollar value of the out of
12 pocket limitation shall not be greater than
13 50 percent of the dollar value of the out of
14 pocket limitation of the basic plan.

15 “(C) A tier in which—

16 “(i) the average reimbursement per-
17 centage is equal to the reimbursement per-
18 centage of the basic plan increased by 17
19 percentage points; and

20 “(ii) the dollar value of the out of
21 pocket limitation shall not be greater than
22 20 percent of the dollar value of the out of
23 pocket limitation of the basic plan.

24 “(2) OUT OF POCKET.—For purposes of this
25 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

1 amount that exceeds 12.5 percent of such indi-
2 vidual's income for the year involved.

3 “(B) REDUCTIONS BASED ON INCOME.—

4 The amount that an eligible individual is re-
5 quired to pay under subparagraph (A) shall be
6 ratably reduced to 1 percent of income in the
7 case of an eligible individual with an adjusted
8 gross income equal to 150 percent of the pov-
9 erty line for a family of the size involved for the
10 year.

11 “(3) SIMPLIFIED SCHEDULE.—The Secretary
12 may establish a schedule of premium credits under
13 this subsection in dollar amounts to simplify the ad-
14 ministration of this section so long as any such
15 schedule does not significantly change the value of
16 the premium credits described in paragraph (2).

17 “(4) LIMITATION OF CREDITS.—

18 “(A) IN GENERAL.—A credit under para-
19 graph (1) may not exceed the lesser of the
20 amount of the reference premium for the indi-
21 vidual involved or the premium of the qualified
22 health plan in which such individual is enrolled.

23 “(B) REFERENCE PREMIUM.—In this sec-
24 tion, the term ‘reference premium’ means—

1 “(i) with respect to an individual en-
2 rolling in coverage whose adjusted gross
3 income does not exceed 200 percent of the
4 poverty line for a family of the size in-
5 volved for the year, the weighted average
6 annual premium of the 3 lowest cost quali-
7 fied health plans that—

8 “(I) meet the criteria for cost
9 sharing and out of pocket limits de-
10 scribed in subsection (a)(1)(C); and

11 “(II) are offered in the commu-
12 nity rating area in which the indi-
13 vidual resides;

14 “(ii) with respect to an individual en-
15 rolling in coverage whose adjusted gross
16 income exceeds 200, but does not exceed
17 300, percent of the poverty line for a fam-
18 ily of the size involved for the year, the
19 weighted average annual premium of the 3
20 lowest cost qualified health plans that—

21 “(I) meet the criteria for cost
22 sharing and out of pocket limits de-
23 scribed in subsection (a)(1)(B); and

1 “(II) are offered in the commu-
2 nity rating area in which the indi-
3 vidual resides; and

4 “(iii) with respect to an individual en-
5 rolling in coverage whose adjusted gross
6 income exceeds 300, but does not exceed
7 400, percent of the poverty line for a fam-
8 ily of the size involved for the year, the
9 weighted average annual premium of the 3
10 lowest cost qualified health plans that—

11 “(I) meet the criteria for cost
12 sharing and out of pocket limits de-
13 scribed in subsection (a)(1)(A); and

14 “(II) are offered in the commu-
15 nity rating area in which the indi-
16 vidual resides.

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

21 “(D) LIMITATION.—In determining the 3
22 lowest cost health plans for purposes of this
23 paragraph, the community health insurance op-
24 tion shall not be considered.

25 “(5) METHOD OF CALCULATION.—

1 “(A) CALCULATION OF CREDIT BASED ON
2 ESSENTIAL HEALTH CARE BENEFITS.—In the
3 case of a qualified health plan that provides re-
4 imbursement for benefits that are not included
5 in the essential health benefits established by
6 the Secretary under section 3103(a)(1)(A), the
7 reference premium shall be determined for pur-
8 poses of paragraph (2) without regard to such
9 reimbursement.

10 “(B) RISK ADJUSTMENT.—The reference
11 premium shall be adjusted to account for pre-
12 mium differences based on age, family size, and
13 geographic variation.

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

21 “(6) INDEXING.—Beginning with calendar
22 years after 2013, the percentages described in para-
23 graph (2) that specify the portion of the reference
24 premium that an individual or family is responsible
25 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-

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

3 “(D) resolving appeals of such determina-
4 tions;

5 “(E) redetermining eligibility on a periodic
6 basis; and

7 “(F) making payments under this section.

8 “(2) DETERMINATION OF ELIGIBILITY.—For
9 purposes of paragraph (1), the Secretary shall estab-
10 lish rules that permit eligibility to be determined
11 based on—

12 “(A) the applicant’s adjusted gross income
13 for the second preceding taxable year; or

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

18 “(i) the applicant’s adjusted gross in-
19 come for the most recent period otherwise
20 practicable; or

21 “(ii) the applicant’s declaration of es-
22 timated annual adjusted gross income for
23 the year involved.

24 “(3) DETERMINING ELIGIBILITY.—

25 “(A) AUTHORITY OF THE SECRETARY.—

1 “(i) IN GENERAL.—The Secretary
2 shall have the authority to make deter-
3 minations (including redeterminations)
4 with respect to the eligibility of individuals
5 submitting applications for credits under
6 this section. The Secretary shall verify,
7 through the Internal Revenue Service or
8 using the income and eligibility verification
9 system utilized for purposes of the Med-
10 icaid program under section 1137 of the
11 Social Security Act, the income data re-
12 ceived from individuals submitting applica-
13 tions for credits under this section.

14 “(ii) AUTHORITY TO USE TAX RE-
15 TURNS.—To be eligible to receive a credit
16 under this section, an individual shall—

17 “(I) authorize the disclosure of
18 the tax return information of the indi-
19 vidual as provided for in section
20 6103(l)(21) of the Internal Revenue
21 Code; or

22 “(II) with respect to individuals
23 who do not file a tax return for the
24 year involved—

1 “(aa) provide satisfactory
2 documentation of adjusted gross
3 income, as determined by the
4 Secretary, which may include a
5 prior year Federal income tax re-
6 turn; and

7 “(bb) authorize the disclo-
8 sure to the Secretary of such in-
9 formation as may be required
10 from the Internal Revenue Serv-
11 ice to verify that such individual
12 has not filed a tax return for the
13 year involved.

14 “(iii) STRINGENCY.—The verification
15 requirements with respect to individuals
16 described in clause (ii)(II) shall be at least
17 as stringent as those required under sec-
18 tion 1137 of the Social Security Act.

19 “(B) DELEGATION OF AUTHORITY.—Ex-
20 cept under the conditions described in subpara-
21 graph (D), the Secretary shall delegate to a
22 Gateway (and, upon request from such State or
23 States, to the State or States in which such
24 Gateway operates) the authority to carry out
25 the activities described in subparagraph (A).

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

5 “(C) REQUIREMENT FOR CONSISTENCY.—
6 A Gateway (and, as applicable, the State or
7 States in which such Gateway operates) shall
8 carry out the activities described in subpara-
9 graph (B) in a manner that is consistent with
10 the regulations promulgated under paragraph
11 (1).

12 “(D) REVOCATION OF AUTHORITY.—If the
13 Secretary determines that a Gateway (or the
14 State or States in which such Gateway oper-
15 ates) is carrying out the activities described in
16 subparagraph (A) in a manner that is substan-
17 tially inconsistent with the regulations promul-
18 gated under paragraph (1), the Secretary may,
19 after notice and opportunity for a hearing, re-
20 voke the delegation of authority under subpara-
21 graph (A). If the Secretary revokes the delega-
22 tion of authority, the references to a Gateway
23 in subparagraph (E) and (F) shall be deemed
24 to be references to the Secretary.

1 “(E) REQUIREMENT TO REPORT CHANGE
2 IN STATUS.—

3 “(i) IN GENERAL.—An individual who
4 has been determined to be eligible for cred-
5 its under this section shall notify the Gate-
6 way of any changes that may affect such
7 eligibility in a manner specified by the Sec-
8 retary.

9 “(ii) REDETERMINATION.—If the
10 Gateway receives a notice from an indi-
11 vidual under clause (i), the Gateway shall
12 promptly redetermine the individual’s eligi-
13 bility for payments.

14 “(F) TERMINATION OF PAYMENTS.—The
15 Gateway shall terminate payments on behalf of
16 an individual (after providing notice to the indi-
17 vidual) if—

18 “(i) the individual fails to provide in-
19 formation for purposes of subparagraph
20 (E)(i) on a timely basis; or

21 “(ii) the Gateway determines that the
22 individual is no longer eligible for such
23 payments.

24 “(G) TERRITORIAL TAX AUTHORITIES.—

25 With respect to determinations of eligibility for,

1 or payment of, credits under this section that
2 require the use of information maintained by a
3 tax authority of a United States territory, the
4 Secretary shall make such determination in co-
5 ordination with such authority under rules and
6 procedures that are similar to the rules and
7 procedures applied to determinations made
8 where such information is obtained from the In-
9 ternal Revenue Service.

10 “(4) APPLICATION.—

11 “(A) METHODS.—The process established
12 under paragraph (1)(A) shall permit applica-
13 tions in person, by mail, telephone, or the Inter-
14 net.

15 “(B) FORM AND CONTENTS.—An applica-
16 tion under paragraph (1)(A) shall be in such
17 form and manner as specified by the Secretary,
18 and may require documentation.

19 “(C) SUBMISSION.—An application under
20 paragraph (1)(A) may be submitted to the
21 Gateway, or to a State agency for a determina-
22 tion under this section.

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

1 uals in the filing of applications under para-
2 graph (1)(A).

3 “(5) RECONCILIATION.—

4 “(A) FILING OF STATEMENT.—In the case
5 of an individual who has received payments
6 under this section for a year and who is claim-
7 ing a significant decrease (as determined by the
8 Secretary) in adjusted gross income from such
9 year, such individual shall file with the Sec-
10 retary an income reconciliation statement, at
11 such time, in such manner, and containing such
12 information as the Secretary may require.

13 “(B) RECONCILIATION.—

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

21 “(ii) OVERPAYMENT OF PAYMENTS.—

22 “(I) IN GENERAL.—Subject to
23 the limitation in subclause (II), if the
24 amount of payments provided on be-
25 half of an individual for a year under

1 this section was significantly greater
2 (as determined by the Secretary) than
3 the amount computed under clause
4 (i), the individual shall be liable to the
5 Secretary for such excess amount.
6 The Secretary may establish methods
7 under which such liability may be as-
8 sessed through a reduction in the
9 amount of any credit otherwise appli-
10 cable under this section with respect
11 to such individual.

12 “(II) LIMITATION.—With respect
13 to any individual described in sub-
14 clause (I) who had a verified adjusted
15 gross income that did not exceed 400
16 percent of the poverty line for a fam-
17 ily of the size involved for such year,
18 the amount of any repayment under
19 such subclause (I) shall not exceed—

20 “(aa) \$250 for an individual
21 who filed an individual tax return
22 for such year; or

23 “(bb) \$400 for an individual
24 who filed a joint tax return for
25 such year.

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

6 “(iii) UNDERPAYMENT OF PAY-
7 MENTS.—If the amount of payments pro-
8 vided to an individual for a year under this
9 section was less than the amount computed
10 under clause (i), the Secretary shall pay to
11 the individual the amount of such deficit.
12 The Secretary may establish methods
13 under which such payments may be pro-
14 vided through an increase in the amount of
15 any credit otherwise applicable under this
16 section with respect to such individual.

17 “(iv) COORDINATION WITH IRS.—The
18 Secretary shall coordinate with the Sec-
19 retary of the Treasury to develop proce-
20 dures to enable the Internal Revenue Serv-
21 ice to administer this subparagraph with
22 respect to the collection of overpayments.

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

1 individual shall not be eligible for further pay-
2 ments until such statement is filed. The Sec-
3 retary shall waive the application of this sub-
4 paragraph if the individual establishes, to the
5 satisfaction of the Secretary, good cause for the
6 failure to file the statement on a timely basis.

7 “(D) DETERMINATIONS.—The Secretary
8 shall make determinations with respect to state-
9 ments submitted under this paragraph based on
10 income data from the most recent tax return
11 filed by the individual.

12 “(6) DETERMINATIONS MADE WITH RESPECT
13 TO SAME TAXABLE YEARS.—In making determina-
14 tions under this section with respect to adjusted
15 gross income as compared to the poverty line, the
16 Secretary shall ensure that the poverty line data
17 used relates to the same taxable year for which the
18 adjusted gross income is determined.

19 “(7) OUTREACH.—The Gateway shall conduct
20 culturally and linguistically appropriate outreach ac-
21 tivities to provide information to individuals that
22 may potentially be eligible for payments under this
23 section. Such activities shall include information on
24 the application process with respect to such pay-
25 ments.

1 “(e) EXCLUSION FROM INCOME.—Amounts received
2 by an individual under this section shall not be considered
3 as income, and shall not be taken into account in deter-
4 mining assets or resources for purposes of determining the
5 eligibility of such individual, or any other individual, for
6 benefits or assistance, or the amount or extent of benefits
7 or assistance, under any Federal program or under any
8 State or local program financed in whole or in part with
9 Federal funds.

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

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

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

20 **“SEC. 3112. SMALL BUSINESS HEALTH OPTIONS PROGRAM**
21 **CREDIT.**

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

1 appropriated, the Secretary shall make a payment to such
2 qualified small employer in the amount described in sub-
3 section (b).

4 “(b) GENERAL CREDIT AMOUNT.—For purposes of
5 this section:

6 “(1) IN GENERAL.—The credit amount de-
7 scribed in this subsection shall be the product of—

8 “(A) the applicable amount specified in
9 paragraph (2);

10 “(B) the employer size factor specified in
11 paragraph (3); and

12 “(C) the percentage of year factor specified
13 in paragraph (4).

14 “(2) APPLICABLE AMOUNT.—For purposes of
15 paragraph (1):

16 “(A) IN GENERAL.—The applicable
17 amount shall be equal to—

18 “(i) \$1,000 for each employee of the
19 employer who receives self-only health in-
20 surance coverage through the employer;

21 “(ii) \$2,000 for each employee of the
22 employer who receives family health insur-
23 ance coverage through the employer; and

24 “(iii) \$1,500 for each employee of the
25 employer who receives health insurance

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

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

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

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

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

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

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

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

7 “(F) With respect to an employer with
8 more than 50 full-time employees, the percent-
9 age shall be 0 percent.

10 “(4) PERCENTAGE OF YEAR FACTOR.—For pur-
11 poses of paragraph (1), the percentage of year factor
12 shall be equal to the ratio of—

13 “(A) the number of months during the
14 year for which the employer paid or incurred at
15 least 60 percent of the qualified employee
16 health insurance expenses of such employer;
17 and

18 “(B) 12.

19 “(c) DEFINITIONS AND SPECIAL RULES.—For pur-
20 poses of this section:

21 “(1) QUALIFIED SMALL EMPLOYER.—

22 “(A) IN GENERAL.—The term ‘qualified
23 small employer’ means an employer (as defined
24 in section 3(d) of the Fair Labor Standards Act

1 of 1938 and including self-employed individ-
2 uals) that—

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

7 “(ii) was—

8 “(I) an employer that—

9 “(aa) employed an average
10 of 50 or fewer full-time employ-
11 ees during the preceding taxable
12 year; and

13 “(bb) had an average wage
14 of less than \$50,000 for full time
15 employees in the preceding tax-
16 able year; or

17 “(II) a self-employed individual
18 that—

19 “(aa) had not less than
20 \$5,000 in net earnings;

21 “(bb) had not greater than
22 \$50,000 in net earnings; and

23 “(cc) has elected not to re-
24 ceive a credit under section 3111.

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

4 “(2) QUALIFIED EMPLOYEE HEALTH INSUR-
5 ANCE EXPENSES.—

6 “(A) IN GENERAL.—The term ‘qualified
7 employee health insurance expenses’ means any
8 amount paid by an employer or an employee of
9 such employer for health insurance coverage to
10 the extent such amount is for coverage—

11 “(i) provided to any employee (as de-
12 fined in section 3(e) of the Fair Labor
13 Standards Act of 1938), or

14 “(ii) for a self-employed individual.

15 “(B) EXCEPTION FOR AMOUNTS PAID
16 UNDER SALARY REDUCTION ARRANGEMENTS.—
17 No amount paid or incurred for health insur-
18 ance coverage pursuant to a salary reduction
19 arrangement shall be taken into account for
20 purposes of subparagraph (A).

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

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

3 “(d) INFLATION ADJUSTMENT.—

4 “(1) IN GENERAL.—For each calendar year
5 after 2010, the dollar amounts specified in sub-
6 sections (b)(2)(A), (b)(2)(B), and (c)(1)(A)(ii) (after
7 the application of this paragraph) shall be the
8 amounts in effect in the preceding calendar year or,
9 if greater, the product of—

10 “(A) the corresponding dollar amount
11 specified in such subsection; and

12 “(B) the ratio of the index of wage infla-
13 tion (as determined by the Bureau of Labor
14 Statistics) for August of the preceding calendar
15 year to such index of wage inflation for August
16 of 2008.

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

21 “(e) APPLICATION OF CERTAIN RULES IN DETER-
22 MINATION OF EMPLOYER SIZE.—For purposes of this sec-
23 tion:

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

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

4 “(2) EMPLOYERS NOT IN EXISTENCE IN PRE-
5 CEDING YEAR.—In the case of an employer which
6 was not in existence for the full preceding taxable
7 year, the determination of whether such employer
8 meets the requirements of this section shall be based
9 on the average number of full-time employees that it
10 is reasonably expected such employer will employ on
11 business days in the employer’s first full taxable
12 year.

13 “(3) PREDECESSORS.—Any reference in this
14 subsection to an employer shall include a reference
15 to any predecessor of such employer.”.

16 **SEC. 152. PROGRAM INTEGRITY.**

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

20 “(21) VOLUNTARY AUTHORIZATION FOR IN-
21 COME VERIFICATION.—

22 “(A) VOLUNTARY AUTHORIZATION.—The
23 Secretary shall provide a mechanism for each
24 taxpayer to indicate whether such taxpayer au-
25 thorizes the Secretary to disclose to the Sec-

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

8 “(B) PROVISION OF INFORMATION.—If a
9 taxpayer authorizes the disclosure described in
10 subparagraph (A), the Secretary shall disclose
11 to the Secretary of Health and Human Services
12 (or, pursuant to a delegation described in sub-
13 section (d)(4)(B), to a State or a Gateway) the
14 minimum necessary amount of information nec-
15 essary to establish whether such individual is el-
16 igible for credits under section 3111 of the
17 Public Health Service Act.

18 “(C) RESTRICTION ON USE OF DISCLOSED
19 INFORMATION.—Return information disclosed
20 under subparagraph (A) may be used by the
21 Secretary (or, pursuant to a delegation de-
22 scribed in subsection (d)(4)(B), a State or a
23 Gateway) only for the purposes of, and to the
24 extent necessary in, establishing the appropriate

1 amount of any payments under section 3111 of
2 the Public Health Service Act.”.

3 (b) COLLECTION OF AMOUNTS.—Section 6305(a) of
4 the Internal Revenue Code of 1986 is amended by insert-
5 ing “or under section 3111 of the Public Health Service
6 Act” after “Social Security Act”.

7 (c) CONFORMING AMENDMENTS.—

8 (1) Paragraph (3) of section 6103(a) of such
9 Code is amended by striking “or (20)” and inserting
10 “(20), or (21)”.

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

15 (3) Paragraph (2) of section 7213(a) of such
16 Code is amended by striking “or (20)” and inserting
17 “(20), or (21)”.

18 **Subtitle D—Shared Responsibility**
19 **for Health Care**

20 **SEC. 161. INDIVIDUAL RESPONSIBILITY.**

21 (a) PAYMENTS.—

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

1 **“PART VIII—SHARED RESPONSIBILITY**
2 **PAYMENTS**

“Sec. 59B. Shared responsibility payments.

3 **“SEC. 59B. SHARED RESPONSIBILITY PAYMENTS.**

4 “(a) REQUIREMENT.—Every individual shall ensure
5 that such individual, and each dependent of such indi-
6 vidual, is covered under qualifying coverage at all times
7 during the taxable year.

8 “(b) PAYMENT.—

9 “(1) IN GENERAL.—

10 “(A) IN GENERAL.—In the case of any in-
11 dividual who did not have in effect qualifying
12 coverage (as defined in section 3116 of the
13 Public Health Service Act) for any month dur-
14 ing the taxable year, there is hereby imposed
15 for the taxable year, in addition to any other
16 amount imposed by this subtitle, an amount
17 equal to the amount established under para-
18 graph (2).

19 “(B) RULE FOR DEPENDENTS.—Any
20 amount to be imposed under this subsection
21 with respect to an individual described in sub-
22 paragraph (A) that is a dependent (as defined
23 in section 152) of another taxpayer shall be im-
24 posed—

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

4 “(ii) in any case in which the taxpayer
5 with respect to whom such individual is a
6 dependent files a joint return, jointly upon
7 the taxpayer and the spouse of the tax-
8 payer.

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

13 “(2) AMOUNT ESTABLISHED.—

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

20 “(B) EFFECTIVE DATE.—The amount es-
21 tablished under subparagraph (A) shall be ef-
22 fective with respect to the taxable year following
23 the date on which the amount under subpara-
24 graph (A) is established.

1 “(C) REQUIRED CONSIDERATION.—Subject
2 to the limitation described in subparagraph (D),
3 in establishing the amount under subparagraph
4 (A), the Secretary shall seek to establish the
5 minimum practicable amount that can accom-
6 plish the goal of enhancing participation in
7 qualifying coverage (as so defined).

8 “(D) LIMITATION.—

9 “(i) IN GENERAL.—Subject to an ad-
10 justment under clause (ii), the amount es-
11 tablished under this subparagraph is \$750.

12 “(ii) INFLATION ADJUSTMENT.—Be-
13 ginning with taxable years after 2011, the
14 amount described in clause (i) shall be ad-
15 justed by the Secretary by notice, pub-
16 lished in the Federal Register, for each fis-
17 cal year to reflect the total percentage
18 change that occurred in the medical care
19 component of the Consumer Price Index
20 for all urban consumers (all items; U.S.
21 city average) during the preceding calendar
22 year.

23 “(c) EXEMPTIONS.—Subsection (b) shall not apply to
24 any individual—

1 “(1) with respect to any month if such month
2 occurs during any period in which such individual
3 did not have qualifying coverage (as so defined) for
4 a period of less than 90 days,

5 “(2) who is a resident of a State that is not a
6 participating State or an establishing State (as such
7 terms are defined in section 3104 of the Public
8 Health Service Act),

9 “(3) who is an Indian as defined in section 4
10 of the Indian Health Care Improvement Act,

11 “(4) for whom affordable health care coverage
12 is not available (as such terms are defined by the
13 Secretary of Health and Human Services under sec-
14 tion 3103 of the Public Health Service Act), or

15 “(5) described in section 3116(a)(4)(C) of the
16 Public Health Service Act.

17 “(d) COORDINATION WITH OTHER PROVISIONS.—

18 “(1) NOT TREATED AS TAX FOR CERTAIN PUR-
19 POSES.—The amount imposed by this section shall
20 not be treated as a tax imposed by this chapter for
21 purposes of determining—

22 “(A) the amount of any credit allowable
23 under this chapter, or

24 “(B) the amount of the minimum tax im-
25 posed by section 55.

1 “(2) TREATMENT UNDER SUBTITLE F.—For
2 purposes of subtitle F, the amount imposed by this
3 section shall be treated as if it were a tax imposed
4 by section 1.

5 “(3) SECTION 15 NOT TO APPLY.—Section 15
6 shall not apply to the amount imposed by this sec-
7 tion.

8 “(4) SECTION NOT TO AFFECT LIABILITY OF
9 POSSESSIONS, ETC.—This section shall not apply for
10 purposes of determining liability to any possession of
11 the United States. For purposes of section 932 and
12 7654, the amount imposed under this section shall
13 not be treated as a tax imposed by this chapter.

14 “(e) USES.—Amounts collected under this section
15 shall be dedicated to premium credits established under
16 section 3111 of the Public Health Service Act.

17 “(f) REGULATIONS.—The Secretary may prescribe
18 such regulations as may be appropriate to carry out the
19 purposes of this section.”.

20 (2) CLERICAL AMENDMENT.—The table of
21 parts for subchapter A of chapter 1 of such Code is
22 amended by adding at the end the following new
23 item:

 “PART VIII—SHARED RESPONSIBILITY PAYMENTS”.

1 (3) EFFECTIVE DATE.—The amendments made
2 by this section shall apply to taxable years beginning
3 after December 31, 2011.

4 (b) REPORTING OF HEALTH INSURANCE COV-
5 ERAGE.—

6 (1) IN GENERAL.—Part III of subchapter A of
7 chapter 61 of the Internal Revenue Code of 1986 is
8 amended by inserting after subpart B the following
9 new subpart:

10 **“Subpart D—Information Regarding Health**
11 **Insurance Coverage**

“Sec. 6055. Reporting of health insurance coverage.

12 **“SEC. 6055. REPORTING OF HEALTH INSURANCE COV-**
13 **ERAGE.**

14 “(a) IN GENERAL.—Every person who provides
15 health insurance that is qualifying coverage shall make a
16 return described in subsection (b).

17 “(b) FORM AND MANNER OF RETURN.—A return is
18 described in this subsection if such return—

19 “(1) is in such form as the Secretary pre-
20 scribes,

21 “(2) contains—

22 “(A) the name, address, and taxpayer
23 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.

1 **SEC. 162. NOTIFICATION ON THE AVAILABILITY OF AF-**
2 **FORDABLE HEALTH CHOICES.**

3 The Fair Labor Standards Act of 1938 is amended
4 by inserting after section 18 (29 U.S.C. 218) the fol-
5 lowing:

6 **“SEC. 18A. NOTICE TO EMPLOYEES.**

7 “(a) IN GENERAL.—In accordance with regulations
8 promulgated by the Secretary, an employer to which this
9 Act applies, shall provide to each employee at the time
10 of hiring (or with respect to current employees, within 90
11 days of the date on which a State becomes an establishing
12 or participating State under section 3104 of the Public
13 Health Service Act), written notice informing the em-
14 ployee of the existence of the American Health Benefits
15 Gateway, including a description of the services provided
16 by such Gateway and the manner in which the employee
17 may contact the Gateway to request assistance.

18 “(b) EFFECTIVE DATE.—Subsection (a) shall take
19 effect with respect to employers in a State beginning 90
20 days after the date on which the State becomes an estab-
21 lishing or participating State under section 3104 of the
22 Public Health Service Act.”.

23 **SEC. 163. SHARED RESPONSIBILITY OF EMPLOYERS.**

24 Subtitle B of title XXXI of the Public Health Service
25 Act, as amended by section 151, is further amended by
26 adding at the end the following:

1 **“SEC. 3115. SHARED RESPONSIBILITY OF EMPLOYERS.**

2 “(a) EMPLOYEES NOT OFFERED COVERAGE.—An
3 employer shall make a payment to the Secretary in the
4 amount described in subsection (b) with respect to each
5 employee—

6 “(1) who is not offered qualifying coverage by
7 such employer during each month where such em-
8 ployee is not offered qualifying coverage; or

9 “(2) on behalf of whom such employer is not
10 contributing at least 60 percent of the monthly pre-
11 miums for such coverage for each such month.

12 “(b) AMOUNT.—

13 “(1) IN GENERAL.—The annual amount de-
14 scribed in this subsection shall be equal to \$750 for
15 each full-time employee described in subsection (a).
16 Such amount shall be pro-rated with respect to each
17 month in which subsection (a) applies with respect
18 to an employee.

19 “(2) PRO RATA APPLICATION FOR PART-TIME
20 EMPLOYEES.—The provisions of paragraph (1) shall
21 apply with respect to part-time employees employed
22 by the employer, except that the annual payment
23 amount described in such paragraph shall be re-
24 duced to \$375 for each part-time employee.

25 “(3) APPLICATION.—The provisions of this sub-
26 section shall only apply with respect to the number

1 of employees employed by the employer in excess of
2 25 employees.

3 “(c) PROCEDURES.—The Secretary shall develop pro-
4 cedures for making determinations with respect to quali-
5 fying coverage and for making the payments required
6 under subsection (a). Such procedures shall provide for
7 the making of payments on a quarterly basis.

8 “(d) USE OF FUNDS.—Amounts shall be collected
9 under subsection (a) and be available for obligation only
10 to the extent and in the amount provided in advance in
11 appropriations Acts. Such amounts are authorized to re-
12 main available until expended.

13 “(e) INFLATION ADJUSTMENT.—Beginning with cal-
14 endar years after 2013, the amounts described in sub-
15 section (b) shall be adjusted by the Secretary by notice,
16 published in the Federal Register, for each fiscal year to
17 reflect the total percentage change that occurred in the
18 medical care component of the Consumer Price Index for
19 all urban consumers (all items; U.S. city average) during
20 the preceding calendar year.

21 “(f) EXEMPTION FOR SMALL EMPLOYERS.—

22 “(1) IN GENERAL.—For purposes of this sec-
23 tion, the term ‘employer’ means an employer that
24 employs more than 25 employees on business days
25 during the preceding calendar year. An employer

1 shall not be considered to employ more than 25 em-
2 ployees if—

3 “(A) the employer’s workforce exceeds 25
4 employees for 120 days or fewer during the cal-
5 endar year; and

6 “(B) the employees employed during such
7 120-day period were seasonal workers.

8 “(2) DEFINITION OF SEASONAL WORKERS.—In
9 this subsection, the term ‘seasonal worker’ means an
10 individual who performs labor or services on a sea-
11 sonal basis where, ordinarily, the employment per-
12 tains to or is of the kind exclusively performed at
13 certain seasons or periods of the year and which,
14 from its nature, may not be continuous or carried on
15 throughout the year.

16 “(3) APPLICATION OF AGGREGATION RULE FOR
17 EMPLOYERS.—All persons treated as a single em-
18 ployer under subsection (b), (c), (m), or (o) of sec-
19 tion 414 of the Internal Revenue Code of 1986 shall
20 be treated as 1 employer.

21 “(4) EMPLOYERS NOT IN EXISTENCE IN PRE-
22 CEDING YEAR.—In the case of an employer which
23 was not in existence throughout the preceding cal-
24 endar year, the determination of whether such em-
25 ployer is a small or large employer shall be based on

1 the average number of employees that it is reason-
2 ably expected such employer will employ on business
3 days in the current calendar year.

4 “(5) PREDECESSORS.—Any reference in this
5 subsection to an employer shall include a reference
6 to any predecessor of such employer.

7 “(g) AUTHORITY TO CERTIFY.—The Secretary, in
8 collaboration with the Secretary of the Treasury and the
9 Secretary of Labor, shall establish procedures for deter-
10 mining the number of employees of employers who are not
11 offered qualifying coverage.

12 “(h) INDEPENDENT CONTRACTORS.—For purposes
13 of determining whether an employer is subject to this sec-
14 tion, any individual who qualifies as an independent con-
15 tractor under Federal law and who is retained by such
16 employer shall not be counted when determining the num-
17 ber of employees employed by the employer.

18 “(i) REGULATIONS.—The Secretary, in consultation
19 with the Secretary of Labor, shall promulgate such regula-
20 tions as may be appropriate to carry out activities under
21 this section.

22 “(j) EFFECTIVE DATE.—This section shall apply
23 with respect to an employer beginning in the calendar year
24 in which the State in which the employer is located be-
25 comes an establishing State or a participating State.

1 **“SEC. 3116. DEFINITIONS.**

2 “(a) IN GENERAL.—In this title:

3 “(1) ELIGIBLE INDIVIDUAL.—The term ‘eligible
4 individual’ means an individual who is—

5 “(A) a citizen or national of the United
6 States or an alien lawfully admitted to the
7 United States for permanent residence or an
8 alien lawfully present in the United States;

9 “(B) a qualified individual;

10 “(C) enrolled in a qualified health plan;
11 and

12 “(D) not receiving full benefits coverage
13 under a State child health plan under title XXI
14 of the Social Security Act (42 U.S.C. 1397aa et
15 seq.) (or full benefits coverage under a dem-
16 onstration project funded through such title
17 XXI).

18 “(2) QUALIFIED EMPLOYER.—

19 “(A) IN GENERAL.—The term ‘qualified
20 employer’ means an employer that—

21 “(i) elects to make all full-time em-
22 ployees of such employer eligible for a
23 qualified health plan; and

24 “(ii)(I) in the case of an employer
25 that elects to make its employees eligible

1 for qualified health plans in an establishing
2 State—

3 “(aa) employs fewer than the
4 number of employees specified in sub-
5 paragraph (B); and

6 “(bb) meets criteria established
7 by the State; or

8 “(II) in the case of an employer that
9 elects to make its employees eligible for
10 qualified health plans in a participating
11 State—

12 “(aa) employs fewer than the
13 number of employees specified in sub-
14 paragraph (B); and

15 “(bb) meets criteria established
16 by the Secretary.

17 “(B) NUMBER OF EMPLOYEES.—

18 “(i) ESTABLISHMENT.—

19 “(I) BY STATE.—In the case of
20 an establishing State, such State may
21 by regulation establish the number of
22 employees described in subparagraph
23 (A)(ii)(I)(aa) but such number may
24 not be less than 50.

1 “(II) BY THE SECRETARY.—In
2 the case of a participating State, the
3 Secretary may by regulation establish
4 the number of employees described in
5 subparagraph (A)(ii)(II)(aa) but such
6 number may not be less than 50.

7 “(ii) DEFAULT.—If a State or the
8 Secretary does not establish the number
9 described in subclause (I) or (II), respec-
10 tively, of clause (i), such number shall be
11 50.

12 “(C) CONTINUATION OF PARTICIPATION.—
13 A qualified employer that is enrolled in a quali-
14 fied health plan and that experiences an in-
15 crease in the number of employees of such em-
16 ployer such that the number of employees of
17 such employer exceeds the number specified in
18 subparagraph (B)(i) or subparagraph (B)(ii), as
19 applicable, shall, notwithstanding such increase,
20 continue to be considered a qualified employer
21 for purposes of this title, provided that such
22 employer remains enrolled in a qualified health
23 plan.

24 “(3) QUALIFIED HEALTH PLAN.—

1 “(A) IN GENERAL.—The term ‘qualified
2 health plan’ means health plan that—

3 “(i) has in effect a certification (which
4 may include a seal or other indication of
5 approval) that such plan meets the criteria
6 for certification described in section
7 3101(m) issued or recognized by each
8 Gateway through which such plan is of-
9 fered; and

10 “(ii) is offered by a health insurance
11 issuer that—

12 “(I) is licensed and in good
13 standing to offer health insurance cov-
14 erage in each State in which such
15 issuer offers health insurance coverage
16 under this title;

17 “(II) agrees to offer at least one
18 qualified health plan in the tier de-
19 scribed in section 3111(a)(1)(A) and
20 at least one plan in the tier described
21 in section 3111(a)(1)(B);

22 “(III) complies with the regula-
23 tions developed by the Secretary
24 under section 3101(m) and such other

1 requirements as an applicable Gate-
2 way may establish; and

3 “(IV) agrees to pay any sur-
4 charge assessed under section
5 3101(c)(4).

6 “(B) INCLUSION OF COMMUNITY HEALTH
7 INSURANCE OPTION.—Any reference in this title
8 to a qualified health plan shall be deemed to in-
9 clude a community health insurance option, un-
10 less specifically provided for otherwise.

11 “(4) QUALIFIED INDIVIDUAL.—

12 “(A) IN GENERAL.—The term ‘qualified
13 individual’ means an individual who is—

14 “(i) residing in a participating State
15 or an establishing State (as defined in sec-
16 tion 3104);

17 “(ii) not incarcerated, except an indi-
18 vidual in custody pending the disposition of
19 charges;

20 “(iii) not entitled to coverage under
21 the Medicare program under part A of title
22 XVIII of the Social Security Act;

23 “(iv) not enrolled in coverage under
24 the Medicare program under part B of title

1 XVIII of the Social Security Act or under
2 part C of such title; and

3 “(v) not eligible for coverage under—

4 “(I) the Medicaid program under
5 a State plan under title XIX of the
6 Social Security Act (42 U.S.C. 1396
7 et seq.), or under a waiver under sec-
8 tion 1115 of such Act;

9 “(II) the TRICARE program
10 under chapter 55 of title 10, United
11 States Code (as defined in section
12 1072(7) of such title);

13 “(III) the Federal employees
14 health benefits program under chapter
15 89 of title 5, United States Code; or

16 “(IV) employer-sponsored cov-
17 erage (except as provided under sub-
18 paragraph (B)).

19 “(B) EMPLOYEES WITHOUT AFFORDABLE
20 COVERAGE.—An individual who is eligible for
21 employer-sponsored coverage shall be deemed to
22 be a qualified individual under subparagraph
23 (A) only if such coverage—

1 “(i) does not meet the criteria estab-
2 lished under section 3103 for minimum
3 qualifying coverage; or

4 “(ii) is not affordable (as such term is
5 defined by the Secretary under section
6 3103) for such employee.

7 “(C) INDIVIDUALS AT LESS THAN 150 PER-
8 CENT OF POVERTY.—An individual with an ad-
9 justed gross income that does not exceed 150
10 percent of the poverty line for a family of the
11 size involved shall not be considered a qualified
12 individual for purposes of this title.

13 “(5) QUALIFYING COVERAGE.—The term ‘quali-
14 fying coverage’ means—

15 “(A) a group health plan or health insur-
16 ance coverage—

17 “(i) that an individual is enrolled in
18 on the date of enactment of this title; or

19 “(ii) that is described in clause (i) and
20 that is renewed by an enrollee as provided
21 for in section 131 of the Affordable Health
22 Choices Act;

23 “(B) a group health plan or health insur-
24 ance coverage that—

1 “(i) is not described in subparagraph
2 (A); and

3 “(ii) meets or exceeds the criteria for
4 minimum qualifying coverage (as defined
5 in section 3103);

6 “(C) Medicare coverage under parts A and
7 B of title XVIII of the Social Security Act or
8 under part C of such title;

9 “(D) Medicaid coverage under a State plan
10 under title XIX of the Social Security Act (or
11 under a waiver under section 1115 of such
12 Act), other than coverage consisting solely of
13 benefits under section 1928 of such Act;

14 “(E) coverage under title XXI of the So-
15 cial Security Act;

16 “(F) coverage under the TRICARE pro-
17 gram under chapter 55 of title 10, United
18 States Code;

19 “(G) coverage under the veteran’s health
20 care program under chapter 17 of title 38,
21 United States Code, but only if the coverage for
22 the individual involved is determined by the
23 Secretary to be not less than the coverage pro-
24 vided under a qualified health plan, based on

1 the individual's priority for services as provided
2 under section 1705(a) of such title;

3 “(H) coverage under the Federal employ-
4 ees health benefits program under chapter 89 of
5 title 5, United States Code;

6 “(I) a State health benefits high risk pool;

7 “(J) a health benefit plan under section
8 2504(e) of title 22, United States Code; or

9 “(K) coverage under a qualified health
10 plan.

11 For purposes of this paragraph, an individual shall
12 be deemed to have qualifying coverage if such indi-
13 vidual is an individual described in section 1402(e)
14 or (g) of the Internal Revenue Code of 1986.

15 “(6) ADJUSTED GROSS INCOME.—The term ‘ad-
16 justed gross income’ with respect to an individual
17 has the meaning given such term for purposes of
18 section 62(a) of the Internal Revenue Code of 1986.

19 “(7) EDUCATED HEALTH CARE CONSUMER.—
20 The term ‘educated health care consumer’ means an
21 individual who is knowledgeable about the health
22 care system, and has background or experience in
23 making informed decisions regarding health, med-
24 ical, and scientific matters.

1 “(b) INCORPORATION OF ADDITIONAL DEFINI-
2 TIONS.—Unless specifically provided for otherwise, the
3 definitions contained in section 2791 shall apply with re-
4 spect to this title.”.

5 **Subtitle E—Improving Access to**
6 **Health Care Services**

7 **SEC. 171. SPENDING FOR FEDERALLY QUALIFIED HEALTH**
8 **CENTERS (FQHCS).**

9 (a) IN GENERAL.—Section 330(r) of the Public
10 Health Service Act (42 U.S.C. 254b(r)) is amended by
11 striking paragraph (1) and inserting the following:

12 “(1) GENERAL AMOUNTS FOR GRANTS.—For
13 the purpose of carrying out this section, in addition
14 to the amounts authorized to be appropriated under
15 subsection (d), there is authorized to be appro-
16 priated the following:

17 “(A) For fiscal year 2010,
18 \$2,988,821,592.

19 “(B) For fiscal year 2011,
20 \$3,862,107,440.

21 “(C) For fiscal year 2012, \$4,990,553,440.

22 “(D) For fiscal year 2013,
23 \$6,448,713,307.

24 “(E) For fiscal year 2014,
25 \$7,332,924,155.

1 “(F) For fiscal year 2015,
2 \$8,332,924,155.

3 “(G) For fiscal year 2016, and each subse-
4 quent fiscal year, the amount appropriated for
5 the preceding fiscal year adjusted by the prod-
6 uct of—

7 “(i) one plus the average percentage
8 increase in costs incurred per patient
9 served; and

10 “(ii) one plus the average percentage
11 increase in the total number of patients
12 served.”.

13 (b) RULE OF CONSTRUCTION.—Section 330(r) of the
14 Public Health Service Act (42 U.S.C. 254b(r)) is amended
15 by adding at the end the following:

16 “(4) RULE OF CONSTRUCTION WITH RESPECT
17 TO RURAL HEALTH CLINICS.—

18 “(A) IN GENERAL.—Nothing in this sec-
19 tion shall be construed to prevent a community
20 health center from contracting with a Federally
21 certified rural health clinic (as defined in sec-
22 tion 1861(aa)(2) of the Social Security Act), a
23 low-volume hospital (as defined for purposes of
24 section 1886 of such Act), a critical access hos-
25 pital, a sole community hospital (as defined for

1 purposes of section 1886(d)(5)(D)(iii) of such
2 Act), or a medicare-dependent share hospital
3 (as defined for purposes of section
4 1886(d)(5)(G)(iv) of such Act) for the delivery
5 of primary health care services that are avail-
6 able at the clinic or hospital to individuals who
7 would otherwise be eligible for free or reduced
8 cost care if that individual were able to obtain
9 that care at the community health center. Such
10 services may be limited in scope to those pri-
11 mary health care services available in that clinic
12 or hospitals.

13 “(B) ASSURANCES.—In order for a clinic
14 or hospital to receive funds under this section
15 through a contract with a community health
16 center under subparagraph (A), such clinic or
17 hospital shall establish policies to ensure—

18 “(i) nondiscrimination based on the
19 ability of a patient to pay; and

20 “(ii) the establishment of a sliding fee
21 scale for low-income patients.”.

22 **SEC. 172. OTHER PROVISIONS.**

23 (a) SETTINGS FOR SERVICE DELIVERY.—Section
24 330(a)(1) of the Public Health Service Act (42 U.S.C.
25 254b(a)(1)) is amended by adding at the end the fol-

1 lowing: “Required primary health services and additional
2 health services may be provided either at facilities directly
3 operated by the center or at any other inpatient or out-
4 patient settings determined appropriate by the center to
5 meet the needs of its patents.”.

6 (b) LOCATION OF SERVICE DELIVERY SITES.—Sec-
7 tion 330(a) of the Public Health Service Act (42 U.S.C.
8 254b(a)) is amended by adding at the end the following:

9 “(3) CONSIDERATIONS.—

10 “(A) LOCATION OF SITES.—Subject to
11 subparagraph (B), a center shall not be re-
12 quired to locate its service facility or facilities
13 within a designated medically underserved area
14 in order to serve either the residents of its
15 catchment area or a special medically under-
16 served population comprised of migratory and
17 seasonal agricultural workers, the homeless, or
18 residents of public housing, if that location is
19 determined by the center to be reasonably ac-
20 cessible to and appropriate to meet the needs of
21 the medically underserved residents of the cen-
22 ter’s catchment area or the special medically
23 underserved population, in accordance with sub-
24 paragraphs (A) and (J) of subsection (k)(3).

1 “(B) LOCATION WITHIN ANOTHER CEN-
2 TER’S AREA.—The Secretary may permit appli-
3 cants for grants under this section to propose
4 the location of a service delivery site within an-
5 other center’s catchment area if the applicant
6 demonstrates sufficient unmet need in such
7 area and can otherwise justify the need for ad-
8 ditional Federal resources in the catchment
9 area. In determining whether to approve such a
10 proposal, the Secretary shall take into consider-
11 ation whether collaboration between the two
12 centers exists, or whether the applicant has
13 made reasonable attempts to establish such col-
14 laboration, and shall consider any comments
15 timely submitted by the affected center con-
16 cerning the potential impact of the proposal on
17 the availability or accessibility of services the
18 affected center currently provides or the finan-
19 cial viability of the affected center.”.

20 (c) AFFILIATION AGREEMENTS.—Section
21 330(k)(3)(B) of the Public Health Service Act (42 U.S.C.
22 254b(k)(3)(B)) is amended by inserting before the semi-
23 colon the following: “, including contractual arrangements
24 as appropriate, while maintaining full compliance with the
25 requirements of this section, including the requirements

1 of subparagraph (H) concerning the composition and au-
2 thorities of the center’s governing board, and, except as
3 otherwise provided in clause (ii) of such subparagraph, en-
4 suring full autonomy of the center over policies, direction,
5 and operations related to health care delivery, personnel,
6 finances, and quality assurance”.

7 (d) GOVERNANCE REQUIREMENTS.—Section
8 330(k)(3) of the Public Health Service Act (42 U.S.C.
9 254b(k)(3)) is amended—

10 (1) in subparagraph (H)—

11 (A) in clause (ii), strike “; and” and in-
12 serting “, except that in the case of a public
13 center (as defined in the second sentence of this
14 paragraph), the public entity may retain au-
15 thority to establish financial and personnel poli-
16 cies for the center; and”;

17 (B) in clause (iii), by adding “and” at the
18 end; and

19 (C) by inserting after clause (iii) the fol-
20 lowing:

21 “(iv) in the case of a co-applicant with
22 a public entity, meets the requirements of
23 clauses (i) and (ii);”;

24 (2) in the second sentence, by inserting before
25 the period the following: “that is governed by a

1 board that satisfies the requirements of subpara-
2 graph (H) or that jointly applies (or has applied) for
3 funding with a co-applicant board that meets such
4 requirements”.

5 (e) ADJUSTMENT IN CENTER’S OPERATING PLAN
6 AND BUDGET.—Section 330(k)(3)(I)(i) of the Public
7 Health Service Act (42 U.S.C. 254b(k)(3)(I)(i)) is amend-
8 ed by adding before the semicolon the following: “, which
9 may be modified by the center at any time during the fis-
10 cal year involved if such modifications do not require addi-
11 tional grant funds, do not compromise the availability or
12 accessibility of services currently provided by the center,
13 and otherwise meet the conditions of subsection (a)(3)(B),
14 except that any such modifications that do not comply
15 with this clause, as determined by the health center, shall
16 be submitted to the Secretary for approval”.

17 (f) JOINT PURCHASING ARRANGEMENTS FOR RE-
18 DUCED COST.—Section 330(l) of the Public Health Serv-
19 ice Act (42 U.S.C. 254b(l)) is amended—

20 (1) by striking “The Secretary” and inserting
21 the following:

22 “(1) IN GENERAL.—The Secretary”; and

23 (2) by adding at the end the following:

24 “(2) ASSISTANCE WITH SUPPLIES AND SERV-
25 ICES COSTS.—The Secretary, directly or through

1 grants or contracts, may carry out projects to estab-
2 lish and administer arrangements under which the
3 costs of providing the supplies and services needed
4 for the operation of federally qualified health centers
5 are reduced through collaborative efforts of the cen-
6 ters, through making purchases that apply to mul-
7 tiple centers, or through such other methods as the
8 Secretary determines to be appropriate.”.

9 (g) OPPORTUNITY TO CORRECT MATERIAL FAILURE
10 REGARDING GRANT CONDITIONS.—Section 330(e) of the
11 Public Health Service Act (42 U.S.C. 254b(e)) is amended
12 by adding at the end the following:

13 “(6) OPPORTUNITY TO CORRECT MATERIAL
14 FAILURE REGARDING GRANT CONDITIONS.—If the
15 Secretary finds that a center materially fails to meet
16 any requirement (except for any requirements
17 waived by the Secretary) necessary to qualify for its
18 grant under this subsection, the Secretary shall pro-
19 vide the center with an opportunity to achieve com-
20 pliance (over a period of up to 1 year from making
21 such finding) before terminating the center’s grant.
22 A center may appeal and obtain an impartial review
23 of any Secretarial determination made with respect
24 to a grant under this subsection, or may appeal and
25 receive a fair hearing on any Secretarial determina-

1 tion involving termination of the center’s grant enti-
2 tlement, modification of the center’s service area,
3 termination of a medically underserved population
4 designation within the center’s service area, disallow-
5 ance of any grant expenditures, or a significant re-
6 duction in a center’s grant amount.”.

7 **SEC. 173. NEGOTIATED RULEMAKING FOR DEVELOPMENT**
8 **OF METHODOLOGY AND CRITERIA FOR DES-**
9 **IGNATING MEDICALLY UNDERSERVED POPU-**
10 **LATIONS AND HEALTH PROFESSIONS SHORT-**
11 **AGE AREAS.**

12 (a) ESTABLISHMENT.—

13 (1) IN GENERAL.—The Secretary of Health and
14 Human Services (in this section referred to as the
15 “Secretary”) shall establish, through a negotiated
16 rulemaking process under subchapter 3 of chapter 5
17 of title 5, United States Code, a comprehensive
18 methodology and criteria for designation of—

19 (A) medically underserved populations in
20 accordance with section 330(b)(3) of the Public
21 Health Service Act (42 U.S.C. 254b(b)(3));

22 (B) health professions shortage areas
23 under section 332 of the Public Health Service
24 Act (42 U.S.C. 254e).

1 (2) FACTORS TO CONSIDER.—In establishing
2 the methodology and criteria under paragraph (1),
3 the Secretary—

4 (A) shall consult with relevant stakeholders
5 who will be significantly affected by a rule
6 (such as national, State and regional organiza-
7 tions representing affected entities), State
8 health offices, community organizations, health
9 centers and other affected entities, and other
10 interested parties; and

11 (B) shall take into account—

12 (i) the timely availability and appro-
13 priateness of data used to determine a des-
14 ignation to potential applicants for such
15 designations;

16 (ii) the impact of the methodology and
17 criteria on communities of various types
18 and on health centers and other safety net
19 providers;

20 (iii) the degree of ease or difficulty
21 that will face potential applicants for such
22 designations in securing the necessary
23 data; and

24 (iv) the extent to which the method-
25 ology accurately measures various barriers

1 that confront individuals and population
2 groups in seeking health care services.

3 (b) PUBLICATION OF NOTICE.—In carrying out the
4 rulemaking process under this subsection, the Secretary
5 shall publish the notice provided for under section 564(a)
6 of title 5, United States Code, by not later than 45 days
7 after the date of the enactment of this Act.

8 (c) TARGET DATE FOR PUBLICATION OF RULE.—As
9 part of the notice under subsection (b), and for purposes
10 of this subsection, the “target date for publication”, as
11 referred to in section 564(a)(5) of title 5, United States
12 Code, shall be July 1, 2010.

13 (d) APPOINTMENT OF NEGOTIATED RULEMAKING
14 COMMITTEE AND FACILITATOR.—The Secretary shall pro-
15 vide for—

16 (1) the appointment of a negotiated rulemaking
17 committee under section 565(a) of title 5, United
18 States Code, by not later than 30 days after the end
19 of the comment period provided for under section
20 564(c) of such title; and

21 (2) the nomination of a facilitator under section
22 566(c) of such title 5 by not later than 10 days after
23 the date of appointment of the committee.

24 (e) PRELIMINARY COMMITTEE REPORT.—The nego-
25 tiated rulemaking committee appointed under subsection

1 (d) shall report to the Secretary, by not later than April
2 1, 2010, regarding the committee's progress on achieving
3 a consensus with regard to the rulemaking proceeding and
4 whether such consensus is likely to occur before one month
5 before the target date for publication of the rule. If the
6 committee reports that the committee has failed to make
7 significant progress toward such consensus or is unlikely
8 to reach such consensus by the target date, the Secretary
9 may terminate such process and provide for the publica-
10 tion of a rule under this section through such other meth-
11 ods as the Secretary may provide.

12 (f) FINAL COMMITTEE REPORT.—If the committee
13 is not terminated under subsection (e), the rulemaking
14 committee shall submit a report containing a proposed
15 rule by not later than one month before the target publica-
16 tion date.

17 (g) INTERIM FINAL EFFECT.—The Secretary shall
18 publish a rule under this section in the Federal Register
19 by not later than the target publication date. Such rule
20 shall be effective and final immediately on an interim
21 basis, but is subject to change and revision after public
22 notice and opportunity for a period (of not less than 90
23 days) for public comment. In connection with such rule,
24 the Secretary shall specify the process for the timely re-

1 view and approval of applications for such designations
2 pursuant to such rules and consistent with this section.

3 (h) PUBLICATION OF RULE AFTER PUBLIC COM-
4 MENT.—The Secretary shall provide for consideration of
5 such comments and republication of such rule by not later
6 than 1 year after the target publication date.

7 **SEC. 174. EQUITY FOR CERTAIN ELIGIBLE SURVIVORS.**

8 (a) REBUTTABLE PRESUMPTION.—Section 411(c)(4)
9 of the Black Lung Benefits Act (30 U.S.C. 921(c)(4)) is
10 amended by striking the last sentence.

11 (b) CONTINUATION OF BENEFITS.—Section 422(l) of
12 the Black Lung Benefits Act (30 U.S.C. 932(l)) is amend-
13 ed by striking “, except with respect to a claim filed under
14 this part on or after the effective date of the Black Lung
15 Benefits Amendments of 1981”.

16 (c) EFFECTIVE DATE.—The amendments made by
17 this section shall apply with respect to claims filed under
18 part B or part C of the Black Lung Benefits Act (30
19 U.S.C. 921 et seq., 931 et seq.) after January 1, 2005,
20 that are pending on or after the date of enactment of this
21 Act.

1 **SEC. 175. REAUTHORIZATION OF THE WAKEFIELD EMER-**
2 **GENCY MEDICAL SERVICES FOR CHILDREN**
3 **PROGRAM.**

4 Section 1910 of the Public Health Service Act (42
5 U.S.C. 300w-9) is amended—

6 (1) in subsection (a), by striking “3-year period
7 (with an optional 4th year” and inserting “4-year
8 period (with an optional 5th year”; and

9 (2) in subsection (d)—

10 (A) by striking “and such sums” and in-
11 serting “such sums”; and

12 (B) by inserting before the period the fol-
13 lowing: “, \$25,000,000 for fiscal year 2010,
14 \$26,250,000 for fiscal year 2011, \$27,562,500
15 for fiscal year 2012, \$28,940,625 for fiscal year
16 2013, and \$30,387,656 for fiscal year 2014”.

17 **SEC. 176. CO-LOCATING PRIMARY AND SPECIALTY CARE IN**
18 **COMMUNITY-BASED MENTAL HEALTH SET-**
19 **TINGS.**

20 Subpart 3 of part B of title V of the Public Health
21 Service Act (42 U.S.C. 290bb-31 et seq.) is amended by
22 adding at the end the following:

23 **“SEC. 520K. GRANTS FOR CO-LOCATING PRIMARY AND SPE-**
24 **CIALTY CARE IN COMMUNITY-BASED MENTAL**
25 **HEALTH SETTINGS.**

26 “(a) DEFINITIONS.—In this section:

1 “(1) ELIGIBLE ENTITY.—The term ‘eligible en-
2 tity’ means a qualified community mental health
3 program defined under section 1913(b)(1).

4 “(2) SPECIAL POPULATIONS.—The term ‘spe-
5 cial populations’ refers to the following 3 groups:

6 “(A) Children and adolescents with mental
7 and emotional disturbances who have co-occur-
8 ring primary care conditions and chronic dis-
9 eases.

10 “(B) Adults with mental illnesses who have
11 co-occurring primary care conditions and chron-
12 ic diseases.

13 “(C) Older adults with mental illnesses
14 who have co-occurring primary care conditions
15 and chronic diseases.

16 “(b) PROGRAM AUTHORIZED.—The Secretary, acting
17 through the Administrator of the Substance Abuse and
18 Mental Health Services Administration and in coordina-
19 tion with the Director of the Health Resources and Serv-
20 ices Administration, shall award grants to eligible entities
21 to establish demonstration projects for the provision of co-
22 ordinated and integrated services to special populations
23 through the co-location of primary and specialty care serv-
24 ices in community-based mental and behavioral health set-
25 tings.

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

1 “(iii) adult and pediatric eye, ear, and
2 dental screenings;

3 “(B) reasonable costs associated with
4 medically necessary referrals to qualified spe-
5 cialty care professionals as well as to other co-
6 ordinators of care or, if permitted by the terms
7 of the grant, for the provision, by qualified spe-
8 cialty care professionals on a reasonable cost
9 basis on site at the eligible entity;

10 “(C) information technology required to
11 accommodate the clinical needs of primary and
12 specialty care professionals; or

13 “(D) facility improvements or modifica-
14 tions needed to bring primary and specialty
15 care professionals on site at the eligible entity.

16 “(2) LIMITATION.—Not to exceed 15 percent of
17 grant funds may be used for activities described in
18 subparagraphs (C) and (D) of paragraph (1).

19 “(e) GEOGRAPHIC DISTRIBUTION.—The Secretary
20 shall ensure that grants awarded under this section are
21 equitably distributed among the geographical regions of
22 the United States and between urban and rural popu-
23 lations.

24 “(f) EVALUATION.—Not later than 3 months after a
25 grant or cooperative agreement awarded under this section

1 expires, an eligible entity shall submit to the Secretary the
2 results of an evaluation to be conducted by the entity con-
3 cerning the effectiveness of the activities carried out under
4 the grant or agreement.

5 “(g) REPORT.—Not later than 5 years after the date
6 of enactment of this section, the Secretary shall prepare
7 and submit to the appropriate committees of Congress a
8 report that shall evaluate the activities funded under this
9 section. The report shall include an evaluation of the im-
10 pact of co-locating primary and specialty care in commu-
11 nity mental and behavioral health settings on overall pa-
12 tient health status and recommendations on whether or
13 not the demonstration program under this section should
14 be made permanent.

15 “(h) AUTHORIZATION OF APPROPRIATIONS.—There
16 are authorized to be appropriated to carry out this section,
17 \$50,000,000 for fiscal year 2010 and such sums as may
18 be necessary for each of fiscal years 2011 through 2014.”.

19 **Subtitle F—Making Health Care**
20 **More Affordable for Retirees**

21 **SEC. 181. REINSURANCE FOR RETIREES.**

22 (a) ADMINISTRATION.—

23 (1) IN GENERAL.—Not later than 90 days after
24 the date of enactment of this section, the Secretary
25 shall establish a temporary reinsurance program to

1 provide reimbursement to participating employment-
2 based plans for a portion of the cost of providing
3 health benefits to retirees whose primary residence is
4 located in any State that is not a participating State
5 or an establishing State (as described in section
6 3104) for a portion of the cost of providing health
7 insurance coverage to retirees (and to the eligible
8 spouses, surviving spouses, and dependents of such
9 retirees) during the period beginning on the date on
10 which such program is established and ending on the
11 date on which such State becomes a participating
12 State or an establishing State.

13 (2) REFERENCE.—In this section:

14 (A) HEALTH BENEFITS.—The term
15 “health benefits” means medical, surgical, hos-
16 pital, prescription drug, and such other benefits
17 as shall be determined by the Secretary, wheth-
18 er self-funded, or delivered through the pur-
19 chase of insurance or otherwise.

20 (B) EMPLOYMENT-BASED PLAN.—The
21 term “employment-based plan” means a group
22 health benefits plan that—

23 (i) is—

24 (I) maintained by one or more
25 current or former employers (includ-

1 ing without limitation any State or
2 local government or political subdivi-
3 sion thereof), employee organization, a
4 voluntary employees' beneficiary asso-
5 ciation, or a committee or board of in-
6 dividuals appointed to administer such
7 plan; or

8 (II) a multiemployer plan (as de-
9 fined in section 3(37) of the Employee
10 Retirement Income Security Act of
11 1974); and

12 (ii) provides health benefits to retir-
13 ees.

14 (C) RETIREES.—The term “retirees”
15 means individuals who are age 55 and older but
16 are not eligible for coverage under title XVIII
17 of the Social Security Act, and who are not ac-
18 tive employees of an employer maintaining , or
19 currently contributing to, the employment-based
20 plan or of any employer that has made substan-
21 tial contributions to fund such plan.

22 (b) PARTICIPATION.—

23 (1) EMPLOYMENT-BASED PLAN ELIGIBILITY.—
24 To be eligible to participate in the program estab-
25 lished under this section, an employment-based plan

1 (as defined in subsection (a)(2) and referred to in
2 this section as a “participating employment-based
3 plan” shall—

4 (A) provide employment-based health plan
5 benefits; and

6 (B) submit to the Secretary an application
7 for participation in the program, at such time,
8 in such manner, and containing such informa-
9 tion as the Secretary shall require.

10 (2) APPROPRIATE EMPLOYMENT-BASED
11 HEALTH BENEFITS.—Appropriate employment-based
12 health benefits described in this paragraph shall—

13 (A) meet the requirements established
14 under section 3103(a)(1)(B);

15 (B) implement programs and procedures to
16 generate cost-savings with respect to partici-
17 pants with chronic and high-cost conditions;

18 (C) provide documentation of the actual
19 cost of medical claims involved; and

20 (D) be certified as appropriate by the Sec-
21 retary.

22 (c) PAYMENTS.—

23 (1) SUBMISSION OF CLAIMS.—

24 (A) IN GENERAL.—A participating employ-
25 ment-based plan shall submit claims for reim-

1 bursement to the Secretary which shall contain
2 documentation of the actual costs of the items
3 and services for which each claim is being sub-
4 mitted.

5 (B) BASIS FOR CLAIMS.—Claims submitted
6 under paragraph (1) shall be based on the ac-
7 tual amount expended by the participating em-
8 ployment-based plan involved within the plan
9 year for the appropriate employment-based
10 health benefits provided to a retiree or the
11 spouse, surviving spouse, or dependent of such
12 retiree. In determining the amount of a claim
13 for purposes of this subsection, the partici-
14 pating employment-based plan shall take into
15 account any negotiated price concessions (such
16 as discounts, direct or indirect subsidies, re-
17 bates, and direct or indirect remunerations) ob-
18 tained by such plan with respect to such health
19 benefit. For purposes of determining the
20 amount of any such claim, the costs paid by the
21 retiree or the retiree's spouse, surviving spouse,
22 or dependent in the form of deductibles, co-pay-
23 ments, or co-insurance shall be included in the
24 amounts paid by the participating employment-
25 based plan.

1 (2) PROGRAM PAYMENTS.—If the Secretary de-
2 termines that a participating employment-based plan
3 has submitted a valid claim under paragraph (1),
4 the Secretary shall reimburse such plan for 80 per-
5 cent of that portion of the costs attributable to such
6 claim that exceed \$15,000, subject to the limits con-
7 tained in paragraph (3).

8 (3) LIMIT.—To be eligible for reimbursement
9 under the program, a claim submitted by a partici-
10 pating employment-based plan shall not be less than
11 \$15,000 nor greater than \$90,000. Such amounts
12 shall be adjusted each fiscal year based on the per-
13 centage increase in the Medical Care Component of
14 the Consumer Price Index for all urban consumers
15 (rounded to the nearest multiple of \$1,000) for the
16 year involved.

17 (4) USE OF PAYMENTS.—Amounts paid to a
18 participating employment-based plan under this sub-
19 section shall be used to lower costs for the plan.
20 Such payments may be used to reduce premium
21 costs for an entity described in subsection
22 (a)(2)(B)(i) or to reduce premium contributions, co-
23 payments, deductibles, co-insurance, or other out-of-
24 pocket costs for plan participants. Such payments
25 shall not be used as general revenues for an entity

1 described in subsection (a)(2)(B)(i). The Secretary
2 shall develop a mechanism to monitor the appro-
3 priate use of such payments by such entities.

4 (5) PAYMENTS NOT TREATED AS INCOME.—
5 Payments received under this subsection shall not be
6 included in determining the gross income of an enti-
7 ty described in subsection (a)(2)(B)(i) that is main-
8 taining or currently contributing to a participating
9 employment-based plan.

10 (6) APPEALS.—The Secretary shall establish—

11 (A) an appeals process to permit partici-
12 pating employment-based plans to appeal a de-
13 termination of the Secretary with respect to
14 claims submitted under this section; and

15 (B) procedures to protect against fraud,
16 waste, and abuse under the program.

17 (d) AUDITS.—The Secretary shall conduct annual au-
18 dits of claims data submitted by participating employ-
19 ment-based plans under this section to ensure that such
20 plans are in compliance with the requirements of this sec-
21 tion.

22 (e) RETIREE RESERVE TRUST FUND.—

23 (1) ESTABLISHMENT OF TRUST FUND.—

24 (A) IN GENERAL.—There is established in
25 the Treasury of the United States a trust fund

1 to be known as the “Retiree Reserve Trust
2 Fund” (referred to in this section as the “Trust
3 Fund”), that shall consist of such amounts as
4 may be appropriated or credited to the Trust
5 Fund as provided for in this subsection to en-
6 able the Secretary to carry out the program
7 under this section. Such amounts shall remain
8 available until expended.

9 (B) FUNDING.—There are hereby appro-
10 priated to the Trust Fund, out of any moneys
11 in the Treasury not otherwise appropriated an
12 amount requested by the Secretary of Health
13 and Human Services as necessary to carry out
14 this section, except that the total of all such
15 amounts requested shall not exceed
16 \$10,000,000,000.

17 (C) APPROPRIATIONS FROM THE TRUST
18 FUND.—Amounts in the Trust Fund may be
19 appropriated to provide funding to carry out
20 this program under this section

21 (2) USE OF TRUST FUND.—The Secretary shall
22 use amounts contained in the Trust Fund to carry
23 out the program under this section.

24 (3) LIMITATIONS.—The Secretary has the au-
25 thority to stop taking applications for participation

1 in the program to comply with the funding limit pro-
2 vided for in paragraph (1)(B).

3 **Subtitle G—Improving the Use of**
4 **Health Information Technology**
5 **for Enrollment; Miscellaneous**
6 **Provisions**

7 **SEC. 185. HEALTH INFORMATION TECHNOLOGY ENROLL-**
8 **MENT STANDARDS AND PROTOCOLS.**

9 Title XXX of the Public Health Service Act (42
10 U.S.C. 300jj et seq.) is amended by adding at the end
11 the following:

12 **“Subtitle C—Other Provisions**

13 **“SEC. 3021. HEALTH INFORMATION TECHNOLOGY ENROLL-**
14 **MENT STANDARDS AND PROTOCOLS.**

15 **“(a) IN GENERAL.—**

16 **“(1) STANDARDS AND PROTOCOLS.—**Not later
17 than 180 days after the date of enactment of this
18 title, the Secretary, in consultation with the HIT
19 Policy Committee and the HIT Standards Com-
20 mittee, shall develop interoperable and secure stand-
21 ards and protocols that facilitate enrollment of indi-
22 viduals in Federal and State health and human serv-
23 ices programs, as determined by the Secretary.

24 **“(2) METHODS.—**The Secretary shall facilitate
25 enrollment in such programs through methods deter-

1 mined appropriate by the Secretary, which shall in-
2 clude providing individuals and third parties author-
3 ized by such individuals and their designees notifica-
4 tion of eligibility and verification of eligibility re-
5 quired under such programs.

6 “(b) CONTENT.—The standards and protocols for
7 electronic enrollment in the Federal and State programs
8 described in subsection (a) shall allow for the following:

9 “(1) Electronic matching against existing Fed-
10 eral and State data, including vital records, employ-
11 ment history, enrollment systems, tax records, and
12 other data determined appropriate by the Secretary
13 to serve as evidence of eligibility and in lieu of
14 paper-based documentation.

15 “(2) Simplification and submission of electronic
16 documentation, digitization of documents, and sys-
17 tems verification of eligibility.

18 “(3) Reuse of stored eligibility information (in-
19 cluding documentation) to assist with retention of el-
20 igible individuals.

21 “(4) Capability for individuals to apply, recer-
22 tify and manage their eligibility information online,
23 including at home, at points of service, and other
24 community-based locations.

1 “(5) Ability to expand the enrollment system to
2 integrate new programs, rules, and functionalities, to
3 operate at increased volume, and to apply stream-
4 lined verification and eligibility processes to other
5 Federal and State programs, as appropriate.

6 “(6) Notification of eligibility, recertification,
7 and other needed communication regarding eligi-
8 bility, which may include communication via email
9 and cellular phones.

10 “(7) Other functionalities necessary to provide
11 eligibles with streamlined enrollment process.

12 “(c) APPROVAL AND NOTIFICATION.—With respect
13 to any standard or protocol developed under subsection (a)
14 that has been approved by the HIT Policy Committee and
15 the HIT Standards Committee, the Secretary—

16 “(1) shall notify States of such standards or
17 protocols; and

18 “(2) may require, as a condition of receiving
19 Federal funds for the health information technology
20 investments, that States or other entities incorporate
21 such standards and protocols into such investments.

22 “(d) GRANTS FOR IMPLEMENTATION OF APPRO-
23 PRIATE ENROLLMENT HIT.—

24 “(1) IN GENERAL.—The Secretary shall award
25 grant to eligible entities to develop new, and adapt

1 existing, technology systems to implement the HIT
2 enrollment standards and protocols developed under
3 subsection (a) (referred to in this subsection as ‘ap-
4 propriate HIT technology’).

5 “(2) ELIGIBLE ENTITIES.—To be eligible for a
6 grant under this subsection, an entity shall—

7 “(A) be a State, political subdivision of a
8 State, or a local governmental entity; and

9 “(B) submit to the Secretary an applica-
10 tion at such time, in such manner, and con-
11 taining—

12 “(i) a plan to adopt and implement
13 appropriate enrollment technology that in-
14 cludes—

15 “(I) proposed reduction in main-
16 tenance costs of technology systems;

17 “(II) elimination or updating of
18 legacy systems; and

19 “(III) demonstrated collaboration
20 with other entities that may receive a
21 grant under this section that are lo-
22 cated in the same State, political sub-
23 division, or locality;

24 “(ii) an assurance that the entity will
25 share such appropriate enrollment tech-

1 nology in accordance with paragraph (4);

2 and

3 “(iii) such other information as the

4 Secretary may require.

5 “(3) SHARING.—

6 “(A) IN GENERAL.—The Secretary shall

7 ensure that appropriate enrollment HIT adopt-

8 ed under grants under this subsection is made

9 available to other qualified State, qualified po-

10 litical subdivisions of a State, or other appro-

11 priate qualified entities (as described in sub-

12 paragraph (B)) at no cost.

13 “(B) QUALIFIED ENTITIES.—The Sec-

14 retary shall determine what entities are quali-

15 fied to receive enrollment HIT under subpara-

16 graph (A), taking into consideration the rec-

17 ommendations of the HIT Policy Committee

18 and the HIT Standards Committee.”.

19 **SEC. 186. RULE OF CONSTRUCTION REGARDING HAWAII’S**

20 **PREPAID HEALTH CARE ACT.**

21 Nothing in this title (or an amendment made by this

22 title) shall be construed to modify or limit the application

23 of the exemption for Hawaii’s Prepaid Health Care Act

24 (Haw. Rev. Stat. §§ 393-1 et seq.) as provided for under

1 section 514(b)(5) of the Employee Retirement Income Se-
2 curity Act of 1974 (29 U.S.C. 1144(b)(5)).

3 **SEC. 187. KEY NATIONAL INDICATORS.**

4 (a) DEFINITIONS.—In this section:

5 (1) ACADEMY.—The term “Academy” means
6 the National Academy of Sciences.

7 (2) COMMISSION.—The term “Commission”
8 means the Commission on Key National Indicators
9 established under subsection (b).

10 (3) INSTITUTE.—The term “Institute” means a
11 Key National Indicators Institute as designated
12 under subsection (c)(3).

13 (b) COMMISSION ON KEY NATIONAL INDICATORS.—

14 (1) ESTABLISHMENT.—There is established a
15 “Commission on Key National Indicators”.

16 (2) MEMBERSHIP.—

17 (A) NUMBER AND APPOINTMENT.—The
18 Commission shall be composed of 8 members, to
19 be appointed equally by the majority and mi-
20 nority leaders of the Senate and the Speaker
21 and minority leader of the House of Represent-
22 atives.

23 (B) PROHIBITED APPOINTMENTS.—Mem-
24 bers of the Commission shall not include Mem-

1 bers of Congress or other elected Federal,
2 State, or local government officials.

3 (C) QUALIFICATIONS.—In making appoint-
4 ments under subparagraph (A), the majority
5 and minority leaders of the Senate and the
6 Speaker and minority leader of the House of
7 Representatives shall appoint individuals who
8 have shown a dedication to improving civic dia-
9 logue and decision-making through the wide use
10 of scientific evidence and factual information.

11 (D) PERIOD OF APPOINTMENT.—Each
12 member of the Commission shall be appointed
13 for a 2-year term, except that 1 initial appoint-
14 ment shall be for 3 years. Any vacancies shall
15 not affect the power and duties of the Commis-
16 sion but shall be filled in the same manner as
17 the original appointment and shall last only for
18 the remainder of that term.

19 (E) DATE.—Members of the Commission
20 shall be appointed by not later than 30 days
21 after the date of enactment of this Act.

22 (F) INITIAL ORGANIZING PERIOD.—Not
23 later than 60 days after the date of enactment
24 of this Act, the Commission shall develop and

1 implement a schedule for completion of the re-
2 view and reports required under subsection (d).

3 (G) CO-CHAIRPERSONS.—The Commission
4 shall select 2 Co-Chairpersons from among its
5 members.

6 (c) DUTIES OF THE COMMISSION.—

7 (1) IN GENERAL.—The Commission shall—

8 (A) conduct comprehensive oversight of a
9 newly established key national indicators system
10 consistent with the purpose described in this
11 subsection;

12 (B) make recommendations on how to im-
13 prove the key national indicators system;

14 (C) coordinate with Federal Government
15 users and information providers to assure ac-
16 cess to relevant and quality data; and

17 (D) enter into contracts with the Academy.

18 (2) REPORTS.—

19 (A) ANNUAL REPORT TO CONGRESS.—Not
20 later than 1 year after the selection of the 2
21 Co-Chairpersons of the Commission, and each
22 subsequent year thereafter, the Commission
23 shall prepare and submit to the appropriate
24 Committees of Congress and the President a re-
25 port that contains a detailed statement of the

1 recommendations, findings, and conclusions of
2 the Commission on the activities of the Acad-
3 emy and a designated Institute related to the
4 establishment of a Key National Indicator Sys-
5 tem.

6 (B) ANNUAL REPORT TO THE ACADEMY.—

7 (i) IN GENERAL.—Not later than 6
8 months after the selection of the 2 Co-
9 Chairpersons of the Commission, and each
10 subsequent year thereafter, the Commis-
11 sion shall prepare and submit to the Acad-
12 emy and a designated Institute a report
13 making recommendations concerning po-
14 tential issue areas and key indicators to be
15 included in the Key National Indicators.

16 (ii) LIMITATION.—The Commission
17 shall not have the authority to direct the
18 Academy or, if established, the Institute,
19 to adopt, modify, or delete any key indica-
20 tors.

21 (3) CONTRACT WITH THE NATIONAL ACADEMY
22 OF SCIENCES.—

23 (A) IN GENERAL.—As soon as practicable
24 after the selection of the 2 Co-Chairpersons of
25 the Commission, the Co-Chairpersons shall

1 enter into an arrangement with the National
2 Academy of Sciences under which the Academy
3 shall—

4 (i) review available public and private
5 sector research on the selection of a set of
6 key national indicators;

7 (ii) determine how best to establish a
8 key national indicator system for the
9 United States, by either creating its own
10 institutional capability or designating an
11 independent private nonprofit organization
12 as an Institute to implement a key national
13 indicator system;

14 (iii) if the Academy designates an
15 independent Institute under clause (ii),
16 provide scientific and technical advice to
17 the Institute and create an appropriate
18 governance mechanism that balances Acad-
19 emy involvement and the independence of
20 the Institute; and

21 (iv) provide an annual report to the
22 Commission addressing scientific and tech-
23 nical issues related to the key national in-
24 dicator system and, if established, the In-

1 stitute, and governance of the Institute's
2 budget and operations.

3 (B) PARTICIPATION.—In executing the ar-
4 rangement under subparagraph (A), the Na-
5 tional Academy of Sciences shall convene a
6 multi-sector, multi-disciplinary process to define
7 major scientific and technical issues associated
8 with developing, maintaining, and evolving a
9 Key National Indicator System and, if an Insti-
10 tute is established, to provide it with scientific
11 and technical advice.

12 (C) ESTABLISHMENT OF A KEY NATIONAL
13 INDICATOR SYSTEM.—

14 (i) IN GENERAL.—In executing the ar-
15 rangement under subparagraph (A), the
16 National Academy of Sciences shall enable
17 the establishment of a key national indi-
18 cator system by—

19 (I) creating its own institutional
20 capability; or

21 (II) partnering with an inde-
22 pendent private nonprofit organization
23 as an Institute to implement a key na-
24 tional indicator system.

1 (ii) INSTITUTE.—If the Academy des-
2 ignates an Institute under clause (i)(II),
3 such Institute shall be a non-profit entity
4 (as defined for purposes of section
5 501(c)(3) of the Internal Revenue Code of
6 1986) with an educational mission, a gov-
7 ernance structure that emphasizes inde-
8 pendence, and characteristics that make
9 such entity appropriate for establishing a
10 key national indicator system.

11 (iii) RESPONSIBILITIES.—Either the
12 Academy or the Institute designated under
13 clause (i)(II) shall be responsible for the
14 following:

15 (I) Identifying and selecting issue
16 areas to be represented by the key na-
17 tional indicators.

18 (II) Identifying and selecting the
19 measures used for key national indica-
20 tors within the issue areas under sub-
21 clause (I).

22 (III) Identifying and selecting
23 data to populate the key national indi-
24 cators described under subclause (II).

1 (IV) Designing, publishing, and
2 maintaining a public website that con-
3 tains a freely accessible database al-
4 lowing public access to the key na-
5 tional indicators.

6 (V) Developing a quality assur-
7 ance framework to ensure rigorous
8 and independent processes and the se-
9 lection of quality data.

10 (VI) Developing a budget for the
11 construction and management of a
12 sustainable, adaptable, and evolving
13 key national indicator system that re-
14 flects all Commission funding of
15 Academy and, if an Institute is estab-
16 lished, Institute activities.

17 (VII) Reporting annually to the
18 Commission regarding its selection of
19 issue areas, key indicators, data, and
20 progress toward establishing a web-ac-
21 cessible database.

22 (VIII) Responding directly to the
23 Commission in response to any Com-
24 mission recommendations and to the

1 Academy regarding any inquiries by
2 the Academy.

3 (iv) GOVERNANCE.—Upon the estab-
4 lishment of a key national indicator sys-
5 tem, the Academy shall create an appro-
6 priate governance mechanism that incor-
7 porates advisory and control functions. If
8 an Institute is designated under clause
9 (i)(II), the governance mechanism shall
10 balance appropriate Academy involvement
11 and the independence of the Institute.

12 (v) MODIFICATION AND CHANGES.—
13 The Academy shall retain the sole discre-
14 tion, at any time, to alter its approach to
15 the establishment of a key national indi-
16 cator system or, if an Institute is des-
17 ignated under clause (i)(II), to alter any
18 aspect of its relationship with the Institute
19 or to designate a different non-profit entity
20 to serve as the Institute.

21 (vi) CONSTRUCTION.—Nothing in this
22 section shall be construed to limit the abil-
23 ity of the Academy or the Institute des-
24 ignated under clause (i)(II) to receive pri-
25 vate funding for activities related to the es-

1 tablishment of a key national indicator sys-
2 tem.

3 (D) ANNUAL REPORT.—As part of the ar-
4 rangement under subparagraph (A), the Na-
5 tional Academy of Sciences shall, not later than
6 270 days after the date of enactment of this
7 Act, and annually thereafter, submit to the Co-
8 Chairpersons of the Commission a report that
9 contains the findings and recommendations of
10 the Academy.

11 (d) GOVERNMENT ACCOUNTABILITY OFFICE STUDY
12 AND REPORT.—

13 (1) GAO STUDY.—The Comptroller General of
14 the United States shall conduct a study of previous
15 work conducted by all public agencies, private orga-
16 nizations, or foreign countries with respect to best
17 practices for a key national indicator system. The
18 study shall be submitted to the appropriate author-
19 izing committees of Congress.

20 (2) GAO FINANCIAL AUDIT.—If an Institute is
21 established under this section, the Comptroller Gen-
22 eral shall conduct an annual audit of the financial
23 statements of the Institute, in accordance with gen-
24 erally accepted government auditing standards and
25 submit a report on such audit to the Commission

1 and the appropriate authorizing committees of Con-
2 gress.

3 (3) GAO PROGRAMMATIC REVIEW.—The Comp-
4 troller General of the United States shall conduct
5 programmatic assessments of the Institute estab-
6 lished under this section as determined necessary by
7 the Comptroller General and report the findings to
8 the Commission and to the appropriate authorizing
9 committees of Congress.

10 (e) AUTHORIZATION OF APPROPRIATIONS.—

11 (1) IN GENERAL.—There are authorized to be
12 appropriated to carry out the purposes of this sec-
13 tion, \$10,000,000 for fiscal year 2010, and
14 \$7,500,000 for each of fiscal year 2011 through
15 2018.

16 (2) AVAILABILITY.—Amounts appropriated
17 under paragraph (1) shall remain available until ex-
18 pended.

19 **SEC. 188. STUDY AND REPORT ON RATES OF PREVENTABLE**
20 **DISEASES IN NEW MEDICARE ENROLLEES.**

21 (a) STUDY.—

22 (1) IN GENERAL.—The Comptroller General of
23 the United States (in this section referred to as the
24 “Comptroller General”) shall conduct a study on—

1 (A) whether applicable new Medicare en-
2 rollees exhibit higher than expected rates of
3 preventable disease when compared to the en-
4 tire population of new Medicare enrollees or an-
5 other appropriate statistical baseline; and

6 (B) if applicable new Medicare enrollees
7 exhibit such a higher than expected rate of pre-
8 ventable disease, whether such rate is related to
9 the failure of the enrollee's previous private
10 health insurance issuer to promote, cover, or
11 adequately pay for preventive health benefits.

12 (2) APPLICABLE NEW MEDICARE ENROLLEE.—
13 In this section, the term “applicable new Medicare
14 enrollee” means an individual—

15 (A) who is entitled to, or enrolled for, ben-
16 efits under part A of title XVII of the Social
17 Security Act (42 U.S.C. 1395 et seq.) or en-
18 rolled for benefits under part B of such title on
19 or after the date of enactment of this Act; and

20 (B) who was covered by private health in-
21 surance or Medicaid or other Federal Govern-
22 ment health programs (as of the day before the
23 date of such entitlement or enrollment).

24 (b) REPORT.—Not later than 3 years after the date
25 on which at least 5 Gateways under title XXXI of the

1 Public Health Service Act, as added by section 142, are
2 operating in the United States, the Comptroller General
3 shall submit to Congress a report containing the results
4 of the study conducted under subsection (a), together with
5 recommendations for such legislation and administrative
6 action as the Comptroller General determines appropriate.

7 **SEC. 189. TRANSPARENCY IN GOVERNMENT.**

8 Not later than 30 days after the date of enactment
9 of this Act, the Secretary of Health and Human Services
10 shall publish on the Internet website of the Department
11 of Health and Human Services, a list of all of the authori-
12 ties provided to the Secretary under this Act (and the
13 amendments made by this Act).

14 **SEC. 189A. PRESERVING THE SOLVENCY OF MEDICARE AND**
15 **SOCIAL SECURITY.**

16 Nothing in this Act (or an amendment made by this
17 Act) shall be carried out in a manner that threatens the
18 solvency of Medicare or Social Security programs.

19 **SEC. 189B. PROHIBITION AGAINST DISCRIMINATION ON AS-**
20 **SISTED SUICIDE.**

21 (a) IN GENERAL.—The Federal Government, and
22 any State or local government or health care provider that
23 receives Federal financial assistance under this Act (or
24 under an amendment made by this Act) or any health plan
25 created under this Act (or under an amendment made by

1 this Act), may not subject an individual or institutional
2 health care entity to discrimination on the basis that the
3 entity does not provide any health care item or service fur-
4 nished for the purpose of causing, or for the purpose of
5 assisting in causing, the death of any individual, such as
6 by assisted suicide, euthanasia, or mercy killing.

7 (b) DEFINITION.—In this section, the term “health
8 care entity” includes an individual physician or other
9 health care professional, a hospital, a provider-sponsored
10 organization, a health maintenance organization, a health
11 insurance plan, or any other kind of health care facility,
12 organization, or plan.

13 (c) CONSTRUCTION AND TREATMENT OF CERTAIN
14 SERVICES.—Nothing in subsection (a) shall be construed
15 to apply to or to affect any limitation relating to—

16 (1) the withholding or withdrawing of medical
17 treatment or medical care;

18 (2) the withholding or withdrawing of nutrition
19 or hydration;

20 (3) abortion; or

21 (4) the use of an item, good, benefit, or service
22 furnished for the purpose of alleviating pain or dis-
23 comfort, even if such use may increase the risk of
24 death, so long as such item, good, benefit, or service
25 is not also furnished for the purpose of causing, or

1 the purpose of assisting in causing, death, for any
2 reason.

3 (d) ADMINISTRATION.—The Office for Civil Rights of
4 the Department of Health and Human Services is des-
5 ignated to receive complaints of discrimination based on
6 this section.

7 **SEC. 189C. ACCESS TO THERAPIES.**

8 Notwithstanding any other provision of the Afford-
9 able Health Choices Act, the Secretary of Health and
10 Human Services shall not promulgate any regulation
11 that—

12 (1) creates any unreasonable barriers to the
13 ability of individuals to obtain appropriate medical
14 care;

15 (2) impedes timely access to health care serv-
16 ices;

17 (3) interferes with communications regarding a
18 full range of treatment options between the patient
19 and the provider;

20 (4) restricts the ability of health care providers
21 to provide full disclosure of all relevant information
22 to patients making health care decisions;

23 (5) violates the principles of informed consent
24 and the ethical standards of health care profes-
25 sionals; or

1 (6) limits the availability of health care treat-
2 ment for the full duration of a patient’s medical
3 needs.

4 **SEC. 189D. FREEDOM NOT TO PARTICIPATE IN FEDERAL**
5 **HEALTH INSURANCE PROGRAMS.**

6 No individual, company, business, nonprofit entity, or
7 health insurer offering group or individual health insur-
8 ance shall be required to participate in any Federal health
9 insurance program created under this Act (or any amend-
10 ments made by this Act), or in any Federal health insur-
11 ance program expanded by this Act (or any such amend-
12 ments), and there shall be no penalty or fine imposed upon
13 any such insurer for choosing not to participate in such
14 programs.

15 **Subtitle H—CLASS Act**

16 **SEC. 190. SHORT TITLE OF SUBTITLE.**

17 This subtitle may be cited as the “Community Living
18 Assistance Services and Supports Act” or the “CLASS
19 Act”.

20 **SEC. 191. ESTABLISHMENT OF NATIONAL VOLUNTARY IN-**
21 **SURANCE PROGRAM FOR PURCHASING COM-**
22 **MUNITY LIVING ASSISTANCE SERVICES AND**
23 **SUPPORT.**

24 (a) ESTABLISHMENT OF CLASS PROGRAM.—

1 (1) IN GENERAL.—The Public Health Service
2 Act (42 U.S.C. 201 et seq.), as amended by section
3 143, is amended by adding at the end the following:

4 **“TITLE XXXII—COMMUNITY LIV-**
5 **ING ASSISTANCE SERVICES**
6 **AND SUPPORTS**

7 **“SEC. 3201. PURPOSE.**

8 “The purpose of this title is to establish a national
9 voluntary insurance program for purchasing community
10 living assistance services and supports in order to—

11 “(1) provide individuals with functional limita-
12 tions with tools that will allow them to maintain
13 their personal and financial independence and live in
14 the community through a new financing strategy for
15 community living assistance services and supports;

16 “(2) establish an infrastructure that will help
17 address the Nation’s community living assistance
18 services and supports needs;

19 “(3) alleviate burdens on family caregivers; and

20 “(4) address institutional bias by providing a fi-
21 nancing mechanism that supports personal choice
22 and independence to live in the community.

23 **“SEC. 3202. DEFINITIONS.**

24 “In this title:

1 “(1) ACTIVE ENROLLEE.—The term ‘active en-
2 rollee’ means an individual who is enrolled in the
3 CLASS program in accordance with section 3204
4 and who has paid any premiums due to maintain
5 such enrollment.

6 “(2) ACTIVELY EMPLOYED.—The term ‘actively
7 employed’ means an individual who—

8 “(A) is reporting for work at the individ-
9 ual’s usual place of employment or at another
10 location to which the individual is required to
11 travel because of the individual’s employment
12 (or in the case of an individual who is a mem-
13 ber of the uniformed services, is on active duty
14 and is physically able to perform the duties of
15 the individual’s position); and

16 “(B) is able to perform all the usual and
17 customary duties of the individual’s employment
18 on the individual’s regular work schedule.

19 “(3) ACTIVITIES OF DAILY LIVING.—The term
20 ‘activities of daily living’ means each of the following
21 activities specified in section 7702B(c)(2)(B) of the
22 Internal Revenue Code of 1986:

23 “(A) Eating.

24 “(B) Toileting.

25 “(C) Transferring.

1 “(D) Bathing.

2 “(E) Dressing.

3 “(F) Continence.

4 “(4) CLASS PROGRAM.—The term ‘CLASS
5 program’ means the program established under this
6 title.

7 “(5) DISABILITY DETERMINATION SERVICE.—
8 The term ‘Disability Determination Service’ means,
9 with respect to each State, the entity that has an
10 agreement with the Commissioner of Social Security
11 to make disability determinations for purposes of
12 title II or XVI of the Social Security Act (42 U.S.C.
13 401 et seq., 1381 et seq.).

14 “(6) ELIGIBLE BENEFICIARY.—

15 “(A) IN GENERAL.—The term ‘eligible
16 beneficiary’ means any individual who is an ac-
17 tive enrollee in the CLASS program and, as of
18 the date described in subparagraph (B)—

19 “(i) has paid premiums for enrollment
20 in such program for at least 60 months;

21 “(ii) has earned, for each calendar
22 year that occurs during the first 60
23 months for which the individual has paid
24 premiums for enrollment in the program,
25 at least an amount equal to the amount of

1 wages and self-employment income which
2 an individual must have in order to be
3 credited with a quarter of coverage under
4 section 213(d) of the Social Security Act
5 for that year; and

6 “(iii) has paid premiums for enroll-
7 ment in such program for at least 24 con-
8 secutive months, if a lapse in premium
9 payments of more than 3 months has oc-
10 curred during the period that begins on the
11 date of the individual’s enrollment and
12 ends on the date of such determination.

13 “(B) DATE DESCRIBED.—For purposes of
14 subparagraph (A), the date described in this
15 subparagraph is the date on which the indi-
16 vidual is determined to have a functional limita-
17 tion described in section 3203(a)(1)(C) that is
18 expected to last for a continuous period of more
19 than 90 days.

20 “(C) REGULATIONS.—The Secretary shall
21 promulgate regulations specifying exceptions to
22 the minimum earnings requirements under sub-
23 paragraph (A)(ii) for purposes of being consid-
24 ered an eligible beneficiary for certain popu-
25 lations.

1 “(7) HOSPITAL; NURSING FACILITY; INTER-
2 MEDIATE CARE FACILITY FOR THE MENTALLY RE-
3 TARDED; INSTITUTION FOR MENTAL DISEASES.—
4 The terms ‘hospital’, ‘nursing facility’, ‘intermediate
5 care facility for the mentally retarded’, and ‘institu-
6 tion for mental diseases’ have the meanings given
7 such terms for purposes of Medicaid.

8 “(8) CLASS INDEPENDENCE ADVISORY COUN-
9 CIL.—The term ‘CLASS Independence Advisory
10 Council’ or ‘Council’ means the Advisory Council es-
11 tablished under section 3207 to advise the Secretary.

12 “(9) CLASS INDEPENDENCE BENEFIT PLAN.—
13 The term ‘CLASS Independence Benefit Plan’
14 means the benefit plan developed and designated by
15 the Secretary in accordance with section 3203.

16 “(10) CLASS INDEPENDENCE FUND.—The
17 term ‘CLASS Independence Fund’ or ‘Fund’ means
18 the fund established under section 3206.

19 “(11) MEDICAID.—The term ‘Medicaid’ means
20 the program established under title XIX of the So-
21 cial Security Act (42 U.S.C. 1396 et seq.).

22 “(12) PROTECTION AND ADVOCACY SYSTEM.—
23 The term ‘Protection and Advocacy System’ means
24 the system for each State established under section

1 143 of the Developmental Disabilities Assistance
2 and Bill of Rights Act of 2000 (42 U.S.C. 15043).

3 **“SEC. 3203. CLASS INDEPENDENCE BENEFIT PLAN.**

4 “(a) PROCESS FOR DEVELOPMENT.—

5 “(1) IN GENERAL.—The Secretary, in consulta-
6 tion with appropriate actuaries and other experts,
7 shall develop at least 3 actuarially sound benefit
8 plans as alternatives for consideration for designa-
9 tion by the Secretary as the CLASS Independence
10 Benefit Plan under which eligible beneficiaries shall
11 receive benefits under this title. Each of the plan al-
12 ternatives developed shall be designed to provide eli-
13 gible beneficiaries with the benefits described in sec-
14 tion 3205 consistent with the following require-
15 ments:

16 “(A) PREMIUMS.—Beginning with the first
17 year of the CLASS program, and for each year
18 thereafter, the Secretary shall establish all pre-
19 miums to be paid by enrollees for the year
20 based on an actuarial analysis of the 75-year
21 costs of the program that ensures solvency
22 throughout such 75-year period.

23 “(B) VESTING PERIOD.—A 5-year vesting
24 period for eligibility for benefits.

1 “(C) BENEFIT TRIGGERS.—A benefit trig-
2 ger for provision of benefits that requires a de-
3 termination that an individual has a functional
4 limitation, as certified by a licensed health care
5 practitioner, described in any of the following
6 clauses that is expected to last for a continuous
7 period of more than 90 days:

8 “(i) The individual is determined to
9 be unable to perform at least the minimum
10 number (which may be 2 or 3) of activities
11 of daily living as are required under the
12 plan for the provision of benefits without
13 substantial assistance (as defined by the
14 Secretary) from another individual.

15 “(ii) The individual requires substan-
16 tial supervision to protect the individual
17 from threats to health and safety due to
18 substantial cognitive impairment.

19 “(iii) The individual has a level of
20 functional limitation similar (as determined
21 under regulations prescribed by the Sec-
22 retary) to the level of functional limitation
23 described in clause (i) or (ii).

24 “(D) CASH BENEFIT.—Payment of a cash
25 benefit that satisfies the following requirements:

1 “(i) MINIMUM REQUIRED AMOUNT.—

2 The benefit amount provides an eligible
3 beneficiary with not less than an average
4 of \$50 per day (as determined based on
5 the reasonably expected distribution of
6 beneficiaries receiving benefits at various
7 benefit levels).

8 “(ii) AMOUNT SCALED TO FUNC-

9 TIONAL ABILITY.—The benefit amount is
10 varied based on a scale of functional abil-
11 ity, with not less than 2, and not more
12 than 6, benefit level amounts.

13 “(iii) DAILY OR WEEKLY.—The ben-
14 efit is paid on a daily or weekly basis.

15 “(iv) NO LIFETIME OR AGGREGATE
16 LIMIT.—The benefit is not subject to any
17 lifetime or aggregate limit.

18 “(E) COORDINATION WITH SUPPLE-
19 MENTAL COVERAGE OBTAINED THROUGH THE
20 EXCHANGE.—The benefits allow for coordina-
21 tion with any supplemental coverage purchased
22 through a Gateway established under section
23 3101.

1 “(2) REVIEW AND RECOMMENDATION BY THE
2 CLASS INDEPENDENCE ADVISORY COUNCIL.—The
3 CLASS Independence Advisory Council shall—

4 “(A) evaluate the alternative benefit plans
5 developed under paragraph (1); and

6 “(B) recommend for designation as the
7 CLASS Independence Benefit Plan for offering
8 to the public the plan that the Council deter-
9 mines best balances price and benefits to meet
10 enrollees’ needs in an actuarially sound manner,
11 while optimizing the probability of the long-
12 term sustainability of the CLASS program.

13 “(3) DESIGNATION BY THE SECRETARY.—Not
14 later than October 1, 2012, the Secretary, taking
15 into consideration the recommendation of the
16 CLASS Independence Advisory Council under para-
17 graph (2)(B), shall designate a benefit plan as the
18 CLASS Independence Benefit Plan. The Secretary
19 shall publish such designation, along with details of
20 the plan and the reasons for the selection by the
21 Secretary, in a final rule that allows for a period of
22 public comment.

23 “(b) ADDITIONAL PREMIUM REQUIREMENTS.—

24 “(1) ADJUSTMENT OF PREMIUMS.—

1 “(A) IN GENERAL.—Except as provided in
2 subparagraphs (B), (C), (D), and (E), the
3 amount of the monthly premium determined for
4 an individual upon such individual’s enrollment
5 in the CLASS program shall remain the same
6 for as long as the individual is an active en-
7 rollee in the program.

8 “(B) RECALCULATED PREMIUM IF RE-
9 QUIRED FOR PROGRAM SOLVENCY.—

10 “(i) IN GENERAL.—Subject to clause
11 (ii), if the Secretary determines, based on
12 the most recent report of the Board of
13 Trustees of the CLASS Independence
14 Fund, the advice of the CLASS Independ-
15 ence Advisory Council, and the annual re-
16 port of the Inspector General of the De-
17 partment of Health and Human Services,
18 and waste, fraud, and abuse, or such other
19 information as the Secretary determines
20 appropriate, that the monthly premiums
21 and income to the CLASS Independence
22 Fund for a year are projected to be insuffi-
23 cient with respect to the 20-year period
24 that begins with that year, the Secretary
25 shall adjust the monthly premiums for in-

1 individuals enrolled in the CLASS program
2 as necessary.

3 “(ii) EXEMPTION FROM INCREASE.—
4 Any increase in a monthly premium im-
5 posed as result of a determination de-
6 scribed in clause (i) shall not apply with
7 respect to the monthly premium of any ac-
8 tive enrollee who—

9 “(I) has attained age 65;

10 “(II) has paid premiums for en-
11 rollment in the program for at least
12 20 years; and

13 “(III) is not actively employed.

14 “(C) RECALCULATED PREMIUM IF RE-
15 ENROLLMENT AFTER MORE THAN A 3-MONTH
16 LAPSE.—

17 “(i) IN GENERAL.—The reenrollment
18 of an individual after a 90-day period dur-
19 ing which the individual failed to pay the
20 monthly premium required to maintain the
21 individual’s enrollment in the CLASS pro-
22 gram shall be treated as an initial enroll-
23 ment for purposes of age-adjusting the
24 premium for enrollment in the program.

1 “(ii) CREDIT FOR PRIOR MONTHS IF
2 REENROLLED WITHIN 5 YEARS.—An indi-
3 vidual who reenrolls in the CLASS pro-
4 gram after such a 90-day period and be-
5 fore the end of the 5-year period that be-
6 gins with the first month for which the in-
7 dividual failed to pay the monthly premium
8 required to maintain the individual’s en-
9 rollment in the program shall be—

10 “(I) credited with any months of
11 paid premiums that accrued prior to
12 the individual’s lapse in enrollment;
13 and

14 “(II) notwithstanding the total
15 amount of any such credited months,
16 required to satisfy section
17 3202(6)(A)(ii) before being eligible to
18 receive benefits.

19 “(D) PENALTY FOR REENOLLMENT AFTER
20 5-YEAR LAPSE.—In the case of an individual
21 who reenrolls in the CLASS program after the
22 end of the 5-year period described in subpara-
23 graph (C)(ii), the monthly premium required
24 for the individual shall be the age-adjusted pre-
25 mium that would be applicable to an initially

1 enrolling individual who is the same age as the
2 reenrolling individual, increased by the greater
3 of—

4 “(i) an amount that the Secretary de-
5 termines is actuarially sound for each
6 month that occurs during the period that
7 begins with the first month for which the
8 individual failed to pay the monthly pre-
9 mium required to maintain the individual’s
10 enrollment in the CLASS program and
11 ends with the month preceding the month
12 in which the reenrollment is effective; or

13 “(ii) 1 percent of the applicable age-
14 adjusted premium for each such month oc-
15 curring in such period.

16 “(2) ADMINISTRATIVE EXPENSES.—In deter-
17 mining the monthly premiums for the CLASS pro-
18 gram the Secretary, in coordination with the Com-
19 missioner of Social Security, may factor in costs for
20 administering the program, not to exceed—

21 “(A) in the case of the first 5 years in
22 which the program is in effect under this title,
23 an amount equal to 3 percent of all premiums
24 paid during each such year; and

1 “(B) in the case of subsequent years, an
2 amount equal to 5 percent of the total amount
3 of all expenditures (including benefits paid)
4 under this title with respect to that year.

5 “(3) NO UNDERWRITING REQUIREMENTS.—No
6 underwriting (other than on the basis of age in ac-
7 cordance with paragraph (2)) shall be used to—

8 “(A) determine the monthly premium for
9 enrollment in the CLASS program; or

10 “(B) prevent an individual from enrolling
11 in the program.

12 **“SEC. 3204. ENROLLMENT AND DISENROLLMENT REQUIRE-**
13 **MENTS.**

14 “(a) AUTOMATIC ENROLLMENT.—

15 “(1) IN GENERAL.—Subject to paragraph (2),
16 the Secretary, in coordination with the Secretary of
17 the Treasury, shall establish procedures under which
18 each individual described in subsection (c) shall be
19 automatically enrolled in the CLASS program by an
20 employer of such individual in the same manner as
21 an employer may elect to automatically enroll em-
22 ployees in a plan under section 401(k), 403(b), or
23 457 of the Internal Revenue Code of 1986.

24 “(2) ALTERNATIVE ENROLLMENT PROCE-
25 DURES.—The procedures established under para-

1 graph (1) shall provide for an alternative enrollment
2 process for an individual described in subsection (c)
3 in the case of such an individual—

4 “(A) who is self-employed;

5 “(B) who has more than 1 employer;

6 “(C) whose employer does not elect to par-
7 ticipate in the automatic enrollment process es-
8 tablished by the Secretary; or

9 “(D) who is a spouse described in sub-
10 section (c)(2) of who is not subject to automatic
11 enrollment.

12 “(3) ADMINISTRATION.—

13 “(A) IN GENERAL.—The Secretary and the
14 Secretary of the Treasury shall, by regulation,
15 establish procedures to—

16 “(i) ensure that an individual is not
17 automatically enrolled in the CLASS pro-
18 gram by more than 1 employer; and

19 “(ii) allow for an individual’s em-
20 ployer to deduct a premium for a spouse
21 described in subsection (c)(1)(B) who is
22 not subject to automatic enrollment.

23 “(B) FORM.—Enrollment in the CLASS
24 program shall be made in such manner as the

1 Secretary may prescribe in order to ensure ease
2 of administration.

3 “(b) ELECTION TO OPT-OUT.—An individual de-
4 scribed in subsection (c) may elect to waive enrollment in
5 the CLASS program at any time in such form and manner
6 as the Secretary and the Secretary of the Treasury shall
7 prescribe.

8 “(c) INDIVIDUAL DESCRIBED.—For purposes of en-
9 rolling in the CLASS program, an individual described in
10 this paragraph is—

11 “(1) an individual—

12 “(A) who has attained age 18;

13 “(B) who—

14 “(i) receives wages on which there is
15 imposed a tax under section 3201(a) of the
16 Internal Revenue Code of 1986; or

17 “(ii) derives self-employment income
18 on which there is imposed a tax under sec-
19 tion 1401(a) of the Internal Revenue Code
20 of 1986;

21 “(C) who is actively employed; and

22 “(D) who is not—

23 “(i) a patient in a hospital or nursing
24 facility, an intermediate care facility for
25 the mentally retarded, or an institution for

1 mental diseases and receiving medical as-
2 sistance under Medicaid; or

3 “(ii) confined in a jail, prison, other
4 penal institution or correctional facility, or
5 by court order pursuant to conviction of a
6 criminal offense or in connection with a
7 verdict or finding described in section
8 202(x)(1)(A)(ii) of the Social Security Act
9 (42 U.S.C. 402(x)(1)(A)(ii)); or

10 “(2) the spouse of an individual described in
11 paragraph (1) and who would be an individual so de-
12 scribed but for subparagraph (B) or (C) of that
13 paragraph.

14 “(d) RULE OF CONSTRUCTION.—Nothing in this title
15 shall be construed as requiring an active enrollee to con-
16 tinue to satisfy subparagraph (B) or (C) of subsection
17 (c)(1) in order to maintain enrollment in the CLASS pro-
18 gram.

19 “(e) PAYMENT.—

20 “(1) PAYROLL DEDUCTION.—An amount equal
21 to the monthly premium for the enrollment in the
22 CLASS program of an individual shall be deducted
23 from the wages or self-employment income of such
24 individual in accordance with such procedures as the
25 Secretary, in coordination with the Secretary of the

1 Treasury, shall establish for employers who elect to
2 deduct and withhold such premiums on behalf of en-
3 rolled employees.

4 “(2) ALTERNATIVE PAYMENT MECHANISM.—
5 The Secretary, in coordination with the Secretary of
6 the Treasury, shall establish alternative procedures
7 for the payment of monthly premiums by an indi-
8 vidual enrolled in the CLASS program—

9 “(A) who does not have an employer who
10 elects to deduct and withhold premiums in ac-
11 cordance with subparagraph (A); or

12 “(B) who does not earn wages or derive
13 self-employment income.

14 “(f) TRANSFER OF PREMIUMS COLLECTED.—

15 “(1) IN GENERAL.—During each calendar year
16 the Secretary of the Treasury shall deposit into the
17 CLASS Independence Fund a total amount equal, in
18 the aggregate, to 100 percent of the premiums col-
19 lected during that year.

20 “(2) TRANSFERS BASED ON ESTIMATES.—The
21 amount deposited pursuant to paragraph (1) shall be
22 transferred in at least monthly payments to the
23 CLASS Independence Fund on the basis of esti-
24 mates by the Secretary and certified to the Sec-
25 retary of the Treasury of the amounts collected in

1 accordance with subparagraphs (A) and (B) of para-
2 graph (5). Proper adjustments shall be made in
3 amounts subsequently transferred to the Fund to
4 the extent prior estimates were in excess of, or were
5 less than, actual amounts collected.

6 “(g) OTHER ENROLLMENT AND DISENROLLMENT
7 OPPORTUNITIES.—The Secretary, in coordination with
8 the Secretary of the Treasury, shall establish procedures
9 under which—

10 “(1) an individual who, in the year of the indi-
11 vidual’s initial eligibility to enroll in the CLASS pro-
12 gram, has elected to waive enrollment in the pro-
13 gram, is eligible to elect to enroll in the program, in
14 such form and manner as the Secretaries shall es-
15 tablish, only during an open enrollment period estab-
16 lished by the Secretaries that is specific to the indi-
17 vidual and that may not occur more frequently than
18 biennially after the date on which the individual first
19 elected to waive enrollment in the program; and

20 “(2) an individual shall only be permitted to
21 disenroll from the program during an annual
22 disenrollment period established by the Secretaries
23 and in such form and manner as the Secretaries
24 shall establish.

1 **“SEC. 3205. BENEFITS.**

2 “(a) DETERMINATION OF ELIGIBILITY.—

3 “(1) APPLICATION FOR RECEIPT OF BENE-
4 FITS.—The Secretary, in coordination with the Com-
5 missioner of Social Security, shall establish proce-
6 dures under which an active enrollee shall apply for
7 receipt of benefits under the CLASS Independence
8 Benefit Plan.

9 “(2) ELIGIBILITY ASSESSMENTS.—

10 “(A) IN GENERAL.—Not later than Janu-
11 ary 1, 2012, the Secretary shall enter into
12 agreements with—

13 “(i) the Disability Determination
14 Service for each State to provide for eligi-
15 bility assessments of active enrollees who
16 apply for receipt of benefits;

17 “(ii) the Protection and Advocacy
18 System for each State to provide advocacy
19 services in accordance with subsection (d);
20 and

21 “(iii) public and private entities to
22 provide advice and assistance counseling in
23 accordance with subsection (e).

24 “(B) REGULATIONS.—The Secretary, in
25 coordination with the Commissioner of Social
26 Security, shall promulgate regulations to de-

1 velop an expedited eligibility determination
2 process, as certified by a licensed health care
3 practitioner, an appeals process, and a redeter-
4 mination process, as certified by a licensed
5 health care practitioner, including whether an
6 applicant is eligible for a cash benefit under the
7 program and if so, the amount of the cash ben-
8 efit (in accordance the sliding scale established
9 under the plan).

10 “(C) PRESUMPTIVE ELIGIBILITY FOR CER-
11 TAIN INSTITUTIONALIZED ENROLLEES PLAN-
12 NING TO DISCHARGE.—An active enrollee shall
13 be deemed presumptively eligible if the en-
14 rollee—

15 “(i) has applied for, and attests is eli-
16 gible for, the maximum cash benefit avail-
17 able under the sliding scale established
18 under the CLASS Independence Benefit
19 Plan;

20 “(ii) is a patient in a hospital (but
21 only if the hospitalization is for long-term
22 care), nursing facility, intermediate care
23 facility for the mentally retarded, or an in-
24 stitution for mental diseases; and

1 “(iii) is in the process of, or about to
2 being the process of, planning to discharge
3 from the hospital, facility, or institution, or
4 within 60 days from the date of discharge
5 from the hospital, facility, or institution.

6 “(D) APPEALS.—The Secretary shall es-
7 tablish procedures under which an applicant for
8 benefits under the CLASS Independence Ben-
9 efit Plan shall be guaranteed the right to ap-
10 peal an adverse determination.

11 “(b) BENEFITS.—An eligible beneficiary shall receive
12 the following benefits under the CLASS Independence
13 Benefit Plan:

14 “(1) CASH BENEFIT.—A cash benefit estab-
15 lished by the Secretary in accordance with the re-
16 quirements of section 3203(a)(1)(D) that—

17 “(A) the first year in which beneficiaries
18 receive the benefits under the plan, is not less
19 than the average dollar amount specified in
20 clause (i) of such section; and

21 “(B) for any subsequent year, is not less
22 than the average per day dollar limit applicable
23 under this subparagraph for the preceding year,
24 increased by the percentage increase in the con-

1 sumer price index for all urban consumers
2 (U.S. city average) over the previous year.

3 “(2) ADVOCACY SERVICES.—Advocacy services
4 in accordance with subsection (d).

5 “(3) ADVICE AND ASSISTANCE COUNSELING.—
6 Advice and assistance counseling in accordance with
7 subsection (e).

8 “(4) ADMINISTRATIVE EXPENSES.—Advocacy
9 services and advise and assistance counseling serv-
10 ices under paragraphs (2) and (3) of this subsection
11 shall be included as administrative expenses under
12 section 3203(b)(3).

13 “(c) PAYMENT OF BENEFITS.—

14 “(1) LIFE INDEPENDENCE ACCOUNT.—

15 “(A) IN GENERAL.—The Secretary shall
16 establish procedures for administering the pro-
17 vision of benefits to eligible beneficiaries under
18 the CLASS Independence Benefit Plan, includ-
19 ing the payment of the cash benefit for the ben-
20 eficiary into a Life Independence Account es-
21 tablished by the Secretary on behalf of each eli-
22 gible beneficiary.

23 “(B) USE OF CASH BENEFITS.—Cash ben-
24 efits paid into a Life Independence Account of
25 an eligible beneficiary shall be used to purchase

1 nonmedical services and supports that the bene-
2 ficiary needs to maintain his or her independ-
3 ence at home or in another residential setting
4 of their choice in the community, including (but
5 not limited to) home modifications, assistive
6 technology, accessible transportation, home-
7 maker services, respite care, personal assistance
8 services, home care aides, and nursing support.
9 Nothing in the preceding sentence shall prevent
10 an eligible beneficiary from using cash benefits
11 paid into a Life Independence Account for ob-
12 taining assistance with decision making con-
13 cerning medical care, including the right to ac-
14 cept or refuse medical or surgical treatment
15 and the right to formulate advance directives or
16 other written instructions recognized under
17 State law, such as a living will or durable power
18 of attorney for health care, in the case that an
19 injury or illness causes the individual to be un-
20 able to make health care decisions.

21 “(C) ELECTRONIC MANAGEMENT OF
22 FUNDS.—The Secretary shall establish proce-
23 dures for—

1 “(i) crediting an account established
2 on behalf of a beneficiary with the bene-
3 ficiary’s cash daily benefit;

4 “(ii) allowing the beneficiary to access
5 such account through debit cards; and

6 “(iii) accounting for withdrawals by
7 the beneficiary from such account.

8 “(D) PRIMARY PAYOR RULES FOR BENE-
9 FICIARIES WHO ARE ENROLLED IN MEDICAID.—
10 In the case of an eligible beneficiary who is en-
11 rolled in Medicaid, the following payment rules
12 shall apply:

13 “(i) INSTITUTIONALIZED BENE-
14 FICIARY.—If the beneficiary is a patient in
15 a hospital, nursing facility, intermediate
16 care facility for the mentally retarded, or
17 an institution for mental diseases, the ben-
18 eficiary shall retain an amount equal to 5
19 percent of the beneficiary’s daily or weekly
20 cash benefit (as applicable) (which shall be
21 in addition to the amount of the bene-
22 ficiary’s personal needs allowance provided
23 under Medicaid), and the remainder of
24 such benefit shall be applied toward the fa-
25 cility’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

1 remainder of a beneficiary's daily or
2 weekly cash benefit under subclause
3 (I) only if the State home and com-
4 munity-based waiver under section
5 1115 of the Social Security Act (42
6 U.S.C. 1315) or subsection (c) or (d)
7 of section 1915 of such Act (42
8 U.S.C. 1396n), or the State plan
9 amendment under subsection (i) of
10 such section does not include a waiver
11 of the requirements of section
12 1902(a)(1) of the Social Security Act
13 (relating to statewideness) or of sec-
14 tion 1902(a)(10)(B) of such Act (re-
15 lating to comparability) and the State
16 offers at a minimum case manage-
17 ment services, personal care services,
18 habilitation services, and respite care
19 under such a waiver or State plan
20 amendment.

21 “(III) DEFINITION OF HOME AND
22 COMMUNITY-BASED SERVICES.—In
23 this clause, the term ‘home and com-
24 munity-based services’ means any
25 services which may be offered under a

1 home and community-based waiver
2 authorized for a State under section
3 1115 of the Social Security Act (42
4 U.S.C. 1315) or subsection (c) or (d)
5 of section 1915 of such Act (42
6 U.S.C. 1396n) or under a State plan
7 amendment under subsection (i) of
8 such section.

9 “(iii) BENEFICIARIES ENROLLED IN
10 PROGRAMS OF ALL-INCLUSIVE CARE FOR
11 THE ELDERLY (PACE).—

12 “(I) IN GENERAL.—Subject to
13 subclause (II), if a beneficiary is re-
14 ceiving medical assistance under Med-
15 icaid for PACE program services
16 under section 1934 of the Social Secu-
17 rity Act (42 U.S.C. 1396u–4), the
18 beneficiary shall retain an amount
19 equal to 50 percent of the bene-
20 ficiary’s daily or weekly cash benefit
21 (as applicable), and the remainder of
22 the daily or weekly cash benefit shall
23 be applied toward the cost to the
24 State of providing such assistance
25 (and shall not be used to claim Fed-

1 eral matching funds under Medicaid),
2 and Medicaid shall provide secondary
3 coverage for the remainder of any
4 costs incurred in providing such as-
5 sistance.

6 “(II) INSTITUTIONALIZED RE-
7 CIPIENTS OF PACE PROGRAM SERV-
8 ICES.—If a beneficiary receiving as-
9 sistance under Medicaid for PACE
10 program services is a patient in a hos-
11 pital, nursing facility, intermediate
12 care facility for the mentally retarded,
13 or an institution for mental diseases,
14 the beneficiary shall be treated as in
15 institutionalized beneficiary under
16 clause (i).

17 “(2) AUTHORIZED REPRESENTATIVES.—

18 “(A) IN GENERAL.—The Secretary shall
19 establish procedures to allow access to a bene-
20 ficiary’s cash benefits by an authorized rep-
21 resentative of the eligible beneficiary on whose
22 behalf such benefits are paid.

23 “(B) QUALITY ASSURANCE AND PROTEC-
24 TION AGAINST FRAUD AND ABUSE.—The proce-
25 dures established under subparagraph (A) shall

1 ensure that authorized representatives of eligi-
2 ble beneficiaries comply with standards of con-
3 duct established by the Secretary, including
4 standards requiring that such representatives
5 provide quality services on behalf of such bene-
6 ficiaries, do not have conflicts of interest, and
7 do not misuse benefits paid on behalf of such
8 beneficiaries or otherwise engage in fraud or
9 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.

14 “(4) **ROLLOVER OPTION FOR LUMP-SUM PAY-**
15 **MENT.**—An eligible beneficiary may elect to—

16 “(A) defer payment of their daily or weekly
17 benefit and to rollover any such deferred bene-
18 fits from month-to-month, but not from year-to-
19 year; and

20 “(B) receive a lump-sum payment of such
21 deferred benefits in an amount that may not
22 exceed the lesser of—

23 “(i) the total amount of the accrued
24 deferred benefits; or

25 “(ii) the applicable annual benefit.

1 “(5) PERIOD FOR DETERMINATION OF ANNUAL
2 BENEFITS.—

3 “(A) IN GENERAL.—The applicable period
4 for determining with respect to an eligible bene-
5 ficiary the applicable annual benefit and the
6 amount of any accrued deferred benefits is the
7 12-month period that commences with the first
8 month in which the beneficiary began to receive
9 such benefits, and each 12-month period there-
10 after.

11 “(B) INCLUSION OF INCREASED BENE-
12 FITS.—The Secretary shall establish procedures
13 under which cash benefits paid to an eligible
14 beneficiary that increase or decrease as a result
15 of a change in the functional status of the bene-
16 ficiary before the end of a 12-month benefit pe-
17 riod shall be included in the determination of
18 the applicable annual benefit paid to the eligible
19 beneficiary.

20 “(C) RECOUPMENT OF UNPAID, ACCRUED
21 BENEFITS.—

22 “(i) IN GENERAL.—The Secretary, in
23 coordination with the Secretary of the
24 Treasury, shall recoup any accrued bene-
25 fits in the event of—

1 “(I) the death of a beneficiary; or

2 “(II) the failure of a beneficiary
3 to elect under paragraph (4)(B) to re-
4 ceive such benefits as a lump-sum
5 payment before the end of the 12-
6 month period in which such benefits
7 accrued.

8 “(ii) PAYMENT INTO CLASS INDE-
9 PENDENCE FUND.—Any benefits recouped
10 in accordance with clause (i) shall be paid
11 into the CLASS Independence Fund and
12 used in accordance with section 3206.

13 “(6) REQUIREMENT TO RECERTIFY ELIGIBILITY
14 FOR RECEIPT OF BENEFITS.—An eligible beneficiary
15 shall periodically, as determined by the Secretary, in
16 coordination with the Commissioner of Social Secu-
17 rity—

18 “(A) recertify by submission of medical
19 evidence the beneficiary’s continued eligibility
20 for receipt of benefits; and

21 “(B) submit records of expenditures attrib-
22 utable to the aggregate cash benefit received by
23 the beneficiary during the preceding year.

24 “(7) SUPPLEMENT, NOT SUPPLANT OTHER
25 HEALTH CARE BENEFITS.—Subject to the Medicaid

1 payment rules under paragraph (1)(D), benefits re-
2 ceived by an eligible beneficiary shall supplement,
3 but not supplant, other health care benefits for
4 which the beneficiary is eligible under Medicaid or
5 any other Federally funded program that provides
6 health care benefits or assistance.

7 “(d) ADVOCACY SERVICES.—An agreement entered
8 into under subsection (a)(2)(A)(ii) shall require the Pro-
9 tection and Advocacy System for the State to—

10 “(1) assign, as needed, an advocacy counselor
11 to each eligible beneficiary that is covered by such
12 agreement and who shall provide an eligible bene-
13 ficiary with—

14 “(A) information regarding how to access
15 the appeals process established for the program;

16 “(B) assistance with respect to the annual
17 recertification and notification required under
18 subsection (c)(6); and

19 “(C) such other assistance with obtaining
20 services as the Secretary, by regulation, shall
21 require; and

22 “(2) ensure that the System and such coun-
23 selors comply with the requirements of subsection
24 (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.

1 “(f) NO EFFECT ON ELIGIBILITY FOR OTHER BENE-
2 FITS.—Benefits paid to an eligible beneficiary under the
3 CLASS program shall be disregarded for purposes of de-
4 termining or continuing the beneficiary’s eligibility for re-
5 ceipt of benefits under any other Federal, State, or locally
6 funded assistance program, including benefits paid under
7 titles II, XVI, XVIII, XIX, or XXI of the Social Security
8 Act (42 U.S.C. 401 et seq., 1381 et seq., 1395 et seq.,
9 1396 et seq., 1397aa et seq.), under the laws administered
10 by the Secretary of Veterans Affairs, under low-income
11 housing assistance programs, or under the supplemental
12 nutrition assistance program established under the Food
13 and Nutrition Act of 2008 (7 U.S.C. 2011 et seq.).

14 “(g) RULE OF CONSTRUCTION.—Nothing in this title
15 shall be construed as prohibiting benefits paid under the
16 CLASS Independence Benefit Plan from being used to
17 compensate a family caregiver for providing community
18 living assistance services and supports to an eligible bene-
19 ficiary.

20 “(h) PROTECTION AGAINST CONFLICT OF INTER-
21 ESTS.—The Secretary shall establish procedures to ensure
22 that the Disability Determination Service and Protection
23 and Advocacy System for a State, advocacy counselors for
24 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-

1 rollee or beneficiary is informed of any financial in-
2 terest that the entity has in a service provider.

3 “(7) The entity provides an active enrollee or
4 beneficiary with a list of available service providers
5 that can meet the needs of the active enrollee or
6 beneficiary.

7 The Secretary shall establish the procedures under this
8 subsection that apply to the Disability Determination
9 Service in coordination with the Commissioner of Social
10 Security.

11 **“SEC. 3206. CLASS INDEPENDENCE FUND.**

12 “(a) ESTABLISHMENT OF CLASS INDEPENDENCE
13 FUND.—There is established in the Treasury of the
14 United States a trust fund to be known as the ‘CLASS
15 Independence Fund’. The Secretary of the Treasury shall
16 serve as Managing Trustee of such Fund. The Fund shall
17 consist of all amounts derived from payments into the
18 Fund under sections 3204(f) and 3205(c)(5)(C)(ii), and
19 remaining after investment of such amounts under sub-
20 section (b), including additional amounts derived as in-
21 come from such investments. The amounts held in the
22 Fund are appropriated and shall remain available without
23 fiscal year limitation—

24 “(1) to be held for investment on behalf of indi-
25 viduals enrolled in the CLASS program;

1 “(2) to pay the administrative expenses related
2 to the Fund and to investment under subsection (b);
3 and

4 “(3) to pay cash benefits to eligible bene-
5 ficiaries under the CLASS Independence Benefit
6 Plan.

7 “(b) INVESTMENT OF FUND BALANCE.—The Sec-
8 retary of the Treasury shall invest and manage the
9 CLASS Independence Fund in the same manner, and to
10 the same extent, as the Federal Supplementary Medical
11 Insurance Trust Fund may be invested and managed
12 under subsections (c), (d), and (e) of section 1841(d) of
13 the Social Security Act (42 U.S.C. 1395t).

14 “(c) LOCK-BOX PROTECTION.—

15 “(1) IN GENERAL.—Notwithstanding any other
16 provision of law, it shall not be in order in the Sen-
17 ate or the House of Representatives to consider any
18 measure that would authorize the payment or use of
19 amounts in the Fund for any purpose other than a
20 purpose authorized under this title.

21 “(2) 60-VOTE WAIVER REQUIRED IN THE SEN-
22 ATE.—

23 “(A) IN GENERAL.—Paragraph (1) may be
24 waived or suspended in the Senate only by the

1 affirmative vote of $\frac{3}{5}$ of the Members, duly
2 chosen and sworn.

3 “(B) APPEALS.—

4 “(i) PROCEDURE.—Appeals in the
5 Senate from the decisions of the Chair re-
6 lating to subparagraph (A) shall be limited
7 to 1 hour, to be equally divided between,
8 and controlled by, the mover and the man-
9 ager of the measure that would authorize
10 the payment or use of amounts in the
11 Fund for a purpose other than a purpose
12 authorized under this title.

13 “(ii) 60-VOTES REQUIRED.—An af-
14 firmative vote of $\frac{3}{5}$ of the Members, duly
15 chosen and sworn, shall be required in the
16 Senate to sustain an appeal of the ruling
17 of the Chair on a point of order raised in
18 relation to subparagraph (A).

19 “(3) RULES OF THE SENATE AND HOUSE OF
20 REPRESENTATIVES.—This subsection is enacted by
21 Congress—

22 “(A) as an exercise of the rulemaking
23 power of the Senate and House of Representa-
24 tives, respectively, and is deemed to be part of
25 the rules of each House, respectively, but appli-

1 cable only with respect to the procedure to be
2 followed in that House in the case of a measure
3 described in paragraph (1), and it supersedes
4 other rules only to the extent that it is incon-
5 sistent with such rules; and

6 “(B) with full recognition of the constitu-
7 tional right of either House to change the rules
8 (so far as they relate to the procedure of that
9 House) at any time, in the same manner, and
10 to the same extent as in the case of any other
11 rule of that House.

12 “(d) BOARD OF TRUSTEES.—

13 “(1) IN GENERAL.—With respect to the CLASS
14 Independence Fund, there is hereby created a body
15 to be known as the Board of Trustees of the CLASS
16 Independence Fund (hereinafter in this section re-
17 ferred to as the ‘Board of Trustees’) composed of
18 the Commissioner of Social Security, the Secretary
19 of the Treasury, the Secretary of Labor, and the
20 Secretary of Health and Human Services, all ex offi-
21 cio, and of two members of the public (both of whom
22 may not be from the same political party), who shall
23 be nominated by the President for a term of 4 years
24 and subject to confirmation by the Senate. A mem-
25 ber of the Board of Trustees serving as a member

1 of the public and nominated and confirmed to fill a
2 vacancy occurring during a term shall be nominated
3 and confirmed only for the remainder of such term.
4 An individual nominated and confirmed as a member
5 of the public may serve in such position after the ex-
6 piration of such member's term until the earlier of
7 the time at which the member's successor takes of-
8 fice or the time at which a report of the Board is
9 first issued under paragraph (2) after the expiration
10 of the member's term. The Secretary of the Treas-
11 ury shall be the Managing Trustee of the Board of
12 Trustees. The Board of Trustees shall meet not less
13 frequently than once each calendar year. A person
14 serving on the Board of Trustees shall not be con-
15 sidered to be a fiduciary and shall not be personally
16 liable for actions taken in such capacity with respect
17 to the Trust Fund.

18 “(2) DUTIES.—

19 “(A) IN GENERAL.—It shall be the duty of
20 the Board of Trustees to do the following:

21 “(i) Hold the CLASS Independence
22 Fund.

23 “(ii) Report to the Congress not later
24 than the first day of April of each year on
25 the operation and status of the CLASS

1 Independence Fund during the preceding
2 fiscal year and on its expected operation
3 and status during the current fiscal year
4 and the next 2 fiscal years.

5 “(iii) Report immediately to the Con-
6 gress whenever the Board is of the opinion
7 that the amount of the CLASS Independ-
8 ence Fund is not actuarially sound in re-
9 gards to the projections under section
10 3203(b)(2)(B)(i).

11 “(iv) Review the general policies fol-
12 lowed in managing the CLASS Independ-
13 ence Fund, and recommend changes in
14 such policies, including necessary changes
15 in the provisions of law which govern the
16 way in which the CLASS Independence
17 Fund is to be managed.

18 “(B) REPORT.—The report provided for in
19 subparagraph (A)(ii) shall—

20 “(i) include—

21 “(I) a statement of the assets of,
22 and the disbursements made from, the
23 CLASS Independence Fund during
24 the preceding fiscal year;

1 “(II) an estimate of the expected
2 income to, and disbursements to be
3 made from, the CLASS Independence
4 Fund during the current fiscal year
5 and each of the next 2 fiscal years;

6 “(III) a statement of the actu-
7 arial status of the CLASS Independ-
8 ence Fund for the current fiscal year,
9 each of the next 2 fiscal years, and as
10 projected over the 75-year period be-
11 ginning with the current fiscal year;

12 “(IV) an actuarial opinion by the
13 Chief Actuary of the Social Security
14 Administration certifying that the
15 techniques and methodologies used
16 are generally accepted within the ac-
17 tuarial profession and that the as-
18 sumptions and cost estimates used are
19 reasonable; and

20 “(V) an opinion by the Commis-
21 sioner of Social Security that the Dis-
22 ability Determination Service per-
23 sonnel are not over burdened by the
24 additional requirements of the CLASS
25 program; and

1 “(ii) be printed as a House document
2 of the session of the Congress to which the
3 report is made.

4 “(C) RECOMMENDATIONS.—If the Board
5 of Trustees determines that enrollment trends
6 and expected future benefit claims on the
7 CLASS Independence Fund are not actuarially
8 sound in regards to the projections under sec-
9 tion 3203(b)(2)(B)(i) and are unlikely to be re-
10 solved with reasonable premium increases or
11 through other means, the Board of Trustees
12 shall include in the report provided for in sub-
13 paragraph (A)(ii) recommendations for such
14 legislative action as the Board of Trustees de-
15 termine to be appropriate, including whether to
16 adjust monthly premiums or impose a tem-
17 porary moratorium on new enrollments.

18 **“SEC. 3207. CLASS INDEPENDENCE ADVISORY COUNCIL.**

19 “(a) ESTABLISHMENT.—There is hereby created an
20 Advisory Committee to be known as the ‘CLASS Inde-
21 pendence Advisory Council’.

22 “(b) MEMBERSHIP.—

23 “(1) IN GENERAL.—The CLASS Independence
24 Advisory Council shall be composed of not more

1 than 15 individuals, not otherwise in the employ of
2 the United States—

3 “(A) who shall be appointed by the Presi-
4 dent without regard to the civil service laws and
5 regulations; and

6 “(B) a majority of whom shall be rep-
7 resentatives of individuals who participate or
8 are likely to participate in the CLASS program,
9 and shall include representatives of older and
10 younger workers, individuals with disabilities,
11 family caregivers of individuals who require
12 services and supports to maintain their inde-
13 pendence at home or in another residential set-
14 ting of their choice in the community, individ-
15 uals with expertise in long-term care or dis-
16 ability insurance, actuarial science, economics,
17 and other relevant disciplines, as determined by
18 the Secretary.

19 “(2) TERMS.—

20 “(A) IN GENERAL.—The members of the
21 CLASS Independence Advisory Council shall
22 serve overlapping terms of 3 years (unless ap-
23 pointed to fill a vacancy occurring prior to the
24 expiration of a term, in which case the indi-

1 vidual shall serve for the remainder of the
2 term).

3 “(B) LIMITATION.—A member shall not be
4 eligible to serve for more than 2 consecutive
5 terms.

6 “(3) CHAIR.—The President shall, from time to
7 time, appoint one of the members of the CLASS
8 Independence Advisory Council to serve as the
9 Chair.

10 “(c) DUTIES.—The CLASS Independence Advisory
11 Council shall advise the Secretary on matters of general
12 policy in the administration of the CLASS program estab-
13 lished under this title and in the formulation of regula-
14 tions under this title including with respect to—

15 “(1) the development of the CLASS Independ-
16 ence Benefit Plan under section 3203; and

17 “(2) the determination of monthly premiums
18 under such plan.

19 “(d) APPLICATION OF FACA.—The Federal Advisory
20 Committee Act (5 U.S.C. App.), other than section 14 of
21 that Act, shall apply to the CLASS Independence Advisory
22 Council.

23 “(e) AUTHORIZATION OF APPROPRIATIONS.—

24 “(1) IN GENERAL.—There are authorized to be
25 appropriated to the CLASS Independence Advisory

1 Council to carry out its duties under this section,
2 such sums as may be necessary for fiscal year 2011
3 and for each fiscal year thereafter.

4 “(2) AVAILABILITY.—Any sums appropriated
5 under the authorization contained in this section
6 shall remain available, without fiscal year limitation,
7 until expended.

8 **“SEC. 3208. REGULATIONS; ANNUAL REPORT.**

9 “(a) REGULATIONS.—The Secretary shall promulgate
10 such regulations as are necessary to carry out the CLASS
11 program in accordance with this title. Such regulations
12 shall include provisions to prevent fraud and abuse under
13 the program.

14 “(b) ANNUAL REPORT.—Beginning January 1, 2014,
15 the Secretary shall submit an annual report to Congress
16 on the CLASS program. Each report shall include the fol-
17 lowing:

18 “(1) The total number of enrollees in the pro-
19 gram.

20 “(2) The total number of eligible beneficiaries
21 during the fiscal year.

22 “(3) The total amount of cash benefits provided
23 during the fiscal year.

24 “(4) A description of instances of fraud or
25 abuse identified during the fiscal year.

1 “(5) Recommendations for such administrative
2 or legislative action as the Secretary determines is
3 necessary to improve the program or to prevent the
4 occurrence of fraud or abuse.

5 **“SEC. 3209. INSPECTOR GENERAL’S REPORT.**

6 “The Inspector General of the Department of Health
7 and Human Services shall submit an annual report to the
8 Secretary and Congress relating to the overall progress of
9 the CLASS program and of the existence of waste, fraud,
10 and abuse in the CLASS program. Each such report shall
11 include findings in the following areas:

12 “(1) The eligibility determination process.

13 “(2) The provision of cash benefits.

14 “(3) Quality assurance and protection against
15 waste, fraud, and abuse.

16 “(4) Recouping of unpaid and accrued benefits.

17 **“SEC. 3210. TAX TREATMENT OF PROGRAM.**

18 “The CLASS program shall be treated for purposes
19 of the Internal Revenue Code of 1986 in the same manner
20 as a qualified long-term care insurance contract for quali-
21 fied long-term care services.”.

22 (2) CONFORMING AMENDMENTS TO MED-
23 ICAID.—Section 1902(a) of the Social Security Act
24 (42 U.S.C. 1396a(a)), as amended by section

1 5006(e)(2)(A) of division B of Public Law 111–5, is
2 amended—

3 (A) in paragraph (72), by striking “and”
4 at the end;

5 (B) in paragraph (73)(B), by striking the
6 period and inserting “; and”; and

7 (C) by inserting after paragraph (73) the
8 following:

9 “(74) provide that the State will comply with
10 such regulations regarding the application of pri-
11 mary and secondary payor rules with respect to indi-
12 viduals who are eligible for medical assistance under
13 this title and are eligible beneficiaries under the
14 CLASS program established under title XXXII of
15 the Public Health Service Act as the Secretary shall
16 establish.”.

17 (b) ASSURANCE OF ADEQUATE INFRASTRUCTURE
18 FOR THE PROVISION OF PERSONAL CARE ATTENDANT
19 WORKERS.—Section 1902(a) of the Social Security Act
20 (42 U.S.C. 1396a(a)), as amended by subsection (a)(2),
21 is amended—

22 (1) in paragraph (73)(B), by striking “and” at
23 the end;

24 (2) in paragraph (74), by striking the period at
25 the end and inserting “; and”; and

1 (3) by inserting after paragraph (74), the fol-
2 lowing:

3 “(75) provide that, not later than 2 years after
4 the date of enactment of the Community Living As-
5 sistance Services and Supports Act, each State
6 shall—

7 “(A) assess the extent to which entities
8 such as providers of home care, home health
9 services, home and community service providers,
10 public authorities created to provide personal
11 care services to individuals eligible for medical
12 assistance under the State plan, and nonprofit
13 organizations, are serving or have the capacity
14 to serve as fiscal agents for, employers of, and
15 providers of employment-related benefits for,
16 personal care attendant workers who provide
17 personal care services to individuals receiving
18 benefits under the CLASS program established
19 under title XXXII of the Public Health Service
20 Act, including in rural and underserved areas;

21 “(B) designate or create such entities to
22 serve as fiscal agents for, employers of, and
23 providers of employment-related benefits for,
24 such workers to ensure an adequate supply of
25 the workers for individuals receiving benefits

1 under the CLASS program, including in rural
2 and underserved areas; and

3 “(C) ensure that the designation or cre-
4 ation of such entities will not negatively alter or
5 impede existing programs, models, methods, or
6 administration of service delivery that provide
7 for consumer controlled or self-directed home
8 and community services and further ensure that
9 such entities will not impede the ability of indi-
10 viduals to direct and control their home and
11 community services, including the ability to se-
12 lect, manage, dismiss, co-employ, or employ
13 such workers or inhibit such individuals from
14 relying on family members for the provision of
15 personal care services.”.

16 (c) PERSONAL CARE ATTENDANTS WORKFORCE AD-
17 VISORY PANEL.—

18 (1) ESTABLISHMENT.—Not later than 90 days
19 after the date of enactment of this Act, the Sec-
20 retary of Health and Human Services shall establish
21 a Personal Care Attendants Workforce Advisory
22 Panel for the purpose of examining and advising the
23 Secretary and Congress on workforce issues related
24 to personal care attendant workers, including with
25 respect to the adequacy of the number of such work-

1 ers, the salaries, wages, and benefits of such work-
2 ers, and access to the services provided by such
3 workers.

4 (2) MEMBERSHIP.—In appointing members to
5 the Personal Care Attendants Workforce Advisory
6 Panel, the Secretary shall ensure that such members
7 include the following:

8 (A) Individuals with disabilities of all ages.

9 (B) Senior individuals.

10 (C) Representatives of individuals with dis-
11 abilities.

12 (D) Representatives of senior individuals.

13 (E) Representatives of workforce and labor
14 organizations.

15 (F) Representatives of home and commu-
16 nity-based service providers.

17 (G) Representatives of assisted living pro-
18 viders.

19 (d) INCLUSION OF INFORMATION ON SUPPLEMENTAL
20 COVERAGE IN THE NATIONAL CLEARINGHOUSE FOR
21 LONG-TERM CARE INFORMATION; EXTENSION OF FUND-
22 ING.—Section 6021(d) of the Deficit Reduction Act of
23 2005 (42 U.S.C. 1396p note) is amended—

24 (1) in paragraph (2)(A)—

1 (A) in clause (ii), by striking “and” at the
2 end;

3 (B) in clause (iii), by striking the period at
4 the end and inserting “; and”; and

5 (C) by adding at the end the following:

6 “(iv) include information regarding
7 the CLASS program established under
8 title XXXII of the Public Health Service
9 Act and coverage available for purchase
10 through a Gateway established under sec-
11 tion 3101 of such Act that is supplemental
12 coverage to the benefits provided under a
13 CLASS Independence Benefit Plan under
14 that program.”; and

15 (2) in paragraph (3), by striking “2010” and
16 inserting “2015”.

17 (e) EFFECTIVE DATE.—The amendments made by
18 subsections (a), (b), and (d) take effect on January 1,
19 2011.

1 **TITLE II—IMPROVING THE**
2 **QUALITY AND EFFICIENCY OF**
3 **HEALTH CARE**

4 **Subtitle A—National Strategy to**
5 **Improve Health Care Quality**

6 **SEC. 201. NATIONAL STRATEGY.**

7 (a) IN GENERAL.—Title III of the Public Health
8 Service Act (42 U.S.C. 241 et seq.) is amended by adding
9 at the end the following:

10 **“PART S—HEALTH CARE QUALITY PROGRAMS**

11 **“Subpart I—National Strategy for Quality**

12 **Improvement in Health Care**

13 **“SEC. 399HH. NATIONAL STRATEGY FOR QUALITY IM-**
14 **PROVEMENT IN HEALTH CARE.**

15 **“(a) ESTABLISHMENT OF NATIONAL STRATEGY AND**
16 **PRIORITIES.—**

17 **“(1) NATIONAL STRATEGY.—**The Secretary,
18 through a transparent collaborative process, shall es-
19 tablish a national strategy to improve the delivery of
20 health care services, patient health outcomes, and
21 population health.

22 **“(2) IDENTIFICATION OF PRIORITIES.—**

23 **“(A) IN GENERAL.—**The Secretary shall
24 identify national priorities for improvement in
25 developing the strategy under paragraph (1).

1 “(B) REQUIREMENTS.—The Secretary
2 shall ensure that priorities identified under sub-
3 paragraph (A) will—

4 “(i) address the health care provided
5 to patients with high-cost chronic diseases;

6 “(ii) improve the design, development,
7 demonstration, dissemination, and adop-
8 tion of infrastructure and innovative meth-
9 odologies and strategies for quality im-
10 provement in the delivery of health care
11 services that represent best practices to
12 improve patient safety and reduce medical
13 errors, preventable admissions and re-
14 admissions, and health care-associated in-
15 fections;

16 “(iii) have the greatest potential for
17 improving the health outcomes, efficiency,
18 and patient-centeredness of health care;

19 “(iv) reduce health disparities across
20 health disparity populations (as defined by
21 section 485E) and geographic areas;

22 “(v) address gaps in quality and
23 health outcomes measures, comparative ef-
24 fectiveness information, and data aggrega-

1 tion techniques, including the use of data
2 registries;

3 “(vi) identify areas in the delivery of
4 health care services that have the potential
5 for rapid improvement in the quality of pa-
6 tient care;

7 “(vii) improve Federal payment policy
8 to emphasize quality;

9 “(viii) enhance the use of health care
10 data to improve quality, transparency, and
11 outcomes; and

12 “(ix) address other areas as deter-
13 mined appropriate by the Secretary.

14 “(C) CONSIDERATIONS.—In identifying
15 priorities under subparagraph (A), the Sec-
16 retary shall take into consideration—

17 “(i) the recommendations submitted
18 by qualified consensus-based entities as re-
19 quired under section 399JJ; and

20 “(ii) the recommendations of the
21 Interagency Working Group on Health
22 Care Quality established under section 202
23 of the Affordable Health Choices Act.

24 “(b) STRATEGIC PLAN.—

1 “(1) IN GENERAL.—The national strategy shall
2 include a comprehensive strategic plan to achieve the
3 priorities described in subsection (a).

4 “(2) REQUIREMENTS.—The strategic plan shall
5 include provisions for addressing, at a minimum, the
6 following:

7 “(A) Coordination among agencies within
8 the Department, which shall include steps to
9 minimize duplication of efforts and utilization
10 of common quality measures, where available.
11 Such common quality measures shall be meas-
12 ures endorsed under section 399JJ.

13 “(B) Agency-specific strategic plans to
14 achieve national priorities.

15 “(C) Establishment of annual benchmarks
16 for each relevant agency to achieve national pri-
17 orities.

18 “(D) A process for regular reporting by
19 the agencies to the Secretary on the implemen-
20 tation of the strategic plan.

21 “(E) Use of common incentives among
22 public and private payers with regard to quality
23 and patient safety efforts.

24 “(F) Incorporating quality improvement
25 and measurement in the strategic plan for

1 health information technology required by the
2 American Recovery and Reinvestment Act of
3 2009 (Public Law 111–5).

4 “(c) PERIODIC UPDATE OF NATIONAL STRATEGY.—
5 The Secretary shall update the national strategy not less
6 than triennially. Any such update shall include a review
7 of short- and long-term goals.

8 “(d) SUBMISSION AND AVAILABILITY OF NATIONAL
9 STRATEGY.—The Secretary shall transmit to the relevant
10 Committees of Congress the national strategy and updates
11 to such strategy.

12 “(e) PUBLIC REPORTING.—

13 “(1) ANNUAL NATIONAL HEALTH CARE QUAL-
14 ITY REPORT CARD.—Not later than January 31,
15 2011, and annually thereafter, the Secretary shall
16 publish a national health care quality report card,
17 which shall include—

18 “(A) the considerations for national prior-
19 ities described in subsection (a)(2);

20 “(B) an analysis of the progress of the
21 strategic plans under subsection (b)(2)(B) in
22 achieving the national priorities under sub-
23 section (a)(2), and any gaps in such strategic
24 plans;

1 “(C) the extent to which private sector
2 strategies have informed Federal quality im-
3 provement efforts; and

4 “(D) a summary of consumer and provider
5 feedback regarding quality improvement prac-
6 tices.

7 “(2) WEBSITE.—Not later than July 1, 2010,
8 the Director shall create an Internet website to
9 make public information regarding—

10 “(A) the national priorities for health care
11 quality improvement established under sub-
12 section (a)(2);

13 “(B) the agency-specific strategic plans for
14 health care quality described in subsection
15 (b)(2)(B);

16 “(C) the annual national health care qual-
17 ity report card described in paragraph (1); and

18 “(D) other information, as the Secretary
19 determines to be appropriate.”.

20 (b) AGENCY QUALITY REVIEW.—

21 (1) IN GENERAL.—Each relevant agency within
22 the Department of Health and Human Services shall
23 review the statutory authority, regulations, policies,
24 and procedures of such agency, as in effect on the
25 date of enactment of this title, for purposes of deter-

1 mining whether there are any deficiencies or incon-
2 sistencies that prohibit full compliance with the in-
3 tent, purposes, and provisions of this title (and the
4 amendments made by this title).

5 (2) PROPOSALS.—Each agency described in
6 paragraph (1) shall, not later than July 1, 2010,
7 submit to the Secretary of Health and Human Serv-
8 ices a proposal of the measures as may be necessary
9 to bring the authority, regulations, policies, and pro-
10 cedures of such agency into conformity with the in-
11 tent, purposes, and provisions of the this title (and
12 the amendments made by this title).

13 **SEC. 202. INTERAGENCY WORKING GROUP ON HEALTH**
14 **CARE QUALITY.**

15 (a) IN GENERAL.—The President shall convene a
16 working group to be known as the Interagency Working
17 Group on Health Care Quality (referred to in this section
18 as the “Working Group”).

19 (b) GOALS.—The goals of the Working Group shall
20 be to achieve the following:

21 (1) Collaboration, cooperation, and consultation
22 between Federal departments and agencies with re-
23 spect to developing and disseminating strategies,
24 goals, models, and timetables that are consistent
25 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.—

1 (A) CHAIR.—The Working Group shall be
2 chaired by the Secretary of Health and Human
3 Services.

4 (B) VICE-CHAIR.—Members of the Work-
5 ing Group, other than the Secretary of Health
6 and Human Services, shall serve as Vice Chair
7 of the Group on a rotating basis, as determined
8 by the Group.

9 (d) REPORT TO CONGRESS.—Not later than Decem-
10 ber 31, 2010, and annually thereafter, the Working Group
11 shall submit to the relevant Committees of Congress, and
12 make public on an Internet website, a report describing
13 the progress and recommendations of the Working Group
14 in meeting the goals described in subsection (b).

15 **SEC. 203. QUALITY MEASURE DEVELOPMENT.**

16 Title IX of the Public Health Service Act (42 U.S.C.
17 299 et seq.) is amended—

18 (1) by redesignating part D as part E;

19 (2) by redesignating sections 931 through 938
20 as sections 941 through 948, respectively;

21 (3) in section 948(1), as so redesignated, by
22 striking “931” and inserting “941”; and

23 (4) by inserting after section 926 the following:

1 **“PART D—HEALTH CARE QUALITY**
2 **IMPROVEMENT**
3 **“Subpart I—Quality Measure Development**

4 **“SEC. 931. QUALITY MEASURE DEVELOPMENT.**

5 “(a) QUALITY MEASURE.—In this subpart, the term
6 ‘quality measure’ means a standard for measuring the per-
7 formance and improvement of population health or of
8 health plans, providers of services, and other clinicians in
9 the delivery of health care services.

10 “(b) IDENTIFICATION OF QUALITY MEASURES.—

11 “(1) IDENTIFICATION.—The Director shall
12 identify, not less often than biennially, gaps where
13 no quality measures exist, or where existing quality
14 measures need improvement, updating, or expansion,
15 consistent with the national strategy under section
16 399HH, for use in programs authorized under this
17 Act. In identifying such gaps, the Director shall take
18 into consideration the gaps identified by a qualified
19 consensus-based entity under section 399JJ.

20 “(2) PUBLICATION.—The Director shall make
21 available to the public on an Internet website a re-
22 port on any gaps identified under paragraph (1) and
23 the process used to make such identification.

24 “(c) GRANTS OR CONTRACTS FOR QUALITY MEAS-
25 URE DEVELOPMENT.—

1 “(1) IN GENERAL.—The Director shall award
2 grants, contracts, or intergovernmental agreements
3 to eligible entities for purposes of developing, im-
4 proving, updating, or expanding quality measures
5 identified under subsection (b).

6 “(2) PRIORITIZATION IN THE DEVELOPMENT
7 OF QUALITY MEASURES.—In awarding grants, con-
8 tracts, or agreements under this subsection, the Di-
9 rector shall give priority to the development of qual-
10 ity measures that allow the assessment of—

11 “(A) health outcomes and functional status
12 of patients;

13 “(B) the continuity, management, and co-
14 ordination of health care and care transitions,
15 including episodes of care, for patients across
16 the continuum of providers, health care set-
17 tings, and health plans;

18 “(C) patient, caregiver, and authorized
19 representative experience, quality and relevance
20 of information provided to patients, caregivers,
21 and authorized representatives, and use of in-
22 formation by patients, caregivers, and author-
23 ized representatives to inform decisionmaking
24 about treatment options and, where appro-
25 priate, 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);

1 “(C) collaborate with a qualified con-
2 sensus-based entity (as defined in section
3 399JJ), as practicable, and the Secretary so
4 that quality measures developed by the eligible
5 entity will meet the requirements to be consid-
6 ered for endorsement by such qualified con-
7 sensus-based entity;

8 “(D) have transparent policies regarding
9 conflicts of interest; and

10 “(E) submit an application to the Director
11 at such time and in such manner, as the Direc-
12 tor may require.

13 “(4) USE OF FUNDS.—An entity that receives
14 a grant, contract, or agreement under this sub-
15 section shall use such award to develop quality
16 measures that meet the following requirements:

17 “(A) Such measures build upon measures
18 developed under section 1139A of Social Secu-
19 rity Act, where applicable.

20 “(B) To the extent practicable, data on
21 such quality measures is able to be collected
22 using health information technologies.

23 “(C) Each quality measure is free of
24 charge to users of such measure.

1 “(D) Each quality measure is publicly
2 available on an Internet website.

3 “(d) OTHER ACTIVITIES BY THE DIRECTOR.—The
4 Director may use amounts available under this section to
5 update and test, where applicable, quality measures en-
6 dorsed by a qualified consensus-based entity (as defined
7 in section 399JJ) or adopted by the Secretary.

8 “(e) FUNDING.—There are authorized to be appro-
9 priated to carry out this section, \$75,000,000 for each of
10 fiscal years 2010 through 2014.”.

11 **SEC. 204. QUALITY MEASURE ENDORSEMENT; PUBLIC RE-**
12 **PORTING; DATA COLLECTION.**

13 Title III of the Public Health Service Act (42 U.S.C.
14 241 et seq.), as amended by section 201, is further amend-
15 ed by adding at the end the following:

16 **“Subpart II—Health Care Quality Programs**

17 **“SEC. 399JJ. QUALITY MEASURE ENDORSEMENT.**

18 “(a) DEFINITIONS.—In this subpart:

19 “(1) QUALIFIED CONSENSUS-BASED ENTITY.—

20 The term ‘qualified consensus-based entity’ means
21 an entity with a contract with the Secretary under
22 section 1890 of the Social Security Act.

23 “(2) QUALITY MEASURE.—The term ‘quality
24 measure’ means a standard for measuring the per-
25 formance and improvement of population health or

1 of health plans, providers of services, and other clini-
2 cians in the delivery of health care services.

3 “(3) MULTI-STAKEHOLDER GROUP.—The term
4 ‘multi-stakeholder group’ means, with respect to a
5 quality measure, a voluntary collaborative of organi-
6 zations representing a broad group of stakeholders
7 interested in or affected by the use of such quality
8 measure.

9 “(b) GRANTS AND CONTRACTS.—A qualified con-
10 sensus-based entity may receive a grant or contract under
11 this subsection to—

12 “(1) make recommendations to the Secretary
13 for national priorities for performance improvement
14 in population health and in the delivery of health
15 care services;

16 “(2) identify gaps in endorsed quality measures,
17 which shall include measures that—

18 “(A) are within priority areas identified by
19 the Secretary under the national strategy estab-
20 lished under section 399HH;

21 “(B) assess common care episodes, patient
22 health outcomes, processes, efficiency, cost, and
23 appropriate use of health care services and re-
24 sources and address health disparities across

1 health disparity populations (as defined in sec-
2 tion 485E) and geographic areas; or

3 “(C) assess use of innovative methodolo-
4 gies and strategies for quality improvement
5 practices in the delivery of health care services
6 that represent best practices for such quality
7 improvement identified in section 933;

8 “(3) identify and endorse quality measures, in-
9 cluding measures that address gaps identified in
10 paragraph (2);

11 “(4) update endorsed quality measures at least
12 every 3 years;

13 “(5) make endorsed quality measures publicly
14 available and have a plan for broad-based dissemina-
15 tion of endorsed measures; and

16 “(6) transmit endorsed quality measures to the
17 Secretary.

18 “(c) ANNUAL REPORTS.—

19 “(1) IN GENERAL.—A qualified consensus-
20 based entity that receives a grant or contract under
21 this section shall provide a report to the Secretary
22 not less than annually—

23 “(A) of where gaps (as described in sub-
24 section (b)(2)) exist and where quality measures

1 are unavailable or inadequate to identify or ad-
2 dress such gaps; and

3 “(B) regarding areas in which evidence is
4 insufficient to support endorsement of quality
5 measures in priority areas identified by the Sec-
6 retary under the national strategy established
7 under section 399HH and where targeted re-
8 search may address such gaps.

9 “(2) IMPACT OF QUALITY MEASURES.—A quali-
10 fied consensus-based entity that receives a grant or
11 contract under this section shall provide a report to
12 the Secretary not less than annually regarding the
13 economic and quality impact of the use of endorsed
14 measures.

15 “(d) PRIORITIES FOR PERFORMANCE IMPROVE-
16 MENT.—

17 “(1) RECOMMENDATION FOR NATIONAL PRIOR-
18 ITIES.—A qualified consensus-based entity that re-
19 ceives a grant or contract under this section shall
20 evaluate evidence and convene multi-stakeholder
21 groups to make recommendations to the Secretary
22 for national priorities for performance improvement
23 in population health and in the delivery of health
24 care services for consideration under the national
25 strategy established under section 399HH. The

1 qualified consensus-based entity shall make such rec-
2 ommendations not less frequently than triennially.

3 “(2) REQUIREMENTS FOR TRANSPARENCY IN
4 PROCESS.—

5 “(A) IN GENERAL.—In convening multi-
6 stakeholder groups under paragraph (1) with
7 respect to recommendations for national prior-
8 ities, the qualified consensus-based entity shall
9 provide for an open and transparent process for
10 the activities conducted pursuant to such con-
11 vening.

12 “(B) SELECTION OF ORGANIZATIONS PAR-
13 TICIPATING IN MULTI-STAKEHOLDER
14 GROUPS.—The process under subparagraph (A)
15 shall ensure that the selection of representatives
16 comprising such groups provides for public
17 nominations for, and the opportunity for public
18 comment on, such selection.

19 “(3) CONSIDERATIONS IN RECOMMENDING PRI-
20 ORITIES.—In making recommendations under para-
21 graph (1), the qualified consensus-based entity shall
22 ensure that priority is given to areas in the delivery
23 of health care services for all populations including
24 children, and other vulnerable populations that—

1 “(A) address the health care provided to
2 patients with prevalent, high-cost chronic dis-
3 eases;

4 “(B) improve the design, development,
5 demonstration, and adoption of infrastructure
6 and innovative methodologies and strategies for
7 quality improvement practices in the delivery of
8 health care services, including those that im-
9 prove patient safety and reduce medical errors,
10 readmissions, and health care-associated infec-
11 tions;

12 “(C) have the greatest potential for im-
13 proving the health outcomes, efficiency, and pa-
14 tient-centeredness of health care;

15 “(D) reduce health disparities across popu-
16 lations (as defined in section 485E) and geo-
17 graphic areas;

18 “(E) address gaps in quality and health
19 outcomes measures, comparative effectiveness
20 information, and data aggregation techniques,
21 including the use of data registries;

22 “(F) identify areas in the delivery of
23 health care services that have the potential for
24 rapid improvement in the quality of patient
25 care; and

1 “(G) address the appropriate use of health
2 care technology, resources and services.

3 “(e) PROCESS FOR CONSULTATION OF STAKE-
4 HOLDER GROUPS.—

5 “(1) CONSULTATION OF SELECTION OF EN-
6 DORSED QUALITY MEASURES.—A qualified con-
7 sensus-based entity that receives a grant or contract
8 under this section shall convene multi-stakeholder
9 groups to provide guidance on the selection of indi-
10 vidual or composite quality measures, for use in re-
11 porting performance information to the public or for
12 use in Federal health programs, from among—

13 “(A) such measures that have been en-
14 dorsed by the qualified consensus-based entity
15 (under section 1890(b) of the Social Security
16 Act or otherwise); and

17 “(B) such measures that have not been
18 considered for endorsement by the qualified
19 consensus-based entity but are used or proposed
20 to be used by the Secretary under subsection
21 (f)(2) under laws under the jurisdiction of the
22 Secretary that require the collection or report-
23 ing of quality measures.

24 “(2) TRANSMISSION OF MULTI-STAKEHOLDER
25 GUIDANCE.—The qualified consensus-based entity

1 shall transmit to the Secretary the guidance of
2 multi-stakeholder groups provided under paragraph
3 (1).

4 “(3) REQUIREMENT FOR TRANSPARENCY IN
5 PROCESS.—

6 “(A) IN GENERAL.—In convening multi-
7 stakeholder groups under paragraph (1) with
8 respect to the selection of quality measures, the
9 qualified consensus-based entity shall provide
10 for an open and transparent process for the ac-
11 tivities conducted pursuant to such convening.

12 “(B) SELECTION OF ORGANIZATIONS PAR-
13 TICIPATING IN MULTI-STAKEHOLDER
14 GROUPS.—The process under subparagraph (A)
15 shall ensure that the selection of representatives
16 comprising such groups provides for public
17 nominations for, and the opportunity for public
18 comment on, such selection.

19 “(f) COORDINATION OF USE OF QUALITY MEAS-
20 URES.—

21 “(1) ENDORSED QUALITY MEASURES.—The
22 Secretary may make a determination under regula-
23 tion or otherwise to use a quality measure described
24 in subsection (e)(1)(A) only after taking into ac-

1 count the guidance of multi-stakeholder groups
2 under subsection (e)(2).

3 “(2) USE OF INTERIM MEASURES.—

4 “(A) IN GENERAL.—The Secretary may
5 make a determination, by regulation or other-
6 wise, to use a quality measure that has not
7 been endorsed as described in subsection
8 (e)(1)(A), provided that the Secretary—

9 “(i) in a timely manner, transmits the
10 measure to the qualified consensus-based
11 entity for consideration for endorsement
12 and for the multi-stakeholder consultation
13 process under subsection (e)(1);

14 “(ii) publishes in the Federal Register
15 the rationale for the use of the measure;
16 and

17 “(iii) phases out use of the measure
18 upon a decision of the qualified consensus-
19 based entity not to endorse the measure,
20 contingent on availability of an adequate
21 alternative endorsed measure (as deter-
22 mined by the Secretary), taking into ac-
23 count guidance from multi-stakeholder con-
24 sultation process under subsection (e)(1).

1 “(B) NO ADEQUATE ALTERNATIVE.—If an
2 adequate alternative endorsed measure is not
3 available, the Secretary shall support the devel-
4 opment of such an alternative endorsed meas-
5 ure, as described in section 931.

6 “(3) REQUIREMENT OF COORDINATION WITH
7 ENTITY.—

8 “(A) REQUIREMENT FOR NOTIFICATION OF
9 ENTITY OF DEADLINE FOR RECOMMENDATIONS
10 FOR QUALITY MEASURES IN PROPOSED REGU-
11 LATIONS.—For each notice of proposed rule-
12 making to implement the collection or reporting
13 of data on quality measures as described in sec-
14 tion 399LL, the Secretary shall establish a
15 process for the regular provision of advance no-
16 tice to the qualified consensus-based entity of
17 the date certain by which recommendations of
18 the entity with respect to quality measures
19 must be submitted to the Secretary for consid-
20 eration in the development of such specified
21 regulation.

22 “(B) TIMELY NOTICE.—Under the process
23 established under subparagraph (A), notice
24 shall be given to the qualified consensus-based

1 entity not less than 120 days before the date
2 certain referred to in subparagraph (A).

3 “(C) PUBLICATION OF DESCRIPTION OF
4 ENTITY RECOMMENDATIONS AND RESPONSES.—
5 In publishing a specified regulation, the Sec-
6 retary shall include a description of each rec-
7 ommendation of the qualified consensus-based
8 entity with respect to quality measures and
9 shall include responses of the Secretary to each
10 such recommendation.

11 “(D) DEFINITION.—In this paragraph, the
12 term ‘specified regulation’ means a notice of
13 proposed rulemaking to implement the collec-
14 tion or reporting of data on quality measures as
15 described in section 399LL.

16 “(4) EFFECTIVE DATE.—This subsection shall
17 apply with respect to determinations or requirements
18 by the Secretary for the use of quality measures
19 made on or after the date of enactment of the Af-
20 fordable Health Choices Act.

21 “(g) REVIEW OF QUALITY MEASURES USED BY THE
22 SECRETARY.—

23 “(1) IN GENERAL.—Not less than once every 3
24 years, the Secretary shall review quality measures

1 used by the Secretary and, with respect to each such
2 measure, shall determine whether to—

3 “(A) maintain the use of such measure; or

4 “(B) phase out such measure.

5 “(2) CONSIDERATIONS.—In conducting the re-
6 view under paragraph (1), the Secretary shall—

7 “(A) seek to avoid duplication of measures
8 used; and

9 “(B) take into consideration current inno-
10 vative methodologies and strategies for quality
11 improvement practices in the delivery of health
12 care services that represent best practices for
13 such quality improvement and measures en-
14 dorsed by a qualified consensus-based entity
15 since the previous review by the Secretary.

16 “(h) PROCESS FOR DISSEMINATION OF MEASURES
17 USED BY THE SECRETARY.—The Secretary shall establish
18 a process for disseminating quality measures used by the
19 Secretary. Such process shall include the incorporation of
20 such measures, where applicable, in workforce programs,
21 training curricula, payment programs, and any other
22 means of dissemination determined by the Secretary. The
23 Secretary shall establish a process to disseminate such
24 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;

1 “(iv) assess the safety, effectiveness,
2 and timeliness of care; and

3 “(v) assess health disparities (as de-
4 fined by section 485E) across populations
5 and geographic areas.

6 “(2) FORM AND MANNER.—The data submitted
7 under the system implemented under paragraph (1)
8 shall be in a form and manner specified by the Sec-
9 retary.

10 “(3) MEASURES DESCRIBED.—The quality
11 measures described in paragraph (1) shall—

12 “(A) be risk adjusted, taking into account
13 differences in patient health status, patient
14 characteristics, and geographic location, as ap-
15 propriate;

16 “(B) be valid, reliable, evidence-based, fea-
17 sible to collect, and actionable by providers,
18 payers and consumers, as appropriate;

19 “(C) minimize the burden of collection and
20 reporting such measures; and

21 “(D) be consistent with the national strat-
22 egy established by the Secretary under section
23 399HH.

24 “(b) DEVELOPMENT OF PERFORMANCE
25 WEBSITES.—The Secretary shall make available to the

1 public performance information summarizing data on
2 quality measures collected in subsection (a) through a se-
3 ries of standardized Internet websites tailored to respond
4 to the differing needs of hospitals and other institutional
5 providers and services, physicians and other clinicians, pa-
6 tients, consumers, researchers, policymakers, States, and
7 such other stakeholders as the Secretary may specify.

8 “(c) DESIGN.—Each standardized Internet website
9 made available under subsection (b) shall be designed to
10 make the use and navigation of that website readily avail-
11 able to individuals accessing it. The Secretary shall de-
12 velop a flexible format to meet the differing needs of the
13 various stakeholders and shall modify the website to per-
14 mit a user to easily customize queries.

15 “(d) INFORMATION ON CONDITIONS.—Performance
16 information made publicly available on a standardized
17 Internet website under subsection (b) shall be presented
18 by, but not limited to, clinical condition to the extent such
19 information is available, and the information presented
20 shall, where appropriate, be provider-specific and suffi-
21 ciently disaggregated and specific to meet the needs of pa-
22 tients with different clinical conditions.

23 “(e) CONSULTATION.—The Secretary shall carry out
24 this section in collaboration with a qualified consensus-
25 based entity under section 399JJ to determine the type

1 of information that is useful to stakeholders and the for-
2 mat that best facilitates use of the reports and of perform-
3 ance reporting Internet websites. The qualified consensus-
4 based entity shall convene multi-stakeholder groups as
5 provided in section 399JJ to review the design and format
6 of each Internet website made available under subsection
7 (b) and shall transmit to the Secretary the views of such
8 multi-stakeholder groups with respect to each such design
9 and format.

10 **“SEC. 399LL. EVALUATION OF DATA COLLECTION PROCESS**
11 **FOR QUALITY MEASUREMENT.**

12 “(a) GAO EVALUATIONS.—The Comptroller General
13 of the United States shall conduct periodic evaluations of
14 the implementation of the data collection processes for
15 quality measures used by the Secretary.

16 “(b) CONSIDERATIONS.—In carrying out the evalua-
17 tion under subsection (a), the Comptroller General shall
18 determine—

19 “(1) whether the system for the collection of
20 data for quality measures provides for validation of
21 data as relevant, fair, and scientifically credible;

22 “(2) whether data collection efforts under the
23 system use the most efficient and cost-effective
24 means in a manner that minimizes administrative
25 burden on persons required to collect data and that

1 adequately protects the privacy of patients’ personal
2 health information and provides data security;

3 “(3) whether standards under the system pro-
4 vide for an opportunity for physicians and other cli-
5 nicians and institutional providers of services to re-
6 view and correct findings; and

7 “(4) the extent to which quality measures—

8 “(A) assess health outcomes and functional
9 status of patients;

10 “(B) assess the continuity and coordina-
11 tion of care and care transitions, including epi-
12 sodes of care, for patients across the continuum
13 of providers, age, and health care settings;

14 “(C) assess patient experience and patient,
15 caregiver, and family engagement;

16 “(D) assess the safety, effectiveness, and
17 timeliness of care;

18 “(E) assess health disparities across health
19 disparity populations (as defined by section
20 485E) and geographic areas;

21 “(F) address the appropriate use of health
22 care resources and services;

23 “(G) are designed to be collected as part of
24 health information technologies supporting bet-
25 ter delivery of health care services;

1 “(H) result in direct or indirect costs to
2 users of such measures; and

3 “(I) provide utility to both the care of indi-
4 viduals and the management of population
5 health.

6 “(c) REPORT.—The Comptroller General shall sub-
7 mit reports to Congress and to the Secretary containing
8 a description of the findings and conclusions of the results
9 of each such evaluation.”.

10 **SEC. 205. COLLECTION AND ANALYSIS OF DATA FOR QUAL-**
11 **ITY AND RESOURCE USE MEASURES.**

12 (a) IN GENERAL.—Part S of title III of the Public
13 Health Service Act, as amended by section 204, is further
14 amended by adding at the end the following:

15 **“SEC. 399MM. COLLECTION AND ANALYSIS OF DATA FOR**
16 **QUALITY AND RESOURCE USE MEASURES.**

17 “(a) PURPOSE.—The purpose of this section is to
18 provide for the development of reports based on Federal
19 health care data and private data that is publicly available
20 or is provided by the entity making the request for the
21 report in order to—

22 “(1) improve the quality and efficiency of
23 health care and advance health care research;

24 “(2) enhance the education and awareness of
25 consumers for evaluating health care services; and

1 “(3) provide the public with reports on national,
2 regional, and provider- and supplier-specific per-
3 formance, which may be in a provider- or supplier-
4 identifiable format.

5 “(b) ESTABLISHMENT OF PROCESS.—The Secretary
6 shall establish a process to collect, and validate, aggregate
7 data on quality measures described in section 399JJ to
8 facilitate public reporting described in section 399KK.
9 Such process shall—

10 “(1) be developed based on guidance of a
11 broad-based, public-private collaboration;

12 “(2) employ methods that are scientifically
13 sound and feasible to implement nationwide through
14 the use of consistent methods for the collection,
15 analysis, and reporting of quality and resource use
16 measures;

17 “(3) over time, where feasible, build on expand-
18 ing availability of health information technology and
19 other data systems that are directly used to improve
20 and coordinate patient care;

21 “(4) allow for the integration of data on quality
22 of care and resource use from a range of data
23 sources used by providers and patients to coordinate
24 and improve care, including public sources, private
25 sources, and public-private collaborations;

1 “(5) be implemented in accordance with an ag-
2 gressive timeline to be established by the Secretary
3 based on the technical and practical feasibility of
4 measures and related data systems; and

5 “(6) utilize clinical and claims data to evaluate
6 the quality and efficiency of health care.

7 “(c) DATA COLLECTION, AGGREGATION, AND ANAL-
8 YSIS.—The Secretary shall ensure the collection and ag-
9 gregation of consistent data on quality and resource use
10 measures from information systems used to support health
11 care delivery to implement the public reporting of perform-
12 ance information as described in section 399KK. The Sec-
13 retary shall ensure that such collection, aggregation, and
14 analysis systems span an increasingly broad range of pa-
15 tient populations, providers, and geographic areas over
16 time.

17 “(d) GRANTS AND CONTRACTS FOR DATA COLLEC-
18 TION.—

19 “(1) IN GENERAL.—The Secretary shall award
20 grants or contracts to eligible entities to support the
21 collection and aggregation of quality and resource
22 use measures described under subsection (c).

23 “(2) ELIGIBLE ENTITIES.—To be eligible for a
24 grant or contract under this subsection, an entity
25 shall—

1 “(A)(i) be a multi-stakeholder entity that
2 coordinates the development of methods and
3 implementation plans for the consistent report-
4 ing of summary quality and cost information;

5 “(ii) be an entity capable of submitting
6 such summary data for a particular population
7 and providers, such as a disease registry, re-
8 gional collaboration, health plan collaboration,
9 or other population-wide source; or

10 “(iii) be a Federal Indian Health Service
11 program or a health program operated by an
12 Indian Tribe (as defined in section 4 of the In-
13 dian Health Care Improvement Act);

14 “(B) promote the use of the systems that
15 provide data to improve and coordinate patient
16 care;

17 “(C) support the provision of timely, con-
18 sistent quality and resource use information to
19 health care providers, and other groups and or-
20 ganizations as appropriate, with an opportunity
21 for providers to correct inaccurate measures;
22 and

23 “(D) support the provision of consistent
24 measures on quality and resource use to the

1 public in accordance with the process estab-
2 lished by the Secretary under subsection (b).

3 “(3) CONSISTENT DATA AGGREGATION.—The
4 Secretary shall award funding under this subsection
5 only to entities enabling summary data that can be
6 integrated and compared across multiple sources.
7 The Secretary shall also provide standards for the
8 protection of the security and privacy of patient
9 data.

10 “(e) PILOT PROGRAMS TO DEVELOP, VALIDATE, AND
11 IMPROVE METHODS USED TO SUPPORT THE NATION-
12 WIDE QUALITY MEASUREMENT AND REPORTING STRAT-
13 EGY.—

14 “(1) IN GENERAL.—

15 “(A) DEVELOPMENT, VALIDATION, AND
16 IMPROVEMENT METHODS.—The Secretary shall
17 support the development, validation, implemen-
18 tation, and refinement of nationally consistent
19 methods used to support quality measurement
20 and reporting under section 399KK.

21 “(B) GRANTS AND CONTRACTS.—The Sec-
22 retary may award grants or contracts to eligible
23 quality data entities to carry out subparagraph
24 (A).

“(2) ELIGIBLE QUALITY DATA ENTITIES.—To
be eligible for a grant or contract under this sub-
section, a quality data entity shall—

“(A) be a public or private organization
with expertise and experience in large-scale
health care data aggregation, integration, anal-
ysis, or reporting; and

8 “(B) support the implementation of quality
9 measurement and reporting under section
10 399KK, including the production of data that
11 can be combined and compared with equivalent
12 information from other entities involved in sup-
13 porting the delivery of care.

14 “(f) GRANTS AND CONTRACTS FOR DATA ANAL-
15 YSIS.—

16 “(1) FEDERAL HEALTH CARE DATA.—In this
17 subsection:

18 “(A) IN GENERAL.—Subject to subpara-
19 graph (B), the term ‘Federal health care data’
20 means—

21 “(i) deidentified enrollment data and
22 deidentified claims data maintained by the
23 Secretary or entities under programs, con-
24 tracts, grants, or memoranda of under-

1 standing administered by the Secretary;
2 and

3 “(ii) where feasible, other deidentified
4 enrollment data and deidentified claims
5 data maintained by the Federal Govern-
6 ment or entities under contract with the
7 Federal Government.

8 “(B) EXCEPTION.—The term ‘Federal
9 health care data’ includes data relating to pro-
10 grams administered by the Secretary under the
11 Social Security Act only to the extent that the
12 disclosure of such data is authorized or required
13 under such Act.

14 “(2) AWARDS.—The Secretary shall award con-
15 tracts to eligible entities to support the analysis of
16 quality and resource use measures described under
17 subsection (c).

18 “(3) ELIGIBLE ENTITIES.—

19 “(A) QUALIFICATIONS.—The Secretary
20 shall enter into a contract with an entity under
21 paragraph (2) only if the Secretary determines
22 that the entity—

23 “(i) has the research capability to
24 conduct and complete reports under this
25 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 PRO-
TECTIONS.—The entity shall be re-
quired to refrain from disclosing data
that could be withheld by the Sec-
retary under section 552 of title 5,
United States Code, or whose disclo-
sure 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.

21 “(iii) DISCLOSURE.—The entity shall
22 disclose—

23 “(I) any financial, reporting, or
24 contractual relationship between the

1 entity and any health care provider or
2 supplier or health care plan; and

3 “(II) if applicable, the fact that
4 the entity is managed, controlled, or
5 operated by any health care provider
6 or supplier or health care plan.

7 “(iv) COMPONENT OF ANOTHER OR-
8 GANIZATION.—If the entity is a component
9 of another organization—

10 “(I) the entity shall maintain
11 Federal health care data and reports
12 separately from the rest of the organi-
13 zation and establish appropriate secu-
14 rity measures to maintain the con-
15 fidentiality and privacy of the Federal
16 health care data and reports; and

17 “(II) the entity shall not make
18 an unauthorized disclosure to the rest
19 of the organization of Federal health
20 care data or reports in breach of such
21 confidentiality and privacy require-
22 ment.

23 “(v) TERMINATION OR NON-
24 RENEWAL.—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

1 include acceptable risk adjustment and
2 case-mix adjustment developed in consulta-
3 tion with providers.

4 “(C) COMPETITIVE PROCEDURES.—Com-
5 petitive procedures (as defined in section 4(5)
6 of the Federal Procurement Policy Act) shall be
7 used to enter into contracts under paragraph
8 (2).

9 “(D) REVIEW OF CONTRACT IN EVENT OF
10 A MERGER OR ACQUISITION.—The Secretary
11 shall review the contract with an entity receiv-
12 ing a contract under this subsection in the
13 event of a merger or acquisition of the entity in
14 order to ensure that the requirements under
15 this subsection will continue to be met.

16 “(4) PROCEDURES FOR THE DEVELOPMENT OF
17 REPORTS.—Notwithstanding section 552(b)(6) or
18 552a(b) of title 5, United States Code, subject to
19 paragraph (1)(B), not later than 12 months after
20 the date of enactment of this section, the Secretary,
21 in accordance with the purpose described in sub-
22 section (a), shall establish and implement procedures
23 under which an entity may submit a request to an
24 entity with a contract under this subsection to de-
25 velop a report based on—

1 “(A) Federal health care data disclosed to
2 the entity under paragraph (5); and

3 “(B) private data that is publicly available
4 or is provided to the entity by the entity mak-
5 ing the request for the report.

6 “(5) ACCESS TO FEDERAL HEALTH CARE
7 DATA.—

8 “(A) IN GENERAL.—The procedures estab-
9 lished under paragraph (4) shall provide for the
10 secure disclosure of Federal health care data to
11 each entity with a contract under paragraph
12 (2).

13 “(B) UPDATE INFORMATION.—Not less
14 than every 6 months, the Secretary shall update
15 the information disclosed under subparagraph
16 (A) to each such entity.

17 “(g) PUBLIC REPORTING OF QUALITY RESOURCE
18 USE MEASURES AT THE PROVIDER, GROUP, SYSTEM, RE-
19 GIONAL, AND OTHER LEVELS.—The Secretary shall make
20 aggregated data, and reports developed under subsection
21 (f), on quality and resource use measures collected under
22 this section available to health care providers and the pub-
23 lic through the process described in 399KK.

24 “(h) RESEARCH ACCESS TO HEALTH CARE DATA
25 AND REPORTING ON PERFORMANCE.—The Secretary

1 shall permit researchers that meet criteria used to evalu-
2 ate the appropriateness of the release data for research
3 purposes (as established by the Secretary) to—

4 “(1) have access to Federal health care data (as
5 defined in subsection (f)); and

6 “(2) report on the performance of health care
7 providers and suppliers, including reporting in a
8 provider- or supplier-identifiable format.

9 “(i) AUTHORIZATION OF APPROPRIATIONS.—There
10 are authorized to be appropriated to carry out this section
11 \$90,000,000 for each of fiscal years 2010 through 2014.”.

12 (b) HIT POLICY COMMITTEE.—Section
13 3002(b)(2)(B) of the Public Health Service Act (42
14 U.S.C. 300jj–12(b)(2)(B)) is amended by adding at the
15 end the following:

16 “(ix) The use of certified electronic
17 health records to collect and report quality
18 measures accepted by the Secretary.”.

1 **Subtitle B—Health Care Quality**
2 **Improvements**

3 **SEC. 211. HEALTH CARE DELIVERY SYSTEM RESEARCH;**
4 **QUALITY IMPROVEMENT TECHNICAL ASSIST-**
5 **ANCE.**

6 Part D of title IX of the Public Health Service Act,
7 as amended by section 203, is further amended by adding
8 at the end the following:

9 **“Subpart II—Health Care Quality Improvement**
10 **Programs**

11 **“SEC. 933. HEALTH CARE DELIVERY SYSTEM RESEARCH.**

12 “(a) PURPOSE.—The purposes of this section are
13 to—

14 “(1) enable the Director to identify, develop,
15 evaluate, disseminate, and provide training in inno-
16 vative methodologies and strategies for quality im-
17 provement practices in the delivery of health care
18 services that represent best practices (referred to as
19 ‘best practices’) in health care quality, safety, and
20 value; and

21 “(2) ensure that the Director is accountable for
22 implementing a model to pursue such research in a
23 collaborative manner with other related Federal
24 agencies.

1 “(b) ESTABLISHMENT OF CENTER.—There is estab-
2 lished within the Agency the Patient Safety Research Cen-
3 ter (referred to in this section as the ‘Center’).

4 “(c) GENERAL FUNCTIONS OF CENTER.—The Center
5 shall—

6 “(1) carry out its functions using research from
7 a variety of disciplines, which may include epidemi-
8 ology, health services, sociology, psychology, human
9 factors engineering, biostatistics, health economics,
10 clinical research, and health informatics;

11 “(2) conduct or support activities for activities
12 identified in subsection (a), and for—

13 “(A) best practices for quality improve-
14 ment practices in the delivery of health care
15 services; and

16 “(B) that include changes in processes of
17 care and the redesign of systems used by pro-
18 viders that will reliably result in intended health
19 outcomes, improve patient safety, and reduce
20 medical errors (such as skill development for
21 health care providers in team-based health care
22 delivery and rapid cycle process improvement)
23 and facilitate adoption of improved workflow;

1 “(3) identify health care providers, including
2 health care systems, single institutions, and indi-
3 vidual providers, that—

4 “(A) deliver consistently high-quality, effi-
5 cient health care services (as determined by the
6 Secretary); and

7 “(B) employ best practices that are adapt-
8 able and scalable to diverse health care settings
9 or effective in improving care across diverse set-
10 tings;

11 “(4) assess research, evidence, and knowledge
12 about what strategies and methodologies are most
13 effective in improving health care delivery;

14 “(5) find ways to translate such information
15 rapidly and effectively into practice, and document
16 the sustainability of those improvements;

17 “(6) create strategies for quality improvement
18 through the development of tools, methodologies,
19 and interventions that can successfully reduce vari-
20 ations in the delivery of health care;

21 “(7) identify, measure, and improve organiza-
22 tional, human, or other causative factors, including
23 those related to the culture and system design of a
24 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,

1 broad development and training, patients, caregivers
2 and families, and frontline health care workers, in-
3 cluding activities for the examination of strategies to
4 share best quality improvement practices and to pro-
5 mote excellence in the delivery of health care serv-
6 ices; and

7 “(10) build capacity at the State and commu-
8 nity level to lead quality and safety efforts through
9 education, training, and mentoring programs to
10 carry out the activities under paragraphs (1)
11 through (9).

12 “(d) RESEARCH FUNCTIONS OF CENTER.—

13 “(1) IN GENERAL.—The Center shall support,
14 such as through a contract or other mechanism, re-
15 search on health care delivery system improvement
16 and the development of tools to facilitate adoption of
17 best practices that improve the quality, safety, and
18 efficiency of health care delivery services. Such sup-
19 port may include establishing a Quality Improve-
20 ment Network Research Program for the purpose of
21 testing, scaling, and disseminating of interventions
22 to improve quality and efficiency in health care. Re-
23 cipients of funding under the Program may include
24 national, State, multi-State, or multi-site quality im-
25 provement networks.

1 “(2) RESEARCH REQUIREMENTS.—The re-
2 search conducted pursuant to paragraph (1) shall—

3 “(A) address the priorities identified by
4 the Secretary in the national strategic plan es-
5 tablished under section 399HH;

6 “(B) identify areas in which evidence is in-
7 sufficient to identify strategies and methodolo-
8 gies, taking into consideration areas of insuffi-
9 cient evidence identified by a qualified con-
10 sensus-based entity in the report required under
11 section 399JJ;

12 “(C) address concerns identified by health
13 care institutions and providers and commu-
14 nicated through the Center pursuant to sub-
15 section (e);

16 “(D) reduce preventable morbidity, mor-
17 tality, and associated costs of morbidity and
18 mortality by building capacity for patient safety
19 research;

20 “(E) support the discovery of processes for
21 the reliable, safe, efficient, and responsive deliv-
22 ery of health care, taking into account discov-
23 eries from clinical research and comparative ef-
24 fectiveness research;

1 “(F) be designed to help improve health
2 care quality and is tested in practice-based set-
3 tings;

4 “(G) allow communication of research find-
5 ings and translate evidence into practice rec-
6 ommendations that are adaptable to a variety
7 of settings, and which, as soon as practicable
8 after the establishment of the Center, shall in-
9 clude—

10 “(i) the implementation of a national
11 application of Intensive Care Unit improve-
12 ment projects relating to the adult (includ-
13 ing geriatric), pediatric, and neonatal pa-
14 tient populations;

15 “(ii) practical methods for addressing
16 health care associated infections, including
17 Methicillin–Resistant Staphylococcus
18 Aureus and Vancomycin–Resistant
19 Enterococcus infections and other emerging
20 infections; and

21 “(iii) practical methods for reducing
22 preventable hospital admissions and re-
23 admissions;

24 “(H) expand demonstration projects for
25 improving the quality of children’s health care

1 and the use of health information technology,
2 such as through Pediatric Quality Improvement
3 Collaboratives and Learning Networks, con-
4 sistent with provisions of section 1139A of the
5 Social Security Act for assessing and improving
6 quality, where applicable;

7 “(I) identify and mitigate hazards by—

8 “(i) analyzing events reported to pa-
9 tient safety reporting systems and patient
10 safety organizations; and

11 “(ii) using the results of such analyses
12 to develop scientific methods of response to
13 such events;

14 “(J) include the conduct of systematic re-
15 views of existing practices that improve the
16 quality, safety, and efficiency of health care de-
17 livery, as well as new research on improving
18 such practices; and

19 “(K) include the examination of how to
20 measure and evaluate the progress of quality
21 and patient safety activities.

22 “(e) DISSEMINATION OF RESEARCH FINDINGS.—

23 “(1) PUBLIC AVAILABILITY.—The Director
24 shall make the research findings of the Center avail-
25 able to the public through multiple media and appro-

1 piate formats to reflect the varying needs of health
2 care providers and consumers and diverse levels of
3 health literacy.

4 “(2) LINKAGE TO HEALTH INFORMATION TECH-
5 NOLOGY.—The Secretary shall ensure that research
6 findings and results generated by the Center are
7 shared with the Office of the National Coordinator
8 of Health Information Technology and used to in-
9 form the activities of the health information tech-
10 nology extension program under section 3012, as
11 well as any relevant standards, certification criteria,
12 or implementation specifications.

13 “(f) PRIORITIZATION.—The Director shall identify
14 and regularly update a list of processes or systems on
15 which to focus research and dissemination activities of the
16 Center, taking into account—

17 “(1) cost to Federal health programs;

18 “(2) consumer assessment of health care experi-
19 ence;

20 “(3) provider assessment of such processes or
21 systems and opportunities to minimize distress and
22 injury to the health care workforce;

23 “(4) potential impact of such processes or sys-
24 tems on health status and function of patients, in-
25 cluding vulnerable populations including children;

1 “(5) areas of insufficient evidence identified
2 under subsection (d)(2)(B); and

3 “(6) the evolution of meaningful use of health
4 information technology, as defined in section 3000.

5 “(g) FUNDING.—There is authorized to be appro-
6 priated to carry out this section \$20,000,000 for fiscal
7 years 2010 through 2014.

8 **“SEC. 934. QUALITY IMPROVEMENT TECHNICAL ASSIST-**
9 **ANCE AND IMPLEMENTATION.**

10 “(a) IN GENERAL.—The Director, through the Pa-
11 tient Safety Research Center established in section 933
12 (referred to in this section as the ‘Center’), shall award—

13 “(1) technical assistance grants or contracts to
14 eligible entities to provide technical support to insti-
15 tutions that deliver health care and health care pro-
16 viders so that such institutions and providers under-
17 stand, adapt, and implement the models and prac-
18 tices identified in the research conducted by the
19 Center, including the Quality Improvement Net-
20 works Research Program; and

21 “(2) implementation grants or contracts to eli-
22 gible entities to implement the models and practices
23 described under paragraph (1).

24 “(b) ELIGIBLE ENTITIES.—

1 “(1) TECHNICAL ASSISTANCE AWARD.—To be
2 eligible to receive a technical assistance grant or
3 contract under subsection (a)(1), an entity—

4 “(A) may be a health care provider, health
5 care provider association, professional society,
6 health care worker organization, Indian health
7 organization, quality improvement organization,
8 patient safety organization, local quality im-
9 provement collaborative, the Joint Commission,
10 academic health center, university, physician-
11 based research network, primary care extension
12 program established under section 399V, a Fed-
13 eral Indian Health Service program or a health
14 program operated by an Indian Tribe (as de-
15 fined in section 4 of the Indian Health Care
16 Improvement Act), or any other entity identi-
17 fied by the Secretary; and

18 “(B) shall have demonstrated expertise in
19 providing information and technical support
20 and assistance to health care providers regard-
21 ing quality improvement.

22 “(2) IMPLEMENTATION AWARD.—To be eligible
23 to receive an implementation grant or contract
24 under subsection (a)(2), an entity—

1 “(A) may be a hospital or other health
2 care provider or consortium or providers, as de-
3 termined by the Secretary; and

4 “(B) shall have demonstrated expertise in
5 providing information and technical support
6 and assistance to health care providers regard-
7 ing quality improvement.

8 “(c) APPLICATION.—

9 “(1) TECHNICAL ASSISTANCE AWARD.—To re-
10 ceive a technical assistance grant or contract under
11 subsection (a)(1), an eligible entity shall submit an
12 application to the Secretary at such time, in such
13 manner, and containing—

14 “(A) a plan for a sustainable business
15 model that may include a system of—

16 “(i) charging fees to institutions and
17 providers that receive technical support
18 from the entity; and

19 “(ii) reducing or eliminating such fees
20 for such institutions and providers that
21 serve low-income populations; and

22 “(B) such other information as the Direc-
23 tor may require.

24 “(2) IMPLEMENTATION AWARD.—To receive a
25 grant or contract under subsection (a)(2), an eligible

1 entity shall submit an application to the Secretary at
2 such time, in such manner, and containing—

3 “(A) a plan for implementation of a model
4 or practice identified in the research conducted
5 by the Center including—

6 “(i) financial cost, staffing require-
7 ments, and timeline for implementation;
8 and

9 “(ii) pre- and projected post-imple-
10 mentation quality measure performance
11 data in targeted improvement areas identi-
12 fied by the Secretary; and

13 “(B) such other information as the Direc-
14 tor may require.

15 “(d) MATCHING FUNDS.—The Director may not
16 award a grant or contract under this section to an entity
17 unless the entity agrees that it will make available (di-
18 rectly or through contributions from other public or pri-
19 vate entities) non-Federal contributions toward the activi-
20 ties to be carried out under the grant or contract in an
21 amount equal to \$1 for each \$5 of Federal funds provided
22 under the grant or contract. Such non-Federal matching
23 funds may be provided directly or through donations from
24 public or private entities and may be in cash or in-kind,
25 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

1 under section 3012(c) and the primary care extension pro-
2 gram established under section 399V regarding the dis-
3 semination of quality improvement, system delivery re-
4 form, and best practices information.”.

5 **SEC. 212. GRANTS TO ESTABLISH COMMUNITY HEALTH**
6 **TEAMS TO SUPPORT THE PATIENT-CEN-**
7 **TERED MEDICAL HOME.**

8 (a) IN GENERAL.—The Secretary of Health and
9 Human Services (referred to in this section as the “Sec-
10 retary”) shall establish a program to provide grants to eli-
11 gible entities to establish community-based interdiscipli-
12 nary, interprofessional teams (referred to in this section
13 as “health teams”) to support primary care practices, in-
14 cluding obstetrics and gynecology practices, within the
15 hospital service areas served by the eligible entities.
16 Grants shall be used to—

17 (1) establish health teams to provide support
18 services to primary care providers; and

19 (2) provide capitated payments to primary care
20 providers as determined by the Secretary.

21 (b) ELIGIBLE ENTITIES.—To be eligible to receive a
22 grant under subsection (a), an entity shall—

23 (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.

1 (c) REQUIREMENTS FOR HEALTH TEAMS.—A health
2 team established pursuant to a grant under subsection (a)
3 shall—

4 (1) establish contractual agreements with pri-
5 mary care providers to provide support services;

6 (2) support patient-centered medical homes, de-
7 fined as mode of care that includes—

8 (A) personal physicians;

9 (B) whole person orientation;

10 (C) coordinated and integrated care;

11 (D) safe and high quality care though evi-
12 dence-informed medicine, appropriate use of
13 health information technology, and continuous
14 quality improvements;

15 (E) expanded access to care; and

16 (F) payment that recognizes added value
17 from additional components of patient-centered
18 care;

19 (3) collaborate with local primary care providers
20 and existing State and community based resources
21 to coordinate disease prevention, chronic disease
22 management, transitioning between health care pro-
23 viders and settings and case management for pa-
24 tients, 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;

1 (E) provide access to pharmacist-delivered
2 medication management services, including
3 medication reconciliation;

4 (F) provide coordination of the appropriate
5 use of complementary and alternative (CAM)
6 services to those who request such services;

7 (G) promote effective strategies for treat-
8 ment planning, monitoring health outcomes and
9 resource use, sharing information, treatment
10 decision support, and organizing care to avoid
11 duplication of service and other medical man-
12 agement approaches intended to improve qual-
13 ity and value of health care services;

14 (H) provide local access to the continuum
15 of health care services in the most appropriate
16 setting, including access to individuals that im-
17 plement the care plans of patients and coordi-
18 nate care, such as integrative health care prac-
19 titioners;

20 (I) collect and report data that permits
21 evaluation of the success of the collaborative ef-
22 fort on patient outcomes, including collection of
23 data on patient experience of care, and identi-
24 fication of areas for improvement; and

1 (J) establish a coordinated system of early
2 identification and referral for children at risk
3 for developmental or behavioral problems such
4 as through the use of infolines, health informa-
5 tion technology, or other means as determined
6 by the Secretary;

7 (7) provide 24-hour care management and sup-
8 port during transitions in care settings including—

9 (A) a transitional care program that pro-
10 vides onsite visits from the care coordinator, as-
11 sists with the development of discharge plans
12 and medication reconciliation upon admission to
13 and discharge from the hospitals, nursing home,
14 or other institution setting;

15 (B) discharge planning and counseling
16 support to providers, patients, caregivers, and
17 authorized representatives;

18 (C) assuring that post-discharge care plans
19 include medication management, as appro-
20 priate;

21 (D) referrals for mental and behavioral
22 health services, which may include the use of
23 infolines; and

24 (E) transitional health care needs from
25 adolescence to adulthood;

1 (8) serve as a liaison to community prevention
2 and treatment programs;

3 (9) demonstrate a capacity to implement and
4 maintain health information technology that meets
5 the requirements of certified EHR technology (as
6 defined in section 3000 of the Public Health Service
7 Act (42 U.S.C. 300jj)) to facilitate coordination
8 among members of the applicable care team and af-
9 filiated primary care practices; and

10 (10) where applicable, report to the Secretary
11 information on quality measures used under section
12 399JJ of the Public Health Service Act.

13 (d) REQUIREMENT FOR PRIMARY CARE PRO-
14 VIDERS.—A provider who contracts with a care team
15 shall—

16 (1) provide a care plan to the care team for
17 each patient participant;

18 (2) provide access to participant health records;
19 and

20 (3) meet regularly with the care team to ensure
21 integration of care.

22 (e) REPORTING TO SECRETARY.—An entity that re-
23 ceives a grant under subsection (a) shall submit to the
24 Secretary a report that describes and evaluates, as re-

1 requested 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

1 law including applicable collaborative pharmacy practice
2 agreements, include—

3 “(1) performing or obtaining necessary assess-
4 ments of the health and functional status of each
5 patient receiving such MTM services;

6 “(2) formulating a medication treatment plan
7 according to therapeutic goals agreed upon by the
8 prescriber and the patient or caregiver or authorized
9 representative of the patient;

10 “(3) selecting, initiating, modifying, recom-
11 mending changes to, or administering medication
12 therapy;

13 “(4) monitoring, which may include access to,
14 ordering, or performing laboratory assessments, and
15 evaluating the response of the patient to therapy, in-
16 cluding safety and effectiveness;

17 “(5) performing an initial comprehensive medi-
18 cation review to identify, resolve, and prevent medi-
19 cation-related problems, including adverse drug
20 events, quarterly targeted medication reviews for on-
21 going monitoring, and additional followup interven-
22 tions on a schedule developed collaboratively with
23 the prescriber;

24 “(6) documenting the care delivered and com-
25 municating essential information about such care,

1 including a summary of the medication review, and
2 the recommendations of the pharmacist to other ap-
3 propriate health care providers of the patient in a
4 timely fashion;

5 “(7) providing education and training designed
6 to enhance the understanding and appropriate use of
7 the medications by the patient, caregiver, and other
8 authorized representative;

9 “(8) providing information, support services,
10 and resources and strategies designed to enhance
11 patient adherence with therapeutic regimens;

12 “(9) coordinating and integrating MTM serv-
13 ices within the broader health care management
14 services provided to the patient; and

15 “(10) such other patient care services allowed
16 under pharmacist scopes of practice in use in other
17 Federal programs that have implemented MTM
18 services.

19 “(d) TARGETED INDIVIDUALS.—MTM services pro-
20 vided by licensed pharmacists under a grant awarded
21 under subsection (a) shall be offered to targeted individ-
22 uals who—

23 “(1) take 4 or more prescribed medications (in-
24 cluding over-the-counter medications and dietary
25 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

1 subsection (c), including quality measures endorsed under
2 399JJ, as determined by the Secretary.

3 “(g) EVALUATION AND REPORT.—The Secretary
4 shall submit to the relevant committees of Congress a re-
5 port which shall—

6 “(1) assess the clinical effectiveness of phar-
7 macist-provided services under the MTM services
8 program, as compared to usual care, including an
9 evaluation of whether enrollees maintained better
10 health with fewer hospitalizations and emergency
11 room visits than similar patients not enrolled in the
12 program;

13 “(2) assess changes in overall health care re-
14 source use by targeted individuals;

15 “(3) assess patient and prescriber satisfaction
16 with MTM services;

17 “(4) assess the impact of patient-cost sharing
18 requirements on medication adherence and rec-
19 ommendations for modifications;

20 “(5) identify and evaluate other factors that
21 may impact clinical and economic outcomes, includ-
22 ing demographic characteristics, clinical characteris-
23 tics, and health services use of the patient, as well
24 as characteristics of the regimen, pharmacy benefit,
25 and MTM services provided; and

1 “(6) evaluate the extent to which participating
2 pharmacists who maintain a dispensing role have a
3 conflict of interest in the provision of MTM services,
4 and if such conflict is found, provide recommenda-
5 tions on how such a conflict might be appropriately
6 addressed.

7 “(h) GRANT TO FUND DEVELOPMENT OF PERFORM-
8 ANCE MEASURES.—Secretary may, through the quality
9 measure development program under section 931 of the
10 Public Health Service Act, award grants or contracts to
11 eligible entities for the purpose of funding the development
12 of performance measures that assess the use and effective-
13 ness of medication therapy management services.”.

14 **SEC. 214. DESIGN AND IMPLEMENTATION OF REGIONAL-**
15 **IZED SYSTEMS FOR EMERGENCY CARE.**

16 (a) IN GENERAL.—Title XII of the Public Health
17 Service Act (42 U.S.C. 300d et seq.) is amended—

18 (1) in section 1203—

19 (A) in the section heading, by inserting
20 “**FOR TRAUMA SYSTEMS**” after “**GRANTS**”;
21 and

22 (B) in subsection (a), by striking “Admin-
23 istrator of the Health Resources and Services
24 Administration” and inserting “Assistant Sec-
25 retary for Preparedness and Response”;

1 (2) by inserting after section 1203 the fol-
2 lowing:

3 **“SEC. 1204. COMPETITIVE GRANTS FOR REGIONALIZED SYS-**
4 **TEMS FOR EMERGENCY CARE RESPONSE.**

5 “(a) IN GENERAL.—The Secretary, acting through
6 the Assistant Secretary for Preparedness and Response,
7 shall award not fewer than 4 multiyear contracts or com-
8 petitive grants to eligible entities to support pilot projects
9 that design, implement, and evaluate innovative models of
10 regionalized, comprehensive, and accountable emergency
11 care and trauma systems.

12 “(b) ELIGIBLE ENTITY; REGION.—In this section:

13 “(1) ELIGIBLE ENTITY.—The term ‘eligible en-
14 tity’ means—

15 “(A) a State or a partnership of 1 or more
16 States and 1 or more local governments; or

17 “(B) an Indian Tribe (as defined in section
18 4 of the Indian Health Care Improvement Act)
19 or a partnership of 1 or more Indian Tribes.

20 “(2) REGION.—The term ‘region’ means an
21 area within a State, an area that lies within multiple
22 States, or a similar area (such as a multicounty
23 area), as determined by the Secretary.

1 “(3) EMERGENCY SERVICES.—The term ‘emer-
2 gency services’ includes acute, prehospital, and trau-
3 ma care.

4 “(c) PILOT PROJECTS.—The Secretary shall award
5 a contract or grant under subsection (a) to an eligible enti-
6 ty that proposes a pilot project to design, implement, and
7 evaluate an emergency medical and trauma system that—

8 “(1) coordinates with public health and safety
9 services, emergency medical services, medical facili-
10 ties, trauma centers, and other entities in a region
11 to develop an approach to emergency medical and
12 trauma system access throughout the region, includ-
13 ing 9–1–1 Public Safety Answering Points and
14 emergency medical dispatch;

15 “(2) includes a mechanism, such as a regional
16 medical direction or transport communications sys-
17 tem, that operates throughout the region to ensure
18 that the patient is taken to the medically appro-
19 priate facility (whether an initial facility or a higher-
20 level facility) in a timely fashion;

21 “(3) allows for the tracking of prehospital and
22 hospital resources, including inpatient bed capacity,
23 emergency department capacity, trauma center ca-
24 pacity, on-call specialist coverage, ambulance diver-
25 sion status, and the coordination of such tracking

1 with regional communications and hospital destina-
2 tion decisions; and

3 “(4) includes a consistent region-wide
4 prehospital, hospital, and interfacility data manage-
5 ment system that—

6 “(A) submits data to the National EMS
7 Information System, the National Trauma Data
8 Bank, and others;

9 “(B) reports data to appropriate Federal
10 and State databanks and registries; and

11 “(C) contains information sufficient to
12 evaluate key elements of prehospital care, hos-
13 pital destination decisions, including initial hos-
14 pital and interfacility decisions, and relevant
15 health outcomes of hospital care.

16 “(d) APPLICATION.—

17 “(1) IN GENERAL.—An eligible entity that
18 seeks a contract or grant described in subsection (a)
19 shall submit to the Secretary an application at such
20 time and in such manner as the Secretary may re-
21 quire.

22 “(2) APPLICATION INFORMATION.—Each appli-
23 cation shall include—

24 “(A) an assurance from the eligible entity
25 that the proposed system—

1 “(i) has been coordinated with the ap-
2 plicable State Office of Emergency Medical
3 Services (or equivalent State office);

4 “(ii) includes consistent indirect and
5 direct medical oversight of prehospital,
6 hospital, and interfacility transport
7 throughout the region;

8 “(iii) coordinates prehospital treat-
9 ment and triage, hospital destination, and
10 interfacility transport throughout the re-
11 gion;

12 “(iv) includes a categorization or des-
13 ignation system for special medical facili-
14 ties throughout the region that is inte-
15 grated with transport and destination pro-
16 tocols;

17 “(v) includes a regional medical direc-
18 tion, patient tracking, and resource alloca-
19 tion system that supports day-to-day emer-
20 gency care and surge capacity and is inte-
21 grated with other components of the na-
22 tional and State emergency preparedness
23 system; and

24 “(vi) addresses pediatric concerns re-
25 lated to integration, planning, prepared-

1 ness, and coordination of emergency med-
2 ical services for infants, children and ado-
3 lescents; and

4 “(B) such other information as the Sec-
5 retary may require.

6 “(e) REQUIREMENT OF MATCHING FUNDS.—

7 “(1) IN GENERAL.—The Secretary may not
8 make a grant under this section unless the State (or
9 consortia of States) involved agrees, with respect to
10 the costs to be incurred by the State (or consortia)
11 in carrying out the purpose for which such grant
12 was made, to make available non-Federal contribu-
13 tions (in cash or in kind under paragraph (2)) to-
14 ward such costs in an amount equal to not less than
15 \$1 for each \$3 of Federal funds provided in the
16 grant. Such contributions may be made directly or
17 through donations from public or private entities.

18 “(2) NON-FEDERAL CONTRIBUTIONS.—Non-
19 Federal contributions required in paragraph (1) may
20 be in cash or in kind, fairly evaluated, including
21 equipment or services (and excluding indirect or
22 overhead costs). Amounts provided by the Federal
23 Government, or services assisted or subsidized to
24 any significant extent by the Federal Government,

1 may not be included in determining the amount of
2 such non-Federal contributions.

3 “(f) PRIORITY.—The Secretary shall give priority for
4 the award of the contracts or grants described in sub-
5 section (a) to any eligible entity that serves a population
6 in a medically underserved area (as defined in section
7 330(b)(3)).

8 “(g) REPORT.—Not later than 90 days after the com-
9 pletion of a pilot project under subsection (a), the recipi-
10 ent of such contract or grant described in shall submit
11 to the Secretary a report containing the results of an eval-
12 uation of the program, including an identification of—

13 “(1) the impact of the regional, accountable
14 emergency care and trauma system on patient health
15 outcomes for various critical care categories, such as
16 trauma, stroke, cardiac emergencies, neurological
17 emergencies, and pediatric emergencies;

18 “(2) the system characteristics that contribute
19 to the effectiveness and efficiency of the program (or
20 lack thereof);

21 “(3) methods of assuring the long-term finan-
22 cial sustainability of the emergency care and trauma
23 system;

24 “(4) the State and local legislation necessary to
25 implement and to maintain the system;

1 “(5) the barriers to developing regionalized, ac-
2 countable emergency care and trauma systems, as
3 well as the methods to overcome such barriers; and

4 “(6) recommendations on the utilization of
5 available funding for future regionalization efforts.

6 “(h) DISSEMINATION OF FINDINGS.—The Secretary
7 shall, as appropriate, disseminate to the public and to the
8 appropriate Committees of the Congress, the information
9 contained in a report made under subsection (g).”; and

10 (3) in section 1232—

11 (A) in subsection (a), by striking “appro-
12 priated” and all that follows through the period
13 at the end and inserting “appropriated
14 \$24,000,000 for each of fiscal years 2010
15 through 2014.”; and

16 (B) by inserting after subsection (c) the
17 following:

18 “(d) AUTHORITY.—For the purpose of carrying out
19 parts A through C, beginning on the date of enactment
20 of the Affordable Health Choices Act, the Secretary shall
21 transfer authority in administering grants and related au-
22 thorities under such parts from the Administrator of the
23 Health Resources and Services Administration to the As-
24 sistant Secretary for Preparedness and Response.”.

1 (b) SUPPORT FOR EMERGENCY MEDICINE RE-
2 SEARCH.—Part H of title IV of the Public Health Service
3 Act (42 U.S.C. 289 et seq.) is amended by inserting after
4 the section 498C the following:

5 **“SEC. 498D. SUPPORT FOR EMERGENCY MEDICINE RE-**
6 **SEARCH.**

7 “(a) EMERGENCY MEDICAL RESEARCH.—The Sec-
8 retary shall support Federal programs administered by the
9 National Institutes of Health, the Agency for Healthcare
10 Research and Quality, the Health Resources and Services
11 Administration, the Centers for Disease Control and Pre-
12 vention, and other agencies involved in improving the
13 emergency care system to expand and accelerate research
14 in emergency medical care systems and emergency medi-
15 cine, including—

16 “(1) the basic science of emergency medicine;

17 “(2) the model of service delivery and the com-
18 ponents of such models that contribute to enhanced
19 patient health outcomes;

20 “(3) the translation of basic scientific research
21 into improved practice; and

22 “(4) the development of timely and efficient de-
23 livery of health services.

24 “(b) PEDIATRIC EMERGENCY MEDICAL RE-
25 SEARCH.—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

1 of, and savings that result from, the implementation of
2 coordinated emergency care systems.

3 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
4 are authorized to be appropriated to carry out this section
5 such sums as may be necessary for each of fiscal years
6 2010 through 2014.”.

7 **SEC. 215. TRAUMA CARE CENTERS AND SERVICE AVAIL-**
8 **ABILITY.**

9 (a) TRAUMA CARE CENTERS.—

10 (1) GRANTS FOR TRAUMA CARE CENTERS.—

11 Section 1241 of the Public Health Service Act (42
12 U.S.C. 300d–41) is amended by striking subsections
13 (a) and (b) and inserting the following:

14 “(a) IN GENERAL.—The Secretary shall establish 3
15 programs to award grants to qualified public, nonprofit,
16 Indian Health Service, Indian tribal, and urban Indian
17 trauma centers—

18 “(1) to assist in defraying substantial uncom-
19 pensated care costs;

20 “(2) to further the core missions of such trau-
21 ma centers, including by addressing costs associated
22 with patient stabilization and transfer, trauma edu-
23 cation and outreach, coordination with local and re-
24 gional trauma systems, essential personnel and other

1 fixed costs, and expenses associated with employee
2 and non-employee physician services; and

3 “(3) to provide emergency relief to ensure the
4 continued and future availability of trauma services.

5 “(b) MINIMUM QUALIFICATIONS OF TRAUMA CEN-
6 TERS.—

7 “(1) PARTICIPATION IN TRAUMA CARE SYSTEM
8 OPERATING UNDER CERTAIN PROFESSIONAL GUIDE-
9 LINES.—Except as provided in paragraph (2), the
10 Secretary may not award a grant to a trauma center
11 under subsection (a) unless the trauma center is a
12 participant in a trauma system that substantially
13 complies with section 1213.

14 “(2) EXEMPTION.—Paragraph (1) shall not
15 apply to trauma centers that are located in States
16 with no existing trauma care system.

17 “(3) QUALIFICATION FOR SUBSTANTIAL UN-
18 COMPENSATED CARE COSTS.—The Secretary shall
19 award substantial uncompensated care grants under
20 subsection (a)(1) only to trauma centers meeting at
21 least 1 of the criteria in 1 of the following 3 cat-
22 egories:

23 “(A) CATEGORY A.—The criteria for cat-
24 egory A are as follows:

1 “(i) At least 40 percent of the visits
2 in the emergency department of the hos-
3 pital in which the trauma center is located
4 were charity or self-pay patients.

5 “(ii) At least 50 percent of the visits
6 in such emergency department were Med-
7 icaid (under title XIX of the Social Secu-
8 rity Act (42 U.S.C. 1396 et seq.)) and
9 charity and self-pay patients combined.

10 “(B) CATEGORY B.—The criteria for cat-
11 egory B are as follows:

12 “(i) At least 35 percent of the visits
13 in the emergency department were charity
14 or self-pay patients.

15 “(ii) At least 50 percent of the visits
16 in the emergency department were Med-
17 icaid and charity and self-pay patients
18 combined.

19 “(C) CATEGORY C.—The criteria for cat-
20 egory C are as follows:

21 “(i) At least 20 percent of the visits
22 in the emergency department were charity
23 or self-pay patients.

24 “(ii) At least 30 percent of the visits
25 in the emergency department were Med-

1 icaid and charity and self-pay patients
2 combined.

3 “(4) TRAUMA CENTERS IN 1115 WAIVER
4 STATES.—Notwithstanding paragraph (3), the Sec-
5 retary may award a substantial uncompensated care
6 grant to a trauma center under subsection (a)(1) if
7 the trauma center qualifies for funds under a Low
8 Income Pool or Safety Net Care Pool established
9 through a waiver approved under section 1115 of the
10 Social Security Act (42 U.S.C. 1315).

11 “(5) DESIGNATION.—The Secretary may not
12 award a grant to a trauma center unless such trau-
13 ma center is verified by the American College of
14 Surgeons or designated by an equivalent State or
15 local agency.

16 “(c) ADDITIONAL REQUIREMENTS.—The Secretary
17 may not award a grant to a trauma center under sub-
18 section (a)(1) unless such trauma center—

19 “(1) submits to the Secretary a plan satisfac-
20 tory to the Secretary that demonstrates a continued
21 commitment to serving trauma patients regardless of
22 their ability to pay; and

23 “(2) has policies in place to assist patients who
24 cannot pay for part or all of the care they receive,

1 including a sliding fee scale, and to ensure fair bill-
2 ing and collection practices.”.

3 (2) CONSIDERATIONS IN MAKING GRANTS.—
4 Section 1242 of the Public Health Service Act (42
5 U.S.C. 300d–42) is amended by striking subsections
6 (a) and (b) and inserting the following:

7 “(a) SUBSTANTIAL UNCOMPENSATED CARE
8 AWARDS.—

9 “(1) IN GENERAL.—The Secretary shall estab-
10 lish an award basis for each eligible trauma center
11 for grants under section 1241(a)(1) according to the
12 percentage described in paragraph (2), subject to the
13 requirements of section 1241(b)(3).

14 “(2) PERCENTAGES.—The applicable percent-
15 ages are as follows:

16 “(A) With respect to a category A trauma
17 center, 100 percent of the uncompensated care
18 costs.

19 “(B) With respect to a category B trauma
20 center, not more than 75 percent of the uncom-
21 pensated care costs.

22 “(C) With respect to a category C trauma
23 center, not more than 50 percent of the uncom-
24 pensated care costs.

25 “(b) CORE MISSION AWARDS.—

1 “(1) IN GENERAL.—In awarding grants under
2 section 1241(a)(2), the Secretary shall—

3 “(A) reserve 25 percent of the amount al-
4 located for core mission awards for Level III
5 and Level IV trauma centers; and

6 “(B) reserve 25 percent of the amount al-
7 located for core mission awards for large urban
8 Level I and II trauma centers—

9 “(i) that have at least 1 graduate
10 medical education fellowship in trauma or
11 trauma related specialties for which de-
12 mand is exceeding supply;

13 “(ii) for which—

14 “(I) annual uncompensated care
15 costs exceed \$10,000,000; or

16 “(II) at least 20 percent of emer-
17 gency department visits are charity or
18 self-pay or Medicaid patients; and

19 “(iii) that are not eligible for substan-
20 tial uncompensated care awards under sec-
21 tion 1241(a)(1).

22 “(c) EMERGENCY AWARDS.—In awarding grants
23 under section 1241(a)(3), the Secretary shall—

24 “(1) give preference to any application sub-
25 mitted by a trauma center that provides trauma care

1 in a geographic area in which the availability of
2 trauma care has significantly decreased or will sig-
3 nificantly decrease if the center is forced to close or
4 downgrade service or growth in demand for trauma
5 services exceeds capacity; and

6 “(2) reallocate any emergency awards funds not
7 obligated due to insufficient, or a lack of qualified,
8 applications to the significant uncompensated care
9 award program.”.

10 (3) CERTAIN AGREEMENTS.—Section 1243 of
11 the Public Health Service Act (42 U.S.C. 300d–43)
12 is amended by striking subsections (a), (b), and (c)
13 and inserting the following:

14 “(a) MAINTENANCE OF FINANCIAL SUPPORT.—The
15 Secretary may require a trauma center receiving a grant
16 under section 1241(a) to maintain access to trauma serv-
17 ices at comparable levels to the prior year during the grant
18 period .

19 “(b) TRAUMA CARE REGISTRY.—The Secretary may
20 require the trauma center receiving a grant under section
21 1241(a) to provide data to a national and centralized reg-
22 istry of trauma cases, in accordance with guidelines devel-
23 oped by the American College of Surgeons, and as the Sec-
24 retary may otherwise require.”.

1 (4) GENERAL PROVISIONS.—Section 1244 of
2 the Public Health Service Act (42 U.S.C. 300d–44)
3 is amended by striking subsections (a), (b), and (c)
4 and inserting the following:

5 “(a) APPLICATION.—The Secretary may not award
6 a grant to a trauma center under section 1241(a) unless
7 such center submits an application for the grant to the
8 Secretary and the application is in such form, is made in
9 such manner, and contains such agreements, assurances,
10 and information as the Secretary determines to be nec-
11 essary to carry out this part.

12 “(b) LIMITATION ON DURATION OF SUPPORT.—The
13 period during which a trauma center receives payments
14 under a grant under section 1241(a)(3) shall be for 3 fis-
15 cal years, except that the Secretary may waive such re-
16 quirement for a center and authorize such center to re-
17 ceive such payments for 1 additional fiscal year.

18 “(c) LIMITATION ON AMOUNT OF GRANT.—Notwith-
19 standing section 1242(a), a grant under section 1241 may
20 not be made in an amount exceeding \$2,000,000 for each
21 fiscal year.

22 “(d) ELIGIBILITY.—Except as provided in section
23 1242(b)(1)(B)(iii), acquisition of, or eligibility for, a grant
24 under section 1241(a) shall not preclude a trauma center

1 from being eligible for other grants described in such sec-
2 tion.

3 “(e) FUNDING DISTRIBUTION.—Of the total amount
4 appropriated for a fiscal year under section 1245, 70 per-
5 cent shall be used for substantial uncompensated care
6 awards under section 1241(a)(1), 20 percent shall be used
7 for core mission awards under section 1241(a)(2), and 10
8 percent shall be used for emergency awards under section
9 1241(a)(3).

10 “(f) MINIMUM ALLOWANCE.—Notwithstanding sub-
11 section (e), if the amount appropriated for a fiscal year
12 under section 1245 is less than \$25,000,000, all available
13 funding for such fiscal year shall be used for substantial
14 uncompensated care awards under section 1241(a)(1).

15 “(g) SUBSTANTIAL UNCOMPENSATED CARE AWARD
16 DISTRIBUTION AND PROPORTIONAL SHARE.—Notwith-
17 standing section 1242(a), of the amount appropriated for
18 substantial uncompensated care grants for a fiscal year,
19 the Secretary shall—

20 “(1) make available—

21 “(A) 50 percent of such funds for category

22 A trauma center grantees;

23 “(B) 35 percent of such funds for category

24 B trauma center grantees; and

1 “(C) 15 percent of such funds for category
2 C trauma center grantees; and

3 “(2) provide available funds within each cat-
4 egory in a manner proportional to the award basis
5 specified in section 1242(a)(2) to each eligible trauma
6 center.

7 “(h) REPORT.—Beginning 2 years after the date of
8 enactment of the Affordable Health Choices Act, and
9 every 2 years thereafter, the Secretary shall biennially re-
10 port to Congress regarding the status of the grants made
11 under section 1241 and on the overall financial stability
12 of trauma centers.”.

13 (5) AUTHORIZATION OF APPROPRIATIONS.—

14 Section 1245 of the Public Health Service Act (42
15 U.S.C. 300d–45) is amended to read as follows:

16 **“SEC. 1245. AUTHORIZATION OF APPROPRIATIONS.**

17 “For the purpose of carrying out this part, there are
18 authorized to be appropriated \$100,000,000 for fiscal year
19 2009, and such sums as may be necessary for each of fis-
20 cal years 2010 through 2015. Such authorization of ap-
21 propriations is in addition to any other authorization of
22 appropriations or amounts that are available for such pur-
23 pose.”.

1 (6) DEFINITION.—Part D of title XII of the
2 Public Health Service Act (42 U.S.C. 300d–41 et
3 seq.) is amended by adding at the end the following:

4 **“SEC. 1246. DEFINITION.**

5 “In this part, the term ‘uncompensated care costs’
6 means unreimbursed costs from serving self-pay, charity,
7 or Medicaid patients, without regard to payment under
8 section 1923 of the Social Security Act, all of which are
9 attributable to emergency care and trauma care, including
10 costs related to subsequent inpatient admissions to the
11 hospital.”.

12 (b) TRAUMA SERVICE AVAILABILITY.—Title XII of
13 the Public Health Service Act (42 U.S.C. 300d et seq.)
14 is amended by adding at the end the following:

15 **“PART H—TRAUMA SERVICE AVAILABILITY**

16 **“SEC. 1281. GRANTS TO STATES.**

17 “(a) ESTABLISHMENT.—To promote universal access
18 to trauma care services provided by trauma centers and
19 trauma-related physician specialties, the Secretary shall
20 provide funding to States to enable such States to award
21 grants to eligible entities for the purposes described in this
22 section.

23 “(b) AWARDING OF GRANTS BY STATES.—Each
24 State may award grants to eligible entities within the
25 State for the purposes described in subparagraph (d).

1 “(c) ELIGIBILITY.—

2 “(1) IN GENERAL.—To be eligible to receive a
3 grant under subsection (b) an entity shall—

4 “(A) be—

5 “(i) a public or nonprofit trauma cen-
6 ter or consortium thereof that meets that
7 requirements of paragraphs (1), (2), and
8 (5) of section 1241(b);

9 “(ii) a safety net public or nonprofit
10 trauma center that meets the requirements
11 of paragraphs (1) through (5) of section
12 1241(b); or

13 “(iii) a hospital in an underserved
14 area (as defined by the State) that seeks
15 to establish new trauma services; and

16 “(B) submit to the State an application at
17 such time, in such manner, and containing such
18 information as the State may require.

19 “(2) LIMITATION.—A State shall use at least
20 40 percent of the amount available to the State
21 under this part for a fiscal year to award grants to
22 safety net trauma centers described in paragraph
23 (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.

1 “(6) Making capital improvements to enhance
2 access and expedite trauma care, including providing
3 helipads and associated safety infrastructure.

4 “(7) Enhancing trauma surge capacity at spe-
5 cific trauma centers.

6 “(8) Ensuring expedient receipt of trauma pa-
7 tients transported by ground or air to the appro-
8 priate trauma center.

9 “(9) Enhancing interstate trauma center col-
10 laboration.

11 “(e) LIMITATION.—

12 “(1) IN GENERAL.—A State may use not more
13 than 20 percent of the amount available to the State
14 under this part for a fiscal year for administrative
15 costs associated with awarding grants and related
16 costs.

17 “(2) MAINTENANCE OF EFFORT.—The Sec-
18 retary may not provide funding to a State under this
19 part unless the State agrees that such funds will be
20 used to supplement and not supplant State funding
21 otherwise available for the activities and costs de-
22 scribed in this part.

23 “(f) DISTRIBUTION OF FUNDS.—The following shall
24 apply with respect to grants provided in this part:

1 “(1) LESS THAN \$10,000,000.—If the amount of
2 appropriations for this part in a fiscal year is less
3 than \$10,000,000, the Secretary shall divide such
4 funding evenly among only those States that have 1
5 or more trauma centers eligible for funding under
6 section 1241(b)(3)(A).

7 “(2) LESS THAN \$20,000,000.—If the amount of
8 appropriations in a fiscal year is less than
9 \$20,000,000, the Secretary shall divide such funding
10 evenly among only those States that have 1 or more
11 trauma centers eligible for funding under subpara-
12 graphs (A) and (B) of section 1241(b)(3).

13 “(3) LESS THAN \$30,000,000.—If the amount of
14 appropriations for this part in a fiscal year is less
15 than \$30,000,000, the Secretary shall divide such
16 funding evenly among only those States that have 1
17 or more trauma centers eligible for funding under
18 section 1241(b)(3).

19 “(4) \$30,000,000 OR MORE.—If the amount of
20 appropriations for this part in a fiscal year is
21 \$30,000,000 or more, the Secretary shall divide such
22 funding evenly among all States.

1 **“SEC. 1282. AUTHORIZATION OF APPROPRIATIONS.**

2 “For the purpose of carrying out this part, there is
3 authorized to be appropriated \$100,000,000 for each of
4 fiscal years 2010 through 2015.”.

5 **SEC. 216. REDUCING AND REPORTING HOSPITAL READMIS-**
6 **SIONS.**

7 (a) IN GENERAL.—Part S of title III of the Public
8 Health Service Act, as amended by section 205, is further
9 amended by adding at the end the following:

10 **“SEC. 399NN. READMISSIONS.**

11 “(a) PURPOSE.—The purpose of this section is to im-
12 prove the quality and value of inpatient hospital services
13 in order to—

14 “(1) improve the coordination of care; and

15 “(2) appropriately reduce inefficiency and
16 waste, such as unnecessary hospital readmissions, in
17 the care furnished.

18 “(b) INFORMATION GATHERING AND ANALYSIS.—
19 Beginning 2010, the Secretary shall analyze and calculate
20 hospital-specific and national applicable readmissions
21 rates based on subsection (e). In developing criteria and
22 carrying out this section, the Secretary shall consider the
23 unique characters of rural and low-volume hospitals (in-
24 cluding critical access hospitals).

25 “(c) DISCLOSURE.—

1 “(1) IN GENERAL.—Beginning in 2011, the
2 Secretary shall establish procedures to provide for
3 the confidential disclosure to hospitals receiving
4 funds under this Act of information on hospital-spe-
5 cific and national applicable readmission rates de-
6 scribed in subsection (b).

7 “(2) PUBLIC DISCLOSURE OF INFORMATION.—
8 Not later than 2 years after the date of enactment
9 of this section, the Secretary shall make the infor-
10 mation on the rates of applicable readmission rates
11 and other statistical information of hospital receiving
12 funds under this Act disclosed under paragraph (1)
13 publicly available in a form and manner determined
14 appropriate by the Secretary.

15 “(3) REPORT.—Not later than 180 days after
16 the date of enactment of this section, the Secretary
17 shall submit to Congress a report that contains—

18 “(A) a summary of the implementation of
19 the procedures under paragraph (1);

20 “(B) a plan for the public disclosure of in-
21 formation under paragraph (2); and

22 “(C) recommendations for such legislation
23 or administrative action as the Secretary deter-
24 mines appropriate.

25 “(d) APPLICABLE READMISSION DEFINED.—

1 “(1) IN GENERAL.—In this section, the term
2 ‘applicable readmission’ means a readmission—

3 “(A) selected by the Secretary under sub-
4 section (e));

5 “(B) that occurs within a time interval (as
6 specified under subsection (f)) following a dis-
7 charge from a hospital; and

8 “(C) which is for a condition or procedure
9 selected under subsection (g).

10 “(2) DETERMINATION OF APPLICABILITY TO
11 READMISSIONS TO CERTAIN HOSPITALS.—The Sec-
12 retary shall determine whether the term ‘applicable
13 readmission’ includes readmissions to the same hos-
14 pital as the prior discharge or readmissions to any
15 hospital.

16 “(e) SELECTION OF READMISSIONS.—Not later 6
17 months after the date of enactment of this section, the
18 Secretary, in consultation with appropriate representatives
19 of the Centers for Medicare & Medicaid Services and the
20 Agency for Healthcare Research and Quality, shall, for
21 each of the conditions or procedures selected under sub-
22 section (g), select readmissions that meet each of the fol-
23 lowing requirements:

24 “(1) The readmission could reasonably have
25 been prevented by the provision of care consistent

1 with evidence-based guidelines during the prior ad-
2 mission or the post discharge follow-up period.

3 “(2) The readmission is for a condition or pro-
4 cedure related to the care provided during the prior
5 admission or post discharge follow-up period, which
6 includes a readmission for the following:

7 “(A) The same condition or procedure as
8 the prior discharge.

9 “(B) An infection or other complication of
10 care.

11 “(C) A condition or procedure indicative of
12 a failed surgical intervention.

13 “(D) Other conditions or procedures as de-
14 termined appropriate by the Secretary.

15 “(f) SPECIFICATION OF TIME INTERVAL.—The Sec-
16 retary shall specify a time interval, of not less than 7 days
17 and not more than 30 days, between the prior discharge
18 and applicable readmission for purposes of this section.

19 “(g) SELECTION OF CONDITIONS OR PROCE-
20 DURES.—

21 “(1) IN GENERAL.—Not later than 6 months
22 after the date of enactment of this section, the Sec-
23 retary shall select at least 2 conditions or procedures
24 which meet each of the following requirements:

1 “(A) Such conditions or procedures have a
2 high volume.

3 “(B) For the time interval specified under
4 subsection (f), such conditions or procedures
5 have a relatively high rate of occurrence of sub-
6 sequent readmissions described in subsection
7 (f), as compared to all other conditions or pro-
8 cedures.

9 “(2) EXPANSION OF CONDITIONS OR PROCE-
10 DURES SELECTED.—The Secretary shall expand the
11 list of readmission conditions analyzed under this
12 section to include at least 8 conditions with the
13 highest volume and highest rate of readmissions. At
14 least one of the conditions selected shall be a condi-
15 tion prevalent in geriatric patients.

16 “(h) QUALITY IMPROVEMENT PROGRAM FOR HOS-
17 PITALS WITH A HIGH SEVERITY ADJUSTED READMISSION
18 RATE.—

19 “(1) ESTABLISHMENT.—

20 “(A) IN GENERAL.—Not later than 2 years
21 after the date of enactment of this section, the
22 Secretary shall establish a program for eligible
23 hospitals to improve their readmission rates
24 through the use of patient safety organizations
25 (as defined in section 921(4)).

1 “(B) ELIGIBLE HOSPITAL DEFINED.—In
2 this subsection, the term ‘eligible hospital’
3 means a hospital which the Secretary deter-
4 mines (based on the most recent available his-
5 torical data) has a severity adjusted readmis-
6 sion rate for the conditions described in sub-
7 section (g) among the highest 25 percent of all
8 hospitals nationally.

9 “(C) RISK ADJUSTMENT.—The Secretary
10 shall utilize appropriate risk adjustment meas-
11 ures to determine eligible hospitals.

12 “(2) REPORT TO THE SECRETARY.—Eligible
13 hospitals and patient safety organizations working
14 with those hospitals shall report to the Secretary on
15 the processes employed by the hospital to improve
16 readmission rates and the impact of such processes
17 on readmission rates.”.

18 (b) GAO STUDY AND REPORT.—

19 (1) STUDY.—The Comptroller General of the
20 United States shall conduct a study on the impact
21 of section 399NN of the Public Health Service Act,
22 as added by subsection (a), on—

23 (A) care furnished to consumers;

24 (B) expenditures under Federal health pro-
25 grams; and

1 (C) the cost and quality of care furnished
2 by hospitals.

3 (2) REPORT.—Not later than January 1, 2013,
4 the Comptroller General of the United States shall
5 submit to Congress a report on the study conducted
6 under paragraph (1), together with recommenda-
7 tions for such legislation and administrative action
8 as the Comptroller General determines appropriate.

9 (c) STUDY BY IOM.—

10 (1) IN GENERAL.—The Secretary of Health and
11 Human Services shall seek to enter into an agree-
12 ment with the Institute of Medicine to submit to
13 Congress, not later than 1 year after the date of en-
14 actment of this Act, a report on recommendations on
15 how to reduce unnecessary hospital readmissions.
16 Such report shall also include recommendations on
17 how to develop a coordinated care plan for patients
18 being discharged from the hospital.

19 (2) AUTHORIZATION.—For the purpose of car-
20 rying out this subsection, there is authorized to be
21 appropriated such sums as may be necessary for fis-
22 cal year 2010.

1 **SEC. 217. PROGRAM TO FACILITATE SHARED DECISION-**
2 **MAKING.**

3 Part D of title IX of the Public Health Service Act,
4 as amended by section 213, is further amended by adding
5 at the end the following:

6 **“SEC. 936. PROGRAM TO FACILITATE SHARED DECISION-**
7 **MAKING.**

8 “(a) PURPOSE.—The purpose of this section is to fa-
9 cilitate collaborative processes between patients, caregivers
10 or authorized representatives, and clinicians that engages
11 the patient, caregiver or authorized representative in deci-
12 sionmaking, provides patients, caregivers or authorized
13 representatives with information about trade-offs among
14 treatment options, and facilitates the incorporation of pa-
15 tient preferences and values into the medical plan.

16 “(b) DEFINITIONS.—In this section:

17 “(1) PATIENT DECISION AID.—The term ‘pa-
18 tient decision aid’ means an educational tool that
19 helps patients, caregivers or authorized representa-
20 tives understand and communicate their beliefs and
21 preferences related to their treatment options, and
22 to decide with their health care provider what treat-
23 ments are best for them based on their treatment
24 options, scientific evidence, circumstances, beliefs,
25 and preferences.

1 “(2) PREFERENCE SENSITIVE CARE.—The term
2 ‘preference sensitive care’ means medical care for
3 which the clinical evidence does not clearly support
4 one treatment option such that the appropriate
5 course of treatment depends on the values of the pa-
6 tient or the preferences of the patient, caregivers or
7 authorized representatives regarding the benefits,
8 harms and scientific evidence for each treatment op-
9 tion, the use of such care should depend on the in-
10 formed patient choice among clinically appropriate
11 treatment options.

12 “(c) ESTABLISHMENT OF INDEPENDENT STANDARDS
13 FOR PATIENT DECISION AIDS FOR PREFERENCE SEN-
14 SITIVE CARE.—

15 “(1) CONTRACT WITH ENTITY TO ESTABLISH
16 STANDARDS AND CERTIFY PATIENT DECISION
17 AIDS.—

18 “(A) IN GENERAL.—For purposes of sup-
19 porting consensus-based standards for patient
20 decision aids for preference sensitive care and a
21 certification process for patient decision aids for
22 use in the Federal health programs and by
23 other interested parties, the Secretary shall
24 have in effect a contract with the qualified con-
25 sensus-based entity identified in section 399JJ.

1 Such contract shall provide that the entity per-
2 form the duties described in paragraph (2).

3 “(B) TIMING FOR FIRST CONTRACT.—As
4 soon as practicable after the date of the enact-
5 ment of this section, the Secretary shall enter
6 into the first contract under subparagraph (A).

7 “(C) PERIOD OF CONTRACT.—A contract
8 under subparagraph (A) shall be for a period of
9 18 months (except such contract may be re-
10 newed after a subsequent bidding process).

11 “(2) DUTIES.—The following duties are de-
12 scribed in this paragraph:

13 “(A) DEVELOP AND IDENTIFY STANDARDS
14 FOR PATIENT DECISION AIDS.—The entity shall
15 synthesize evidence and convene a broad range
16 of experts and key stakeholders to develop and
17 identify consensus-based standards to evaluate
18 patient decision aids for preference sensitive
19 care.

20 “(B) ENDORSE PATIENT DECISION AIDS.—
21 The entity shall review patient decision aids
22 and develop a certification process whether pa-
23 tient decision aids meet the standards developed
24 and identified under subparagraph (A). The en-
25 tity shall give priority to the review and certifi-

1 cation of patient decision aids for preference
2 sensitive care.

3 “(d) PROGRAM TO DEVELOP, UPDATE AND PATIENT
4 DECISION AIDS TO ASSIST HEALTH CARE PROVIDERS
5 AND PATIENTS.—

6 “(1) IN GENERAL.—The Secretary, acting
7 through the Director, and in coordination with heads
8 of other relevant agencies, such as the Director of
9 the Centers for Disease Control and Prevention and
10 the Director of the National Institutes of Health,
11 shall establish a program to award grants or con-
12 tracts—

13 “(A) to develop, update, and produce pa-
14 tient decision aids for preference sensitive care
15 to assist health care providers in educating pa-
16 tients, caregivers, and authorized representa-
17 tives concerning the relative safety, relative ef-
18 fectiveness (including possible health outcomes
19 and impact on functional status), and relative
20 cost of treatment or, where appropriate, pallia-
21 tive care options;

22 “(B) to test such materials to ensure such
23 materials are balanced and evidence based in
24 aiding health care providers and patients, care-
25 givers, 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 rricula.

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

1 “(D) shall address health care decisions
2 across the age span, including those affecting
3 vulnerable populations including children.

4 “(3) DISTRIBUTION.—The Director shall ensure
5 that patient decision aids produced with grants or
6 contracts under this section are available to the pub-
7 lic.

8 “(4) NONDUPLICATION OF EFFORTS.—The Di-
9 rector shall ensure that the activities under this sec-
10 tion of the Agency and other agencies, including the
11 Centers for Disease Control and Prevention and the
12 National Institutes of Health, are free of unneces-
13 sary duplication of effort.

14 “(e) GRANTS TO SUPPORT SHARED DECISION MAK-
15 ING IMPLEMENTATION.—

16 “(1) IN GENERAL.—The Secretary shall estab-
17 lish a program to provide for the phased-in develop-
18 ment, implementation, and evaluation of shared deci-
19 sionmaking using patient decision aids to meet the
20 objective of improving the understanding of patients
21 of their medical treatment options.

22 “(2) SHARED DECISIONMAKING RESOURCE CEN-
23 TERS.—

24 “(A) IN GENERAL.—The Secretary shall
25 provide grants for the establishment and sup-

1 port of Shared Decision Making Resource Cen-
2 ters (referred to in this subsection as ‘Centers’)
3 to provide technical assistance to providers and
4 to develop and disseminate best practices and
5 other information to support and accelerate
6 adoption, implementation, and effective use of
7 patient decision aids and shared decision mak-
8 ing by providers.

9 “(B) OBJECTIVES.—The objective of a
10 Center is to enhance and promote the adoption
11 of patient decision aids and shared decision-
12 making through—

13 “(i) providing assistance to eligible
14 providers with the implementation and ef-
15 fective use of, and training on, patient de-
16 cision aids; and

17 “(ii) the dissemination of best prac-
18 tices and research on the implementation
19 and effective use of patient decision aids.

20 “(3) SHARED DECISIONMAKING PARTICIPATION
21 GRANTS.—

22 “(A) IN GENERAL.—The Secretary shall
23 provide grants to health care providers for the
24 development and implementation of shared deci-
25 sionmaking techniques.

1 “(B) PREFERENCE.—In order to facilitate
2 the use of best practices, the Secretary shall
3 provide a preference in making grants under
4 this subsection to health care providers who
5 participate in training by Shared Decision Mak-
6 ing Resource Centers or comparable training.

7 “(C) LIMITATION.—Funds under this
8 paragraph shall not be used to purchase or im-
9 plement use of patient decision aids other than
10 those certified under the process identified in
11 subsection (c).

12 “(4) GUIDANCE.—The Secretary may issue
13 guidance to eligible grantees under this subsection
14 on the use of patient decision aids.

15 “(5) QUALITY MEASURES.—

16 “(A) IN GENERAL.—The Secretary shall
17 measure the quality of shared decisionmaking.
18 For purposes of making such measurements,
19 the Secretary shall select quality measures as
20 described in section 399JJ.

21 “(B) REPORTING DATA ON MEASURES.—A
22 provider receiving a grant under this subsection
23 shall report to the Secretary data on quality
24 measures selected under subparagraph (A) in

1 accordance with procedures established by the
2 Secretary.

3 “(C) FEEDBACK ON MEASURES.—The Sec-
4 retary shall provide confidential reports to eligi-
5 ble providers receiving a grant under this sec-
6 tion on the performance of the eligible provider
7 on quality measures selected by the Secretary
8 under subparagraph (A), the aggregate per-
9 formance of all eligible providers participating
10 in the program, and any improvements in such
11 performance. Such reports shall be made pub-
12 licly available not less than 3 years after the
13 date of enactment of this section.

14 “(D) GRANT TO FUND DEVELOPMENT OF
15 PERFORMANCE MEASURES.—The Director may,
16 through the quality measure development pro-
17 gram under section 931, award grants or con-
18 tracts to eligible entities to fund development of
19 performance measures which assess the use by
20 health care providers of shared decisionmaking
21 processes or patient decision aids.

22 “(E) CONTENTS OF REPORT.—Each report
23 submitted under this paragraph shall—

24 “(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-

1 making under the applicable phase of the
2 program.

3 “(f) FUNDING.—For purposes of carrying out this
4 section there are authorized to be appropriated such sums
5 as may be necessary for fiscal year 2010 and each subse-
6 quent fiscal year.”.

7 **SEC. 218. PRESENTATION OF PRESCRIPTION DRUG BEN-**
8 **EFIT AND RISK INFORMATION.**

9 (a) IN GENERAL.—The Secretary of Health and
10 Human Services (referred to in this section as the “Sec-
11 retary”), acting through the Commissioner of Food and
12 Drugs, shall determine whether the addition of quan-
13 titative summaries of the benefits and risks of prescription
14 drugs in a standardized format (such as a table or drug
15 facts box) to the promotional labeling or print advertising
16 of such drugs would improve health care decisionmaking
17 by clinicians and patients and consumers.

18 (b) REVIEW AND CONSULTATION.—In making the
19 determination under subsection (a), the Secretary shall re-
20 view all available scientific evidence and research on deci-
21 sionmaking and social and cognitive psychology and con-
22 sult with drug manufacturers, clinicians, patients and con-
23 sumers, experts in health literacy, representatives of racial
24 and ethnic minorities, and experts in women’s and pedi-
25 atric health.

1 (c) REPORT.—Not later than 1 year after the date
2 of enactment of this Act, the Secretary shall submit to
3 Congress a report that provides—

4 (1) the determination by the Secretary under
5 subsection (a); and

6 (2) the reasoning and analysis underlying that
7 determination.

8 (d) AUTHORITY.—If the Secretary determines under
9 subsection (a) that the addition of quantitative summaries
10 of the benefits and risks of prescription drugs in a stand-
11 ardized format (such as a table or drug facts box) to the
12 promotional labeling or print advertising of such drugs
13 would improve health care decision-making by clinicians
14 and patients and consumers, then the Secretary, not later
15 than 3 years after the date of submission of the report
16 under subsection (c), shall promulgate proposed regula-
17 tions as necessary to implement such format.

18 (e) CLARIFICATION.—Nothing in this section shall be
19 construed to restrict the existing authorities of the Sec-
20 retary with respect to benefit and risk information.

21 **SEC. 219. CENTER FOR HEALTH OUTCOMES RESEARCH AND**
22 **EVALUATION.**

23 Part D of title IX of the Public Health Service Act,
24 as amended by section 217, is further amended by adding
25 at the end the following:

1 **“SEC. 937. CENTER FOR HEALTH OUTCOMES RESEARCH**
2 **AND EVALUATION.**

3 “(a) ESTABLISHMENT.—The Secretary shall estab-
4 lish within the Agency the Center for Health Outcomes
5 Research and Evaluation (referred to in this section as
6 the ‘Center’) to collect, conduct, support, and synthesize
7 research with respect to comparing health outcomes, effec-
8 tiveness, and appropriateness of health care services and
9 procedures in order to identify the manner in which dis-
10 eases, disorders, and other health conditions can most ef-
11 fectively and appropriately be prevented, diagnosed, treat-
12 ed, and managed clinically.

13 “(b) DUTIES.—The Center shall—

14 “(1) coordinate, conduct, support, and syn-
15 thesize research relevant to the comparative health
16 outcomes and effectiveness of the full spectrum of
17 health care treatments, including pharmaceuticals,
18 medical devices, medical and surgical procedures,
19 screening and diagnostics, behavioral health care,
20 oral health, and other health interventions;

21 “(2) coordinate, conduct, and support system-
22 atic reviews of clinical research, including original
23 research conducted subsequent to the date of the en-
24 actment of this section;

25 “(3) coordinate, conduct, support, and syn-
26 thesize research that—

1 “(A) identifies which treatment is most ef-
2 fective and least toxic for each individual given
3 each individual’s genetic makeup and coexisting
4 conditions; and

5 “(B) reduces treatment disparities, among
6 ethnic and racial minorities, children, and vul-
7 nerable populations;

8 “(4) use a broad range of methodologies, in-
9 cluding randomized controlled clinical trials, observa-
10 tional studies and other approaches;

11 “(5) create informational tools that organize,
12 synthesize, and disseminate research findings to pro-
13 viders, patients, and public and private payers;

14 “(6) develop a publicly available resource data-
15 base that collects and contains high-quality, inde-
16 pendent evidence to inform healthcare decision-
17 making, which shall include reliable evidence from
18 government and non-government sources;

19 “(7) submit to the Secretary, and Congress ap-
20 propriate relevant reports described in subsection
21 (h);

22 “(8) encourage, as appropriate, the development
23 and use of clinical registries and the development of
24 health outcomes research data networks from elec-
25 tronic health records, post marketing drug and med-

1 ical device surveillance efforts, and other forms of
2 electronic health data; and

3 “(9) not later than one year after the date of
4 the enactment of this section, develop minimum
5 methodological standards to be used when con-
6 ducting studies of comparative health outcomes and
7 value (and procedures for use of such standards) in
8 order to help ensure accurate and effective compari-
9 sons and assessments of treatment options, and up-
10 date such standards at least biennially.

11 “(c) POWERS.—

12 “(1) OBTAINING OFFICIAL DATA.—The Center
13 may secure directly from any department or agency
14 of the United States information necessary to enable
15 the Center to carry out this section. Upon request
16 of the Center, the head of that department or agen-
17 cy shall furnish that information to the Center on an
18 agreed upon schedule.

19 “(2) DATA COLLECTION.—In order to carry out
20 its functions, the Center shall—

21 “(A) utilize existing information, both pub-
22 lished and unpublished, where possible, collected
23 and assessed either by the staff of the Center
24 or under other arrangements made in accord-
25 ance with this section;

1 “(B) carry out, or award grants or con-
2 tracts for, original research and experimen-
3 tation, where existing information is inad-
4 equate;

5 “(C) adopt procedures allowing any inter-
6 ested party to submit information for use by
7 the Center or the Advisory Counsel under sub-
8 section (d) in making reports and recommenda-
9 tions; and

10 “(D) comply with any existing data privacy
11 standards applicable to the Center.

12 “(3) PERIODIC AUDIT.—The Center shall be
13 subject to periodic audit by the Comptroller General.

14 “(d) ADVISORY COUNCIL.—

15 “(1) IN GENERAL.—To ensure transparency,
16 the Secretary shall establish through the Agency’s
17 National Advisory Council, an advisory council (re-
18 ferred to in this section as the ‘Council’) that in-
19 cludes representatives from the scientific research,
20 patient, provider, and health industry communities.

21 “(2) COMPOSITION OF COUNCIL.—

22 “(A) IN GENERAL.—The members of the
23 Council shall consist of—

24 “(i) 2 ex officio members who shall
25 be—

1 “(I) the Director; and

2 “(II) the Chief Medical Officer of
3 the Centers for Medicare & Medicaid
4 Services; and

5 “(ii) 19 additional members who shall
6 represent broad constituencies of stake-
7 holders.

8 “(B) QUALIFICATIONS.—

9 “(i) DIVERSE REPRESENTATION OF
10 PERSPECTIVES.—The members of the
11 Council shall represent a broad range of
12 perspectives and shall collectively have ex-
13 perience in the following areas:

14 “(I) Epidemiology.

15 “(II) Health services research.

16 “(III) Bioethics.

17 “(IV) Communication and deci-
18 sion sciences.

19 “(V) Health economics.

20 “(VI) Safe use of medical prod-
21 ucts.

22 “(VII) The practice of medicine.

23 “(ii) DIVERSE REPRESENTATION OF
24 HEALTH CARE COMMUNITY.—At least one

1 member shall represent each of the fol-
2 lowing health care communities:

3 “(I) Consumers.

4 “(II) Practicing physicians, in-
5 cluding surgeons.

6 “(III) Nurses.

7 “(IV) State licensed practitioners
8 and other health care professionals.

9 “(V) Employers.

10 “(VI) Public payers.

11 “(VII) Insurance plans.

12 “(VIII) Clinical researchers who
13 conduct research on behalf of pharma-
14 ceutical or device manufacturers.

15 “(IX) Clinical researchers who
16 conduct research related to personal-
17 ized medicine.

18 “(X) Clinical researchers who
19 conduct research related to reducing
20 health disparities.

21 “(3) APPOINTMENT.—The Secretary or the
22 Secretary’s designee shall appoint the members of
23 the Council.

24 “(4) TERMS.—

1 “(A) IN GENERAL.—Except as provided
2 in subparagraph (B), each member of the
3 Council shall be appointed for a term of 4
4 years.

5 “(B) TERMS OF INITIAL APPOINTEES.—
6 Of the members first appointed—

7 “(i) 10 shall be appointed for a term
8 of 4 years; and

9 “(ii) 9 shall be appointed for a term
10 of 2 years.

11 “(5) CONFLICTS OF INTEREST.—In appointing
12 the members of the Council, the Secretary shall take
13 into consideration any financial conflicts of interest.

14 “(e) RARE DISEASE RESEARCH.—In the case of a re-
15 search study of a rare disease, the Secretary shall appoint
16 a clinical expert advisory panel for purposes of assisting
17 in the design of such research study and determining the
18 feasibility of recruiting for and conducting such research
19 study.

20 “(f) EXPERT ADVISORY PANELS.—The Center may
21 appoint expert advisory panels to advise the Center and
22 the agency, instrumentality, or entity conducting the re-
23 search regarding the research question involved and the
24 research design or protocol, including important patient
25 subgroups and other parameters of the research. Such ex-

1 pert advisory panels may include individuals with experi-
2 ence in the relevant topic, project, or category for which
3 the panel is established, including practicing and research
4 clinicians and relevant specialists and subspecialists.

5 “(g) RESEARCH REQUIREMENTS.—Any research con-
6 ducted, supported, or synthesized under this section shall
7 meet the following requirements:

8 “(1) ENSURING TRANSPARENCY, CREDIBILITY,
9 AND ACCESS.—The establishment of the agenda and
10 conduct of the research shall be insulated from
11 undue political or stakeholder influence, in accord-
12 ance with the following:

13 “(A) Methods of conducting such research
14 shall be scientifically based and take into ac-
15 count scientific advances in personalized medi-
16 cine and reduces treatment disparities that in-
17 clude ethnic and racial minorities and children.

18 “(B) All aspects of the prioritization of re-
19 search, conduct of the research, and develop-
20 ment of conclusions based on the research shall
21 be transparent to all stakeholders.

22 “(C) The process and methods for con-
23 ducting such research shall be publicly docu-
24 mented and available to all stakeholders.

1 “(D) The Center shall establish a process
2 for stakeholders involved to review and provide
3 comment on the methods and findings of such
4 research.

5 “(2) STAKEHOLDER INPUT.—The priorities of
6 the research, the research, and the dissemination of
7 the research shall involve the consultation of pa-
8 tients, health care providers, experts in wellness and
9 health promotion, and health care consumer rep-
10 resentatives through transparent mechanisms rec-
11 ommended by the Council.

12 “(h) PUBLIC ACCESS TO HEALTH OUTCOMES INFOR-
13 MATION.—

14 “(1) IN GENERAL.—To the extent practicable,
15 not later than 180 days after receipt by the Center
16 of a relevant report described in paragraph (2), ap-
17 propriate information contained in such report shall
18 be posted on the official public Internet site of the
19 Center, as applicable.

20 “(2) RELEVANT REPORTS DESCRIBED.—For
21 purposes of this section, a relevant report is each of
22 the following submitted by a grantee or contractor
23 of the Center:

24 “(A) An interim progress report.

1 “(B) A draft final report that is available
2 to stakeholders for review.

3 “(C) Stakeholder comments and response
4 to same.

5 “(D) A final progress report on new re-
6 search submitted for publication by a peer re-
7 view journal.

8 “(E) A final report.

9 “(3) BENEFIT TO SUBPOPULATIONS.—All re-
10 ports described in paragraph (2) shall assess wheth-
11 er the research demonstrates a benefit of the ther-
12 apy with respect to a specific subpopulation of indi-
13 viduals, even if the outcome of the research dem-
14 onstrates that, on average, with respect to the gen-
15 eral population, the clinical benefits of the treatment
16 do not exceed the harm.

17 “(i) ACCESS BY CONGRESS AND THE COUNSEL TO
18 CENTER INFORMATION.—The Secretary shall establish a
19 process for the Center to share with Congress reports and
20 non-proprietary data of the Center.

21 “(j) DISSEMINATION, INCORPORATION, AND FEED-
22 BACK OF INFORMATION.—

23 “(1) DISSEMINATION.—The Center shall pro-
24 vide for the dissemination of findings produced by
25 research supported, conducted, or synthesized under

1 this section to health care providers, patients, ven-
2 dors of health information technology focused on
3 clinical decision support, appropriate professional as-
4 sociations, and Federal and private health plans.
5 Center reports and recommendations shall not be
6 construed as mandates for payment, coverage, or
7 treatment.

8 “(2) INCORPORATION.—The Center shall assist
9 users of health information technology focused on
10 clinical decision support to promote the timely incor-
11 poration of the findings described in paragraph (1)
12 into clinical practices and to promote the ease of use
13 of such incorporation.

14 “(3) FEEDBACK.—The Center shall establish a
15 process to receive feedback from providers, patients,
16 vendors of health information technology focused on
17 clinical decision support, appropriate professional as-
18 sociations, and Federal and private health plans
19 about the value of the information disseminated
20 under this section.

21 “(k) REPORTS TO CONGRESS.—

22 “(1) ANNUAL REPORTS.—Beginning not later
23 than one year after the date of enactment of this
24 section, the Director shall submit to Congress an an-
25 nual report on the activities of the Center and the

1 Council, and the research conducted, under this sec-
2 tion.

3 “(2) ANALYSIS AND REVIEW.—Not later than
4 December 31, 2011, the Secretary, shall submit to
5 Congress a report on all activities conducted or sup-
6 ported under this section as of such date. Such re-
7 port shall—

8 “(A) include an evaluation of the impact
9 from such activities, the overall costs of such
10 activities, and an analysis of the backlog of any
11 research proposals approved but not funded;
12 and

13 “(B) address whether Congress should ex-
14 pand the responsibilities of the Center to in-
15 clude studies of the effectiveness of various as-
16 pects of the health care delivery system, includ-
17 ing health plans and delivery models, such as
18 health plan features, benefit designs and per-
19 formance, and the ways in which health services
20 are organized, managed, and delivered.”.

1 **SEC. 220. DEMONSTRATION PROGRAM TO INTEGRATE**
2 **QUALITY IMPROVEMENT AND PATIENT SAFE-**
3 **TY TRAINING INTO CLINICAL EDUCATION OF**
4 **HEALTH PROFESSIONALS.**

5 (a) IN GENERAL.—The Secretary may award grants
6 to eligible entities or consortia under this section to carry
7 out demonstration projects to develop and implement aca-
8 demic curricula that integrates quality improvement and
9 patient safety in the clinical education of health profes-
10 sionals. Such awards shall be made on a competitive basis
11 and pursuant to peer review.

12 (b) ELIGIBILITY.—To be eligible to receive a grant
13 under subsection (a), an entity or consortium shall—

14 (1) submit to the Secretary an application at
15 such time, in such manner, and containing such in-
16 formation as the Secretary may require;

17 (2) be or include—

18 (A) a health professions school;

19 (B) a school of public health;

20 (C) a school of social work;

21 (D) a school of nursing;

22 (E) a school of pharmacy;

23 (F) an institution with a graduate medical
24 education program; or

25 (G) a school of health care administration;

1 (3) collaborate in the development of curricula
2 described in subsection (a) with an organization that
3 accredits such school or institution;

4 (4) provide for the collection of data regarding
5 the effectiveness of the demonstration project; and

6 (5) provide matching funds in accordance with
7 subsection (c).

8 (c) MATCHING FUNDS.—

9 (1) IN GENERAL.—The Secretary may award a
10 grant to an entity or consortium under this section
11 only if the entity or consortium agrees to make
12 available non-Federal contributions toward the costs
13 of the program to be funded under the grant in an
14 amount that is not less than \$1 for each \$5 of Fed-
15 eral funds provided under the grant.

16 (2) DETERMINATION OF AMOUNT CONTRIB-
17 UTED.—Non-Federal contributions under paragraph
18 (1) may be in cash or in kind, fairly evaluated, in-
19 cluding equipment or services. Amounts provided by
20 the Federal Government, or services assisted or sub-
21 sidized to any significant extent by the Federal Gov-
22 ernment, may not be included in determining the
23 amount of such contributions.

24 (d) EVALUATION.—The Secretary shall take such ac-
25 tion as may be necessary to evaluate the projects funded

1 under this section and publish, make publicly available,
2 and disseminate the results of such evaluations on as wide
3 a basis as is practicable.

4 (e) REPORTS.—Not later than 2 years after the date
5 of enactment of this section, and annually thereafter, the
6 Secretary shall submit to the Committee on Health, Edu-
7 cation, Labor, and Pensions and the Committee on Fi-
8 nance of the Senate and the Committee on Energy and
9 Commerce and the Committee on Ways and Means of the
10 House of Representatives a report that—

11 (1) describes the specific projects supported
12 under this section; and

13 (2) contains recommendations for Congress
14 based on the evaluation conducted under subsection

15 (d).

16 **SEC. 221. OFFICE OF WOMEN'S HEALTH.**

17 (a) HEALTH AND HUMAN SERVICES OFFICE ON
18 WOMEN'S HEALTH.—

19 (1) ESTABLISHMENT.—Part A of title II of the
20 Public Health Service Act (42 U.S.C. 202 et seq.)
21 is amended by adding at the end the following:

22 **“SEC. 229. HEALTH AND HUMAN SERVICES OFFICE ON**
23 **WOMEN'S HEALTH.**

24 **“(a) ESTABLISHMENT OF OFFICE.—**There is estab-
25 lished within the Office of the Secretary, an Office on

1 Women's Health (referred to in this section as the 'Of-
2 fice'). The Office shall be headed by a Deputy Assistant
3 Secretary for Women's Health who may report to the Sec-
4 retary.

5 “(b) DUTIES.—The Secretary, acting through the Of-
6 fice, with respect to the health concerns of women, shall—

7 “(1) establish short-range and long-range goals
8 and objectives within the Department of Health and
9 Human Services and, as relevant and appropriate,
10 coordinate with other appropriate offices on activi-
11 ties within the Department that relate to disease
12 prevention, health promotion, service delivery, re-
13 search, and public and health care professional edu-
14 cation, for issues of particular concern to women
15 throughout their lifespan;

16 “(2) provide expert advice and consultation to
17 the Secretary concerning scientific, legal, ethical,
18 and policy issues relating to women's health;

19 “(3) monitor the Department of Health and
20 Human Services' offices, agencies, and regional ac-
21 tivities regarding women's health and identify needs
22 regarding the coordination of activities, including in-
23 tramural and extramural multidisciplinary activities;

24 “(4) establish a Department of Health and
25 Human Services Coordinating Committee on Wom-

1 en's Health, which shall be chaired by the Deputy
2 Assistant Secretary for Women's Health and com-
3 posed of senior level representatives from each of the
4 agencies and offices of the Department of Health
5 and Human Services;

6 "(5) establish a National Women's Health In-
7 formation Center to—

8 "(A) facilitate the exchange of information
9 regarding matters relating to health informa-
10 tion, health promotion, preventive health serv-
11 ices, research advances, and education in the
12 appropriate use of health care;

13 "(B) facilitate access to such information;

14 "(C) assist in the analysis of issues and
15 problems relating to the matters described in
16 this paragraph; and

17 "(D) provide technical assistance with re-
18 spect to the exchange of information (including
19 facilitating the development of materials for
20 such technical assistance);

21 "(6) coordinate efforts to promote women's
22 health programs and policies with the private sector;
23 and

24 "(7) through publications and any other means
25 appropriate, provide for the exchange of information

1 between the Office and recipients of grants, con-
2 tracts, and agreements under subsection (c), and be-
3 tween the Office and health professionals and the
4 general public.

5 “(c) GRANTS AND CONTRACTS REGARDING DU-
6 TIES.—

7 “(1) AUTHORITY.—In carrying out subsection
8 (b), the Secretary may make grants to, and enter
9 into cooperative agreements, contracts, and inter-
10 agency agreements with, public and private entities,
11 agencies, and organizations.

12 “(2) EVALUATION AND DISSEMINATION.—The
13 Secretary shall directly or through contracts with
14 public and private entities, agencies, and organiza-
15 tions, provide for evaluations of projects carried out
16 with financial assistance provided under paragraph
17 (1) and for the dissemination of information devel-
18 oped as a result of such projects.

19 “(d) REPORTS.—Not later than 1 year after the date
20 of enactment of this section, and every second year there-
21 after, the Secretary shall prepare and submit to the appro-
22 priate committees of Congress a report describing the ac-
23 tivities carried out under this section during the period
24 for which the report is being prepared.

1 “(e) AUTHORIZATION OF APPROPRIATIONS.—For the
2 purpose of carrying out this section, there are authorized
3 to be appropriated such sums as may be necessary for
4 each of the fiscal years 2010 through 2014.”.

5 (2) TRANSFER OF FUNCTIONS.—There are
6 transferred to the Office on Women’s Health (estab-
7 lished under section 229 of the Public Health Serv-
8 ice Act, as added by this section), all functions exer-
9 cised by the Office on Women’s Health of the Public
10 Health Service prior to the date of enactment of this
11 section, including all personnel and compensation
12 authority, all delegation and assignment authority,
13 and all remaining appropriations. All orders, deter-
14 minations, rules, regulations, permits, agreements,
15 grants, contracts, certificates, licenses, registrations,
16 privileges, and other administrative actions that—

17 (A) have been issued, made, granted, or al-
18 lowed to become effective by the President, any
19 Federal agency or official thereof, or by a court
20 of competent jurisdiction, in the performance of
21 functions transferred under this paragraph; and

22 (B) are in effect at the time this section
23 takes effect, or were final before the date of en-
24 actment of this section and are to become effec-
25 tive on or after such date,

1 shall continue in effect according to their terms until
2 modified, terminated, superseded, set aside, or re-
3 voked in accordance with law by the President, the
4 Secretary, or other authorized official, a court of
5 competent jurisdiction, or by operation of law.

6 (b) CENTERS FOR DISEASE CONTROL AND PREVEN-
7 TION OFFICE OF WOMEN’S HEALTH.—Part A of title III
8 of the Public Health Service Act (42 U.S.C. 241 et seq.)
9 is amended by adding at the end the following:

10 **“SEC. 310A. CENTERS FOR DISEASE CONTROL AND PREVEN-**
11 **TION OFFICE OF WOMEN’S HEALTH.**

12 “(a) ESTABLISHMENT.—There is established within
13 the Office of the Director of the Centers for Disease Con-
14 trol and Prevention, an office to be known as the Office
15 of Women’s Health (referred to in this section as the ‘Of-
16 fice’). The Office shall be headed by a director who shall
17 be appointed by the Director of such Centers.

18 “(b) PURPOSE.—The Director of the Office shall—

19 “(1) report to the Director of the Centers for
20 Disease Control and Prevention on the current level
21 of the Centers’ activity regarding women’s health
22 conditions across, where appropriate, age, biological,
23 and sociocultural contexts, in all aspects of the Cen-
24 ters’ work, including prevention programs, public
25 and professional education, services, and treatment;

1 “(2) establish short-range and long-range goals
2 and objectives within the Centers for women’s health
3 and, as relevant and appropriate, coordinate with
4 other appropriate offices on activities within the
5 Centers that relate to prevention, research, edu-
6 cation and training, service delivery, and policy de-
7 velopment, for issues of particular concern to
8 women;

9 “(3) identify projects in women’s health that
10 should be conducted or supported by the Centers;

11 “(4) consult with health professionals, non-
12 governmental organizations, consumer organizations,
13 women’s health professionals, and other individuals
14 and groups, as appropriate, on the policy of the Cen-
15 ters with regard to women; and

16 “(5) serve as a member of the Department of
17 Health and Human Services Coordinating Com-
18 mittee on Women’s Health (established under sec-
19 tion 229(b)(4)).

20 “(c) DEFINITION.—As used in this section, the term
21 ‘women’s health conditions’, with respect to women of all
22 age, ethnic, and racial groups, means diseases, disorders,
23 and conditions—

24 “(1) unique to, significantly more serious for,
25 or significantly more prevalent in women; and

1 “(2) for which the factors of medical risk or
2 type of medical intervention are different for women,
3 or for which there is reasonable evidence that indi-
4 cates that such factors or types may be different for
5 women.

6 “(d) AUTHORIZATION OF APPROPRIATIONS.—For the
7 purpose of carrying out this section, there are authorized
8 to be appropriated such sums as may be necessary for
9 each of the fiscal years 2010 through 2014.”.

10 (c) OFFICE OF WOMEN’S HEALTH RESEARCH.—Sec-
11 tion 486(a) of the Public Health Service Act (42 U.S.C.
12 287d(a)) is amended by inserting “and who shall report
13 directly to the Director” before the period at the end
14 thereof .

15 (d) SUBSTANCE ABUSE AND MENTAL HEALTH
16 SERVICES ADMINISTRATION.—Section 501(f) of the Pub-
17 lic Health Service Act (42 U.S.C. 290aa(f)) is amended—

18 (1) in paragraph (1), by inserting “who shall
19 report directly to the Administrator” before the pe-
20 riod;

21 (2) by redesignating paragraph (4) as para-
22 graph (5); and

23 (3) by inserting after paragraph (3), the fol-
24 lowing:

1 “(4) OFFICE.—Nothing in this subsection shall
2 be construed to preclude the Secretary from estab-
3 lishing within the Substance Abuse and Mental
4 Health Administration an Office of Women’s
5 Health.”.

6 (e) AGENCY FOR HEALTHCARE RESEARCH AND
7 QUALITY ACTIVITIES REGARDING WOMEN’S HEALTH.—
8 Part C of title IX of the Public Health Service Act (42
9 U.S.C. 299c et seq.) is amended—

10 (1) by redesignating sections 925 and 926 as
11 sections 926 and 927, respectively; and

12 (2) by inserting after section 924 the following:

13 **“SEC. 925. ACTIVITIES REGARDING WOMEN’S HEALTH.**

14 “(a) ESTABLISHMENT.—There is established within
15 the Office of the Director, an Office of Women’s Health
16 and Gender-Based Research (referred to in this section
17 as the ‘Office’). The Office shall be headed by a director
18 who shall be appointed by the Director of Healthcare and
19 Research Quality.

20 “(b) PURPOSE.—The official designated under sub-
21 section (a) shall—

22 “(1) report to the Director on the current
23 Agency level of activity regarding women’s health,
24 across, where appropriate, age, biological, and
25 sociocultural contexts, in all aspects of Agency work,

1 including the development of evidence reports and
2 clinical practice protocols and the conduct of re-
3 search into patient outcomes, delivery of health care
4 services, quality of care, and access to health care;

5 “(2) establish short-range and long-range goals
6 and objectives within the Agency for research impor-
7 tant to women’s health and, as relevant and appro-
8 priate, coordinate with other appropriate offices on
9 activities within the Agency that relate to health
10 services and medical effectiveness research, for
11 issues of particular concern to women;

12 “(3) identify projects in women’s health that
13 should be conducted or supported by the Agency;

14 “(4) consult with health professionals, non-
15 governmental organizations, consumer organizations,
16 women’s health professionals, and other individuals
17 and groups, as appropriate, on Agency policy with
18 regard to women; and

19 “(5) serve as a member of the Department of
20 Health and Human Services Coordinating Com-
21 mittee on Women’s Health (established under sec-
22 tion 229(b)(4)).”.

23 “(c) AUTHORIZATION OF APPROPRIATIONS.—For the
24 purpose of carrying out this section, there are authorized

1 to be appropriated such sums as may be necessary for
2 each of the fiscal years 2010 through 2014.”.

3 (f) HEALTH RESOURCES AND SERVICES ADMINIS-
4 TRATION OFFICE OF WOMEN’S HEALTH.—Title VII of
5 the Social Security Act (42 U.S.C. 901 et seq.) is amended
6 by adding at the end the following:

7 **“SEC. 713. OFFICE OF WOMEN’S HEALTH.**

8 “(a) ESTABLISHMENT.—The Secretary shall estab-
9 lish within the Office of the Administrator of the Health
10 Resources and Services Administration, an office to be
11 known as the Office of Women’s Health. The Office shall
12 be headed by a director who shall be appointed by the Ad-
13 ministrator.

14 “(b) PURPOSE.—The Director of the Office shall—

15 “(1) report to the Administrator on the current
16 Administration level of activity regarding women’s
17 health across, where appropriate, age, biological, and
18 sociocultural contexts;

19 “(2) establish short-range and long-range goals
20 and objectives within the Health Resources and
21 Services Administration for women’s health and, as
22 relevant and appropriate, coordinate with other ap-
23 propriate offices on activities within the Administra-
24 tion 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.

1 “(2) ADMINISTRATOR.—The term ‘Adminis-
2 trator’ means the Administrator of the Health Re-
3 sources and Services Administration.

4 “(3) OFFICE.—The term ‘Office’ means the Of-
5 fice of Women’s Health established under this sec-
6 tion in the Administration.

7 “(e) AUTHORIZATION OF APPROPRIATIONS.—For the
8 purpose of carrying out this section, there are authorized
9 to be appropriated such sums as may be necessary for
10 each of the fiscal years 2010 through 2014.”.

11 (g) FOOD AND DRUG ADMINISTRATION OFFICE OF
12 WOMEN’S HEALTH.—Chapter X of the Federal Food,
13 Drug, and Cosmetic Act (21 U.S.C. 391 et seq.) is amend-
14 ed by adding at the end the following:

15 **“SEC. 1011. OFFICE OF WOMEN’S HEALTH.**

16 “(a) ESTABLISHMENT.—There is established within
17 the Office of the Commissioner, an office to be known as
18 the Office of Women’s Health (referred to in this section
19 as the ‘Office’). The Office shall be headed by a director
20 who shall be appointed by the Commissioner of Food and
21 Drugs.

22 “(b) PURPOSE.—The Director of the Office shall—

23 “(1) report to the Commissioner of Food and
24 Drugs on current Food and Drug Administration
25 (referred to in this section as the ‘Administration’)

1 levels of activity regarding women's participation in
2 clinical trials and the analysis of data by sex in the
3 testing of drugs, medical devices, and biological
4 products across, where appropriate, age, biological,
5 and sociocultural contexts;

6 “(2) establish short-range and long-range goals
7 and objectives within the Administration for issues
8 of particular concern to women's health within the
9 jurisdiction of the Administration, including, where
10 relevant and appropriate, adequate inclusion of
11 women and analysis of data by sex in Administration
12 protocols and policies;

13 “(3) provide information to women and health
14 care providers on those areas in which differences
15 between men and women exist;

16 “(4) consult with pharmaceutical, biologics, and
17 device manufacturers, health professionals with ex-
18 pertise in women's issues, consumer organizations,
19 and women's health professionals on Administration
20 policy with regard to women;

21 “(5) make annual estimates of funds needed to
22 monitor clinical trials and analysis of data by sex in
23 accordance with needs that are identified; and

24 “(6) serve as a member of the Department of
25 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 its 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

1 construed to limit the authority of the Secretary of Health
2 and Human Services with respect to women's health, or
3 with respect to activities carried out through the Depart-
4 ment of Health and Human Services on the date of enact-
5 ment of this section.

6 **SEC. 222. ADMINISTRATIVE SIMPLIFICATION.**

7 (a) STANDARDS FOR FINANCIAL AND ADMINISTRA-
8 TIVE TRANSACTIONS.—

9 (1) IN GENERAL.—The Secretary shall adopt
10 and regularly update standards, implementation
11 specifications, and operating rules for the electronic
12 exchange and use of health information for purposes
13 of financial and administrative transactions (as pro-
14 vided for in paragraph (2)).

15 (2) ADDITIONAL REQUIREMENTS FOR FINAN-
16 CIAL AND ADMINISTRATIVE TRANSACTIONS.—The
17 standards, implementation specifications, and oper-
18 ating rules provided for in paragraph (1) shall—

19 (A) be unique with no conflicting or redun-
20 dant standards;

21 (B) be authoritative, requiring no addi-
22 tional standards or companion guides;

23 (C) be comprehensive and robust, requiring
24 minimal augmentation by paper transactions or
25 clarification by phone calls;

1 (D) enable the real time determination of
2 a patient's financial responsibility at the point
3 of service and, to the extent possible, prior to
4 service, including whether a patient is eligible
5 for a specific service with a specific physician at
6 a specific facility, which may include a machine-
7 readable health plan identification card;

8 (E) provide for timely acknowledgment;
9 and

10 (F) require that all data elements within a
11 standard or specification (such as reason and
12 remark codes) be described in unambiguous
13 terms (with no optional fields permitted and a
14 requirement that data elements be either re-
15 quired or conditioned upon set values in other
16 fields) with additional conditions being prohib-
17 ited.

18 (3) TIME FOR ADOPTION.—Not later than 2
19 years after the date of enactment of this section, the
20 Secretary shall adopt standards, implementation
21 specifications, and operating rules under this sec-
22 tion.

23 (4) REQUIREMENTS FOR INITIAL STAND-
24 ARDS.—The initial set of standards, implementation

1 specifications, and operating rules under paragraph
2 (1) shall include—

3 (A) requirements to clarify, refine, and ex-
4 pand, as needed, standards required under sec-
5 tion 1173 of the Social Security Act;

6 (B) requirements for acknowledgments,
7 such as those for receipt of a claim;

8 (C) requirements to permit electronic
9 funds transfers (to allow automated reconcili-
10 ation with the related health care payment and
11 remittance advice);

12 (D) the requirements of timely and trans-
13 parent claim and denial management processes,
14 including tracking, adjudication, and appeal
15 processing (for all participants, including health
16 insurance issuers, health care providers, and
17 patients); and

18 (E) other requirements relating to admin-
19 istrative simplification as identified by the Sec-
20 retary, in consultation with stakeholders.

21 (5) BUILDING ON EXISTING STANDARDS.—In
22 developing the standards, implementation specifica-
23 tions, and operating rules under paragraph (1), the
24 Secretary shall build upon existing and planned

1 standards, implementation specifications, and oper-
2 ating rules.

3 (6) EXPEDITED PROCEDURES FOR ADOPTION
4 OF ADDITIONS AND MODIFICATIONS TO STAND-
5 ARDS.—Notwithstanding any other provision of law,
6 the Secretary may use the following expedited proce-
7 dures for purposes of paragraph (1):

8 (A) EXPEDITED UPGRADE PROGRAM.—The
9 Secretary shall provide for an expedited up-
10 grade program (in this paragraph referred to as
11 the “upgrade program”), in accordance with
12 this paragraph, to develop and approve addi-
13 tions and modifications to the standards de-
14 scribed in paragraph (4) to improve the quality
15 of such standards or to extend the functionality
16 of such standards to meet evolving require-
17 ments in health care.

18 (B) PUBLICATION OF NOTICES.—Under
19 the upgrade program:

20 (i) VOLUNTARY NOTICE OF INITI-
21 ATION OF PROCESS.—Not later than 30
22 days after the date the Secretary receives
23 a notice from a standard setting organiza-
24 tion that the organization is initiating a
25 process to develop an addition or modifica-

1 tion to a standard described in paragraph
2 (4), the Secretary shall publish a notice in
3 the Federal Register that—

4 (I) identifies the subject matter
5 of the addition or modification;

6 (II) provides a description of how
7 persons may participate in the devel-
8 opment process; and

9 (III) invites public participation
10 in such process.

11 (ii) VOLUNTARY NOTICE OF PRELIMI-
12 NARY DRAFT OF ADDITIONS OR MODIFICA-
13 TIONS TO STANDARDS.—Not later than 30
14 days after the date the Secretary receives
15 a notice from a standard setting organiza-
16 tion that the organization has prepared a
17 preliminary draft of an addition or modi-
18 fication to a standard described in para-
19 graph (4), the Secretary shall publish a no-
20 tice in the Federal Register that—

21 (I) identifies the subject matter
22 of (and summarizes) the addition or
23 modification;

24 (II) specifies the procedure for
25 obtaining the draft;

1 (III) provides a description of
2 how persons may submit comments in
3 writing and at any public hearing or
4 meeting held by the organization on
5 the addition or modification; and

6 (IV) invites submission of such
7 comments and participation in such
8 hearing or meeting without requiring
9 the public to pay a fee to participate.

10 (iii) NOTICE OF PROPOSED ADDITION
11 OR MODIFICATION TO STANDARDS.—Not
12 later than 30 days after the date the Sec-
13 retary receives a notice from a standard
14 setting organization that the organization
15 has a proposed addition or modification to
16 a standard described in paragraph (4) that
17 the organization intends to submit under
18 subparagraph (D)(iii), the Secretary shall
19 publish a notice in the Federal Register
20 that contains, with respect to the proposed
21 addition or modification, the information
22 required in the notice under clause (ii)
23 with respect to the addition or modifica-
24 tion.

1 (iv) CONSTRUCTION.—Nothing in this
2 paragraph shall be construed as requiring
3 a standard setting organization to request
4 the notices described in clauses (i) and (ii)
5 with respect to an addition or modification
6 to a standard in order to qualify for an ex-
7 pedited determination under subparagraph
8 (C) with respect to a proposal submitted to
9 the Secretary for adoption of such addition
10 or modification.

11 (C) PROVISION OF EXPEDITED DETER-
12 MINATION.—Under the upgrade program and
13 with respect to a proposal by a standard setting
14 organization for an addition or modification to
15 a standard described in paragraph (4), if the
16 Secretary determines that the standard setting
17 organization developed such addition or modi-
18 fication in accordance with the requirements of
19 subparagraph (D) and the National Committee
20 on Vital and Health Statistics recommends ap-
21 proval of such addition or modification under
22 subparagraph (E), the Secretary shall provide
23 for expedited treatment of such proposal in ac-
24 cordance 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);

1 (II) makes publicly available a
2 written explanation for its response in
3 the proposed addition or modification
4 to comments submitted on a timely
5 basis; and

6 (III) makes public comments re-
7 ceived under clause (I) available, or
8 provides access to such comments, to
9 the Secretary.

10 (iii) SUBMITTAL OF FINAL PROPOSED
11 ADDITION OR MODIFICATION TO NCVHS.—
12 After completion of the process under
13 clause (ii), the standard setting organiza-
14 tion submits the proposed addition or
15 modification to the National Committee on
16 Vital and Health Statistics for review and
17 consideration under subparagraph (E).
18 Such submission shall include information
19 on the organization's compliance with the
20 notice and comment requirements (and re-
21 sponses to those comments) under clause
22 (ii).

23 (E) HEARINGS AND RECOMMENDATIONS
24 BY NATIONAL COMMITTEE ON VITAL AND
25 HEALTH STATISTICS.—Under the upgrade pro-

1 gram, upon receipt of a proposal submitted by
2 a standard setting organization under subpara-
3 graph (D)(iii) for the adoption of an addition or
4 modification to a standard, the National Com-
5 mittee on Vital and Health Statistics shall pro-
6 vide notice to the public and a reasonable op-
7 portunity for public testimony at a hearing on
8 such addition or modification. The Secretary
9 may participate in such hearing in such capac-
10 ity (including presiding ex officio) as the Sec-
11 retary shall determine appropriate. Not later
12 than 120 days after the date of receipt of the
13 proposal, the Committee shall submit to the
14 Secretary its recommendation to adopt (or not
15 adopt) the proposed addition or modification.

16 (F) DETERMINATION BY SECRETARY TO
17 ACCEPT OR REJECT NATIONAL COMMITTEE ON
18 VITAL AND HEALTH STATISTICS RECOMMENDA-
19 TION.—

20 (i) TIMELY DETERMINATION.—Under
21 the upgrade program, if the National Com-
22 mittee on Vital and Health Statistics sub-
23 mits to the Secretary a recommendation
24 under subparagraph (E) to adopt a pro-
25 posed addition or modification, not later

1 than 90 days after the date of receipt of
2 such recommendation the Secretary shall
3 make a determination to accept or reject
4 the recommendation and shall publish no-
5 tice of such determination in the Federal
6 Register not later than 90 days after the
7 date of the determination.

8 (ii) CONTENTS OF NOTICE.—If the
9 determination is to reject the recommenda-
10 tion, such notice shall include the reasons
11 for the rejection. If the determination is to
12 accept the recommendation, as part of
13 such notice the Secretary shall promulgate
14 the modified standard (including the ac-
15 cepted proposed addition or modification
16 accepted) as a final rule under this sub-
17 section without any further notice or public
18 comment period.

19 (iii) LIMITATION ON CONSIDER-
20 ATION.—The Secretary shall not consider a
21 proposal under this subparagraph unless
22 the Secretary determines that the require-
23 ments of subparagraph (D) (including pub-
24 lication of notice and opportunity for pub-

1 lic comment) have been met with respect to
2 the proposal.

3 (G) EXEMPTION FROM PAPERWORK RE-
4 DUCTION ACT.—Chapter 35 of title 44, United
5 States Code, shall not apply to a final rule pro-
6 mulgated under subparagraph (F).

7 (H) TREATMENT AS SATISFYING REQUIRE-
8 MENTS FOR NOTICE AND COMMENT.—Any re-
9 quirements under section 553 of title 5, United
10 States Code, relating to notice and an oppor-
11 tunity for public comment with respect to a
12 final rule promulgated under subparagraph (F)
13 shall be treated as having been met by meeting
14 the requirements of the notice and opportunity
15 for public comment provided under provisions
16 of subparagraphs (B)(iii), (D), and (E).

17 (I) MODIFICATION DEFINED.—For pur-
18 poses of this section, the term “modification”
19 includes a new version or a version upgrade.

20 (7) IMPLEMENTATION AND ENFORCEMENT.—
21 Not later than 2 years after the date of enactment
22 of this section, the Secretary shall submit to the ap-
23 propriate committees of Congress a plan for the im-
24 plementation and enforcement, by not later than 5
25 years after such date of enactment, of the standards,

1 implementation specifications, and operating rules
2 provided for under paragraph (1).

3 (b) HEALTH PLAN IDENTIFIER.—Not later than 1
4 year after the date of enactment of this section, the Sec-
5 retary shall promulgate a final rule to establish a National
6 Health Plan Identifier system.

7 **SEC. 223. PATIENT NAVIGATOR PROGRAM.**

8 Section 340A of the Public Health Service Act (42
9 U.S.C. 256a) is amended—

10 (1) in subsection (e), by adding at the end the
11 following:

12 “(3) MINIMUM CORE PROFICIENCIES.—The
13 Secretary shall not award a grant to an entity under
14 this section unless such entity provides assurances
15 that patient navigators recruited, assigned, trained,
16 or employed using grant funds meet minimum core
17 proficiencies, as defined by the entity that submits
18 the application, that are tailored for the main focus
19 or intervention of the navigator involved.”; and

20 (2) in subsection (m)—

21 (A) in paragraph (1), by striking “and
22 \$3,500,000 for fiscal year 2010.” and inserting
23 “\$3,500,000 for fiscal year 2010, and such
24 sums as may be necessary for each of fiscal
25 years 2011 through 2015.”; and

1 (B) in paragraph (2), by striking “2010”
2 and inserting “2015”.

3 **SEC. 224. AUTHORIZATION OF APPROPRIATIONS.**

4 Except where otherwise provided in this subtitle (or
5 an amendment made by this subtitle), there is authorized
6 to be appropriated such sums as may be necessary to carry
7 out this subtitle (and such amendments made by this sub-
8 title).

9 **Subtitle C—Civil and Criminal**
10 **Penalties for Acts Involving**
11 **Federal Health Care Programs;**
12 **Exception to Limitation on Cer-**
13 **tain Physician Referrals**

14 **SEC. 231. SAFE HARBORS TO ANTIKICKBACK CIVIL PEN-**
15 **ALTIES AND CRIMINAL PENALTIES FOR PRO-**
16 **VISION OF HEALTH INFORMATION TECH-**
17 **NOLOGY AND TRAINING SERVICES.**

18 (a) FOR CIVIL PENALTIES.—Section 1128A of the
19 Social Security Act (42 U.S.C. 1320a–7a) is amended—

20 (1) in subsection (b), by adding at the end the
21 following new paragraph:

22 “(4) For purposes of this subsection, inducements to
23 reduce or limit services described in paragraph (1) shall
24 not include the practical or other advantages resulting

1 from health information technology or related installation,
2 maintenance, support, or training services.”; and

3 (2) in subsection (i), by adding at the end the
4 following new paragraph:

5 “(8) The term ‘health information technology’
6 means hardware, software, license, right, intellectual
7 property, equipment, or other information tech-
8 nology (including new versions, upgrades, and
9 connectivity) designed or provided primarily for the
10 electronic creation, maintenance, or exchange of
11 health information to better coordinate care or im-
12 prove health care quality, efficiency, or research.”.

13 (b) FOR CRIMINAL PENALTIES.—Section 1128B of
14 such Act (42 U.S.C. 1320a–7b) is amended—

15 (1) in subsection (b)(3)—

16 (A) in subparagraph (G), by striking
17 “and” at the end;

18 (B) in the subparagraph (H) added by sec-
19 tion 237(d) of the Medicare Prescription Drug,
20 Improvement, and Modernization Act of 2003
21 (Public Law 108–173; 117 Stat. 2213)—

22 (i) by moving such subparagraph 2
23 ems to the left; and

24 (ii) by striking the period at the end
25 and inserting a semicolon;

1 (C) in the subparagraph (H) added by sec-
2 tion 431(a) of such Act (117 Stat. 2287)—

3 (i) by redesignating such subpara-
4 graph as subparagraph (I);

5 (ii) by moving such subparagraph 2
6 ems to the left; and

7 (iii) by striking the period at the end
8 and inserting “; and”; and

9 (D) by adding at the end the following new
10 subparagraph:

11 “(J) any nonmonetary remuneration (in the
12 form of health information technology, as defined in
13 section 1128A(i)(8), or related installation, mainte-
14 nance, support or training services) made to a per-
15 son by a specified entity (as defined in subsection
16 (g)) if—

17 “(i) the provision of such remuneration is
18 without an agreement between the parties or
19 legal condition that—

20 “(I) limits or restricts the use of the
21 health information technology to services
22 provided by the physician to individuals re-
23 ceiving services at the specified entity;

24 “(II) limits or restricts the use of the
25 health information technology in conjunc-

1 tion with other health information tech-
2 nology; or

3 “(III) conditions the provision of such
4 remuneration on the referral of patients or
5 business to the specified entity;

6 “(ii) such remuneration is arranged for in
7 a written agreement that is signed by the par-
8 ties involved (or their representatives) and that
9 specifies the remuneration solicited or received
10 (or offered or paid) and states that the provi-
11 sion of such remuneration is made for the pri-
12 mary purpose of better coordination of care or
13 improvement of health quality, efficiency, or re-
14 search; and

15 “(iii) the specified entity providing the re-
16 muneration (or a representative of such entity)
17 has not taken any action to disable any basic
18 feature of any hardware or software component
19 of such remuneration that would permit inter-
20 operability.”; and

21 (2) by adding at the end the following new sub-
22 section:

23 “(g) SPECIFIED ENTITY DEFINED.—For purposes of
24 subsection (b)(3)(J), the term ‘specified entity’ means an
25 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 (1) IN GENERAL.—The Secretary of Health and
2 Human Services shall conduct a study to determine
3 the impact of each of the safe harbors described in
4 paragraph (3). In particular, the study shall examine
5 the following:

6 (A) The effectiveness of each safe harbor
7 in increasing the adoption of health information
8 technology.

9 (B) The types of health information tech-
10 nology provided under each safe harbor.

11 (C) The extent to which the financial or
12 other business relationships between providers
13 under each safe harbor have changed as a re-
14 sult of the safe harbor in a way that adversely
15 affects or benefits the health care system or
16 choices available to consumers.

17 (D) The impact of the adoption of health
18 information technology on health care quality,
19 cost, and access under each safe harbor.

20 (2) REPORT.—Not later than 3 years after the
21 effective date described in subsection (c)(1), the Sec-
22 retary of Health and Human Services shall submit
23 to Congress a report on the study under paragraph
24 (1).

1 (3) SAFE HARBORS DESCRIBED.—For purposes
2 of paragraphs (1) and (2), the safe harbors de-
3 scribed in this paragraph are—

4 (A) the safe harbor under section
5 1128A(b)(4) of such Act (42 U.S.C. 1320a-
6 7a(b)(4)), as added by subsection (a)(1); and

7 (B) the safe harbor under section
8 1128B(b)(3)(J) of such Act (42 U.S.C. 1320a-
9 7b(b)(3)(J)), as added by subsection (b).

10 **SEC. 232. EXCEPTION TO LIMITATION ON CERTAIN PHYSI-**
11 **CIAN REFERRALS (UNDER STARK) FOR PRO-**
12 **VISION OF HEALTH INFORMATION TECH-**
13 **NOLOGY AND TRAINING SERVICES TO**
14 **HEALTH CARE PROFESSIONALS.**

15 (a) IN GENERAL.—Section 1877(b) of the Social Se-
16 curity Act (42 U.S.C. 1395nn(b)) is amended by adding
17 at the end the following new paragraph:

18 “(6) INFORMATION TECHNOLOGY AND TRAIN-
19 ING SERVICES.—

20 “(A) IN GENERAL.—Any nonmonetary re-
21 muneration (in the form of health information
22 technology or related installation, maintenance,
23 support or training services) made by a speci-
24 fied entity to a physician if—

1 “(i) the provision of such remunera-
2 tion is without an agreement between the
3 parties or legal condition that—

4 “(I) limits or restricts the use of
5 the health information technology to
6 services provided by the physician to
7 individuals receiving services at the
8 specified entity;

9 “(II) limits or restricts the use of
10 the health information technology in
11 conjunction with other health informa-
12 tion technology; or

13 “(III) conditions the provision of
14 such remuneration on the referral of
15 patients or business to the specified
16 entity;

17 “(ii) such remuneration is arranged
18 for in a written agreement that is signed
19 by the parties involved (or their represent-
20 atives) and that specifies the remuneration
21 made and states that the provision of such
22 remuneration is made for the primary pur-
23 pose of better coordination of care or im-
24 provement of health quality, efficiency, or
25 research; and

1 “(iii) the specified entity (or a rep-
2 resentative of such entity) has not taken
3 any action to disable any basic feature of
4 any hardware or software component of
5 such remuneration that would permit
6 interoperability.

7 “(B) HEALTH INFORMATION TECHNOLOGY
8 DEFINED.—For purposes of this paragraph, the
9 term ‘health information technology’ means
10 hardware, software, license, right, intellectual
11 property, equipment, or other information tech-
12 nology (including new versions, upgrades, and
13 connectivity) designed or provided primarily for
14 the electronic creation, maintenance, or ex-
15 change of health information to better coordi-
16 nate care or improve health care quality, effi-
17 ciency, or research.

18 “(C) SPECIFIED ENTITY DEFINED.—For
19 purposes of this paragraph, the term ‘specified
20 entity’ means an entity that is a hospital, group
21 practice, prescription drug plan sponsor, a
22 Medicare Advantage organization, or any other
23 such entity specified by the Secretary, consid-
24 ering the goals and objectives of this section, as
25 well as the goals to better coordinate the deliv-

1 ery of health care and to promote the adoption
2 and use of health information technology.”.

3 (b) EFFECTIVE DATE; EFFECT ON STATE LAWS.—

4 (1) EFFECTIVE DATE.—The amendment made
5 by subsection (a) shall take effect on the date that
6 is 120 days after the date of the enactment of this
7 Act.

8 (2) PREEMPTION OF STATE LAWS.—No State
9 (as defined in section 1101(a) of the Social Security
10 Act (42 U.S.C. 1301(a)) for purposes of title XI of
11 such Act) shall have in effect a State law that im-
12 poses a criminal or civil penalty for a transaction de-
13 scribed in section 1877(b)(6) of such Act, as added
14 by subsection (a), if the conditions described in such
15 section, with respect to such transaction, are met.

16 (c) STUDY AND REPORT TO ASSESS EFFECT OF EX-
17 CEPTION ON HEALTH SYSTEM.—

18 (1) IN GENERAL.—The Secretary of Health and
19 Human Services shall conduct a study to determine
20 the impact of the exception under section 1877(b)(6)
21 of such Act (42 U.S.C. 1395nn(b)(6)), as added by
22 subsection (a). In particular, the study shall examine
23 the following:

1 (A) The effectiveness of the exception in
2 increasing the adoption of health information
3 technology.

4 (B) The types of health information tech-
5 nology provided under the exception.

6 (C) The extent to which the financial or
7 other business relationships between providers
8 under the exception have changed as a result of
9 the exception in a way that adversely affects or
10 benefits the health care system or choices avail-
11 able to consumers.

12 (D) The impact of the adoption of health
13 information technology on health care quality,
14 cost, and access under the exception.

15 (2) REPORT.—Not later than 3 years after the
16 effective date described in subsection (b)(1), the Sec-
17 retary of Health and Human Services shall submit
18 to Congress a report on the study under paragraph
19 (1).

20 **SEC. 233. RULES OF CONSTRUCTION REGARDING USE OF**
21 **CONSORTIA.**

22 (a) APPLICATION TO SAFE HARBOR FROM CRIMINAL
23 PENALTIES.—Section 1128B(b)(3) of the Social Security
24 Act (42 U.S.C. 1320a–7b(b)(3)) is amended by adding
25 after and below subparagraph (J), as added by section

1 231(b)(1), the following: “For purposes of subparagraph
2 (J), nothing in such subparagraph shall be construed as
3 preventing a specified entity, consistent with the specific
4 requirements of such subparagraph, from forming a con-
5 sortium composed of health care providers, payers, em-
6 ployers, and other interested entities to collectively pur-
7 chase and donate health information technology, or from
8 offering health care providers a choice of health informa-
9 tion technology products in order to take into account the
10 varying needs of such providers receiving such products.”.

11 (b) APPLICATION TO STARK EXCEPTION.—Para-
12 graph (6) of section 1877(b) of the Social Security Act
13 (42 U.S.C. 1395nn(b)), as added by section 232(a), is
14 amended by adding at the end the following new subpara-
15 graph:

16 “(D) RULE OF CONSTRUCTION.—For pur-
17 poses of subparagraph (A), nothing in such
18 subparagraph shall be construed as preventing
19 a specified entity, consistent with the specific
20 requirements of such subparagraph, from—

21 “(i) forming a consortium composed
22 of health care providers, payers, employers,
23 and other interested entities to collectively
24 purchase and donate health information
25 technology; or

1 “(ii) offering health care providers a
2 choice of health information technology
3 products in order to take into account the
4 varying needs of such providers receiving
5 such products.”.

6 **TITLE III—IMPROVING THE**
7 **HEALTH OF THE AMERICAN**
8 **PEOPLE**

9 **Subtitle A—Modernizing Disease**
10 **Prevention and Public Health**
11 **Systems**

12 **SEC. 301. NATIONAL PREVENTION, HEALTH PROMOTION**
13 **AND PUBLIC HEALTH COUNCIL.**

14 (a) ESTABLISHMENT.—The President shall establish
15 a council to be known as the “National Prevention, Health
16 Promotion and Public Health Council” (referred to in this
17 section as the “Council”).

18 (b) CHAIRPERSON.—The President shall appoint an
19 individual to serve as the chairperson of the Council.

20 (c) COMPOSITION.—The Council shall be composed
21 of—

22 (1) the Secretary of Health and Human Serv-
23 ices;

24 (2) the Secretary of Agriculture;

25 (3) the Secretary of Education;

1 (4) the Chairman of the Federal Trade Com-
2 mission;

3 (5) the Chairman of the Federal Communica-
4 tions Commission;

5 (6) the Secretary of Transportation;

6 (7) the Secretary of Defense;

7 (8) the Secretary of Veterans Affairs;

8 (9) the Secretary of the Interior;

9 (10) the Secretary of Labor;

10 (11) the Secretary of Homeland Security;

11 (12) the Secretary of Housing and Urban De-
12 velopment;

13 (13) the Director of the United States Patent
14 and Trademark Office;

15 (14) the Administrator of the Environmental
16 Protection Agency;

17 (15) the Director of the Domestic Policy Coun-
18 cil;

19 (16) the Director of the Office of Personnel
20 Management;

21 (17) the Director of the Office of National
22 Drug Control Policy;

23 (18) the Chairman of the Corporation for Na-
24 tional and Community Service; and

1 (19) the head of any other Federal agency that
2 the chairperson determines is appropriate.

3 (d) PURPOSES AND DUTIES.—The Council shall—

4 (1) provide coordination and leadership at the
5 Federal level, and among all Federal departments
6 and agencies, with respect to prevention, wellness
7 and health promotion practices, the public health
8 system, and integrative health care in the United
9 States;

10 (2) after obtaining input from relevant stake-
11 holders, develop a national prevention, health pro-
12 motion, public health, and integrative health care
13 strategy that incorporates the most effective and
14 achievable means of improving the health status of
15 Americans and reducing the incidence of preventable
16 illness and disability in the United States;

17 (3) provide recommendations to the President
18 and Congress concerning the most pressing health
19 issues confronting the United States and changes in
20 Federal policy to achieve national wellness, health
21 promotion, and public health goals, including the re-
22 duction of tobacco use, sedentary behavior, and poor
23 nutrition;

24 (4) consider and propose evidence-based models,
25 policies, and innovative approaches for the pro-

1 motion of transformative models of prevention, inte-
2 grative health, and public health on individual and
3 community levels across the United States;

4 (5) establish processes for continual public
5 input, including input from State, regional, and local
6 leadership communities and other relevant stake-
7 holders, including Indian tribes and tribal organiza-
8 tions;

9 (6) submit the reports required under sub-
10 section (g); and

11 (7) carry out other activities determined appro-
12 priate by the President.

13 (e) MEETINGS.—The Council shall meet at the call
14 of the Chairperson.

15 (f) NATIONAL PREVENTION AND HEALTH PRO-
16 MOTION STRATEGY.—Not later than 1 year after the date
17 of enactment of this Act, the Chairperson, in consultation
18 with the Council, shall develop and make public a national
19 prevention, health promotion and public health strategy,
20 and shall review and revise such strategy periodically.
21 Such strategy shall—

22 (1) set specific goals and objectives for improv-
23 ing the health of the United States through feder-
24 ally-supported prevention, health promotion, and

1 public health programs, consistent with ongoing goal
2 setting efforts conducted by specific agencies;

3 (2) establish specific and measurable actions
4 and timelines to carry out the strategy, and deter-
5 mine accountability for meeting those timelines,
6 within and across Federal departments and agencies;
7 and

8 (3) make recommendations to improve Federal
9 efforts relating to prevention, health promotion, pub-
10 lic health, and integrative health care practices to
11 ensure Federal efforts are consistent with available
12 standards and evidence.

13 (g) REPORT.—Not later than July 1, 2010, and an-
14 nually thereafter through January 1, 2015, the Council
15 shall submit to the President and the relevant committees
16 of Congress, a report that—

17 (1) describes the activities and efforts on pre-
18 vention, health promotion, and public health and ac-
19 tivities to develop a national strategy conducted by
20 the Council during the period for which the report
21 is prepared;

22 (2) describes the national progress in meeting
23 specific prevention, health promotion, and public
24 health goals defined in the strategy and further de-
25 scribes corrective actions recommended by the Coun-

1 cil and taken by relevant agencies and organizations
2 to meet these goals;

3 (3) contains a list of national priorities on
4 health promotion and disease prevention to address
5 lifestyle behavior modification (smoking cessation,
6 proper nutrition, and appropriate exercise) and the
7 prevention measures for the 5 leading disease killers
8 in the United States;

9 (4) contains specific science-based initiatives to
10 achieve the measurable goals of Healthy People
11 2010 regarding nutrition, exercise, and smoking ces-
12 sation, and targeting the 5 leading disease killers in
13 the United States;

14 (5) contains specific plans for consolidating
15 Federal health programs and Centers that exist to
16 promote healthy behavior and reduce disease risk
17 (including eliminating programs and offices deter-
18 mined to be ineffective in meeting the priority goals
19 of Healthy People 2010);

20 (6) contains specific plans to ensure that all
21 Federal health care programs are fully coordinated
22 with science-based prevention recommendations by
23 the Director of the Centers for Disease Control and
24 Prevention;

1 (7) contains specific plans to ensure that all
2 non-Department of Health and Human Services pre-
3 vention programs are based on the science-based
4 guidelines developed by the Centers for Disease Con-
5 trol and Prevention under paragraph (4); and

6 (8) contains a list of new non-Federal and non-
7 government partners identified by the council to
8 build Federal capacity in health promotion and dis-
9 ease prevention efforts.

10 (h) PERIODIC REVIEWS.—The Secretary and the
11 Comptroller General of the United States shall jointly con-
12 duct periodic reviews, not less than every 5 years, and
13 evaluations of every Federal disease prevention and health
14 promotion initiative, program, and agency. Such reviews
15 shall be evaluated based on effectiveness in meeting
16 metrics-based goals with an analysis posted on such agen-
17 cies' public Internet websites.

18 (i) ANNUAL REQUEST TO GIVE TESTIMONY.—The
19 Chairperson shall annually request an opportunity to tes-
20 tify before Congress concerning—

21 (1) the progress made by the United States in
22 meeting the prevention, health promotion, and public
23 health goals defined in the strategy and the effec-
24 tiveness of Federal programs related to these goals;
25 and

1 (2) the amount and sources of Federal funds
2 that are targeted to prevention, health promotion,
3 and public health initiatives and results of program
4 evaluations.

5 **SEC. 302. PREVENTION AND PUBLIC HEALTH FUND.**

6 (a) PURPOSE.—It is the purpose of this section to
7 establish a Prevention and Public Health Fund (referred
8 to in this section as the “Fund”), to be administered
9 through the Department of Health and Human Services,
10 Office of the Secretary, to provide for expanded and sus-
11 tained national investment in prevention and public health
12 programs to improve health and help restrain the rate of
13 growth in private and public sector health care costs.

14 (b) FUNDING.—There are hereby authorized to be
15 appropriated, and appropriated, to the Fund, out of any
16 monies in the Treasury not otherwise appropriated—

- 17 (1) for fiscal year 2010, \$2,000,000,000;
18 (2) for fiscal year 2011, \$4,000,000,000;
19 (3) for fiscal year 2012, \$6,000,000,000;
20 (4) for fiscal year 2013, \$8,000,000,000;
21 (5) for fiscal year 2014, \$10,000,000,000;
22 (6) for fiscal year 2015, \$ 10,000,000,000;
23 (7) for fiscal year 2016, \$10,000,000,000;
24 (8) for fiscal year 2017, \$10,000,000,000;
25 (9) for fiscal year 2018, \$10,000,000,000; and

1 (10) for fiscal year 2019, and each fiscal year
2 thereafter, \$10,000,000,000.

3 (c) USE OF FUND.—The Secretary shall transfer
4 amounts in the Fund to accounts within the Department
5 of Health and Human Services to increase funding, over
6 the fiscal year 2008 level, for programs authorized by the
7 Public Health Service Act, for prevention, wellness and
8 public health activities including prevention research and
9 health screenings. Such transfers shall be subject to the
10 transfer authority provided for in the annual appropria-
11 tions Act for the fiscal year in which the funds become
12 available.

13 (d) TRANSFER AUTHORITY .—The Committee on Ap-
14 propriations of the Senate and the Committee on Appro-
15 priations of the House of Representatives may provide for
16 the transfer of funds in the Fund to eligible activities
17 under this section, subject to subsection (c).

18 **SEC. 303. CLINICAL AND COMMUNITY PREVENTIVE SERV-**
19 **ICES.**

20 (a) PREVENTIVE SERVICES TASK FORCE.—Section
21 915 of the Public Health Service Act (42 U.S.C. 299b-
22 4) is amended by striking subsection (a) and inserting the
23 following:

24 “(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-

1 tute of Medicine, specialty medical associations, pa-
2 tient groups, and scientific societies.

3 “(2) DUTIES.—The duties of the Task Force
4 shall include—

5 “(A) the development of additional topic
6 areas for new recommendations and interven-
7 tions related to those topic areas, including
8 those related to specific sub-populations and
9 age groups;

10 “(B) at least once during every 5-year pe-
11 riod, review interventions and update rec-
12 ommendations related to existing topic areas,
13 including new or improved techniques to assess
14 the health effects of interventions;

15 “(C) improved integration with Federal
16 Government health objectives and related target
17 setting for health improvement;

18 “(D) the enhanced dissemination of rec-
19 ommendations;

20 “(E) the provision of technical assistance
21 to those health care professionals, agencies and
22 organizations that request help in implementing
23 the Guide recommendations; and

24 “(F) the submission of yearly reports to
25 Congress and related agencies identifying gaps

1 in research, such as preventive services that re-
2 ceive an insufficient evidence statement, and
3 recommending priority areas that deserve fur-
4 ther examination, including areas related to
5 populations and age groups not adequately ad-
6 dressed by current recommendations.

7 “(3) ROLE OF AGENCY.—The Agency shall pro-
8 vide ongoing administrative, research, and technical
9 support for the operations of the Task Force, includ-
10 ing coordinating and supporting the dissemination of
11 the recommendations of the Task Force, ensuring
12 adequate staff resources, and assistance to those or-
13 ganizations requesting it for implementation of the
14 Guide’s recommendations.

15 “(4) COORDINATION WITH COMMUNITY PRE-
16 VENTIVE SERVICES TASK FORCE.—The Task Force
17 shall take appropriate steps to coordinate its work
18 with the Community Preventive Services Task Force
19 and the Advisory Committee on Immunization Prac-
20 tices, including the examination of how each task
21 force’s recommendations interact at the nexus of
22 clinic and community.

23 “(5) OPERATION.—Operation. In carrying out
24 the duties under paragraph (2), the Task Force is

1 not subject to the provisions of Appendix 2 of title
2 5, United States Code.

3 “(6) INDEPENDENCE.—All members of the
4 Task Force convened under this subsection, and any
5 recommendations made by such members, shall be
6 independent and, to the extent practicable, not sub-
7 ject to political pressure.

8 “(7) AUTHORIZATION OF APPROPRIATIONS.—
9 There are authorized to be appropriated such sums
10 as may be necessary for each fiscal year to carry out
11 the activities of the Task Force.”.

12 (b) COMMUNITY PREVENTIVE SERVICES TASK
13 FORCE.—Part P of title III of the Public Health Service
14 Act is amended by adding at the end the following:

15 **“SEC. 399S. COMMUNITY PREVENTIVE SERVICES TASK**
16 **FORCE.**

17 “(a) ESTABLISHMENT AND PURPOSE.—The Director
18 of the Centers for Disease Control and Prevention shall
19 convene an independent Community Preventive Services
20 Task Force (referred to in this subsection as the ‘Task
21 Force’) to be composed of individuals with appropriate ex-
22 pertise. Such Task Force shall review the scientific evi-
23 dence related to the effectiveness, appropriateness, and
24 cost-effectiveness of community preventive interventions
25 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-

1 proved techniques to assess the health effects of
2 interventions, including health impact assessment
3 and population health modeling;

4 “(3) improved integration with Federal Govern-
5 ment health objectives and related target setting for
6 health improvement;

7 “(4) the enhanced dissemination of rec-
8 ommendations;

9 “(5) the provision of technical assistance to
10 those health care professionals, agencies, and organi-
11 zations that request help in implementing the Guide
12 recommendations; and

13 “(6) providing yearly reports to Congress and
14 related agencies identifying gaps in research and
15 recommending priority areas that deserve further ex-
16 amination, including areas related to populations
17 and age groups not adequately addressed by current
18 recommendations.

19 “(c) **ROLE OF AGENCY.**—The Director shall provide
20 ongoing administrative, research, and technical support
21 for the operations of the Task Force, including coordi-
22 nating and supporting the dissemination of the rec-
23 ommendations of the Task Force, ensuring adequate staff
24 resources, and assistance to those organizations request-
25 ing it for implementation of Guide recommendations.

1 “(d) COORDINATION WITH PREVENTIVE SERVICES
2 TASK FORCE.—The Task Force shall take appropriate
3 steps to coordinate its work with the U.S. Preventive Serv-
4 ices Task Force and the Advisory Committee on Immuni-
5 zation Practices, including the examination of how each
6 task force’s recommendations interact at the nexus of clin-
7 ic and community.

8 “(e) OPERATION.—In carrying out the duties under
9 subsection (b), the Task Force shall not be subject to the
10 provisions of Appendix 2 of title 5, United States Code.

11 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
12 are authorized to be appropriated such sums as may be
13 necessary for each fiscal year to carry out the activities
14 of the Task Force.”.

15 **SEC. 304. EDUCATION AND OUTREACH CAMPAIGN REGARD-**
16 **ING PREVENTIVE BENEFITS.**

17 (a) IN GENERAL.—The Secretary of Health and
18 Human Services (referred to in this section as the “Sec-
19 retary”) shall provide for the planning and implementa-
20 tion of a national public–private partnership for a preven-
21 tion and health promotion outreach and education cam-
22 paign to raise public awareness of health improvement
23 across the life span. Such campaign shall include the dis-
24 semination of information that—

1 (1) describes the importance of utilizing preven-
2 tive services to promote wellness, reduce health dis-
3 parities, and mitigate chronic disease;

4 (2) promotes the use of preventive services rec-
5 ommended by the United States Preventive Services
6 Task Force and the Community Preventive Services
7 Task Force;

8 (3) encourages healthy behaviors linked to the
9 prevention of chronic diseases;

10 (4) explains the preventive services covered
11 under health plans offered through a Gateway;

12 (5) describes additional preventive care sup-
13 ported by the Centers for Disease Control and Pre-
14 vention, the Health Resources and Services Adminis-
15 tration, the Substance Abuse and Mental Health
16 Services Administration, the Advisory Committee on
17 Immunization Practices, and other appropriate agen-
18 cies; and

19 (6) includes general health promotion informa-
20 tion.

21 (b) CONSULTATION.—In coordinating the campaign
22 under subsection (a), the Secretary shall consult with the
23 Institute of Medicine to provide ongoing advice on evi-
24 dence-based scientific information for policy, program de-
25 velopment, and evaluation.

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

4 **Subtitle B—Increasing Access to**
5 **Clinical Preventive Services**

6 **SEC. 311. RIGHT CHOICES PROGRAM.**

7 (a) IN GENERAL.—Beginning on the date of enact-
8 ment of this Act, the Secretary shall award an annual
9 grant to each State for the establishment of “Right
10 Choices Programs”.

11 (b) ADMINISTRATION.—A State shall use amounts re-
12 ceived under a grant under subsection (a) to establish and
13 implement a Right Choices Program. A State may admin-
14 ister the program through the State Medicaid program or
15 through a comparable program. Under such program the
16 State shall—

17 (1) conduct outreach activities through State
18 health and human services programs, through safety
19 net facilities, or through other mechanisms deter-
20 mined appropriate by the State and the Secretary,
21 to identify uninsured individuals; and

22 (2) provide individuals identified under para-
23 graph (1), who are eligible individuals, with a Right
24 Choices Card to be used to access the services de-
25 scribed in subsection (d).

1 (c) ELIGIBLE INDIVIDUALS.—To be eligible to par-
2 ticipate in a Right Choices program under this section,
3 an individual shall—

4 (1) be a citizen or national of the United States
5 or an alien lawfully admitted to the United States
6 for permanent residence or otherwise residing in the
7 United States under color of law;

8 (2) not be covered under any health insurance
9 coverage during the 6-month period immediately
10 preceding the date of the determination of eligibility;

11 (3) have a family income that does not exceed
12 350 percent of the Federal poverty level for a family
13 of the size involved; and

14 (4) not be eligible for health care benefits pro-
15 vided through Medicare, Medicaid, the State Chil-
16 dren's Health Insurance Program, the armed serv-
17 ices, or the Department of Veterans Affairs.

18 (d) SERVICES.—Services described in this subsection
19 include the following:

20 (1) RISK-STRATIFIED CARE PLAN.—

21 (A) IN GENERAL.—An eligible individual
22 participating in the Right Choices Program
23 shall receive—

24 (i) a one-time health risk appraisal;

25 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).

10 (B) REFERRALS.—A care plan under sub-
11 paragraph (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

1 Administration, and other appropriate
2 sources); and

3 (ii) to the extent feasible, shall include
4 referrals by the State of individuals to
5 State and Federal programs for which they
6 may be eligible.

7 (2) TREATMENT.—An eligible individual partici-
8 pating in the Right Choices Program who has been
9 diagnosed with an illnesses shall be referred for
10 treatment to existing Federal or State safety net
11 providers or facilities, as appropriate (such as public
12 hospitals, community health centers, and rural
13 health clinics).

14 (e) PAYMENT OF PROVIDERS.—

15 (1) IN GENERAL.—The State shall be required
16 to reimburse health care providers that provide serv-
17 ices to individuals under the Right Choices Program.
18 Such reimbursement shall be approved by the Sec-
19 retary and determined based on the amount paid by
20 the State for similar services under the Medicaid
21 program in the State. Such reimbursement shall not
22 exceed the reimbursement provided for similar serv-
23 ices under the Medicare program.

24 (2) COST SHARING.—A State shall require that
25 an eligible individual with a family income that ex-

1 ceeds 200 percent of the Federal poverty level for a
2 family of the size involved that is participating in
3 the State's Right Choices Program, contribute a
4 portion of the cost of care under such Program on
5 a sliding scale as determined by the Secretary.

6 (f) AMOUNT OF GRANT.—The amount of a grant to
7 a State under this section for a year shall be determined
8 by the Secretary based on the rates of uninsured per cap-
9 ita of adults and children in the State (as compared to
10 all States) and the prevalence of the most common costly
11 chronic diseases in the State (as compared to all States).
12 The Secretary shall determine what amount of the grant
13 can be used for State administration of the program. The
14 Secretary may also set aside not more than 20 percent
15 of the funds appropriated to carry out this section to allo-
16 cate to programs that fund the treatment of individuals
17 participating in a Right Choices Program.

18 (g) PAYMENTS.—The Secretary shall determine the
19 manner in which payments shall be made to States under
20 this section on a prospective basis to enable the State to
21 provide individuals with access to items and services until
22 the Federal or State Gateways are available.

23 (h) LIMITATION ON FUNDS.—The Secretary shall not
24 obligate in excess of \$5,000,000,000 for any fiscal year
25 under this section.

1 (i) DEFINITION.—In this section, the term “State”
2 means each of the several States, the District of Columbia,
3 and each of the territories of the United States, and shall
4 include Indian tribes and tribal organizations (as such
5 terms are defined in section 4(b) and section 4(c) of the
6 Indian Self-Determination and Education Assistance Act).

7 (j) EVALUATION.—The Secretary shall conduct an
8 annual evaluation of the effectiveness of the pilot program
9 under this section.

10 (k) LIMITATION.—Nothing in this title (or an amend-
11 ment made by this title) shall require that a State use
12 State revenue to fund programs under this section.

13 (l) SUNSET.—The program under this section shall
14 terminate with respect to a State, on the date on which
15 the Federal or State Gateways are available.

16 **SEC. 312. SCHOOL-BASED HEALTH CLINICS.**

17 Part Q of title III of the Public Health Service Act
18 (42 U.S.C. 280h et seq.) is amended by adding at the end
19 the following:

20 **“SEC. 399Z-1. SCHOOL-BASED HEALTH CLINICS.**

21 **“(a) DEFINITIONS; ESTABLISHMENT OF CRITERIA.—**
22 **In this section:**

23 **“(1) COMPREHENSIVE PRIMARY HEALTH SERV-**
24 **ICES.—**The term ‘comprehensive primary health
25 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-

1 cally underserved children and adolescents
2 under subparagraph (A) that shall—

3 “(i) take into account any comments
4 received by the Secretary from the chief
5 executive officer of a State and local offi-
6 cials in a State; and

7 “(ii) include factors indicative of the
8 health status of such children and adoles-
9 cents of an area, including the ability of
10 the residents of such area to pay for health
11 services, the accessibility of such services,
12 the availability of health professionals to
13 such children and adolescents, and other
14 factors as determined appropriate by the
15 Secretary.

16 “(3) SCHOOL-BASED HEALTH CLINIC.—The
17 term ‘school-based health clinic’ means a health clin-
18 ic that—

19 “(A) is located in or near a school facility
20 of a school district or board;

21 “(B) is organized through school, commu-
22 nity, and health provider relationships;

23 “(C) is administered by a sponsoring facil-
24 ity; and

1 “(D) provides, at a minimum, comprehen-
2 sive primary health services during school hours
3 to children and adolescents by health profes-
4 sionals in accordance with established stand-
5 ards, community practice, reporting laws, and
6 other State laws, including parental consent
7 and notification laws that are not inconsistent
8 with Federal law.

9 “(4) SPONSORING FACILITY.—The term ‘spon-
10 soring facility’ is a community-based organization,
11 which may include—

12 “(A) a hospital;

13 “(B) a public health department;

14 “(C) a community health center;

15 “(D) a nonprofit health care agency;

16 “(E) a local education agency;

17 “(F) a faith-based organization; or

18 “(G) any other entity determined appro-
19 priate by the Secretary.

20 “(b) AUTHORITY TO AWARD GRANTS.—The Sec-
21 retary shall award grants for the costs of the operation
22 of school-based health clinics (referred to in this section
23 as ‘SBHCs’) that meet the requirements of this section.

24 “(c) APPLICATIONS.—To be eligible to receive a grant
25 under this section, an entity shall—

1 “(1) be an SBHC (as defined in subsection
2 (a)(4)); and

3 “(2) submit to the Secretary an application at
4 such time, in such manner, and containing—

5 “(A) evidence that the applicant meets all
6 criteria necessary to be designated an SBHC;

7 “(B) evidence of local need for the services
8 to be provided by the SBHC;

9 “(C) an assurance that—

10 “(i) SBHC services will be provided to
11 those children and adolescents for whom
12 parental or guardian consent has been ob-
13 tained in cooperation with Federal, State,
14 and local laws governing health care serv-
15 ice provision to children and adolescents;

16 “(ii) the SBHC has made and will
17 continue to make every reasonable effort to
18 establish and maintain collaborative rela-
19 tionships with other health care providers
20 in the catchment area of the SBHC;

21 “(iii) the SBHC will provide on-site
22 access during the academic day when
23 school is in session and 24-hour coverage
24 through an on-call system and through its
25 backup health providers to ensure access to

1 services on a year-round basis when the
2 school or the SBHC is closed;

3 “(iv) the SBHC will be integrated into
4 the school environment and will coordinate
5 health services with school personnel, such
6 as administrators, teachers, nurses, coun-
7 selors, and support personnel, as well as
8 with other community providers co-located
9 at the school;

10 “(v) the SBHC sponsoring facility as-
11 sumes all responsibility for the SBHC ad-
12 ministration, operations, and oversight;
13 and

14 “(vi) the SBHC will comply with Fed-
15 eral, State, and local laws concerning pa-
16 tient privacy and student records, includ-
17 ing regulations promulgated under the
18 Health Insurance Portability and Account-
19 ability Act of 1996 and section 444 of the
20 General Education Provisions Act; and

21 “(D) such other information as the Sec-
22 retary may require.

23 “(d) PREFERENCES.—In reviewing applications, the
24 Secretary may give preference to applicants who dem-
25 onstrate an ability to serve the following:

1 “(1) Communities that have evidenced barriers
2 to primary health care and mental health and sub-
3 stance use disorder prevention services for children
4 and adolescents.

5 “(2) Communities with high per capita numbers
6 of children and adolescents who are uninsured,
7 underinsured, or enrolled in public health insurance
8 programs.

9 “(3) Populations of children and adolescents
10 that have historically demonstrated difficulty in ac-
11 cessing health and mental health and substance use
12 disorder prevention services.

13 “(e) WAIVER OF REQUIREMENTS.—The Secretary
14 may—

15 “(1) under appropriate circumstances, waive
16 the application of all or part of the requirements of
17 this subsection with respect to an SBHC for not to
18 exceed 2 years; and

19 “(2) upon a showing of good cause, waive the
20 requirement that the SBHC provide all required
21 comprehensive primary health services for a des-
22 ignated period of time to be determined by the Sec-
23 retary.

24 “(f) USE OF FUNDS.—

1 “(1) FUNDS.—Funds awarded under a grant
2 under this section may be used for

3 “(A) acquiring and leasing equipment (in-
4 cluding the costs of amortizing the principle of,
5 and paying interest on, loans for such equip-
6 ment);

7 “(B) providing training related to the pro-
8 vision of required comprehensive primary health
9 services and additional health services;

10 “(C) the management and operation of
11 health center programs; and

12 “(D) the payment of salaries for physi-
13 cians, nurses, and other personnel of the
14 SBHC.

15 “(2) CONSTRUCTION.—The Secretary may
16 award grants which may be used to pay the costs as-
17 sociated with expanding and modernizing existing
18 buildings for use as an SBHC, including the pur-
19 chase of trailers or manufactured buildings to install
20 on the school property.

21 “(3) AMOUNT.—The amount of any grant made
22 in any fiscal year to an SBHC shall be determined
23 by the Secretary, taking into account—

24 “(A) the financial need of the SBHC;

1 “(B) State, local, or other operation fund-
2 ing provided to the SBHC; and

3 “(C) other factors as determined appro-
4 priate by the Secretary.

5 “(4) LIMITATION.—Any provider of services
6 that is determined by a State to be in violation of
7 a State law described in subsection (a)(4)(D) with
8 respect to activities carried out at a SBHC shall not
9 be eligible to receive additional funding under this
10 section.

11 “(g) MATCHING REQUIREMENT.—

12 “(1) IN GENERAL.—Each eligible entity that re-
13 ceives a grant under this section shall provide, from
14 non-Federal sources, an amount equal to 20 percent
15 of the amount of the grant (which may be provided
16 in cash or in-kind) to carry out the activities sup-
17 ported by the grant.

18 “(2) WAIVER.—The Secretary may waive all or
19 part of the matching requirement described in para-
20 graph (1) for any fiscal year for the SBHC if the
21 Secretary determines that applying the matching re-
22 quirement to the SBHC would result in serious
23 hardship or an inability to carry out the purposes of
24 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.

1 “(l) AUTHORIZATION OF APPROPRIATIONS.—For
2 purposes of carrying out this section, there are authorized
3 to be appropriated such sums as may be necessary for
4 each of the fiscal years 2010 through 2014.”.

5 **SEC. 313. ORAL HEALTHCARE PREVENTION ACTIVITIES.**

6 (a) IN GENERAL.—Title III of the Public Health
7 Service Act (42 U.S.C. 241 et seq.) is amended by adding
8 at the end the following:

9 **“PART S—ORAL HEALTHCARE PREVENTION**
10 **ACTIVITIES**

11 **“SEC. 399GG. ORAL HEALTHCARE PREVENTION EDUCATION**
12 **CAMPAIGN.**

13 “(a) ESTABLISHMENT.—The Secretary, acting
14 through the Director of the Centers for Disease Control
15 and Prevention and in consultation with professional oral
16 health organizations, shall, subject to the availability of
17 appropriations, establish a 5-year national, public edu-
18 cation campaign (referred to in this section as the ‘cam-
19 paign’) that is focused on oral healthcare prevention and
20 education, including prevention of oral disease such as
21 early childhood and other caries, periodontal disease, and
22 oral cancer.

23 “(b) REQUIREMENTS.—In establishing the campaign,
24 the Secretary shall—

1 “(1) ensure that activities are targeted towards
2 specific populations such as children, pregnant
3 women, parents, the elderly, individuals with disabili-
4 ties, and ethnic and racial minority populations, in-
5 cluding Indians, Alaska Natives and Native Hawai-
6 ians (as defined in section 4(c) of the Indian Health
7 Care Improvement Act) in a culturally and linguis-
8 tically appropriate manner; and

9 “(2) utilize science-based strategies to convey
10 oral health prevention messages that include, but are
11 not limited to, community water fluoridation and
12 dental sealants.

13 “(c) PLANNING AND IMPLEMENTATION.—Not later
14 than 2 years after the date of enactment of this section,
15 the Secretary shall begin implementing the 5-year cam-
16 paign. During the 2-year period referred to in the previous
17 sentence, the Secretary shall conduct planning activities
18 with respect to the campaign.

19 **“SEC. 399GG-1. RESEARCH-BASED DENTAL CARIES DISEASE**
20 **MANAGEMENT.**

21 “(a) IN GENERAL.—The Secretary, acting through
22 the Director of the Centers for Disease Control and Pre-
23 vention, shall award demonstration grants to eligible enti-
24 ties to demonstrate the effectiveness of research-based
25 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

1 section in planning and implementing the public education
2 campaign under section 399GG.

3 **“SEC. 399GG-2. AUTHORIZATION OF APPROPRIATIONS.**

4 “There is authorized to be appropriated to carry out
5 this part, such sums as may be necessary.”.

6 **SEC. 314. ORAL HEALTH IMPROVEMENT.**

7 (a) SCHOOL-BASED SEALANT PROGRAMS.—Section
8 317M(c)(1) of the Public Health Service Act (42 U.S.C.
9 247b-14(c)(1)) is amended by striking “may award grants
10 to States and Indian tribes” and inserting “shall award
11 a grant to each of the 50 States and territories and to
12 Indians, Indian tribes, tribal organizations and urban In-
13 dian organizations (as such terms are defined in section
14 4 of the Indian Health Care Improvement Act)”.

15 (b) ORAL HEALTH INFRASTRUCTURE.—Section
16 317M of the Public Health Service Act (42 U.S.C. 247b-
17 14) is amended—

18 (1) by redesignating subsections (d) and (e) as
19 subsections (e) and (f), respectively; and

20 (2) by inserting after subsection (c), the fol-
21 lowing:

22 “(d) ORAL HEALTH INFRASTRUCTURE.—

23 “(1) COOPERATIVE AGREEMENTS.—The Sec-
24 retary, acting through the Director of the Centers
25 for Disease Control and Prevention, shall enter into

1 cooperative agreements with State, territorial, and
2 Indian tribes or tribal organizations (as those terms
3 are defined in section 4 of the Indian Health Care
4 Improvement Act) to establish oral health leadership
5 and program guidance, oral health data collection
6 and interpretation, (including determinants of poor
7 oral health among vulnerable populations), a multi-
8 dimensional delivery system for oral health, and to
9 implement science-based programs (including dental
10 sealants and community water fluoridation) to im-
11 prove oral health.

12 “(2) AUTHORIZATION OF APPROPRIATIONS.—
13 There is authorized to be appropriated such sums as
14 necessary to carry out this subsection for fiscal years
15 2010 through 2014.”.

16 (c) UPDATING NATIONAL ORAL HEALTHCARE SUR-
17 VEILLANCE ACTIVITIES.—

18 (1) PRAMS.—

19 (A) IN GENERAL.—The Secretary of
20 Health and Human Services (referred to in this
21 subsection as the “Secretary”) shall carry out
22 activities to update and improve the Pregnancy
23 Risk Assessment Monitoring System (referred
24 to in this section as “PRAMS”) as it relates to
25 oral healthcare.

1 (B) STATE REPORTS AND MANDATORY
2 MEASUREMENTS.—

3 (i) IN GENERAL.—Not later than 5
4 years after the date of enactment of this
5 Act, and every 5 years thereafter, a State
6 shall submit to the Secretary a report con-
7 cerning activities conducted within the
8 State under PRAMS.

9 (ii) MEASUREMENTS.—The oral
10 healthcare measurements developed by the
11 Secretary for use under PRAMS shall be
12 mandatory with respect to States for pur-
13 poses of the State reports under clause (i).

14 (C) FUNDING.—There is authorized to be
15 appropriated to carry out this paragraph, such
16 sums as may be necessary.

17 (2) NATIONAL HEALTH AND NUTRITION EXAM-
18 INATION SURVEY.—The Secretary shall develop oral
19 healthcare components that shall include tooth-level
20 surveillance for inclusion in the National Health and
21 Nutrition Examination Survey. Such components
22 shall be updated by the Secretary at least every 6
23 years. For purposes of this paragraph, the term
24 “tooth-level surveillance” means a clinical examina-
25 tion where an examiner looks at each dental surface,

1 on each tooth in the mouth and as expanded by the
2 Division of Oral Health of the Centers for Disease
3 Control and Prevention.

4 (3) MEDICAL EXPENDITURES PANEL SURVEY.—
5 The Secretary shall ensure that the Medical Expend-
6 itures Panel Survey by the Agency for Healthcare
7 Research and Quality includes the verification of
8 dental utilization, expenditure, and coverage findings
9 through conduct of a look-back analysis.

10 (4) NATIONAL ORAL HEALTH SURVEILLANCE
11 SYSTEM.—

12 (A) APPROPRIATIONS.—There is author-
13 ized to be appropriated, such sums as may be
14 necessary for each of fiscal years 2010 through
15 2014 to increase the participation of States in
16 the National Oral Health Surveillance System
17 from 16 States to all 50 States, territories, and
18 District of Columbia.

19 (B) REQUIREMENTS.—The Secretary shall
20 ensure that the National Oral Health Surveil-
21 lance System include the measurement of early
22 childhood caries.

1 **Subtitle C—Creating Healthier**
2 **Communities**

3 **SEC. 321. COMMUNITY TRANSFORMATION GRANTS.**

4 (a) IN GENERAL.—The Secretary of Health and
5 Human Services (referred to in this section as the “Sec-
6 retary”), acting through the Director of the Centers for
7 Disease Control and Prevention (referred to in this section
8 as the “Director”), shall award competitive grants to
9 State and local governmental agencies and community-
10 based organizations for the implementation, evaluation,
11 and dissemination of evidence-based community preventive
12 health activities in order to reduce chronic disease rates,
13 address health disparities, and develop a stronger evi-
14 dence-base of effective prevention programming.

15 (b) ELIGIBILITY.—To be eligible to receive a grant
16 under subsection (a), an entity shall—

17 (1) be a—

18 (A) State governmental agency;

19 (B) local governmental agency;

20 (C) national network of community-based
21 organizations; or

22 (D) Indian tribe; and

23 (2) submit to the Director an application at
24 such time, in such a manner, and containing such
25 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-

1 tion curricula, and activities to prevent
2 chronic diseases;

3 (ii) creating the infrastructure to sup-
4 port active living and access to nutritious
5 foods in a safe environment;

6 (iii) developing and promoting pro-
7 grams targeting a variety of age levels to
8 increase access to nutrition, physical activ-
9 ity and smoking cessation, enhance safety
10 in a community, or address any other
11 chronic disease priority area identified by
12 the grantee;

13 (iv) assessing and implementing work-
14 site wellness programming and incentives;

15 (v) working to highlight healthy op-
16 tions at restaurants and other food venues;

17 (vi) prioritizing strategies to reduce
18 racial and ethnic disparities, including so-
19 cial determinants of health; and

20 (vii) addressing the needs of special
21 populations, including all age groups and
22 individuals with disabilities.

23 (3) COMMUNITY-BASED PREVENTION HEALTH
24 ACTIVITIES.—

1 (A) IN GENERAL.—An eligible entity shall
2 use amounts received under a grant under this
3 section to implement a variety of programs,
4 policies, and infrastructure improvements to
5 promote healthier lifestyles.

6 (B) ACTIVITIES.—An eligible entity shall
7 implement activities detailed in the community
8 transformation plan under paragraph (2).

9 (C) IN-KIND SUPPORT.—An eligible entity
10 shall provide in-kind resources such as staff,
11 equipment, or office space in carrying out ac-
12 tivities under this section.

13 (4) EVALUATION.—

14 (A) IN GENERAL.—An eligible entity shall
15 use amounts provided under a grant under this
16 section to conduct activities to measure changes
17 in the prevalence of chronic disease risk factors
18 among community members participating in
19 preventive health activities

20 (B) TYPES OF MEASURES.—In carrying
21 out subparagraph (A), the eligible entity shall,
22 with respect to residents in the community,
23 measure—

24 (i) changes in weight;

25 (ii) changes in proper nutrition;

- 1 (iii) changes in physical activity;
- 2 (iv) changes in tobacco use prevalence;
- 3 (v) other factors using community-
- 4 specific data from the Behavioral Risk
- 5 Factor Surveillance Survey; and
- 6 (vi) other factors as determined by the
- 7 Secretary.

8 (C) REPORTING.—An eligible entity shall
9 annually submit to the Director a report con-
10 taining an evaluation of activities carried out
11 under the grant.

12 (5) DISSEMINATION.—A grantee under this sec-
13 tion shall—

14 (A) meet at least annually in regional or
15 national meetings to discuss challenges, best
16 practices, and lessons learned with respect to
17 activities carried out under the grant; and

18 (B) develop models for the replication of
19 successful programs and activities and the men-
20 toring of other eligible entities.

21 (d) TRAINING.—

22 (1) IN GENERAL.—The Director shall develop a
23 program to provide training for eligible entities on
24 effective strategies for the prevention and control of
25 chronic disease

1 (2) COMMUNITY TRANSFORMATION PLAN.—The
2 Director shall provide appropriate feedback and
3 technical assistance to grantees to establish commu-
4 nity transformation plans

5 (3) EVALUATION.—The Director shall provide a
6 literature review and framework for the evaluation
7 of programs conducted as part of the grant program
8 under this section, in addition to working with aca-
9 demic institutions or other entities with expertise in
10 outcome evaluation.

11 (e) PROHIBITION.—A grantee shall not use funds
12 provided under a grant under this section to create video
13 games or to carry out any other activities that may lead
14 to higher rates of obesity or inactivity.

15 (f) AUTHORIZATION OF APPROPRIATIONS.—There
16 are authorized to be appropriated to carry out this section,
17 such sums as may be necessary for each fiscal years 2010
18 through 2014.

19 **SEC. 322. HEALTHY AGING, LIVING WELL.**

20 (a) IN GENERAL.—The Secretary of Health and
21 Human Services (referred to in this section as the “Sec-
22 retary”), acting through the Director of the Centers for
23 Disease Control and Prevention, shall award grants to
24 State or local health departments and Indian tribes to
25 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.

1 (c) USE OF FUNDS.—

2 (1) IN GENERAL.—A State or local health de-
3 partment shall use amounts received under a grant
4 under this section to carry out a program to provide
5 the services described in this subsection to individ-
6 uals who are between 55 and 64 years of age.

7 (2) PUBLIC HEALTH INTERVENTIONS.—

8 (A) IN GENERAL.—In developing and im-
9 plementing such activities, a grantee shall col-
10 laborate with the Centers for Disease Control
11 and Prevention and the Administration on
12 Aging, and relevant local agencies and organi-
13 zations.

14 (B) TYPES OF INTERVENTION ACTIVI-
15 TIES.—Intervention activities conducted under
16 this paragraph may include efforts to improve
17 nutrition, increase physical activity, reduce to-
18 bacco use and substance abuse, improve mental
19 health, and promote healthy lifestyles among
20 the target population.

21 (3) COMMUNITY PREVENTIVE SCREENINGS.—

22 (A) IN GENERAL.—In addition to commu-
23 nity-wide public health interventions, a State or
24 local health department shall use amounts re-
25 ceived under a grant under this section to con-

1 duct ongoing health screening to identify risk
2 factors for cardiovascular disease, stroke, and
3 diabetes among individuals who are between 55
4 and 64 years of age.

5 (B) TYPES OF SCREENING ACTIVITIES.—
6 Screening activities conducted under this para-
7 graph may include—

- 8 (i) mental health/behavioral health
9 and substance use disorders;
10 (ii) physical activity, smoking, and nu-
11 trition; and
12 (iii) any other measures deemed ap-
13 propriate by the Secretary.

14 (C) MONITORING.—Grantees under this
15 section shall maintain records of screening re-
16 sults under this paragraph to establish the
17 baseline data for monitoring the targeted popu-
18 lation

19 (4) CLINICAL REFERRAL/TREATMENT FOR
20 CHRONIC DISEASES.—

21 (A) IN GENERAL.—A State or local health
22 department shall use amounts received under a
23 grant under this section to ensure that individ-
24 uals between 55 and 64 years of age who are
25 found to have chronic disease risk factors

1 through the screening activities described in
2 paragraph (3)(B), receive clinical referral/treat-
3 ment for follow-up services to reduce such risk.

4 (B) MECHANISM.—

5 (i) IDENTIFICATION AND DETERMINA-
6 TION OF STATUS.—With respect to each
7 individual with risk factors for or having
8 heart disease, stroke, diabetes, or any
9 other condition for which such individual
10 was screened under paragraph (3), a
11 grantee under this section shall determine
12 whether or not such individual is covered
13 under any public or private health insur-
14 ance program.

15 (ii) INSURED INDIVIDUALS.—An indi-
16 vidual determined to be covered under a
17 health insurance program under clause (i)
18 shall be referred by the grantee to the ex-
19 isting providers under such program or, if
20 such individual does not have a current
21 provider, to a provider who is in-network
22 with respect to the program involved.

23 (iii) UNINSURED INDIVIDUALS.—With
24 respect to an individual determined to be
25 uninsured under clause (i), the grantee's

1 community-based clinical partner described
2 in subsection (b)(4) shall assist the indi-
3 vidual in determining eligibility for avail-
4 able public coverage options and identify
5 other appropriate community health care
6 resources and assistance programs.

7 (C) PUBLIC HEALTH INTERVENTION PRO-
8 GRAM.—A State or local health department
9 shall use amounts received under a grant under
10 this section to enter into contracts with commu-
11 nity health centers or rural health clinics and
12 mental health and substance use disorder serv-
13 ice providers to assist in the referral/treatment
14 of at risk patients to community resources for
15 clinical follow-up and help determine eligibility
16 for other public programs.

17 (5) GRANTEE EVALUATION.—An eligible entity
18 shall use amounts provided under a grant under this
19 section to conduct activities to measure changes in
20 the prevalence of chronic disease risk factors among
21 participants.

22 (d) PILOT PROGRAM EVALUATION.—The Secretary
23 shall conduct an annual evaluation of the effectiveness of
24 the pilot program under this section. In determining such
25 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-

1 fices, clinics, emergency rooms, hospitals, and other med-
2 ical settings. The standards shall ensure that such equip-
3 ment is accessible to, and usable by, individuals with ac-
4 cessibility needs, and shall allow independent entry to, use
5 of, and exit from the equipment by such individuals to the
6 maximum extent possible.

7 “(b) MEDICAL DIAGNOSTIC EQUIPMENT COV-
8 ERED.—The standards issued under subsection (a) for
9 medical diagnostic equipment shall apply to equipment
10 that includes examination tables, examination chairs (in-
11 cluding chairs used for eye examinations or procedures,
12 and dental examinations or procedures), weight scales,
13 mammography equipment, x-ray machines, and other radi-
14 ological equipment commonly used for diagnostic purposes
15 by health professionals.

16 “(c) REVIEW AND AMENDMENT.—The Architectural
17 and Transportation Barriers Compliance Board, in con-
18 sultation with the Commissioner of the Food and Drug
19 Administration, shall periodically review and, as appro-
20 priate, amend the standards in accordance with the Ad-
21 ministrative Procedure Act (2 U.S.C. 551 et seq.).”.

22 **SEC. 324. IMMUNIZATIONS.**

23 (a) STATE AUTHORITY TO PURCHASE REC-
24 OMMENDED VACCINES FOR ADULTS.—Section 317 of the

1 Public Health Service Act (42 U.S.C. 247b) is amended
2 by adding at the end the following:

3 “(l) AUTHORITY TO PURCHASE RECOMMENDED VAC-
4 CINES FOR ADULTS.—

5 “(1) IN GENERAL.—The Secretary may nego-
6 tiate and enter into contracts with manufacturers of
7 vaccines for the purchase and delivery of vaccines
8 for adults as provided for under subsection (e).

9 “(2) STATE PURCHASE.—A State may obtain
10 additional quantities of such adult vaccines (subject
11 to amounts specified to the Secretary by the State
12 in advance of negotiations) through the purchase of
13 vaccines from manufacturers at the applicable price
14 negotiated by the Secretary under this subsection.”.

15 (b) DEMONSTRATION PROGRAM TO IMPROVE IMMU-
16 NIZATION COVERAGE.—Section 317 of the Public Health
17 Service Act (42 U.S.C. 247b), as amended by subsection
18 (a), is further amended by adding at the end the following:

19 “(m) DEMONSTRATION PROGRAM TO IMPROVE IM-
20 MUNIZATION COVERAGE.—

21 “(1) IN GENERAL.—The Secretary, acting
22 through the Director of the Centers for Disease
23 Control and Prevention, shall establish a demonstra-
24 tion program to award grants to States to improve
25 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

1 in combination with one or more other interven-
2 tions;

3 “(C) reducing out-of-pocket costs for fami-
4 lies for vaccines and their administration;

5 “(D) carrying out immunization-promoting
6 strategies for participants or clients of public
7 programs, including assessments of immuniza-
8 tion status, referrals to health care providers,
9 education, provision of on-site immunizations,
10 or incentives for immunization;

11 “(E) providing for home visits that pro-
12 mote immunization through education, assess-
13 ments of need, referrals, provision of immuniza-
14 tions, or other services;

15 “(F) providing reminders or recalls for im-
16 munization providers;

17 “(G) conducting assessments of, and pro-
18 viding feedback to, immunization providers;

19 “(H) any combination of one or more
20 interventions described in this paragraph; or

21 “(I) immunization information systems to
22 allow all States to have electronic databases for
23 immunization records.

24 “(4) CONSIDERATION.—In awarding grants
25 under this subsection, the Secretary shall consider

1 any reviews or recommendations of the Task Force
2 on Community Preventive Services.

3 “(5) EVALUATION.—Not later than 3 years
4 after the date on which a State receives a grant
5 under this subsection, the State shall submit to the
6 Secretary an evaluation of progress made toward im-
7 proving immunization coverage rates among high-
8 risk populations within the State.

9 “(6) REPORT TO CONGRESS.—Not later than 4
10 years after the date of enactment of the Affordable
11 Health Choices Act, the Secretary shall submit to
12 Congress a report concerning the effectiveness of the
13 demonstration program established under this sub-
14 section together with recommendations on whether
15 to continue and expand such program.

16 “(7) AUTHORIZATION OF APPROPRIATIONS.—
17 There is authorized to be appropriated to carry out
18 this subsection, such sums as may be necessary for
19 each of fiscal years 2010 through 2014.”.

20 (c) REAUTHORIZATION OF IMMUNIZATION PRO-
21 GRAM.—Section 317(j) of the Public Health Service Act
22 (42 U.S.C. 247b(j)) is amended—

23 (1) in paragraph (1), by striking “for each of
24 the fiscal years 1998 through 2005”; and

1 (2) in paragraph (2), by striking “after October
2 1, 1997,”.

3 (d) **RULE OF CONSTRUCTION REGARDING ACCESS TO**
4 **IMMUNIZATIONS.**—Nothing in this section (including the
5 amendments made by this section), or any other provision
6 of this Act (including any amendments made by this Act)
7 shall be construed to decrease children’s access to immuni-
8 zations.

9 **SEC. 325. NUTRITION LABELING OF STANDARD MENU**
10 **ITEMS AT CHAIN RESTAURANTS AND OF AR-**
11 **TICLES OF FOOD SOLD FROM VENDING MA-**
12 **CHINES.**

13 (a) **TECHNICAL AMENDMENTS.**—Section
14 403(q)(5)(A) of the Federal Food, Drug, and Cosmetic
15 Act (21 U.S.C. 343(q)(5)(A)) is amended—

16 (1) in subitem (i), by inserting at the beginning
17 “except as provided in clause (H)(ii)(III),”; and

18 (2) in subitem (ii), by inserting at the begin-
19 ning “except as provided in clause (H)(ii)(III),”.

20 (b) **LABELING REQUIREMENTS.**—Section 403(q)(5)
21 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
22 343(q)(5)) is amended by adding at the end the following:

23 “(H) **RESTAURANTS, RETAIL FOOD ESTABLISH-**
24 **MENTS, AND VENDING MACHINES.**—

1 “(i) GENERAL REQUIREMENTS FOR RES-
2 TAURANTS AND SIMILAR RETAIL FOOD ESTABLISH-
3 MENTS.—Except for food described in subclause
4 (vii), in the case of food that is a standard menu
5 item that is offered for sale in a restaurant or simi-
6 lar retail food establishment that is part of a chain
7 with 20 or more locations doing business under the
8 same name (regardless of the type of ownership of
9 the locations) and offering for sale substantially the
10 same menu items, the restaurant or similar retail
11 food establishment shall disclose the information de-
12 scribed in subclauses (ii) and (iii).

13 “(ii) INFORMATION REQUIRED TO BE DIS-
14 CLOSED BY RESTAURANTS AND RETAIL FOOD ES-
15 TABLISHMENTS.—Except as provided in subclause
16 (vii), the restaurant or similar retail food establish-
17 ment shall disclose in a clear and conspicuous man-
18 ner—

19 “(I)(aa) in a nutrient content disclosure
20 statement adjacent to the name of the standard
21 menu item, so as to be clearly associated with
22 the standard menu item, on the menu listing
23 the item for sale, the number of calories con-
24 tained in the standard menu item, as usually
25 prepared and offered for sale; and

1 “(bb) a succinct statement concerning sug-
2 gested daily caloric intake, as specified by the
3 Secretary by regulation and posted prominently
4 on the menu and designed to enable the public
5 to understand, in the context of a total daily
6 diet, the significance of the caloric information
7 that is provided on the menu;

8 “(II)(aa) in a nutrient content disclosure
9 statement adjacent to the name of the standard
10 menu item, so as to be clearly associated with
11 the standard menu item, on the menu board,
12 including a drive-through menu board, the
13 number of calories contained in the standard
14 menu item, as usually prepared and offered for
15 sale; and

16 “(bb) a succinct statement concerning sug-
17 gested daily caloric intake, as specified by the
18 Secretary by regulation and posted prominently
19 on the menu board, designed to enable the pub-
20 lic to understand, in the context of a total daily
21 diet, the significance of the nutrition informa-
22 tion that is provided on the menu board;

23 “(III) in a written form, available on the prem-
24 ises of the restaurant or similar retail establishment
25 and to the consumer upon request, the nutrition in-

1 formation required under clauses (C) and (D) of
2 subparagraph (1); and

3 “(IV) on the menu or menu board, a promi-
4 nent, clear, and conspicuous statement regarding the
5 availability of the information described in item
6 (III).

7 “(iii) SELF-SERVICE FOOD AND FOOD ON DIS-
8 PLAY.—Except as provided in subclause (vii), in the
9 case of food sold at a salad bar, buffet line, cafeteria
10 line, or similar self-service facility, and for self-serv-
11 ice beverages or food that is on display and that is
12 visible to customers, a restaurant or similar retail
13 food establishment shall place adjacent to each food
14 offered a sign that lists calories per displayed food
15 item or per serving.

16 “(iv) REASONABLE BASIS.—For the purposes of
17 this clause, a restaurant or similar retail food estab-
18 lishment shall have a reasonable basis for its nutri-
19 ent content disclosures, including nutrient databases,
20 cookbooks, laboratory analyses, and other reasonable
21 means, as described in section 101.10 of title 21,
22 Code of Federal Regulations (or any successor regu-
23 lation) or in a related guidance of the Food and
24 Drug Administration.

1 “(v) MENU VARIABILITY AND COMBINATION
2 MEALS.—The Secretary shall establish by regulation
3 standards for determining and disclosing the nutri-
4 ent content for standard menu items that come in
5 different flavors, varieties, or combinations, but
6 which are listed as a single menu item, such as soft
7 drinks, ice cream, pizza, doughnuts, or children’s
8 combination meals, through means determined by
9 the Secretary, including ranges, averages, or other
10 methods.

11 “(vi) ADDITIONAL INFORMATION.—If the Sec-
12 retary determines that a nutrient, other than a nu-
13 trient required under subclause (ii)(III), should be
14 disclosed for the purpose of providing information to
15 assist consumers in maintaining healthy dietary
16 practices, the Secretary may require, by regulation,
17 disclosure of such nutrient in the written form re-
18 quired under subclause (ii)(III).

19 “(vii) NONAPPLICABILITY TO CERTAIN FOOD.—

20 “(I) IN GENERAL.—Subclauses (i) through
21 (vi) do not apply to—

22 “(aa) items that are not listed on a
23 menu or menu board (such as condiments
24 and other items placed on the table or
25 counter for general use);

1 “(bb) daily specials, temporary menu
2 items appearing on the menu for less than
3 60 days per calendar year, or custom or-
4 ders; or

5 “(cc) such other food that is part of
6 a customary market test appearing on the
7 menu for less than 90 days, under terms
8 and conditions established by the Sec-
9 retary.

10 “(II) WRITTEN FORMS.—Subparagraph
11 (5)(C) shall apply to any regulations promul-
12 gated under subclauses (ii)(III) and (vi).

13 “(viii) VENDING MACHINES.—

14 “(I) IN GENERAL.—In the case of an arti-
15 cle of food sold from a vending machine that—

16 “(aa) does not permit a prospective
17 purchaser to examine the Nutrition Facts
18 Panel before purchasing the article or does
19 not otherwise provide visible nutrition in-
20 formation at the point of purchase; and

21 “(bb) is operated by a person who is
22 engaged in the business of owning or oper-
23 ating 20 or more vending machines,
24 the vending machine operator shall provide a
25 sign in close proximity to each article of food or

1 the selection button that includes a clear and
2 conspicuous statement disclosing the number of
3 calories contained in the article.

4 “(ix) VOLUNTARY PROVISION OF NUTRITION IN-
5 FORMATION.—

6 “(I) IN GENERAL.—An authorized official
7 of any restaurant or similar retail food estab-
8 lishment or vending machine operator not sub-
9 ject to the requirements of this clause may elect
10 to be subject to the requirements of such
11 clause, by registering biannually the name and
12 address of such restaurant or similar retail food
13 establishment or vending machine operator with
14 the Secretary, as specified by the Secretary by
15 regulation.

16 “(II) REGISTRATION.—Within 120 days of
17 enactment of this clause, the Secretary shall
18 publish a notice in the Federal Register speci-
19 fying the terms and conditions for implementa-
20 tion of item (I), pending promulgation of regu-
21 lations.

22 “(III) RULE OF CONSTRUCTION.—Nothing
23 in this subclause shall be construed to authorize
24 the Secretary to require an application, review,

1 or licensing process for any entity to register
2 with the Secretary, as described in such item.

3 “(x) REGULATIONS.—

4 “(I) PROPOSED REGULATION.—Not later
5 than 1 year after the date of enactment of this
6 clause, the Secretary shall promulgate proposed
7 regulations to carry out this clause.

8 “(II) CONTENTS.—In promulgating regula-
9 tions, the Secretary shall—

10 “(aa) consider standardization of rec-
11 ipes and methods of preparation, reason-
12 able variation in serving size and formula-
13 tion of menu items, space on menus and
14 menu boards, inadvertent human error,
15 training of food service workers, variations
16 in ingredients, and other factors, as the
17 Secretary determines; and

18 “(bb) specify the format and manner
19 of the nutrient content disclosure require-
20 ments under this subclause.

21 “(III) REPORTING.—The Secretary shall
22 submit to the Committee on Health, Education,
23 Labor, and Pensions of the Senate and the
24 Committee on Energy and Commerce of the
25 House of Representatives a quarterly report

1 that describes the Secretary’s progress toward
2 promulgating final regulations under this sub-
3 paragraph.

4 “(xi) DEFINITION.—In this clause, the term
5 ‘menu’ or ‘menu board’ means the primary writing
6 of the restaurant or other similar retail food estab-
7 lishment from which a consumer makes an order se-
8 lection.”

9 (c) NATIONAL UNIFORMITY.—Section 403A(a)(4) of
10 the Federal Food, Drug, and Cosmetic Act (21 U.S.C.
11 343-1(a)(4)) is amended by striking “except a require-
12 ment for nutrition labeling of food which is exempt under
13 subclause (i) or (ii) of section 403(q)(5)(A)” and inserting
14 “except that this paragraph does not apply to food that
15 is offered for sale in a restaurant or similar retail food
16 establishment that is not part of a chain with 20 or more
17 locations doing business under the same name (regardless
18 of the type of ownership of the locations) and offering for
19 sale substantially the same menu items unless such res-
20 taurant or similar retail food establishment complies with
21 the voluntary provision of nutrition information require-
22 ments under section 403(q)(5)(H)(ix)”.

23 (d) RULE OF CONSTRUCTION.—Nothing in the
24 amendments made by this section shall be construed—

1 (1) to preempt any provision of State or local
2 law, unless such provision establishes or continues
3 into effect nutrient content disclosures of the type
4 required under section 403(q)(5)(H) of the Federal
5 Food, Drug, and Cosmetic Act (as added by sub-
6 section (b)) and is expressly preempted under sub-
7 section (a)(4) of such section;

8 (2) to apply to any State or local requirement
9 respecting a statement in the labeling of food that
10 provides for a warning concerning the safety of the
11 food or component of the food; or

12 (3) except as provided in section
13 403(q)(5)(H)(ix) of the Federal Food, Drug, and
14 Cosmetic Act (as added by subsection (b)), to apply
15 to any restaurant or similar retail food establish-
16 ment other than a restaurant or similar retail food
17 establishment described in section 403(q)(5)(H)(i) of
18 such Act.

19 **SEC. 326. ENCOURAGING EMPLOYER-SPONSORED**
20 **WELLNESS PROGRAMS.**

21 A group health plan and a health insurance issuer
22 offering health insurance coverage in connection with a
23 group health plan may offer incentives to an individual
24 who voluntarily participates in a wellness program that is
25 reasonably-designed to promote health or prevent disease.

1 Nothing in this Act (or an amendment made by this Act)
2 shall be construed to limit the ability of a group health
3 plan or health insurance issuer, under regulations in effect
4 on the date of enactment of this Act, to offer participants
5 variations in employee contributions towards the cost of
6 coverage for participation in wellness programs.

7 **SEC. 327. DEMONSTRATION PROJECT CONCERNING INDIVIDUALIZED WELLNESS PLAN.**

9 Section 330 of the Public Health Service Act (42
10 U.S.C. 245b) is amended by adding at the end the following:
11

12 “(s) PILOT PROGRAM FOR INDIVIDUALIZED
13 WELLNESS PLANS.—

14 “(1) IN GENERAL.—The Secretary shall establish
15 a pilot program to test the impact of providing
16 at-risk populations who utilize community health
17 centers funded under this section an individualized
18 wellness plan that is designed to reduce risk factors
19 for preventable conditions as identified by a comprehensive
20 risk-factor assessment.

21 “(2) AGREEMENTS.—The Secretary shall enter
22 into agreements with not more than 10 community
23 health centers funded under this section to conduct
24 activities under the pilot program under paragraph
25 (1).

1 “(3) WELLNESS PLANS.—

2 “(A) IN GENERAL.—An individualized
3 wellness plan prepared under the pilot program
4 under this subsection may include one or more
5 of the following as appropriate to the individ-
6 ual’s identified risk factors:

7 “(i) Nutritional counseling.

8 “(ii) A physical activity plan.

9 “(iii) Alcohol and smoking cessation
10 counseling and services.

11 “(iv) Stress management.

12 “(v) Dietary supplements that have
13 health claims approved by the Secretary.

14 “(vi) Compliance assistance provided
15 by a community health center employee.

16 “(B) RISK FACTORS.—Wellness plan risk
17 factors shall include—

18 “(i) weight;

19 “(ii) tobacco and alcohol use;

20 “(iii) exercise rates;

21 “(iv) nutritional status; and

22 “(v) blood pressure.

23 “(C) COMPARISONS.—Individualized
24 wellness plans shall make comparisons between
25 the individual involved and a control group of

1 individuals with respect to the risk factors de-
2 scribed in subparagraph (B).

3 “(4) AUTHORIZATION OF APPROPRIATIONS.—

4 There is authorized to be appropriated to carry out
5 this subsection, such sums as may be necessary.”.

6 **SEC. 328. REASONABLE BREAK TIME FOR NURSING MOTH-**
7 **ERS.**

8 Section 7 of the Fair Labor Standards Act of 1938
9 (29 U.S.C. 207) is amended by adding at the end the fol-
10 lowing:

11 “(r)(1) An employer shall provide—

12 “(A) a reasonable break time for an employee
13 to express breast milk for her nursing child for 1
14 year after the child’s birth each time such employee
15 has need to express the milk; and

16 “(B) a place, other than a bathroom, that is
17 shielded from view and free from intrusion from co-
18 workers and the public, which may be used by an
19 employee to express breast milk.

20 “(2) An employer shall not be required to compensate
21 an employee receiving reasonable break time under para-
22 graph (1) for any work time spent for such purpose.

23 “(3) An employer that employs less than 50 employ-
24 ees shall not be subject to the requirements of this sub-
25 section, if such requirements would impose an undue hard-

1 ship by causing the employer significant difficulty or ex-
2 pense when considered in relation to the size, financial re-
3 sources, nature, or structure of the employer's business.'".

4 **Subtitle D—Support for Prevention**
5 **and Public Health Innovation**

6 **SEC. 331. RESEARCH ON OPTIMIZING THE DELIVERY OF**
7 **PUBLIC HEALTH SERVICES.**

8 (a) IN GENERAL.—The Secretary of Health and
9 Human Services (referred to in this section as the “Sec-
10 retary”), acting through the Director of the Centers for
11 Disease Control and Prevention, shall provide funding for
12 research in the area of public health services and systems.

13 (b) REQUIREMENTS OF RESEARCH.—Research sup-
14 ported under this section shall include—

15 (1) examining evidence-based practices relating
16 to prevention, with a particular focus on high pri-
17 ority areas as identified by the Secretary in the Na-
18 tional Prevention Strategy or Healthy People 2020,
19 and including comparing community-based public
20 health interventions in terms of effectiveness and
21 cost;

22 (2) analyzing the translation of interventions
23 from academic settings to real world settings; and

24 (3) identifying effective strategies for orga-
25 nizing, financing, or delivering public health services

1 in real world community settings, including com-
2 paring State and local health department structures
3 and systems in terms of effectiveness and cost.

4 (c) EXISTING PARTNERSHIPS.—Research supported
5 under this section shall be coordinated with the Commu-
6 nity Preventive Services Task Force and carried out by
7 building on existing partnerships within the Federal Gov-
8 ernment while also considering initiatives at the State and
9 local levels and in the private sector.

10 (d) ANNUAL REPORT.—The Secretary shall, on an
11 annual basis, submit to Congress a report concerning the
12 activities and findings with respect to research supported
13 under this section.

14 **SEC. 332. UNDERSTANDING HEALTH DISPARITIES: DATA**
15 **COLLECTION AND ANALYSIS.**

16 The Public Health Service Act (42 U.S.C. 201 et
17 seq.) as amended by section 172, is further amended by
18 adding at the end the following:

19 **“TITLE XXXIII—DATA COLLEC-**
20 **TION, ANALYSIS, AND QUAL-**
21 **ITY**

22 **“SEC. 3301. DATA COLLECTION, ANALYSIS, AND QUALITY.**

23 **“(a) DATA COLLECTION.—**

24 **“(1) IN GENERAL.—**The Secretary shall ensure
25 that, by not later than 1 year after the date of en-

1 actment of this title, any ongoing or federally con-
2 ducted or supported health care or public health pro-
3 gram, activity or survey collects and reports—

4 “(A) data on race and ethnicity for appli-
5 cants, recipients, or beneficiaries;

6 “(B) data on gender, geographic location,
7 socioeconomic status (including education, em-
8 ployment or income), primary language, and,
9 disability status data for applicants, recipients,
10 or beneficiaries;

11 “(C) data at the smallest geographic level
12 such as State, local, or institutional levels if
13 such data can be aggregated;

14 “(D) if practicable, data by racial and eth-
15 nic subgroups for applicants, recipients or bene-
16 ficiaries using, if needed, statistical oversamples
17 of these subpopulations; and

18 “(E) any other demographic data as
19 deemed appropriate by the Secretary regarding
20 health disparities.

21 “(2) COLLECTION STANDARDS.—In collecting
22 data described in paragraph (1), the Secretary or
23 designee shall—

1 “(A) use Office of Management and Budg-
2 et standards, at a minimum, for race and eth-
3 nicity measures;

4 “(B) develop standards for the measure-
5 ment of gender, geographic location, socio-
6 economic status, primary language and dis-
7 ability measures; and

8 “(C) develop standards for the collection of
9 data described in paragraph (1) that, at a min-
10 imum—

11 “(i) collects self-reported data by the
12 applicant, recipient, or beneficiary; and

13 “(ii) collects data from a parent or
14 legal guardian if the applicant, recipient,
15 or beneficiary is a minor or legally inca-
16 pacitated.

17 “(3) DATA MANAGEMENT.—In collecting data
18 described in paragraph (1), the Secretary, acting
19 through the National Coordinator for Health Infor-
20 mation Technology shall—

21 “(A) develop national standards for the
22 management of data collected; and

23 “(B) develop interoperability and security
24 systems for data management.

25 “(b) DATA ANALYSIS.—

1 “(1) IN GENERAL.—For each federally con-
2 ducted or supported health care or public health pro-
3 gram or activity, the Secretary shall analyze data
4 collected under paragraph (a) to detect and monitor
5 trends in health disparities (as defined in section
6 485E) at the Federal and State levels.

7 “(c) DATA REPORTING AND DISSEMINATION.—

8 “(1) IN GENERAL.—The Secretary shall make
9 the analyses described in (b) available to—

10 “(A) the Office of Minority Health;

11 “(B) the National Center on Minority
12 Health and Health Disparities;

13 “(C) the Agency for Healthcare Research
14 and Quality;

15 “(D) the Centers for Disease Control and
16 Prevention;

17 “(E) the Centers for Medicare & Medicaid
18 Services;

19 “(F) the Indian Health Service and epide-
20 miology centers funded under the Indian Health
21 Care Improvement Act;

22 “(G) other agencies within the Department
23 of Health and Human Services; and

24 “(H) other entities as determined appro-
25 priate by the Secretary.

1 “(2) REPORTING OF DATA.—The Secretary
2 shall report data and analyses described in (a) and
3 (b) through—

4 “(A) public postings on the Internet
5 websites of the Department of Health and
6 Human Services; and

7 “(B) any other reporting or dissemination
8 mechanisms determined appropriate by the Sec-
9 retary.

10 “(3) AVAILABILITY OF DATA.—The Secretary
11 may make data described in (a) and (b) available for
12 additional research, analyses, and dissemination to
13 other Federal agencies, non-governmental entities,
14 and the public.

15 “(d) LIMITATIONS ON USE OF DATA.—Nothing in
16 this section shall be construed to permit the use of infor-
17 mation collected under this section in a manner that would
18 adversely affect any individual.

19 “(e) PROTECTION OF DATA.—The Secretary shall en-
20 sure (through the promulgation of regulations or other-
21 wise) that all data collected pursuant to subsection (a) is
22 protected—

23 “(1) under the same privacy protections that
24 are at least as broad as those that the Secretary ap-
25 plies 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.”.

1 **SEC. 333. HEALTH IMPACT ASSESSMENTS.**

2 (a) PURPOSE.—It is the purpose of this section to
3 determine if the built environment has an impact on
4 health.

5 (b) DEFINITION.—In this section:

6 (1) ADMINISTRATOR.—The term “Adminis-
7 trator” means the Administrator of the Environ-
8 mental Protection Agency.

9 (2) BUILT ENVIRONMENT.—The term “built
10 environment” means an environment consisting of
11 building, spaces, and products that are created or
12 modified by individuals and entities, including
13 homes, schools, workplaces, greenways, business
14 areas, transportation systems, and parks and recre-
15 ation areas, electrical transmission lines, waste dis-
16 posal sites, and land-use planning and policies that
17 impact urban, rural and suburban communities.

18 (3) DIRECTOR.—The term “Director” means
19 the Director of the Centers for Disease Control and
20 Prevention.

21 (4) ENVIRONMENTAL HEALTH.—The term “en-
22 vironmental health” means the health and wellbeing
23 of a population as affected by the direct pathological
24 effects of chemicals, radiation or biological agents,
25 and the effects, including the indirect effects, of the

1 broad physical, psychological, social and aesthetic
2 environment.

3 (5) HEALTH IMPACT ASSESSMENT.—The term
4 “health impact assessment” means a combination of
5 procedures, methods, and tools by which a regula-
6 tion, program, or other project is assessed as to its
7 potential effects on the health of a population, and
8 the distribution of those effects within the popu-
9 lation.

10 (6) SECRETARY.—The term “Secretary” means
11 the Secretary of Health and Human Services.

12 (c) FOSTERING HEALTH IMPACT ASSESSMENT.—

13 (1) ESTABLISHMENT.—The Secretary, acting
14 through the Director and in coordination with the
15 Administrator, shall establish a program at the Na-
16 tional Center of Environmental Health at the Cen-
17 ters for Disease Control and Prevention to foster ad-
18 vances and provide technical support in the field of
19 health impact assessments.

20 (2) ACTIVITIES.—Through the program under
21 paragraph (1), the Secretary shall—

22 (A) collect and disseminate evidence-based
23 practices relating to health impact assessments;

1 (B) manage capacity building grants, tech-
2 nical assistance, and training on the use of
3 health impact assessments; and

4 (C) provide guidance on health impact as-
5 sessments including similar international ef-
6 forts, known associations between the built en-
7 vironment and health outcomes, forecasting of
8 potential health effects of the built environ-
9 ment, and best practices relating to the inclu-
10 sion of the public in planning processes.

11 **SEC. 334. CDC AND EMPLOYER-BASED WELLNESS PRO-**
12 **GRAMS.**

13 Title III of the Public Health Service Act (42 U.S.C.
14 241 et seq.), as amended by section 314) is further
15 amended by adding at the end the following:

16 **“PART T—EMPLOYER-BASED WELLNESS**
17 **PROGRAM**

18 **“SEC. 399HH. WORKPLACE WELLNESS MARKETING CAM-**
19 **PAIGN.**

20 “Subject to appropriations Acts, the Director of the
21 Centers for Disease Control and Prevention (referred to
22 in this section as the ‘Director’), in coordination with rel-
23 evant worksite health promotion organizations, State and
24 local health departments, the Indian Health Service, In-

1 dian tribes and tribal organizations, and academic institu-
2 tions, shall conduct targeted educational campaigns to—

3 “(1) make employers, employer groups, and
4 other interested parties aware of the benefits of em-
5 ployer-based wellness programs;

6 “(2) establish a culture of health by empha-
7 sizing health promotion and disease prevention;

8 “(3) emphasize an integrated and coordinated
9 approach to workplace wellness; and

10 “(4) ensure informed decisions through high
11 quality information to organizational leaders.

12 **“SEC. 399HH-1. TECHNICAL ASSISTANCE FOR EMPLOYER-**
13 **BASED WELLNESS PROGRAMS.**

14 “In order to expand the utilization of evidence-based
15 prevention and health promotion approaches in the work-
16 place, the Director shall—

17 “(1) provide employers (including small, me-
18 dium, and large employers, as determined by the Di-
19 rector) with technical assistance, consultation, tools,
20 and other resources in evaluating such employers’
21 employer-based wellness programs, including—

22 “(A) measuring the participation and
23 methods to increase participation of employees
24 in such programs;

1 “(B) developing standardized measures
2 that assess policy, environmental and systems
3 changes necessary to have a positive health im-
4 pact on employees’ health behaviors, health out-
5 comes, and health care expenditures; and

6 “(C) evaluating such programs as they re-
7 late to changes in the health status of employ-
8 ees, the absenteeism of employees, the produc-
9 tivity of employees, the rate of workplace in-
10 jury, and the medical costs incurred by employ-
11 ees; and

12 “(2) build evaluation capacity among workplace
13 staff by training employers on how to evaluate em-
14 ployer-based wellness programs by ensuring evalua-
15 tion resources, technical assistance, and consultation
16 are available to workplace staff as needed through
17 such mechanisms as web portals, call centers, or
18 other means.

19 **“SEC. 399HH-2. NATIONAL WORKSITE HEALTH POLICIES**
20 **AND PROGRAMS STUDY.**

21 “(a) IN GENERAL.—In order to assess, analyze, and
22 monitor over time data about workplace policies and pro-
23 grams, and to develop instruments to assess and evaluate
24 comprehensive workplace chronic disease prevention and
25 health promotion programs, policies and practices, not

1 later than 2 years after the date of enactment of this part,
2 and at regular intervals (to be determined by the Director)
3 thereafter, the Director shall conduct a national worksite
4 health policies and programs survey to assess employer-
5 based health policies and programs.

6 “(b) REPORT.—Upon the completion of each study
7 under subsection (a), the Director shall submit to Con-
8 gress a report that includes the recommendations of the
9 Director for the implementation of effective employer-
10 based health policies and programs.

11 **“SEC. 399HH-3. RESEARCH IN WORKPLACE WELLNESS.**

12 “(a) WORKPLACE DEMONSTRATION STUDIES.—To
13 expand the science base for effective prevention and health
14 promotion approaches in the workplace, the Director, in
15 collaboration with academic institutions and employers,
16 shall institute workplace demonstration projects across
17 small, medium, and large employers. Such demonstration
18 projects shall be designed to determine how best to trans-
19 form the work environment for health, safety, and
20 wellness, how to create a strong, sustainable, coordinated,
21 and integrated workplace health promotion and wellness
22 program, and how to create innovative and sustainable
23 policy and environmental strategies to improve employee
24 health and wellness.

1 “(b) REPORT.—Upon the completion of the study
2 under subsection (b), the Director shall submit to Con-
3 gress a report that includes the recommendations of the
4 Director for the implementation of effective employer-
5 based health policies and programs.

6 **“SEC. 399HH-4. PRIORITIZATION OF EVALUATION BY SEC-**
7 **RETARY.**

8 “The Secretary shall evaluate, in accordance with this
9 part, all programs funded through the Centers for Disease
10 Control and Prevention before conducting such an evalua-
11 tion of privately funded programs unless an entity with
12 a privately funded wellness program requests such an eval-
13 uation.

14 **“SEC. 399HH-5. PROHIBITION OF FEDERAL WORKPLACE**
15 **WELLNESS REQUIREMENTS.**

16 “Notwithstanding any other provision of this part,
17 any recommendations, data, or assessments carried out
18 under this part shall not be used to mandate requirements
19 for workplace wellness programs.”.

20 **SEC. 335. EPIDEMIOLOGY-LABORATORY CAPACITY GRANTS.**

21 Title XXVIII of the Public Health Service Act (42
22 U.S.C. 300hh et seq.) is amended by adding at the end
23 the following:

1 **“Subtitle C—Strengthening Public**
2 **Health Surveillance Systems**

3 **“SEC. 2821. EPIDEMIOLOGY-LABORATORY CAPACITY**
4 **GRANTS.**

5 “(a) IN GENERAL.—Subject to the availability of ap-
6 propriations, the Secretary, acting through the Director
7 of the Centers for Disease Control and Prevention, shall
8 establish an Epidemiology and Laboratory Capacity Grant
9 Program to award grants to eligible entities to assist pub-
10 lic health agencies in improving surveillance for, and re-
11 sponse to, infectious diseases and other conditions of pub-
12 lic health importance by—

- 13 “(1) strengthening epidemiologic capacity;
14 “(2) enhancing laboratory practice;
15 “(3) improving information systems; and
16 “(4) developing and implementing prevention
17 and control strategies.

18 “(b) ELIGIBLE ENTITIES.—In this section, the term
19 ‘eligible entity’ means an entity that—

- 20 “(1) is—
21 “(A) a State health department;
22 “(B) a local health department that meets
23 such criteria as the Director of the Centers for
24 Diseases Control and Prevention determines for
25 purposes of this section;

1 “(C) a tribal jurisdiction that meets such
2 criteria as the Director of the Centers for Dis-
3 ease Control and Prevention determines for
4 purposes of this section; or

5 “(D) a partnership established for pur-
6 poses of this section between one or more eligi-
7 ble entities described in subparagraph (A), (B),
8 or (C) and an academic center; and

9 “(2) submits to the Secretary an application at
10 such time, in such manner, and containing such in-
11 formation as the Secretary may require.

12 “(c) USE OF FUNDS.—

13 “(1) IN GENERAL.—An eligible entity shall use
14 amounts received under a grant under this section
15 for core functions described in this subsection in-
16 cluding—

17 “(A) building public health capacity to
18 identify and monitor the occurrence of infec-
19 tious diseases and other conditions of public
20 health importance;

21 “(B) detecting new and emerging infec-
22 tious disease threats, including laboratory ca-
23 pacity to detect antimicrobial resistant infec-
24 tions;

1 “(C) identifying and responding to disease
2 outbreaks;

3 “(D) hiring necessary staff;

4 “(E) conducting needed staff training and
5 educational development; and

6 “(F) other activities that improve surveil-
7 lance as determined by the Director of the Cen-
8 ters for Disease Control and Prevention.

9 “(2) DEVELOPMENT AND MAINTENANCE OF IN-
10 FORMATION EXCHANGE.—

11 “(A) NATIONAL STANDARDS.—Not later
12 than 180 days after the date of the enactment
13 of this subtitle, the Secretary, acting through
14 the Director of the Centers for Disease Control
15 and Prevention, and in consultation with the
16 National Coordinator for Health Information
17 Technology, shall issue guidelines for public
18 health entities that—

19 “(i) are designed to ensure that all
20 State and local health departments and
21 public health laboratories have access to
22 information systems to receive, monitor,
23 and report infectious diseases and other
24 urgent conditions of public health impor-
25 tance; 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

1 such reports immediately to the Centers
2 for Disease Control and Prevention at the
3 time of receipt;

4 “(iii) to manage, link, and process dif-
5 ferent types of data, including information
6 on newly reported cases, exposed contacts,
7 laboratory results, number of people vac-
8 cinated or given prophylactic medications,
9 adverse events monitoring and follow-up, in
10 an integrated outbreak management sys-
11 tem;

12 “(iv) to geocode analyze, display, re-
13 port, and map, using Geographic Informa-
14 tion System technology, accumulated data
15 and to share data with other local health
16 departments, State health departments,
17 and the Centers for Disease Control and
18 Prevention;

19 “(v) to receive, manage, and dissemi-
20 nate alerts, protocols, and other informa-
21 tion, including Health Alert Network and
22 Epi-X information, as appropriate, for
23 public health workers, health care pro-
24 viders, and public health partners in emer-
25 gency response within each health depart-

1 ment’s jurisdiction and to automate the ex-
2 change and cascading of such information
3 with external partners using national
4 standards;

5 “(vi) to have information technology
6 security and critical infrastructure protec-
7 tion as appropriate to protect public health
8 information;

9 “(vii) to have the technical infrastruc-
10 ture needed to ensure availability, backup,
11 and disaster recovery of data, application
12 services, and communications systems dur-
13 ing natural disasters such as floods, tor-
14 nados, hurricanes, and power outages; and

15 “(viii) to provide for other capabilities
16 as the Secretary determines appropriate.

17 “(C) LABORATORY SYSTEMS.—An eligible
18 entity shall use amounts received under a grant
19 under this section to ensure that State or local
20 public health laboratories are utilizing web-
21 based, secure systems that are in compliance
22 with the guidelines developed by the Secretary
23 under subparagraph (A) and that—

24 “(i) are fully integrated laboratory in-
25 formation systems;

1 “(ii) provide for the reporting of elec-
2 tronic test results to the appropriate local
3 and State health departments using cur-
4 rently existing national format and coding
5 standards;

6 “(iii) have information technology se-
7 curity and critical infrastructure protection
8 to protect public health information (as de-
9 termined by the Secretary);

10 “(iv) have the technical infrastructure
11 needed to ensure availability, backup, and
12 disaster recovery of data, application serv-
13 ices, and communications systems during
14 natural disasters including floods, torna-
15 does, hurricanes, and power outages; and

16 “(v) address other capabilities as the
17 Secretary determines appropriate.

18 “(D) OTHER USES.—In addition to the ac-
19 tivities described in subparagraphs (B) and (C),
20 an eligible entity (including the entity’s public
21 health laboratory) may use amounts received
22 under a grant under this section for systems
23 development and maintenance, hiring necessary
24 staff, and staff technical training. Grantees
25 under this section may elect to develop their

1 own systems or use federally developed systems
2 in carrying out activities under this paragraph.

3 “(d) PRIORITY.—In allocating funds under sub-
4 section (f)(2) for activities under subsection (c)(2)(B) (re-
5 lating to secure information systems), the Secretary shall
6 give priority to eligible entities that demonstrate need.

7 “(e) REPORTS.—Not later than September 30, 2011,
8 and each September 30 thereafter, the Secretary shall
9 submit to Congress an annual report on the activities car-
10 ried out under this section by recipients of assistance
11 under this section.

12 “(f) AUTHORIZATION OF APPROPRIATIONS.—There
13 are authorized to be appropriated to carry out this section
14 \$190,000,000 for each of fiscal years 2010 through 2013,
15 of which—

16 “(1) not less than \$95,000,000 shall be made
17 available each such fiscal year for activities under
18 subsection (c)(1);

19 “(2) not less than \$60,000,000 shall be made
20 available each such fiscal year for activities under
21 subsection (c)(2)(B); and

22 “(3) not less than \$32,000,000 shall be made
23 available each such fiscal year for activities under
24 subsection (c)(2)(C).”.

1 **SEC. 336. FEDERAL MESSAGING ON HEALTH PROMOTION**
2 **AND DISEASE PREVENTION.**

3 (a) MEDIA CAMPAIGN.—

4 (1) IN GENERAL.—Not later than 1 year after
5 the date of enactment of this Act, the Secretary of
6 Health and Human Services (referred to in this sec-
7 tion as the “Secretary”), acting through the Direc-
8 tor of the Centers for Disease Control and Preven-
9 tion, shall establish and implement a national
10 science-based media campaign on health promotion
11 and disease prevention.

12 (2) REQUIREMENTS OF CAMPAIGN.—The cam-
13 paign implemented under paragraph (1)—

14 (A) shall be designed to address proper nu-
15 trition, regular exercise, smoking cessation, obe-
16 sity reduction, the 5 leading disease killers in
17 the United States, and secondary prevention
18 through disease screening promotion;

19 (B) shall be carried out through competi-
20 tively bid contracts awarded to entities pro-
21 viding for the professional production and de-
22 sign of such campaign;

23 (C) may include the use of television,
24 radio, Internet, and other commercial mar-
25 keting 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

1 and disease prevention information consistent with na-
2 tional priorities, to health care providers who participate
3 in Federal programs, including programs administered by
4 the Indian Health Service, the Department of Veterans
5 Affairs, the Department of Defense, and the Health Re-
6 sources and Services Administration, and the Medicare
7 and Medicaid Programs.

8 (d) PERSONALIZED PREVENTION PLANS.—

9 (1) CONTRACT.—The Secretary, acting through
10 the Director of the Centers for Disease Control and
11 Prevention, shall enter into a contract with a quali-
12 fied entity for the development and operation of a
13 Federal Internet website personalized prevention
14 plan tool.

15 (2) USE.—The website developed under para-
16 graph (1) shall be designed to be used as a source
17 of the most up-to-date scientific evidence relating to
18 disease prevention for use by individuals. Such
19 website shall contain a component that enables an
20 individual to determine their disease risk (based on
21 personal health and family history, BMI, and other
22 relevant information) relating to the 5 leading dis-
23 eases in the United States, and obtain personalized
24 suggestions for preventing such diseases.

1 (e) INTERNET PORTAL.—The Secretary shall estab-
2 lish an Internet portal for accessing risk-assessment tools
3 developed and maintained by private and academic enti-
4 ties.

5 (f) PRIORITY FUNDING.—Funding for the activities
6 authorized under this section shall take priority over fund-
7 ing provided through the Centers for Disease Control and
8 Prevention for grants to States and other entities for simi-
9 lar purposes and goals as provided for in this section. Not
10 to exceed \$500,000,000 shall be expended on the cam-
11 paigns and activities required under this section.

12 **Subtitle E—Advancing Research**
13 **and Treatment for Pain Care**
14 **Management**

15 **SEC. 341. INSTITUTE OF MEDICINE CONFERENCE ON PAIN.**

16 (a) CONVENING.—Not later than June 30, 2010, the
17 Secretary of Health and Human Services shall seek to
18 enter into an agreement with the Institute of Medicine of
19 the National Academies to convene a Conference on Pain
20 (in this section referred to as “the Conference”).

21 (b) PURPOSES.—The purposes of the Conference
22 shall be to—

23 (1) increase the recognition of pain as a signifi-
24 cant public health problem in the United States;

1 (2) evaluate the adequacy of assessment, diag-
2 nosis, treatment, and management of acute and
3 chronic pain in the general population, and in identi-
4 fied racial, ethnic, gender, age, and other demo-
5 graphic groups that may be disproportionately af-
6 fected by inadequacies in the assessment, diagnosis,
7 treatment, and management of pain;

8 (3) identify barriers to appropriate pain care,
9 including—

10 (A) lack of understanding and education
11 among employers, patients, health care pro-
12 viders, regulators, and third-party payors;

13 (B) barriers to access to care at the pri-
14 mary, specialty, and tertiary care levels, includ-
15 ing barriers—

16 (i) specific to those populations that
17 are disproportionately undertreated for
18 pain;

19 (ii) related to physician concerns over
20 regulatory and law enforcement policies
21 applicable to some pain therapies; and

22 (iii) attributable to benefit, coverage,
23 and payment policies in both the public
24 and private sectors; and

1 (C) gaps in basic and clinical research on
2 the symptoms and causes of pain, and potential
3 assessment methods and new treatments to im-
4 prove pain care; and

5 (4) establish an agenda for action in both the
6 public and private sectors that will reduce such bar-
7 riers and significantly improve the state of pain care
8 research, education, and clinical care in the United
9 States.

10 (c) OTHER APPROPRIATE ENTITY.—If the Institute
11 of Medicine declines to enter into an agreement under sub-
12 section (a), the Secretary of Health and Human Services
13 may enter into such agreement with another appropriate
14 entity.

15 (d) REPORT.—A report summarizing the Con-
16 ference's findings and recommendations shall be sub-
17 mitted to the Congress not later than June 30, 2011.

18 (e) AUTHORIZATION OF APPROPRIATIONS.—For the
19 purpose of carrying out this section, there is authorized
20 to be appropriated \$500,000 for each of fiscal years 2010
21 and 2011.

1 **SEC. 342. PAIN RESEARCH AT NATIONAL INSTITUTES OF**
2 **HEALTH.**

3 Part B of title IV of the Public Health Service Act
4 (42 U.S.C. 284 et seq.) is amended by adding at the end
5 the following:

6 **“SEC. 409J. PAIN RESEARCH.**

7 “(a) RESEARCH INITIATIVES.—

8 “(1) IN GENERAL.—The Director of NIH is en-
9 couraged to continue and expand, through the Pain
10 Consortium, an aggressive program of basic and
11 clinical research on the causes of and potential treat-
12 ments for pain.

13 “(2) ANNUAL RECOMMENDATIONS.—Not less
14 than annually, the Pain Consortium, in consultation
15 with the Division of Program Coordination, Plan-
16 ning, and Strategic Initiatives, shall develop and
17 submit to the Director of NIH recommendations on
18 appropriate pain research initiatives that could be
19 undertaken with funds reserved under section
20 402A(c)(1) for the Common Fund or otherwise
21 available for such initiatives.

22 “(3) DEFINITION.—In this subsection, the term
23 ‘Pain Consortium’ means the Pain Consortium of
24 the National Institutes of Health or a similar trans-
25 National Institutes of Health coordinating entity

1 designated by the Secretary for purposes of this sub-
2 section.

3 “(b) INTERAGENCY PAIN RESEARCH COORDINATING
4 COMMITTEE.—

5 “(1) ESTABLISHMENT.—The Secretary shall es-
6 tablish not later than 1 year after the date of the
7 enactment of this section and as necessary maintain
8 a committee, to be known as the Interagency Pain
9 Research Coordinating Committee (in this section
10 referred to as the ‘Committee’), to coordinate all ef-
11 forts within the Department of Health and Human
12 Services and other Federal agencies that relate to
13 pain research.

14 “(2) MEMBERSHIP.—

15 “(A) IN GENERAL.—The Committee shall
16 be composed of the following voting members:

17 “(i) Not more than 7 voting Federal
18 representatives as follows:

19 “(I) The Director of the Centers
20 for Disease Control and Prevention.

21 “(II) The Director of the Na-
22 tional Institutes of Health and the di-
23 rectors of such national research insti-
24 tutes and national centers as the Sec-
25 retary determines appropriate.

1 “(III) The heads of such other
2 agencies of the Department of Health
3 and Human Services as the Secretary
4 determines appropriate.

5 “(IV) Representatives of other
6 Federal agencies that conduct or sup-
7 port pain care research and treat-
8 ment, including the Department of
9 Defense and the Department of Vet-
10 erans Affairs.

11 “(ii) 12 additional voting members ap-
12 pointed under subparagraph (B).

13 “(B) ADDITIONAL MEMBERS.—The Com-
14 mittee shall include additional voting members
15 appointed by the Secretary as follows:

16 “(i) 6 members shall be appointed
17 from among scientists, physicians, and
18 other health professionals, who—

19 “(I) are not officers or employees
20 of the United States;

21 “(II) represent multiple dis-
22 ciplines, including clinical, basic, and
23 public health sciences;

1 “(III) represent different geo-
2 graphical regions of the United
3 States; and

4 “(IV) are from practice settings,
5 academia, manufacturers or other re-
6 search settings; and

7 “(ii) 6 members shall be appointed
8 from members of the general public, who
9 are representatives of leading research, ad-
10 vocacy, and service organizations for indi-
11 viduals with pain-related conditions.

12 “(C) NONVOTING MEMBERS.—The Com-
13 mittee shall include such nonvoting members as
14 the Secretary determines to be appropriate.

15 “(3) CHAIRPERSON.—The voting members of
16 the Committee shall select a chairperson from
17 among such members. The selection of a chairperson
18 shall be subject to the approval of the Director of
19 NIH.

20 “(4) MEETINGS.—The Committee shall meet at
21 the call of the chairperson of the Committee or upon
22 the request of the Director of NIH, but in no case
23 less often than once each year.

24 “(5) DUTIES.—The Committee shall—

1 “(A) develop a summary of advances in
2 pain care research supported or conducted by
3 the Federal agencies relevant to the diagnosis,
4 prevention, and treatment of pain and diseases
5 and disorders associated with pain;

6 “(B) identify critical gaps in basic and
7 clinical research on the symptoms and causes of
8 pain;

9 “(C) make recommendations to ensure that
10 the activities of the National Institutes of
11 Health and other Federal agencies, including
12 the Department of Defense and the Department
13 of Veteran Affairs, are free of unnecessary du-
14 plication of effort;

15 “(D) make recommendations on how best
16 to disseminate information on pain care; and

17 “(E) make recommendations on how to ex-
18 pand partnerships between public entities, in-
19 cluding Federal agencies, and private entities to
20 expand collaborative, cross-cutting research.

21 “(6) REVIEW.—The Secretary shall review the
22 necessity of the Committee at least once every 2
23 years.”.

1 **SEC. 343. PAIN CARE EDUCATION AND TRAINING.**

2 Part D of title VII of the Public Health Service Act
3 (42 U.S.C. 294 et seq.) is amended by adding at the end
4 the following new section:

5 **“SEC. 759. PROGRAM FOR EDUCATION AND TRAINING IN**
6 **PAIN CARE.**

7 “(a) IN GENERAL.—The Secretary may make awards
8 of grants, cooperative agreements, and contracts to health
9 professions schools, hospices, and other public and private
10 entities for the development and implementation of pro-
11 grams to provide education and training to health care
12 professionals in pain care.

13 “(b) PRIORITIES.—In making awards under sub-
14 section (a), the Secretary shall give priority to awards for
15 the implementation of programs under such subsection.

16 “(c) CERTAIN TOPICS.—An award may be made
17 under subsection (a) only if the applicant for the award
18 agrees that the program carried out with the award will
19 include information and education on—

20 “(1) recognized means for assessing, diag-
21 nosing, treating, and managing pain and related
22 signs and symptoms, including the medically appro-
23 priate use of controlled substances;

24 “(2) applicable laws, regulations, rules, and
25 policies on controlled substances, including the de-
26 gree to which misconceptions and concerns regarding

1 such laws, regulations, rules, and policies, or the en-
2 forcement thereof, may create barriers to patient ac-
3 cess to appropriate and effective pain care;

4 “(3) interdisciplinary approaches to the delivery
5 of pain care, including delivery through specialized
6 centers providing comprehensive pain care treatment
7 expertise;

8 “(4) cultural, linguistic, literacy, geographic,
9 and other barriers to care in underserved popu-
10 lations; and

11 “(5) recent findings, developments, and im-
12 provements in the provision of pain care.

13 “(d) PROGRAM SITES.—Education and training
14 under subsection (a) may be provided at or through health
15 professions schools, residency training programs, and
16 other graduate programs in the health professions; entities
17 that provide continuing education in medicine, pain man-
18 agement, dentistry, psychology, social work, nursing, and
19 pharmacy; hospices; and such other programs or sites as
20 the Secretary determines to be appropriate.

21 “(e) EVALUATION OF PROGRAMS.—The Secretary
22 shall (directly or through grants or contracts) provide for
23 the evaluation of programs implemented under subsection
24 (a) in order to determine the effect of such programs on
25 knowledge and practice of pain care.

1 “(f) PEER REVIEW GROUPS.—In carrying out section
2 799(f) with respect to this section, the Secretary shall en-
3 sure that the membership of each peer review group in-
4 volved includes individuals with expertise and experience
5 in pain care.

6 “(g) PAIN CARE DEFINED.—For purposes of this
7 section the term ‘pain care’ means the assessment, diag-
8 nosis, treatment, or management of acute or chronic pain
9 regardless of causation or body location.

10 “(h) AUTHORIZATION OF APPROPRIATIONS.—There
11 is authorized to be appropriated to carry out this section,
12 \$5,000,000 for each of the fiscal years 2010 through
13 2012. Amounts appropriated under this subsection shall
14 remain available until expended.”.

15 **SEC. 344. PUBLIC AWARENESS CAMPAIGN ON PAIN MAN-**
16 **AGEMENT.**

17 Part B of title II of the Public Health Service Act
18 (42 U.S.C. 238 et seq.) is amended by adding at the end
19 the following:

20 **“SEC. 249. NATIONAL EDUCATION OUTREACH AND AWARE-**
21 **NESS CAMPAIGN ON PAIN MANAGEMENT.**

22 “(a) ESTABLISHMENT.—Not later than June 30,
23 2010, the Secretary shall establish and implement a na-
24 tional pain care education outreach and awareness cam-
25 paign 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—

1 “(A) appropriate assessment, diagnosis,
2 treatment, and management options for all
3 types of pain and pain-related symptoms; and

4 “(B) conditions for which no treatment op-
5 tions are yet recognized; and

6 “(7) other issues the Secretary deems appro-
7 priate.

8 “(c) CONSULTATION.—In designing and imple-
9 menting the public awareness campaign required by this
10 section, the Secretary shall consult with organizations rep-
11 resenting patients in pain and other consumers, employ-
12 ers, physicians including physicians specializing in pain
13 care, other pain management professionals, medical device
14 manufacturers, and pharmaceutical companies.

15 “(d) COORDINATION.—

16 “(1) LEAD OFFICIAL.—The Secretary shall des-
17 ignate one official in the Department of Health and
18 Human Services to oversee the campaign established
19 under this section.

20 “(2) AGENCY COORDINATION.—The Secretary
21 shall ensure the involvement in the public awareness
22 campaign under this section of the Surgeon General
23 of the Public Health Service, the Director of the
24 Centers for Disease Control and Prevention, and
25 such other representatives of offices and agencies of

1 the Department of Health and Human Services as
2 the Secretary determines appropriate.

3 “(e) UNDERSERVED AREAS AND POPULATIONS.—In
4 designing the public awareness campaign under this sec-
5 tion, the Secretary shall—

6 “(1) take into account the special needs of geo-
7 graphic areas and racial, ethnic, gender, age, and
8 other demographic groups that are currently under-
9 served; and

10 “(2) provide resources that will reduce dispari-
11 ties in access to appropriate diagnosis, assessment,
12 and treatment.

13 “(f) GRANTS AND CONTRACTS.—The Secretary may
14 make awards of grants, cooperative agreements, and con-
15 tracts to public agencies and private nonprofit organiza-
16 tions to assist with the development and implementation
17 of the public awareness campaign under this section.

18 “(g) EVALUATION AND REPORT.—Not later than the
19 end of fiscal year 2012, the Secretary shall prepare and
20 submit to the Congress a report evaluating the effective-
21 ness of the public awareness campaign under this section
22 in educating the general public with respect to the matters
23 described in subsection (b).

24 “(h) AUTHORIZATION OF APPROPRIATIONS.—For
25 purposes of carrying out this section, there are authorized

1 to be appropriated \$2,000,000 for fiscal year 2010 and
2 \$4,000,000 for each of fiscal years 2011 through 2012.”.

3 **Subtitle F—Coordinated Environ-**
4 **mental Public Health Network**

5 **SEC. 351. AMENDMENT TO THE PUBLIC HEALTH SERVICE**
6 **ACT.**

7 The Public Health Service Act (42 U.S.C. 201 et
8 seq.), as amended by section 332, is further amended by
9 adding at the end the following:

10 **“TITLE XXXIV—COORDINATED**
11 **ENVIRONMENTAL PUBLIC**
12 **HEALTH NETWORK**

13 **“SEC. 3400. DEFINITIONS.**

14 “In this title:

15 “(1) ADMINISTRATOR.—The term ‘Adminis-
16 trator’ means the Administrator of the Environ-
17 mental Protection Agency.

18 “(2) COORDINATED NETWORK.—The term ‘Co-
19 ordinated Network’ means the Coordinated Environ-
20 mental Public Health Network established under
21 section 3401(a).

22 “(3) DIRECTOR.—The term ‘Director’ means
23 the Director of the Centers for Disease Control and
24 Prevention.

1 “(4) DIRECTOR OF CENTER.—The term ‘Direc-
2 tor of Center’ means the Director of the National
3 Center for Environmental Health at the Centers for
4 Disease Control and Prevention.

5 “(5) MEDICAL PRIVACY REGULATIONS.—The
6 term ‘medical privacy regulations’ means the regula-
7 tions promulgated under section 264(c) of the
8 Health Insurance Portability and Accountability Act
9 of 1996.

10 “(6) PRIORITY CHRONIC CONDITIONS AND
11 HEALTH EFFECTS.—The term ‘priority chronic con-
12 ditions and health effects’ means the conditions, as
13 specified by the Secretary, to be tracked in the Co-
14 ordinated Network and the State Networks.

15 “(7) STATE NETWORK.—The term ‘State Net-
16 work’ means a State Environmental Public Health
17 Network established under section 3401(b).

18 “(8) STATE.—The term ‘State’ means a State,
19 local government, territory, or Indian tribe that is
20 eligible to receive a health tracking grant under sec-
21 tion 3401(b).

1 **“SEC. 3401. ESTABLISHMENT OF COORDINATED AND STATE**
2 **ENVIRONMENTAL PUBLIC HEALTH NET-**
3 **WORKS.**

4 “(a) COORDINATED ENVIRONMENTAL PUBLIC
5 HEALTH NETWORK.—Not later than 36 months after the
6 date of the enactment of this title, the Secretary, acting
7 through the Director, in consultation with the Adminis-
8 trator and the Director of Center, and with the involve-
9 ment of other Federal agencies, and State and local health
10 departments, shall establish and operate a Coordinated
11 Environmental Public Health Network. In establishing
12 and operating the Coordinated Network, the Secretary
13 shall, as practicable—

14 “(1) identify, build upon, expand, and coordi-
15 nate among existing data and surveillance systems,
16 surveys, registries, and other Federal public health
17 and environmental infrastructure as practicable;

18 “(2) provide for public access to an electronic
19 national database that accepts data from the State
20 Networks on the incidence and prevalence of priority
21 chronic conditions and health effects and relevant
22 environmental and other factors, in a manner which
23 protects personal privacy consistent with the medical
24 privacy regulations;

25 “(3) prepare, publish, and submit to Con-
26 gress—

1 “(A) not later than 12 months after the
2 date of enactment of this title, and annually
3 thereafter, a Coordinated Network Status Re-
4 port, including a statement of the activities car-
5 ried out under this title, the identification of
6 gaps in the data of the coordinated Network,
7 including diseases of concern and environmental
8 exposures not tracked, and identification of key
9 milestones achieved in the preceding year, with
10 such report to be made available to the public
11 on the websites of the Centers for Disease Con-
12 trol and Prevention and the Environmental
13 Protection Agency; and

14 “(B) not later than 2 years after the date
15 of enactment of this title, and biennially there-
16 after, a Coordinated Network Health and Envi-
17 ronment Report, including a statement of the
18 activities carried out under this title, an anal-
19 ysis of the most currently available incidence,
20 prevalence, and trends of priority chronic condi-
21 tions and health effects, and potentially relevant
22 environmental and other factors, by State and,
23 as practicable by local areas, and recommenda-
24 tions regarding high risk populations, public
25 health concerns, response and prevention strate-

1 gies, and additional tracking needs, in order to
2 allow the public to access and understand infor-
3 mation about environmental health at the Fed-
4 eral, State, and, where practicable, local level;

5 “(4) provide for the establishment of State Net-
6 works, and coordinate the State Networks as pro-
7 vided for under subsection (b);

8 “(5) provide technical assistance to support the
9 State Networks;

10 “(6) not later than 12 months after the date of
11 the enactment of this title, develop minimum stand-
12 ards and procedures for data collection and report-
13 ing for the State Networks, to be updated not less
14 than annually thereafter; and

15 “(7) in developing the minimum standards and
16 procedures under subparagraph (F), include mecha-
17 nisms for allowing the States to set priorities, and
18 allocate resources accordingly.

19 “(b) STATE ENVIRONMENTAL PUBLIC HEALTH NET-
20 WORKS.—

21 “(1) GRANTS.—Not later than 12 months after
22 the date of the enactment of this title, the Secretary,
23 acting through the Director, in consultation with the
24 Administrator and the Director of Center shall
25 award grants to States for the establishment, main-

1 tenance, and operation of State Networks in accord-
2 ance with the minimum standards and procedures
3 established by the Secretary under subsection (a)(3).

4 “(2) SPECIALIZED ASSISTANCE.—The Coordi-
5 nated Network shall provide specialized assistance to
6 grantees in the establishment, maintenance, and op-
7 eration of State Networks.

8 “(3) REQUIREMENTS.—A State receiving a
9 grant under this subsection shall use the grant—

10 “(A) to establish an environmental public
11 health network that will provide—

12 “(i) for the tracking of the incidence,
13 prevalence, and trends of priority chronic
14 conditions and health effects, as well as
15 any additional priority chronic conditions
16 and health effects and potentially related
17 environmental exposures of concern to that
18 State;

19 “(ii) for identification of priority
20 chronic conditions and health effects and
21 potentially relevant environmental and
22 other factors that disproportionately im-
23 pact low income and minority communities;

24 “(iii) for the protection of the con-
25 fidentiality of all personal data reported, in

1 accordance with the medical privacy regu-
2 lations;

3 “(iv) a means by which confidential
4 data may, in accordance with Federal and
5 State law, be disclosed to researchers for
6 the purposes of public health research;

7 “(v) the fullest possible public access
8 to data collected by the State Network or
9 through the Coordinated Network, while
10 ensuring that individual privacy is pro-
11 tected in accordance with subsection
12 (a)(1)(B); and

13 “(vi) for the collection of exposure
14 data through biomonitoring and other
15 methods, which may include the entering
16 into of cooperative agreements as described
17 in section 3404;

18 “(B) to develop a publicly available plan
19 for establishing the State Network in order to
20 meet minimum standards and procedures as de-
21 veloped by the Secretary under subsection
22 (a)(1)(F);

23 “(C) to appoint a lead public health de-
24 partment or agency that will be responsible for
25 the development, operation, and maintenance of

1 the State Network, and ensure the appropriate
2 coordination among State and local agencies,
3 including environmental agencies, regarding the
4 development, operation, and maintenance of the
5 State Network; and

6 “(D) to recruit and train public health of-
7 ficials to continue to expand the State Network.

8 “(4) LIMITATION.—A State that receives a
9 grant under this section may not use more than 10
10 percent of the funds made available through the
11 grant for administrative costs.

12 “(5) APPLICATION.—To seek a grant under this
13 section, a State shall submit to the Secretary an ap-
14 plication at such time, in such form and manner,
15 and accompanied by such information as the Sec-
16 retary may specify.

17 “(c) PILOT PROJECTS.—

18 “(1) IN GENERAL.—A State may apply for a
19 grant under this subsection to implement a pilot
20 project that is approved by the Secretary, acting
21 through the Director and in consultation with the
22 Administrator, and the Director of Center.

23 “(2) ACTIVITIES.—A State shall use amounts
24 received under a grant under this subsection to
25 carry out a pilot project designed to develop State

1 Network enhancements and to develop programs to
2 address specific local and regional concerns.

3 “(3) RESULTS.—The Secretary may consider
4 the results of the pilot projects under this subsection
5 for inclusion into the Coordinated Network.

6 “(d) PRIVACY.—In establishing and operating the
7 Coordinated Network under subsection (a), and in making
8 grants under subsections (b) and (c), the Secretary shall
9 ensure the protection of privacy of individually identifiable
10 health information, including ensuring protection con-
11 sistent with the regulations promulgated under section
12 264(c) of the Health Insurance Portability and Account-
13 ability Act of 1996 (42 U.S.C. 1320d–2 note).

14 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
15 is authorized to be appropriated to carry out this section
16 such sums as may be necessary for each of fiscal years
17 2010 through 2014.

18 **“SEC. 3402. INCREASING PUBLIC HEALTH PERSONNEL CA-**
19 **PACITY.**

20 “(a) IN GENERAL.—Beginning in fiscal year 2010,
21 the Secretary, acting through the Director, shall enter into
22 a cooperative agreement with the Council of State and
23 Territorial Epidemiologists to train and place, in State
24 and local health departments, applied epidemiology fellows
25 to enhance State and local public health capacity in the

1 areas of environmental health, chronic and other noninfec-
2 tious diseases and conditions, and public health surveil-
3 lance.

4 “(b) AUTHORIZATION OF APPROPRIATIONS.—There
5 is authorized to be appropriated to carry out this section
6 such sums as may be necessary for each of fiscal years
7 2010 through 2014.

8 **“SEC. 3403. GENERAL PROVISION.**

9 “The Secretary shall integrate the enactment of this
10 title with all environmental health tracking programs
11 funded prior to the date of enactment of this title, includ-
12 ing by integrating the programs, in existence on the date
13 of enactment of this title, to develop State Network en-
14 hancements and to develop programs to address specific
15 local and regional concerns.

16 **“SEC. 3404. EXPANSION OF BIOMONITORING CAPABILITIES**
17 **AND DATA COLLECTION.**

18 “(a) PURPOSE.—It is the purpose of this section to
19 expand the scope and amount of biomonitoring data col-
20 lected and analyzed by the Centers for Disease Control
21 and Prevention, State laboratories, and consortia of State
22 laboratories, in order to obtain robust information, includ-
23 ing information by geographically defined areas and sub-
24 populations, about a range of environmental exposures.

1 “(b) IN GENERAL.—In meeting the purpose of this
2 section, the Secretary shall ensure that biomonitoring data
3 are collected intramurally through appropriate sources, in-
4 cluding the National Health and Nutrition Examination
5 Survey, and extramurally shall enter into collaboration or
6 partnerships with other entities to obtain additional infor-
7 mation regarding vulnerable subpopulations or other sub-
8 populations.

9 “(c) COOPERATIVE AGREEMENTS.—

10 “(1) IN GENERAL.—The Secretary, acting
11 through the Director, shall enter into cooperative
12 agreements with States or consortia of States to
13 support the purposes of this title.

14 “(2) APPLICATIONS.—Applications for such co-
15 operative agreements by consortia of States shall ad-
16 dress the manner in which such States will coordi-
17 nate activities with other States in the region, and
18 shall designate a lead State for administrative pur-
19 poses.

20 “(3) TRAINING AND QUALITY ASSURANCE.—
21 The Secretary, acting through the Director, shall
22 through the cooperative agreements with States or a
23 consortia of States provide laboratory training and
24 quality assurance.

1 “(d) PRIVACY.—In carrying out this section, the Sec-
2 retary shall ensure the protection of privacy of individually
3 identifiable health information, including ensuring protec-
4 tion consistent with the regulations promulgated under
5 section 264(c) of the Health Insurance Portability and Ac-
6 countability Act of 1996 (42 U.S.C. 1320d–2 note).

7 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
8 is 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 **Subtitle G—Miscellaneous**
12 **Provisions**

13 **SEC. 361. SENSE OF THE SENATE CONCERNING CBO SCOR-**
14 **ING.**

15 (a) FINDING.—The Senate finds that the costs of
16 prevention programs are difficult to estimate due in part
17 because prevention initiatives are hard to measure and re-
18 sults may occur outside the 5 and 10 year budget win-
19 dows.

20 (b) SENSE OF CONGRESS.—It is the sense of the Sen-
21 ate that Congress should work with the Congressional
22 Budget Office to develop better methodologies for scoring
23 progress to be made in prevention and wellness programs.

1 **SEC. 362. EFFECTIVENESS OF FEDERAL HEALTH AND**
2 **WELLNESS INITIATIVES.**

3 To determine whether existing Federal health and
4 wellness initiatives are effective in achieving their stated
5 goals, the Secretary of Health and Human Services
6 shall—

7 (1) conduct an evaluation of such programs as
8 they relate to changes in health status of the Amer-
9 ican public and specifically on the health status of
10 the Federal workforce, including absenteeism of em-
11 ployees, the productivity of employees, the rate of
12 workplace injury, and the medical costs incurred by
13 employees, and health conditions, including work-
14 place fitness, healthy food and beverages, and incen-
15 tives in the Federal Employee Health Benefits Pro-
16 gram; and

17 (2) submit to Congress a report concerning
18 such evaluation, which shall include conclusions con-
19 cerning the reasons that such existing programs
20 have proven successful or not successful and what
21 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:

573

(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—

25 (i) a secondary school diploma; and

1 (ii) a postsecondary degree, an ap-
2 prenticeship or other occupational certifi-
3 cation, a certificate, or a license.

4 (2) INSTITUTION OF HIGHER EDUCATION.—The
5 term “institution of higher education” has the
6 meaning given the term in sections 101 and 102 of
7 the Higher Education Act of 1965 (20 U.S.C. 1001
8 and 1002).

9 (3) LOW INCOME INDIVIDUAL, STATE WORK-
10 FORCE INVESTMENT BOARD, AND LOCAL WORK-
11 FORCE INVESTMENT BOARD.—The terms “low-in-
12 come individual”, “State workforce investment
13 board”, and “local workforce investment board”,
14 have the meanings given the terms in section 101 of
15 the Workforce investment Act of 1998 (29 U.S.C.
16 2801).

17 (4) POSTSECONDARY EDUCATION.—The term
18 “postsecondary education” means—

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

24 (B) a certificate or registered apprentice-
25 ship program at the postsecondary level offered

1 by an institution of higher education or a non-
2 profit educational institution.

3 (5) REGISTERED APPRENTICESHIP PROGRAM.—

4 The term “registered apprenticeship program”
5 means an industry skills training program at the
6 postsecondary level that combines technical and the-
7 oretical training through structure on the job learn-
8 ing with related instruction (in a classroom or
9 through distance learning) while an individual is em-
10 ployed, working under the direction of qualified per-
11 sonnel or a mentor, and earning incremental wage
12 increases aligned to enhance job proficiency, result-
13 ing in the acquisition of a nationally recognized and
14 portable certificate, under a plan approved by the
15 Office of Apprenticeship or a State agency recog-
16 nized by the Department of Labor.

17 (b) TITLE VII OF THE PUBLIC HEALTH SERVICE
18 ACT.—Section 799B of the Public Health Service Act (42
19 U.S.C. 295p) is amended—

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

22 “(3) PHYSICIAN ASSISTANT EDUCATION PRO-
23 GRAM.—The term ‘physician assistant education
24 program’ means an educational program in a public
25 or private institution in a State that—

1 “(A) has as its objective the education of
2 individuals who, upon completion of their stud-
3 ies in the program, be qualified to provide pri-
4 mary care medical services with the supervision
5 of a physician; and

6 “(B) is accredited by the Accreditation Re-
7 view Commission on Education for the Physi-
8 cian Assistant.”; and

9 (2) by adding at the end the following:

10 “(12) AREA HEALTH EDUCATION CENTER.—

11 The term ‘area health education center’ means a
12 public or nonprofit private organization that has a
13 cooperative agreement or contract in effect with an
14 entity that has received an award under subsection
15 (b) or (c) of section 751, satisfies the requirements
16 in section 751(d)(1), and has as one of its principal
17 functions the operation of an area health education
18 center. Appropriate organizations may include hos-
19 pitals, health organizations with accredited primary
20 care training programs, accredited physician assist-
21 ant educational programs associated with a college
22 or university, and universities or colleges not oper-
23 ating a school of medicine or osteopathic medicine.

24 “(13) AREA HEALTH EDUCATION CENTER PRO-
25 GRAM.—The term ‘area health education center pro-

1 gram’ means cooperative program consisting of an
2 entity that has received an award under subsection
3 (b) or (c) of section 751 for the purpose of planning,
4 developing, operating, and evaluating an area health
5 education center program and one or more area
6 health education centers, which carries out the re-
7 quired activities described in subsection (b)(4) or
8 (c)(4) of section 751, satisfies the program require-
9 ments in such section, has as one of its principal
10 functions identifying and implementing strategies
11 and activities that address health care workforce
12 needs in its service area, in coordination with the
13 local workforce investment boards.

14 “(14) CLINICAL SOCIAL WORKER.—The term
15 ‘clinical social worker’ has the meaning given the
16 term in section 1861(hh)(1) of the Social Security
17 Act (42 U.S.C. 1395x(hh)(1)).

18 “(15) CULTURAL COMPETENCY.—The term
19 ‘cultural competency’ shall be defined by the Sec-
20 retary in a manner consistent with section
21 1707(d)(3).

22 “(16) DIRECT CARE WORKER.—The term ‘di-
23 rect care worker’ has the meaning given that term
24 in the 2010 Standard Occupational Classifications of
25 the Department of Labor for Home Health Aides

1 [31–1011], Psychiatric Aides [31–1013], Nursing
2 Assistants [31–1014], and Personal Care Aides [39–
3 9021].

4 “(17) FEDERALLY QUALIFIED HEALTH CEN-
5 TER.—The term ‘Federally qualified health center’
6 has the meaning given that term in section 1861(aa)
7 of the Social Security Act (42 U.S.C. 1395x(aa)).

8 “(18) FRONTIER HEALTH PROFESSIONAL
9 SHORTAGE AREA.—The term ‘frontier health profes-
10 sional shortage area’ means an area—

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

14 “(B) with respect to which the distance or
15 time for the population to access care is exces-
16 sive.

17 “(19) GRADUATE PSYCHOLOGY.—The term
18 ‘graduate psychology’ means an accredited program
19 in professional psychology.

20 “(20) HEALTH DISPARITY POPULATION.—The
21 term ‘health disparity population’ has the meaning
22 given such term in section 903(d)(1).

23 “(21) HEALTH LITERACY.—The term ‘health
24 literacy’ means the degree to which an individual has
25 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

1 services, including substance abuse prevention and
2 treatment services.

3 “(25) RACIAL AND ETHNIC MINORITY GROUP;
4 RACIAL AND ETHNIC MINORITY POPULATION.—The
5 terms ‘racial and ethnic minority group’ and ‘racial
6 and ethnic minority population’ have the meaning
7 given the term ‘racial and ethnic minority group’ in
8 section 1707.

9 “(26) RURAL HEALTH CLINIC.—The term
10 ‘rural health clinic’ has the meaning given that term
11 in section 1861(aa) of the Social Security Act (42
12 U.S.C. 1395x(aa)).”.

13 (c) TITLE VIII OF THE PUBLIC HEALTH SERVICE
14 ACT.—Section 801 of the Public Health Service Act (42
15 U.S.C. 296) is amended—

16 (1) in paragraph (2)—

17 (A) by striking “means a” and inserting
18 “means an accredited (as defined in paragraph
19 6)”; and

20 (B) by striking the period as inserting the
21 following: “where graduates are—

22 “(A) authorized to sit for the National
23 Council Licensure EXamination-Registered
24 Nurse (NCLEX-RN); or

1 “(B) licensed registered nurses who will re-
2 ceive a graduate or equivalent degree or train-
3 ing to become an advanced education nurse as
4 defined by section 811(b).”; and

5 (2) by adding at the end the following:

6 “(16) ACCELERATED NURSING DEGREE PRO-
7 GRAM.—The term ‘accelerated nursing degree pro-
8 gram’ means a program of education in professional
9 nursing offered by an accredited school of nursing in
10 which an individual holding a bachelors degree in
11 another discipline receives a BSN or MSN degree in
12 an accelerated time frame as determined by the ac-
13 credited school of nursing.

14 “(17) BRIDGE OR DEGREE COMPLETION PRO-
15 GRAM.—The term ‘bridge or degree completion pro-
16 gram’ means a program of education in professional
17 nursing offered by an accredited school of nursing,
18 as defined in paragraph (2), that leads to a bacca-
19 laureate degree in nursing. Such programs may in-
20 clude, Registered Nurse (RN) to Bachelor’s of
21 Science of Nursing (BSN) programs, RN to MSN
22 (Master of Science of Nursing) programs, or BSN to
23 Doctoral programs.”.

1 **Subtitle B—Innovations in the**
2 **Health Care Workforce**

3 **SEC. 411. NATIONAL HEALTH CARE WORKFORCE COMMIS-**
4 **SION.**

5 (a) PURPOSE.—It is the purpose of this section to
6 establish a National Health Care Workforce Commission
7 that—

8 (1) serves as a national resource for Congress,
9 the President, States, and localities by—

10 (A) disseminating information on current
11 and projected health care workforce supply and
12 demand;

13 (B) disseminating information on health
14 care workforce education and training capacity
15 and instruction or delivery models and best
16 practices;

17 (C) recognizing efforts of Federal, State,
18 and local partnerships to develop and offer
19 health care career pathways of proven effective-
20 ness;

21 (D) disseminating information on prom-
22 ising retention practices for health care profes-
23 sionals;

24 (E) communicating information on impor-
25 tant policies and practices that affect the re-

1 cruitment, education and training, and reten-
2 tion of the health care workforce; and

3 (F) disseminating recommendations on the
4 development of a fiscally sustainable integrated
5 workforce that supports a high-quality health
6 care delivery system that meets the needs of pa-
7 tients and populations;

8 (2) communicates and coordinates with the De-
9 partments of Health and Human Services, Labor,
10 Veterans Affairs, Homeland Security, and Education
11 on related activities administered by one or more of
12 such Departments;

13 (3) develops and commissions evaluations of
14 education and training activities to determine wheth-
15 er the demand for health care workers is being met;

16 (4) identifies barriers to improved coordination
17 at the Federal, State, and local levels and rec-
18 ommend ways to address such barriers; and

19 (5) encourages innovations to address popu-
20 lation needs, constant changes in technology, and
21 other environmental factors.

22 (b) ESTABLISHMENT.—There is hereby established
23 the National Health Care Workforce Commission (in this
24 section referred to as the “Commission”).

25 (c) MEMBERSHIP.—

1 (1) NUMBER AND APPOINTMENT.—The Com-
2 mission shall be composed of 15 members to be ap-
3 pointed by the Comptroller General, without regard
4 to section 5 of the Federal Advisory Committee Act
5 (5 U.S.C. App.).

6 (2) QUALIFICATIONS.—

7 (A) IN GENERAL.—The membership of the
8 Commission shall include individuals—

9 (i) with national recognition for their
10 expertise in health care labor market anal-
11 ysis, including health care workforce anal-
12 ysis; health care finance and economics;
13 health care facility management; health
14 care plans and integrated delivery systems;
15 health care workforce education and train-
16 ing; health care philanthropy; providers of
17 health care services; and other related
18 fields; and

19 (ii) who will provide a combination of
20 professional perspectives, broad geographic
21 representation, and a balance between
22 urban, suburban, rural, and frontier rep-
23 resentatives.

24 (B) INCLUSION.—

1 (i) IN GENERAL.—The membership of
2 the Commission shall include no less than
3 one representative of—

4 (I) the health care workforce and
5 health professionals;

6 (II) employers;

7 (III) third-party payers;

8 (IV) individuals skilled in the
9 conduct and interpretation of health
10 care services and health economics re-
11 search;

12 (V) representatives of consumers;

13 (VI) labor unions;

14 (VII) State or local workforce in-
15 vestment boards; and

16 (VIII) educational institutions
17 (which may include elementary and
18 secondary institutions, institutions of
19 higher education, including 2 and 4
20 year institutions, or registered ap-
21 prenticeship programs).

22 (ii) ADDITIONAL MEMBERS.—The re-
23 maining membership may include addi-
24 tional representatives from clause (i) and
25 other individuals as determined appro-

1 prie by the Comptroller General of the
2 United States.

3 (C) MAJORITY NON-PROVIDERS.—Individ-
4 uals who are directly involved in health profes-
5 sions education or practice shall not constitute
6 a majority of the membership of the Commis-
7 sion.

8 (D) ETHICAL DISCLOSURE.—The Comp-
9 troller General shall establish a system for pub-
10 lic disclosure by members of the Commission of
11 financial and other potential conflicts of interest
12 relating to such members. Members of the
13 Commission shall be treated as employees of
14 Congress for purposes of applying title I of the
15 Ethics in Government Act of 1978. Members of
16 the Commission shall not be treated as special
17 government employees under title 18, United
18 States Code.

19 (3) TERMS.—

20 (A) IN GENERAL.—The terms of members
21 of the Commission shall be for 3 years except
22 that the Comptroller General shall designate
23 staggered terms for the members first ap-
24 pointed.

1 (B) VACANCIES.—Any member appointed
2 to fill a vacancy occurring before the expiration
3 of the term for which the member's predecessor
4 was appointed shall be appointed only for the
5 remainder of that term. A member may serve
6 after the expiration of that members term until
7 a successor has taken office. A vacancy in the
8 Commission shall be filled in the manner in
9 which the original appointment was made.

10 (C) INITIAL APPOINTMENTS.—The Comp-
11 troller General shall make initial appointments
12 of members to the Commission not later than
13 September 30, 2010.

14 (4) COMPENSATION.—While serving on the
15 business of the Commission (including travel time),
16 a member of the Commission shall be entitled to
17 compensation at the per diem equivalent of the rate
18 provided for level IV of the Executive Schedule
19 under section 5315 of tile 5, United States Code,
20 and while so serving away from home and the mem-
21 ber's regular place of business, a member may be al-
22 lowed travel expenses, as authorized by the Chair-
23 man of the Commission. Physicians serving as per-
24 sonnel of the Commission may be provided a physi-
25 cian comparability allowance by the Commission in

1 the same manner as Government physicians may be
2 provided such an allowance by an agency under sec-
3 tion 5948 of title 5, United States Code, and for
4 such purpose subsection (i) of such section shall
5 apply to the Commission in the same manner as it
6 applies to the Tennessee Valley Authority. For pur-
7 poses of pay (other than pay of members of the
8 Commission) and employment benefits, rights, and
9 privileges, all personnel of the Commission shall be
10 treated as if they were employees of the United
11 States Senate. Personnel of the Commission shall
12 not be treated as employees of the Government Ac-
13 countability Office for any purpose.

14 (5) CHAIRMAN, VICE CHAIRMAN.—The Comp-
15 troller General shall designate a member of the
16 Commission, at the time of appointment of the mem-
17 ber, as Chairman and a member as Vice Chairman
18 for that term of appointment, except that in the case
19 of vacancy of the chairmanship or vice chairman-
20 ship, the Comptroller General may designate another
21 member for the remainder of that member's term.

22 (6) MEETINGS.—The Commission shall meet at
23 the call of the chairman, but no less frequently than
24 on a quarterly basis.

25 (d) DUTIES.—

1 (1) REVIEW OF HEALTH CARE WORKFORCE
2 AND ANNUAL REPORTS.—In order to develop a fis-
3 cally sustainable integrated workforce that supports
4 a high-quality, readily accessible health care delivery
5 system that meets the needs of patients and popu-
6 lations, the Commission, in consultation with rel-
7 evant Federal, State, and local agencies, shall—

8 (A) review current and projected health
9 care workforce supply and demand, including
10 the topics described in paragraph (2);

11 (B) make recommendations to Congress
12 and the Administration concerning national
13 health care workforce priorities, goals, and poli-
14 cies;

15 (C) by not later than October 1 of each
16 year (beginning with 2011), submit a report to
17 Congress and the Administration containing the
18 results of such reviews and recommendations
19 concerning related policies; and

20 (D) by not later than April 1 of each year
21 (beginning with 2011), submit a report to Con-
22 gress and the Administration containing a re-
23 view of, and recommendations on, at a min-
24 imum one high priority area as described in
25 paragraph (3).

1 (2) SPECIFIC TOPICS TO BE REVIEWED.—The
2 topics described in this paragraph include—

3 (A) current health care workforce supply
4 and distribution, including demographics, skill
5 sets, and demands, with projected demands
6 during the subsequent 10 and 25 year periods;

7 (B) health care workforce education and
8 training capacity, including the number of stu-
9 dents who have completed education and train-
10 ing, including registered apprenticeships; the
11 number of qualified faculty; the education and
12 training infrastructure; and the education and
13 training demands, with projected demands dur-
14 ing the subsequent 10 and 25 year periods, and
15 including identified models of education and
16 training delivery and best practices;

17 (C) the education loan and grant programs
18 in titles VII and VIII of the Public Health
19 Service Act (42 U.S.C. 292 et seq. and 296 et
20 seq.), with recommendations on whether such
21 programs should become part of the Higher
22 Education Act of 1965 (20 U.S.C. 1001 et
23 seq);

24 (D) the implications of new and existing
25 Federal policies which affect the health care

1 workforce, including Medicare and Medicaid
2 graduate medical education policies, titles VII
3 and VIII of the Public Health Service Act (42
4 U.S.C. 292 et seq. and 296 et seq.), the Na-
5 tional Health Service Corps (with recommenda-
6 tions for aligning such programs with national
7 health workforce priorities and goals), and
8 other health care workforce programs, including
9 those supported through the Workforce Invest-
10 ment Act of 1998 (29 U.S.C. 2801 et seq.), the
11 Carl D. Perkins Career and Technical Edu-
12 cation Act of 2006 (20 U.S.C. 2301 et seq.),
13 the Higher Education Act of 1965 (20 U.S.C.
14 1001 et seq.), and any other Federal health
15 care workforce programs;

16 (E) the health care workforce needs of spe-
17 cial populations, such as minorities, rural popu-
18 lations, medically underserved populations, gen-
19 der specific needs, individuals with disabilities,
20 and geriatric and pediatric populations with
21 recommendations for new and existing Federal
22 policies to meet the needs of these special popu-
23 lations; and

24 (F) recommendations creating or revising
25 national loan repayment programs and scholar-

1 ship programs to require low-income, minority
2 medical students to serve in their home commu-
3 nities, if designated as medical underserved
4 community.

5 (3) HIGH PRIORITY AREAS.—

6 (A) IN GENERAL.—The initial high priority
7 topics described in this paragraph include—

8 (i) integrated health care workforce
9 planning that identifies health care profes-
10 sional skills needed and maximizes the skill
11 sets of health care professionals across dis-
12 ciplines;

13 (ii) an analysis of the nature, scopes
14 of practice, and demands for health care
15 workers in the enhanced information tech-
16 nology and management workplace;

17 (iii) Medicare and Medicaid graduate
18 medical education policies and rec-
19 ommendations, including increasing direct
20 payments to community based training
21 sites and medical training programs, for
22 aligning with national workforce goals;

23 (iv) nursing workforce capacity at all
24 levels, including education and training ca-

1 capacity, projected demands, and integration
2 within the health care delivery system;

3 (v) oral health care workforce capac-
4 ity, including education and training ca-
5 pacity, projected demands, and integration
6 within the health care delivery system;

7 (vi) mental and behavioral health care
8 workforce capacity, including education
9 and training capacity, projected demands,
10 and integration within the health care de-
11 livery system;

12 (vii) allied health and public health
13 care workforce capacity, including edu-
14 cation and training capacity, projected de-
15 mands, and integration within the health
16 care delivery system;

17 (viii) the geographic distribution of
18 health care providers as compared to the
19 identified health care workforce needs of
20 States and regions; and

21 (ix) emergency medical service work-
22 force capacity, including training and the
23 retention and recruitment of the volunteer
24 workforce.

1 (B) FUTURE DETERMINATIONS.—The
2 Commission may require that additional topics
3 be included under subparagraph (A). The ap-
4 propriate committees of Congress may rec-
5 ommend to the Commission the inclusion of
6 other topics for health care workforce develop-
7 ment areas that require special attention.

8 (4) GRANT PROGRAM.—The Commission shall
9 review implementation progress reports on, and re-
10 port to Congress about, the State Health Care
11 Workforce Development Grants program established
12 in section 412.

13 (5) STUDY.—The Commission shall study effec-
14 tive mechanisms for financing education and train-
15 ing for careers in health care, including public health
16 and allied health.

17 (6) RECOMMENDATIONS.—The Commission
18 shall submit recommendations to Congress, the De-
19 partment of Labor, and the Department of Health
20 and Human Services about improving safety, health,
21 and worker protections in the workplace for the
22 health care workforce.

23 (7) ASSESSMENT.—The Commission shall as-
24 sess and receive reports from the National Center

1 for Health Care Workforce Analysis established
2 under title VII of the Public Service Health Act.

3 (e) CONSULTATION WITH FEDERAL, STATE, AND
4 LOCAL AGENCIES, CONGRESS, AND OTHER ORGANIZA-
5 TIONS.—

6 (1) IN GENERAL.—The Commission shall con-
7 sult with Federal agencies (including the Depart-
8 ments of Health and Human Services, Labor, Edu-
9 cation, Commerce, Agriculture, Defense, and Vet-
10 erans Affairs and the Environmental Protection
11 Agency), Congress, the Medicare Payment Advisory
12 Commission, the Medicaid and CHIP Payment and
13 Access Commission, and, to the extent practicable,
14 with State and local agencies, Indian tribes, vol-
15 untary health care organizations, professional soci-
16 eties, and other relevant public-private health care
17 partnerships.

18 (2) OBTAINING OFFICIAL DATA.—The Commis-
19 sion, consistent with established privacy rules, may
20 secure directly from any department or agency of
21 the Executive Branch information necessary to en-
22 able the Commission to carry out this section.

23 (3) DETAIL OF FEDERAL GOVERNMENT EM-
24 PLOYEES.—An employee of the Federal Government
25 may be detailed to the Commission without reim-

1 bursement. The detail of such an employee shall be
2 without interruption or loss of civil service status.

3 (f) DIRECTOR AND STAFF; EXPERTS AND CONSULT-
4 ANTS.—Subject to such review as the Comptroller General
5 of the United States determines to be necessary to ensure
6 the efficient administration of the Commission, the Com-
7 mission may—

8 (1) employ and fix the compensation of an exec-
9 utive director that shall not exceed the rate of basic
10 pay payable for level V of the Executive Schedule
11 and such other personnel as may be necessary to
12 carry out its duties (without regard to the provisions
13 of title 5, United States Code, governing appoint-
14 ments in the competitive service);

15 (2) seek such assistance and support as may be
16 required in the performance of its duties from ap-
17 propriate Federal departments and agencies;

18 (3) enter into contracts or make other arrange-
19 ments, as may be necessary for the conduct of the
20 work of the Commission (without regard to section
21 3709 of the Revised Statutes (41 U.S.C. 5));

22 (4) make advance, progress, and other pay-
23 ments which relate to the work of the Commission;

24 (5) provide transportation and subsistence for
25 persons serving without compensation; and

1 (6) prescribe such rules and regulations as the
2 Commission determines to be necessary with respect
3 to the internal organization and operation of the
4 Commission.

5 (g) POWERS.—

6 (1) DATA COLLECTION.—In order to carry out
7 its functions under this section, the Commission
8 shall—

9 (A) utilize existing information, both pub-
10 lished and unpublished, where possible, collected
11 and assessed either by its own staff or under
12 other arrangements made in accordance with
13 this section, including coordination with the Bu-
14 reau of Labor Statistics;

15 (B) carry out, or award grants or con-
16 tracts for the carrying out of, original research
17 and development, where existing information is
18 inadequate, and

19 (C) adopt procedures allowing interested
20 parties to submit information for the Commis-
21 sion's use in making reports and recommenda-
22 tions.

23 (2) ACCESS OF THE GOVERNMENT ACCOUNT-
24 ABILITY OFFICE TO INFORMATION.—The Comp-
25 troller 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

1 workers, physical therapists, public health pro-
2 fessionals, clinical pharmacists, allied health
3 professionals, doctors of chiropractic, commu-
4 nity health workers, school nurses, certified
5 nurse midwives, podiatrists, licensed com-
6plementary and alternative medicine providers,
7 the EMS workforce (including professional and
8 volunteer ambulance personnel and firefighters
9 who perform emergency medical services), and
10 integrative health practitioners;

11 (B) national representatives of health pro-
12 fessionals;

13 (C) representatives of schools of medicine,
14 osteopathy, nursing, dentistry, optometry, phar-
15 macy, chiropractic, allied health, educational
16 programs for public health professionals, behav-
17 ioral and mental health professionals (as so de-
18 fined), social workers, pharmacists, physical
19 therapists, oral health care industry dentistry
20 and dental hygiene, and physician assistants;

21 (D) representatives of public and private
22 teaching hospitals, and ambulatory health facili-
23 ties, including Federal medical facilities; and

1 (E) any other health professional the
2 Comptroller General of the United States deter-
3 mines appropriate.

4 (j) REIMBURSEMENT OF COSTS.—The Commission
5 shall reimburse the Government Accountability Office for
6 the full cost of carrying out its activities under this section
7 as billed therefore by the Comptroller General of the
8 United States. Such reimbursements shall be credited to
9 the appropriation account “Salaries and Expenses, Gov-
10 ernment Accountability Office” current when the payment
11 is received and remain available until expended.

12 **SEC. 412. STATE HEALTH CARE WORKFORCE DEVELOP-**
13 **MENT GRANTS.**

14 (a) ESTABLISHMENT.—There is established a com-
15 petitive health care workforce development grant program
16 (referred to in this section as the “program”) for the pur-
17 pose of enabling State partnerships to complete com-
18 prehensive planning and to carry out activities leading to
19 coherent and comprehensive health care workforce devel-
20 opment strategies at the State and local levels.

21 (b) ASSESSMENT AND REPORTING.—

22 (1) DUTIES OF COMMISSION.—The National
23 Health Care Workforce Commission established in
24 section 411 (referred to in this section as the “Com-
25 mission”) shall—

1 (A) in collaboration with the Department
2 of Labor and in coordination with the Depart-
3 ment of Education and other relevant Federal
4 agencies, make recommendations to the fiscal
5 and administrative agent under paragraph (2)
6 for grant recipients;

7 (B) assess the implementation of the
8 grants; and

9 (C) collect performance and report infor-
10 mation, including identified models and best
11 practices, on grants from the fiscal and admin-
12 istrative agent and distribute this information
13 to Congress, relevant Federal agencies, and to
14 the public.

15 (2) FISCAL AND ADMINISTRATIVE AGENT.—The
16 Health Resources and Services Administration of the
17 Department of Health and Human Services (re-
18 ferred to in this section as the “Administration”)
19 shall be the fiscal and administrative agent for the
20 grants awarded under this section. The Administra-
21 tion is authorized to carry out the program, in con-
22 sultation with the Commission, which shall review
23 reports on the development, implementation, and
24 evaluation activities of the grant program, includ-
25 ing—

1 (A) administering the grants;

2 (B) providing technical assistance to grant-
3 ees; and

4 (C) reporting performance information to
5 the Commission.

6 (c) PLANNING GRANTS.—

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

11 (2) ELIGIBILITY.—To be eligible to receive a
12 planning grant, an entity shall be an eligible part-
13 nership. An eligible partnership shall be a State
14 workforce investment board, if it includes or modi-
15 fies the members to include at least one representa-
16 tive from each of the following: health care em-
17 ployer, labor organization, a public 2-year institution
18 of higher education, a public 4-year institution of
19 higher education, the recognized State federation of
20 labor, the State public secondary education agency,
21 the State P-16 or P-20 Council if such a council ex-
22 ists, and a philanthropic organization that is actively
23 engaged in providing learning, mentoring, and work
24 opportunities to recruit, educate, and train individ-

1 uals for, and retain individuals in, careers in health
2 care and related industries.

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

7 (4) APPLICATION.—Each State partnership de-
8 siring a planning grant shall submit an application
9 to the Administrator of the Administration at such
10 time and in such manner, and accompanied by such
11 information as the Administrator may reasonable re-
12 quire. Each application submitted for a planning
13 grant shall describe the members of the State part-
14 nership, the activities for which assistance is sought,
15 the proposed performance benchmarks to be used to
16 measure progress under the planning grant, a budg-
17 et for use of the funds to complete the required ac-
18 tivities described in paragraph (5), and such addi-
19 tional assurance and information as the Adminis-
20 trator determines to be essential to ensure compli-
21 ance with the grant program requirements.

22 (5) REQUIRED ACTIVITIES.—A State partner-
23 ship receiving a planning grant shall carry out the
24 following:

1 (A) Analyze State labor market informa-
2 tion in order to create health care career path-
3 ways for students and adults.

4 (B) Identify current and projected high de-
5 mand State or regional health care sectors for
6 purposes of planning career pathways.

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

11 (D) Describe the academic and health care
12 industry skill standards for high school gradua-
13 tion, for entry into postsecondary education,
14 and for various credentials and licensure.

15 (E) Describe State secondary and postsec-
16 ondary education and training policies, models,
17 or practices for the health care sector, including
18 career information and guidance counseling.

19 (F) Identify Federal or State policies or
20 rules to developing a coherent and comprehen-
21 sive health care workforce development strategy
22 and barriers and a plan to resolve these bar-
23 riers.

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

1 (6) PERFORMANCE AND EVALUATION.—Before
2 the State partnership receives a planning grant,
3 such partnership and the Administrator of the Ad-
4 ministration shall jointly determine the performance
5 benchmarks that will be established for the purposes
6 of the planning grant.

7 (7) MATCH.—Each State partnership receiving
8 a planning grant shall provide an amount, in cash
9 or in kind, that is not less than 15 percent of the
10 amount of the grant, to carry out the activities sup-
11 ported by the grant. The matching requirement may
12 be provided from funds available under other Fed-
13 eral, State, local or private sources to carry out the
14 activities.

15 (8) REPORT.—

16 (A) REPORT TO ADMINISTRATION.—Not
17 later than 1 year after a State partnership re-
18 ceives a planning grant, the partnership shall
19 submit a report to the Administration on the
20 State's performance of the activities under the
21 grant, including the use of funds, including
22 matching funds, to carry out required activities,
23 and a description of the progress of the State
24 workforce investment board in meeting the per-
25 formance benchmarks.

1 (B) REPORT TO CONGRESS.—The Admin-
2 istration shall submit a report to Congress ana-
3 lyzing the planning activities, performance, and
4 fund utilization of each State grant recipient,
5 including an identification of promising prac-
6 tices and a profile of the activities of each State
7 grant recipient.

8 (d) IMPLEMENTATION GRANTS.—

9 (1) IN GENERAL.—The Administration shall—

10 (A) competitively award implementation
11 grants to State partnerships to enable such
12 partnerships to implement activities that will
13 result in a coherent and comprehensive plan for
14 health workforce development that will address
15 current and projected workforce demands with-
16 in the State; and

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

19 (2) DURATION.—An implementation grant shall
20 be awarded for a period of no more than 2 years,
21 except in those cases where the Administration de-
22 termines that the grantee is high performing and the
23 activities supported by the grant warrant up to 1 ad-
24 ditional year of funding.

1 (3) ELIGIBILITY.—To be eligible for an imple-
2 mentation grant, a State partnership shall have—

3 (A) received a planning grant under sub-
4 section (c) and completed all requirements of
5 such grant; or

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

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

15 (5) APPLICATION.—Each eligible State partner-
16 ship desiring an implementation grant shall submit
17 an application to the Administration at such time, in
18 such manner, and accompanied by such information
19 as the Administration may reasonably require. Each
20 application submitted shall include—

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

23 (B) a description of how the State partner-
24 ship completed the required activities under the
25 planning grant, if applicable;

1 (C) a description of the activities for which
2 implementation grant funds are sought, includ-
3 ing grants to regions by the State partnership
4 to advance coherent and comprehensive regional
5 health care workforce planning activities;

6 (D) a description of how the State partner-
7 ship will coordinate with required partners and
8 complete the required partnership activities
9 during the duration of an implementation
10 grant.

11 (E) a budget proposal of the cost of the
12 activities supported by the implementation
13 grant and a timeline for the provision of match-
14 ing funds required;

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

18 (G) a description of how the State partner-
19 ship will collect data to report progress in grant
20 activities; and

21 (H) such additional assurances as the Ad-
22 ministration determines to be essential to en-
23 sure compliance with grant requirements.

24 (6) REQUIRED ACTIVITIES.—

1 (A) IN GENERAL.—A State partnership
2 that receives an implementation grant may re-
3 serve not less than 60 percent of the grant
4 funds to make grants to be competitively
5 awarded by the State partnership, consistent
6 with State procurement rules, to encourage re-
7 gional partnerships to address health care
8 workforce development needs and to promote
9 innovative health care workforce career pathway
10 activities, including career counseling, learning,
11 and employment.

12 (B) ELIGIBLE PARTNERSHIP DUTIES.—An
13 eligible State partnership receiving an imple-
14 mentation grant shall—

15 (i) identify and convene regional lead-
16 ership to discuss opportunities to engage in
17 statewide health care workforce develop-
18 ment planning, including potential use of
19 grants to be competitively awarded by the
20 State partnership to encourage innovative
21 approaches to improving the supply, diver-
22 sity, distribution, and development of re-
23 gional health care workforces, including
24 the alignment of curricula (and pre-
25 requisites) for health care careers, the ex-

1 pansion of and access to quality and timely
2 career information and guidance, and edu-
3 cation and training programs;

4 (ii) in consultation with key stake-
5 holders and regional leaders, take appro-
6 priate steps to reduce Federal, State, or
7 local barriers to a comprehensive and co-
8 herent strategy, including changes in State
9 or local policies to foster coherent and
10 comprehensive health care workforce devel-
11 opment activities, including health care ca-
12 reer pathways at the State and regional
13 levels and career planning information, and
14 as appropriate, requests for Federal pro-
15 gram or administrative waivers;

16 (iii) develop and disseminate a pre-
17 liminary statewide strategy that addresses
18 short- and long-term health care workforce
19 development supply versus demand, includ-
20 ing the solicitation of comments or feed-
21 back from key stakeholders and the gen-
22 eral public, and refine accordingly;

23 (iv) convene State partnership mem-
24 bers on a regular basis, and at least on a
25 semiannual basis;

1 (v) assist leaders at the regional level
2 to form partnerships, including the provi-
3 sion of technical assistance and capacity
4 building activities such as the dissemina-
5 tion of best practices and tools within the
6 State;

7 (vi) collect and assess data on and re-
8 port on the performance benchmarks se-
9 lected by the State partnership and the
10 Administration for implementation activi-
11 ties carried out by regional and State part-
12 nerships; and

13 (vii) participate in the Administra-
14 tion's evaluation and reporting activities.

15 (7) PERFORMANCE AND EVALUATION.—Before
16 the State partnership receives an implementation
17 grant, it and the Administrator shall jointly deter-
18 mine the performance benchmarks that shall be es-
19 tablished for the purposes of the implementation
20 grant.

21 (8) MATCH.—Each State partnership receiving
22 an implementation grant shall provide an amount, in
23 cash or in kind that is not less than 25 percent of
24 the amount of the grant, to carry out the activities
25 supported by the grant. The matching funds may be

1 provided from funds available from other Federal,
2 State, local, or private sources to carry out such ac-
3 tivities.

4 (9) REPORTS.—

5 (A) REPORT TO ADMINISTRATION.—For
6 each year of the implementation grant, the
7 State partnership receiving the implementation
8 grant shall submit a report to the Administra-
9 tion on the performance of the State of the
10 grant activities, including a description of the
11 use of the funds, including matched funds, to
12 complete activities, and a description of the per-
13 formance of the State partnership in meeting
14 the performance benchmarks.

15 (B) REPORT TO CONGRESS.—The Admin-
16 istration shall submit a report to Congress ana-
17 lyzing implementation activities, performance,
18 and fund utilization of the State grantees, in-
19 cluding an identification of promising practices
20 and a profile of the activities of each State
21 grantee.

22 (e) AUTHORIZATION FOR APPROPRIATIONS.—

23 (1) PLANNING GRANTS.—There are authorized
24 to be appropriated to award planning grants under
25 subsection (c) \$8,000,000 for fiscal year 2010, and

1 such sums as may be necessary for each subsequent
2 fiscal year.

3 (2) IMPLEMENTATION GRANTS.—There are au-
4 thorized to be appropriated to award implementation
5 grants under subsection (d), \$150,000,000 for fiscal
6 year 2010, and such sums as may be necessary for
7 each subsequent fiscal year.

8 **SEC. 413. HEALTH CARE WORKFORCE PROGRAM ASSESS-**
9 **MENT.**

10 (a) IN GENERAL.—Section 761 of the Public Health
11 Service Act (42 U.S.C. 294m) is amended—

12 (1) by redesignating subsection (c) as sub-
13 section (e);

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

16 “(b) NATIONAL CENTER FOR HEALTH CARE WORK-
17 FORCE ANALYSIS.—

18 “(1) ESTABLISHMENT.—The Secretary shall es-
19 tablish the National Center for Health Workforce
20 Analysis (referred to in this section as the ‘National
21 Center’).

22 “(2) PURPOSES.—The purposes of the National
23 Center are to—

24 “(A) provide for the development of infor-
25 mation describing the health care workforce and

1 the analysis of health care workforce related
2 issues;

3 “(B) carry out the activities under section
4 792(a); and

5 “(C) collect, analyze, and report data re-
6 lated to programs under this title in coordina-
7 tion with the State and Regional Centers for
8 Health Workforce Analysis described in sub-
9 section (c) (referred to in this section as the
10 ‘State and Regional Centers’) and with the
11 State agency responsible for the statewide em-
12 ployment statistics system under section 15(e)
13 of the Wagner-Peyser Act (29 U.S.C. 491–2).

14 “(3) FUNCTIONS.—The National Center shall,
15 in coordination with the Commission established in
16 section 411 of the Affordable Health Choices Act—

17 “(A) annually evaluate the effectiveness of
18 programs under this title;

19 “(B) develop and publish benchmarks for
20 performance for programs under this title;

21 “(C) establish, maintain, and make pub-
22 licly available through the Internet a national
23 health workforce database to collect data
24 from—

1 “(i) longitudinal evaluations (as de-
2 scribed in subsection (d)(2) on perform-
3 ance measures (as developed under sec-
4 tions 749(d)(3), 757(d)(3), and 762(a)(3));
5 and

6 “(ii) the State and Regional Centers
7 described in subsection (c); and

8 “(D) and establish and maintain a registry
9 of each grant awarded under this title.

10 “(4) COLLABORATION AND DATA SHARING.—

11 “(A) IN GENERAL.—The National Center
12 shall collaborate with Federal agencies, health
13 professions education organizations, health pro-
14 fessions organizations, and professional medical
15 societies for the purpose of linking data regard-
16 ing grants awarded under this title with 1 or
17 more of the following:

18 “(i) Data maintained by the Depart-
19 ment of Health and Human Services and
20 its various agencies.

21 “(ii) Data maintained by the Bureau
22 of Labor Statistics.

23 “(iii) Data maintained by the Census
24 Bureau.

1 “(iv) Data maintained by the Depart-
2 ments of Defense and Veterans Affairs.

3 “(v) Data sets maintained by health
4 professions education organizations, health
5 professions organizations, or professional
6 medical societies.

7 “(vi) Other data sets, as the Secretary
8 determines appropriate.

9 “(B) CONTRACTS FOR HEALTH WORK-
10 FORCE ANALYSIS.—For the purpose of carrying
11 out the activities described in subparagraph
12 (A), the National Center may enter into con-
13 tracts with health professions education organi-
14 zations, health professions organizations, or
15 professional medical societies.

16 “(c) STATE AND REGIONAL CENTERS FOR HEALTH
17 WORKFORCE ANALYSIS.—

18 “(1) IN GENERAL.—The Secretary shall award
19 grants to, or enter into contracts with, eligible enti-
20 ties for purposes of—

21 “(A) collecting, analyzing, and reporting to
22 the National Center data regarding programs
23 under this title;

1 “(B) conducting and broadly disseminating
2 research and reports on State, regional, and na-
3 tional health workforce issues;

4 “(C) evaluating the effectiveness of pro-
5 grams under this title; and

6 “(D) providing technical assistance to local
7 and regional entities on the collection, analysis,
8 and reporting of data related to health work-
9 force issues.

10 “(2) ELIGIBLE ENTITIES.—To be eligible for a
11 grant or contract under this subsection, an entity
12 shall—

13 “(A) be a State (including a State Office
14 of Rural Health), a State workforce investment
15 board, a public health or health professions
16 school, an academic health center (including an
17 area health education center program), or an
18 appropriate public or private nonprofit entity or
19 a partnership of such entities, such as a com-
20 munity college system; and

21 “(B) submit to the Secretary an applica-
22 tion at such time, in such manner, and con-
23 taining such information as the Secretary may
24 require.

1 “(d) INCREASE IN GRANTS FOR LONGITUDINAL
2 EVALUATIONS.—

3 “(1) IN GENERAL.—The Secretary shall in-
4 crease the amount of a grant or contract awarded to
5 an eligible entity under this title for the establish-
6 ment and maintenance of a longitudinal evaluation
7 of students, residents, fellows, interns, or faculty
8 who have received education, training, or financial
9 assistance from programs under this title.

10 “(2) CAPABILITY.—A longitudinal evaluation
11 shall be capable of—

12 “(A) studying participation in the National
13 Health Service Corps, practice in federally
14 qualified health centers, practice in health pro-
15 fessional shortage areas and medically under-
16 served areas, and practice in primary care; and

17 “(B) collecting and reporting data on per-
18 formance measures developed under sections
19 749(d)(3), 757(d)(3), and 762(a)(3).

20 “(3) GUIDELINES.—A longitudinal evaluation
21 shall comply with guidelines issued under sections
22 749(d)(4), 757(d)(4), and 762(a)(4).

23 “(4) ELIGIBLE ENTITIES.—To be eligible to ob-
24 tain an increase under this section, an entity shall
25 be a recipient of a grant or contract under this title

1 and have not previously received an increase under
2 this section.”; and

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

4 (A) by striking paragraph (1) and insert-
5 ing the following:

6 “(1) IN GENERAL.—

7 “(A) NATIONAL CENTER FOR HEALTH
8 WORKFORCE ANALYSIS.—To carry out sub-
9 section (b), there are authorized to be appro-
10 priated \$5,000,000 for each of fiscal years
11 2010 and 2011, \$10,000,000 for each of fiscal
12 years 2012 through 2014, and such sums as
13 may be necessary for each subsequent fiscal
14 year.

15 “(B) STATE AND REGIONAL CENTERS.—
16 To carry out subsection (c), there are author-
17 ized to be appropriated \$4,500,000 for each of
18 fiscal years 2010 through 2014, and such sums
19 as may be necessary for each subsequent fiscal
20 year.

21 “(C) GRANTS FOR LONGITUDINAL EVALUA-
22 TIONS.—To carry out subsection (d), there are
23 authorized to be appropriated such sums as
24 may be necessary for fiscal years 2010 through
25 2014.

1 “(D) CARRYOVER FUNDS.—An entity that
2 receives an award under this section may carry
3 over funds from 1 fiscal year to another without
4 obtaining approval from the Secretary. In no
5 case may any funds be carried over pursuant to
6 the preceding sentence for more than 3 years.”;
7 and

8 (4) in paragraph (2), by striking “subsection
9 (a)” and inserting “paragraph (1)”.

10 (b) TRANSFER OF FUNCTIONS.—Not later than 180
11 days after the date of enactment of this Act, all of the
12 functions, authorities, and resources of the National Cen-
13 ter for Health Workforce Analysis of the Health Resources
14 and Services Administration, as in effect on the date be-
15 fore the date of enactment of this Act, shall be transferred
16 to the National Center for Health Workforce Analysis es-
17 tablished under section 761 of the Public Health Service
18 Act, as amended by subsection (a).

19 (c) PRIORITY FOR USE OF LONGITUDINAL EVALUA-
20 TIONS.—Section 791(a)(1) of the Public Health Service
21 Act (42 U.S.C. 295j(a)(1)) is amended—

22 (1) in subparagraph (A), by striking “or” at
23 the end;

24 (2) in subparagraph (B), by striking the period
25 and inserting “; or”; and

1 (3) by adding at the end the following:

2 “(C) utilizes a longitudinal evaluation (as
3 described in section 761(d)(2)) and reports data
4 from such system to the national workforce
5 database (as established under section
6 761(b)(3)(D)).”.

7 (d) PERFORMANCE MEASURES; GUIDELINES FOR
8 LONGITUDINAL EVALUATIONS.—

9 (1) ADVISORY COMMITTEE ON TRAINING IN PRI-
10 MARY CARE MEDICINE AND DENTISTRY.—Section
11 748(d) of the Public Health Service Act is amend-
12 ed—

13 (A) in paragraph (1), by striking “and” at
14 the end;

15 (B) in paragraph (2), by striking the pe-
16 riod and inserting a semicolon; and

17 (C) by adding at the end the following:

18 “(3) not later than 3 years after the date of en-
19 actment of the Affordable Health Choices Act, de-
20 velop, publish, and implement performance meas-
21 ures, which shall be quantitative to the extent pos-
22 sible, for programs under this part;

23 “(4) develop and publish guidelines for longitu-
24 dinal evaluations (as described in section 761(d)(2))
25 for programs under this part; and

1 “(5) recommend appropriation levels for pro-
2 grams under this part.”.

3 (2) ADVISORY COMMITTEE ON INTERDISCIPLI-
4 NARY, COMMUNITY-BASED LINKAGES.—Section
5 756(d) of the Public Health Service Act is amend-
6 ed—

7 (A) in paragraph (1), by striking “and” at
8 the end;

9 (B) in paragraph (2), by striking the pe-
10 riod and inserting a semicolon; and

11 (C) by adding at the end the following:

12 “(3) not later than 3 years after the date of en-
13 actment of the Affordable Health Choices Act, de-
14 velop, publish, and implement performance meas-
15 ures, which shall be quantitative to the extent pos-
16 sible, for programs under this part;

17 “(4) develop and publish guidelines for longitu-
18 dinal evaluations (as described in section 761(d)(2))
19 for programs under this part; and

20 “(5) recommend appropriation levels for pro-
21 grams under this part.”.

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

1 (A) in paragraph (1), by striking “and” at
2 the end;

3 (B) in paragraph (2), by striking the pe-
4 riod and inserting a semicolon; and

5 (C) by adding at the end the following:

6 “(3) not later than 3 years after the date of en-
7 actment of the Affordable Health Choices Act de-
8 velop, publish, and implement performance meas-
9 ures, which shall be quantitative to the extent pos-
10 sible, for programs under this title, except for pro-
11 grams under part C or D;

12 “(4) develop and publish guidelines for longitu-
13 dinal evaluations (as described in section 761(d)(2))
14 for programs under this title, except for programs
15 under part C or D; and

16 “(5) recommend appropriation levels for pro-
17 grams under this title, except for programs under
18 part C or D.”.

19 **Subtitle C—Increasing the Supply**
20 **of the Health Care Workforce**

21 **SEC. 421. FEDERALLY SUPPORTED STUDENT LOAN FUNDS.**

22 (a) MEDICAL SCHOOLS AND PRIMARY HEALTH
23 CARE.—Section 723 of the Public Health Service Act (42
24 U.S.C. 292s) is amended—

25 (1) in subsection (a)—

1 (A) in paragraph (1), by striking subpara-
2 graph (B) and inserting the following:

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

7 (B) by striking paragraph (3) and insert-
8 ing the following:

9 “(3) NONCOMPLIANCE BY STUDENT.—Each
10 agreement entered into with a student pursuant to
11 paragraph (1) shall provide that, if the student fails
12 to comply with such agreement, the loan involved
13 will begin to accrue interest at a rate of 2 percent
14 per year greater than the rate at which the student
15 would pay if compliant in such year.”; and

16 (2) by adding at the end the following:

17 “(d) SENSE OF CONGRESS.—It is the sense of Con-
18 gress that funds repaid under the loan program under this
19 section should not be transferred to the Treasury of the
20 United States or otherwise used for any other purpose
21 other than to carry out this section.”.

22 (b) STUDENT LOAN GUIDELINES.—The Secretary of
23 Health and Human Services shall not require parental fi-
24 nancial information for an independent student to deter-
25 mine financial need under section 723 of the Public

1 Health Service Act (42 U.S.C. 292s) and the determina-
2 tion of need for such information shall be at the discretion
3 of applicable school loan officer. The Secretary shall
4 amend guidelines issued by the Health Resources and
5 Services Administration in accordance with the preceding
6 sentence.

7 **SEC. 422. NURSING STUDENT LOAN PROGRAM.**

8 (a) LOAN AGREEMENTS.—Section 836(a) of the Pub-
9 lic Health Service Act (42 U.S.C. 297b(a)) is amended—

10 (1) by striking “\$2,500” and inserting
11 “\$3,300”;

12 (2) by striking “\$4,000” and inserting
13 “\$5,200”; and

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

21 (b) LOAN PROVISIONS.—Section 836(b) of the Public
22 Health Service Act (42 U.S.C. 297b(b)) is amended—

23 (1) in paragraph (1)(C), by striking “1986”
24 and inserting “2000”; and

1 (2) in paragraph (3), by striking “the date of
2 enactment of the Nurse Training Amendments of
3 1979” and inserting “September 29, 1995”.

4 **SEC. 423. HEALTH CARE WORKFORCE LOAN REPAYMENT**
5 **PROGRAMS.**

6 Part E of title VII of the Public Health Service Act
7 (42 U.S.C. 294n et seq.) is amended by adding at the end
8 the following:

9 **“Subpart 3—Recruitment and Retention Programs**

10 **“SEC. 775. INVESTMENT IN TOMORROW’S PEDIATRIC**
11 **HEALTH CARE WORKFORCE.**

12 “(a) ESTABLISHMENT.—The Secretary shall estab-
13 lish and carry out a pediatric specialty loan repayment
14 program under which the eligible individual agrees to be
15 employed full-time for a specified period (which shall not
16 be less than 2 years) in providing pediatric medical sub-
17 specialty, pediatric surgical specialty, or child and adoles-
18 cent mental and behavioral health care, including sub-
19 stance abuse prevention and treatment services.

20 “(b) PROGRAM ADMINISTRATION.—Through the pro-
21 gram established under this section, the Secretary shall
22 enter into contracts with qualified health professionals
23 under which—

24 “(1) such qualified health professionals will
25 agree to provide pediatric medical subspecialty, pedi-

1 atric surgical specialty, or child and adolescent men-
2 tal and behavioral health care in an area with a
3 shortage of the specified pediatric subspecialty that
4 has a sufficient pediatric population to support such
5 pediatric subspecialty, as determined by the Sec-
6 retary; and

7 “(2) the Secretary agrees to make payments on
8 the principal and interest of undergraduate, grad-
9 uate, or graduate medical education loans of profes-
10 sionals described in paragraph (1) of not more than
11 \$35,000 a year for each year of agreed upon service
12 under such paragraph for a period of not more than
13 3 years during the qualified health professional’s—

14 “(A) participation in an accredited pedi-
15 atric medical subspecialty, pediatric surgical
16 specialty, or child and adolescent mental health
17 subspecialty residency or fellowship; or

18 “(B) employment as a pediatric medical
19 subspecialist, pediatric surgical specialist, or
20 child and adolescent mental health professional
21 serving an area or population described in such
22 paragraph.

23 “(c) IN GENERAL.—

24 “(1) ELIGIBLE INDIVIDUALS.—

1 “(A) PEDIATRIC MEDICAL SPECIALISTS
2 AND PEDIATRIC SURGICAL SPECIALISTS.—For
3 purposes of contracts with respect to pediatric
4 medical specialists and pediatric surgical spe-
5 cialists, the term ‘qualified health professional’
6 means a licensed physician who—

7 “(i) is entering or receiving training
8 in an accredited pediatric medical sub-
9 specialty or pediatric surgical specialty
10 residency or fellowship; or

11 “(ii) has completed (but not prior to
12 the end of the calendar year in which this
13 section is enacted) the training described
14 in subparagraph (B).

15 “(B) CHILD AND ADOLESCENT MENTAL
16 AND BEHAVIORAL HEALTH.—For purposes of
17 contracts with respect to child and adolescent
18 mental and behavioral health care, the term
19 ‘qualified health professional’ means a health
20 care professional who—

21 “(i) has received specialized training
22 or clinical experience in child and adoles-
23 cent mental health in psychiatry, psy-
24 chology, school psychology, behavioral pedi-
25 atrics, psychiatric nursing, social work,

1 school social work, substance abuse dis-
2 order prevention and treatment, marriage
3 and family therapy, school counseling, or
4 professional counseling;

5 “(ii) has a license or certification in a
6 State to practice allopathic medicine, os-
7 teopathic medicine, psychology, school psy-
8 chology, psychiatric nursing, social work,
9 school social work, marriage and family
10 therapy, school counseling, or professional
11 counseling; or

12 “(iii) is a mental health service pro-
13 fessional who completed (but not before
14 the end of the calendar year in which this
15 section is enacted) specialized training or
16 clinical experience in child and adolescent
17 mental health described in clause (i).

18 “(2) ADDITIONAL ELIGIBILITY REQUIRE-
19 MENTS.—The Secretary may not enter into a con-
20 tract under this subsection with an eligible indi-
21 vidual unless—

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

1 “(B) the individual is a United States cit-
2 izen or a permanent legal United States resi-
3 dent; and

4 “(C) if the individual is enrolled in a grad-
5 uate program, the program is accredited, and
6 the individual has an acceptable level of aca-
7 demic standing (as determined by the Sec-
8 retary).

9 “(d) PRIORITY.—In entering into contracts under
10 this subsection, the Secretary shall give priority to appli-
11 cants who—

12 “(1) are or will be working in a school or other
13 pre-kindergarten, elementary, or secondary edu-
14 cation setting;

15 “(2) have familiarity with evidence-based meth-
16 ods and cultural and linguistic competence health
17 care services; and

18 “(3) demonstrate financial need.

19 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
20 is authorized to be appropriated \$30,000,000 for each of
21 fiscal years 2010 through 2014 to carry out subsection
22 (c)(1)(A) and \$20,000,000 for each of fiscal years 2010
23 through 2013 to carry out subsection (c)(1)(B).”.

1 **SEC. 424. PUBLIC HEALTH WORKFORCE RECRUITMENT**
2 **AND RETENTION PROGRAMS.**

3 Part E of title VII of the Public Health Service Act
4 (42 U.S.C. 294n et seq.), as amended by section 423, is
5 further amended by adding at the end the following:

6 **“SEC. 776. PUBLIC HEALTH WORKFORCE LOAN REPAYMENT**
7 **PROGRAM.**

8 “(a) ESTABLISHMENT.—The Secretary shall estab-
9 lish the Public Health Workforce Loan Repayment Pro-
10 gram (referred to in this section as the ‘Program’) to as-
11 sure an adequate supply of public health professionals to
12 eliminate critical public health workforce shortages in
13 Federal, State, local, and tribal public health agencies.

14 “(b) ELIGIBILITY.—To be eligible to participate in
15 the Program, an individual shall—

16 “(1)(A) be accepted for enrollment, or be en-
17 rolled, as a student in an accredited academic edu-
18 cational institution in a State or territory in the
19 final year of a course of study or program leading
20 to a public health or health professions degree or
21 certificate; and have accepted employment with a
22 Federal, State, local, or tribal public health agency,
23 or a related training fellowship, as recognized by the
24 Secretary, to commence upon graduation;

25 “(B)(i) have graduated, during the preceding
26 10-year period, from an accredited educational insti-

1 tution in a State or territory and received a public
2 health or health professions degree or certificate;
3 and

4 “(ii) be employed by, or have accepted employ-
5 ment with, a Federal, State, local, or tribal public
6 health agency or a related training fellowship, as
7 recognized by the Secretary;

8 “(2) be a United States citizen; and

9 “(3)(A) submit an application to the Secretary
10 to participate in the Program;

11 “(B) execute a written contract as required in
12 subsection (c); and

13 “(4) not have received, for the same service, a
14 reduction of loan obligations under section 455(m),
15 428J, 428K, 428L, or 460 of the Higher Education
16 Act of 1965.

17 “(c) CONTRACT.—The written contract (referred to
18 in this section as the ‘written contract’) between the Sec-
19 retary and an individual shall contain—

20 “(1) an agreement on the part of the Secretary
21 that the Secretary will repay on behalf of the indi-
22 vidual loans incurred by the individual in the pursuit
23 of the relevant degree or certificate in accordance
24 with the terms of the contract;

1 “(2) an agreement on the part of the individual
2 that the individual will serve in the full-time employ-
3 ment of a Federal, State, local, or tribal public
4 health agency or a related fellowship program in a
5 position related to the course of study or program
6 for which the contract was awarded for a period of
7 time (referred to in this section as the ‘period of ob-
8 ligated service’) equal to the greater of—

9 “(A) 3 years; or

10 “(B) such longer period of time as deter-
11 mined appropriate by the Secretary and the in-
12 dividual;

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

18 “(4) a provision that any financial obligation of
19 the United States arising out of a contract entered
20 into under this section and any obligation of the in-
21 dividual that is conditioned thereon, is contingent on
22 funds being appropriated for loan repayments under
23 this section;

1 “(5) a statement of the damages to which the
2 United States is entitled, under this section for the
3 individual’s breach of the contract; and

4 “(6) such other statements of the rights and li-
5 abilities of the Secretary and of the individual, not
6 inconsistent with this section.

7 “(d) PAYMENTS.—

8 “(1) IN GENERAL.—A loan repayment provided
9 for an individual under a written contract under the
10 Program shall consist of payment, in accordance
11 with paragraph (2), on behalf of the individual of
12 the principal, interest, and related expenses on gov-
13 ernment and commercial loans received by the indi-
14 vidual regarding the undergraduate or graduate edu-
15 cation of the individual (or both), which loans were
16 made for tuition expenses incurred by the individual.

17 “(2) PAYMENTS FOR YEARS SERVED.—For
18 each year of obligated service that an individual con-
19 tracts to serve under subsection (c) the Secretary
20 may pay up to \$35,000 on behalf of the individual
21 for loans described in paragraph (1). With respect to
22 participants under the Program whose total eligible
23 loans are less than \$105,000, the Secretary shall
24 pay an amount that does not exceed $\frac{1}{3}$ of the eligi-

1 ble loan balance for each year of obligated service of
2 the individual.

3 “(3) TAX LIABILITY.—For the purpose of pro-
4 viding reimbursements for tax liability resulting
5 from payments under paragraph (2) on behalf of an
6 individual, the Secretary shall, in addition to such
7 payments, make payments to the individual in an
8 amount not to exceed 39 percent of the total amount
9 of loan repayments made for the taxable year in-
10 volved.

11 “(e) POSTPONING OBLIGATED SERVICE.—With re-
12 spect to an individual receiving a degree or certificate from
13 a health professions or other related school, the date of
14 the initiation of the period of obligated service may be
15 postponed as approved by the Secretary.

16 “(f) BREACH OF CONTRACT.—An individual who fails
17 to comply with the contract entered into under subsection
18 (c) shall be subject to the same financial penalties as pro-
19 vided for under section 338E for breaches of loan repay-
20 ment contracts under section 338B.

21 “(g) AUTHORIZATION OF APPROPRIATIONS.—There
22 is authorized to be appropriated to carry out this section
23 \$195,000,000 for fiscal year 2010, and such sums as may
24 be necessary for each of fiscal years 2011 through 2015.”.

1 **SEC. 425. ALLIED HEALTH WORKFORCE RECRUITMENT**
2 **AND RETENTION PROGRAMS.**

3 (a) PURPOSE.—The purpose of this section is to as-
4 sure an adequate supply of allied health professionals to
5 eliminate critical allied health workforce shortages in Fed-
6 eral, State, local, and tribal public health agencies or in
7 settings where patients might require health care services,
8 including acute care facilities, ambulatory care facilities,
9 personal residences and other settings, as recognized by
10 the Secretary of Health and Human Services by author-
11 izing an Allied Health Loan Forgiveness Program.

12 (b) ALLIED HEALTH WORKFORCE RECRUITMENT
13 AND RETENTION PROGRAM.—Section 428K of the Higher
14 Education Act of 1965 (20 U.S.C. 1078–11) is amend-
15 ed—

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

18 “(18) ALLIED HEALTH PROFESSIONALS.—The
19 individual is employed full-time as an allied health
20 professional—

21 “(A) in a Federal, State, local, or tribal
22 public health agency; or

23 “(B) in a setting where patients might re-
24 quire health care services, including acute care
25 facilities, ambulatory care facilities, personal
26 residences and other settings located in health

1 professional shortage areas, medically under-
2 served areas, or medically underserved popu-
3 lations, as recognized by the Secretary of
4 Health and Human Services.”; and

5 (2) in subsection (g)—

6 (A) by redesignating paragraphs (1)
7 through (9) as paragraphs (2) through (10), re-
8 spectively; and

9 (B) by inserting before paragraph (2) (as
10 redesignated by subparagraph (A)) the fol-
11 lowing:

12 “(1) ALLIED HEALTH PROFESSIONAL.—The
13 term ‘allied health professional’ means an allied
14 health professional as defined in section 799B(5) of
15 the Public Health Service Act (42 U.S.C. 295p(5))
16 who—

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

20 “(B) is employed with a Federal, State,
21 local or tribal public health agency, or in a set-
22 ting where patients might require health care
23 services, including acute care facilities, ambula-
24 tory care facilities, personal residences and
25 other settings located in health professional

1 shortage areas, medically underserved areas, or
2 medically underserved populations, as recog-
3 nized by the Secretary of Health and Human
4 Services.”.

5 **SEC. 426. GRANTS FOR STATE AND LOCAL PROGRAMS.**

6 (a) IN GENERAL.—Section 765(d) of the Public
7 Health Service Act (42 U.S.C. 295(d)) is amended—

8 (1) in paragraph (7), by striking “; or” and in-
9 serting a semicolon;

10 (2) by redesignating paragraph (8) as para-
11 graph (9); and

12 (3) by inserting after paragraph (7) the fol-
13 lowing:

14 “(8) public health workforce loan repayment
15 programs; or”.

16 (b) TRAINING FOR MID-CAREER PUBLIC HEALTH
17 PROFESSIONALS.—Part E of title VII of the Public
18 Health Service Act (42 U.S.C. 294n et seq.), as amended
19 by section 424, is further amended by adding at the end
20 the following:

21 **“SEC. 777. TRAINING FOR MID-CAREER PUBLIC AND ALLIED**
22 **HEALTH PROFESSIONALS.**

23 “(a) IN GENERAL.—The Secretary may make grants
24 to, or enter into contracts with, any eligible entity to
25 award scholarships to eligible individuals to enroll in de-

1 gree or professional training programs for the purpose of
2 enabling mid-career professionals in the public health and
3 allied health workforce to receive additional training in the
4 field of public health and allied health.

5 “(b) ELIGIBILITY.—

6 “(1) ELIGIBLE ENTITY.—The term ‘eligible en-
7 tity’ indicates an accredited educational institution
8 that offers a course of study, certificate program, or
9 professional training program in public or allied
10 health or a related discipline, as determined by the
11 Secretary

12 “(2) ELIGIBLE INDIVIDUALS.—The term ‘eligi-
13 ble individuals’ includes those individuals employed
14 in public and allied health positions at the Federal,
15 State, tribal, or local level who are interested in re-
16 taining or upgrading their education.

17 “(c) AUTHORIZATION OF APPROPRIATIONS.—There
18 is authorized to be appropriated to carry out this section,
19 \$60,000,000 for fiscal year 2010 and such sums as may
20 be necessary for each of fiscal years 2011 through 2015.
21 Fifty percent of appropriated funds shall be allotted to
22 public health mid-career professionals and 50 percent shall
23 be allotted to allied health mid-career professionals.”.

1 **SEC. 427. FUNDING FOR NATIONAL HEALTH SERVICE**
2 **CORPS.**

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

5 “(a) AUTHORIZATION OF APPROPRIATIONS.—For the
6 purpose of carrying out this section, there is authorized
7 to be appropriated, out of any funds in the Treasury not
8 otherwise appropriated, the following:

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

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

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

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

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

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

15 “(7) For fiscal year 2016, and each subsequent
16 fiscal year, the amount appropriated for the pre-
17 ceding fiscal year adjusted by the product of—

18 “(A) one plus the average percentage in-
19 crease in the costs of health professions edu-
20 cation during the prior fiscal year; and

21 “(B) one plus the average percentage
22 change in the number of individuals residing in
23 health professions shortage areas designated
24 under section 333 during the prior fiscal year,
25 relative to the number of individuals residing in
26 such areas during the previous fiscal year.”.

1 **【NOTE: this section is the same as section 173**
2 **of title I.】**

3 **SEC. 428. NURSE-MANAGED HEALTH CLINICS.**

4 (a) **PURPOSE.**—The purpose of this section is to fund
5 the development and operation of nurse-managed health
6 clinics in order to provide comprehensive primary health
7 care and wellness services to vulnerable populations living
8 in the Nation’s medically underserved communities, and
9 to reduce the level of health disparities experienced by vul-
10 nerable populations.

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

14 **“SEC. 330A-1. GRANTS TO NURSE-MANAGED HEALTH CLIN-**
15 **ICS.**

16 “(a) **DEFINITIONS.**—

17 “(1) **COMPREHENSIVE PRIMARY HEALTH CARE**
18 **SERVICES.**—In this section, the term ‘comprehensive
19 primary health care services’ means the primary
20 health services described in section 330(b)(1).

21 “(2) **NURSE-MANAGED HEALTH CLINIC.**—The
22 term ‘nurse-managed health clinic’ means a nurse-
23 practice arrangement, managed by advanced practice
24 nurses, that provides primary care or wellness serv-
25 ices to underserved or vulnerable populations and

1 that is associated with a school, college, university or
2 department of nursing, federally qualified health
3 center, or independent nonprofit health or social
4 services agency.

5 “(b) AUTHORITY TO AWARD GRANTS.—The Sec-
6 retary shall award grants for the cost of the operation of
7 nurse-managed health clinics that meet the requirements
8 of this section.

9 “(c) APPLICATIONS.—To be eligible to receive a grant
10 under this section, an entity shall—

11 “(1) be an NMHC; and

12 “(2) submit to the Secretary an application at
13 such time, in such manner, and containing—

14 “(A) assurances that nurses are the major
15 providers of services at the NMHC and that at
16 least 1 advanced practice nurse holds an execu-
17 tive management position within the organiza-
18 tional structure of the NMHC;

19 “(B) an assurance that the NMHC will
20 continue providing comprehensive primary
21 health care services or wellness services without
22 regard to income or insurance status of the pa-
23 tient for the duration of the grant period; and

24 “(C) an assurance that, not later than 90
25 days of receiving a grant under this section, the

1 NMHC will establish a community advisory
2 committee, for which a majority of the members
3 shall be individuals who are served by the
4 NMHC.

5 “(d) GRANT AMOUNT.—The amount of any grant
6 made under this section for any fiscal year shall be deter-
7 mined by the Secretary, taking into account—

8 “(1) the financial need of the NMHC, consid-
9 ering State, local, and other operational funding pro-
10 vided to the NMHC; and

11 “(2) other factors, as the Secretary determines
12 appropriate.

13 “(e) AUTHORIZATION OF APPROPRIATIONS.—For the
14 purposes of carrying out this section, there are authorized
15 to be appropriated \$50,000,000 for the fiscal year 2010
16 and such sums as may be necessary for each of the fiscal
17 years 2011 through 2014.”.

18 **SEC. 429. ELIMINATION OF CAP ON COMMISSIONED CORPS.**

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

22 **SEC. 430. ESTABLISHING A READY RESERVE CORPS.**

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

1 **“SEC. 203. COMMISSIONED CORPS AND READY RESERVE**
2 **CORPS.**

3 “(a) ESTABLISHMENT.—

4 “(1) IN GENERAL.—There shall be in the Serv-
5 ice a commissioned Regular Corps and a Ready Re-
6 serve Corps for service in time of national emer-
7 gency.

8 “(2) REQUIREMENT.—All commissioned officers
9 shall be citizens of the United States and shall be
10 appointed without regard to the civil-service laws
11 and compensated without regard to the Classifica-
12 tion Act of 1923, as amended.

13 “(3) APPOINTMENT.—Commissioned officers of
14 the Ready Reserve Corps shall be appointed by the
15 President and commissioned officers of the Regular
16 Corps shall be appointed by the President with the
17 advice and consent of the Senate.

18 “(4) ACTIVE DUTY.—Commissioned officers of
19 the Ready Reserve Corps shall at all times be sub-
20 ject to call to active duty by the Surgeon General,
21 including active duty for the purpose of training.

22 “(5) WARRANT OFFICERS.—Warrant officers
23 may be appointed to the Service for the purpose of
24 providing support to the health and delivery systems
25 maintained by the Service and any warrant officer
26 appointed to the Service shall be considered for pur-

1 poses of this Act and title 37, United States Code,
2 to be a commissioned officer within the Commis-
3 sioned Corps of the Service.

4 “(b) ASSIMILATING RESERVE CORP OFFICERS INTO
5 THE REGULAR CORPS.—Effective on the date of enact-
6 ment of the Affordable Health Choices Act, all individuals
7 classified as officers in the Reserve Corps under this sec-
8 tion (as such section existed on the day before the date
9 of enactment of such Act) and serving on active duty shall
10 be deemed to be commissioned officers of the Regular
11 Corps.

12 “(c) PURPOSE AND USE OF READY RESEARCH.—

13 “(1) PURPOSE.—The purpose of the Ready Re-
14 serve Corps is to fulfill the need to have additional
15 Commissioned Corps personnel available on short
16 notice (similar to the uniformed service’s reserve
17 program) to assist regular Commissioned Corps per-
18 sonnel to meet both routine public health and emer-
19 gency response missions.

20 “(2) USES.—The Ready Reserve Corps shall—

21 “(A) participate in routine training to
22 meet the general and specific needs of the Com-
23 missioned Corps;

24 “(B) be available and ready for involuntary
25 calls to active duty during national emergencies

1 and public health crises, similar to the uni-
2 formed service reserve personnel;

3 “(C) be available for backfilling critical po-
4 sitions left vacant during deployment of active
5 duty Commissioned Corps members, as well as
6 for deployment to respond to public health
7 emergencies, both foreign and domestic; and

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

12 “(d) FUNDING.—For the purpose of carrying out the
13 duties and responsibilities of the Commissioned Corps
14 under this section, there are authorized to be appropriated
15 \$5,000,000 for each of fiscal years 2010 through 2014
16 for recruitment and training and \$12,500,000 for each of
17 fiscal years 2010 through 2014 for the Ready Reserve
18 Corps.”.

19 **Subtitle D—Enhancing Health Care**
20 **Workforce Education and Training**

21 **SEC. 431. TRAINING IN FAMILY MEDICINE, GENERAL INTER-**
22 **NAL MEDICINE, GENERAL PEDIATRICS, AND**
23 **PHYSICIAN ASSISTANTSHIP.**

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

1 **“SEC. 747. PRIMARY CARE TRAINING AND ENHANCEMENT.**

2 “(a) SUPPORT AND DEVELOPMENT OF PRIMARY
3 CARE TRAINING PROGRAMS.—

4 “(1) IN GENERAL.—The Secretary may make
5 grants to, or enter into contracts with, an accredited
6 public or nonprofit private hospital, school of medi-
7 cine or osteopathic medicine, academically affiliated
8 physician assistant training program, or a public or
9 private nonprofit entity which the Secretary has de-
10 termined is capable of carrying out such grant or
11 contract—

12 “(A) to plan, develop, operate, or partici-
13 pate in an accredited professional training pro-
14 gram, including an accredited residency or in-
15 ternship program in the field of family medi-
16 cine, general internal medicine, or general pedi-
17 atrics for medical students, interns, residents,
18 or practicing physicians as defined by the Sec-
19 retary;

20 “(B) to provide need-based financial assist-
21 ance in the form of traineeships and fellowships
22 to medical students, interns, residents, prac-
23 ticing physicians, or other medical personnel,
24 who are participants in any such program, and
25 who plan to specialize or work in the practice
26 of the fields defined in subparagraph (A);

1 “(C) to plan, develop, and operate a pro-
2 gram for the training of physicians who plan to
3 teach in family medicine, general internal medi-
4 cine, or general pediatrics training programs;

5 “(D) to plan, develop, and operate a pro-
6 gram for the training of physicians teaching in
7 community-based settings;

8 “(E) to provide financial assistance in the
9 form of traineeships and fellowships to physi-
10 cians who are participants in any such pro-
11 grams and who plan to teach or conduct re-
12 search in a family medicine, general internal
13 medicine, or general pediatrics training pro-
14 gram;

15 “(F) to plan, develop, and operate a physi-
16 cian assistant education program, and for the
17 training of individuals who will teach in pro-
18 grams to provide such training;

19 “(G) to plan, develop, and operate a dem-
20 onstration program that provides training in
21 new competencies, as recommended by the Ad-
22 visory Committee on Training in Primary Care
23 Medicine and Dentistry and the National
24 Health Care Workforce Commission established

1 in section 411 of the Affordable Health Choices
2 Act, which may include—

3 “(i) providing training to primary
4 care physicians relevant to providing care
5 through patient-centered medical homes
6 (as defined by the Secretary for purposes
7 of this section);

8 “(ii) developing tools and curricula
9 relevant to patient-centered medical homes;
10 and

11 “(iii) providing continuing education
12 to primary care physicians relevant to pa-
13 tient-centered medical homes; and

14 “(H) to plan, develop, and operate joint
15 degree programs to provide interdisciplinary
16 and interprofessional graduate training in pub-
17 lic health and other health professions to pro-
18 vide training in environmental health, infectious
19 disease control, disease prevention and health
20 promotion, epidemiological studies and injury
21 control.

22 “(2) DURATION OF AWARDS.—The period dur-
23 ing which payments are made to an entity from an
24 award of a grant or contract under this subsection
25 shall be 5 years.

1 “(b) CAPACITY BUILDING IN PRIMARY CARE.—

2 “(1) IN GENERAL.—The Secretary may make
3 grants to or enter into contracts with accredited
4 schools of medicine or osteopathic medicine to estab-
5 lish, maintain, or improve—

6 “(A) academic units (which may be depart-
7 ments, divisions, or other units) or programs
8 that improve clinical teaching and research in
9 fields defined in subsection (a)(1)(A); or

10 “(B) programs that integrate academic ad-
11 ministrative units in fields defined in subsection
12 (a)(1)(A) to enhance interdisciplinary recruit-
13 ment, training, and faculty development.

14 “(2) PREFERENCE IN MAKING AWARDS UNDER
15 THIS SUBSECTION.—In making awards of grants
16 and contracts under paragraph (1), the Secretary
17 shall give preference to any qualified applicant for
18 such an award that agrees to expend the award for
19 the purpose of—

20 “(A) establishing academic units or pro-
21 grams in fields defined in subsection (a)(1)(A);
22 or

23 “(B) substantially expanding such units or
24 programs.

1 “(3) PRIORITIES IN MAKING AWARDS.—In
2 awarding grants or contracts under paragraph (1),
3 the Secretary shall give priority to qualified appli-
4 cants that—

5 “(A) proposes a collaborative project be-
6 tween academic administrative units of primary
7 care;

8 “(B) proposes innovative approaches to
9 clinical teaching using models of primary care,
10 such as the patient centered medical home,
11 team management of chronic disease, and inter-
12 professional integrated models of health care
13 that incorporate transitions in health care set-
14 tings and integration physical and mental
15 health provision;

16 “(C) have a record of training the greatest
17 percentage of providers, or that have dem-
18 onstrated significant improvements in the per-
19 centage of providers trained, who enter and re-
20 main in primary care practice;

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

24 “(E) provide training in the care of vulner-
25 able populations such as children, older adults,

1 homeless individuals, victims of abuse or trauma,
2 ma, individuals with mental health or substance-related disorders, individuals with HIV/
3 AIDS, and individuals with disabilities;

4 “(F) establish formal relationships and
5 submit joint applications with federally qualified
6 health centers, rural health clinics, area health
7 education centers, or clinics located in underserved areas or that serve underserved populations;
8
9
10

11 “(G) teach trainees the skills to provide
12 interprofessional, integrated care through collaboration among health professionals;
13

14 “(H) provide training in enhanced communication with patients, evidence-based practice,
15 chronic disease management, preventive care,
16 health information technology, or other competencies as recommended by the Advisory
17 Committee on Training in Primary Care Medicine and Dentistry and the National Health
18 Care Workforce Commission established in section 411 of the Affordable Health Choices Act;
19
20
21
22
23 or

24 “(I) provide training in cultural competency and health literacy.
25

1 “(4) DURATION OF AWARDS.—The period dur-
2 ing which payments are made to an entity from an
3 award of a grant or contract under this subsection
4 shall be 5 years.

5 “(c) AUTHORIZATION OF APPROPRIATIONS.—

6 “(1) IN GENERAL.—For purposes of carrying
7 out this section (other than subsection (b)(1)(B)),
8 there are authorized to be appropriated
9 \$125,000,000 for fiscal year 2010, and such sums
10 as may be necessary for each of fiscal years 2011
11 through 2014.

12 “(2) TRAINING PROGRAMS.—Fifteen percent of
13 the amount appropriated pursuant to paragraph (1)
14 in each such fiscal year shall be allocated to the phy-
15 sician assistant training programs described in sub-
16 section (a)(1)(F), which prepare students for prac-
17 tice in primary care.

18 “(3) INTEGRATING ACADEMIC ADMINISTRATIVE
19 UNITS.—For purposes of carrying out subsection
20 (b)(1)(B), there are authorized to be appropriated
21 \$750,000 for each of fiscal years 2010 through
22 2014.”.

1 SEC. 432. TRAINING OPPORTUNITIES FOR DIRECT CARE
2 WORKERS.

3 Part C of title VII of the Public Health Service Act
4 (42 U.S.C. 293k et seq.) is amended by inserting after
5 section 747, as amended by section 431, the following:

6 **“SEC. 747A. TRAINING OPPORTUNITIES FOR DIRECT CARE**
7 **WORKERS.**

8 “(a) IN GENERAL.—The Secretary shall award
9 grants to eligible entities to enable such entities to provide
10 new training opportunities for direct care workers who are
11 employed in long-term care settings such as nursing
12 homes (as defined in section 1908(e)(1) of the Social Se-
13 curity Act (42 U.S.C. 1396g(e)(1)), assisted living facili-
14 ties and skilled nursing facilities, intermediate care facili-
15 ties for individuals with mental retardation, home and
16 community based settings, and any other setting the Sec-
17 retary determines to be appropriate.

18 “(b) ELIGIBILITY.—To be eligible to receive a grant
19 under this section, an entity shall—

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

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

1 “(B) has established a public-private edu-
2 cational partnership with a nursing home or
3 skilled nursing facility, agency or entity pro-
4 viding home and community based services to
5 individuals with disabilities, or other long-term
6 care provider; and

7 “(2) submit to the Secretary an application at
8 such time, in such manner, and containing such in-
9 formation as the Secretary may require.

10 “(c) USE OF FUNDS.—An eligible entity shall use
11 amounts awarded under a grant under this section to pro-
12 vide assistance to eligible individuals to offset the cost of
13 tuition and required fees for enrollment in academic pro-
14 grams provided by such entity.

15 “(d) ELIGIBLE INDIVIDUAL.—

16 “(1) ELIGIBILITY.—To be eligible for assistance
17 under this section, an individual shall be enrolled in
18 courses provided by a grantee under this subsection
19 and maintain satisfactory academic progress in such
20 courses.

21 “(2) CONDITION OF ASSISTANCE.—As a condi-
22 tion of receiving assistance under this section, an in-
23 dividual shall agree that, following completion of the
24 assistance period, the individual will work in the
25 field of geriatrics, disability services, long term serv-

1 ices and supports, or chronic care management for
2 a minimum of 2 years under guidelines set by the
3 Secretary.

4 “(e) AUTHORIZATION OF APPROPRIATIONS.—There
5 is authorized to be appropriated to carry out this section,
6 \$10,000,000 for the period of fiscal years 2011 through
7 2013.”.

8 **SEC. 433. TRAINING IN GENERAL, PEDIATRIC, AND PUBLIC**
9 **HEALTH DENTISTRY.**

10 Part C of Title VII of the Public Health Service Act
11 (42 U.S.C. 293k et seq.) is amended by—

12 (1) redesignating section 748, as amended by
13 section 413 of this Act, as section 749; and

14 (2) inserting after section 747A, as added by
15 section 432, the following:

16 **“SEC. 748. TRAINING IN GENERAL, PEDIATRIC, AND PUBLIC**
17 **HEALTH DENTISTRY.**

18 “(a) SUPPORT AND DEVELOPMENT OF DENTAL
19 TRAINING PROGRAMS.—

20 “(1) IN GENERAL.—The Secretary may make
21 grants to, or enter into contracts with, a school of
22 dentistry, public or nonprofit private hospital, or a
23 public or private nonprofit entity which the Sec-
24 retary has determined is capable of carrying out
25 such grant or contract—

1 “(A) to plan, develop, and operate, or par-
2 ticipate in, an approved professional training
3 program in the field of general dentistry, pedi-
4 atric dentistry, or public health dentistry for
5 dental students, residents, practicing dentists,
6 dental hygienists, or other approved primary
7 care dental trainees, that emphasizes training
8 for general, pediatric, or public health dentistry;

9 “(B) to provide financial assistance to den-
10 tal students, residents, practicing dentists, and
11 dental hygiene students who are in need there-
12 of, who are participants in any such program,
13 and who plan to work in the practice of general,
14 pediatric, public health dentistry, or dental hy-
15 giene;

16 “(C) to plan, develop, and operate a pro-
17 gram for the training of oral health care pro-
18 viders who plan to teach in general, pediatric,
19 public health dentistry, or dental hygiene;

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

24 “(E) to meet the costs of projects to estab-
25 lish, maintain, or improve dental faculty devel-

1 opment programs in primary care (which may
2 be departments, divisions or other units);

3 “(F) to meet the costs of projects to estab-
4 lish, maintain, or improve predoctoral and
5 postdoctoral training in primary care programs;

6 “(G) to create a loan repayment program
7 for faculty in dental programs; and

8 “(H) to provide technical assistance to pe-
9 diatric training programs in developing and im-
10 plementing instruction regarding the oral health
11 status, dental care needs, and risk-based clin-
12 ical disease management of all pediatric popu-
13 lations with an emphasis on underserved chil-
14 dren.

15 “(2) FACULTY LOAN REPAYMENT.—

16 “(A) IN GENERAL.—A grant or contract
17 under subsection (a)(1)(G) may be awarded to
18 a program of general, pediatric, or public health
19 dentistry described in such subsection to plan,
20 develop, and operate a loan repayment program
21 under which—

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

24 “(ii) the program of general, pediatric
25 or public health dentistry agrees to pay the

1 principal and interest on the outstanding
2 student loans of the individuals.

3 “(B) MANNER OF PAYMENTS.—With re-
4 spect to the payments described in subpara-
5 graph (A)(ii), upon completion by an individual
6 of each of the first, second, third, fourth, and
7 fifth years of service, the program shall pay an
8 amount equal to 10, 15, 20, 25, and 30 per-
9 cent, respectively, of the individual’s student
10 loan balance as calculated based on principal
11 and interest owed at the initiation of the agree-
12 ment.

13 “(b) ELIGIBLE ENTITY.—For purposes of this sub-
14 section, entities eligible for such grants or contracts in
15 general, pediatric, or public health dentistry shall include
16 entities that have programs in dental or dental hygiene
17 schools, or approved residency or advanced education pro-
18 grams in the practice of general, pediatric, or public health
19 dentistry. Eligible entities may partner with schools of
20 public health to permit the education of dental students,
21 residents, and dental hygiene students for a master’s year
22 in public health at a school of public health.

23 “(c) PRIORITIES IN MAKING AWARDS.—With respect
24 to training provided for under this section, the Secretary

1 shall give priority in awarding grants or contracts to the
2 following:

3 “(1) Qualified applicants that propose collabo-
4 rative projects between departments of primary care
5 medicine and departments of general, pediatric, or
6 public health dentistry.

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

12 “(3) Qualified applicants that have a record of
13 training individuals who are from a rural or dis-
14 advantaged background, or from underrepresented
15 minorities.

16 “(4) Qualified applicants that establish formal
17 relationships with Federally qualified health centers,
18 rural health centers, or accredited teaching facilities
19 and that conduct training of students, residents, fel-
20 lows, or faculty at the center or facility.

21 “(5) Qualified applicants that conduct teaching
22 programs targeting vulnerable populations such as
23 older adults, homeless individuals, victims of abuse
24 or trauma, individuals with mental health or sub-

1 stance-related disorders, individuals with disabilities,
2 and individuals with HIV/AIDS.

3 “(6) Qualified applicants that include edu-
4 cational activities in cultural competency and health
5 literacy.

6 “(7) Qualified applicants that provide instruc-
7 tion regarding the oral health status, dental care
8 needs, and risk-based clinical disease management of
9 all populations, with an emphasis on underserved
10 children.

11 “(8) Qualified applicants that intend to estab-
12 lish a special populations oral health care education
13 center or training program for the didactic and clin-
14 ical education of dentists, dental health profes-
15 sionals, and dental hygienists who plan to teach oral
16 health care for people with developmental disabili-
17 ties, cognitive impairment, complex medical prob-
18 lems, significant physical limitations, and vulnerable
19 elderly.

20 “(d) PREFERENCE IN MAKING AWARDS.—In making
21 awards of grants or contracts under this section, the Sec-
22 retary shall give preference to any qualified applicant
23 that—

24 “(1) has a high rate for placing graduates in
25 practice settings having the principal focus of serv-

1 ing in underserved areas or health disparity popu-
2 lations (including serving patients eligible for Med-
3 icaid or the Children’s Health Insurance Program,
4 or those with special health care needs); or

5 “(2) during the 2-year period before the fiscal
6 year for which such an award is sought, has
7 achieved a significant increase in the rate of placing
8 graduates in such settings or graduating practi-
9 tioners who serve health disparity populations in
10 their practices.

11 “(e) APPLICATION.—An eligible entity desiring a
12 grant under this section shall submit to the Secretary an
13 application at such time, in such manner, and containing
14 such information as the Secretary may require.

15 “(f) DURATION OF AWARD.—The period during
16 which payments are made to an entity from an award of
17 a grant or contract under subsection (a) shall be 5 years.
18 The provision of such payments shall be subject to annual
19 approval by the Secretary and subject to the availability
20 of appropriations for the fiscal year involved to make the
21 payments.

22 “(g) AUTHORIZATIONS OF APPROPRIATIONS.—For
23 the purpose of carrying out subsections (a) and (b), there
24 is authorized to be appropriated \$30,000,000 for fiscal

1 year 2010 and such sums as may be necessary for each
2 of fiscal years 2011 through 2015.

3 “(h) CARRYOVER FUNDS.—An entity that receives an
4 award under this section may carry over funds from 1 fis-
5 cal year to another without obtaining approval from the
6 Secretary. In no case may any funds be carried over pur-
7 suant to the preceding sentence for more than 3 years.”.

8 **SEC. 434. ALTERNATIVE DENTAL HEALTH CARE PRO-**
9 **VIDERS DEMONSTRATION PROJECT.**

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

13 **“SEC. 340H. DEMONSTRATION PROGRAM.**

14 “(a) IN GENERAL.—

15 “(1) AUTHORIZATION.—The Secretary is au-
16 thorized to award grants to 15 eligible entities to en-
17 able such entities to establish a demonstration pro-
18 gram to establish training programs to train, or to
19 employ, alternative dental health care providers in
20 order to increase access to dental health care serv-
21 ices in rural and other underserved communities.

22 “(2) DEFINITION.—The term ‘alternative den-
23 tal health care providers’ includes community dental
24 health coordinators, advance practice dental hygien-
25 ists, independent dental hygienists, supervised dental

1 hygienists, primary care physicians, dental thera-
2 pists, dental health aides, and any other health pro-
3 fessional that the Secretary determines appropriate.

4 “(b) TIMEFRAME.—The demonstration projects fund-
5 ed under this section shall begin not later than 2 years
6 after the date of enactment of this section, and shall con-
7 clude not later than 7 years after such date of enactment.

8 “(c) ELIGIBLE ENTITIES.—To be eligible to receive
9 a grant under subsection (a), an entity shall—

10 “(1) be—

11 “(A) an institution of higher education, in-
12 cluding a community college;

13 “(B) a public-private partnership;

14 “(C) a federally qualified health center;

15 “(D) an Indian Health Service facility or a
16 tribe or tribal organization (as such terms are
17 defined in section 4 of the Indian Self-Deter-
18 mination and Education Assistance Act);

19 “(E) a State or county public health clinic,
20 a health facility operated by an Indian tribe or
21 tribal organization, or urban Indian organiza-
22 tion providing dental services; or

23 “(F) a public hospital or health system;

24 “(2) be within a program accredited by the
25 Commission on Dental Accreditation or within a

1 dental education program in an accredited institu-
2 tion; and

3 “(3) shall submit an application to the Sec-
4 retary at such time, in such manner, and containing
5 such information as the Secretary may require.

6 “(d) ADMINISTRATIVE PROVISIONS.—

7 “(1) AMOUNT OF GRANT.—Each grant under
8 this section shall be in an amount that is not less
9 than \$4,000,000 for the 5-year period during which
10 the demonstration project being conducted.

11 “(2) DISBURSEMENT OF FUNDS.—

12 “(A) PRELIMINARY DISBURSEMENTS.—Be-
13 ginning 1 year after the enactment of this sec-
14 tion, the Secretary may disperse to any entity
15 receiving a grant under this section not more
16 than 20 percent of the total funding awarded to
17 such entity under such grant, for the purpose
18 of enabling the entity to plan the demonstration
19 project to be conducted under such grant.

20 “(B) SUBSEQUENT DISBURSEMENTS.—The
21 remaining amount of grant funds not dispersed
22 under subparagraph (A) shall be dispersed such
23 that not less than 15 percent of such remaining
24 amount is dispersed each subsequent year.

1 “(e) COMPLIANCE WITH STATE REQUIREMENTS.—

2 Each entity receiving a grant under this section shall cer-
3 tify that it is in compliance with all applicable State licens-
4 ing requirements.

5 “(f) EVALUATION.—

6 “(1) IN GENERAL.—The Secretary shall con-
7 tract with the Director of the Institute of Medicine
8 (referred to in this subsection as the ‘Director’) to
9 conduct a study of the demonstration programs con-
10 ducted under this section that shall provide analysis,
11 based upon quantitative and qualitative data, re-
12 garding access to dental health care in the United
13 States.

14 “(2) DATA COLLECTION.—

15 “(A) BASELINE DATA.—The Director shall
16 gather data from each demonstration project
17 not later than 24 months after the commence-
18 ment of the project, which shall serve as base-
19 line data for the study.

20 “(B) COMPARISON DATA.—The Director
21 shall begin collecting data from each dem-
22 onstration project 1 year after such project con-
23 cludes, and shall conclude such data collection
24 not later than 18 months after the conclusion
25 of the project.

1 “(g) CLARIFICATION REGARDING DENTAL HEALTH
2 AIDE PROGRAM.—Nothing in this section shall prohibit a
3 dental health aide training program approved by the In-
4 dian Health Service from being eligible for a grant under
5 this section.

6 “(h) AUTHORIZATION OF APPROPRIATIONS.—There
7 is authorized to be appropriated such sums as may be nec-
8 essary to carry out this section.”.

9 **SEC. 435. GERIATRIC EDUCATION AND TRAINING; CAREER**
10 **AWARDS; COMPREHENSIVE GERIATRIC EDU-**
11 **CATION.**

12 (a) WORKFORCE DEVELOPMENT; CAREER
13 AWARDS.—Section 753 of the Public Health Service Act
14 (42 U.S.C. 294c) is amended by adding at the end the
15 following:

16 “(d) GERIATRIC WORKFORCE DEVELOPMENT.—

17 “(1) IN GENERAL.—The Secretary shall award
18 grants or contracts under this subsection to entities
19 that operate a geriatric education center pursuant to
20 subsection (a)(1).

21 “(2) APPLICATION.—To be eligible for an
22 award under paragraph (1), an entity described in
23 such paragraph shall submit to the Secretary an ap-
24 plication at such time, in such manner, and con-

1 taining such information as the Secretary may re-
2 quire.

3 “(3) USE OF FUNDS.—Amounts awarded under
4 a grant or contract under paragraph (1) shall be
5 used to—

6 “(A) carry out the fellowship program de-
7 scribed in paragraph (4); and

8 “(B) carry out 1 of the 2 activities de-
9 scribed in paragraph (5).

10 “(4) FELLOWSHIP PROGRAM.—

11 “(A) IN GENERAL.—Pursuant to para-
12 graph (3), a geriatric education center that re-
13 ceives an award under this subsection shall use
14 such funds to offer short-term intensive courses
15 (referred to in this subsection as a ‘fellowship’)
16 that focus on geriatrics, chronic care manage-
17 ment, and long-term care that provide supple-
18 mental training for faculty members in medical
19 schools and other health professions schools
20 with programs in psychology, pharmacy, nurs-
21 ing, social work, dentistry, public health, allied
22 health, or other health disciplines, as approved
23 by the Secretary. Such a fellowship shall be
24 open to current faculty, and appropriately
25 credentialed volunteer faculty and practitioners,

1 who do not have formal training in geriatrics,
2 to upgrade their knowledge and clinical skills
3 for the care of older adults and adults with
4 functional limitations and to enhance their
5 interdisciplinary teaching skills.

6 “(B) LOCATION.—A fellowship shall be of-
7 fered either at the geriatric education center
8 that is sponsoring the course, in collaboration
9 with other geriatric education centers, or at
10 medical schools, schools of dentistry, schools of
11 nursing, schools of pharmacy, schools of social
12 work, graduate programs in psychology, or al-
13 lied health and other health professions schools
14 approved by the Secretary with which the geri-
15 atric education centers are affiliated.

16 “(C) CME CREDIT.—Participation in a fel-
17 lowship under this paragraph shall be accepted
18 with respect to complying with continuing
19 health profession education requirements. As a
20 condition of such acceptance, the recipient shall
21 agree to subsequently provide a minimum of 18
22 hours of voluntary instructional support
23 through a geriatric education center that is pro-
24 viding clinical training to students or trainees
25 in long-term care settings.

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

6 “(A) FAMILY CAREGIVER AND DIRECT
7 CARE PROVIDER TRAINING.—A geriatric edu-
8 cation center that receives an award under this
9 subsection shall offer at least 2 courses each
10 year, at no charge or nominal cost, to family
11 caregivers and direct care providers that are de-
12 signed to provide practical training for sup-
13 porting frail elders and individuals with disabil-
14 ities. The Secretary shall require such Centers
15 to work with appropriate community partners
16 to develop training program content and to
17 publicize the availability of training courses in
18 their service areas. All family caregiver and di-
19 rect care provider training programs shall in-
20 clude instruction on the management of psycho-
21 logical and behavioral aspects of dementia, com-
22 munication techniques for working with individ-
23 uals who have dementia, and the appropriate,
24 safe, and effective use of medications for older
25 adults.

1 “(B) INCORPORATION OF BEST PRAC-
2 TICES.—A geriatric education center that re-
3 ceives an award under this subsection shall de-
4 velop and include material on depression and
5 other mental disorders common among older
6 adults, medication safety issues for older adults,
7 and management of the psychological and be-
8 havioral aspects of dementia and communica-
9 tion techniques with individuals who have de-
10 mentia in all training courses, where appro-
11 priate.

12 “(6) TARGETS.—A geriatric education center
13 that receives an award under this subsection shall
14 meet targets approved by the Secretary for providing
15 geriatric training to a certain number of faculty or
16 practitioners during the term of the award, as well
17 as other parameters established by the Secretary, in-
18 cluding guidelines for the content of the fellowships.

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

23 “(8) MAINTENANCE OF EFFORT.—A geriatric
24 education center that receives an award under this
25 subsection shall provide assurances to the Secretary

1 that funds provided to the geriatric education center
2 under this subsection will be used only to supple-
3 ment, not to supplant, the amount of Federal, State,
4 and local funds otherwise expended by the geriatric
5 education center.

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

11 “(e) GERIATRIC CAREER INCENTIVE AWARDS.—

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

18 “(2) ELIGIBLE INDIVIDUALS.—To be eligible to
19 received an award under paragraph (1), an indi-
20 vidual shall—

21 “(A) be an advanced practice nurse, a clin-
22 ical social worker, a pharmacist, or student of
23 psychology who is pursuing a doctorate or other
24 advanced degree in geriatrics or related fields in
25 an accredited health professions school; and

1 “(B) submit to the Secretary an applica-
2 tion at such time, in such manner, and con-
3 taining such information as the Secretary may
4 require.

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

12 “(4) AUTHORIZATION OF APPROPRIATIONS.—
13 There is authorized to be appropriated to carry out
14 this subsection, \$10,000,000 for the period of fiscal
15 years 2011 through 2013.”.

16 (b) EXPANSION OF ELIGIBILITY FOR GERIATRIC
17 ACADEMIC CAREER AWARDS; PAYMENT TO INSTITU-
18 TION.—Section 753(c) of the Public Health Service Act
19 294(c)) is amended—

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

22 (2) by striking paragraph (2) through para-
23 graph (3) and inserting the following:

1 “(2) ELIGIBLE INDIVIDUALS.—To be eligible to
2 receive an Award under paragraph (1), an individual
3 shall—

4 “(A) be board certified or board eligible in
5 internal medicine, family practice, psychiatry,
6 or licensed dentistry, or have completed any re-
7 quired training in a discipline and employed in
8 an accredited health professions school that is
9 approved by the Secretary;

10 “(B) have completed an approved fellow-
11 ship program in geriatrics; and

12 “(C) have a junior (non-tenured) faculty
13 appointment at an accredited (as determined by
14 the Secretary) school of medicine, osteopathic
15 medicine, nursing, social work, psychology, den-
16 tistry, pharmacy, or other allied health dis-
17 ciplines in an accredited health professions
18 school that is approved by the Secretary.

19 “(3) LIMITATIONS.—No Award under para-
20 graph (1) may be made to an eligible individual un-
21 less the individual—

22 “(A) has submitted to the Secretary an ap-
23 plication, at such time, in such manner, and
24 containing such information as the Secretary

1 may require, and the Secretary has approved
2 such application;

3 “(B) provides, in such form and manner as
4 the Secretary may require, assurances that the
5 individual will meet the service requirement de-
6 scribed in paragraph (6); and

7 “(C) provides, in such form and manner as
8 the Secretary may require, assurances that the
9 individual has a full-time faculty appointment
10 in a health professions institution and docu-
11 mented commitment from such institution to
12 spend 75 percent of the total time of such indi-
13 vidual on teaching and developing skills in
14 interdisciplinary education in geriatrics.

15 “(4) MAINTENANCE OF EFFORT.—An eligible
16 individual that receives an Award under paragraph
17 (1) shall provide assurances to the Secretary that
18 funds provided to the eligible individual under this
19 subsection will be used only to supplement, not to
20 supplant, the amount of Federal, State, and local
21 funds otherwise expended by the eligible individual.”;
22 and

23 (3) in paragraph (5), as so designated—

24 (A) in subparagraph (A)—

1 (i) by inserting “for individuals who
2 are physicians” after “this section”; and

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

8 (B) by adding at the end the following:

9 “(C) PAYMENT TO INSTITUTION.—The
10 Secretary shall transfer funds awarded to an in-
11 dividual under this section to the institution
12 where such individual will carry out the award,
13 in order to facilitate financial management of
14 the reward pursuant to guidelines of the Health
15 Resources and Services Administration.”.

16 (c) COMPREHENSIVE GERIATRIC EDUCATION.—Sec-
17 tion 855 of the Public Health Service Act (42 U.S.C. 298)
18 is amended—

19 (1) in subsection (b)—

20 (A) in paragraph (3), by striking “or” at
21 the end;

22 (B) in paragraph (4), by striking the pe-
23 riod and inserting “; or”; and

24 (C) by adding at the end the following:

1 “(5) establish traineeships for individuals who
2 are preparing for advanced education nursing de-
3 grees in geriatric nursing, long-term care, gero-psy-
4 chiatric nursing or other nursing areas that spe-
5 cialize in the care of the elderly population.”; and

6 (2) in subsection (e), by striking “2003 through
7 2007” and inserting “2010 through 2014”.

8 **SEC. 436. MENTAL AND BEHAVIORAL HEALTH EDUCATION**
9 **AND TRAINING GRANTS.**

10 (a) IN GENERAL.—Part D of title VII (42 U.S.C.
11 294 et seq.) is amended by—

12 (1) striking section 757;

13 (2) redesignating section 756 (as amended by
14 section 413) as section 757; and

15 (3) inserting after section 755 the following:

16 **“SEC. 756. MENTAL AND BEHAVIORAL HEALTH EDUCATION**
17 **AND TRAINING GRANTS.**

18 “(a) GRANTS AUTHORIZED.—The Secretary may
19 award grants to eligible institutions of higher education
20 to support the recruitment of students for, and education
21 and clinical experience of the students in—

22 “(1) baccalaureate, master’s, and doctoral de-
23 gree programs of social work, as well as the develop-
24 ment of faculty in social work;

1 “(2) accredited master’s, doctoral, internship,
2 and post-doctoral residency programs of psychology
3 for the development and implementation of inter-
4 disciplinary training of psychology graduate students
5 for providing behavioral and mental health services,
6 including substance abuse prevention and treatment
7 services;

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

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

22 “(b) ELIGIBILITY REQUIREMENTS.—To be eligible
23 for a grant under this section, an institution shall dem-
24 onstrate—

1 “(1) participation in the institutions’ programs
2 of individuals and groups from different racial, eth-
3 nic, cultural, geographic, religious, linguistic, and
4 class backgrounds, and different genders and sexual
5 orientations;

6 “(2) knowledge and understanding of the con-
7 cerns of the individuals and groups described in sub-
8 section (a);

9 “(3) any internship or other field placement
10 program assisted under the grant will prioritize cul-
11 tural and linguistic competency;

12 “(4) the institution will provide to the Secretary
13 such data, assurances, and information as the Sec-
14 retary may require; and

15 “(5) with respect to any violation of the agree-
16 ment between the Secretary and the institution, the
17 institution will pay such liquidated damages as pre-
18 scribed by the Secretary by regulation.

19 “(c) INSTITUTIONAL REQUIREMENT.—For grants
20 authorized under subsection (a)(1), at least 4 of the grant
21 recipients shall be historically black colleges or universities
22 or other minority-serving institutions.

23 “(d) PRIORITY.—

1 “(1) In selecting the grant recipients in social
2 work under subsection (a)(1), the Secretary shall
3 give priority to applicants that—

4 “(A) are accredited by the Council on So-
5 cial Work Education;

6 “(B) have a graduation rate of not less
7 than 80 percent for social work students; and

8 “(C) exhibit an ability to recruit social
9 workers from and place social workers in areas
10 with a high need and high demand population.

11 “(2) In selecting the grant recipients in grad-
12 uate psychology under subsection (a)(2), the Sec-
13 retary shall give priority to institutions in which
14 training focuses on the needs of vulnerable groups
15 such as older adults and children, individuals with
16 mental health or substance-related disorders, victims
17 of abuse or trauma and of combat stress disorders
18 such as posttraumatic stress disorder and traumatic
19 brain injuries, homeless individuals, chronically ill
20 persons, and their families.

21 “(3) In selecting the grant recipients in profes-
22 sional training programs in child and adolescent
23 mental health under subsection (a)(3), the Secretary
24 shall give priority to applicants that—

1 “(A) have demonstrated the ability to col-
2 lect data on the number of students trained in
3 child and adolescent mental health and the pop-
4 ulations served by such students after gradua-
5 tion;

6 “(B) have demonstrated familiarity with
7 evidence-based methods in child and adolescent
8 mental health services, including substance
9 abuse prevention and treatment services;

10 “(C) have programs designed to increase
11 the number of paraprofessionals serving high-
12 priority populations and to applicants who come
13 from high-priority communities and plan to
14 serve in Health Professional Shortage Areas,
15 Medically Underserved Areas, or Medically Un-
16 derserved Populations; and

17 “(D) offer curriculum taught collabo-
18 ratively with a family on the consumer and
19 family lived experience or the importance of
20 family-professional partnership.

21 “(4) In selecting the grant recipients to offer
22 preservice or in-service training of paraprofessional
23 child and adolescent mental health workers under
24 subsection (a)(4), the Secretary shall give priority to
25 applicants that—

1 “(A) have demonstrated the ability to col-
2 lect data on the number of paraprofessional
3 child and adolescent mental health workers
4 trained by the applicant and the populations
5 served by these workers after the completion of
6 the training;

7 “(B) have demonstrated familiarity with
8 evidence-based methods in child and adolescent
9 mental health services;

10 “(C) have programs designed to increase
11 the number of professionals serving high-pri-
12 ority populations, or who come from high-pri-
13 ority communities and plan to serve medically
14 underserved populations or in health profes-
15 sional shortage areas or medically underserved
16 areas;

17 “(D) offer curriculum taught collabo-
18 ratively with a family on the consumer and
19 family lived experience or the importance of
20 family-paraprofessional partnership; and

21 “(E) provide services through a community
22 mental health program described in section
23 1913(b)(1).

1 “(e) AUTHORIZATION OF APPROPRIATION.—For the
2 fiscal years 2010 through 2013, there is authorized to be
3 appropriated to carry out this section—

4 “(1) \$8,000,000 for training in social work in
5 subsection (a)(1);

6 “(2) \$12,000,000 for training in graduate psy-
7 chology in subsection (a)(2), of which not less than
8 \$10,000,000 shall be allocated for doctoral,
9 postdoctoral, and internship level training;

10 “(3) \$10,000,000 for training in professional
11 child and adolescent mental health in subsection
12 (a)(3); and

13 “(4) \$5,000,000 for training in paraprofes-
14 sional child and adolescent work in subsection
15 (a)(4).”.

16 (b) CONFORMING AMENDMENTS.—Section 757(b)(2)
17 of the Public Health Service Act, as redesignated by sub-
18 section (a), is amended by striking “sections 751(a)(1)(A),
19 751(a)(1)(B), 753(b), 754(3)(A), and 755(b)” and insert-
20 ing “sections 751(b), 753(b), and 755(b)”.

1 **SEC. 437. CULTURAL COMPETENCY, PREVENTION AND PUB-**
2 **LIC HEALTH AND INDIVIDUALS WITH DIS-**
3 **ABILITIES TRAINING.**

4 Part B of title VII of the Public Health Service Act
5 (42 U.S.C. 293 et seq.) is amended by adding at the end
6 the following:

7 **“SEC. 742. CULTURAL COMPETENCY, PREVENTION AND**
8 **PUBLIC HEALTH AND INDIVIDUALS WITH DIS-**
9 **ABILITIES TRAINING.**

10 “(a) IN GENERAL.—The Secretary shall support the
11 development, evaluation, and dissemination of model cur-
12 ricula for cultural competency, prevention, and public
13 health proficiency and aptitude for working with individ-
14 uals with disabilities training for use in health professions
15 schools and continuing education programs, and for other
16 purposes determined appropriate by the Secretary.

17 “(b) CURRICULA.—

18 “(1) COLLABORATION.—In carrying out sub-
19 section (a), the Secretary shall collaborate with
20 health professional societies, licensing and accredita-
21 tion entities, health professions schools, and experts
22 in minority health and cultural competency, preven-
23 tion and public health and disability groups, commu-
24 nity-based organizations, and other organizations as
25 determined appropriate by the Secretary.

1 “(2) FOCUS.—Curricula developed under this
2 section shall include a focus on cultural competency
3 measures, prevention and public health competency
4 measures, and working with individuals with disabili-
5 ties competency measures. In addition, cultural
6 competency, prevention and public health pro-
7 ficiency, and working with individuals with disabili-
8 ties aptitude self-assessment methodology for health
9 providers, systems, and institutions.

10 “(c) DISSEMINATION.—

11 “(1) IN GENERAL.—Model curricula developed
12 under this section shall be disseminated through the
13 Internet Clearinghouse under section 270 and such
14 other means as determined appropriate by the Sec-
15 retary.

16 “(2) EVALUATION.—The Secretary shall evalu-
17 ate the adoption and the implementation of cultural
18 competency, prevention and public health, and work-
19 ing with individuals with a disability training cur-
20 ricula, and the facilitate inclusion of these com-
21 petency measures in quality measurement systems as
22 appropriate.

23 “(d) AUTHORIZATION OF APPROPRIATIONS.—There
24 is authorized to be appropriated to carry out this section

1 such sums as necessary for each of the fiscal years 2010
2 through 2015.”.

3 **SEC. 438. ADVANCED NURSING EDUCATION GRANTS.**

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

6 (1) in subsection (c)—

7 (A) in the subsection heading, by striking

8 “AND NURSE MIDWIFERY PROGRAMS”; and

9 (B) by striking “and nurse midwifery”;

10 (2) in subsection (f)—

11 (A) by striking paragraph (2); and

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

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

16 (4) by inserting after subsection (c), the fol-
17 lowing:

18 “(d) AUTHORIZED NURSE-MIDWIFERY PROGRAMS.—

19 Midwifery programs that are eligible for support under
20 this section are educational programs that—

21 “(1) have as their objective the education of
22 midwives, who will upon completion of their studies
23 in such programs, be qualified to effectively provide
24 primary health care services to women at locations
25 where women might require health care services, in-

1 cluding acute care facilities, ambulatory care facili-
2 ties, birth centers, personal residences, and other
3 settings as authorized by State or Federal law; and
4 “(2) are accredited by the American College of
5 Nurse-Midwives Accreditation Commission for Mid-
6 wifery Education.”.

7 **SEC. 439. NURSE EDUCATION, PRACTICE, AND RETENTION**
8 **GRANTS.**

9 (a) IN GENERAL.—Section 831 of the Public Health
10 Service Act (42 U.S.C. 296p) is amended—

11 (1) in the section heading, by striking “**RETEN-**
12 **TION**” and inserting “**QUALITY**”;

13 (2) in subsection (a)—

14 (A) in paragraph (1), by adding “or” after
15 the semicolon;

16 (B) by striking paragraph (2); and

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

19 (3) in subsection (b)(3), by striking “managed
20 care, quality improvement” and inserting “coordi-
21 nated care”;

22 (4) in subsection (g), by inserting “, as defined
23 in section 801(2),” after “school of nursing”; and

24 (5) in subsection (h), by striking “2003
25 through 2007” and inserting “2010 through 2014”.

1 (b) NURSE RETENTION GRANTS.—Title VIII of the
2 Public Health Service Act is amended by inserting after
3 section 831 (42 U.S.C. 296b) the following:

4 **“SEC. 831A. NURSE RETENTION GRANTS.**

5 “(a) RETENTION PRIORITY AREAS.—The Secretary
6 may award grants to, and enter into contracts with, eligi-
7 ble entities to enhance the nursing workforce by initiating
8 and maintaining nurse retention programs pursuant to
9 subsection (b) or (c).

10 “(b) GRANTS FOR CAREER LADDER PROGRAM.—The
11 Secretary may award grants to, and enter into contracts
12 with, eligible entities for programs—

13 “(1) to promote career advancement for individ-
14 uals including licensed practical nurses, licensed vo-
15 cational nurses, certified nurse assistants, home
16 health aides, diploma degree or associate degree
17 nurses, to become baccalaureate prepared registered
18 nurses or advanced education nurses in order to
19 meet the needs of the registered nurse workforce;

20 “(2) developing and implementing internships
21 and residency programs in collaboration with an ac-
22 credited school of nursing, as defined by section
23 801(2), to encourage mentoring and the development
24 of specialties; or

1 “(3) to assist individuals in obtaining education
2 and training required to enter the nursing profession
3 and advance within such profession, such as by pro-
4 viding career counseling and mentoring.

5 “(c) ENHANCING PATIENT CARE DELIVERY SYS-
6 TEMS.—

7 “(1) GRANTS.—The Secretary may award
8 grants to eligible entities to improve the retention of
9 nurses and enhance patient care that is directly re-
10 lated to nursing activities by enhancing collaboration
11 and communication among nurses and other health
12 care professionals, and by promoting nurse involve-
13 ment in the organizational and clinical decision-mak-
14 ing processes of a health care facility.

15 “(2) PRIORITY.—In making awards of grants
16 under this subsection, the Secretary shall give pref-
17 erence to applicants that have not previously re-
18 ceived an award under this subsection (or section
19 831(c) as such section existed on the day before the
20 date of enactment of this section).

21 “(3) CONTINUATION OF AN AWARD.—The Sec-
22 retary shall make continuation of any award under
23 this subsection beyond the second year of such
24 award contingent on the recipient of such award
25 having demonstrated to the Secretary measurable

1 and substantive improvement in nurse retention or
2 patient care.

3 “(d) OTHER PRIORITY AREAS.—The Secretary may
4 award grants to, or enter into contracts with, eligible enti-
5 ties to address other areas that are of high priority to
6 nurse retention, as determined by the Secretary.

7 “(e) REPORT.—The Secretary shall submit to the
8 Congress before the end of each fiscal year a report on
9 the grants awarded and the contracts entered into under
10 this section. Each such report shall identify the overall
11 number of such grants and contracts and provide an ex-
12 planation of why each such grant or contract will meet
13 the priority need of the nursing workforce.

14 “(f) ELIGIBLE ENTITY.—For purposes of this sec-
15 tion, the term ‘eligible entity’ includes an accredited school
16 of nursing, as defined by section 801(2), a health care fa-
17 cility, or a partnership of such a school and facility.

18 “(g) AUTHORIZATION OF APPROPRIATIONS.—There
19 are authorized to be appropriated to carry out this section
20 such sums as may be necessary for each of fiscal years
21 2010 through 2012.”.

22 **SEC. 440. LOAN REPAYMENT AND SCHOLARSHIP PROGRAM.**

23 (a) LOAN REPAYMENTS AND SCHOLARSHIPS.—Sec-
24 tion 846(a)(3) of the Public Health Service Act (42 U.S.C.
25 297n(a)(3)) is amended by inserting before the semicolon

1 the following: “, or in a accredited school of nursing, as
2 defined by section 801(2), as nurse faculty”.

3 (b) TECHNICAL AND CONFORMING AMENDMENTS.—

4 Title VIII (42 U.S.C. 296 et seq.) is amended—

5 (1) by redesignating section 810 (relating to
6 prohibition against discrimination by schools on the
7 basis of sex) as section 809 and moving such section
8 so that it follows section 808;

9 (2) in sections 835, 836, 838, 840, and 842, by
10 striking the term “this subpart” each place it ap-
11 pears and inserting “this part”;

12 (3) in section 836(h), by striking the last sen-
13 tence;

14 (4) in section 836, by redesignating subsection
15 (l) as subsection (k);

16 (5) in section 839, by striking “839” and all
17 that follows through “(a)” and inserting “839. (a)”;

18 (6) in section 835(b), by striking “841” each
19 place it appears and inserting “871”;

20 (7) by redesignating section 841 as section 871,
21 moving part F to the end of the title, and redesign-
22 ating such part as part I;

23 (8) in part G—

24 (A) by redesignating section 845 as section
25 851; and

1 (B) by redesignating part G as part F;

2 (9) in part H—

3 (A) by redesignating sections 851 and 852

4 as sections 861 and 862, respectively; and

5 (B) by redesignating part H as part G;

6 and

7 (10) in part I—

8 (A) by redesignating section 855, as

9 amended by section 435, as section 865; and

10 (B) by redesignating part I as part H.

11 **SEC. 441. NURSE FACULTY LOAN PROGRAM.**

12 (a) IN GENERAL.—Section 846A of the Public
13 Health Service Act (42 U.S.C. 297n–1) is amended—

14 (1) in subsection (a)—

15 (A) in the subsection heading, by striking

16 “ESTABLISHMENT” and inserting “SCHOOL OF

17 NURSING STUDENT LOAN FUND”; and

18 (B) by inserting “accredited” after “agree-

19 ment with any”;

20 (2) in subsection (c)—

21 (A) in paragraph (2), by striking

22 “\$30,000” and all that follows through the

23 semicolon and inserting “\$35,500, during fiscal

24 years 2010 and 2011 fiscal years (after fiscal

25 year 2011, such amounts shall be adjusted to

1 provide for a cost-of-attendance increase for the
2 yearly loan rate and the aggregate loan;” and

3 (B) in paragraph (3)(A), by inserting “an
4 accredited” after “faculty member in”;

5 (3) in subsection (e), by striking “a school” and
6 inserting “an accredited school”; and

7 (4) in subsection (f), by striking “2003 through
8 2007” and inserting “2010 through 2014”.

9 (b) ELIGIBLE INDIVIDUAL STUDENT LOAN REPAY-
10 MENT.—Title VIII of the Public Health Service Act is
11 amended by inserting after section 846A (42 U.S.C.
12 297n–1) the following:

13 **“SEC. 847. ELIGIBLE INDIVIDUAL STUDENT LOAN REPAY-**
14 **MENT.**

15 “(a) IN GENERAL.—The Secretary, acting through
16 the Administrator of the Health Resources and Services
17 Administration, may enter into an agreement with eligible
18 individuals for the repayment of education loans, in ac-
19 cordance with this section, to increase the number of
20 qualified nursing faculty.

21 “(b) AGREEMENTS.—Each agreement entered into
22 under this subsection shall require that the eligible indi-
23 vidual shall serve as a full-time member of the faculty of
24 an accredited school of nursing, for a total period, in the

1 aggregate, of at least 4 years during the 6-year period be-
2 ginning on the later of—

3 “(1) the date on which the individual receives
4 a master’s or doctorate nursing degree from an ac-
5 credited school of nursing; or

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

8 “(c) AGREEMENT PROVISIONS.—Agreements entered
9 into pursuant to subsection (b) shall be entered into on
10 such terms and conditions as the Secretary may deter-
11 mine, except that—

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

21 “(2) for an individual who has completed a
22 master’s in nursing or equivalent degree in nurs-
23 ing—

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

1 “(B) total payments may not exceed
2 \$40,000 during the 2010 and 2011 fiscal years
3 (after fiscal year 2011, such amounts shall be
4 adjusted to provide for a cost-of-attendance in-
5 crease for the yearly loan rate and the aggre-
6 gate loan); and

7 “(3) for an individual who has completed a doc-
8 torate or equivalent degree in nursing—

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

11 “(B) total payments may not exceed
12 \$80,000 during the 2010 and 2011 fiscal years
13 (adjusted for subsequent fiscal years as pro-
14 vided for in the same manner as in paragraph
15 (2)(B)).

16 “(d) BREACH OF AGREEMENT.—

17 “(1) IN GENERAL.—In the case of any agree-
18 ment made under subsection (b), the individual is
19 liable to the Federal Government for the total
20 amount paid by the Secretary under such agree-
21 ment, and for interest on such amount at the max-
22 imum legal prevailing rate, if the individual fails to
23 meet the agreement terms required under such sub-
24 section.

1 “(2) WAIVER OR SUSPENSION OF LIABILITY.—

2 In the case of an individual making an agreement
3 for purposes of paragraph (1), the Secretary shall
4 provide for the waiver or suspension of liability
5 under such paragraph if compliance by the indi-
6 vidual with the agreement involved is impossible or
7 would involve extreme hardship to the individual or
8 if enforcement of the agreement with respect to the
9 individual would be unconscionable.

10 “(3) DATE CERTAIN FOR RECOVERY.—Subject
11 to paragraph (2), any amount that the Federal Gov-
12 ernment is entitled to recover under paragraph (1)
13 shall be paid to the United States not later than the
14 expiration of the 3-year period beginning on the date
15 the United States becomes so entitled.

16 “(4) AVAILABILITY.—Amounts recovered under
17 paragraph (1) shall be available to the Secretary for
18 making loan repayments under this section and shall
19 remain available for such purpose until expended.

20 “(e) ELIGIBLE INDIVIDUAL DEFINED.—For pur-
21 poses of this section, the term ‘eligible individual’ means
22 an individual who—

23 “(1) is a United States citizen, national, or law-
24 ful permanent resident;

1 “(2) holds an unencumbered license as a reg-
2 istered nurse; and

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

7 “(f) PRIORITY.—For the purposes of this section and
8 section 846A, funding priority will be awarded to School
9 of Nursing Student Loans that support doctoral nursing
10 students or Individual Student Loan Repayment that sup-
11 port doctoral nursing students.

12 “(g) AUTHORIZATION OF APPROPRIATIONS.—There
13 are authorized to be appropriated to carry out this section
14 such sums as may be necessary for each of fiscal years
15 2010 through 2014.”.

16 **SEC. 442. AUTHORIZATION OF APPROPRIATIONS FOR**
17 **PARTS B THROUGH D OF TITLE VIII.**

18 Section 871 of the Public Health Service Act, as re-
19 designated and moved by section 440, is amended to read
20 as follows:

21 **“SEC. 871. AUTHORIZATION OF APPROPRIATIONS.**

22 “For the purpose of carrying out parts B, C, and D
23 (subject to section 851(g)), there are authorized to be ap-
24 propriated \$338,000,000 for fiscal year 2010, and such

1 sums as may be necessary for each of the fiscal years 2011
2 through 2016.”.

3 **SEC. 443. GRANTS TO PROMOTE THE COMMUNITY HEALTH**
4 **WORKFORCE.**

5 (a) IN GENERAL.—Part P of title III of the Public
6 Health Service Act (42 U.S.C. 280g et seq.), as amended
7 by subsection (b), is amended by adding at the end the
8 following:

9 **“SEC. 399U. GRANTS TO PROMOTE POSITIVE HEALTH BE-**
10 **HAVIORS AND OUTCOMES.**

11 “(a) GRANTS AUTHORIZED.—The Director of the
12 Centers for Disease Control and Prevention, in collabora-
13 tion with the Secretary, shall award grants to eligible enti-
14 ties to promote positive health behaviors and outcomes for
15 populations in medically underserved communities through
16 the use of community health workers.

17 “(b) USE OF FUNDS.—Grants awarded under sub-
18 section (a) shall be used to support community health
19 workers—

20 “(1) to educate, guide, and provide outreach in
21 a community setting regarding health problems prev-
22 alent in medically underserved communities, particu-
23 larly racial and ethnic minority populations;

1 “(2) to educate, guide, and provide experiential
2 learning opportunities that target behavioral risk
3 factors;

4 “(3) to educate and provide guidance regarding
5 effective strategies to promote positive health behav-
6 iors within the family;

7 “(4) to educate and provide outreach regarding
8 enrollment in health insurance including the State
9 Children’s Health Insurance Program under title
10 XXI of the Social Security Act, Medicare under title
11 XVIII of such Act and Medicaid under title XIX of
12 such Act;

13 “(5) to educate and refer underserved popu-
14 lations to appropriate healthcare agencies and com-
15 munity-based programs and organizations in order
16 to increase access to quality healthcare services and
17 to eliminate duplicative care; or

18 “(6) to educate, guide, and provide home visita-
19 tion services regarding maternal health and prenatal
20 care.

21 “(c) APPLICATION.—Each eligible entity that desires
22 to receive a grant under subsection (a) shall submit an
23 application to the Secretary, at such time, in such manner,
24 and accompanied by such information as the Secretary
25 may require.

1 “(d) PRIORITY.—In awarding grants under sub-
2 section (a), the Secretary shall give priority to applicants
3 that—

4 “(1) propose to target geographic areas—

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

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

10 “(C) with a high infant mortality rate;

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

14 “(3) have documented community activity and
15 experience with community health workers.

16 “(e) COLLABORATION WITH ACADEMIC INSTITU-
17 TIONS AND THE ONE-STOP DELIVERY SYSTEM.—The Sec-
18 retary shall encourage community health worker programs
19 receiving funds under this section to collaborate with aca-
20 demic institutions and one-stop delivery systems under
21 section 134(c) of the Workforce Investment Act of 1998.
22 Nothing in this section shall be construed to require such
23 collaboration.

24 “(f) EVIDENCE-BASED INTERVENTIONS.—The Sec-
25 retary 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-

1 zation located in the neighborhood in which a partic-
2 ipant in the program under this section resides.

3 “(3) ELIGIBLE ENTITY.—The term ‘eligible en-
4 tity’ means a public or nonprofit private entity (in-
5 cluding a State or public subdivision of a State, a
6 public health department, a free health clinic, a hos-
7 pital, or a Federally-qualified health center (as de-
8 fined in section 1861(aa) of the Social Security
9 Act)), or a consortium of any such entities.

10 “(4) MEDICALLY UNDERSERVED COMMUNITY.—
11 The term ‘medically underserved community’ means
12 a community identified by a State—

13 “(A) that has a substantial number of in-
14 dividuals who are members of a medically un-
15 derserved population, as defined by section
16 330(b)(3); and

17 “(B) a significant portion of which is a
18 health professional shortage area as designated
19 under section 332.”.

20 (b) TECHNICAL AMENDMENTS.—

21 (1) Section 399R of the Public Health Service
22 Act (as added by section 2 of the ALS Registry Act
23 (Public Law 110-373; 122 Stat. 4047)) is redesign-
24 nated as section 399S.

1 (2) Section 399R of such Act (as added by sec-
2 tion 3 of the Prenatally and Postnatally Diagnosed
3 Conditions Awareness Act (Public Law 110–374;
4 122 Stat. 4051)) is redesignated as section 399T.

5 **SEC. 444. YOUTH PUBLIC HEALTH PROGRAM.**

6 Section 751(b)(4)(A) of the Public Health Service
7 Act, as amended by section 453, is further amended by
8 adding at the end the following:

9 “(vii) Establish a youth public health
10 program to expose and recruit high school
11 students into health careers, with a focus
12 on careers in public health.”.

13 **SEC. 445. FELLOWSHIP TRAINING IN PUBLIC HEALTH.**

14 Part E of title VII of the Public Health Service Act
15 (42 U.S.C. 294n et seq.), as amended by section 426, is
16 further amended by adding at the end the following:

17 **“SEC. 778. FELLOWSHIP TRAINING IN APPLIED PUBLIC**
18 **HEALTH EPIDEMIOLOGY, PUBLIC HEALTH**
19 **LABORATORY SCIENCE, PUBLIC HEALTH**
20 **INFORMATICS, AND EXPANSION OF THE EPI-**
21 **DEMIC INTELLIGENCE SERVICE.**

22 “(a) IN GENERAL.—The Secretary may carry out ac-
23 tivities to address documented workforce shortages in
24 State and local health departments in the critical areas
25 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 “(1) \$5,000,000 shall be made available in each
2 such fiscal year for epidemiology fellowship training
3 program activities under subsections (b) and (c);

4 “(2) \$5,000,000 shall be made available in each
5 such fiscal year for laboratory fellowship training
6 programs under subsection (b);

7 “(3) \$5,000,000 shall be made available in each
8 such fiscal year for the Public Health Informatics
9 Fellowship Program under subsection (e); and

10 “(4) \$24,500,000 shall be made available for
11 expanding the Epidemic Intelligence Service under
12 subsection (a).”.

13 **SEC. 446. UNITED STATES PUBLIC HEALTH SCIENCES**
14 **TRACK.**

15 Title II of the Public Health Service Act (42 U.S.C.
16 202 et seq.) is amended by adding at the end the fol-
17 lowing:

18 **“PART D—UNITED STATES PUBLIC HEALTH**
19 **SCIENCES TRACK**

20 **“SEC. 271. ESTABLISHMENT.**

21 “(a) UNITED STATES PUBLIC HEALTH SERVICES
22 TRACK.—

23 “(1) IN GENERAL.—There is hereby authorized
24 to be established a United States Public Health
25 Sciences Track (referred to in this part as the

1 ‘Track’), at sites to be selected by the Secretary,
2 with authority to grant appropriate advanced de-
3 grees in a manner that uniquely emphasizes team-
4 based service, public health, epidemiology, and emer-
5 gency preparedness and response. It shall be so or-
6 ganized as to graduate not less than—

7 “(A) 150 medical students annually, 10 of
8 whom shall be awarded studentships to the Uni-
9 formed Services University of Health Sciences;

10 “(B) 100 dental students annually;

11 “(C) 250 nursing students annually;

12 “(D) 100 public health students annually;

13 “(E) 100 behavioral and mental health
14 professional students annually;

15 “(F) 100 physician assistant or nurse
16 practitioner students annually; and

17 “(G) 50 pharmacy students annually.

18 “(2) LOCATIONS.—The Track shall be located
19 at existing and accredited, affiliated health profes-
20 sions education training programs at academic
21 health centers located in regions of the United
22 States determined appropriate by the Surgeon Gen-
23 eral, in consultation with the National Health Care
24 Workforce Commission.

1 “(b) NUMBER OF GRADUATES.—Except as provided
2 in subsection (a), the number of persons to be graduated
3 from the Track shall be prescribed by the Secretary. In
4 so prescribing the number of persons to be graduated from
5 the Track, the Secretary shall institute actions necessary
6 to ensure the maximum number of first-year enrollments
7 in the Track consistent with the academic capacity of the
8 affiliated sites and the needs of the United States for med-
9 ical, dental, and nursing personnel.

10 “(c) DEVELOPMENT.—The development of the Track
11 may be by such phases as the Secretary may prescribe
12 subject to the requirements of subsection (a).

13 “(d) INTEGRATED LONGITUDINAL PLAN.—The Sur-
14 geon General shall develop an integrated longitudinal plan
15 for health professions continuing education throughout the
16 continuum of health-related education, training, and prac-
17 tice. Training under such plan shall emphasize patient-
18 centered, interdisciplinary, and care coordination skills.
19 Experience with deployment of emergency response teams
20 shall be included during the clinical experiences.

21 “(e) FACULTY DEVELOPMENT.—The Surgeon Gen-
22 eral shall develop faculty development programs and cur-
23 ricula in decentralized venues of health care, to balance
24 urban, tertiary, and inpatient venues.

1 **“SEC. 272. ADMINISTRATION.**

2 “(a) IN GENERAL.—The business of the Track shall
3 be conducted by the Surgeon General with funds appro-
4 priated for and provided by the Department of Health and
5 Human Services. The National Health Workforce Com-
6 mission shall assist the Surgeon General in an advisory
7 capacity.

8 “(b) FACULTY.—

9 “(1) IN GENERAL.—The Surgeon General, after
10 considering the recommendations of the National
11 Health Workforce Commission, shall obtain the serv-
12 ices of such professors, instructors, and administra-
13 tive and other employees as may be necessary to op-
14 erate the Track, but utilize when possible, existing
15 affiliated health professions training institutions.
16 Members of the faculty and staff shall be employed
17 under salary schedules and granted retirement and
18 other related benefits prescribed by the Secretary so
19 as to place the employees of the Track faculty on a
20 comparable basis with the employees of fully accred-
21 ited schools of the health professions within the
22 United States.

23 “(2) TITLES.—The Surgeon General may con-
24 fer academic titles, as appropriate, upon the mem-
25 bers of the faculty.

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

6 “(c) AGREEMENTS.—The Surgeon General may ne-
7 gotiate agreements with agencies of the Federal Govern-
8 ment to utilize on a reimbursable basis appropriate exist-
9 ing Federal medical resources located in the United States
10 (or locations selected in accordance with section
11 271(a)(2)). Under such agreements the facilities con-
12 cerned will retain their identities and basic missions. The
13 Surgeon General may negotiate affiliation agreements
14 with accredited universities and health professions train-
15 ing institutions in the United States. Such agreements
16 may include provisions for payments for educational serv-
17 ices provided students participating in Department of
18 Health and Human Services educational programs.

19 “(d) PROGRAMS.—The Surgeon General may estab-
20 lish the following educational programs for Track stu-
21 dents:

22 “(1) Postdoctoral, postgraduate, and techno-
23 logical programs.

1 “(2) A cooperative program for medical, dental,
2 physician assistant, pharmacy, behavioral and men-
3 tal health, public health, and nursing students.

4 “(3) Other programs that the Surgeon General
5 determines necessary in order to operate the Track
6 in a cost-effective manner.

7 “(e) CONTINUING MEDICAL EDUCATION.—The Sur-
8 geon General shall establish programs in continuing med-
9 ical education for members of the health professions to
10 the end that high standards of health care may be main-
11 tained within the United States.

12 “(f) AUTHORITY OF THE SURGEON GENERAL.—

13 “(1) IN GENERAL.—The Surgeon General is au-
14 thorized—

15 “(A) to enter into contracts with, accept
16 grants from, and make grants to any nonprofit
17 entity for the purpose of carrying out coopera-
18 tive enterprises in medical, dental, physician as-
19 sistant, pharmacy, behavioral and mental
20 health, public health, and nursing research,
21 consultation, and education;

22 “(B) to enter into contracts with entities
23 under which the Surgeon General may furnish
24 the services of such professional, technical, or
25 clerical personnel as may be necessary to fulfill

1 cooperative enterprises undertaken by the
2 Track;

3 “(C) to accept, hold, administer, invest,
4 and spend any gift, devise, or bequest of per-
5 sonal property made to the Track, including
6 any gift, devise, or bequest for the support of
7 an academic chair, teaching, research, or dem-
8 onstration project;

9 “(D) to enter into agreements with entities
10 that may be utilized by the Track for the pur-
11 pose of enhancing the activities of the Track in
12 education, research, and technological applica-
13 tions of knowledge; and

14 “(E) to accept the voluntary services of
15 guest scholars and other persons.

16 “(2) LIMITATION.—The Surgeon General may
17 not enter into any contract with an entity if the con-
18 tract would obligate the Track to make outlays in
19 advance of the enactment of budget authority for
20 such outlays.

21 “(3) SCIENTISTS.—Scientists or other medical,
22 dental, or nursing personnel utilized by the Track
23 under an agreement described in paragraph (1) may
24 be appointed to any position within the Track and

1 may be permitted to perform such duties within the
2 Track as the Surgeon General may approve.

3 “(4) VOLUNTEER SERVICES.—A person who
4 provides voluntary services under the authority of
5 subparagraph (E) of paragraph (1) shall be consid-
6 ered to be an employee of the Federal Government
7 for the purposes of chapter 81 of title 5, relating to
8 compensation for work-related injuries, and to be an
9 employee of the Federal Government for the pur-
10 poses of chapter 171 of title 28, relating to tort
11 claims. Such a person who is not otherwise employed
12 by the Federal Government shall not be considered
13 to be a Federal employee for any other purpose by
14 reason of the provision of such services.

15 **“SEC. 273. STUDENTS; SELECTION; OBLIGATION.**

16 “(a) STUDENT SELECTION.—

17 “(1) IN GENERAL.—Medical, dental, physician
18 assistant, pharmacy, behavioral and mental health,
19 public health, and nursing students at the Track
20 shall be selected under procedures prescribed by the
21 Surgeon General. In so prescribing, the Surgeon
22 General shall consider the recommendations of the
23 National Health Workforce Commission.

24 “(2) PRIORITY.—In developing admissions pro-
25 cedures under paragraph (1), the Surgeon General

1 shall ensure that such procedures give priority to ap-
2 plicant medical, dental, physician assistant, phar-
3 macy, behavioral and mental health, public health,
4 and nursing students from rural communities and
5 underrepresented minorities.

6 “(b) CONTRACT AND SERVICE OBLIGATION.—

7 “(1) CONTRACT.—Upon being admitted to the
8 Track, a medical, dental, physician assistant, phar-
9 macy, behavioral and mental health, public health,
10 or nursing student shall enter into a written con-
11 tract with the Surgeon General that shall contain—

12 “(A) an agreement under which—

13 “(i) subject to subparagraph (B), the
14 Surgeon General agrees to provide the stu-
15 dent with tuition (or tuition remission) and
16 a student stipend (described in paragraph
17 (2)) in each school year for a period of
18 years (not to exceed 4 school years) deter-
19 mined by the student, during which period
20 the student is enrolled in the Track at an
21 affiliated or other participating health pro-
22 fessions institution pursuant to an agree-
23 ment between the Track and such institu-
24 tion; and

1 “(ii) subject to subparagraph (B), the
2 student agrees—

3 “(I) to accept the provision of
4 such tuition and student stipend to
5 the student;

6 “(II) to maintain enrollment at
7 the Track until the student completes
8 the course of study involved;

9 “(III) while enrolled in such
10 course of study, to maintain an ac-
11 ceptable level of academic standing
12 (as determined by the Surgeon Gen-
13 eral);

14 “(IV) if pursuing a degree from
15 a school of medicine or osteopathic
16 medicine, dental, public health, or
17 nursing school or a physician assist-
18 ant, pharmacy, or behavioral and
19 mental health professional program,
20 to complete a residency or internship
21 in a specialty that the Surgeon Gen-
22 eral determines is appropriate; and

23 “(V) to serve for a period of time
24 (referred to in this part as the ‘period
25 of obligated service’) within the Com-

1 missioned Corps of the Public Health
2 Service equal to 2 years for each
3 school year during which such indi-
4 vidual was enrolled at the College, re-
5 duced as provided for in paragraph
6 (3);

7 “(B) a provision that any financial obliga-
8 tion of the United States arising out of a con-
9 tract entered into under this part and any obli-
10 gation of the student which is conditioned
11 thereon, is contingent upon funds being appro-
12 priated to carry out this part;

13 “(C) a statement of the damages to which
14 the United States is entitled for the student’s
15 breach of the contract; and

16 “(D) such other statements of the rights
17 and liabilities of the Secretary and of the indi-
18 vidual, not inconsistent with the provisions of
19 this part.

20 “(2) TUITION AND STUDENT STIPEND.—

21 “(A) TUITION REMISSION RATES.—The
22 Surgeon General, based on the recommenda-
23 tions of the National Health Workforce Com-
24 mission established under section 411 of the Af-
25 fordable Health Choices Act, shall establish

1 Federal tuition remission rates to be used by
2 the Track to provide reimbursement to affili-
3 ated and other participating health professions
4 institutions for the cost of educational services
5 provided by such institutions to Track students.
6 The agreement entered into by such partici-
7 pating institutions under paragraph (1)(A)(i)
8 shall contain an agreement to accept as pay-
9 ment in full the established remission rate
10 under this subparagraph.

11 “(B) STIPEND.—The Surgeon General,
12 based on the recommendations of the National
13 Health Workforce Commission, shall establish
14 and update Federal stipend rates for payment
15 to students under this part.

16 “(3) REDUCTIONS IN THE PERIOD OF OBLI-
17 GATED SERVICE.—The period of obligated service
18 under paragraph (1)(A)(ii)(V) shall be reduced—

19 “(A) in the case of a student who elects to
20 participate in a high-needs speciality residency
21 (as determined by the National Health Work-
22 force Commission), by 3 months for each year
23 of such participation (not to exceed a total of
24 12 months); and

1 “(B) in the case of a student who, upon
2 completion of their residency, elects to practice
3 in a Federal medical facility (as defined in sec-
4 tion 781(e)) that is located in a health profes-
5 sional shortage area (as defined in section 332),
6 by 3 months for year of full-time practice in
7 such a facility (not to exceed a total of 12
8 months).

9 “(c) SECOND 2 YEARS OF SERVICE.—During the
10 third and fourth years in which a medical, dental, physi-
11 cian assistant, pharmacy, behavioral and mental health,
12 public health, or nursing student is enrolled in the Track,
13 training should be designed to prioritize clinical rotations
14 in Federal medical facilities in health professional short-
15 age areas, and emphasize a balance of hospital and com-
16 munity-based experiences, and training within inter-
17 disciplinary teams.

18 “(d) DENTIST, PHYSICIAN ASSISTANT, PHARMACIST,
19 BEHAVIORAL AND MENTAL HEALTH PROFESSIONAL,
20 PUBLIC HEALTH PROFESSIONAL, AND NURSE TRAIN-
21 ING.—The Surgeon General shall establish provisions ap-
22 plicable with respect to dental, physician assistant, phar-
23 macy, behavioral and mental health, public health, and
24 nursing students that are comparable to those for medical
25 students under this section, including service obligations,

1 tuition support, and stipend support. The Surgeon Gen-
2 eral shall give priority to health professions training insti-
3 tutions that train medical, dental, physician assistant,
4 pharmacy, behavioral and mental health, public health,
5 and nursing students for some significant period of time
6 together, but at a minimum have a discrete and shared
7 core curriculum.

8 “(e) ELITE FEDERAL DISASTER TEAMS.—The Sur-
9 geon General, in consultation with the Secretary, the Di-
10 rector of the Centers for Disease Control and Prevention,
11 and other appropriate military and Federal government
12 agencies, shall develop criteria for the appointment of
13 highly qualified Track faculty, medical, dental, physician
14 assistant, pharmacy, behavioral and mental health, public
15 health, and nursing students, and graduates to elite Fed-
16 eral disaster preparedness teams to train and to respond
17 to public health emergencies, natural disasters, bioter-
18 rorism events, and other emergencies.

19 “(f) STUDENT DROPPED FROM TRACK IN AFFILIATE
20 SCHOOL.—A medical, dental, physician assistant, phar-
21 macy, behavioral and mental health, public health, or
22 nursing student who, under regulations prescribed by the
23 Surgeon General, is dropped from the Track in an affili-
24 ated school for deficiency in conduct or studies, or for

1 other reasons, shall be liable to the United States for all
2 tuition and stipend support provided to the student.

3 **“SEC. 274. FUNDING.**

4 “Beginning with fiscal year 2010, the Secretary shall
5 transfer from the Public Health and Social Services Emer-
6 gency Fund such sums as may be necessary to carry out
7 this part.”.

8 **Subtitle E—Supporting the**
9 **Existing Health Care Workforce**

10 **SEC. 451. CENTERS OF EXCELLENCE.**

11 Section 736 of the Public Health Service Act (42
12 U.S.C. 293) is amended by striking subsection (h) and in-
13 serting the following:

14 “(h) **FORMULA FOR ALLOCATIONS.—**

15 “(1) **ALLOCATIONS.—**Based on the amount ap-
16 propriated under subsection (i) for a fiscal year, the
17 following subparagraphs shall apply as appropriate:

18 “(A) **IN GENERAL.—**If the amounts appro-
19 priated under subsection (i) for a fiscal year are
20 \$24,000,000 or less—

21 “(i) the Secretary shall make available
22 \$12,000,000 for grants under subsection
23 (a) to health professions schools that meet
24 the conditions described in subsection
25 (c)(2)(A); and

1 “(ii) and available after grants are
2 made with funds under clause (i), the Sec-
3 retary shall make available—

4 “(I) 60 percent of such amount
5 for grants under subsection (a) to
6 health professions schools that meet
7 the conditions described in paragraph
8 (3) or (4) of subsection (c) (including
9 meeting the conditions under sub-
10 section (e)); and

11 “(II) 40 percent of such amount
12 for grants under subsection (a) to
13 health professions schools that meet
14 the conditions described in subsection
15 (c)(5).

16 “(B) FUNDING IN EXCESS OF
17 \$24,000,000.—If amounts appropriated under
18 subsection (i) for a fiscal year exceed
19 \$24,000,000 but are less than \$30,000,000—

20 “(i) 80 percent of such excess
21 amounts shall be made available for grants
22 under subsection (a) to health professions
23 schools that meet the requirements de-
24 scribed in paragraph (3) or (4) of sub-

1 section (c) (including meeting conditions
2 pursuant to subsection (e)); and

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

8 “(C) FUNDING IN EXCESS OF
9 \$30,000,000.—If amounts appropriated under
10 subsection (i) for a fiscal year exceed
11 \$30,000,000 but are less than \$40,000,000, the
12 Secretary shall make available—

13 “(i) not less than \$12,000,000 for
14 grants under subsection (a) to health pro-
15 fessions schools that meet the conditions
16 described in subsection (c)(2)(A);

17 “(ii) not less than \$12,000,000 for
18 grants under subsection (a) to health pro-
19 fessions schools that meet the conditions
20 described in paragraph (3) or (4) of sub-
21 section (c) (including meeting conditions
22 pursuant to subsection (e));

23 “(iii) not less than \$6,000,000 for
24 grants under subsection (a) to health pro-

1 fessions schools that meet the conditions
2 described in subsection (c)(5); and

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

10 “(D) FUNDING IN EXCESS OF
11 \$40,000,000.—If amounts appropriated under
12 subsection (i) for a fiscal year are \$40,000,000
13 or more, the Secretary shall make available—

14 “(i) not less than \$16,000,000 for
15 grants under subsection (a) to health pro-
16 fessions schools that meet the conditions
17 described in subsection (c)(2)(A);

18 “(ii) not less than \$16,000,000 for
19 grants under subsection (a) to health pro-
20 fessions schools that meet the conditions
21 described in paragraph (3) or (4) of sub-
22 section (c) (including meeting conditions
23 pursuant to subsection (e));

24 “(iii) not less than \$8,000,000 for
25 grants under subsection (a) to health pro-

1 fessions schools that meet the conditions
2 described in subsection (c)(5); and

3 “(iv) after grants are made with
4 funds under clauses (i) through (iii), any
5 remaining funds for grants under sub-
6 section (a) to health professions schools
7 that meet the conditions described in para-
8 graph (2)(A), (3), (4), or (5) of subsection
9 (c).

10 “(2) NO LIMITATION.—Nothing in this sub-
11 section shall be construed as limiting the centers of
12 excellence referred to in this section to the des-
13 ignated amount, or to preclude such entities from
14 competing for grants under this section.

15 “(3) MAINTENANCE OF EFFORT.—

16 “(A) IN GENERAL.—With respect to activi-
17 ties for which a grant made under this part are
18 authorized to be expended, the Secretary may
19 not make such a grant to a center of excellence
20 for any fiscal year unless the center agrees to
21 maintain expenditures of non-Federal amounts
22 for such activities at a level that is not less
23 than the level of such expenditures maintained
24 by the center for the fiscal year preceding the

1 fiscal year for which the school receives such a
2 grant.

3 “(B) USE OF FEDERAL FUNDS.—With re-
4 spect to any Federal amounts received by a cen-
5 ter of excellence and available for carrying out
6 activities for which a grant under this part is
7 authorized to be expended, the center shall, be-
8 fore expending the grant, expend the Federal
9 amounts obtained from sources other than the
10 grant, unless given prior approval from the Sec-
11 retary.

12 “(i) AUTHORIZATION OF APPROPRIATIONS.—There
13 are authorized to be appropriated to carry out this sec-
14 tion—

15 “(1) \$50,000,000 for each of the fiscal years
16 2010 through 2015; and

17 “(2) and such sums as are necessary for each
18 subsequent fiscal year.”.

19 **SEC. 452. HEALTH CARE PROFESSIONALS TRAINING FOR**
20 **DIVERSITY.**

21 (a) LOAN REPAYMENTS AND FELLOWSHIPS REGARD-
22 ING FACULTY POSITIONS.—Section 738(a)(1) of the Pub-
23 lic Health Service Act (42 U.S.C. 293b(a)(1)) is amended
24 by striking “\$20,000 of the principal and interest of the
25 educational loans of such individuals.” and inserting

1 “\$30,000 of the principal and interest of the educational
2 loans of such individuals.”.

3 (b) SCHOLARSHIPS FOR DISADVANTAGED STU-
4 DENTS.—Section 740(a) of such Act (42 U.S.C. 293d(a))
5 is amended by striking “\$37,000,000” and all that follows
6 through “2002” and inserting “\$51,000,000 for fiscal
7 year 2010, and such sums as may be necessary for each
8 of the fiscal years 2011 through 2014”.

9 (c) REAUTHORIZATION FOR LOAN REPAYMENTS AND
10 FELLOWSHIPS REGARDING FACULTY POSITIONS.—Sec-
11 tion 740(b) of such Act (42 U.S.C. 293d(b)) is amended
12 by striking “appropriated” and all that follows through
13 the period at the end and inserting “appropriated,
14 \$5,000,000 for each of the fiscal years 2010 through
15 2014.”.

16 (d) REAUTHORIZATION FOR EDUCATIONAL ASSIST-
17 ANCE IN THE HEALTH PROFESSIONS REGARDING INDIV-
18 IDUALS FROM A DISADVANTAGED BACKGROUND.—Sec-
19 tion 740(c) of such Act (42 U.S.C. 293d(c)) is amended
20 by striking the first sentence and inserting the following:
21 “For the purpose of grants and contracts under section
22 739(a)(1), there is authorized to be appropriated
23 \$60,000,000 for fiscal year 2010 and such sums as may
24 be necessary for each of the fiscal years 2011 through
25 2014.”

1 **SEC. 453. INTERDISCIPLINARY, COMMUNITY-BASED LINK-**
2 **AGES.**

3 (a) AREA HEALTH EDUCATION CENTERS.—Section
4 751 of the Public Health Service Act (42 U.S.C. 294a)
5 is amended to read as follows:

6 **“SEC. 751. AREA HEALTH EDUCATION CENTERS.**

7 “(a) ESTABLISHMENT OF AWARDS.—The Secretary
8 shall make awards in accordance with this section.

9 “(b) INFRASTRUCTURE DEVELOPMENT AWARD.—

10 “(1) IN GENERAL.—The Secretary shall make
11 awards to eligible entities to enable such entities to
12 initiate health care workforce educational programs
13 or to continue to carry out comparable programs
14 that are operating at the time the award is made by
15 planning, developing, operating, and evaluating of an
16 area health education center program.

17 “(2) ELIGIBLE ENTITY.—For purposes of this
18 subsection, an ‘eligible entity’ means a school of
19 medicine or osteopathic medicine, an incorporated
20 consortium of such schools, or the parent institu-
21 tions of such a school. With respect to a State in
22 which no area health education center program is in
23 operation, the Secretary may award a grant or con-
24 tract under paragraph (1) to a school of nursing.

25 “(3) APPLICATION.—An eligible entity desiring
26 to receive an award under this subsection shall sub-

1 mit to the Secretary an application at such time, in
2 such manner, and containing such information as
3 the Secretary may require.

4 “(4) USE OF FUNDS.—

5 “(A) REQUIRED ACTIVITIES.—An eligible
6 entity shall use amounts awarded under a grant
7 under paragraph (1) to carry out the following
8 activities:

9 “(i) Develop and implement strate-
10 gies, in coordination with the applicable
11 one-stop delivery system under section
12 134(c) of the Workforce Investment Act of
13 1998, to recruit individuals from underrep-
14 resented minority populations or from dis-
15 advantaged or rural backgrounds into
16 health professions, and support such indi-
17 viduals in attaining such careers.

18 “(ii) Develop and implement strate-
19 gies to foster and provide community-based
20 training and education to individuals seek-
21 ing careers in health professions within un-
22 derserved areas for the purpose of devel-
23 oping and maintaining a diverse health
24 care workforce that is prepared to deliver
25 high-quality care, with an emphasis on pri-

1 mary care, in underserved areas or for
2 health disparity populations, in collabora-
3 tion with other Federal and State health
4 care workforce development programs, the
5 State workforce agency, and local work-
6 force investment boards, and in health care
7 safety net sites.

8 “(iii) Prepare individuals to more ef-
9 fectively provide health services to under-
10 served areas and health disparity popu-
11 lations through field placements or precep-
12 torships in conjunction with community-
13 based organizations, accredited primary
14 care residency training programs, Feder-
15 ally qualified health centers, rural health
16 clinics, public health departments, or other
17 appropriate facilities.

18 “(iv) Conduct and participate in inter-
19 disciplinary training that involves physi-
20 cians, physician assistants, nurse practi-
21 tioners, nurse midwives, dentists, psycholo-
22 gists, pharmacists, optometrists, commu-
23 nity health workers, public and allied
24 health professionals, or other health pro-
25 fessionals, as practicable.

1 “(v) Deliver or facilitate continuing
2 education and information dissemination
3 programs for health care professionals,
4 with an emphasis on individuals providing
5 care in underserved areas and for health
6 disparity populations.

7 “(vi) Propose and implement effective
8 program and outcomes measurement and
9 evaluation strategies.

10 “(B) INNOVATIVE OPPORTUNITIES.—An
11 eligible entity may use amounts awarded under
12 a grant under paragraph (1) to carry out any
13 of the following activities:

14 “(i) Develop and implement innovative
15 curricula in collaboration with community-
16 based accredited primary care residency
17 training programs, Federally qualified
18 health centers, rural health clinics, behav-
19 ioral and mental health facilities, public
20 health departments, or other appropriate
21 facilities, with the goal of increasing the
22 number of primary care physicians and
23 other primary care providers prepared to
24 serve in underserved areas and health dis-
25 parity populations.

1 “(ii) Coordinate community-based
2 participatory research with academic
3 health centers, and facilitate rapid flow
4 and dissemination of evidence-based health
5 care information, research results, and best
6 practices to improve quality, efficiency, and
7 effectiveness of health care and health care
8 systems within community settings.

9 “(iii) Develop and implement other
10 strategies to address identified workforce
11 needs and increase and enhance the health
12 care workforce in the area served by the
13 area health education center program.

14 “(c) POINT OF SERVICE MAINTENANCE AND EN-
15 HANCEMENT AWARD.—

16 “(1) IN GENERAL.—The Secretary shall make
17 awards to eligible entities to maintain and improve
18 the effectiveness and capabilities of an existing area
19 health education center program, and make other
20 modifications to the program that are appropriate
21 due to changes in demographics, needs of the popu-
22 lations served, or other similar issues affecting the
23 program.

24 “(2) ELIGIBLE ENTITY.—For purposes of this
25 subsection, the term ‘eligible entity’ means an entity

1 that has received funds under this section (as this
2 section was in effect on the day before the date of
3 enactment of the Affordable Health Choices Act), is
4 operating an area health education center program,
5 including area health education centers, and has a
6 center or centers that are no longer eligible to re-
7 ceive financial assistance under subsection (b).

8 “(3) APPLICATION.—An eligible entity desiring
9 to receive an award under this subsection shall sub-
10 mit to the Secretary an application at such time, in
11 such manner, and containing such information as
12 the Secretary may require.

13 “(4) USE OF FUNDS.—

14 “(A) REQUIRED ACTIVITIES.—An eligible
15 entity shall use amounts awarded under a grant
16 under paragraph (1) to carry out the following
17 activities:

18 “(i) Develop and implement strategies
19 in coordination with the applicable one-
20 stop delivery system under section 134(c)
21 of the Workforce Investment Act of 1998
22 to recruit individuals from underrep-
23 resented minority groups, underserved
24 areas, or with rural backgrounds into

1 health care careers, and support such indi-
2 viduals in attaining such careers.

3 “(ii) Develop and implement strate-
4 gies to foster and provide community-based
5 training and education to individuals seek-
6 ing careers in health professions within un-
7 derserved areas for the purpose of devel-
8 oping and maintaining a diverse health
9 care workforce that is prepared to deliver
10 high-quality care, with an emphasis on pri-
11 mary care, in underserved areas and to
12 health disparity populations, in collabora-
13 tion with other Federal and State health
14 care workforce development programs, and
15 in health care safety net sites.

16 “(iii) Prepare individuals to more ef-
17 fectively provide health services to under-
18 served areas or health disparity popu-
19 lations through field placements or precep-
20 torships in conjunction with community-
21 based organizations, accredited primary
22 care residency training programs, Feder-
23 ally qualified health centers, rural health
24 clinics, behavioral and mental health facili-

1 ties, public health departments, or other
2 appropriate facilities.

3 “(iv) Conduct and participate in inter-
4 disciplinary training that involves physi-
5 cians, physician assistants, nurse practi-
6 tioners, nurse midwives, dentists, psycholo-
7 gists, pharmacists, optometrists, commu-
8 nity health workers, public and allied
9 health professionals, or other health pro-
10 fessionals, as practicable.

11 “(v) Deliver or facilitate continuing
12 education and information dissemination
13 programs for health care professionals,
14 with an emphasis on individuals providing
15 care in underserved areas and for health
16 disparity populations.

17 “(vi) Propose and implement effective
18 program and outcomes measurement and
19 evaluation strategies.

20 “(B) INNOVATIVE OPPORTUNITIES.—An
21 eligible entity shall use amounts awarded under
22 a grant under paragraph (1) to carry out at
23 least 1 of the following activities:

24 “(i) Develop innovative curricula in
25 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 “(1) AREA HEALTH EDUCATION CENTER PRO-
2 GRAM.—In carrying out this section, the Secretary
3 shall ensure the following:

4 “(A) An entity that receives an award
5 under this section shall conduct at least 10 per-
6 cent of clinical education required for medical
7 students in community settings that are re-
8 moved from the primary teaching facility of the
9 contracting institution for grantees that operate
10 a school of medicine or osteopathic medicine. In
11 States in which an entity that receives an
12 award under this section is a nursing school or
13 its parent institution, the Secretary shall alter-
14 natively ensure that—

15 “(i) the nursing school places at least
16 10 percent of its students in training sites
17 affiliated with an area health education
18 center that is remote from the primary
19 teaching facility of the school; and

20 “(ii) the entity receiving the award
21 maintains a written agreement with a
22 school of medicine or osteopathic medicine
23 to place at least 10 percent of students
24 from that school in training sites in the
25 area health education center program area.

1 “(B) An entity receiving funds under sub-
2 section (c) does not distribute such funding to
3 a center that is eligible to receive funding under
4 subsection (b).

5 “(2) AREA HEALTH EDUCATION CENTER.—The
6 Secretary shall ensure that each area health edu-
7 cation center program includes at least 1 area health
8 education center, and that each such center—

9 “(A) is a public or private organization
10 whose structure, governance, and operation is
11 independent from the awardee and the parent
12 institution of the awardee;

13 “(B) is not a school of medicine or osteo-
14 pathic medicine, the parent institution of such
15 a school, or a branch campus or other subunit
16 of a school of medicine or osteopathic medicine
17 or its parent institution, or a consortium of
18 such entities;

19 “(C) designates an underserved area or
20 population to be served by the center which is
21 in a location removed from the main location of
22 the teaching facilities of the schools partici-
23 pating in the program with such center and
24 does not duplicate, in whole or in part, the geo-

1 graphic area or population served by any other
2 center;

3 “(D) fosters networking and collaboration
4 among communities and between academic
5 health centers and community-based centers;

6 “(E) serves communities with a dem-
7 onstrated need of health professionals in part-
8 nership with academic medical centers;

9 “(F) addresses the health care workforce
10 needs of the communities served in coordination
11 with the public workforce investment system;
12 and

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

16 “(e) MATCHING FUNDS.—With respect to the costs
17 of operating a program through a grant under this section,
18 to be eligible for financial assistance under this section,
19 an entity shall make available (directly or through con-
20 tributions from State, county or municipal governments,
21 or the private sector) recurring non-Federal contributions
22 in cash or in kind, toward such costs in an amount that
23 is equal to not less than 50 percent of such costs. At least
24 25 percent of the total required non-Federal contributions
25 shall be in cash. An entity may apply to the Secretary

1 for a waiver of not more than 75 percent of the matching
2 fund amount required by the entity for each of the first
3 3 years the entity is funded through a grant under sub-
4 section (b).

5 “(f) LIMITATION.—Not less than 75 percent of the
6 total amount provided to an area health education center
7 program under subsection (b) or (c) shall be allocated to
8 the area health education centers participating in the pro-
9 gram under this section. To provide needed flexibility to
10 newly funded area health education center programs, the
11 Secretary may waive the requirement in the sentence for
12 the first 2 years of a new area health education center
13 program funded under subsection (b).

14 “(g) AWARD.—An award to an entity under this sec-
15 tion shall be not less than \$250,000 annually per area
16 health education center included in the program involved.
17 If amounts appropriated to carry out this section are not
18 sufficient to comply with the preceding sentence, the Sec-
19 retary may reduce the per center amount provided for in
20 such sentence as necessary, provided the distribution es-
21 tablished in subsection (k)(2) is maintained.

22 “(h) PROJECT TERMS.—

23 “(1) IN GENERAL.—Except as provided in para-
24 graph (2), the period during which payments may be

1 made under an award under subsection (b) may not
2 exceed—

3 “(A) in the case of a program, 12 years;
4 or

5 “(B) in the case of a center within a pro-
6 gram, 6 years.

7 “(2) EXCEPTION.—The periods described in
8 paragraph (1) shall not apply to programs receiving
9 point of service maintenance and enhancement
10 awards under subsection (c) to maintain existing
11 centers and activities.

12 “(i) INAPPLICABILITY OF PROVISION.—Notwith-
13 standing any other provision of this title, section 791(a)
14 shall not apply to an area health education center funded
15 under this section.

16 “(j) AUTHORIZATION OF APPROPRIATIONS.—

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

20 “(2) REQUIREMENTS.—Of the amounts appro-
21 priated for a fiscal year under paragraph (1)—

22 “(A) not more than 35 percent shall be
23 used for awards under subsection (b);

24 “(B) not less than 60 percent shall be used
25 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.

9 “(3) CARRYOVER FUNDS.—An entity that re-
10 ceives an award under this section may carry over
11 funds from 1 fiscal year to another without obtain-
12 ing approval from the Secretary. In no case may any
13 funds be carried over pursuant to the preceding sen-
14 tence for more than 3 years.

15 “(k) SENSE OF CONGRESS.—It is the sense of the
16 Congress that every State have an area health education
17 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:

1 **“SEC. 752. CONTINUING EDUCATIONAL SUPPORT FOR**
2 **HEALTH PROFESSIONALS SERVING IN UN-**
3 **DESERVED COMMUNITIES.**

4 “(a) IN GENERAL.—The Secretary shall make grants
5 to, and enter into contracts with, eligible entities to im-
6 prove health care, increase retention, increase representa-
7 tion of minority faculty members, enhance the practice en-
8 vironment, and provide information dissemination and
9 educational support to reduce professional isolation
10 through the timely dissemination of research findings
11 using relevant resources.

12 “(b) ELIGIBLE ENTITIES.—For purposes of this sec-
13 tion, the term ‘eligible entity’ means an entity described
14 in section 799(b).

15 “(c) APPLICATION.—An eligible entity desiring to re-
16 ceive an award under this section shall submit to the Sec-
17 retary an application at such time, in such manner, and
18 containing such information as the Secretary may require.

19 “(d) USE OF FUNDS.—An eligible entity shall use
20 amounts awarded under a grant or contract under this
21 section to provide innovative supportive activities to en-
22 hance education through distance learning, continuing
23 educational activities, collaborative conferences, and elec-
24 tronic and telelearning activities, with priority for primary
25 care.

1 “(e) AUTHORIZATION.—There is authorized to be ap-
2 propriated to carry out this section \$5,000,000 for each
3 of the fiscal years 2010 through 2014, and such sums as
4 may be necessary for each subsequent fiscal year.”.

5 **SEC. 454. WORKFORCE DIVERSITY GRANTS.**

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

8 (1) in subsection (a)—

9 (A) by striking “The Secretary may” and
10 inserting the following:

11 “(1) AUTHORITY.—The Secretary may”;

12 (B) by striking “pre-entry preparation,
13 and retention activities” and inserting the fol-
14 lowing: “stipends for diploma or associate de-
15 gree nurses to enter a bridge or degree comple-
16 tion program, student scholarships or stipends
17 for accelerated nursing degree programs, pre-
18 entry preparation, advanced education prepara-
19 tion, and retention activities”; and

20 (2) in subsection (b)—

21 (A) by striking “First” and all that follows
22 through “including the” and inserting “Na-
23 tional Advisory Council on Nurse Education
24 and Practice and consult with nursing associa-

1 tions including the National Coalition of Ethnic
2 Minority Nurse Associations,”; and

3 (B) by inserting before the period the fol-
4 lowing: “, and other organizations determined
5 appropriate by the Secretary”.

6 **SEC. 455. PRIMARY CARE EXTENSION PROGRAM.**

7 Part P of title III of the Public Health Service Act
8 (42 U.S.C. 280g et seq.), as amended by section 443, is
9 further amended by adding at the end the following:

10 **“SEC. 399V. PRIMARY CARE EXTENSION PROGRAM.**

11 “(a) ESTABLISHMENT, PURPOSE AND DEFINI-
12 TION.—

13 “(1) IN GENERAL.—The Secretary, acting
14 through the Director of the Agency for Healthcare
15 Research and Quality, shall establish a Primary
16 Care Extension Program.

17 “(2) PURPOSE.—The Primary Care Extension
18 Program shall provide support and assistance to pri-
19 mary care providers to educate providers about pre-
20 ventive medicine, health promotion, chronic disease
21 management, mental and behavioral health services
22 (including substance abuse prevention and treatment
23 services), and evidence-based and evidence-informed
24 therapies and techniques, in order to enable pro-
25 viders to incorporate such matters into their practice

1 and to improve community health by working with
2 community-based health connectors (referred to in
3 this section as ‘Health Extension Agents’).

4 “(3) DEFINITIONS.—In this section:

5 “(A) HEALTH EXTENSION AGENT.—The
6 term ‘Health Extension Agent’ means any local,
7 community-based health worker who facilitates
8 and provides assistance to primary care prac-
9 tices by implementing quality improvement or
10 system redesign, incorporating the principles of
11 the patient-centered medical home to provide
12 high-quality, effective, efficient, and safe pri-
13 mary care and to provide guidance to patients
14 in culturally and linguistically appropriate ways,
15 and linking practices to diverse health system
16 resources.

17 “(B) PRIMARY CARE PROVIDER.—The
18 term ‘primary care provider’ means a clinician
19 who provides integrated, accessible health care
20 services and who is accountable for addressing
21 a large majority of personal health care needs,
22 including providing preventive and health pro-
23 motion services for men, women, and children
24 of all ages, developing a sustained partnership
25 with patients, and practicing in the context of

1 family and community, as recognized by a State
2 licensing or regulatory authority, unless other-
3 wise specified in this section.

4 “(b) GRANTS TO ESTABLISH STATE HUBS AND
5 LOCAL PRIMARY CARE EXTENSION AGENCIES.—

6 “(1) GRANTS.—The Secretary shall award com-
7 petitive grants to States for the establishment of
8 State- or multistate-level primary care Primary Care
9 Extension Program State Hubs (referred to in this
10 section as ‘Hubs’).

11 “(2) COMPOSITION OF HUBS.—A Hub estab-
12 lished by a State pursuant to paragraph (1)—

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

21 “(B) may include entities such as hospital
22 associations, primary care practice-based re-
23 search networks, health professional societies,
24 State primary care associations, State licensing
25 boards, organizations with a contract with the

1 Secretary under section 1153 of the Social Se-
2 curity Act, consumer groups, and other appro-
3 priate entities.

4 “(c) STATE AND LOCAL ACTIVITIES.—

5 “(1) HUB ACTIVITIES.—Hubs established under
6 a grant under subsection (b) shall—

7 “(A) submit to the Secretary a plan to co-
8 ordinate functions with quality improvement or-
9 ganizations and area health education centers if
10 such entities are members of the Hub not de-
11 scribed in subsection (b)(2)(A);

12 “(B) contract with a county- or local-level
13 entity that shall serve as the Primary Care Ex-
14 tension Agency to administer the services de-
15 scribed in paragraph (2);

16 “(C) organize and administer grant funds
17 to county- or local-level Primary Care Exten-
18 sion Agencies that serve a catchment area, as
19 determined by the State; and

20 “(D) organize State-wide or multistate net-
21 works of local-level Primary Care Extension
22 Agencies to share and disseminate information
23 and practices.

24 “(2) LOCAL PRIMARY CARE EXTENSION AGENCY
25 ACTIVITIES.—

1 “(A) REQUIRED ACTIVITIES.—Primary
2 Care Extension Agencies established by a Hub
3 under paragraph (1) shall—

4 “(i) assist primary care providers to
5 implement a patient-centered medical home
6 to improve the accessibility, quality, and
7 efficiency of primary care services;

8 “(ii) develop and support primary care
9 learning communities to enhance the dis-
10 semination of research findings for evi-
11 dence-based practice, assess implementa-
12 tion of practice improvement, share best
13 practices, and involve community clinicians
14 in the generation of new knowledge and
15 identification of important questions for
16 research;

17 “(iii) participate in a national network
18 of Primary Care Extension Hubs and pro-
19 pose how the Primary Care Extension
20 Agency will share and disseminate lessons
21 learned and best practices; and

22 “(iv) develop a plan for financial sus-
23 tainability involving State, local, and pri-
24 vate contributions, to provide for the re-
25 duction in Federal funds that is expected

1 after an initial 6-year period of program
2 establishment, infrastructure development,
3 and planning.

4 “(B) DISCRETIONARY ACTIVITIES.—Pri-
5 mary Care Extension Agencies established by a
6 Hub under paragraph (1) may—

7 “(i) provide technical assistance,
8 training, and organizational support for
9 community health teams established under
10 section 212 of the Affordable Health
11 Choices Act;

12 “(ii) collect data and provision of pri-
13 mary care provider feedback from stand-
14 ardized measurements of processes and
15 outcomes to aid in continuous performance
16 improvement;

17 “(iii) collaborate with local health de-
18 partments, community health centers,
19 tribes and tribal entities, and other com-
20 munity agencies to identify community
21 health priorities and local health workforce
22 needs, and participate in community-based
23 efforts to address the social and primary
24 determinants of health, strengthen the

1 local primary care workforce, and eliminate
2 health disparities;

3 “(iv) develop measures to monitor the
4 impact of the proposed program on the
5 health of practice enrollees and of the
6 wider community served; and

7 “(v) participate in other activities, as
8 determined appropriate by the Secretary.

9 “(d) FEDERAL PROGRAM ADMINISTRATION.—

10 “(1) GRANTS; TYPES.—Grants awarded under
11 subsection (b) shall be—

12 “(A) program grants, that are awarded to
13 State or multistate entities that submit fully-de-
14 veloped plans for the implementation of a Hub,
15 for a period of 6 years; or

16 “(B) planning grants, that are awarded to
17 State or multistate entities with the goal of de-
18 veloping a plan for a Hub, for a period of 2
19 years.

20 “(2) APPLICATIONS.—To be eligible for a grant
21 under subsection (b), a State or multistate entity
22 shall submit to the Secretary an application, at such
23 time, in such manner, and containing such informa-
24 tion as the Secretary may require.

1 “(3) EVALUATION.—A State that receives a
2 grant under subsection (b) shall be evaluated at the
3 end of the grant period by an evaluation panel ap-
4 pointed by the Secretary.

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

13 “(5) LIMITATION.—A State shall not use in ex-
14 cess of 10 percent of the amount received under a
15 grant to carry out administrative activities under
16 this section. Funds awarded pursuant to this section
17 shall not be used for funding direct patient care.

18 “(e) REQUIREMENTS ON THE SECRETARY.—In car-
19 rying out this section, the Secretary shall consult with the
20 heads of other Federal agencies with demonstrated experi-
21 ence and expertise in health care and preventive medicine,
22 such as the Centers for Disease Control and Prevention,
23 the Substance Abuse and Mental Health Administration,
24 the Health Resources and Services Administration, the
25 National Institutes of Health, the Office of the National

1 Coordinator for Health Information Technology, the In-
2 dian Health Service, the Agricultural Cooperative Exten-
3 sion Service of the Department of Agriculture, and other
4 entities, as the Secretary determines appropriate.

5 “(f) AUTHORIZATION OF APPROPRIATIONS.—To
6 awards grants as provided in subsection (d), there are au-
7 thorized to be appropriated \$120,000,000 for each of fis-
8 cal years 2011 and 2012, and such sums as may be nec-
9 essary to carry out this section for each of fiscal years
10 2013 through 2014.”.

11 **SEC. 456. DEFINITION OF ECONOMIC HARDSHIP.**

12 Section 435(o) of the Higher Education Act of 1965
13 (20 U.S.C. 1085(o)) is amended—

14 (1) in paragraph (1)—

15 (A) in subparagraph (A)(ii), by striking
16 “or” after the semicolon;

17 (B) by redesignating subparagraph (B) as
18 subparagraph (C); and

19 (C) by inserting after subparagraph (A)
20 the following:

21 “(B) such borrower is working full-time
22 and has a Federal educational debt burden that
23 equals or exceeds 20 percent of such borrower’s
24 adjusted gross income, and the difference be-
25 tween such borrower’s adjusted gross income

1 minus such burden is less than 220 percent of
2 the greater of—

3 “(i) the annual earnings of an indi-
4 vidual earning the minimum wage under
5 section 6 of the Fair Labor Standards Act
6 of 1938; or

7 “(ii) 150 percent of the poverty line,
8 as defined under section 673(2) of the
9 Community Services Block Grant Act, ap-
10 plicable to such borrower’s family size; or”;
11 and

12 (2) in paragraph (2), by striking “(1)(B)” and
13 inserting “(1)(C)”.

14 **Subtitle F—General Provisions**

15 **SEC. 461. REPORTS.**

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

22 (b) REPORTS BY RECIPIENTS OF FUNDS.—The Sec-
23 retary of Health and Human Services may require, as a
24 condition of receiving funds under the amendments made
25 by this title, that the entity receiving such award submit

1 to such Secretary such reports as the such Secretary may
2 require on activities carried out with such award, and the
3 effectiveness of such activities.

4 **TITLE V—PREVENTING FRAUD**
5 **AND ABUSE**

6 **Subtitle A—Establishment of New**
7 **Health and Human Services and**
8 **Department of Justice Health**
9 **Care Fraud Positions**

10 **SEC. 501. HEALTH AND HUMAN SERVICES SENIOR ADVISOR.**

11 Part C of title XXVII of the Public Health Service
12 Act (42 U.S.C. 300gg-91 et seq.) is amended—

13 (1) by redesignating section 2792 as section
14 2796; and

15 (2) by inserting after section 2791, the fol-
16 lowing:

17 **“SEC. 2792. SENIOR ADVISOR FOR HEALTH CARE FRAUD.**

18 “(a) ESTABLISHMENT.—The Secretary shall appoint
19 an individual to serve as the Senior Advisor for Health
20 Care Fraud (referred to in this section as the ‘Senior Ad-
21 visor’) within the Office of the Deputy Secretary. The Sen-
22 ior Advisory shall be the principal advisor on policy and
23 program development and oversight with respect to—

24 “(1) the detection and prevention of health care
25 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;

1 “(2) provided under the veteran’s health care
2 program under chapter 17 of title 38, United States
3 Code;

4 “(3) provided through the Indian Health Serv-
5 ice;

6 “(4) under the TRICARE program under chap-
7 ter 55 of title 10, United States Code; and

8 “(5) under the Federal Employees Health Ben-
9 efits Program under chapter 89 of title 5, United
10 States Code.”.

11 **SEC. 502. DEPARTMENT OF JUSTICE POSITION.**

12 Chapter 41 of title 28, United States Code, is amend-
13 ed by adding at the end the following:

14 **“§ 614. Senior Counsel for Health Care Fraud En-**
15 **forcement**

16 “The Attorney General shall appoint an individual to
17 serve as the Senior Counsel for Health Care Fraud En-
18 forcement (referred to in this section as the ‘Senior Coun-
19 sel’) within the Office of the Deputy Attorney General to
20 serve as the principal advisor to the Attorney General on
21 policy and program development and oversight with re-
22 spect to—

23 “(1) the investigation and prosecution of health
24 care fraud and abuse involving public and private

1 health insurance coverage (as defined in section
2 2791 of the Public Health Service Act); and

3 “(2) the coordination of such efforts within the
4 Department of Justice and with the Inspector Gen-
5 eral, the Department of Health and Human Serv-
6 ices, other Federal agencies as appropriate, State
7 and local law enforcement, State regulatory agen-
8 cies, and private health insurance coverage.”.

9 **SEC. 503. REPORTS TO CONGRESS.**

10 (a) **REPORTS.**—The Senior Advisor for Health Care
11 Fraud appointed under section 2792 of the Public Health
12 Service Act and the Senior Counsel for Health Care Fraud
13 Enforcement appointed under section 614 of title 28,
14 United States Code, shall annually report to the Com-
15 mittee On Health, Education, Labor, and Pensions and
16 the Committee on Finance of the Senate and the Com-
17 mittee on Ways and Means of the House of Representa-
18 tives regarding the detection and prevention of health care
19 fraud, waste, and abuse involving public health insurance
20 and private health insurance coverage.

21 (b) **DEFINITION.**—In this section, the term “public
22 health insurance coverage” means coverage—

23 (1) provided under title XVIII, XIX, or XXI of
24 the Social Security Act;

1 (2) provided under the veteran's health care
2 program under chapter 17 of title 38, United States
3 Code;

4 (3) provided through the Indian Health Service;

5 (4) under the TRICARE program under chap-
6 ter 55 of title 10, United States Code; and

7 (5) under the Federal Employees Health Bene-
8 fits Program under chapter 89 of title 5, United
9 States Code.

10 **SEC. 504. FRAUD, WASTE, AND ABUSE COMMISSION.**

11 (a) ESTABLISHMENT.—Not later than 180 days after
12 the date of enactment of this Act, the President shall es-
13 tablish a commission to be composed of representatives ap-
14 pointed by the President from insurers, employers, health
15 care providers, anti-fraud organizations, consumers and
16 patient groups, and Federal officials to review Federal
17 health care programs and private health insurance with
18 respect to policies and procedures to eliminate fraud,
19 waste, and abuse under such programs and to more effec-
20 tively align public and private sector efforts to combat
21 fraud, waste, and abuse.

22 (b) PERIOD OF REVIEW.—The commission under
23 subsection (a) shall review the programs involved for a pe-
24 riod of 2 years following the date on which such commis-
25 sion is established.

1 (c) REPORT.—Not later than 3 years after the date
2 on which the commission under subsection (a) is estab-
3 lished, the commission shall submit to the Committee on
4 Health, Education, Labor, and Pensions and the Com-
5 mittee on Finance of the Senate and the Committee on
6 Ways and Means and the Committee on Energy and Com-
7 merce of the House of Representatives a report concerning
8 the review conducted under such subsection. Such report
9 shall include recommendations for modify such programs
10 and other recommendations to better coordinate public
11 and private efforts to combat fraud and abuse.

12 (d) COOPERATION.—The President shall direct Fed-
13 eral officials to cooperate in the activities of the commis-
14 sion under this section. Commissioners shall have experi-
15 ence in fighting waste, fraud or abuse in the public and
16 private sectors.

17 (e) AUTHORIZATION OF APPROPRIATIONS.—There is
18 authorized to be appropriated to carry out this section,
19 \$5,000,000.

20 **Subtitle B—Health Care Program**
21 **Integrity Coordinating Council**

22 **SEC. 511. ESTABLISHMENT.**

23 Part C of title XXVII of the Public Health Service
24 Act (42 U.S.C. 300gg-91 et seq.), as amended by section

1 501, is further amended by inserting after section 2793,
2 the following:

3 **“SEC. 2794. HEALTH CARE PROGRAM INTEGRITY COORDI-**
4 **NATING COUNCIL.**

5 “(a) ESTABLISHMENT.—There is established a coun-
6 cil to be known as the ‘Health Care Program Integrity
7 Coordinating Council’ (referred to in this section as the
8 ‘Council’).

9 “(b) MEMBERSHIP.—The Council shall be composed
10 of—

11 “(1) the Secretary of Health and Human Serv-
12 ices;

13 “(2) the Attorney General;

14 “(3) the Inspector General for the Department
15 of Health and Human Services;

16 “(4) the Secretary of Labor;

17 “(5) the Secretary of Defense;

18 “(6) the Director of the Office of Personnel
19 Management;

20 “(7) the Under Secretary for Health for the
21 Veterans Health Administration of the Department
22 of Veterans Affairs;

23 “(8) the Commissioner of the Social Security
24 Administration;

1 “(9) the President of the National Association
2 of Insurance Commissioners;

3 “(10) the President of the National Association
4 of Medicaid Fraud Control Units;

5 “(11) the Comptroller General of the United
6 States;

7 “(12) the Inspector General of the Department
8 of Labor;

9 “(13) the Inspector General of the Department
10 of Defense;

11 “(14) the Inspector General of the Department
12 of Veterans Affairs;

13 “(15) the Inspector General of the Department
14 of Justice;

15 “(16) the chairperson and ranking member of
16 relevant committees of jurisdiction of the Senate and
17 the House of Representatives; and

18 “(17) any other member, the appointment of
19 whom a majority of the members of the Council de-
20 termines is necessary to carry out this title, except
21 that an individual who is a representative of an enti-
22 ty subject to regulation under such Act shall not be
23 appointed under this subparagraph.

24 “(c) DUTIES.—The Council shall—

1 “(1) not later than 6 months after the date of
2 enactment of this section, develop a strategic plan
3 for improving the coordination and information shar-
4 ing among Federal agencies, State agencies, and pri-
5 vate health insurance coverage with respect to the
6 prevention, detection, and control of fraud, waste,
7 and abuse, including fraud and abuse of consumers
8 of the health care program or private health insur-
9 ance issuers;

10 “(2) annually submit to Congress a report on
11 actions taken to implement the strategic plan re-
12 quired under paragraph (1);

13 “(3) in carrying out the responsibilities identi-
14 fied under paragraph (1), evaluate ways to ensure
15 that private health insurance coverage is included in
16 investigative and data sharing programs, to the max-
17 imum extent feasible, with adequate protection pro-
18 vided for law enforcement-related data that is sen-
19 sitive because of concerns for the identities of crimi-
20 nal subjects or targets, and that recognizes that pri-
21 vate coverage may be responsible for fraud, waste,
22 and abuse of public and policyholder funds;

23 “(4) not later than 12 months after the date of
24 enactment of this section, develop and issue guide-
25 lines for purposes of carrying out the strategic plan

1 under paragraph (1), recognizing that fraudulent ac-
2 tivity in the health care system can affect both pub-
3 lic and private sector health insurance coverage, and
4 that the prevention, detection, investigation, and
5 prosecution of fraud against private health insurance
6 coverage is integral to the overall effort to combat
7 health care fraud;

8 “(5) at least once during every 5-year period,
9 update the strategic plan issued pursuant to para-
10 graph (1) and the guidelines issued pursuant to
11 paragraph (4);

12 “(6) develop recommendations, in consultation
13 with the Office of Management and Budget, for
14 measures to estimate the amount of fraud, waste,
15 and abuse in connection with public and private
16 health insurance coverage, and the annual savings
17 resulting from specific program integrity measures;

18 “(7) identify improvements needed for purposes
19 of information-sharing systems and activities used in
20 implementing the strategic plan under paragraph
21 (1); and

22 “(8) establish a consultative panel composed of
23 representatives of the private sector health insurance
24 industry and consult with this panel in the formula-
25 tion of Council recommendations.

1 “(d) EXEMPTIONS.—The Council shall be exempt
2 from—

3 “(1) sections 553, 556, and 557 of title 5,
4 United States Code, in the issuance of guidelines
5 pursuant to subsection (c)(4); and

6 “(2) the Federal Advisory Committee Act (5
7 U.S.C. app.) in order to protect against the release
8 of information which might undermine Federal,
9 State, or local health care fraud control efforts.

10 “(e) PUBLIC PARTICIPATION.—The Council shall
11 provide for reasonable public participation in matters be-
12 fore the Council to the extent that such participation
13 would not compromise the Council’s, or any other Federal,
14 State, or local government entity’s, efforts to control
15 health care fraud and abuse.”.

16 **Subtitle C—False Statements and**
17 **Representations**

18 **SEC. 521. PROHIBITION ON FALSE STATEMENTS AND REP-**
19 **RESENTATIONS.**

20 (a) PROHIBITION.—Part 5 of subtitle B of title I of
21 the Employee Retirement Income Security Act of 1974
22 (29 U.S.C. 1131 et seq.) is amended by adding at the end
23 the following:

1 **“SEC. 519. PROHIBITION ON FALSE STATEMENTS AND REP-**
2 **RESENTATIONS.**

3 “No person, in connection with a plan or other ar-
4 rangement that is multiple employer welfare arrangement
5 described in section 3(40), shall make a false statement
6 or false representation of fact, knowing it to be false, in
7 connection with the marketing or sale of such plan or ar-
8 rangement, to any employee, any member of an employee
9 organization, any beneficiary, any employer, any employee
10 organization, the Secretary, or any State, or the represent-
11 ative or agent of any such person, State, or the Secretary,
12 concerning—

13 “(1) the financial condition or solvency of such
14 plan or arrangement;

15 “(2) the benefits provided by such plan or ar-
16 rangement;

17 “(3) the regulatory status of such plan or other
18 arrangement under any Federal or State law gov-
19 erning collective bargaining, labor management rela-
20 tions, or intern union affairs; or

21 “(4) the regulatory status of such plan or other
22 arrangement regarding exemption from state regu-
23 latory authority under this Act.

24 This section shall not apply to any plan or arrangement
25 that does not fall within the meaning of the term ‘multiple
26 employer welfare arrangement’ under section 3(40(A)).”.

1 (b) CRIMINAL PENALTIES.—Section 501 of the Em-
2 ployee Retirement Income Security Act of 1974 (29
3 U.S.C. 1131) is amended—

4 (1) by inserting “(a)” before “Any person”; and

5 (2) by adding at the end the following:

6 “(b) Any person that violates section 519 shall upon
7 conviction be imprisoned not more than 10 years or fined
8 under title 18, United States Code, or both.”.

9 (c) CONFORMING AMENDMENT.—The table of sec-
10 tions for part 5 of subtitle B of title I of the Employee
11 Retirement Income Security Act of 1974 is amended by
12 adding at the end the following:

“Sec. 519. Prohibition on false statement and representations.”.

13 **Subtitle D—Federal Health Care**
14 **Offense**

15 **SEC. 531. CLARIFYING DEFINITION.**

16 Section 24(a)(2) of title 18, United States Code, is
17 amended by inserting “or section 411, 518, or 511 of the
18 Employee Retirement Income Security Act of 1974,” after
19 “1954 of this title”.

20 **Subtitle E—Uniformity in Fraud**
21 **and Abuse Reporting**

22 **SEC. 541. DEVELOPMENT OF MODEL UNIFORM REPORT**
23 **FORM.**

24 Part C of title XXVII of the Public Health Service
25 Act (42 U.S.C. 300gg-91 et seq.), as amended by section

1 511, is further amended by inserting after section 2794,
2 the following:

3 **“SEC. 2795. UNIFORM FRAUD AND ABUSE REFERRAL FOR-**
4 **MAT.**

5 “The Secretary shall request the National Associa-
6 tion of Insurance Commissioners to develop a model uni-
7 form report form for private health insurance issuer seek-
8 ing to refer suspected fraud and abuse to State insurance
9 departments or other responsible State agencies for inves-
10 tigation. The Secretary shall request that the National As-
11 sociation of Insurance Commissioners develop rec-
12 ommendations for uniform reporting standards for such
13 referrals.”.

14 **Subtitle F—Applicability of State**
15 **Law to Combat Fraud and Abuse**

16 **SEC. 551. APPLICABILITY OF STATE LAW TO COMBAT**
17 **FRAUD AND ABUSE.**

18 (a) IN GENERAL.—Part 5 of subtitle B of title I of
19 the Employee Retirement Income Security Act of 1974
20 (29 U.S.C. 1131 et seq.), as amended by section 521, is
21 further amended by adding at the end the following:

22 **“SEC. 520. APPLICABILITY OF STATE LAW TO COMBAT**
23 **FRAUD AND ABUSE.**

24 “The Secretary may, for the purpose of identifying,
25 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.”.

1 **Subtitle G—Enabling the Depart-**
2 **ment of Labor to Issue Adminis-**
3 **trative Summary Cease and De-**
4 **sist Orders and Summary Sei-**
5 **zures Orders Against Plans That**
6 **Are in Financially Hazardous**
7 **Condition**

8 **SEC. 561. ENABLING THE DEPARTMENT OF LABOR TO**
9 **ISSUE ADMINISTRATIVE SUMMARY CEASE**
10 **AND DESIST ORDERS AND SUMMARY SEI-**
11 **ZURES ORDERS AGAINST PLANS THAT ARE IN**
12 **FINANCIALLY HAZARDOUS CONDITION.**

13 (a) IN GENERAL.—Part 5 of subtitle B of title I of
14 the Employee Retirement Income Security Act of 1974
15 (29 U.S.C. 1131 et seq.), as amended by section 551, is
16 further amended by adding at the end the following:

17 **“SEC. 521. ADMINISTRATIVE SUMMARY CEASE AND DESIST**
18 **ORDERS AND SUMMARY SEIZURE ORDERS**
19 **AGAINST MULTIPLE EMPLOYER WELFARE**
20 **ARRANGEMENTS IN FINANCIALLY HAZ-**
21 **ARDOUS CONDITION.**

22 “(a) IN GENERAL.—The Secretary may issue a cease
23 and desist (ex parte) order under this title if it appears
24 to the Secretary that the alleged conduct of a multiple em-
25 ployer welfare arrangement described in section 3(40),

1 other than a plan or arrangement described in subsection
2 (g), is fraudulent, or creates an immediate danger to the
3 public safety or welfare, or is causing or can be reasonably
4 expected to cause significant, imminent, and irreparable
5 public injury.

6 “(b) HEARING.—A person that is adversely affected
7 by the issuance of a cease and desist order under sub-
8 section (a) may request a hearing by the Secretary regard-
9 ing such order. The Secretary may require that a pro-
10 ceeding under this section, including all related informa-
11 tion and evidence, be conducted in a confidential manner.

12 “(c) BURDEN OF PROOF.—The burden of proof in
13 any hearing conducted under subsection (b) shall be on
14 the party requesting the hearing to show cause why the
15 cease and desist order should be set aside.

16 “(d) DETERMINATION.—Based upon the evidence
17 presented at a hearing under subsection (b), the cease and
18 desist order involved may be affirmed, modified, or set
19 aside by the Secretary in whole or in part.

20 “(e) SEIZURE.—The Secretary may issue a summary
21 seizure order under this title if it appears that a multiple
22 employer welfare arrangement is in a financially haz-
23 ardous condition.

1 “(f) REGULATIONS.—The Secretary may promulgate
2 such regulations or other guidance as may be necessary
3 or appropriate to carry out this section.

4 “(g) EXCEPTION.—This section shall not apply to
5 any plan or arrangement that does not fall within the
6 meaning of the term ‘multiple employer welfare arrange-
7 ment’ under section 3(40(A)).”.

8 (b) CONFORMING AMENDMENT.—The table of sec-
9 tions for part 5 of subtitle B of title I of the Employee
10 Retirement Income Security Act of 1974, as amended by
11 section 551, is further amended by adding at the end the
12 following:

“Sec. 521. Administrative summary cease and desist orders and summary sei-
zure orders against health plans in financially hazardous condi-
tion.”.

13 **Subtitle H—Requiring Multiple**
14 **Employer Welfare Arrangement**
15 **(MEWA) Plans to File a Reg-**
16 **istration Form With the Depart-**
17 **ment of Labor Prior to Enroll-**
18 **ing Anyone in the Plan**

19 **SEC. 571. MEWA PLAN REGISTRATION WITH DEPARTMENT**
20 **OF LABOR.**

21 Section 101(g) of the Employee Retirement Income
22 Security Act of 1974 (29 U.S.C. 1021(g)) is amended—

23 (1) by striking “Secretary may” and inserting
24 “Secretary shall”; and

1 (2) by inserting “to register with the Secretary
2 prior to operating in a State and may, by regulation,
3 require such multiple employer welfare arrange-
4 ments” after “not group health plans”.

5 **Subtitle I—Permitting Evidentiary**
6 **Privilege and Confidential Com-**
7 **munications**

8 **SEC. 581. PERMITTING EVIDENTIARY PRIVILEGE AND CON-**
9 **FIDENTIAL COMMUNICATIONS.**

10 Section 504 of the Employee Retirement Income Se-
11 curity Act of 1974 (29 U.S.C. 1134) is amended by adding
12 at the end the following:

13 “(d) The Secretary may promulgate a regulation that
14 provides an evidentiary privilege for, and provides for the
15 confidentiality of communications between or among, any
16 of the following entities or their agents, consultants, or
17 employees:

18 “(1) A State insurance department.

19 “(2) A State attorney general.

20 “(3) The National Association of Insurance
21 Commissioners.

22 “(4) The Department of Labor.

23 “(5) The Department of the Treasury.

24 “(6) The Department of Justice.

1 “(7) The Department of Health and Human
2 Services.

3 “(8) Any other Federal or State authority that
4 the Secretary determines is appropriate for the pur-
5 poses of enforcing the provisions of this title.

6 “(e) The privilege established under subsection (d)
7 shall apply to communications related to any investigation,
8 audit, examination, or inquiry conducted or coordinated
9 by any of the agencies. A communication that is privileged
10 under subsection (d) shall not waive any privilege other-
11 wise available to the communicating agency or to any per-
12 son who provided the information that is communicated.”.

13 **TITLE VI—IMPROVING ACCESS**
14 **TO INNOVATIVE MEDICAL**
15 **THERAPIES**

16 **Subtitle A—Biologics Price**
17 **Competition and Innovation**

18 **SEC. 601. SHORT TITLE.**

19 (a) IN GENERAL.—This subtitle may be cited as the
20 “Biologics Price Competition and Innovation Act of
21 2009”.

22 (b) SENSE OF THE SENATE.—It is the sense of the
23 Senate that a biosimilars pathway balancing innovation
24 and consumer interests should be established.

1 **SEC. 602. APPROVAL PATHWAY FOR BIOSIMILAR BIOLOGI-**
2 **CAL PRODUCTS.**

3 (a) LICENSURE OF BIOLOGICAL PRODUCTS AS BIO-
4 SIMILAR OR INTERCHANGEABLE.—Section 351 of the
5 Public Health Service Act (42 U.S.C. 262) is amended—

6 (1) in subsection (a)(1)(A), by inserting “under
7 this subsection or subsection (k)” after “biologics li-
8 cense”; and

9 (2) by adding at the end the following:

10 “(k) LICENSURE OF BIOLOGICAL PRODUCTS AS BIO-
11 SIMILAR OR INTERCHANGEABLE.—

12 “(1) IN GENERAL.—Any person may submit an
13 application for licensure of a biological product
14 under this subsection.

15 “(2) CONTENT.—

16 “(A) IN GENERAL.—

17 “(i) REQUIRED INFORMATION.—An
18 application submitted under this subsection
19 shall include information demonstrating
20 that—

21 “(I) the biological product is bio-
22 similar to a reference product based
23 upon data derived from—

24 “(aa) analytical studies that
25 demonstrate that the biological
26 product is highly similar to the

1 reference product notwith-
2 standing minor differences in
3 clinically inactive components;

4 “(bb) animal studies (includ-
5 ing the assessment of toxicity);
6 and

7 “(cc) a clinical study or
8 studies (including the assessment
9 of immunogenicity and phar-
10 macokinetics or
11 pharmacodynamics) that are suf-
12 ficient to demonstrate safety, pu-
13 rity, and potency in 1 or more
14 appropriate conditions of use for
15 which the reference product is li-
16 censed and intended to be used
17 and for which licensure is sought
18 for the biological product;

19 “(II) the biological product and
20 reference product utilize the same
21 mechanism or mechanisms of action
22 for the condition or conditions of use
23 prescribed, recommended, or sug-
24 gested in the proposed labeling, but
25 only to the extent the mechanism or

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1 mechanisms of action are known for
2 the reference product;

3 “(III) the condition or conditions
4 of use prescribed, recommended, or
5 suggested in the labeling proposed for
6 the biological product have been pre-
7 viously approved for the reference
8 product;

9 “(IV) the route of administra-
10 tion, the dosage form, and the
11 strength of the biological product are
12 the same as those of the reference
13 product; and

14 “(V) the facility in which the bio-
15 logical product is manufactured, proc-
16 essed, packed, or held meets stand-
17 ards designed to assure that the bio-
18 logical product continues to be safe,
19 pure, and potent.

20 “(ii) DETERMINATION BY SEC-
21 RETARY.—The Secretary may determine,
22 in the Secretary’s discretion, that an ele-
23 ment described in clause (i)(I) is unneces-
24 sary in an application submitted under this
25 subsection.

1 “(iii) ADDITIONAL INFORMATION.—

2 An application submitted under this sub-
3 section—

4 “(I) shall include publicly-avail-
5 able information regarding the Sec-
6 retary’s previous determination that
7 the reference product is safe, pure,
8 and potent; and

9 “(II) may include any additional
10 information in support of the applica-
11 tion, including publicly-available infor-
12 mation with respect to the reference
13 product or another biological product.

14 “(B) INTERCHANGEABILITY.—An applica-
15 tion (or a supplement to an application) sub-
16 mitted under this subsection may include infor-
17 mation demonstrating that the biological prod-
18 uct meets the standards described in paragraph
19 (4).

20 “(3) EVALUATION BY SECRETARY.—Upon re-
21 view of an application (or a supplement to an appli-
22 cation) submitted under this subsection, the Sec-
23 retary shall license the biological product under this
24 subsection if—

1 “(A) the Secretary determines that the in-
2 formation submitted in the application (or the
3 supplement) is sufficient to show that the bio-
4 logical product—

5 “(i) is biosimilar to the reference
6 product; or

7 “(ii) meets the standards described in
8 paragraph (4), and therefore is inter-
9 changeable with the reference product; and

10 “(B) the applicant (or other appropriate
11 person) consents to the inspection of the facility
12 that is the subject of the application, in accord-
13 ance with subsection (c).

14 “(4) SAFETY STANDARDS FOR DETERMINING
15 INTERCHANGEABILITY.—Upon review of an applica-
16 tion submitted under this subsection or any supple-
17 ment to such application, the Secretary shall deter-
18 mine the biological product to be interchangeable
19 with the reference product if the Secretary deter-
20 mines that the information submitted in the applica-
21 tion (or a supplement to such application) is suffi-
22 cient to show that—

23 “(A) the biological product—

24 “(i) is biosimilar to the reference
25 product; and

1 “(ii) can be expected to produce the
2 same clinical result as the reference prod-
3 uct in any given patient; and

4 “(B) for a biological product that is ad-
5 ministered more than once to an individual, the
6 risk in terms of safety or diminished efficacy of
7 alternating or switching between use of the bio-
8 logical product and the reference product is not
9 greater than the risk of using the reference
10 product without such alternation or switch.

11 “(5) GENERAL RULES.—

12 “(A) ONE REFERENCE PRODUCT PER AP-
13 PPLICATION.—A biological product, in an appli-
14 cation submitted under this subsection, may not
15 be evaluated against more than 1 reference
16 product.

17 “(B) REVIEW.—An application submitted
18 under this subsection shall be reviewed by the
19 division within the Food and Drug Administra-
20 tion that is responsible for the review and ap-
21 proval of the application under which the ref-
22 erence product is licensed.

23 “(C) RISK EVALUATION AND MITIGATION
24 STRATEGIES.—The authority of the Secretary
25 with respect to risk evaluation and mitigation

1 strategies under the Federal Food, Drug, and
2 Cosmetic Act shall apply to biological products
3 licensed under this subsection in the same man-
4 ner as such authority applies to biological prod-
5 ucts licensed under subsection (a).

6 “(6) EXCLUSIVITY FOR FIRST INTERCHANGE-
7 ABLE BIOLOGICAL PRODUCT.—Upon review of an
8 application submitted under this subsection relying
9 on the same reference product for which a prior bio-
10 logical product has received a determination of inter-
11 changeability for any condition of use, the Secretary
12 shall not make a determination under paragraph (4)
13 that the second or subsequent biological product is
14 interchangeable for any condition of use until the
15 earlier of—

16 “(A) 1 year after the first commercial
17 marketing of the first interchangeable bio-
18 similar biological product to be approved as
19 interchangeable for that reference product;

20 “(B) 18 months after—

21 “(i) a final court decision on all pat-
22 ents in suit in an action instituted under
23 subsection (l)(6) against the applicant that
24 submitted the application for the first ap-

1 proved interchangeable biosimilar biological
2 product; or

3 “(ii) the dismissal with or without
4 prejudice of an action instituted under sub-
5 section (l)(6) against the applicant that
6 submitted the application for the first ap-
7 proved interchangeable biosimilar biological
8 product; or

9 “(C)(i) 42 months after approval of the
10 first interchangeable biosimilar biological prod-
11 uct if the applicant that submitted such appli-
12 cation has been sued under subsection (l)(6)
13 and such litigation is still ongoing within such
14 42-month period; or

15 “(ii) 18 months after approval of the first
16 interchangeable biosimilar biological product if
17 the applicant that submitted such application
18 has not been sued under subsection (l)(6).

19 For purposes of this paragraph, the term ‘final court
20 decision’ means a final decision of a court from
21 which no appeal (other than a petition to the United
22 States Supreme Court for a writ of certiorari) has
23 been or can be taken.

24 “(7) EXCLUSIVITY FOR REFERENCE PROD-
25 UCT.—

“(A) EFFECTIVE DATE OF BIOSIMILAR AP-
PLICATION APPROVAL.—Approval of an applica-
tion under this subsection may not be made ef-
fective by the Secretary until the date that is
12 years after the date on which the reference
product was first licensed under subsection (a).

1 dosing schedule, dosage form, delivery
2 system, delivery device, or strength; or
3 “(II) a modification to the struc-
4 ture of the biological product that
5 does not result in a change in safety,
6 purity, or potency.

7 “(8) GUIDANCE DOCUMENTS.—

8 “(A) IN GENERAL.—The Secretary may,
9 after opportunity for public comment, issue
10 guidance in accordance, except as provided in
11 subparagraph (B)(i), with section 701(h) of the
12 Federal Food, Drug, and Cosmetic Act with re-
13 spect to the licensure of a biological product
14 under this subsection. Any such guidance may
15 be general or specific.

16 “(B) PUBLIC COMMENT.—

17 “(i) IN GENERAL.—The Secretary
18 shall provide the public an opportunity to
19 comment on any proposed guidance issued
20 under subparagraph (A) before issuing
21 final guidance.

22 “(ii) INPUT REGARDING MOST VALU-
23 ABLE GUIDANCE.—The Secretary shall es-
24 tablish a process through which the public

1 may provide the Secretary with input re-
2 garding priorities for issuing guidance.

3 “(C) NO REQUIREMENT FOR APPLICATION
4 CONSIDERATION.—The issuance (or non-
5 issuance) of guidance under subparagraph (A)
6 shall not preclude the review of, or action on,
7 an application submitted under this subsection.

8 “(D) REQUIREMENT FOR PRODUCT CLASS-
9 SPECIFIC GUIDANCE.—If the Secretary issues
10 product class-specific guidance under subpara-
11 graph (A), such guidance shall include a de-
12 scription of—

13 “(i) the criteria that the Secretary will
14 use to determine whether a biological prod-
15 uct is highly similar to a reference product
16 in such product class; and

17 “(ii) the criteria, if available, that the
18 Secretary will use to determine whether a
19 biological product meets the standards de-
20 scribed in paragraph (4).

21 “(E) CERTAIN PRODUCT CLASSES.—

22 “(i) GUIDANCE.—The Secretary may
23 indicate in a guidance document that the
24 science and experience, as of the date of
25 such guidance, with respect to a product or

1 product class (not including any recom-
2 binant protein) does not allow approval of
3 an application for a license as provided
4 under this subsection for such product or
5 product class.

6 “(ii) MODIFICATION OR REVERSAL.—
7 The Secretary may issue a subsequent
8 guidance document under subparagraph
9 (A) to modify or reverse a guidance docu-
10 ment under clause (i).

11 “(iii) NO EFFECT ON ABILITY TO
12 DENY LICENSE.—Clause (i) shall not be
13 construed to require the Secretary to ap-
14 prove a product with respect to which the
15 Secretary has not indicated in a guidance
16 document that the science and experience,
17 as described in clause (i), does not allow
18 approval of such an application.

19 “(l) PATENTS.—

20 “(1) CONFIDENTIAL ACCESS TO SUBSECTION
21 (k) APPLICATION.—

22 “(A) APPLICATION OF PARAGRAPH.—Un-
23 less otherwise agreed to by a person that sub-
24 mits an application under subsection (k) (re-
25 ferred to in this subsection as the ‘subsection

1 (k) applicant’) and the sponsor of the applica-
2 tion for the reference product (referred to in
3 this subsection as the ‘reference product spon-
4 sor’), the provisions of this paragraph shall
5 apply to the exchange of information described
6 in this subsection.

7 “(B) IN GENERAL.—

8 “(i) PROVISION OF CONFIDENTIAL IN-
9 FORMATION.—When a subsection (k) ap-
10 plicant submits an application under sub-
11 section (k), such applicant shall provide to
12 the persons described in clause (ii), subject
13 to the terms of this paragraph, confidential
14 access to the information required to be
15 produced pursuant to paragraph (2) and
16 any other information that the subsection
17 (k) applicant determines, in its sole discre-
18 tion, to be appropriate (referred to in this
19 subsection as the ‘confidential informa-
20 tion’).

21 “(ii) RECIPIENTS OF INFORMATION.—

22 The persons described in this clause are
23 the following:

24 “(I) OUTSIDE COUNSEL.—One or
25 more attorneys designated by the ref-

1 erence product sponsor who are em-
2 ployees of an entity other than the
3 reference product sponsor (referred to
4 in this paragraph as the ‘outside
5 counsel’), provided that such attor-
6 neys do not engage, formally or infor-
7 mally, in patent prosecution relevant
8 or related to the reference product.

9 “(II) IN-HOUSE COUNSEL.—One
10 attorney that represents the reference
11 product sponsor who is an employee
12 of the reference product sponsor, pro-
13 vided that such attorney does not en-
14 gage, formally or informally, in patent
15 prosecution relevant or related to the
16 reference product.

17 “(iii) PATENT OWNER ACCESS.—A
18 representative of the owner of a patent ex-
19 clusively licensed to a reference product
20 sponsor with respect to the reference prod-
21 uct and who has retained a right to assert
22 the patent or participate in litigation con-
23 cerning the patent may be provided the
24 confidential information, provided that the
25 representative informs the reference prod-

1 uct sponsor and the subsection (k) appli-
2 cant of his or her agreement to be subject
3 to the confidentiality provisions set forth in
4 this paragraph, including those under
5 clause (ii).

6 “(C) LIMITATION ON DISCLOSURE.—No
7 person that receives confidential information
8 pursuant to subparagraph (B) shall disclose
9 any confidential information to any other per-
10 son or entity, including the reference product
11 sponsor employees, outside scientific consult-
12 ants, or other outside counsel retained by the
13 reference product sponsor, without the prior
14 written consent of the subsection (k) applicant,
15 which shall not be unreasonably withheld.

16 “(D) USE OF CONFIDENTIAL INFORMA-
17 TION.—Confidential information shall be used
18 for the sole and exclusive purpose of deter-
19 mining, with respect to each patent assigned to
20 or exclusively licensed by the reference product
21 sponsor, whether a claim of patent infringement
22 could reasonably be asserted if the subsection
23 (k) applicant engaged in the manufacture, use,
24 offering for sale, sale, or importation into the
25 United States of the biological product that is

1 the subject of the application under subsection
2 (k).

3 “(E) OWNERSHIP OF CONFIDENTIAL IN-
4 FORMATION.—The confidential information dis-
5 closed under this paragraph is, and shall re-
6 main, the property of the subsection (k) appli-
7 cant. By providing the confidential information
8 pursuant to this paragraph, the subsection (k)
9 applicant does not provide the reference product
10 sponsor or the outside counsel any interest in or
11 license to use the confidential information, for
12 purposes other than those specified in subpara-
13 graph (D).

14 “(F) EFFECT OF INFRINGEMENT AC-
15 TION.—In the event that the reference product
16 sponsor files a patent infringement suit, the use
17 of confidential information shall continue to be
18 governed by the terms of this paragraph until
19 such time as a court enters a protective order
20 regarding the information. Upon entry of such
21 order, the subsection (k) applicant may redesign-
22 nate confidential information in accordance
23 with the terms of that order. No confidential in-
24 formation shall be included in any publicly-
25 available complaint or other pleading. In the

1 event that the reference product sponsor does
2 not file an infringement action by the date spec-
3 ified in paragraph (6), the reference product
4 sponsor shall return or destroy all confidential
5 information received under this paragraph, pro-
6 vided that if the reference product sponsor opts
7 to destroy such information, it will confirm de-
8 struction in writing to the subsection (k) appli-
9 cant.

10 “(G) RULE OF CONSTRUCTION.—Nothing
11 in this paragraph shall be construed—

12 “(i) as an admission by the subsection
13 (k) applicant regarding the validity, en-
14 forceability, or infringement of any patent;
15 or

16 “(ii) as an agreement or admission by
17 the subsection (k) applicant with respect to
18 the competency, relevance, or materiality
19 of any confidential information.

20 “(H) EFFECT OF VIOLATION.—The disclo-
21 sure of any confidential information in violation
22 of this paragraph shall be deemed to cause the
23 subsection (k) applicant to suffer irreparable
24 harm for which there is no adequate legal rem-
25 edy and the court shall consider immediate in-

1 junctive relief to be an appropriate and nec-
2 essary remedy for any violation or threatened
3 violation of this paragraph.

4 “(2) SUBSECTION (k) APPLICATION INFORMA-
5 TION.—Not later than 20 days after the Secretary
6 notifies the subsection (k) applicant that the applica-
7 tion has been accepted for review, the subsection (k)
8 applicant—

9 “(A) shall provide to the reference product
10 sponsor a copy of the application submitted to
11 the Secretary under subsection (k), and such
12 other information that describes the process or
13 processes used to manufacture the biological
14 product that is the subject of such application;
15 and

16 “(B) may provide to the reference product
17 sponsor additional information requested by or
18 on behalf of the reference product sponsor.

19 “(3) LIST AND DESCRIPTION OF PATENTS.—

20 “(A) LIST BY REFERENCE PRODUCT SPON-
21 SOR.—Not later than 60 days after the receipt
22 of the application and information under para-
23 graph (2), the reference product sponsor shall
24 provide to the subsection (k) applicant—

1 “(i) a list of patents for which the ref-
2 erence product sponsor believes a claim of
3 patent infringement could reasonably be
4 asserted by the reference product sponsor,
5 or by a patent owner that has granted an
6 exclusive license to the reference product
7 sponsor with respect to the reference prod-
8 uct, if a person not licensed by the ref-
9 erence product sponsor engaged in the
10 making, using, offering to sell, selling, or
11 importing into the United States of the bi-
12 ological product that is the subject of the
13 subsection (k) application; and

14 “(ii) an identification of the patents
15 on such list that the reference product
16 sponsor would be prepared to license to the
17 subsection (k) applicant.

18 “(B) LIST AND DESCRIPTION BY SUB-
19 SECTION (k) APPLICANT.—Not later than 60
20 days after receipt of the list under subpara-
21 graph (A), the subsection (k) applicant—

22 “(i) may provide to the reference
23 product sponsor a list of patents to which
24 the subsection (k) applicant believes a
25 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

1 biological product before the date that
2 such patent expires; and

3 “(iii) shall provide to the reference
4 product sponsor a response regarding each
5 patent identified by the reference product
6 sponsor under subparagraph (A)(ii).

7 “(C) DESCRIPTION BY REFERENCE PROD-
8 UCT SPONSOR.—Not later than 60 days after
9 receipt of the list and statement under subpara-
10 graph (B), the reference product sponsor shall
11 provide to the subsection (k) applicant a de-
12 tailed statement that describes, with respect to
13 each patent described in subparagraph
14 (B)(ii)(I), on a claim by claim basis, the factual
15 and legal basis of the opinion of the reference
16 product sponsor that such patent will be in-
17 fringed by the commercial marketing of the bio-
18 logical product that is the subject of the sub-
19 section (k) application and a response to the
20 statement concerning validity and enforceability
21 provided under subparagraph (B)(ii)(I).

22 “(4) PATENT RESOLUTION NEGOTIATIONS.—

23 “(A) IN GENERAL.—After receipt by the
24 subsection (k) applicant of the statement under
25 paragraph (3)(C), the reference product spon-

1 sor and the subsection (k) applicant shall en-
2 gage in good faith negotiations to agree on
3 which, if any, patents listed under paragraph
4 (3) by the subsection (k) applicant or the ref-
5 erence product sponsor shall be the subject of
6 an action for patent infringement under para-
7 graph (6).

8 “(B) FAILURE TO REACH AGREEMENT.—
9 If, within 15 days of beginning negotiations
10 under subparagraph (A), the subsection (k) ap-
11 plicant and the reference product sponsor fail to
12 agree on a final and complete list of which, if
13 any, patents listed under paragraph (3) by the
14 subsection (k) applicant or the reference prod-
15 uct sponsor shall be the subject of an action for
16 patent infringement under paragraph (6), the
17 provisions of paragraph (5) shall apply to the
18 parties.

19 “(5) PATENT RESOLUTION IF NO AGREE-
20 MENT.—

21 “(A) NUMBER OF PATENTS.—The sub-
22 section (k) applicant shall notify the reference
23 product sponsor of the number of patents that
24 such applicant will provide to the reference
25 product sponsor under subparagraph (B)(i)(I).

1 “(B) EXCHANGE OF PATENT LISTS.—

2 “(i) IN GENERAL.—On a date agreed
3 to by the subsection (k) applicant and the
4 reference product sponsor, but in no case
5 later than 5 days after the subsection (k)
6 applicant notifies the reference product
7 sponsor under subparagraph (A), the sub-
8 section (k) applicant and the reference
9 product sponsor shall simultaneously ex-
10 change—

11 “(I) the list of patents that the
12 subsection (k) applicant believes
13 should be the subject of an action for
14 patent infringement under paragraph
15 (6); and

16 “(II) the list of patents, in ac-
17 cordance with clause (ii), that the ref-
18 erence product sponsor believes should
19 be the subject of an action for patent
20 infringement under paragraph (6).

21 “(ii) NUMBER OF PATENTS LISTED BY
22 REFERENCE PRODUCT SPONSOR.—

23 “(I) IN GENERAL.—Subject to
24 subclause (II), the number of patents
25 listed by the reference product spon-

1 sor under clause (i)(II) may not ex-
2 ceed the number of patents listed by
3 the subsection (k) applicant under
4 clause (i)(I).

5 “(II) EXCEPTION.—If a sub-
6 section (k) applicant does not list any
7 patent under clause (i)(I), the ref-
8 erence product sponsor may list 1 pat-
9 ent under clause (i)(II).

10 “(6) IMMEDIATE PATENT INFRINGEMENT AC-
11 TION.—

12 “(A) ACTION IF AGREEMENT ON PATENT
13 LIST.—If the subsection (k) applicant and the
14 reference product sponsor agree on patents as
15 described in paragraph (4), not later than 30
16 days after such agreement, the reference prod-
17 uct sponsor shall bring an action for patent in-
18 fringement with respect to each such patent.

19 “(B) ACTION IF NO AGREEMENT ON PAT-
20 ENT LIST.—If the provisions of paragraph (5)
21 apply to the parties as described in paragraph
22 (4)(B), not later than 30 days after the ex-
23 change of lists under paragraph (5)(B), the ref-
24 erence product sponsor shall bring an action for

1 patent infringement with respect to each patent
2 that is included on such lists.

3 “(C) NOTIFICATION AND PUBLICATION OF
4 COMPLAINT.—

5 “(i) NOTIFICATION TO SECRETARY.—

6 Not later than 30 days after a complaint
7 is served to a subsection (k) applicant in
8 an action for patent infringement described
9 under this paragraph, the subsection (k)
10 applicant shall provide the Secretary with
11 notice and a copy of such complaint.

12 “(ii) PUBLICATION BY SECRETARY.—

13 The Secretary shall publish in the Federal
14 Register notice of a complaint received
15 under clause (i).

16 “(7) NEWLY ISSUED OR LICENSED PATENTS.—

17 In the case of a patent that—

18 “(A) is issued to, or exclusively licensed by,
19 the reference product sponsor after the date
20 that the reference product sponsor provided the
21 list to the subsection (k) applicant under para-
22 graph (3)(A); and

23 “(B) the reference product sponsor reason-
24 ably believes that, due to the issuance of such
25 patent, a claim of patent infringement could

1 reasonably be asserted by the reference product
2 sponsor if a person not licensed by the ref-
3 erence product sponsor engaged in the making,
4 using, offering to sell, selling, or importing into
5 the United States of the biological product that
6 is the subject of the subsection (k) application,
7 not later than 30 days after such issuance or licens-
8 ing, the reference product sponsor shall provide to
9 the subsection (k) applicant a supplement to the list
10 provided by the reference product sponsor under
11 paragraph (3)(A) that includes such patent, not
12 later than 30 days after such supplement is pro-
13 vided, the subsection (k) applicant shall provide a
14 statement to the reference product sponsor in ac-
15 cordance with paragraph (3)(B), and such patent
16 shall be subject to paragraph (8).

17 “(8) NOTICE OF COMMERCIAL MARKETING AND
18 PRELIMINARY INJUNCTION.—

19 “(A) NOTICE OF COMMERCIAL MAR-
20 KETING.—The subsection (k) applicant shall
21 provide notice to the reference product sponsor
22 not later than 180 days before the date of the
23 first commercial marketing of the biological
24 product licensed under subsection (k).

1 “(B) PRELIMINARY INJUNCTION.—After
2 receiving the notice under subparagraph (A)
3 and before such date of the first commercial
4 marketing of such biological product, the ref-
5 erence product sponsor may seek a preliminary
6 injunction prohibiting the subsection (k) appli-
7 cant from engaging in the commercial manufac-
8 ture or sale of such biological product until the
9 court decides the issue of patent validity, en-
10 forcement, and infringement with respect to any
11 patent that is—

12 “(i) included in the list provided by
13 the reference product sponsor under para-
14 graph (3)(A) or in the list provided by the
15 subsection (k) applicant under paragraph
16 (3)(B); and

17 “(ii) not included, as applicable, on—

18 “(I) the list of patents described
19 in paragraph (4); or

20 “(II) the lists of patents de-
21 scribed in paragraph (5)(B).

22 “(C) REASONABLE COOPERATION.—If the
23 reference product sponsor has sought a prelimi-
24 nary injunction under subparagraph (B), the
25 reference product sponsor and the subsection

1 (k) applicant shall reasonably cooperate to ex-
2 pedite such further discovery as is needed in
3 connection with the preliminary injunction mo-
4 tion.

5 “(9) LIMITATION ON DECLARATORY JUDGMENT
6 ACTION.—

7 “(A) SUBSECTION (k) APPLICATION PRO-
8 VIDED.—If a subsection (k) applicant provides
9 the application and information required under
10 paragraph (2)(A), neither the reference product
11 sponsor nor the subsection (k) applicant may,
12 prior to the date notice is received under para-
13 graph (8)(A), bring any action under section
14 2201 of title 28, United States Code, for a dec-
15 laration of infringement, validity, or enforce-
16 ability of any patent that is described in clauses
17 (i) and (ii) of paragraph (8)(B).

18 “(B) SUBSEQUENT FAILURE TO ACT BY
19 SUBSECTION (k) APPLICANT.—If a subsection
20 (k) applicant fails to complete an action re-
21 quired of the subsection (k) applicant under
22 paragraph (3)(B)(ii), paragraph (5), paragraph
23 (6)(C)(i), paragraph (7), or paragraph (8)(A),
24 the reference product sponsor, but not the sub-
25 section (k) applicant, may bring an action

1 under section 2201 of title 28, United States
2 Code, for a declaration of infringement, validity,
3 or enforceability of any patent included in the
4 list described in paragraph (3)(A), including as
5 provided under paragraph (7).

6 “(C) SUBSECTION (k) APPLICATION NOT
7 PROVIDED.—If a subsection (k) applicant fails
8 to provide the application and information re-
9 quired under paragraph (2)(A), the reference
10 product sponsor, but not the subsection (k) ap-
11 plicant, may bring an action under section 2201
12 of title 28, United States Code, for a declara-
13 tion of infringement, validity, or enforceability
14 of any patent that claims the biological product
15 or a use of the biological product.”.

16 (b) DEFINITIONS.—Section 351(i) of the Public
17 Health Service Act (42 U.S.C. 262(i)) is amended—

18 (1) by striking “In this section, the term ‘bio-
19 logical product’ means” and inserting the following:
20 “In this section:

21 “(1) The term ‘biological product’ means”;

22 (2) in paragraph (1), as so designated, by in-
23 serting “protein (except any chemically synthesized
24 polypeptide),” after “allergenic product,”; and

25 (3) by adding at the end the following:

1 “(2) The term ‘biosimilar’ or ‘biosimilarity’, in
2 reference to a biological product that is the subject
3 of an application under subsection (k), means—

4 “(A) that the biological product is highly
5 similar to the reference product notwith-
6 standing minor differences in clinically inactive
7 components; and

8 “(B) there are no clinically meaningful dif-
9 ferences between the biological product and the
10 reference product in terms of the safety, purity,
11 and potency of the product.

12 “(3) The term ‘interchangeable’ or ‘inter-
13 changeability’, in reference to a biological product
14 that is shown to meet the standards described in
15 subsection (k)(4), means that the biological product
16 may be substituted for the reference product without
17 the intervention of the health care provider who pre-
18 scribed the reference product.

19 “(4) The term ‘reference product’ means the
20 single biological product licensed under subsection
21 (a) against which a biological product is evaluated in
22 an application submitted under subsection (k).”.

23 (c) CONFORMING AMENDMENTS RELATING TO PAT-
24 ENTS.—

1 (1) PATENTS.—Section 271(e) of title 35,
2 United States Code, is amended—

3 (A) in paragraph (2)—

4 (i) in subparagraph (A), by striking
5 “or” at the end;

6 (ii) in subparagraph (B), by adding
7 “or” at the end; and

8 (iii) by inserting after subparagraph
9 (B) the following:

10 “(C)(i) with respect to a patent that is identi-
11 fied in the list of patents described in section
12 351(l)(3) of the Public Health Service Act (including
13 as provided under section 351(l)(7) of such Act), an
14 application seeking approval of a biological product,
15 or

16 “(ii) if the applicant for the application fails to
17 provide the application and information required
18 under section 351(l)(2)(A) of such Act, an applica-
19 tion seeking approval of a biological product for a
20 patent that could be identified pursuant to section
21 351(l)(3)(A)(i) of such Act,”; and

22 (iv) in the matter following subpara-
23 graph (C) (as added by clause (iii)), by
24 striking “or veterinary biological product”

1 and inserting “, veterinary biological prod-
2 uct, or biological product”;

3 (B) in paragraph (4)—

4 (i) in subparagraph (B), by—

5 (I) striking “or veterinary bio-
6 logical product” and inserting “, vet-
7 erinary biological product, or biologi-
8 cal product”; and

9 (II) striking “and” at the end;

10 (ii) in subparagraph (C), by—

11 (I) striking “or veterinary bio-
12 logical product” and inserting “, vet-
13 erinary biological product, or biologi-
14 cal product”; and

15 (II) striking the period and in-
16 serting “, and”;

17 (iii) by inserting after subparagraph
18 (C) the following:

19 “(D) the court shall order a permanent injunc-
20 tion prohibiting any infringement of the patent by
21 the biological product involved in the infringement
22 until a date which is not earlier than the date of the
23 expiration of the patent that has been infringed
24 under paragraph (2)(C), provided the patent is the
25 subject of a final court decision, as defined in sec-

1 tion 351(k)(6) of the Public Health Service Act, in
2 an action for infringement of the patent under sec-
3 tion 351(l)(6) of such Act, and the biological prod-
4 uct has not yet been approved because of section
5 351(k)(7) of such Act.”; and

6 (iv) in the matter following subpara-
7 graph (D) (as added by clause (iii)), by
8 striking “and (C)” and inserting “(C), and
9 (D)”;

10 (C) by adding at the end the following:

11 “(6)(A) Subparagraph (B) applies, in lieu of para-
12 graph (4), in the case of a patent—

13 “(i) that is identified, as applicable, in the list
14 of patents described in section 351(l)(4) of the Pub-
15 lic Health Service Act or the lists of patents de-
16 scribed in section 351(l)(5)(B) of such Act with re-
17 spect to a biological product; and

18 “(ii) for which an action for infringement of the
19 patent with respect to the biological product—

20 “(I) was brought after the expiration of
21 the 30-day period described in subparagraph
22 (A) or (B), as applicable, of section 351(l)(6) of
23 such Act; or

24 “(II) was brought before the expiration of
25 the 30-day period described in subclause (I),

1 but which was dismissed without prejudice or
2 was not prosecuted to judgment in good faith.

3 “(B) In an action for infringement of a patent de-
4 scribed in subparagraph (A), the sole and exclusive remedy
5 that may be granted by a court, upon a finding that the
6 making, using, offering to sell, selling, or importation into
7 the United States of the biological product that is the sub-
8 ject of the action infringed the patent, shall be a reason-
9 able royalty.

10 “(C) The owner of a patent that should have been
11 included in the list described in section 351(l)(3)(A) of
12 the Public Health Service Act, including as provided under
13 section 351(l)(7) of such Act for a biological product, but
14 was not timely included in such list, may not bring an
15 action under this section for infringement of the patent
16 with respect to the biological product.”.

17 (2) CONFORMING AMENDMENT UNDER TITLE
18 28.—Section 2201(b) of title 28, United States
19 Code, is amended by inserting before the period the
20 following: “, or section 351 of the Public Health
21 Service Act”.

22 (d) CONFORMING AMENDMENTS UNDER THE FED-
23 ERAL FOOD, DRUG, AND COSMETIC ACT.—

24 (1) CONTENT AND REVIEW OF APPLICA-
25 TIONS.—Section 505(b)(5)(B) of the Federal Food,

1 Drug, and Cosmetic Act (21 U.S.C. 355(b)(5)(B)) is
2 amended by inserting before the period at the end
3 of the first sentence the following: “or, with respect
4 to an applicant for approval of a biological product
5 under section 351(k) of the Public Health Service
6 Act, any necessary clinical study or studies”.

7 (2) NEW ACTIVE INGREDIENT.—Section 505B
8 of the Federal Food, Drug, and Cosmetic Act (21
9 U.S.C. 355c) is amended by adding at the end the
10 following:

11 “(n) NEW ACTIVE INGREDIENT.—

12 “(1) NON-INTERCHANGEABLE BIOSIMILAR BIO-
13 LOGICAL PRODUCT.—A biological product that is
14 biosimilar to a reference product under section 351
15 of the Public Health Service Act, and that the Sec-
16 retary has not determined to meet the standards de-
17 scribed in subsection (k)(4) of such section for inter-
18 changeability with the reference product, shall be
19 considered to have a new active ingredient under
20 this section.

21 “(2) INTERCHANGEABLE BIOSIMILAR BIOLOGI-
22 CAL PRODUCT.—A biological product that is inter-
23 changeable with a reference product under section
24 351 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

1 (ii) is submitted to the Secretary not
2 later than the date that is 10 years after
3 the date of enactment of this Act.

4 (3) LIMITATION.—Notwithstanding paragraph
5 (2), an application for a biological product may not
6 be submitted under section 505 of the Federal Food,
7 Drug, and Cosmetic Act (21 U.S.C. 355) if there is
8 another biological product approved under sub-
9 section (a) of section 351 of the Public Health Serv-
10 ice Act that could be a reference product with re-
11 spect to such application (within the meaning of
12 such section 351) if such application were submitted
13 under subsection (k) of such section 351.

14 (4) DEEMED APPROVED UNDER SECTION
15 351.—An approved application for a biological prod-
16 uct under section 505 of the Federal Food, Drug,
17 and Cosmetic Act (21 U.S.C. 355) shall be deemed
18 to be a license for the biological product under such
19 section 351 on the date that is 10 years after the
20 date of enactment of this Act.

21 (5) DEFINITIONS.—For purposes of this sub-
22 section, the term “biological product” has the mean-
23 ing given such term under section 351 of the Public
24 Health Service Act (42 U.S.C. 262) (as amended by
25 this Act).

1 (f) FOLLOW-ON BIOLOGICS USER FEES.—

2 (1) DEVELOPMENT OF USER FEES FOR BIO-
3 SIMILAR BIOLOGICAL PRODUCTS.—

4 (A) IN GENERAL.—Beginning not later
5 than October 1, 2010, the Secretary shall de-
6 velop recommendations to present to Congress
7 with respect to the goals, and plans for meeting
8 the goals, for the process for the review of bio-
9 similar biological product applications sub-
10 mitted under section 351(k) of the Public
11 Health Service Act (as added by this Act) for
12 the first 5 fiscal years after fiscal year 2012. In
13 developing such recommendations, the Sec-
14 retary shall consult with—

15 (i) the Committee on Health, Edu-
16 cation, Labor, and Pensions of the Senate;

17 (ii) the Committee on Energy and
18 Commerce of the House of Representa-
19 tives;

20 (iii) scientific and academic experts;

21 (iv) health care professionals;

22 (v) representatives of patient and con-
23 sumer advocacy groups; and

24 (vi) the regulated industry.

1 (B) PUBLIC REVIEW OF RECOMMENDA-
2 TIONS.—After negotiations with the regulated
3 industry, the Secretary shall—

4 (i) present the recommendations de-
5 veloped under subparagraph (A) to the
6 Congressional committees specified in such
7 subparagraph;

8 (ii) publish such recommendations in
9 the Federal Register;

10 (iii) provide for a period of 30 days
11 for the public to provide written comments
12 on such recommendations;

13 (iv) hold a meeting at which the pub-
14 lic may present its views on such rec-
15 ommendations; and

16 (v) after consideration of such public
17 views and comments, revise such rec-
18 ommendations as necessary.

19 (C) TRANSMITTAL OF RECOMMENDA-
20 TIONS.—Not later than January 15, 2012, the
21 Secretary shall transmit to Congress the revised
22 recommendations under subparagraph (B), a
23 summary of the views and comments received
24 under such subparagraph, and any changes

1 made to the recommendations in response to
2 such views and comments.

3 (2) ESTABLISHMENT OF USER FEE PRO-
4 GRAM.—It is the sense of the Senate that, based on
5 the recommendations transmitted to Congress by the
6 Secretary pursuant to paragraph (1)(C), Congress
7 should authorize a program, effective on October 1,
8 2012, for the collection of user fees relating to the
9 submission of biosimilar biological product applica-
10 tions under section 351(k) of the Public Health
11 Service Act (as added by this Act).

12 (3) TRANSITIONAL PROVISIONS FOR USER FEES
13 FOR BIOSIMILAR BIOLOGICAL PRODUCTS.—

14 (A) APPLICATION OF THE PRESCRIPTION
15 DRUG USER FEE PROVISIONS.—Section
16 735(1)(B) of the Federal Food, Drug, and Cos-
17 metic Act (21 U.S.C. 379g(1)(B)) is amended
18 by striking “section 351” and inserting “sub-
19 section (a) or (k) of section 351”.

20 (B) EVALUATION OF COSTS OF REVIEWING
21 BIOSIMILAR BIOLOGICAL PRODUCT APPLICA-
22 TIONS.—During the period beginning on the
23 date of enactment of this Act and ending on
24 October 1, 2010, the Secretary shall collect and
25 evaluate data regarding the costs of reviewing

1 applications for biological products submitted
2 under section 351(k) of the Public Health Serv-
3 ice Act (as added by this Act) during such pe-
4 riod.

5 (C) AUDIT.—

6 (i) IN GENERAL.—On the date that is
7 2 years after first receiving a user fee ap-
8 plicable to an application for a biological
9 product under section 351(k) of the Public
10 Health Service Act (as added by this Act),
11 and on a biennial basis thereafter until Oc-
12 tober 1, 2013, the Secretary shall perform
13 an audit of the costs of reviewing such ap-
14 plications under such section 351(k). Such
15 an audit shall compare—

16 (I) the costs of reviewing such
17 applications under such section
18 351(k) to the amount of the user fee
19 applicable to such applications; and

20 (II)(aa) such ratio determined
21 under subclause (I); to

22 (bb) the ratio of the costs of re-
23 viewing applications for biological
24 products under section 351(a) of such
25 Act (as amended by this Act) to the

1 amount of the user fee applicable to
2 such applications under such section
3 351(a).

4 (ii) ALTERATION OF USER FEE.—If
5 the audit performed under clause (i) indi-
6 cates that the ratios compared under sub-
7 clause (II) of such clause differ by more
8 than 5 percent, then the Secretary shall
9 alter the user fee applicable to applications
10 submitted under such section 351(k) to
11 more appropriately account for the costs of
12 reviewing such applications.

13 (iii) ACCOUNTING STANDARDS.—The
14 Secretary shall perform an audit under
15 clause (i) in conformance with the account-
16 ing principles, standards, and requirements
17 prescribed by the Comptroller General of
18 the United States under section 3511 of
19 title 31, United State Code, to ensure the
20 validity of any potential variability.

21 (4) AUTHORIZATION OF APPROPRIATIONS.—
22 There is authorized to be appropriated to carry out
23 this subsection such sums as may be necessary for
24 each of fiscal years 2010 through 2012.

1 (g) ALLOCATION OF SAVINGS; SPECIAL RESERVE
2 FUND.—

3 (1) DETERMINATION OF SAVINGS.—The Sec-
4 retary of the Treasury, in consultation with the Sec-
5 retary, shall for each fiscal year determine the
6 amount of the savings to the Federal Government as
7 a result of the enactment of this subtitle and shall
8 transfer such amount to the Fund established under
9 paragraph (2) pursuant to a relevant appropriations
10 Act.

11 (2) SPECIAL RESERVE FUND.—

12 (A) IN GENERAL.—There is established in
13 the Treasury of the United States a fund to be
14 designated as the “Biological Product Savings
15 Fund” to be made available to the Secretary
16 without fiscal year limitation.

17 (B) USE OF FUND.—The amounts made
18 available to the Secretary through the Fund
19 under subparagraph (A) shall be expended on
20 activities authorized under the Public Health
21 Service Act.

22 (3) AUTHORIZATION OF APPROPRIATIONS.—
23 There is authorized to be appropriated for each fis-
24 cal year to the Fund established under paragraph

1 (2), the amount of the savings determined for such
2 fiscal year under paragraph (1).

3 (h) GOVERNMENT ACCOUNTABILITY OFFICE
4 STUDY.—

5 (1) IN GENERAL.—Not later than 3 years after
6 the date of enactment of this Act, the Comptroller
7 General of the United States shall study and report
8 to Congress regarding—

9 (A) the extent to which pediatric studies of
10 biological products are being required under the
11 Federal Food, Drug, and Cosmetic Act (21
12 U.S.C. 301 et seq.); and

13 (B) any pediatric needs not being met
14 under existing authority.

15 (2) CONTENT OF STUDY.—The study under
16 paragraph (1) shall review and assess—

17 (A) the extent to which pediatric studies of
18 biological products are required under sub-
19 sections (a) and (b) of section 505B of the Fed-
20 eral Food, Drug and Cosmetic Act (21 U.S.C.
21 355c);

22 (B) the extent to which pediatric studies of
23 biological products are required as part of risk
24 evaluation and mitigation strategies under such
25 Act;

1 (C) the number, importance, and
2 prioritization of any biological products that are
3 not being tested for pediatric use; and

4 (D) recommendations for ensuring pedi-
5 atric testing of products identified in subpara-
6 graph (C), including the consideration of any
7 incentives, such as those provided under the
8 Best Pharmaceuticals for Children Act.

9 (i) ORPHAN PRODUCTS.—If a reference product, as
10 defined in section 351 of the Public Health Service Act
11 (42 U.S.C. 262) (as amended by this Act) has been des-
12 ignated under section 526 of the Federal Food, Drug, and
13 Cosmetic Act (21 U.S.C. 360bb) for a rare disease or con-
14 dition, a biological product seeking approval for such dis-
15 ease or condition under subsection (k) of such section 351
16 as biosimilar to, or interchangeable with, such reference
17 product may be licensed by the Secretary only after the
18 expiration for such reference product of the later of—

19 (1) the 7-year period described in section
20 527(a) of the Federal Food, Drug, and Cosmetic Act
21 (21 U.S.C. 360cc(a)); and

22 (2) the 12-year period described in subsection
23 (k)(7) of such section 351.

1 **SEC. 603. SAVINGS.**

2 (a) DETERMINATION.—The Secretary of the Treas-
3 ury, in consultation with the Secretary of Health and
4 Human Services, shall for each fiscal year determine the
5 amount of savings to the Federal Government as a result
6 of the enactment of this subtitle.

7 (b) USE.—Notwithstanding any other provision of
8 this subtitle (or an amendment made by this subtitle), the
9 savings to the Federal Government generated as a result
10 of the enactment of this subtitle shall be used for deficit
11 reduction.

12 **Subtitle B—More Affordable Medi-**
13 **cines for Children and Under-**
14 **served Communities**

15 **SEC. 611. EXPANDED PARTICIPATION IN 340B PROGRAM.**

16 (a) EXPANSION OF COVERED ENTITIES RECEIVING
17 DISCOUNTED PRICES.—Section 340B(a)(4) of the Public
18 Health Service Act (42 U.S.C. 256b(a)(4)) is amended by
19 adding at the end the following:

20 “(M) A children’s hospital excluded from
21 the Medicare prospective payment system pur-
22 suant to section 1886(d)(1)(B)(iii) of the Social
23 Security Act, or a free-standing cancer hospital
24 excluded from the Medicare prospective pay-
25 ment system pursuant to section
26 1886(d)(1)(B)(v) of the Social Security Act,

1 that would meet the requirements of subpara-
2 graph (L), including the disproportionate share
3 adjustment percentage requirement under
4 clause (ii) of such subparagraph, if the hospital
5 were a subsection (d) hospital as defined by sec-
6 tion 1886(d)(1)(B) of the Social Security Act.

7 “(N) An entity that is a critical access hos-
8 pital (as determined under section 1820(c)(2)
9 of the Social Security Act), and that meets the
10 requirements of subparagraph (L)(i).

11 “(O) An entity that is a rural referral cen-
12 ter, as defined by section 1886(d)(5)(C)(i) of
13 the Social Security Act, or a sole community
14 hospital, as defined by section
15 1886(d)(5)(C)(iii) of such Act, and that both
16 meets the requirements of subparagraph (L)(i)
17 and has a disproportionate share adjustment
18 percentage equal to or greater than 8 percent.”.

19 (b) EXTENSION OF DISCOUNT TO INPATIENT
20 DRUGS.—Section 340B of the Public Health Service Act
21 (42 U.S.C. 256b) is amended—

22 (1) in paragraphs (2), (5), (7), and (9) of sub-
23 section (a), by striking “outpatient” each place it
24 appears; and

25 (2) in subsection (b)—

1 (A) by striking “OTHER DEFINITION” and
2 all that follows through “In this section” and
3 inserting the following: “OTHER DEFINI-
4 TIONS.—

5 “(1) IN GENERAL.—In this section”; and

6 (B) by adding at the end the following new
7 paragraph:

8 “(2) COVERED DRUG.—In this section, the term
9 ‘covered drug’—

10 “(A) means a covered outpatient drug (as
11 defined in section 1927(k)(2) of the Social Se-
12 curity Act); and

13 “(B) includes, notwithstanding paragraph
14 (3)(A) of section 1927(k) of such Act, a drug
15 used in connection with an inpatient or out-
16 patient service provided by a hospital described
17 in subparagraph (L), (M), (N), or (O) of sub-
18 section (a)(4) that is enrolled to participate in
19 the drug discount program under this section.”.

20 (c) PROHIBITION ON GROUP PURCHASING ARRANGE-
21 MENTS.—Section 340B(a) of the Public Health Service
22 Act (42 U.S.C. 256b(a)) is amended—

23 (1) in paragraph (4)(L)—

24 (A) in clause (i), by adding “and” at the
25 end;

1 (B) in clause (ii), by striking “; and” and
2 inserting a period; and

3 (C) by striking clause (iii); and

4 (2) in paragraph (5), as amended by subsection
5 (b)—

6 (A) by redesignating subparagraphs (C)
7 and (D) as subparagraphs (D) and (E); respec-
8 tively; and

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

11 “(C) PROHIBITION ON GROUP PURCHASING
12 ARRANGEMENTS.—

13 “(i) IN GENERAL.—A hospital de-
14 scribed in subparagraph (L), (M), (N), or
15 (O) of paragraph (4) shall not obtain cov-
16 ered outpatient drugs through a group
17 purchasing organization or other group
18 purchasing arrangement, except as per-
19 mitted or provided for pursuant to clauses
20 (ii) or (iii).

21 “(ii) INPATIENT DRUGS.—Clause (i)
22 shall not apply to drugs purchased for in-
23 patient use.

1 “(iii) EXCEPTIONS.—The Secretary
2 shall establish reasonable exceptions to
3 clause (i)—

4 “(I) with respect to a covered
5 outpatient drug that is unavailable to
6 be purchased through the program
7 under this section due to a drug
8 shortage problem, manufacturer non-
9 compliance, or any other circumstance
10 beyond the hospital’s control;

11 “(II) to facilitate generic substi-
12 tution when a generic covered out-
13 patient drug is available at a lower
14 price; or

15 “(III) to reduce in other ways
16 the administrative burdens of man-
17 aging both inventories of drugs sub-
18 ject to this section and inventories of
19 drugs that are not subject to this sec-
20 tion, so long as the exceptions do not
21 create a duplicate discount problem in
22 violation of subparagraph (A) or a di-
23 version problem in violation of sub-
24 paragraph (B).

1 “(iv) PURCHASING ARRANGEMENTS
2 FOR INPATIENT DRUGS.—The Secretary
3 shall ensure that a hospital described in
4 subparagraph (L), (M), (N), or (O) of sub-
5 section (a)(4) that is enrolled to partici-
6 pate in the drug discount program under
7 this section shall have multiple options for
8 purchasing covered drugs for inpatients,
9 including by utilizing a group purchasing
10 organization or other group purchasing ar-
11 rangement, establishing and utilizing its
12 own group purchasing program, pur-
13 chasing directly from a manufacturer, and
14 any other purchasing arrangements that
15 the Secretary determines is appropriate to
16 ensure access to drug discount pricing
17 under this section for inpatient drugs tak-
18 ing into account the particular needs of
19 small and rural hospitals.”.

20 (d) MEDICAID CREDITS ON INPATIENT DRUGS.—
21 Section 340B of the Public Health Service Act (42 U.S.C.
22 256b) is amended by striking subsection (c) and inserting
23 the following:

24 “(c) MEDICAID CREDIT.—Not later than 90 days
25 after the date of filing of the hospital’s most recently filed

1 Medicare cost report, the hospital shall issue a credit as
2 determined by the Secretary to the State Medicaid pro-
3 gram for inpatient covered drugs provided to Medicaid re-
4 cipients.”.

5 (e) EFFECTIVE DATES.—

6 (1) IN GENERAL.—The amendments made by
7 this section and section 612 shall take effect on Jan-
8 uary 1, 2010, and shall apply to drugs purchased on
9 or after January 1, 2010.

10 (2) EFFECTIVENESS.—The amendments made
11 by this section and section 612 shall be effective and
12 shall be taken into account in determining whether
13 a manufacturer is deemed to meet the requirements
14 of section 340B(a) of the Public Health Service Act
15 (42 U.S.C. 256b(a)), notwithstanding any other pro-
16 vision of law.

17 **SEC. 612. IMPROVEMENTS TO 340B PROGRAM INTEGRITY.**

18 (a) INTEGRITY IMPROVEMENTS.—Subsection (d) of
19 section 340B of the Public Health Service Act (42 U.S.C.
20 256b) is amended to read as follows:

21 “(d) IMPROVEMENTS IN PROGRAM INTEGRITY.—

22 “(1) MANUFACTURER COMPLIANCE.—

23 “(A) IN GENERAL.—From amounts appro-
24 priated under paragraph (4), the Secretary
25 shall provide for improvements in compliance by

1 manufacturers with the requirements of this
2 section in order to prevent overcharges and
3 other violations of the discounted pricing re-
4 quirements specified in this section.

5 “(B) IMPROVEMENTS.—The improvements
6 described in subparagraph (A) shall include the
7 following:

8 “(i) The development of a system to
9 enable the Secretary to verify the accuracy
10 of ceiling prices calculated by manufactur-
11 ers under subsection (a)(1) and charged to
12 covered entities, which shall include the
13 following:

14 “(I) Developing and publishing
15 through an appropriate policy or regu-
16 latory issuance, precisely defined
17 standards and methodology for the
18 calculation of ceiling prices under
19 such subsection.

20 “(II) Comparing regularly the
21 ceiling prices calculated by the Sec-
22 retary with the quarterly pricing data
23 that is reported by manufacturers to
24 the Secretary.

1 “(III) Performing spot checks of
2 sales transactions by covered entities.

3 “(IV) Inquiring into the cause of
4 any pricing discrepancies that may be
5 identified and either taking, or requir-
6 ing manufacturers to take, such cor-
7 rective action as is appropriate in re-
8 sponse to such price discrepancies.

9 “(ii) The establishment of procedures
10 for manufacturers to issue refunds to cov-
11 ered entities in the event that there is an
12 overcharge by the manufacturers, including
13 the following:

14 “(I) Providing the Secretary with
15 an explanation of why and how the
16 overcharge occurred, how the refunds
17 will be calculated, and to whom the
18 refunds will be issued.

19 “(II) Oversight by the Secretary
20 to ensure that the refunds are issued
21 accurately and within a reasonable pe-
22 riod of time, both in routine instances
23 of retroactive adjustment to relevant
24 pricing data and exceptional cir-
25 cumstances such as erroneous or in-

1 tentional overcharging for covered
2 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.

14 “(iv) The development of a mecha-
15 nism by which—

16 “(I) rebates and other discounts
17 provided by manufacturers to other
18 purchasers subsequent to the sale of
19 covered drugs to covered entities are
20 reported to the Secretary; and

21 “(II) appropriate credits and re-
22 funds are issued to covered entities if
23 such discounts or rebates have the ef-
24 fect of lowering the applicable ceiling

1 price for the relevant quarter for the
2 drugs involved.

3 “(v) Selective auditing of manufactur-
4 ers and wholesalers to ensure the integrity
5 of the drug discount program under this
6 section.

7 “(vi) The imposition of sanctions in
8 the form of civil monetary penalties,
9 which—

10 “(I) shall be assessed according
11 to standards established in regulations
12 to be promulgated by the Secretary
13 not later than 180 days after the date
14 of enactment of Affordable Health
15 Choices Act;

16 “(II) shall not exceed \$5,000 for
17 each instance of overcharging a cov-
18 ered entity that may have occurred;
19 and

20 “(III) shall apply to any manu-
21 facturer with an agreement under this
22 section that knowingly and inten-
23 tionally charges a covered entity a
24 price for purchase of a drug that ex-

1 ceeds the maximum applicable price
2 under subsection (a)(1).

3 “(2) COVERED ENTITY COMPLIANCE.—

4 “(A) IN GENERAL.—From amounts appro-
5 priated under paragraph (4), the Secretary
6 shall provide for improvements in compliance by
7 covered entities with the requirements of this
8 section in order to prevent diversion and viola-
9 tions of the duplicate discount provision and
10 other requirements specified under subsection
11 (a)(5).

12 “(B) IMPROVEMENTS.—The improvements
13 described in subparagraph (A) shall include the
14 following:

15 “(i) The development of procedures to
16 enable and require covered entities to regu-
17 larly update (at least annually) the infor-
18 mation on the Internet website of the De-
19 partment of Health and Human Services
20 relating to this section.

21 “(ii) The development of a system for
22 the Secretary to verify the accuracy of in-
23 formation regarding covered entities that is
24 listed on the website described in clause
25 (i).

1 “(iii) The development of more de-
2 tailed guidance describing methodologies
3 and options available to covered entities for
4 billing covered drugs to State Medicaid
5 agencies in a manner that avoids duplicate
6 discounts pursuant to subsection (a)(5)(A).

7 “(iv) The establishment of a single,
8 universal, and standardized identification
9 system by which each covered entity site
10 can be identified by manufacturers, dis-
11 tributors, covered entities, and the Sec-
12 retary for purposes of facilitating the or-
13 dering, purchasing, and delivery of covered
14 drugs under this section, including the
15 processing of chargebacks for such drugs.

16 “(v) The imposition of sanctions, in
17 appropriate cases as determined by the
18 Secretary, additional to those to which cov-
19 ered entities are subject under subpara-
20 graph (a)(5)(E), through one or more of
21 the following actions:

22 “(I) Where a covered entity
23 knowingly and intentionally violates
24 subparagraph (a)(5)(B), the covered
25 entity shall be required to pay a mon-

1 etary penalty to a manufacturer or
2 manufacturers in the form of interest
3 on sums for which the covered entity
4 is found liable under paragraph
5 (a)(5)(E), such interest to be com-
6 pounded monthly and equal to the
7 current short term interest rate as de-
8 termined by the Federal Reserve for
9 the time period for which the covered
10 entity is liable.

11 “(II) Where the Secretary deter-
12 mines a violation of subparagraph
13 (a)(5)(B) was systematic and egre-
14 gious as well as knowing and inten-
15 tional, removing the covered entity
16 from the drug discount program
17 under this section and disqualifying
18 the entity from re-entry into such pro-
19 gram for a reasonable period of time
20 to be determined by the Secretary.

21 “(III) Referring matters to ap-
22 propriate Federal authorities within
23 the Food and Drug Administration,
24 the Office of Inspector General of De-
25 partment of Health and Human Serv-

1 ices, or other Federal agencies for
2 consideration of appropriate action
3 under other Federal statutes, such as
4 the Prescription Drug Marketing Act
5 (21 U.S.C. 353).

6 “(3) ADMINISTRATIVE DISPUTE RESOLUTION
7 PROCESS.—

8 “(A) IN GENERAL.—Not later than 180
9 days after the date of enactment of Affordable
10 Health Choices Act, the Secretary shall promul-
11 gate regulations to establish and implement an
12 administrative process for the resolution of
13 claims by covered entities that they have been
14 overcharged for drugs purchased under this sec-
15 tion, and claims by manufacturers, after the
16 conduct of audits as authorized by subsection
17 (a)(5)(D), of violations of subsections (a)(5)(A)
18 or (a)(5)(B), including appropriate procedures
19 for the provision of remedies and enforcement
20 of determinations made pursuant to such proc-
21 ess through mechanisms and sanctions de-
22 scribed in paragraphs (1)(B) and (2)(B).

23 “(B) DEADLINES AND PROCEDURES.—
24 Regulations promulgated by the Secretary
25 under subparagraph (A) shall—

1 “(i) designate or establish a decision-
2 making official or decision-making body
3 within the Department of Health and
4 Human Services to be responsible for re-
5 viewing and finally resolving claims by cov-
6 ered entities that they have been charged
7 prices for covered drugs in excess of the
8 ceiling price described in subsection (a)(1),
9 and claims by manufacturers that viola-
10 tions of subsection (a)(5)(A) or (a)(5)(B)
11 have occurred;

12 “(ii) establish such deadlines and pro-
13 cedures as may be necessary to ensure that
14 claims shall be resolved fairly, efficiently,
15 and expeditiously;

16 “(iii) establish procedures by which a
17 covered entity may discover and obtain
18 such information and documents from
19 manufacturers and third parties as may be
20 relevant to demonstrate the merits of a
21 claim that charges for a manufacturer’s
22 product have exceeded the applicable ceil-
23 ing price under this section, and may sub-
24 mit such documents and information to the

1 administrative official or body responsible
2 for adjudicating such claim;

3 “(iv) require that a manufacturer con-
4 duct an audit of a covered entity pursuant
5 to subsection (a)(5)(D) as a prerequisite to
6 initiating administrative dispute resolution
7 proceedings against a covered entity;

8 “(v) permit the official or body des-
9 ignated under clause (i), at the request of
10 a manufacturer or manufacturers, to con-
11 solidate claims brought by more than one
12 manufacturer against the same covered en-
13 tity where, in the judgment of such official
14 or body, consolidation is appropriate and
15 consistent with the goals of fairness and
16 economy of resources; and

17 “(vi) include provisions and proce-
18 dures to permit multiple covered entities to
19 jointly assert claims of overcharges by the
20 same manufacturer for the same drug or
21 drugs in one administrative proceeding,
22 and permit such claims to be asserted on
23 behalf of covered entities by associations or
24 organizations representing the interests of

1 such covered entities and of which the cov-
2 ered entities are members.

3 “(C) FINALITY OF ADMINISTRATIVE RESO-
4 LUTION.—The administrative resolution of a
5 claim or claims under the regulations promul-
6 gated under subparagraph (A) shall be a final
7 agency decision and shall be binding upon the
8 parties involved, unless invalidated by an order
9 of a court of competent jurisdiction.

10 “(4) AUTHORIZATION OF APPROPRIATIONS.—
11 There are authorized to be appropriated to carry out
12 this subsection, such sums as may be necessary for
13 fiscal year 2010 and each succeeding fiscal year.”.

14 (b) CONFORMING AMENDMENTS.—Section 340B(a)
15 of the Public Health Service Act (42 U.S.C. 256b(a)) is
16 amended—

17 (1) in subsection (a)(1), by adding at the end
18 the following: “Each such agreement shall require
19 that the manufacturer furnish the Secretary with re-
20 ports, on a quarterly basis, of the price for each cov-
21 ered drug subject to the agreement that, according
22 to the manufacturer, represents the maximum price
23 that covered entities may permissibly be required to
24 pay for the drug (referred to in this section as the
25 ‘ceiling price’), and shall require that the manufac-

1 turer offer each covered entity covered drugs for
2 purchase at or below the applicable ceiling price if
3 such drug is made available to any other purchaser
4 at any price.”; and

5 (2) in the first sentence of subsection (a)(5)(E),
6 as redesignated by section 611(c), by inserting
7 “after audit as described in subparagraph (D) and”
8 after “finds,”.

9 **SEC. 613. GAO STUDY TO MAKE RECOMMENDATIONS ON IM-**
10 **PROVING THE 340B PROGRAM.**

11 (a) **REPORT.**—Not later than 18 months after the
12 date of enactment of this Act, the Comptroller General
13 of the United States shall submit to Congress a report
14 that examines whether those individuals served by the cov-
15 ered entities under the program under section 340B of
16 the Public Health Service Act (42 U.S.C. 256b) (referred
17 to in this section as the “340B program”) are receiving
18 optimal health care services.

19 (b) **RECOMMENDATIONS.**—The report under sub-
20 section (a) shall include recommendations on the fol-
21 lowing:

22 (1) Whether the 340B program should be ex-
23 panded since it is anticipated that the 47,000,000
24 individuals who are uninsured as of the date of en-

1 actment of this Act will have health care coverage
2 once this Act is implemented.

3 (2) Whether mandatory sales of certain prod-
4 ucts by the 340B program could hinder patients ac-
5 cess to those therapies through any provider.

6 (3) Whether income from the 340B program is
7 being used by the covered entities under the pro-
8 gram to further the program objectives.