

**AMENDMENT IN THE NATURE OF A SUBSTITUTE
OFFERED BY MR. BOEHNER OF OHIO**

Base text: HR 3962 as posted for Rules

Strike all after the enacting clause and insert the following:

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

2 (a) **SHORT TITLE.**—This Act may be cited as the
3 “Affordable Health Care for America Act”.

4 (b) **PURPOSE.**—The purpose of this Act is to take
5 meaningful steps to lower health care costs and increase
6 access to health insurance coverage (especially for individ-
7 uals with preexisting conditions) without—

- 8 (1) raising taxes;
- 9 (2) cutting Medicare benefits for seniors;
- 10 (3) adding to the national deficit;
- 11 (4) intervening in the doctor-patient relation-
12 ship; or
- 13 (5) instituting a government takeover of health
14 care.

15 (c) **TABLE OF CONTENTS.**—The table of contents of
16 this Act is as follows:

Sec. 1. Short title; purpose; table of contents.

DIVISION A—MAKING HEALTH CARE COVERAGE AFFORDABLE
FOR EVERY AMERICAN

TITLE I—ENSURING COVERAGE FOR INDIVIDUALS WITH PRE-
EXISTING CONDITIONS AND MULTIPLE HEALTH CARE NEEDS

- Sec. 101. Establish universal access programs to improve high risk pools and reinsurance markets.
- Sec. 102. Elimination of certain requirements for guaranteed availability in individual market.
- Sec. 103. No annual or lifetime spending caps.
- Sec. 104. Preventing unjust cancellation of insurance coverage.

TITLE II—REDUCING HEALTH CARE PREMIUMS AND THE
NUMBER OF UNINSURED AMERICANS

- Sec. 111. State innovation programs.
- Sec. 112. Health plan finders.
- Sec. 113. Administrative simplification.

DIVISION B—IMPROVING ACCESS TO HEALTH CARE

TITLE I—EXPANDING ACCESS AND LOWERING COSTS FOR SMALL
BUSINESSES

- Sec. 201. Rules governing association health plans.
- Sec. 202. Clarification of treatment of single employer arrangements.
- Sec. 203. Enforcement provisions relating to association health plans.
- Sec. 204. Cooperation between Federal and State authorities.
- Sec. 205. Effective date and transitional and other rules.

TITLE II—TARGETED EFFORTS TO EXPAND ACCESS

- Sec. 211. Extending coverage of dependents.
- Sec. 212. Allowing auto-enrollment for employer sponsored coverage.

TITLE III—EXPANDING CHOICES BY ALLOWING AMERICANS TO
BUY HEALTH CARE COVERAGE ACROSS STATE LINES

- Sec. 221. Interstate purchasing of Health Insurance.

TITLE IV—IMPROVING HEALTH SAVINGS ACCOUNTS

- Sec. 231. Saver's credit for contributions to health savings accounts.
- Sec. 232. HSA funds for premiums for high deductible health plans.
- Sec. 233. Requiring greater coordination between HDHP administrators and HSA account administrators so that enrollees can enroll in both at the same time.
- Sec. 234. Special rule for certain medical expenses incurred before establishment of account.

DIVISION C—ENACTING REAL MEDICAL LIABILITY REFORM

- Sec. 301. Encouraging speedy resolution of claims.
- Sec. 302. Compensating patient injury.
- Sec. 303. Maximizing patient recovery.
- Sec. 304. Additional health benefits.
- Sec. 305. Punitive damages.

- Sec. 306. Authorization of payment of future damages to claimants in health care lawsuits.
- Sec. 307. Definitions.
- Sec. 308. Effect on other laws.
- Sec. 309. State flexibility and protection of states' rights.
- Sec. 310. Applicability; effective date.

DIVISION D—PROTECTING THE DOCTOR-PATIENT RELATIONSHIP

- Sec. 401. Rule of construction.
- Sec. 402. Repeal of Federal Coordinating Council for Comparative Effectiveness Research.

DIVISION E—INCENTIVIZING WELLNESS AND QUALITY IMPROVEMENTS

- Sec. 501. Incentives for prevention and wellness programs.

DIVISION F—PROTECTING TAXPAYERS

- Sec. 601. Provide full funding to HHS OIG and HCFAC.
- Sec. 602. Prohibiting taxpayer funded abortions and conscience protections.
- Sec. 603. Improved enforcement of the Medicare and Medicaid secondary payer provisions.
- Sec. 604. Strengthen Medicare provider enrollment standards and safeguards.
- Sec. 605. Tracking banned providers across State lines.

DIVISION G—PATHWAY FOR BIOSIMILAR BIOLOGICAL PRODUCTS

- Sec. 701. Approval pathway for biosimilar biological products.
- Sec. 702. Amendments to certain patent provisions.

1 **DIVISION A—MAKING HEALTH**
 2 **CARE COVERAGE AFFORD-**
 3 **ABLE FOR EVERY AMERICAN**
 4 **TITLE I—ENSURING COVERAGE**
 5 **FOR INDIVIDUALS WITH PRE-**
 6 **EXISTING CONDITIONS AND**
 7 **MULTIPLE HEALTH CARE**
 8 **NEEDS**

9 **SEC. 101. ESTABLISH UNIVERSAL ACCESS PROGRAMS TO**
 10 **IMPROVE HIGH RISK POOLS AND REINSUR-**
 11 **ANCE MARKETS.**

12 (a) STATE REQUIREMENT.—

1 (1) IN GENERAL.—Not later than January 1,
2 2010, each State shall—

3 (A) subject to paragraph (3), operate—

4 (i) a qualified State reinsurance pro-
5 gram described in subsection (b); or

6 (ii) qualifying State high risk pool de-
7 scribed in subsection (c)(1); and

8 (B) subject to paragraph (4), apply to the
9 operation of such a program from State funds
10 an amount equivalent to the portion of State
11 funds derived from State premium assessments
12 (as defined by the Secretary) that are not oth-
13 erwise used on State health care programs.

14 (2) RELATION TO CURRENT QUALIFIED HIGH
15 RISK POOL PROGRAM.—

16 (A) STATES NOT OPERATING A QUALIFIED
17 HIGH RISK POOL.—In the case of a State that
18 is not operating a current section 2745 quali-
19 fied high risk pool as of the date of the enact-
20 ment of this Act—

21 (i) the State may only meet the re-
22 quirement of paragraph (1) through the
23 operation of a qualified State reinsurance
24 program described in subsection (b); and

1 (ii) the State's operation of such a re-
2 insurance program shall be treated, for
3 purposes of section 2745 of the Public
4 Health Service Act, as the operation of a
5 qualified high risk pool described in such
6 section.

7 (B) STATE OPERATING A QUALIFIED HIGH
8 RISK POOL.—In the case of a State that is op-
9 erating a current section 2745 qualified high
10 risk pool as of the date of the enactment of this
11 Act—

12 (i) as of January 1, 2010, such a pool
13 shall not be treated as a qualified high risk
14 pool under section 2745 of the Public
15 Health Service Act unless the pool is a
16 qualifying State high risk pool described in
17 subsection (c)(1); and

18 (ii) the State may use premium as-
19 sessment funds described in paragraph
20 (1)(B) to transition from operation of such
21 a pool to operation of a qualified State re-
22 insurance program described in subsection
23 (b).

24 (3) APPLICATION OF FUNDS.—If the program
25 or pool operated under paragraph (1)(A) is in strong

1 fiscal health, as determined in accordance with
2 standards established by the National Association of
3 Insurance Commissioners and as approved by the
4 State Insurance Commissioner involved, the require-
5 ment of paragraph (1)(B) shall be deemed to be
6 met.

7 (b) QUALIFIED STATE REINSURANCE PROGRAM.—

8 (1) IN GENERAL.—For purposes of this section,
9 a “qualified State reinsurance program” means a
10 program operated by a State program that provides
11 reinsurance for health insurance coverage offered in
12 the small group market in accordance with the
13 model for such a program established (as of the date
14 of the enactment of this Act).

15 (2) FORM OF PROGRAM.—A qualified State re-
16 insurance program may provide reinsurance—

17 (A) on a prospective or retrospective basis;

18 and

19 (B) on a basis that protects health insur-
20 ance issuers against the annual aggregate
21 spending of their enrollees as well as purchase
22 protection against individual catastrophic costs.

23 (3) SATISFACTION OF HIPAA REQUIREMENT.—

24 A qualified State reinsurance program shall be
25 deemed, for purposes of section 2745 of the Public

1 Health Service Act, to be a qualified high-risk pool
2 under such section.

3 (c) QUALIFYING STATE HIGH RISK POOL.—

4 (1) IN GENERAL.—A qualifying State high risk
5 pool described in this subsection means a current
6 section 2745 qualified high risk pool that meets the
7 following requirements:

8 (A) The pool must provide at least two
9 coverage options, one of which must be a high
10 deductible health plan coupled with a health
11 savings account.

12 (B) The pool must be funded with a stable
13 funding source.

14 (C) The pool must eliminate any waiting
15 lists so that all eligible residents who are seek-
16 ing coverage through the pool should be allowed
17 to receive coverage through the pool.

18 (D) The pool must allow for coverage of
19 individuals who, but for the 24-month disability
20 waiting period under section 226(b) of the So-
21 cial Security Act, would be eligible for Medicare
22 during the period of such waiting period.

23 (E) The pool must limit the pool premiums
24 to no more than 150 percent of the average

1 premium for applicable standard risk rates in
2 that State.

3 (F) The pool must conduct education and
4 outreach initiatives so that residents and bro-
5 kers understand that the pool is available to eli-
6 gible residents.

7 (G) The pool must provide coverage for
8 preventive services and disease management for
9 chronic diseases.

10 (2) VERIFICATION OF CITIZENSHIP OR ALIEN
11 QUALIFICATION.—

12 (A) IN GENERAL.—Notwithstanding any
13 other provision of law, only citizens and nation-
14 als of the United States shall be eligible to par-
15 ticipate in a qualifying State high risk pool that
16 receives funds under section 2745 of the Public
17 Health Service Act or this section.

18 (B) CONDITION OF PARTICIPATION.—As a
19 condition of a State receiving such funds, the
20 Secretary shall require the State to certify, to
21 the satisfaction of the Secretary, that such
22 State requires all applicants for coverage in the
23 qualifying State high risk pool to provide satis-
24 factory documentation of citizenship or nation-

1 ality in a manner consistent with section
2 1903(x) of the Social Security Act.

3 (C) RECORDS.—The Secretary shall keep
4 sufficient records such that a determination of
5 citizenship or nationality only has to be made
6 once for any individual under this paragraph.

7 (3) RELATION TO SECTION 2745.—As of Janu-
8 ary 1, 2010, a pool shall not qualify as qualified
9 high risk pool under section 2745 of the Public
10 Health Service Act unless the pool is a qualifying
11 State high risk pool described in paragraph (1).

12 (d) WAIVERS.—In order to accommodate new and in-
13 novative programs, the Secretary may waive such require-
14 ments of this section for qualified State reinsurance pro-
15 grams and for qualifying State high risk pools as the Sec-
16 retary deems appropriate.

17 (e) FUNDING.—In addition to any other amounts ap-
18 propriated, there is appropriated to carry out section 2745
19 of the Public Health Service Act (including through a pro-
20 gram or pool described in subsection (a)(1)),
21 \$15,000,000,000 for the period of fiscal years 2010
22 through 2019.

23 (f) DEFINITIONS.—In this section:

24 (1) HEALTH INSURANCE COVERAGE; HEALTH
25 INSURANCE ISSUER.—The terms “health insurance

1 coverage” and “health insurance issuer” have the
2 meanings given such terms in section 2791 of the
3 Public Health Service Act.

4 (2) CURRENT SECTION 2745 QUALIFIED HIGH
5 RISK POOL.—The term “current section 2745 quali-
6 fied high risk pool” has the meaning given the term
7 “qualified high risk pool” under section 2745(g) of
8 the Public Health Service Act as in effect as of the
9 date of the enactment of this Act.

10 (3) SECRETARY.—The term “Secretary” means
11 Secretary of Health and Human Services.

12 (4) STANDARD RISK RATE.—The term “stand-
13 ard risk rate” means a rate that—

14 (A) is determined under the State high
15 risk pool by considering the premium rates
16 charged by other health insurance issuers offer-
17 ing health insurance coverage to individuals in
18 the insurance market served;

19 (B) is established using reasonable actu-
20 arial techniques; and

21 (C) reflects anticipated claims experience
22 and expenses for the coverage involved.

23 (5) STATE.—The term “State” means any of
24 the 50 States or the District of Columbia.

1 **SEC. 102. ELIMINATION OF CERTAIN REQUIREMENTS FOR**
2 **GUARANTEED AVAILABILITY IN INDIVIDUAL**
3 **MARKET.**

4 (a) IN GENERAL.—Section 2741(b) of the Public
5 Health Service Act (42 U.S.C. 300gg–41(b)) is amend-
6 ed—

7 (1) in paragraph (1)—

8 (A) by striking “(1)(A)” and inserting
9 “(1)”; and

10 (B) by striking “and (B)” and all that fol-
11 lows up to the semicolon at the end;

12 (2) by adding “and” at the end of paragraph
13 (2);

14 (3) in paragraph (3)—

15 (A) by striking “(1)(A)” and inserting
16 “(1)”; and

17 (B) by striking the semicolon at the end
18 and inserting a period; and

19 (4) by striking paragraphs (4) and (5).

20 (b) EFFECTIVE DATE.—The amendments made by
21 subsection (a) shall take effect on the date of the enact-
22 ment of this Act.

23 **SEC. 103. NO ANNUAL OR LIFETIME SPENDING CAPS.**

24 Notwithstanding any other provision of law, a health
25 insurance issuer (including an entity licensed to sell insur-
26 ance with respect to a State or group health plan) may

1 not apply an annual or lifetime aggregate spending cap
2 on any health insurance coverage or plan offered by such
3 issuer.

4 **SEC. 104. PREVENTING UNJUST CANCELLATION OF INSUR-**
5 **ANCE COVERAGE.**

6 (a) CLARIFICATION REGARDING APPLICATION OF
7 GUARANTEED RENEWABILITY OF INDIVIDUAL HEALTH
8 INSURANCE COVERAGE.—Section 2742 of the Public
9 Health Service Act (42 U.S.C. 300gg–42) is amended—

10 (1) in its heading, by inserting “, **CONTINU-**
11 **ATION IN FORCE, INCLUDING PROHIBITION OF**
12 **RESCISSION,”** after “**GUARANTEED RENEW-**
13 **ABILITY”**;

14 (2) in subsection (a), by inserting “, including
15 without rescission,” after “continue in force”; and

16 (3) in subsection (b)(2), by inserting before the
17 period at the end the following: “, including inten-
18 tional concealment of material facts regarding a
19 health condition related to the condition for which
20 coverage is being claimed”.

21 (b) OPPORTUNITY FOR INDEPENDENT, EXTERNAL
22 THIRD PARTY REVIEW IN CERTAIN CASES.—Subpart 1
23 of part B of title XXVII of the Public Health Service Act
24 is amended by adding at the end the following new section:

1 **“SEC. 2746. OPPORTUNITY FOR INDEPENDENT, EXTERNAL**
2 **THIRD PARTY REVIEW IN CERTAIN CASES.**

3 “(a) NOTICE AND REVIEW RIGHT.—If a health in-
4 surance issuer determines to nonrenew or not continue in
5 force, including rescind, health insurance coverage for an
6 individual in the individual market on the basis described
7 in section 2742(b)(2) before such nonrenewal, discontinu-
8 ation, or rescission, may take effect the issuer shall pro-
9 vide the individual with notice of such proposed non-
10 renewal, discontinuation, or rescission and an opportunity
11 for a review of such determination by an independent, ex-
12 ternal third party under procedures specified by the Sec-
13 retary.

14 “(b) INDEPENDENT DETERMINATION.—If the indi-
15 vidual requests such review by an independent, external
16 third party of a nonrenewal, discontinuation, or rescission
17 of health insurance coverage, the coverage shall remain in
18 effect until such third party determines that the coverage
19 may be nonrenewed, discontinued, or rescinded under sec-
20 tion 2742(b)(2).”.

21 (c) EFFECTIVE DATE.—The amendments made by
22 this section shall apply after the date of the enactment
23 of this Act with respect to health insurance coverage
24 issued before, on, or after such date.

1 **TITLE II—REDUCING HEALTH**
2 **CARE PREMIUMS AND THE**
3 **NUMBER OF UNINSURED**
4 **AMERICANS**

5 **SEC. 111. STATE INNOVATION PROGRAMS.**

6 (a) PROGRAMS THAT REDUCE THE COST OF
7 HEALTH INSURANCE PREMIUMS.—

8 (1) PAYMENTS TO STATES.—

9 (A) FOR PREMIUM REDUCTIONS IN THE
10 SMALL GROUP MARKET.—If the Secretary de-
11 termines that a State has reduced the average
12 per capita premium for health insurance cov-
13 erage in the small group market in year 3, in
14 year 6, or year 9 (as defined in subsection (c))
15 below the premium baseline for such year (as
16 defined paragraph (2)), the Secretary shall pay
17 the State an amount equal to the product of—

18 (i) bonus premium percentage (as de-
19 fined in paragraph (3)) for the State, mar-
20 ket, and year; and

21 (ii) the maximum State premium pay-
22 ment amount (as defined in paragraph (4))
23 for the State, market, and year

24 (B) FOR PREMIUM REDUCTIONS IN THE
25 INDIVIDUAL MARKET.—If the Secretary deter-

1 mines that a State has reduced the average per
2 capita premium for health insurance coverage
3 in the individual market in year 3, in year 6,
4 or in year 9 below the premium baseline for
5 such year, the Secretary shall pay the State an
6 amount equal to the product of—

7 (i) bonus premium percentage for the
8 State, market, and year; and

9 (ii) the maximum State premium pay-
10 ment amount for the State, market, and
11 year.

12 (2) PREMIUM BASELINE.—For purposes of this
13 subsection, the term “premium baseline” means, for
14 a market in a State—

15 (A) for year 1, the average per capita pre-
16 miums for health insurance coverage in such
17 market in the State in such year; or

18 (B) for a subsequent year, the baseline for
19 the market in the State for the previous year
20 under this paragraph increased by a percentage
21 specified in accordance with a formula estab-
22 lished by the Secretary, in consultation with the
23 Congressional Budget Office and the Bureau of
24 the Census, that takes into account at least the
25 following:

1 (i) GROWTH FACTOR.—The inflation
 2 in the costs of inputs to health care serv-
 3 ices in the year.

4 (ii) HISTORIC PREMIUM GROWTH
 5 RATES.—Historic growth rates, during the
 6 10 years before year 1, of per capita pre-
 7 miums for health insurance coverage.

8 (iii) DEMOGRAPHIC CONSIDER-
 9 ATIONS.—Historic average changes in the
 10 demographics of the population covered
 11 that impact on the rate of growth of per
 12 capita health care costs.

13 (3) BONUS PREMIUM PERCENTAGE DEFINED.—

14 (A) IN GENERAL.—For purposes of this
 15 subsection, the term “bonus premium percent-
 16 age” means, for the small group market or indi-
 17 vidual market in a State for a year, such per-
 18 centage as determined in accordance with the
 19 following table based on the State’s premium
 20 performance level (as defined in subparagraph

21 (B)) for such market and year:

The bonus premium percentage for a State is—	For year 3 if the premium performance level of the State is—	For year 6 if the premium performance level of the State is—	For year 9 if the premium performance level of the State is—
100 percent	at least 8.5%	at least 11%	at least 13.5%

The bonus premium percentage for a State is—	For year 3 if the premium performance level of the State is—	For year 6 if the premium performance level of the State is—	For year 9 if the premium performance level of the State is—
50 percent	at least 6.38%, but less than 8.5%	at least 10.38%, but less than 11%	at least 12.88%, but less than 13.5%
25 percent	at least 4.25%, but less than 6.38%	at least 9.75%, but less than 10.38%	at least 12.25%, but less than 12.88%
0 percent	less than 4.25%	less than 9.75%	less than 12.25%

1 (B) PREMIUM PERFORMANCE LEVEL.—For
2 purposes of this subsection, the term “premium
3 performance level” means, for a State, market,
4 and year, the percentage reduction in the aver-
5 age per capita premiums for health insurance
6 coverage for the State, market, and year, as
7 compared to the premium baseline for such
8 State, market, and year.

9 (4) MAXIMUM STATE PREMIUM PAYMENT
10 AMOUNT DEFINED.—For purposes of this sub-
11 section, the term “maximum State premium pay-
12 ment amount” means, for a State for the small
13 group market or the individual market for a year,
14 the product of—

15 (A) the proportion (as determined by the
16 Secretary), of the number of nonelderly individ-
17 uals lawfully residing in all the States who are
18 enrolled in health insurance coverage in the re-

1 spective market in the year, who are residents
2 of the State; and

3 (B) the amount available for obligation
4 from amounts appropriated under subsection
5 (d) for such market with respect to perform-
6 ance in such year.

7 (5) METHODOLOGY FOR CALCULATING AVER-
8 AGE PER CAPITA PREMIUMS.—

9 (A) ESTABLISHMENT.—The Secretary
10 shall establish, by rule and consistent with this
11 subsection, a methodology for computing the
12 average per capita premiums for health insur-
13 ance coverage for the small group market and
14 for the individual market in each State for each
15 year beginning with year 1.

16 (B) ADJUSTMENTS.—Under such method-
17 ology, the Secretary shall provide for the fol-
18 lowing adjustments (in a manner determined
19 appropriate by the Secretary):

20 (i) EXCLUSION OF ILLEGAL ALIENS.—

21 An adjustment so as not to take into ac-
22 count enrollees who are not lawfully
23 present in the United States and their pre-
24 mium costs.

1 (ii) TREATING STATE PREMIUM SUB-
2 SIDIES AS PREMIUM COSTS.—An adjust-
3 ment so as to increase per capita pre-
4 miums to remove the impact of premium
5 subsidies made directly by a State to re-
6 duce health insurance premiums.

7 (6) CONDITIONS OF PAYMENT.—As a condition
8 of receiving a payment under paragraph (1), a State
9 must agree to submit aggregate, non-individually
10 identifiable data to the Secretary, in a form and
11 manner specified by the Secretary, for use by the
12 Secretary to determine the State's premium baseline
13 and premium performance level for purposes of this
14 subsection.

15 (b) PROGRAMS THAT REDUCE THE NUMBER OF UN-
16 INSURED.—

17 (1) IN GENERAL.—If the Secretary determines
18 that a State has reduced the percentage of unin-
19 sured nonelderly residents in year 5, year 7, or year
20 9, below the uninsured baseline (as defined in para-
21 graph (2)) for the State for the year, the Secretary
22 shall pay the State an amount equal to the product
23 of—

1 (A) bonus uninsured percentage (as de-
2 fined in paragraph (3)) for the State and year;
3 and

4 (B) the maximum uninsured payment
5 amount (as defined in paragraph (4)) for the
6 State and year.

7 (2) UNINSURED BASELINE.—

8 (A) IN GENERAL.—For purposes of this
9 subsection, and subject to subparagraph (B),
10 the term “uninsured baseline” means, for a
11 State, the percentage of nonelderly residents in
12 the State who are uninsured in year 1.

13 (B) ADJUSTMENT.—The Secretary may, at
14 the written request of a State, adjust the unin-
15 sured baseline for States for a year to take into
16 account unanticipated and exceptional changes,
17 such as an unanticipated migration, of non-
18 elderly individuals into, or out of, States in a
19 manner that does not reflect substantially the
20 proportion of uninsured nonelderly residents in
21 the States involved in year 1. Any such adjust-
22 ment shall only be done in a manner that does
23 not result in the average of the uninsured base-
24 lines for nonelderly residents for all States
25 being changed.

1 (3) BONUS UNINSURED PERCENTAGE.—

2 (A) BONUS UNINSURED PERCENTAGE.—

3 For purposes of this subsection, the term
 4 “bonus uninsured percentage” means, for a
 5 State for a year, such percentage as determined
 6 in accordance with the following table, based on
 7 the uninsured performance level (as defined in
 8 subparagraph (B)) for such State and year:

The bonus uninsured percentage for a State is—	For year 5 if the uninsured performance level of the State is—	For year 7 if the uninsured performance level of the State is—	For year 9 if the uninsured performance level of the State is—
100 percent	at least 10%	at least 15%	at least 20%
50 percent	at least 7.5% but less than 10%	at least 13.75% but less than 15%	at least 18.75% but less than 20%
25 percent	at least 5% but less than 7.5%	at least 12.5% but less than 13.75%	at least 17.5% but less than 18.75%
0 percent	less than 5%	less than 12.5%	less than 17.5%

9 (B) UNINSURED PERFORMANCE LEVEL.—

10 For purposes of this subsection, the term “un-
 11 insured performance level” means, for a State
 12 for a year, the reduction (expressed as a per-
 13 centage) in the percentage of uninsured non-
 14 elderly residents in such State in the year as
 15 compared to the uninsured baseline for such
 16 State for such year.

17 (4) MAXIMUM STATE UNINSURED PAYMENT
 18 AMOUNT DEFINED.—For purposes of this sub-

1 section, the term “maximum State uninsured pay-
2 ment amount” means, for a State for a year, the
3 product of—

4 (A) the proportion (as determined by the
5 Secretary), of the number of uninsured non-
6 elderly individuals lawfully residing in all the
7 States in the year, who are residents of the
8 State; and

9 (B) the amount available for obligation
10 under this subsection from amounts appro-
11 priated under subsection (d) with respect to
12 performance in such year.

13 (5) METHODOLOGY FOR COMPUTING THE PER-
14 CENTAGE OF UNINSURED NONELDERLY RESIDENTS
15 IN A STATE.—

16 (A) ESTABLISHMENT.—The Secretary
17 shall establish, by rule and consistent with this
18 subsection, a methodology for computing the
19 percentage of nonelderly residents in a State
20 who are uninsured in each year beginning with
21 year 1.

22 (B) RULES.—

23 (i) TREATMENT OF UNINSURED.—
24 Such methodology shall treat as uninsured
25 those residents who do not have health in-

1 surance coverage or other creditable cov-
2 erage (as defined in section 9801(c)(1) of
3 the Internal Revenue Code of 1986), ex-
4 cept that such methodology shall rely upon
5 data on the nonelderly and uninsured pop-
6 ulations within each State in such year
7 provided through population surveys con-
8 ducted by federal agencies.

9 (ii) LIMITATION TO NONELDERLY.—
10 Such methodology shall exclude individuals
11 who are 65 years of age or older.

12 (iii) EXCLUSION OF ILLEGAL
13 ALIENS.—Such methodology shall exclude
14 individuals not lawfully present in the
15 United States.

16 (6) CONDITIONS OF PAYMENT.—As a condition
17 of receiving a payment under paragraph (1), a State
18 must agree to submit aggregate, non-individually
19 identifiable data to the Secretary, in a form and
20 manner specified by the Secretary, for use by the
21 Secretary in determining the State's uninsured base-
22 line and uninsured performance level for purposes of
23 this subsection.

24 (c) DEFINITIONS.—For purposes of this section:

1 (1) GROUP HEALTH PLAN.—The term “group
2 health plan” has the meaning given such term in
3 section 9832(a) of the Internal Revenue Code of
4 1986.

5 (2) HEALTH INSURANCE COVERAGE.—The term
6 “health insurance coverage” has the meaning given
7 such term in section 9832(b)(1) of the Internal Rev-
8 enue Code of 1986.

9 (3) INDIVIDUAL MARKET.—Except as the Sec-
10 retary may otherwise provide in the case of group
11 health plans that have fewer than 2 participants as
12 current employees on the first day of a plan year,
13 the term “individual market” means the market for
14 health insurance coverage offered to individuals
15 other than in connection with a group health plan.

16 (4) SECRETARY.—The term “Secretary” means
17 the Secretary of Health and Human Services.

18 (5) SMALL GROUP MARKET.—The term “small
19 group market” means the market for health insur-
20 ance coverage under which individuals obtain health
21 insurance coverage (directly or through any arrange-
22 ment) on behalf of themselves (and their depend-
23 ents) through a group health plan maintained by an
24 employer who employed on average at least 2 but

1 not more than 50 employees on business days during
2 a calendar year.

3 (6) STATE.—The term “State” means any of
4 the 50 States and the District of Columbia.

5 (7) YEARS.—The terms “year 1”, “year 2”,
6 “year 3”, and similar subsequently numbered years
7 mean 2010, 2011, 2012, and subsequent sequen-
8 tially numbered years.

9 (d) APPROPRIATIONS; PAYMENTS.—

10 (1) PAYMENTS FOR REDUCTIONS IN COST OF
11 HEALTH INSURANCE COVERAGE.—

12 (A) SMALL GROUP MARKET.—

13 (i) IN GENERAL.—From any funds in
14 the Treasury not otherwise appropriated,
15 there is appropriated for payments under
16 subsection (a)(1)(A)—

17 (I) \$18,000,000,000 with respect
18 to performance in year 3;

19 (II) \$5,000,000,000 with respect
20 to performance in year 6; and

21 (III) \$2,000,000,000 with re-
22 spect to performance in year 9.

23 (ii) AVAILABILITY OF APPROPRIATED
24 FUNDS.—Funds appropriated under clause

25 (i) shall remain available until expended.

1 (B) INDIVIDUAL MARKET.—

2 (i) IN GENERAL.—Subject to clause
3 (ii), from any funds in the Treasury not
4 otherwise appropriated, there is appro-
5 priated for payments under subsection
6 (a)(1)(B)—

7 (I) \$7,000,000,000 with respect
8 to performance in year 3;

9 (II) \$2,000,000,000 with respect
10 to performance in year 6; and

11 (III) \$1,000,000,000 with re-
12 spect to performance in year 9.

13 (ii) AVAILABILITY OF APPROPRIATED
14 FUNDS.—Of the funds appropriated under
15 clause (i) that are not expended or obli-
16 gated by the end of the year following the
17 year for which the funds are appro-
18 priated—

19 (I) 75 percent shall remain avail-
20 able until expended for payments
21 under subsection (a)(1)(B); and

22 (II) 25 percent shall remain
23 available until expended for payments
24 under subsection (a)(1)(A).

1 (2) PAYMENTS FOR REDUCTIONS IN THE PER-
2 CENTAGE OF UNINSURED.—

3 (A) IN GENERAL.—From any funds in the
4 Treasury not otherwise appropriated, there is
5 appropriated for payments under subsection
6 (b)(1)—

7 (i) \$10,000,000,000 with respect to
8 performance in year 5;

9 (ii) \$3,000,000,000 with respect to
10 performance in year 7; and

11 (iii) \$2,000,000,000 with respect to
12 performance in year 9

13 (B) AVAILABILITY OF APPROPRIATED
14 FUNDS.—Funds appropriated under subpara-
15 graph (A) shall remain available until expended.

16 (3) PAYMENT TIMING.—Payments under this
17 section shall be made in a form and manner speci-
18 fied by the Secretary in the year after the perform-
19 ance year involved.

20 **SEC. 112. HEALTH PLAN FINDERS.**

21 (a) STATE PLAN FINDERS.—Not later than 12
22 months after the date of the enactment of this Act, each
23 State may contract with a private entity to develop and
24 operate a plan finder website (referred to in this section
25 as a “State plan finder”) which shall provide information

1 to individuals in such State on plans of health insurance
2 coverage that are available to individuals in such State (in
3 this section referred to as a “health insurance plan”) .
4 Such State may not operate a plan finder itself.

5 (b) MULTI-STATE PLAN FINDERS.—

6 (1) IN GENERAL.—A private entity may operate
7 a multi-State finder that operates under this section
8 in the States involved in the same manner as a State
9 plan finder would operate in a single State.

10 (2) SHARING OF INFORMATION.—States shall
11 regulate the manner in which data is shared between
12 plan finders to ensure consistency and accuracy in
13 the information about health insurance plans con-
14 tained in such finders.

15 (c) REQUIREMENTS FOR PLAN FINDERS.—Each plan
16 finder shall meet the following requirements:

17 (1) The plan finder shall ensure that each
18 health insurance plan in the plan finder meets the
19 requirements for such plans under subsection (d).

20 (2) The plan finder shall present complete in-
21 formation on the costs and benefits of health insur-
22 ance plans (including information on monthly pre-
23 mium, copayments, and deductibles) in a uniform
24 manner that—

1 (A) uses the standard definitions developed
2 under paragraph (3); and

3 (B) is designed to allow consumers to eas-
4 ily compare such plans.

5 (3) The plan finder shall be available on the
6 internet and accessible to all individuals in the State
7 or, in the case of a multi-State plan finder, in all
8 States covered by the multi-State plan finder.

9 (4) The plan finder shall allow consumers to
10 search and sort data on the health insurance plans
11 in the plan finder on criteria such as coverage of
12 specific benefits (such as coverage of disease man-
13 agement services or pediatric care services), as well
14 as data available on quality.

15 (5) The plan finder shall meet all relevant State
16 laws and regulations, including laws and regulations
17 related to the marketing of insurance products. In
18 the case of a multi-State plan finder, the finder shall
19 meet such laws and regulations for all of the States
20 involved.

21 (6) The plan finder shall meet solvency, finan-
22 cial, and privacy requirements established by the
23 State or States in which the plan finder operates or
24 the Secretary for multi-State finders.

1 (7) The plan finder and the employees of the
2 plan finder shall be appropriately licensed in the
3 State or States in which the plan finder operates, if
4 such licensure is required by such State or States.

5 (8) Notwithstanding subsection (f)(1), the plan
6 finder shall assist individuals who are eligible for the
7 Medicaid program under title XIX of the Social Se-
8 curity Act or State Children's Health Insurance Pro-
9 gram under title XXI of such Act by including infor-
10 mation on Medicaid options, eligibility, and how to
11 enroll.

12 (d) REQUIREMENTS FOR PLANS PARTICIPATING IN
13 A PLAN FINDER.—

14 (1) IN GENERAL.—Each State shall ensure that
15 health insurance plans participating in the State
16 plan finder or in a multi-State plan finder meet the
17 requirements of paragraph (2) (relating to adequacy
18 of insurance coverage, consumer protection, and fi-
19 nancial strength).

20 (2) SPECIFIC REQUIREMENTS.—In order to
21 participate in a plan finder, a health insurance plan
22 must meet all of the following requirements, as de-
23 termined by each State in which such plan operates:

24 (A) The health insurance plan shall be ac-
25 tuarially sound.

1 (B) The health insurance plan may not
2 have a history of abusive policy rescissions.

3 (C) The health insurance plan shall meet
4 financial and solvency requirements.

5 (D) The health insurance plan shall dis-
6 close—

7 (i) all financial arrangements involv-
8 ing the sale and purchase of health insur-
9 ance, such as the payment of fees and
10 commissions; and

11 (ii) such arrangements may not be
12 abusive.

13 (E) The health insurance plan shall main-
14 tain electronic health records that comply with
15 the requirements of the American Recovery and
16 Reinvestment Act of 2009 (Public Law 111–5)
17 related to electronic health records.

18 (F) The health insurance plan shall make
19 available to plan enrollees via the finder, wheth-
20 er by information provided to the finder or by
21 a website link directing the enrollee from the
22 finder to the health insurance plan website,
23 data that includes the price and cost to the in-
24 dividual of services offered by a provider ac-
25 cording to the terms and conditions of the

1 health plan. Data described in this paragraph is
2 not made public by the finder, only made avail-
3 able to the individual once enrolled in the
4 health plan.

5 (e) PROHIBITIONS.—

6 (1) DIRECT ENROLLMENT.—The State plan
7 finder may not directly enroll individuals in health
8 insurance plans.

9 (2) CONFLICTS OF INTEREST.—

10 (A) COMPANIES.—A health insurance
11 issuer offering a health insurance plan through
12 a plan finder may not—

13 (i) be the private entity developing
14 and maintaining a plan finder under sub-
15 sections (a) and (b); or

16 (ii) have an ownership interest in such
17 private entity or in the plan finder.

18 (B) INDIVIDUALS.—An individual em-
19 ployed by a health insurance issuer offering a
20 health insurance plan through a plan finder
21 may not serve as a director or officer for—

22 (i) the private entity developing and
23 maintaining a plan finder under sub-
24 sections (a) and (b); or

25 (ii) the plan finder.

1 (f) CONSTRUCTION.—Nothing in this section shall be
2 construed to allow the Secretary authority to regulate ben-
3 efit packages or to prohibit health insurance brokers and
4 agents from—

5 (1) utilizing the plan finder for any purpose; or

6 (2) marketing or offering health insurance
7 products.

8 (g) PLAN FINDER DEFINED.—For purposes of this
9 section, the term “plan finder” means a State plan finder
10 under subsection (a) or a multi-State plan finder under
11 subsection (b).

12 (h) STATE DEFINED.—In this section, the term
13 “State” has the meaning given such term for purposes of
14 title XIX of the Social Security Act.

15 **SEC. 113. ADMINISTRATIVE SIMPLIFICATION.**

16 (a) OPERATING RULES FOR HEALTH INFORMATION
17 TRANSACTIONS.—

18 (1) DEFINITION OF OPERATING RULES.—Sec-
19 tion 1171 of the Social Security Act (42 U.S.C.
20 1320d) is amended by adding at the end the fol-
21 lowing:

22 “(9) OPERATING RULES.—The term ‘operating
23 rules’ means the necessary business rules and guide-
24 lines for the electronic exchange of information that

1 are not defined by a standard or its implementation
2 specifications as adopted for purposes of this part.”.

3 (2) OPERATING RULES AND COMPLIANCE.—

4 Section 1173 of the Social Security Act (42 U.S.C.
5 1320d–2) is amended—

6 (A) in subsection (a)(2), by adding at the
7 end the following new subparagraph:

8 “(J) Electronic funds transfers.”; and

9 (B) by adding at the end the following new
10 subsections:

11 “(g) OPERATING RULES.—

12 “(1) IN GENERAL.—The Secretary shall adopt
13 a single set of operating rules for each transaction
14 described in subsection (a)(2) with the goal of cre-
15 ating as much uniformity in the implementation of
16 the electronic standards as possible. Such operating
17 rules shall be consensus-based and reflect the nec-
18 essary business rules affecting health plans and
19 health care providers and the manner in which they
20 operate pursuant to standards issued under Health
21 Insurance Portability and Accountability Act of
22 1996.

23 “(2) OPERATING RULES DEVELOPMENT.—In
24 adopting operating rules under this subsection, the
25 Secretary shall rely on recommendations for oper-

1 ating rules developed by a qualified nonprofit entity,
2 as selected by the Secretary, that meets the fol-
3 lowing requirements:

4 “(A) The entity focuses its mission on ad-
5 ministrative simplification.

6 “(B) The entity demonstrates an estab-
7 lished multi-stakeholder and consensus-based
8 process for development of operating rules, in-
9 cluding representation by or participation from
10 health plans, health care providers, vendors, rel-
11 evant Federal agencies, and other standard de-
12 velopment organizations.

13 “(C) The entity has established a public
14 set of guiding principles that ensure the oper-
15 ating rules and process are open and trans-
16 parent.

17 “(D) The entity coordinates its activities
18 with the HIT Policy Committee and the HIT
19 Standards Committee (as established under
20 title XXX of the Public Health Service Act)
21 and complements the efforts of the Office of the
22 National Healthcare Coordinator and its related
23 health information exchange goals.

24 “(E) The entity incorporates national
25 standards, including the transaction standards

1 issued under Health Insurance Portability and
2 Accountability Act of 1996.

3 “(F) The entity supports nondiscrimina-
4 tion and conflict of interest policies that dem-
5 onstrate a commitment to open, fair, and non-
6 discriminatory practices.

7 “(G) The entity allows for public review
8 and updates of the operating rules.

9 “(3) REVIEW AND RECOMMENDATIONS.—The
10 National Committee on Vital and Health Statistics
11 shall—

12 “(A) review the operating rules developed
13 by a nonprofit entity described under paragraph
14 (2);

15 “(B) determine whether such rules rep-
16 resent a consensus view of the health care in-
17 dustry and are consistent with and do not alter
18 current standards;

19 “(C) evaluate whether such rules are con-
20 sistent with electronic standards adopted for
21 health information technology; and

22 “(D) submit to the Secretary a rec-
23 ommendation as to whether the Secretary
24 should adopt such rules.

25 “(4) IMPLEMENTATION.—

1 “(A) IN GENERAL.—The Secretary shall
2 adopt operating rules under this subsection, by
3 regulation in accordance with subparagraph
4 (C), following consideration of the rules devel-
5 oped by the non-profit entity described in para-
6 graph (2) and the recommendation submitted
7 by the National Committee on Vital and Health
8 Statistics under paragraph (3)(D) and having
9 ensured consultation with providers.

10 “(B) ADOPTION REQUIREMENTS; EFFEC-
11 TIVE DATES.—

12 “(i) ELIGIBILITY FOR A HEALTH
13 PLAN AND HEALTH CLAIM STATUS.—The
14 set of operating rules for transactions for
15 eligibility for a health plan and health
16 claim status shall be adopted not later
17 than July 1, 2011, in a manner ensuring
18 that such rules are effective not later than
19 January 1, 2013, and may allow for the
20 use of a machine readable identification
21 card.

22 “(ii) ELECTRONIC FUNDS TRANSFERS
23 AND HEALTH CARE PAYMENT AND REMIT-
24 TANCE ADVICE.—The set of operating
25 rules for electronic funds transfers and

1 health care payment and remittance advice
2 shall be adopted not later than July 1,
3 2012, in a manner ensuring that such
4 rules are effective not later than January
5 1, 2014.

6 “(iii) OTHER COMPLETED TRANS-
7 ACTIONS.—The set of operating rules for
8 the remainder of the completed trans-
9 actions described in subsection (a)(2), in-
10 cluding health claims or equivalent encoun-
11 ter information, enrollment and
12 disenrollment in a health plan, health plan
13 premium payments, and referral certifi-
14 cation and authorization, shall be adopted
15 not later than July 1, 2014, in a manner
16 ensuring that such rules are effective not
17 later than January 1, 2016.

18 “(C) EXPEDITED RULEMAKING.—The Sec-
19 retary shall promulgate an interim final rule
20 applying any standard or operating rule rec-
21 ommended by the National Committee on Vital
22 and Health Statistics pursuant to paragraph
23 (3). The Secretary shall accept public comments
24 on any interim final rule published under this

1 subparagraph for 60 days after the date of such
2 publication.

3 “(h) COMPLIANCE.—

4 “(1) HEALTH PLAN CERTIFICATION.—

5 “(A) ELIGIBILITY FOR A HEALTH PLAN,
6 HEALTH CLAIM STATUS, ELECTRONIC FUNDS
7 TRANSFERS, HEALTH CARE PAYMENT AND RE-
8 MITTANCE ADVICE.—Not later than December
9 31, 2013, a health plan shall file a statement
10 with the Secretary, in such form as the Sec-
11 retary may require, certifying that the data and
12 information systems for such plan are in com-
13 pliance with any applicable standards (as de-
14 scribed under paragraph (7) of section 1171)
15 and operating rules (as described under para-
16 graph (9) of such section) for electronic funds
17 transfers, eligibility for a health plan, health
18 claim status, and health care payment and re-
19 mittance advice, respectively.

20 “(B) OTHER COMPLETED TRANS-
21 ACTIONS.—Not later than December 31, 2015,
22 a health plan shall file a statement with the
23 Secretary, in such form as the Secretary may
24 require, certifying that the data and informa-
25 tion systems for such plan are in compliance

1 with any applicable standards and operating
2 rules for the remainder of the completed trans-
3 actions described in subsection (a)(2), including
4 health claims or equivalent encounter informa-
5 tion, enrollment and disenrollment in a health
6 plan, health plan premium payments, and refer-
7 ral certification and authorization, respectively.
8 A health plan shall provide the same level of
9 documentation to certify compliance with such
10 transactions as is required to certify compliance
11 with the transactions specified in subparagraph
12 (A).

13 “(2) DOCUMENTATION OF COMPLIANCE.—A
14 health plan shall provide the Secretary, in such form
15 as the Secretary may require, with adequate docu-
16 mentation of compliance with the standards and op-
17 erating rules described under paragraph (1). A
18 health plan shall not be considered to have provided
19 adequate documentation and shall not be certified as
20 being in compliance with such standards, unless the
21 health plan—

22 “(A) demonstrates to the Secretary that
23 the plan conducts the electronic transactions
24 specified in paragraph (1) in a manner that

1 fully complies with the regulations of the Sec-
2 retary; and

3 “(B) provides documentation showing that
4 the plan has completed end-to-end testing for
5 such transactions with their partners, such as
6 hospitals and physicians.

7 “(3) SERVICE CONTRACTS.—A health plan shall
8 be required to comply with any applicable certifi-
9 cation and compliance requirements (and provide the
10 Secretary with adequate documentation of such com-
11 pliance) under this subsection for any entities that
12 provide services pursuant to a contract with such
13 health plan.

14 “(4) CERTIFICATION BY OUTSIDE ENTITY.—
15 The Secretary may contract with an independent,
16 outside entity to certify that a health plan has com-
17 plied with the requirements under this subsection,
18 provided that the certification standards employed
19 by such entities are in accordance with any stand-
20 ards or rules issued by the Secretary.

21 “(5) COMPLIANCE WITH REVISED STANDARDS
22 AND RULES.—A health plan (including entities de-
23 scribed under paragraph (3)) shall comply with the
24 certification and documentation requirements under
25 this subsection for any interim final rule promul-

1 gated by the Secretary under subsection (i) that
2 amends any standard or operating rule described
3 under paragraph (1) of this subsection. A health
4 plan shall comply with such requirements not later
5 than the effective date of the applicable interim final
6 rule.

7 “(6) AUDITS OF HEALTH PLANS.—The Sec-
8 retary shall conduct periodic audits to ensure that
9 health plans (including entities described under
10 paragraph (3)) are in compliance with any standards
11 and operating rules that are described under para-
12 graph (1).

13 “(i) REVIEW AND AMENDMENT OF STANDARDS AND
14 RULES.—

15 “(1) ESTABLISHMENT.—Not later than Janu-
16 ary 1, 2014, the Secretary shall establish a review
17 committee (as described under paragraph (4)).

18 “(2) EVALUATIONS AND REPORTS.—

19 “(A) HEARINGS.—Not later than April 1,
20 2014, and not less than biennially thereafter,
21 the Secretary, acting through the review com-
22 mittee, shall conduct hearings to evaluate and
23 review the existing standards and operating
24 rules established under this section.

1 “(B) REPORT.—Not later than July 1,
2 2014, and not less than biennially thereafter,
3 the review committee shall provide rec-
4 ommendations for updating and improving such
5 standards and rules. The review committee
6 shall recommend a single set of operating rules
7 per transaction standard and maintain the goal
8 of creating as much uniformity as possible in
9 the implementation of the electronic standards.

10 “(3) INTERIM FINAL RULEMAKING.—

11 “(A) IN GENERAL.—Any recommendations
12 to amend existing standards and operating
13 rules that have been approved by the review
14 committee and reported to the Secretary under
15 paragraph (2)(B) shall be adopted by the Sec-
16 retary through promulgation of an interim final
17 rule not later than 90 days after receipt of the
18 committee’s report.

19 “(B) PUBLIC COMMENT.—

20 “(i) PUBLIC COMMENT PERIOD.—The
21 Secretary shall accept public comments on
22 any interim final rule published under this
23 paragraph for 60 days after the date of
24 such publication.

1 “(ii) EFFECTIVE DATE.—The effective
2 date of any amendment to existing stand-
3 ards or operating rules that is adopted
4 through an interim final rule published
5 under this paragraph shall be 25 months
6 following the close of such public comment
7 period.

8 “(4) REVIEW COMMITTEE.—

9 “(A) DEFINITION.—For the purposes of
10 this subsection, the term ‘review committee’
11 means a committee within the Department of
12 Health and Human services that has been des-
13 ignated by the Secretary to carry out this sub-
14 section, including—

15 “(i) the National Committee on Vital
16 and Health Statistics; or

17 “(ii) any appropriate committee as de-
18 termined by the Secretary.

19 “(B) COORDINATION OF HIT STAND-
20 ARDS.—In developing recommendations under
21 this subsection, the review committee shall con-
22 sider the standards approved by the Office of
23 the National Coordinator for Health Informa-
24 tion Technology.

25 “(j) PENALTIES.—

1 “(1) PENALTY FEE.—

2 “(A) IN GENERAL.—Not later than April
3 1, 2014, and annually thereafter, the Secretary
4 shall assess a penalty fee (as determined under
5 subparagraph (B)) against a health plan that
6 has failed to meet the requirements under sub-
7 section (h) with respect to certification and docu-
8 mentation of compliance with the standards
9 (and their operating rules) as described under
10 paragraph (1) of such subsection.

11 “(B) FEE AMOUNT.—Subject to subpara-
12 graphs (C), (D), and (E), the Secretary shall
13 assess a penalty fee against a health plan in the
14 amount of \$1 per covered life until certification
15 is complete. The penalty shall be assessed per
16 person covered by the plan for which its data
17 systems for major medical policies are not in
18 compliance and shall be imposed against the
19 health plan for each day that the plan is not in
20 compliance with the requirements under sub-
21 section (h).

22 “(C) ADDITIONAL PENALTY FOR MIS-
23 REPRESENTATION.—A health plan that know-
24 ingly provides inaccurate or incomplete informa-
25 tion in a statement of certification or docu-

1 mentation of compliance under subsection (h)
2 shall be subject to a penalty fee that is double
3 the amount that would otherwise be imposed
4 under this subsection.

5 “(D) ANNUAL FEE INCREASE.—The
6 amount of the penalty fee imposed under this
7 subsection shall be increased on an annual basis
8 by the annual percentage increase in total na-
9 tional health care expenditures, as determined
10 by the Secretary.

11 “(E) PENALTY LIMIT.—A penalty fee as-
12 sessed against a health plan under this sub-
13 section shall not exceed, on an annual basis—

14 “(i) an amount equal to \$20 per cov-
15 ered life under such plan; or

16 “(ii) an amount equal to \$40 per cov-
17 ered life under the plan if such plan has
18 knowingly provided inaccurate or incom-
19 plete information (as described under sub-
20 paragraph (C)).

21 “(F) DETERMINATION OF COVERED INDI-
22 VIDUALS.—The Secretary shall determine the
23 number of covered lives under a health plan
24 based upon the most recent statements and fil-

1 ings that have been submitted by such plan to
2 the Securities and Exchange Commission.

3 “(2) NOTICE AND DISPUTE PROCEDURE.—The
4 Secretary shall establish a procedure for assessment
5 of penalty fees under this subsection that provides a
6 health plan with reasonable notice and a dispute res-
7 olution procedure prior to provision of a notice of as-
8 sessment by the Secretary of the Treasury (as de-
9 scribed under paragraph (4)(B)).

10 “(3) PENALTY FEE REPORT.—Not later than
11 May 1, 2014, and annually thereafter, the Secretary
12 shall provide the Secretary of the Treasury with a
13 report identifying those health plans that have been
14 assessed a penalty fee under this subsection.

15 “(4) COLLECTION OF PENALTY FEE.—

16 “(A) IN GENERAL.—The Secretary of the
17 Treasury, acting through the Financial Man-
18 agement Service, shall administer the collection
19 of penalty fees from health plans that have been
20 identified by the Secretary in the penalty fee re-
21 port provided under paragraph (3).

22 “(B) NOTICE.—Not later than August 1,
23 2014, and annually thereafter, the Secretary of
24 the Treasury shall provide notice to each health
25 plan that has been assessed a penalty fee by the

1 Secretary under this subsection. Such notice
2 shall include the amount of the penalty fee as-
3 sessed by the Secretary and the due date for
4 payment of such fee to the Secretary of the
5 Treasury (as described in subparagraph (C)).

6 “(C) PAYMENT DUE DATE.—Payment by a
7 health plan for a penalty fee assessed under
8 this subsection shall be made to the Secretary
9 of the Treasury not later than November 1,
10 2014, and annually thereafter.

11 “(D) UNPAID PENALTY FEES.—Any
12 amount of a penalty fee assessed against a
13 health plan under this subsection for which pay-
14 ment has not been made by the due date pro-
15 vided under subparagraph (C) shall be—

16 “(i) increased by the interest accrued
17 on such amount, as determined pursuant
18 to the underpayment rate established
19 under section 6601 of the Internal Rev-
20 enue Code of 1986; and

21 “(ii) treated as a past-due, legally en-
22 forceable debt owed to a Federal agency
23 for purposes of section 6402(d) of the In-
24 ternal Revenue Code of 1986.

1 “(E) ADMINISTRATIVE FEES.—Any fee
2 charged or allocated for collection activities con-
3 ducted by the Financial Management Service
4 will be passed on to a health plan on a pro-rata
5 basis and added to any penalty fee collected
6 from the plan.”.

7 (b) PROMULGATION OF RULES.—

8 (1) UNIQUE HEALTH PLAN IDENTIFIER.—The
9 Secretary shall promulgate a final rule to establish
10 a unique health plan identifier (as described in sec-
11 tion 1173(b) of the Social Security Act (42 U.S.C.
12 1320d-2(b))) based on the input of the National
13 Committee of Vital and Health Statistics. The Sec-
14 retary may do so on an interim final basis and such
15 rule shall be effective not later than October 1,
16 2012.

17 (2) ELECTRONIC FUNDS TRANSFER.—The Sec-
18 retary shall promulgate a final rule to establish a
19 standard for electronic funds transfers (as described
20 in section 1173(a)(2)(J) of the Social Security Act,
21 as added by subsection (a)(2)(A)). The Secretary
22 may do so on an interim final basis and shall adopt
23 such standard not later than January 1, 2012, in a
24 manner ensuring that such standard is effective not
25 later than January 1, 2014.

1 (c) EXPANSION OF ELECTRONIC TRANSACTIONS IN
2 MEDICARE.—Section 1862(a) of the Social Security Act
3 (42 U.S.C. 1395y(a)) is amended—

4 (1) in paragraph (23), by striking the “or” at
5 the end;

6 (2) in paragraph (24), by striking the period
7 and inserting “; or”; and

8 (3) by inserting after paragraph (24) the fol-
9 lowing new paragraph:

10 “(25) not later than January 1, 2014, for
11 which the payment is other than by electronic funds
12 transfer (EFT) or an electronic remittance in a form
13 as specified in ASC X12 835 Health Care Payment
14 and Remittance Advice or subsequent standard.”.

15 (d) MEDICARE AND MEDICAID COMPLIANCE RE-
16 PORTS.—Not later than July 1, 2013, the Secretary of
17 Health and Human Services shall submit a report to the
18 Chairs and Ranking Members of the Committee on Ways
19 and Means and the Committee on Energy and Commerce
20 of the House of Representatives and the Chairs and Rank-
21 ing Members of the Committee on Health, Education,
22 Labor, and Pensions and the Committee on Finance of
23 the Senate on the extent to which the Medicare program
24 and providers that serve beneficiaries under that program,
25 and State Medicaid programs and providers that serve

1 beneficiaries under those programs, transact electronically
2 in accordance with transaction standards issued under the
3 Health Insurance Portability and Accountability Act of
4 1996, part C of title XI of the Social Security Act, and
5 regulations promulgated under such Acts.

6 **DIVISION B—IMPROVING**
7 **ACCESS TO HEALTH CARE**
8 **TITLE I—EXPANDING ACCESS**
9 **AND LOWERING COSTS FOR**
10 **SMALL BUSINESSES**

11 **SEC. 201. RULES GOVERNING ASSOCIATION HEALTH**
12 **PLANS.**

13 (a) IN GENERAL.—Subtitle B of title I of the Em-
14 ployee Retirement Income Security Act of 1974 is amend-
15 ed by adding after part 7 the following new part:

16 **“PART 8—RULES GOVERNING ASSOCIATION**
17 **HEALTH PLANS**

18 **“SEC. 801. ASSOCIATION HEALTH PLANS.**

19 “(a) IN GENERAL.—For purposes of this part, the
20 term ‘association health plan’ means a group health plan
21 whose sponsor is (or is deemed under this part to be) de-
22 scribed in subsection (b).

23 “(b) SPONSORSHIP.—The sponsor of a group health
24 plan is described in this subsection if such sponsor—

1 “(1) is organized and maintained in good faith,
2 with a constitution and bylaws specifically stating its
3 purpose and providing for periodic meetings on at
4 least an annual basis, as a bona fide trade associa-
5 tion, a bona fide industry association (including a
6 rural electric cooperative association or a rural tele-
7 phone cooperative association), a bona fide profes-
8 sional association, or a bona fide chamber of com-
9 merce (or similar bona fide business association, in-
10 cluding a corporation or similar organization that
11 operates on a cooperative basis (within the meaning
12 of section 1381 of the Internal Revenue Code of
13 1986)), for substantial purposes other than that of
14 obtaining or providing medical care;

15 “(2) is established as a permanent entity which
16 receives the active support of its members and re-
17 quires for membership payment on a periodic basis
18 of dues or payments necessary to maintain eligibility
19 for membership in the sponsor; and

20 “(3) does not condition membership, such dues
21 or payments, or coverage under the plan on the
22 basis of health status-related factors with respect to
23 the employees of its members (or affiliated mem-
24 bers), or the dependents of such employees, and does

1 not condition such dues or payments on the basis of
2 group health plan participation.

3 Any sponsor consisting of an association of entities which
4 meet the requirements of paragraphs (1), (2), and (3)
5 shall be deemed to be a sponsor described in this sub-
6 section.

7 **“SEC. 802. CERTIFICATION OF ASSOCIATION HEALTH**
8 **PLANS.**

9 “(a) IN GENERAL.—The applicable authority shall
10 prescribe by regulation a procedure under which, subject
11 to subsection (b), the applicable authority shall certify as-
12 sociation health plans which apply for certification as
13 meeting the requirements of this part.

14 “(b) STANDARDS.—Under the procedure prescribed
15 pursuant to subsection (a), in the case of an association
16 health plan that provides at least one benefit option which
17 does not consist of health insurance coverage, the applica-
18 ble authority shall certify such plan as meeting the re-
19 quirements of this part only if the applicable authority is
20 satisfied that the applicable requirements of this part are
21 met (or, upon the date on which the plan is to commence
22 operations, will be met) with respect to the plan.

23 “(c) REQUIREMENTS APPLICABLE TO CERTIFIED
24 PLANS.—An association health plan with respect to which
25 certification under this part is in effect shall meet the ap-

1 plicable requirements of this part, effective on the date
2 of certification (or, if later, on the date on which the plan
3 is to commence operations).

4 “(d) REQUIREMENTS FOR CONTINUED CERTIFI-
5 CATION.—The applicable authority may provide by regula-
6 tion for continued certification of association health plans
7 under this part.

8 “(e) CLASS CERTIFICATION FOR FULLY INSURED
9 PLANS.—The applicable authority shall establish a class
10 certification procedure for association health plans under
11 which all benefits consist of health insurance coverage.
12 Under such procedure, the applicable authority shall pro-
13 vide for the granting of certification under this part to
14 the plans in each class of such association health plans
15 upon appropriate filing under such procedure in connec-
16 tion with plans in such class and payment of the pre-
17 scribed fee under section 807(a).

18 “(f) CERTIFICATION OF SELF-INSURED ASSOCIATION
19 HEALTH PLANS.—An association health plan which offers
20 one or more benefit options which do not consist of health
21 insurance coverage may be certified under this part only
22 if such plan consists of any of the following:

23 “(1) a plan which offered such coverage on the
24 date of the enactment of the Small Business Health
25 Fairness Act of 2009,

1 “(2) a plan under which the sponsor does not
2 restrict membership to one or more trades and busi-
3 nesses or industries and whose eligible participating
4 employers represent a broad cross-section of trades
5 and businesses or industries, or

6 “(3) a plan whose eligible participating employ-
7 ers represent one or more trades or businesses, or
8 one or more industries, consisting of any of the fol-
9 lowing: agriculture; equipment and automobile deal-
10 erships; barbering and cosmetology; certified public
11 accounting practices; child care; construction; dance,
12 theatrical and orchestra productions; disinfecting
13 and pest control; financial services; fishing; food
14 service establishments; hospitals; labor organiza-
15 tions; logging; manufacturing (metals); mining; med-
16 ical and dental practices; medical laboratories; pro-
17 fessional consulting services; sanitary services; trans-
18 portation (local and freight); warehousing; whole-
19 saling/distributing; or any other trade or business or
20 industry which has been indicated as having average
21 or above-average risk or health claims experience by
22 reason of State rate filings, denials of coverage, pro-
23 posed premium rate levels, or other means dem-
24 onstrated by such plan in accordance with regula-
25 tions.

1 **“SEC. 803. REQUIREMENTS RELATING TO SPONSORS AND**
2 **BOARDS OF TRUSTEES.**

3 “(a) SPONSOR.—The requirements of this subsection
4 are met with respect to an association health plan if the
5 sponsor has met (or is deemed under this part to have
6 met) the requirements of section 801(b) for a continuous
7 period of not less than 3 years ending with the date of
8 the application for certification under this part.

9 “(b) BOARD OF TRUSTEES.—The requirements of
10 this subsection are met with respect to an association
11 health plan if the following requirements are met:

12 “(1) FISCAL CONTROL.—The plan is operated,
13 pursuant to a trust agreement, by a board of trust-
14 ees which has complete fiscal control over the plan
15 and which is responsible for all operations of the
16 plan.

17 “(2) RULES OF OPERATION AND FINANCIAL
18 CONTROLS.—The board of trustees has in effect
19 rules of operation and financial controls, based on a
20 3-year plan of operation, adequate to carry out the
21 terms of the plan and to meet all requirements of
22 this title applicable to the plan.

23 “(3) RULES GOVERNING RELATIONSHIP TO
24 PARTICIPATING EMPLOYERS AND TO CONTRAC-
25 TORS.—

26 “(A) BOARD MEMBERSHIP.—

1 “(i) IN GENERAL.—Except as pro-
2 vided in clauses (ii) and (iii), the members
3 of the board of trustees are individuals se-
4 lected from individuals who are the owners,
5 officers, directors, or employees of the par-
6 ticipating employers or who are partners in
7 the participating employers and actively
8 participate in the business.

9 “(ii) LIMITATION.—

10 “(I) GENERAL RULE.—Except as
11 provided in subclauses (II) and (III),
12 no such member is an owner, officer,
13 director, or employee of, or partner in,
14 a contract administrator or other
15 service provider to the plan.

16 “(II) LIMITED EXCEPTION FOR
17 PROVIDERS OF SERVICES SOLELY ON
18 BEHALF OF THE SPONSOR.—Officers
19 or employees of a sponsor which is a
20 service provider (other than a contract
21 administrator) to the plan may be
22 members of the board if they con-
23 stitute not more than 25 percent of
24 the membership of the board and they

1 do not provide services to the plan
2 other than on behalf of the sponsor.

3 “(III) TREATMENT OF PRO-
4 VIDERS OF MEDICAL CARE.—In the
5 case of a sponsor which is an associa-
6 tion whose membership consists pri-
7 marily of providers of medical care,
8 subclause (I) shall not apply in the
9 case of any service provider described
10 in subclause (I) who is a provider of
11 medical care under the plan.

12 “(iii) CERTAIN PLANS EXCLUDED.—
13 Clause (i) shall not apply to an association
14 health plan which is in existence on the
15 date of the enactment of the Small Busi-
16 ness Health Fairness Act of 2009.

17 “(B) SOLE AUTHORITY.—The board has
18 sole authority under the plan to approve appli-
19 cations for participation in the plan and to con-
20 tract with a service provider to administer the
21 day-to-day affairs of the plan.

22 “(c) TREATMENT OF FRANCHISE NETWORKS.—In
23 the case of a group health plan which is established and
24 maintained by a franchiser for a franchise network con-
25 sisting of its franchisees—

1 except that, in the case of a sponsor which is a pro-
2 fessional association or other individual-based asso-
3 ciation, if at least one of the officers, directors, or
4 employees of an employer, or at least one of the in-
5 dividuals who are partners in an employer and who
6 actively participates in the business, is a member or
7 such an affiliated member of the sponsor, partici-
8 pating employers may also include such employer;
9 and

10 “(2) all individuals commencing coverage under
11 the plan after certification under this part must
12 be—

13 “(A) active or retired owners (including
14 self-employed individuals), officers, directors, or
15 employees of, or partners in, participating em-
16 ployers; or

17 “(B) the beneficiaries of individuals de-
18 scribed in subparagraph (A).

19 “(b) COVERAGE OF PREVIOUSLY UNINSURED EM-
20 PLOYEES.—In the case of an association health plan in
21 existence on the date of the enactment of the Small Busi-
22 ness Health Fairness Act of 2009, an affiliated member
23 of the sponsor of the plan may be offered coverage under
24 the plan as a participating employer only if—

1 “(1) the affiliated member was an affiliated
2 member on the date of certification under this part;
3 or

4 “(2) during the 12-month period preceding the
5 date of the offering of such coverage, the affiliated
6 member has not maintained or contributed to a
7 group health plan with respect to any of its employ-
8 ees who would otherwise be eligible to participate in
9 such association health plan.

10 “(c) INDIVIDUAL MARKET UNAFFECTED.—The re-
11 quirements of this subsection are met with respect to an
12 association health plan if, under the terms of the plan,
13 no participating employer may provide health insurance
14 coverage in the individual market for any employee not
15 covered under the plan which is similar to the coverage
16 contemporaneously provided to employees of the employer
17 under the plan, if such exclusion of the employee from cov-
18 erage under the plan is based on a health status-related
19 factor with respect to the employee and such employee
20 would, but for such exclusion on such basis, be eligible
21 for coverage under the plan.

22 “(d) PROHIBITION OF DISCRIMINATION AGAINST
23 EMPLOYERS AND EMPLOYEES ELIGIBLE TO PARTICI-
24 PATE.—The requirements of this subsection are met with
25 respect to an association health plan if—

1 “(1) under the terms of the plan, all employers
2 meeting the preceding requirements of this section
3 are eligible to qualify as participating employers for
4 all geographically available coverage options, unless,
5 in the case of any such employer, participation or
6 contribution requirements of the type referred to in
7 section 2711 of the Public Health Service Act are
8 not met;

9 “(2) upon request, any employer eligible to par-
10 ticipate is furnished information regarding all cov-
11 erage options available under the plan; and

12 “(3) the applicable requirements of sections
13 701, 702, and 703 are met with respect to the plan.

14 **“SEC. 805. OTHER REQUIREMENTS RELATING TO PLAN**
15 **DOCUMENTS, CONTRIBUTION RATES, AND**
16 **BENEFIT OPTIONS.**

17 “(a) IN GENERAL.—The requirements of this section
18 are met with respect to an association health plan if the
19 following requirements are met:

20 “(1) CONTENTS OF GOVERNING INSTRU-
21 MENTS.—The instruments governing the plan in-
22 clude a written instrument, meeting the require-
23 ments of an instrument required under section
24 402(a)(1), which—

1 “(A) provides that the board of trustees
2 serves as the named fiduciary required for plans
3 under section 402(a)(1) and serves in the ca-
4 pacity of a plan administrator (referred to in
5 section 3(16)(A));

6 “(B) provides that the sponsor of the plan
7 is to serve as plan sponsor (referred to in sec-
8 tion 3(16)(B)); and

9 “(C) incorporates the requirements of sec-
10 tion 806.

11 “(2) CONTRIBUTION RATES MUST BE NON-
12 DISCRIMINATORY.—

13 “(A) The contribution rates for any par-
14 ticipating small employer do not vary on the
15 basis of any health status-related factor in rela-
16 tion to employees of such employer or their
17 beneficiaries and do not vary on the basis of the
18 type of business or industry in which such em-
19 ployer is engaged.

20 “(B) Nothing in this title or any other pro-
21 vision of law shall be construed to preclude an
22 association health plan, or a health insurance
23 issuer offering health insurance coverage in
24 connection with an association health plan,
25 from—

1 “(i) setting contribution rates based
2 on the claims experience of the plan; or

3 “(ii) varying contribution rates for
4 small employers in a State to the extent
5 that such rates could vary using the same
6 methodology employed in such State for
7 regulating premium rates in the small
8 group market with respect to health insur-
9 ance coverage offered in connection with
10 bona fide associations (within the meaning
11 of section 2791(d)(3) of the Public Health
12 Service Act),

13 subject to the requirements of section 702(b)
14 relating to contribution rates.

15 “(3) FLOOR FOR NUMBER OF COVERED INDI-
16 VIDUALS WITH RESPECT TO CERTAIN PLANS.—If
17 any benefit option under the plan does not consist
18 of health insurance coverage, the plan has as of the
19 beginning of the plan year not fewer than 1,000 par-
20 ticipants and beneficiaries.

21 “(4) MARKETING REQUIREMENTS.—

22 “(A) IN GENERAL.—If a benefit option
23 which consists of health insurance coverage is
24 offered under the plan, State-licensed insurance
25 agents shall be used to distribute to small em-

1 employers coverage which does not consist of
2 health insurance coverage in a manner com-
3 parable to the manner in which such agents are
4 used to distribute health insurance coverage.

5 “(B) STATE-LICENSED INSURANCE
6 AGENTS.—For purposes of subparagraph (A),
7 the term ‘State-licensed insurance agents’
8 means one or more agents who are licensed in
9 a State and are subject to the laws of such
10 State relating to licensure, qualification, test-
11 ing, examination, and continuing education of
12 persons authorized to offer, sell, or solicit
13 health insurance coverage in such State.

14 “(5) REGULATORY REQUIREMENTS.—Such
15 other requirements as the applicable authority deter-
16 mines are necessary to carry out the purposes of this
17 part, which shall be prescribed by the applicable au-
18 thority by regulation.

19 “(b) ABILITY OF ASSOCIATION HEALTH PLANS TO
20 DESIGN BENEFIT OPTIONS.—Subject to section 514(d),
21 nothing in this part or any provision of State law (as de-
22 fined in section 514(e)(1)) shall be construed to preclude
23 an association health plan, or a health insurance issuer
24 offering health insurance coverage in connection with an
25 association health plan, from exercising its sole discretion

1 in selecting the specific items and services consisting of
2 medical care to be included as benefits under such plan
3 or coverage, except (subject to section 514) in the case
4 of (1) any law to the extent that it is not preempted under
5 section 731(a)(1) with respect to matters governed by sec-
6 tion 711, 712, or 713, or (2) any law of the State with
7 which filing and approval of a policy type offered by the
8 plan was initially obtained to the extent that such law pro-
9 hibits an exclusion of a specific disease from such cov-
10 erage.

11 **“SEC. 806. MAINTENANCE OF RESERVES AND PROVISIONS**
12 **FOR SOLVENCY FOR PLANS PROVIDING**
13 **HEALTH BENEFITS IN ADDITION TO HEALTH**
14 **INSURANCE COVERAGE.**

15 “(a) IN GENERAL.—The requirements of this section
16 are met with respect to an association health plan if—

17 “(1) the benefits under the plan consist solely
18 of health insurance coverage; or

19 “(2) if the plan provides any additional benefit
20 options which do not consist of health insurance cov-
21 erage, the plan—

22 “(A) establishes and maintains reserves
23 with respect to such additional benefit options,
24 in amounts recommended by the qualified actu-
25 ary, consisting of—

1 “(i) a reserve sufficient for unearned
2 contributions;

3 “(ii) a reserve sufficient for benefit li-
4 abilities which have been incurred, which
5 have not been satisfied, and for which risk
6 of loss has not yet been transferred, and
7 for expected administrative costs with re-
8 spect to such benefit liabilities;

9 “(iii) a reserve sufficient for any other
10 obligations of the plan; and

11 “(iv) a reserve sufficient for a margin
12 of error and other fluctuations, taking into
13 account the specific circumstances of the
14 plan; and

15 “(B) establishes and maintains aggregate
16 and specific excess/stop loss insurance and sol-
17 vency indemnification, with respect to such ad-
18 ditional benefit options for which risk of loss
19 has not yet been transferred, as follows:

20 “(i) The plan shall secure aggregate
21 excess/stop loss insurance for the plan with
22 an attachment point which is not greater
23 than 125 percent of expected gross annual
24 claims. The applicable authority may by
25 regulation provide for upward adjustments

1 in the amount of such percentage in speci-
2 fied circumstances in which the plan spe-
3 cifically provides for and maintains re-
4 serves in excess of the amounts required
5 under subparagraph (A).

6 “(ii) The plan shall secure specific ex-
7 cess/stop loss insurance for the plan with
8 an attachment point which is at least equal
9 to an amount recommended by the plan’s
10 qualified actuary. The applicable authority
11 may by regulation provide for adjustments
12 in the amount of such insurance in speci-
13 fied circumstances in which the plan spe-
14 cifically provides for and maintains re-
15 serves in excess of the amounts required
16 under subparagraph (A).

17 “(iii) The plan shall secure indem-
18 nification insurance for any claims which
19 the plan is unable to satisfy by reason of
20 a plan termination.

21 Any person issuing to a plan insurance described in clause
22 (i), (ii), or (iii) of subparagraph (B) shall notify the Sec-
23 retary of any failure of premium payment meriting can-
24 cellation of the policy prior to undertaking such a cancella-
25 tion. Any regulations prescribed by the applicable author-

1 ity pursuant to clause (i) or (ii) of subparagraph (B) may
2 allow for such adjustments in the required levels of excess/
3 stop loss insurance as the qualified actuary may rec-
4 ommend, taking into account the specific circumstances
5 of the plan.

6 “(b) MINIMUM SURPLUS IN ADDITION TO CLAIMS
7 RESERVES.—In the case of any association health plan de-
8 scribed in subsection (a)(2), the requirements of this sub-
9 section are met if the plan establishes and maintains sur-
10 plus in an amount at least equal to—

11 “(1) \$500,000, or

12 “(2) such greater amount (but not greater than
13 \$2,000,000) as may be set forth in regulations pre-
14 scribed by the applicable authority, considering the
15 level of aggregate and specific excess/stop loss insur-
16 ance provided with respect to such plan and other
17 factors related to solvency risk, such as the plan’s
18 projected levels of participation or claims, the nature
19 of the plan’s liabilities, and the types of assets avail-
20 able to assure that such liabilities are met.

21 “(c) ADDITIONAL REQUIREMENTS.—In the case of
22 any association health plan described in subsection (a)(2),
23 the applicable authority may provide such additional re-
24 quirements relating to reserves, excess/stop loss insurance,
25 and indemnification insurance as the applicable authority

1 considers appropriate. Such requirements may be provided
2 by regulation with respect to any such plan or any class
3 of such plans.

4 “(d) ADJUSTMENTS FOR EXCESS/STOP LOSS INSUR-
5 ANCE.—The applicable authority may provide for adjust-
6 ments to the levels of reserves otherwise required under
7 subsections (a) and (b) with respect to any plan or class
8 of plans to take into account excess/stop loss insurance
9 provided with respect to such plan or plans.

10 “(e) ALTERNATIVE MEANS OF COMPLIANCE.—The
11 applicable authority may permit an association health plan
12 described in subsection (a)(2) to substitute, for all or part
13 of the requirements of this section (except subsection
14 (a)(2)(B)(iii)), such security, guarantee, hold-harmless ar-
15 rangement, or other financial arrangement as the applica-
16 ble authority determines to be adequate to enable the plan
17 to fully meet all its financial obligations on a timely basis
18 and is otherwise no less protective of the interests of par-
19 ticipants and beneficiaries than the requirements for
20 which it is substituted. The applicable authority may take
21 into account, for purposes of this subsection, evidence pro-
22 vided by the plan or sponsor which demonstrates an as-
23 sumption of liability with respect to the plan. Such evi-
24 dence may be in the form of a contract of indemnification,
25 lien, bonding, insurance, letter of credit, recourse under

1 applicable terms of the plan in the form of assessments
2 of participating employers, security, or other financial ar-
3 rangement.

4 “(f) MEASURES TO ENSURE CONTINUED PAYMENT
5 OF BENEFITS BY CERTAIN PLANS IN DISTRESS.—

6 “(1) PAYMENTS BY CERTAIN PLANS TO ASSO-
7 CIATION HEALTH PLAN FUND.—

8 “(A) IN GENERAL.—In the case of an as-
9 sociation health plan described in subsection
10 (a)(2), the requirements of this subsection are
11 met if the plan makes payments into the Asso-
12 ciation Health Plan Fund under this subpara-
13 graph when they are due. Such payments shall
14 consist of annual payments in the amount of
15 \$5,000, and, in addition to such annual pay-
16 ments, such supplemental payments as the Sec-
17 retary may determine to be necessary under
18 paragraph (2). Payments under this paragraph
19 are payable to the Fund at the time determined
20 by the Secretary. Initial payments are due in
21 advance of certification under this part. Pay-
22 ments shall continue to accrue until a plan’s as-
23 sets are distributed pursuant to a termination
24 procedure.

1 “(B) PENALTIES FOR FAILURE TO MAKE
2 PAYMENTS.—If any payment is not made by a
3 plan when it is due, a late payment charge of
4 not more than 100 percent of the payment
5 which was not timely paid shall be payable by
6 the plan to the Fund.

7 “(C) CONTINUED DUTY OF THE SEC-
8 RETARY.—The Secretary shall not cease to
9 carry out the provisions of paragraph (2) on ac-
10 count of the failure of a plan to pay any pay-
11 ment when due.

12 “(2) PAYMENTS BY SECRETARY TO CONTINUE
13 EXCESS/STOP LOSS INSURANCE COVERAGE AND IN-
14 DEMNIFICATION INSURANCE COVERAGE FOR CER-
15 TAIN PLANS.—In any case in which the applicable
16 authority determines that there is, or that there is
17 reason to believe that there will be: (A) a failure to
18 take necessary corrective actions under section
19 809(a) with respect to an association health plan de-
20 scribed in subsection (a)(2); or (B) a termination of
21 such a plan under section 809(b) or 810(b)(8) (and,
22 if the applicable authority is not the Secretary, cer-
23 tifies such determination to the Secretary), the Sec-
24 retary shall determine the amounts necessary to
25 make payments to an insurer (designated by the

1 Secretary) to maintain in force excess/stop loss in-
2 surance coverage or indemnification insurance cov-
3 erage for such plan, if the Secretary determines that
4 there is a reasonable expectation that, without such
5 payments, claims would not be satisfied by reason of
6 termination of such coverage. The Secretary shall, to
7 the extent provided in advance in appropriation
8 Acts, pay such amounts so determined to the insurer
9 designated by the Secretary.

10 “(3) ASSOCIATION HEALTH PLAN FUND.—

11 “(A) IN GENERAL.—There is established
12 on the books of the Treasury a fund to be
13 known as the ‘Association Health Plan Fund’.
14 The Fund shall be available for making pay-
15 ments pursuant to paragraph (2). The Fund
16 shall be credited with payments received pursu-
17 ant to paragraph (1)(A), penalties received pur-
18 suant to paragraph (1)(B); and earnings on in-
19 vestments of amounts of the Fund under sub-
20 paragraph (B).

21 “(B) INVESTMENT.—Whenever the Sec-
22 retary determines that the moneys of the fund
23 are in excess of current needs, the Secretary
24 may request the investment of such amounts as
25 the Secretary determines advisable by the Sec-

1 retary of the Treasury in obligations issued or
2 guaranteed by the United States.

3 “(g) EXCESS/STOP LOSS INSURANCE.—For purposes
4 of this section—

5 “(1) AGGREGATE EXCESS/STOP LOSS INSUR-
6 ANCE.—The term ‘aggregate excess/stop loss insur-
7 ance’ means, in connection with an association
8 health plan, a contract—

9 “(A) under which an insurer (meeting such
10 minimum standards as the applicable authority
11 may prescribe by regulation) provides for pay-
12 ment to the plan with respect to aggregate
13 claims under the plan in excess of an amount
14 or amounts specified in such contract;

15 “(B) which is guaranteed renewable; and

16 “(C) which allows for payment of pre-
17 miums by any third party on behalf of the in-
18 sured plan.

19 “(2) SPECIFIC EXCESS/STOP LOSS INSUR-
20 ANCE.—The term ‘specific excess/stop loss insur-
21 ance’ means, in connection with an association
22 health plan, a contract—

23 “(A) under which an insurer (meeting such
24 minimum standards as the applicable authority
25 may prescribe by regulation) provides for pay-

1 ment to the plan with respect to claims under
2 the plan in connection with a covered individual
3 in excess of an amount or amounts specified in
4 such contract in connection with such covered
5 individual;

6 “(B) which is guaranteed renewable; and

7 “(C) which allows for payment of pre-
8 miums by any third party on behalf of the in-
9 sured plan.

10 “(h) INDEMNIFICATION INSURANCE.—For purposes
11 of this section, the term ‘indemnification insurance’
12 means, in connection with an association health plan, a
13 contract—

14 “(1) under which an insurer (meeting such min-
15 imum standards as the applicable authority may pre-
16 scribe by regulation) provides for payment to the
17 plan with respect to claims under the plan which the
18 plan is unable to satisfy by reason of a termination
19 pursuant to section 809(b) (relating to mandatory
20 termination);

21 “(2) which is guaranteed renewable and
22 noncancellable for any reason (except as the applica-
23 ble authority may prescribe by regulation); and

24 “(3) which allows for payment of premiums by
25 any third party on behalf of the insured plan.

1 “(i) RESERVES.—For purposes of this section, the
2 term ‘reserves’ means, in connection with an association
3 health plan, plan assets which meet the fiduciary stand-
4 ards under part 4 and such additional requirements re-
5 garding liquidity as the applicable authority may prescribe
6 by regulation.

7 “(j) SOLVENCY STANDARDS WORKING GROUP.—

8 “(1) IN GENERAL.—Within 90 days after the
9 date of the enactment of the Small Business Health
10 Fairness Act of 2009, the applicable authority shall
11 establish a Solvency Standards Working Group. In
12 prescribing the initial regulations under this section,
13 the applicable authority shall take into account the
14 recommendations of such Working Group.

15 “(2) MEMBERSHIP.—The Working Group shall
16 consist of not more than 15 members appointed by
17 the applicable authority. The applicable authority
18 shall include among persons invited to membership
19 on the Working Group at least one of each of the
20 following:

21 “(A) a representative of the National Asso-
22 ciation of Insurance Commissioners;

23 “(B) a representative of the American
24 Academy of Actuaries;

1 “(C) a representative of the State govern-
2 ments, or their interests;

3 “(D) a representative of existing self-in-
4 sured arrangements, or their interests;

5 “(E) a representative of associations of the
6 type referred to in section 801(b)(1), or their
7 interests; and

8 “(F) a representative of multiemployer
9 plans that are group health plans, or their in-
10 terests.

11 **“SEC. 807. REQUIREMENTS FOR APPLICATION AND RE-**
12 **LATED REQUIREMENTS.**

13 “(a) **FILING FEE.**—Under the procedure prescribed
14 pursuant to section 802(a), an association health plan
15 shall pay to the applicable authority at the time of filing
16 an application for certification under this part a filing fee
17 in the amount of \$5,000, which shall be available in the
18 case of the Secretary, to the extent provided in appropria-
19 tion Acts, for the sole purpose of administering the certifi-
20 cation procedures applicable with respect to association
21 health plans.

22 “(b) **INFORMATION TO BE INCLUDED IN APPLICA-**
23 **TION FOR CERTIFICATION.**—An application for certifi-
24 cation under this part meets the requirements of this sec-
25 tion only if it includes, in a manner and form which shall

1 be prescribed by the applicable authority by regulation, at
2 least the following information:

3 “(1) IDENTIFYING INFORMATION.—The names
4 and addresses of—

5 “(A) the sponsor; and

6 “(B) the members of the board of trustees
7 of the plan.

8 “(2) STATES IN WHICH PLAN INTENDS TO DO
9 BUSINESS.—The States in which participants and
10 beneficiaries under the plan are to be located and
11 the number of them expected to be located in each
12 such State.

13 “(3) BONDING REQUIREMENTS.—Evidence pro-
14 vided by the board of trustees that the bonding re-
15 quirements of section 412 will be met as of the date
16 of the application or (if later) commencement of op-
17 erations.

18 “(4) PLAN DOCUMENTS.—A copy of the docu-
19 ments governing the plan (including any bylaws and
20 trust agreements), the summary plan description,
21 and other material describing the benefits that will
22 be provided to participants and beneficiaries under
23 the plan.

24 “(5) AGREEMENTS WITH SERVICE PRO-
25 VIDERS.—A copy of any agreements between the

1 plan and contract administrators and other service
2 providers.

3 “(6) FUNDING REPORT.—In the case of asso-
4 ciation health plans providing benefits options in ad-
5 dition to health insurance coverage, a report setting
6 forth information with respect to such additional
7 benefit options determined as of a date within the
8 120-day period ending with the date of the applica-
9 tion, including the following:

10 “(A) RESERVES.—A statement, certified
11 by the board of trustees of the plan, and a
12 statement of actuarial opinion, signed by a
13 qualified actuary, that all applicable require-
14 ments of section 806 are or will be met in ac-
15 cordance with regulations which the applicable
16 authority shall prescribe.

17 “(B) ADEQUACY OF CONTRIBUTION
18 RATES.—A statement of actuarial opinion,
19 signed by a qualified actuary, which sets forth
20 a description of the extent to which contribution
21 rates are adequate to provide for the payment
22 of all obligations and the maintenance of re-
23 quired reserves under the plan for the 12-
24 month period beginning with such date within
25 such 120-day period, taking into account the

1 expected coverage and experience of the plan. If
2 the contribution rates are not fully adequate,
3 the statement of actuarial opinion shall indicate
4 the extent to which the rates are inadequate
5 and the changes needed to ensure adequacy.

6 “(C) CURRENT AND PROJECTED VALUE OF
7 ASSETS AND LIABILITIES.—A statement of ac-
8 tuarial opinion signed by a qualified actuary,
9 which sets forth the current value of the assets
10 and liabilities accumulated under the plan and
11 a projection of the assets, liabilities, income,
12 and expenses of the plan for the 12-month pe-
13 riod referred to in subparagraph (B). The in-
14 come statement shall identify separately the
15 plan’s administrative expenses and claims.

16 “(D) COSTS OF COVERAGE TO BE
17 CHARGED AND OTHER EXPENSES.—A state-
18 ment of the costs of coverage to be charged, in-
19 cluding an itemization of amounts for adminis-
20 tration, reserves, and other expenses associated
21 with the operation of the plan.

22 “(E) OTHER INFORMATION.—Any other
23 information as may be determined by the appli-
24 cable authority, by regulation, as necessary to
25 carry out the purposes of this part.

1 “(c) FILING NOTICE OF CERTIFICATION WITH
2 STATES.—A certification granted under this part to an
3 association health plan shall not be effective unless written
4 notice of such certification is filed with the applicable
5 State authority of each State in which at least 25 percent
6 of the participants and beneficiaries under the plan are
7 located. For purposes of this subsection, an individual
8 shall be considered to be located in the State in which a
9 known address of such individual is located or in which
10 such individual is employed.

11 “(d) NOTICE OF MATERIAL CHANGES.—In the case
12 of any association health plan certified under this part,
13 descriptions of material changes in any information which
14 was required to be submitted with the application for the
15 certification under this part shall be filed in such form
16 and manner as shall be prescribed by the applicable au-
17 thority by regulation. The applicable authority may re-
18 quire by regulation prior notice of material changes with
19 respect to specified matters which might serve as the basis
20 for suspension or revocation of the certification.

21 “(e) REPORTING REQUIREMENTS FOR CERTAIN AS-
22 SOCIATION HEALTH PLANS.—An association health plan
23 certified under this part which provides benefit options in
24 addition to health insurance coverage for such plan year
25 shall meet the requirements of section 103 by filing an

1 annual report under such section which shall include infor-
2 mation described in subsection (b)(6) with respect to the
3 plan year and, notwithstanding section 104(a)(1)(A), shall
4 be filed with the applicable authority not later than 90
5 days after the close of the plan year (or on such later date
6 as may be prescribed by the applicable authority). The ap-
7 plicable authority may require by regulation such interim
8 reports as it considers appropriate.

9 “(f) ENGAGEMENT OF QUALIFIED ACTUARY.—The
10 board of trustees of each association health plan which
11 provides benefits options in addition to health insurance
12 coverage and which is applying for certification under this
13 part or is certified under this part shall engage, on behalf
14 of all participants and beneficiaries, a qualified actuary
15 who shall be responsible for the preparation of the mate-
16 rials comprising information necessary to be submitted by
17 a qualified actuary under this part. The qualified actuary
18 shall utilize such assumptions and techniques as are nec-
19 essary to enable such actuary to form an opinion as to
20 whether the contents of the matters reported under this
21 part—

22 “(1) are in the aggregate reasonably related to
23 the experience of the plan and to reasonable expecta-
24 tions; and

1 “(2) represent such actuary’s best estimate of
2 anticipated experience under the plan.

3 The opinion by the qualified actuary shall be made with
4 respect to, and shall be made a part of, the annual report.

5 **“SEC. 808. NOTICE REQUIREMENTS FOR VOLUNTARY TER-**
6 **MINATION.**

7 “Except as provided in section 809(b), an association
8 health plan which is or has been certified under this part
9 may terminate (upon or at any time after cessation of ac-
10 cruals in benefit liabilities) only if the board of trustees,
11 not less than 60 days before the proposed termination
12 date—

13 “(1) provides to the participants and bene-
14 ficiaries a written notice of intent to terminate stat-
15 ing that such termination is intended and the pro-
16 posed termination date;

17 “(2) develops a plan for winding up the affairs
18 of the plan in connection with such termination in
19 a manner which will result in timely payment of all
20 benefits for which the plan is obligated; and

21 “(3) submits such plan in writing to the appli-
22 cable authority.

23 Actions required under this section shall be taken in such
24 form and manner as may be prescribed by the applicable
25 authority by regulation.

1 **“SEC. 809. CORRECTIVE ACTIONS AND MANDATORY TERMI-**
2 **NATION.**

3 “(a) ACTIONS TO AVOID DEPLETION OF RE-
4 SERVES.—An association health plan which is certified
5 under this part and which provides benefits other than
6 health insurance coverage shall continue to meet the re-
7 quirements of section 806, irrespective of whether such
8 certification continues in effect. The board of trustees of
9 such plan shall determine quarterly whether the require-
10 ments of section 806 are met. In any case in which the
11 board determines that there is reason to believe that there
12 is or will be a failure to meet such requirements, or the
13 applicable authority makes such a determination and so
14 notifies the board, the board shall immediately notify the
15 qualified actuary engaged by the plan, and such actuary
16 shall, not later than the end of the next following month,
17 make such recommendations to the board for corrective
18 action as the actuary determines necessary to ensure com-
19 pliance with section 806. Not later than 30 days after re-
20 ceiving from the actuary recommendations for corrective
21 actions, the board shall notify the applicable authority (in
22 such form and manner as the applicable authority may
23 prescribe by regulation) of such recommendations of the
24 actuary for corrective action, together with a description
25 of the actions (if any) that the board has taken or plans
26 to take in response to such recommendations. The board

1 shall thereafter report to the applicable authority, in such
2 form and frequency as the applicable authority may speci-
3 fy to the board, regarding corrective action taken by the
4 board until the requirements of section 806 are met.

5 “(b) MANDATORY TERMINATION.—In any case in
6 which—

7 “(1) the applicable authority has been notified
8 under subsection (a) (or by an issuer of excess/stop
9 loss insurance or indemnity insurance pursuant to
10 section 806(a)) of a failure of an association health
11 plan which is or has been certified under this part
12 and is described in section 806(a)(2) to meet the re-
13 quirements of section 806 and has not been notified
14 by the board of trustees of the plan that corrective
15 action has restored compliance with such require-
16 ments; and

17 “(2) the applicable authority determines that
18 there is a reasonable expectation that the plan will
19 continue to fail to meet the requirements of section
20 806,

21 the board of trustees of the plan shall, at the direction
22 of the applicable authority, terminate the plan and, in the
23 course of the termination, take such actions as the appli-
24 cable authority may require, including satisfying any
25 claims referred to in section 806(a)(2)(B)(iii) and recov-

1 ering for the plan any liability under subsection
2 (a)(2)(B)(iii) or (e) of section 806, as necessary to ensure
3 that the affairs of the plan will be, to the maximum extent
4 possible, wound up in a manner which will result in timely
5 provision of all benefits for which the plan is obligated.

6 **“SEC. 810. TRUSTEESHIP BY THE SECRETARY OF INSOL-**
7 **VENT ASSOCIATION HEALTH PLANS PRO-**
8 **VIDING HEALTH BENEFITS IN ADDITION TO**
9 **HEALTH INSURANCE COVERAGE.**

10 “(a) APPOINTMENT OF SECRETARY AS TRUSTEE FOR
11 INSOLVENT PLANS.—Whenever the Secretary determines
12 that an association health plan which is or has been cer-
13 tified under this part and which is described in section
14 806(a)(2) will be unable to provide benefits when due or
15 is otherwise in a financially hazardous condition, as shall
16 be defined by the Secretary by regulation, the Secretary
17 shall, upon notice to the plan, apply to the appropriate
18 United States district court for appointment of the Sec-
19 retary as trustee to administer the plan for the duration
20 of the insolvency. The plan may appear as a party and
21 other interested persons may intervene in the proceedings
22 at the discretion of the court. The court shall appoint such
23 Secretary trustee if the court determines that the trustee-
24 ship is necessary to protect the interests of the partici-
25 pants and beneficiaries or providers of medical care or to

1 avoid any unreasonable deterioration of the financial con-
2 dition of the plan. The trusteeship of such Secretary shall
3 continue until the conditions described in the first sen-
4 tence of this subsection are remedied or the plan is termi-
5 nated.

6 “(b) POWERS AS TRUSTEE.—The Secretary, upon
7 appointment as trustee under subsection (a), shall have
8 the power—

9 “(1) to do any act authorized by the plan, this
10 title, or other applicable provisions of law to be done
11 by the plan administrator or any trustee of the plan;

12 “(2) to require the transfer of all (or any part)
13 of the assets and records of the plan to the Sec-
14 retary as trustee;

15 “(3) to invest any assets of the plan which the
16 Secretary holds in accordance with the provisions of
17 the plan, regulations prescribed by the Secretary,
18 and applicable provisions of law;

19 “(4) to require the sponsor, the plan adminis-
20 trator, any participating employer, and any employee
21 organization representing plan participants to fur-
22 nish any information with respect to the plan which
23 the Secretary as trustee may reasonably need in
24 order to administer the plan;

1 “(5) to collect for the plan any amounts due the
2 plan and to recover reasonable expenses of the trust-
3 eeship;

4 “(6) to commence, prosecute, or defend on be-
5 half of the plan any suit or proceeding involving the
6 plan;

7 “(7) to issue, publish, or file such notices, state-
8 ments, and reports as may be required by the Sec-
9 retary by regulation or required by any order of the
10 court;

11 “(8) to terminate the plan (or provide for its
12 termination in accordance with section 809(b)) and
13 liquidate the plan assets, to restore the plan to the
14 responsibility of the sponsor, or to continue the
15 trusteeship;

16 “(9) to provide for the enrollment of plan par-
17 ticipants and beneficiaries under appropriate cov-
18 erage options; and

19 “(10) to do such other acts as may be nec-
20 essary to comply with this title or any order of the
21 court and to protect the interests of plan partici-
22 pants and beneficiaries and providers of medical
23 care.

1 “(c) NOTICE OF APPOINTMENT.—As soon as prac-
2 ticable after the Secretary’s appointment as trustee, the
3 Secretary shall give notice of such appointment to—

4 “(1) the sponsor and plan administrator;

5 “(2) each participant;

6 “(3) each participating employer; and

7 “(4) if applicable, each employee organization
8 which, for purposes of collective bargaining, rep-
9 resents plan participants.

10 “(d) ADDITIONAL DUTIES.—Except to the extent in-
11 consistent with the provisions of this title, or as may be
12 otherwise ordered by the court, the Secretary, upon ap-
13 pointment as trustee under this section, shall be subject
14 to the same duties as those of a trustee under section 704
15 of title 11, United States Code, and shall have the duties
16 of a fiduciary for purposes of this title.

17 “(e) OTHER PROCEEDINGS.—An application by the
18 Secretary under this subsection may be filed notwith-
19 standing the pendency in the same or any other court of
20 any bankruptcy, mortgage foreclosure, or equity receiver-
21 ship proceeding, or any proceeding to reorganize, conserve,
22 or liquidate such plan or its property, or any proceeding
23 to enforce a lien against property of the plan.

24 “(f) JURISDICTION OF COURT.—

1 “(1) IN GENERAL.—Upon the filing of an appli-
2 cation for the appointment as trustee or the issuance
3 of a decree under this section, the court to which the
4 application is made shall have exclusive jurisdiction
5 of the plan involved and its property wherever lo-
6 cated with the powers, to the extent consistent with
7 the purposes of this section, of a court of the United
8 States having jurisdiction over cases under chapter
9 11 of title 11, United States Code. Pending an adju-
10 dication under this section such court shall stay, and
11 upon appointment by it of the Secretary as trustee,
12 such court shall continue the stay of, any pending
13 mortgage foreclosure, equity receivership, or other
14 proceeding to reorganize, conserve, or liquidate the
15 plan, the sponsor, or property of such plan or spon-
16 sor, and any other suit against any receiver, conser-
17 vator, or trustee of the plan, the sponsor, or prop-
18 erty of the plan or sponsor. Pending such adjudica-
19 tion and upon the appointment by it of the Sec-
20 retary as trustee, the court may stay any proceeding
21 to enforce a lien against property of the plan or the
22 sponsor or any other suit against the plan or the
23 sponsor.

24 “(2) VENUE.—An action under this section
25 may be brought in the judicial district where the

1 sponsor or the plan administrator resides or does
2 business or where any asset of the plan is situated.
3 A district court in which such action is brought may
4 issue process with respect to such action in any
5 other judicial district.

6 “(g) PERSONNEL.—In accordance with regulations
7 which shall be prescribed by the Secretary, the Secretary
8 shall appoint, retain, and compensate accountants, actu-
9 aries, and other professional service personnel as may be
10 necessary in connection with the Secretary’s service as
11 trustee under this section.

12 **“SEC. 811. STATE ASSESSMENT AUTHORITY.**

13 “(a) IN GENERAL.—Notwithstanding section 514, a
14 State may impose by law a contribution tax on an associa-
15 tion health plan described in section 806(a)(2), if the plan
16 commenced operations in such State after the date of the
17 enactment of the Small Business Health Fairness Act of
18 2009.

19 “(b) CONTRIBUTION TAX.—For purposes of this sec-
20 tion, the term ‘contribution tax’ imposed by a State on
21 an association health plan means any tax imposed by such
22 State if—

23 “(1) such tax is computed by applying a rate to
24 the amount of premiums or contributions, with re-
25 spect to individuals covered under the plan who are

1 residents of such State, which are received by the
2 plan from participating employers located in such
3 State or from such individuals;

4 “(2) the rate of such tax does not exceed the
5 rate of any tax imposed by such State on premiums
6 or contributions received by insurers or health main-
7 tenance organizations for health insurance coverage
8 offered in such State in connection with a group
9 health plan;

10 “(3) such tax is otherwise nondiscriminatory;
11 and

12 “(4) the amount of any such tax assessed on
13 the plan is reduced by the amount of any tax or as-
14 sessment otherwise imposed by the State on pre-
15 miums, contributions, or both received by insurers or
16 health maintenance organizations for health insur-
17 ance coverage, aggregate excess/stop loss insurance
18 (as defined in section 806(g)(1)), specific excess/stop
19 loss insurance (as defined in section 806(g)(2)),
20 other insurance related to the provision of medical
21 care under the plan, or any combination thereof pro-
22 vided by such insurers or health maintenance organi-
23 zations in such State in connection with such plan.

24 **“SEC. 812. DEFINITIONS AND RULES OF CONSTRUCTION.**

25 “(a) DEFINITIONS.—For purposes of this part—

1 “(1) GROUP HEALTH PLAN.—The term ‘group
2 health plan’ has the meaning provided in section
3 733(a)(1) (after applying subsection (b) of this sec-
4 tion).

5 “(2) MEDICAL CARE.—The term ‘medical care’
6 has the meaning provided in section 733(a)(2).

7 “(3) HEALTH INSURANCE COVERAGE.—The
8 term ‘health insurance coverage’ has the meaning
9 provided in section 733(b)(1).

10 “(4) HEALTH INSURANCE ISSUER.—The term
11 ‘health insurance issuer’ has the meaning provided
12 in section 733(b)(2).

13 “(5) APPLICABLE AUTHORITY.—The term ‘ap-
14 plicable authority’ means the Secretary, except that,
15 in connection with any exercise of the Secretary’s
16 authority regarding which the Secretary is required
17 under section 506(d) to consult with a State, such
18 term means the Secretary, in consultation with such
19 State.

20 “(6) HEALTH STATUS-RELATED FACTOR.—The
21 term ‘health status-related factor’ has the meaning
22 provided in section 733(d)(2).

23 “(7) INDIVIDUAL MARKET.—

24 “(A) IN GENERAL.—The term ‘individual
25 market’ means the market for health insurance

1 coverage offered to individuals other than in
2 connection with a group health plan.

3 “(B) TREATMENT OF VERY SMALL
4 GROUPS.—

5 “(i) IN GENERAL.—Subject to clause
6 (ii), such term includes coverage offered in
7 connection with a group health plan that
8 has fewer than 2 participants as current
9 employees or participants described in sec-
10 tion 732(d)(3) on the first day of the plan
11 year.

12 “(ii) STATE EXCEPTION.—Clause (i)
13 shall not apply in the case of health insur-
14 ance coverage offered in a State if such
15 State regulates the coverage described in
16 such clause in the same manner and to the
17 same extent as coverage in the small group
18 market (as defined in section 2791(e)(5) of
19 the Public Health Service Act) is regulated
20 by such State.

21 “(8) PARTICIPATING EMPLOYER.—The term
22 ‘participating employer’ means, in connection with
23 an association health plan, any employer, if any indi-
24 vidual who is an employee of such employer, a part-
25 ner in such employer, or a self-employed individual

1 who is such employer (or any dependent, as defined
2 under the terms of the plan, of such individual) is
3 or was covered under such plan in connection with
4 the status of such individual as such an employee,
5 partner, or self-employed individual in relation to the
6 plan.

7 “(9) APPLICABLE STATE AUTHORITY.—The
8 term ‘applicable State authority’ means, with respect
9 to a health insurance issuer in a State, the State in-
10 surance commissioner or official or officials des-
11 ignated by the State to enforce the requirements of
12 title XXVII of the Public Health Service Act for the
13 State involved with respect to such issuer.

14 “(10) QUALIFIED ACTUARY.—The term ‘quali-
15 fied actuary’ means an individual who is a member
16 of the American Academy of Actuaries.

17 “(11) AFFILIATED MEMBER.—The term ‘affili-
18 ated member’ means, in connection with a sponsor—

19 “(A) a person who is otherwise eligible to
20 be a member of the sponsor but who elects an
21 affiliated status with the sponsor,

22 “(B) in the case of a sponsor with mem-
23 bers which consist of associations, a person who
24 is a member of any such association and elects
25 an affiliated status with the sponsor, or

1 “(C) in the case of an association health
2 plan in existence on the date of the enactment
3 of the Small Business Health Fairness Act of
4 2009, a person eligible to be a member of the
5 sponsor or one of its member associations.

6 “(12) LARGE EMPLOYER.—The term ‘large em-
7 ployer’ means, in connection with a group health
8 plan with respect to a plan year, an employer who
9 employed an average of at least 51 employees on
10 business days during the preceding calendar year
11 and who employs at least 2 employees on the first
12 day of the plan year.

13 “(13) SMALL EMPLOYER.—The term ‘small em-
14 ployer’ means, in connection with a group health
15 plan with respect to a plan year, an employer who
16 is not a large employer.

17 “(b) RULES OF CONSTRUCTION.—

18 “(1) EMPLOYERS AND EMPLOYEES.—For pur-
19 poses of determining whether a plan, fund, or pro-
20 gram is an employee welfare benefit plan which is an
21 association health plan, and for purposes of applying
22 this title in connection with such plan, fund, or pro-
23 gram so determined to be such an employee welfare
24 benefit plan—

1 “(A) in the case of a partnership, the term
2 ‘employer’ (as defined in section 3(5)) includes
3 the partnership in relation to the partners, and
4 the term ‘employee’ (as defined in section 3(6))
5 includes any partner in relation to the partner-
6 ship; and

7 “(B) in the case of a self-employed indi-
8 vidual, the term ‘employer’ (as defined in sec-
9 tion 3(5)) and the term ‘employee’ (as defined
10 in section 3(6)) shall include such individual.

11 “(2) PLANS, FUNDS, AND PROGRAMS TREATED
12 AS EMPLOYEE WELFARE BENEFIT PLANS.—In the
13 case of any plan, fund, or program which was estab-
14 lished or is maintained for the purpose of providing
15 medical care (through the purchase of insurance or
16 otherwise) for employees (or their dependents) cov-
17 ered thereunder and which demonstrates to the Sec-
18 retary that all requirements for certification under
19 this part would be met with respect to such plan,
20 fund, or program if such plan, fund, or program
21 were a group health plan, such plan, fund, or pro-
22 gram shall be treated for purposes of this title as an
23 employee welfare benefit plan on and after the date
24 of such demonstration.”.

1 (b) CONFORMING AMENDMENTS TO PREEMPTION
2 RULES.—

3 (1) Section 514(b)(6) of such Act (29 U.S.C.
4 1144(b)(6)) is amended by adding at the end the
5 following new subparagraph:

6 “(E) The preceding subparagraphs of this paragraph
7 do not apply with respect to any State law in the case
8 of an association health plan which is certified under part
9 8.”.

10 (2) Section 514 of such Act (29 U.S.C. 1144)
11 is amended—

12 (A) in subsection (b)(4), by striking “Sub-
13 section (a)” and inserting “Subsections (a) and
14 (d)”;

15 (B) in subsection (b)(5), by striking “sub-
16 section (a)” in subparagraph (A) and inserting
17 “subsection (a) of this section and subsections
18 (a)(2)(B) and (b) of section 805”, and by strik-
19 ing “subsection (a)” in subparagraph (B) and
20 inserting “subsection (a) of this section or sub-
21 section (a)(2)(B) or (b) of section 805”;

22 (C) by redesignating subsections (d) and
23 (e) as subsections (e) and (f), respectively; and

24 (D) by inserting after subsection (c) the
25 following new subsection:

1 “(d)(1) Except as provided in subsection (b)(4), the
2 provisions of this title shall supersede any and all State
3 laws insofar as they may now or hereafter preclude, or
4 have the effect of precluding, a health insurance issuer
5 from offering health insurance coverage in connection with
6 an association health plan which is certified under part
7 8.

8 “(2) Except as provided in paragraphs (4) and (5)
9 of subsection (b) of this section—

10 “(A) In any case in which health insurance cov-
11 erage of any policy type is offered under an associa-
12 tion health plan certified under part 8 to a partici-
13 pating employer operating in such State, the provi-
14 sions of this title shall supersede any and all laws
15 of such State insofar as they may preclude a health
16 insurance issuer from offering health insurance cov-
17 erage of the same policy type to other employers op-
18 erating in the State which are eligible for coverage
19 under such association health plan, whether or not
20 such other employers are participating employers in
21 such plan.

22 “(B) In any case in which health insurance cov-
23 erage of any policy type is offered in a State under
24 an association health plan certified under part 8 and
25 the filing, with the applicable State authority (as de-

1 fined in section 812(a)(9)), of the policy form in
2 connection with such policy type is approved by such
3 State authority, the provisions of this title shall su-
4 percede any and all laws of any other State in which
5 health insurance coverage of such type is offered, in-
6 sofar as they may preclude, upon the filing in the
7 same form and manner of such policy form with the
8 applicable State authority in such other State, the
9 approval of the filing in such other State.

10 “(3) Nothing in subsection (b)(6)(E) or the preceding
11 provisions of this subsection shall be construed, with re-
12 spect to health insurance issuers or health insurance cov-
13 erage, to supersede or impair the law of any State—

14 “(A) providing solvency standards or similar
15 standards regarding the adequacy of insurer capital,
16 surplus, reserves, or contributions, or

17 “(B) relating to prompt payment of claims.

18 “(4) For additional provisions relating to association
19 health plans, see subsections (a)(2)(B) and (b) of section
20 805.

21 “(5) For purposes of this subsection, the term ‘asso-
22 ciation health plan’ has the meaning provided in section
23 801(a), and the terms ‘health insurance coverage’, ‘par-
24 ticipating employer’, and ‘health insurance issuer’ have

1 the meanings provided such terms in section 812, respec-
2 tively.”.

3 (3) Section 514(b)(6)(A) of such Act (29
4 U.S.C. 1144(b)(6)(A)) is amended—

5 (A) in clause (i)(II), by striking “and” at
6 the end;

7 (B) in clause (ii), by inserting “and which
8 does not provide medical care (within the mean-
9 ing of section 733(a)(2)),” after “arrange-
10 ment,” and by striking “title.” and inserting
11 “title, and”; and

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

14 “(iii) subject to subparagraph (E), in the case
15 of any other employee welfare benefit plan which is
16 a multiple employer welfare arrangement and which
17 provides medical care (within the meaning of section
18 733(a)(2)), any law of any State which regulates in-
19 surance may apply.”.

20 (4) Section 514(e) of such Act (as redesignated
21 by paragraph (2)(C)) is amended—

22 (A) by striking “Nothing” and inserting
23 “(1) Except as provided in paragraph (2), noth-
24 ing”; and

1 (B) by adding at the end the following new
2 paragraph:

3 “(2) Nothing in any other provision of law enacted
4 on or after the date of the enactment of the Small Busi-
5 ness Health Fairness Act of 2009 shall be construed to
6 alter, amend, modify, invalidate, impair, or supersede any
7 provision of this title, except by specific cross-reference to
8 the affected section.”.

9 (c) PLAN SPONSOR.—Section 3(16)(B) of such Act
10 (29 U.S.C. 102(16)(B)) is amended by adding at the end
11 the following new sentence: “Such term also includes a
12 person serving as the sponsor of an association health plan
13 under part 8.”.

14 (d) DISCLOSURE OF SOLVENCY PROTECTIONS RE-
15 LATED TO SELF-INSURED AND FULLY INSURED OPTIONS
16 UNDER ASSOCIATION HEALTH PLANS.—Section 102(b)
17 of such Act (29 U.S.C. 102(b)) is amended by adding at
18 the end the following: “An association health plan shall
19 include in its summary plan description, in connection
20 with each benefit option, a description of the form of sol-
21 vency or guarantee fund protection secured pursuant to
22 this Act or applicable State law, if any.”.

23 (e) SAVINGS CLAUSE.—Section 731(c) of such Act is
24 amended by inserting “or part 8” after “this part”.

1 (f) REPORT TO THE CONGRESS REGARDING CERTIFI-
2 CATION OF SELF-INSURED ASSOCIATION HEALTH
3 PLANS.—Not later than January 1, 2012, the Secretary
4 of Labor shall report to the Committee on Education and
5 the Workforce of the House of Representatives and the
6 Committee on Health, Education, Labor, and Pensions of
7 the Senate the effect association health plans have had,
8 if any, on reducing the number of uninsured individuals.

9 (g) CLERICAL AMENDMENT.—The table of contents
10 in section 1 of the Employee Retirement Income Security
11 Act of 1974 is amended by inserting after the item relat-
12 ing to section 734 the following new items:

“PART 8—RULES GOVERNING ASSOCIATION HEALTH PLANS

“801. Association health plans.

“802. Certification of association health plans.

“803. Requirements relating to sponsors and boards of trustees.

“804. Participation and coverage requirements.

“805. Other requirements relating to plan documents, contribution rates, and
benefit options.

“806. Maintenance of reserves and provisions for solvency for plans providing
health benefits in addition to health insurance coverage.

“807. Requirements for application and related requirements.

“808. Notice requirements for voluntary termination.

“809. Corrective actions and mandatory termination.

“810. Trusteeship by the Secretary of insolvent association health plans pro-
viding health benefits in addition to health insurance coverage.

“811. State assessment authority.

“812. Definitions and rules of construction.”.

13 **SEC. 202. CLARIFICATION OF TREATMENT OF SINGLE EM-**
14 **PLOYER ARRANGEMENTS.**

15 Section 3(40)(B) of the Employee Retirement Income
16 Security Act of 1974 (29 U.S.C. 1002(40)(B)) is amend-
17 ed—

1 (1) in clause (i), by inserting after “control
2 group,” the following: “except that, in any case in
3 which the benefit referred to in subparagraph (A)
4 consists of medical care (as defined in section
5 812(a)(2)), two or more trades or businesses, wheth-
6 er or not incorporated, shall be deemed a single em-
7 ployer for any plan year of such plan, or any fiscal
8 year of such other arrangement, if such trades or
9 businesses are within the same control group during
10 such year or at any time during the preceding 1-year
11 period,”;

12 (2) in clause (iii), by striking “(iii) the deter-
13 mination” and inserting the following:

14 “(iii)(I) in any case in which the benefit re-
15 ferred to in subparagraph (A) consists of medical
16 care (as defined in section 812(a)(2)), the deter-
17 mination of whether a trade or business is under
18 ‘common control’ with another trade or business
19 shall be determined under regulations of the Sec-
20 retary applying principles consistent and coextensive
21 with the principles applied in determining whether
22 employees of two or more trades or businesses are
23 treated as employed by a single employer under sec-
24 tion 4001(b), except that, for purposes of this para-
25 graph, an interest of greater than 25 percent may

1 not be required as the minimum interest necessary
2 for common control, or

3 “(II) in any other case, the determination”;

4 (3) by redesignating clauses (iv) and (v) as
5 clauses (v) and (vi), respectively; and

6 (4) by inserting after clause (iii) the following
7 new clause:

8 “(iv) in any case in which the benefit referred
9 to in subparagraph (A) consists of medical care (as
10 defined in section 812(a)(2)), in determining, after
11 the application of clause (i), whether benefits are
12 provided to employees of two or more employers, the
13 arrangement shall be treated as having only one par-
14 ticipating employer if, after the application of clause
15 (i), the number of individuals who are employees and
16 former employees of any one participating employer
17 and who are covered under the arrangement is
18 greater than 75 percent of the aggregate number of
19 all individuals who are employees or former employ-
20 ees of participating employers and who are covered
21 under the arrangement,”.

22 **SEC. 203. ENFORCEMENT PROVISIONS RELATING TO ASSO-**
23 **CIATION HEALTH PLANS.**

24 (a) **CRIMINAL PENALTIES FOR CERTAIN WILLFUL**
25 **MISREPRESENTATIONS.**—Section 501 of the Employee

1 Retirement Income Security Act of 1974 (29 U.S.C. 1131)

2 is amended—

3 (1) by inserting “(a)” after “Sec. 501.”; and

4 (2) by adding at the end the following new sub-

5 section:

6 “(b) Any person who willfully falsely represents, to
7 any employee, any employee’s beneficiary, any employer,
8 the Secretary, or any State, a plan or other arrangement
9 established or maintained for the purpose of offering or
10 providing any benefit described in section 3(1) to employ-
11 ees or their beneficiaries as—

12 “(1) being an association health plan which has
13 been certified under part 8;

14 “(2) having been established or maintained
15 under or pursuant to one or more collective bar-
16 gaining agreements which are reached pursuant to
17 collective bargaining described in section 8(d) of the
18 National Labor Relations Act (29 U.S.C. 158(d)) or
19 paragraph Fourth of section 2 of the Railway Labor
20 Act (45 U.S.C. 152, paragraph Fourth) or which are
21 reached pursuant to labor-management negotiations
22 under similar provisions of State public employee re-
23 lations laws; or

24 “(3) being a plan or arrangement described in
25 section 3(40)(A)(i),

1 shall, upon conviction, be imprisoned not more than 5
2 years, be fined under title 18, United States Code, or
3 both.”.

4 (b) CEASE ACTIVITIES ORDERS.—Section 502 of
5 such Act (29 U.S.C. 1132) is amended by adding at the
6 end the following new subsection:

7 “(n) ASSOCIATION HEALTH PLAN CEASE AND DE-
8 SIST ORDERS.—

9 “(1) IN GENERAL.—Subject to paragraph (2),
10 upon application by the Secretary showing the oper-
11 ation, promotion, or marketing of an association
12 health plan (or similar arrangement providing bene-
13 fits consisting of medical care (as defined in section
14 733(a)(2))) that—

15 “(A) is not certified under part 8, is sub-
16 ject under section 514(b)(6) to the insurance
17 laws of any State in which the plan or arrange-
18 ment offers or provides benefits, and is not li-
19 censed, registered, or otherwise approved under
20 the insurance laws of such State; or

21 “(B) is an association health plan certified
22 under part 8 and is not operating in accordance
23 with the requirements under part 8 for such
24 certification,

1 a district court of the United States shall enter an
2 order requiring that the plan or arrangement cease
3 activities.

4 “(2) EXCEPTION.—Paragraph (1) shall not
5 apply in the case of an association health plan or
6 other arrangement if the plan or arrangement shows
7 that—

8 “(A) all benefits under it referred to in
9 paragraph (1) consist of health insurance cov-
10 erage; and

11 “(B) with respect to each State in which
12 the plan or arrangement offers or provides ben-
13 efits, the plan or arrangement is operating in
14 accordance with applicable State laws that are
15 not superseded under section 514.

16 “(3) ADDITIONAL EQUITABLE RELIEF.—The
17 court may grant such additional equitable relief, in-
18 cluding any relief available under this title, as it
19 deems necessary to protect the interests of the pub-
20 lic and of persons having claims for benefits against
21 the plan.”.

22 (c) RESPONSIBILITY FOR CLAIMS PROCEDURE.—
23 Section 503 of such Act (29 U.S.C. 1133) is amended by
24 inserting “(a) IN GENERAL.—” before “In accordance”,
25 and by adding at the end the following new subsection:

1 “(b) ASSOCIATION HEALTH PLANS.—The terms of
2 each association health plan which is or has been certified
3 under part 8 shall require the board of trustees or the
4 named fiduciary (as applicable) to ensure that the require-
5 ments of this section are met in connection with claims
6 filed under the plan.”.

7 **SEC. 204. COOPERATION BETWEEN FEDERAL AND STATE**
8 **AUTHORITIES.**

9 Section 506 of the Employee Retirement Income Se-
10 curity Act of 1974 (29 U.S.C. 1136) is amended by adding
11 at the end the following new subsection:

12 “(d) CONSULTATION WITH STATES WITH RESPECT
13 TO ASSOCIATION HEALTH PLANS.—

14 “(1) AGREEMENTS WITH STATES.—The Sec-
15 retary shall consult with the State recognized under
16 paragraph (2) with respect to an association health
17 plan regarding the exercise of—

18 “(A) the Secretary’s authority under sec-
19 tions 502 and 504 to enforce the requirements
20 for certification under part 8; and

21 “(B) the Secretary’s authority to certify
22 association health plans under part 8 in accord-
23 ance with regulations of the Secretary applica-
24 ble to certification under part 8.

1 “(2) RECOGNITION OF PRIMARY DOMICILE
2 STATE.—In carrying out paragraph (1), the Sec-
3 retary shall ensure that only one State will be recog-
4 nized, with respect to any particular association
5 health plan, as the State with which consultation is
6 required. In carrying out this paragraph—

7 “(A) in the case of a plan which provides
8 health insurance coverage (as defined in section
9 812(a)(3)), such State shall be the State with
10 which filing and approval of a policy type of-
11 fered by the plan was initially obtained, and

12 “(B) in any other case, the Secretary shall
13 take into account the places of residence of the
14 participants and beneficiaries under the plan
15 and the State in which the trust is main-
16 tained.”.

17 **SEC. 205. EFFECTIVE DATE AND TRANSITIONAL AND**
18 **OTHER RULES.**

19 (a) EFFECTIVE DATE.—The amendments made by
20 this title shall take effect 1 year after the date of the en-
21 actment of this Act. The Secretary of Labor shall first
22 issue all regulations necessary to carry out the amend-
23 ments made by this title within 1 year after the date of
24 the enactment of this Act.

1 (b) TREATMENT OF CERTAIN EXISTING HEALTH
2 BENEFITS PROGRAMS.—

3 (1) IN GENERAL.—In any case in which, as of
4 the date of the enactment of this Act, an arrange-
5 ment is maintained in a State for the purpose of
6 providing benefits consisting of medical care for the
7 employees and beneficiaries of its participating em-
8 ployers, at least 200 participating employers make
9 contributions to such arrangement, such arrange-
10 ment has been in existence for at least 10 years, and
11 such arrangement is licensed under the laws of one
12 or more States to provide such benefits to its par-
13 ticipating employers, upon the filing with the appli-
14 cable authority (as defined in section 812(a)(5) of
15 the Employee Retirement Income Security Act of
16 1974 (as amended by this subtitle)) by the arrange-
17 ment of an application for certification of the ar-
18 rangement under part 8 of subtitle B of title I of
19 such Act—

20 (A) such arrangement shall be deemed to
21 be a group health plan for purposes of title I
22 of such Act;

23 (B) the requirements of sections 801(a)
24 and 803(a) of the Employee Retirement Income

1 Security Act of 1974 shall be deemed met with
2 respect to such arrangement;

3 (C) the requirements of section 803(b) of
4 such Act shall be deemed met, if the arrange-
5 ment is operated by a board of directors
6 which—

7 (i) is elected by the participating em-
8 ployers, with each employer having one
9 vote; and

10 (ii) has complete fiscal control over
11 the arrangement and which is responsible
12 for all operations of the arrangement;

13 (D) the requirements of section 804(a) of
14 such Act shall be deemed met with respect to
15 such arrangement; and

16 (E) the arrangement may be certified by
17 any applicable authority with respect to its op-
18 erations in any State only if it operates in such
19 State on the date of certification.

20 The provisions of this subsection shall cease to apply
21 with respect to any such arrangement at such time
22 after the date of the enactment of this Act as the
23 applicable requirements of this subsection are not
24 met with respect to such arrangement.

1 (2) DEFINITIONS.—For purposes of this sub-
2 section, the terms “group health plan”, “medical
3 care”, and “participating employer” shall have the
4 meanings provided in section 812 of the Employee
5 Retirement Income Security Act of 1974, except
6 that the reference in paragraph (7) of such section
7 to an “association health plan” shall be deemed a
8 reference to an arrangement referred to in this sub-
9 section.

10 **TITLE II—TARGETED EFFORTS** 11 **TO EXPAND ACCESS**

12 **SEC. 211. EXTENDING COVERAGE OF DEPENDENTS.**

13 (a) ERISA.—

14 (1) IN GENERAL.—Part 7 of subtitle B of title
15 I of the Employee Retirement Income Security Act
16 of 1974 is amended by inserting after section 2714
17 the following new section:

18 **“SEC. 715. EXTENDING COVERAGE OF DEPENDENTS.**

19 “(a) IN GENERAL.—In the case of a group health
20 plan, or health insurance coverage offered in connection
21 with a group health plan, that treats as a beneficiary
22 under the plan an individual who is a dependent child of
23 a participant or beneficiary under the plan, the plan or
24 coverage shall continue to treat the individual as a depend-
25 ent child without regard to the individual’s age through

1 at least the end of the plan year in which the individual
2 turns an age specified in the plan, but not less than 25
3 years of age.

4 “(b) CONSTRUCTION.—Nothing in this section shall
5 be construed as requiring a group health plan to provide
6 benefits for dependent children as beneficiaries under the
7 plan or to require a participant to elect coverage of de-
8 pendent children.”.

9 (2) CLERICAL AMENDMENT.—The table of con-
10 tents of such Act is amended by inserting after the
11 item relating to section 714 the following new item:

“Sec. 715. Extending coverage of dependents through plan year that includes
25th birthday.”.

12 (b) PHSA.—Title XXVII of the Public Health Serv-
13 ice Act is amended by inserting after section 2707 the fol-
14 lowing new section:

15 **“SEC. 2708. EXTENDING COVERAGE OF DEPENDENTS.**

16 “(a) IN GENERAL.—In the case of a group health
17 plan, or health insurance coverage offered in connection
18 with a group health plan, that treats as a beneficiary
19 under the plan an individual who is a dependent child of
20 a participant or beneficiary under the plan, the plan or
21 coverage shall continue to treat the individual as a depend-
22 ent child without regard to the individual’s age through
23 at least the end of the plan year in which the individual

1 turns an age specified in the plan, but not less than 25
2 years of age..

3 “(b) CONSTRUCTION.—Nothing in this section shall
4 be construed as requiring a group health plan to provide
5 benefits for dependent children as beneficiaries under the
6 plan or to require a participant to elect coverage of de-
7 pendent children.”.

8 (c) IRC.—

9 (1) IN GENERAL.—Subchapter B of chapter
10 100 of the Internal Revenue Code of 1986 is amend-
11 ed by adding at the end the following new section:

12 **“SEC. 9814. EXTENDING COVERAGE OF DEPENDENTS.**

13 “(a) IN GENERAL.—In the case of a group health
14 plan that treats as a beneficiary under the plan an indi-
15 vidual who is a dependent child of a participant or bene-
16 ficiary under the plan, the plan shall continue to treat the
17 individual as a dependent child without regard to the indi-
18 vidual’s age through at least the end of the plan year in
19 which the individual turns an age specified in the plan,
20 but not less than 25 years of age.

21 “(b) CONSTRUCTION.—Nothing in this section shall
22 be construed as requiring a group health plan to provide
23 coverage for dependent children as beneficiaries under the
24 plan or to require a participant to elect coverage of de-
25 pendent children.”.

1 (2) CLERICAL AMENDMENT.—The table of sec-
2 tions in such subchapter is amended by adding at
3 the end the following new item:

“Sec. 9814. Extending coverage of dependents through plan year that includes
25th birthday.”.

4 (d) EFFECTIVE DATE.—The amendments made by
5 this section shall apply to group health plans for plan
6 years beginning more than 3 months after the date of the
7 enactment of this Act and shall apply to individuals who
8 are dependent children under a group health plan, or
9 health insurance coverage offered in connection with such
10 a plan, on or after such date.

11 **SEC. 212. ALLOWING AUTO-ENROLLMENT FOR EMPLOYER**
12 **SPONSORED COVERAGE.**

13 (a) IN GENERAL.—No State shall establish a law
14 that prevents an employer from instituting auto-enroll-
15 ment for coverage of a participant or beneficiary, including
16 current employees, under a group health plan, or health
17 insurance coverage offered in connection with such a plan,
18 so long as the participant or beneficiary has the option
19 of declining such coverage.

20 (b) AUTOENROLLMENT.—

21 (1) NOTICE REQUIRED.—Employers with auto-
22 enrollment under a group health plan or health in-
23 surance coverage shall provide annual notification,
24 within a reasonable period before the beginning of

1 each plan year, to each employee eligible to partici-
2 pate in the plan. The notice shall explain the em-
3 ployee contribution to such plan and the employee's
4 right to decline coverage.

5 (2) TREATMENT OF NON-ACTION.—After a rea-
6 sonable period of time after receipt of the notice, if
7 an employee fails to make an affirmative declaration
8 declining coverage, then such an employee may be
9 enrolled in the group health plan or health insurance
10 coverage offered in connection with such a plan.”

11 (c) CONSTRUCTION.—Nothing in this section shall be
12 construed to supersede State law which establishes, imple-
13 ments, or continues in effect any standard or requirement
14 relating to employers in connection with payroll or the
15 sponsoring of employer sponsored health insurance cov-
16 erage except to the extent that such standard or require-
17 ment prevents an employer from instituting the auto-en-
18 rollment described in subsection (a).

1 **TITLE III—EXPANDING CHOICES**
2 **BY ALLOWING AMERICANS TO**
3 **BUY HEALTH CARE COV-**
4 **ERAGE ACROSS STATE LINES**

5 **SEC. 221. INTERSTATE PURCHASING OF HEALTH INSUR-**
6 **ANCE.**

7 (a) IN GENERAL.—Title XXVII of the Public Health
8 Service Act (42 U.S.C. 300gg et seq.) is amended by add-
9 ing at the end the following new part:

10 **“PART D—COOPERATIVE GOVERNING OF**
11 **INDIVIDUAL HEALTH INSURANCE COVERAGE**

12 **“SEC. 2795. DEFINITIONS.**

13 “In this part:

14 “(1) PRIMARY STATE.—The term ‘primary
15 State’ means, with respect to individual health insur-
16 ance coverage offered by a health insurance issuer,
17 the State designated by the issuer as the State
18 whose covered laws shall govern the health insurance
19 issuer in the sale of such coverage under this part.
20 An issuer, with respect to a particular policy, may
21 only designate one such State as its primary State
22 with respect to all such coverage it offers. Such an
23 issuer may not change the designated primary State
24 with respect to individual health insurance coverage
25 once the policy is issued, except that such a change

1 may be made upon renewal of the policy. With re-
2 spect to such designated State, the issuer is deemed
3 to be doing business in that State.

4 “(2) SECONDARY STATE.—The term ‘secondary
5 State’ means, with respect to individual health insur-
6 ance coverage offered by a health insurance issuer,
7 any State that is not the primary State. In the case
8 of a health insurance issuer that is selling a policy
9 in, or to a resident of, a secondary State, the issuer
10 is deemed to be doing business in that secondary
11 State.

12 “(3) HEALTH INSURANCE ISSUER.—The term
13 ‘health insurance issuer’ has the meaning given such
14 term in section 2791(b)(2), except that such an
15 issuer must be licensed in the primary State and be
16 qualified to sell individual health insurance coverage
17 in that State.

18 “(4) INDIVIDUAL HEALTH INSURANCE COV-
19 ERAGE.—The term ‘individual health insurance cov-
20 erage’ means health insurance coverage offered in
21 the individual market, as defined in section
22 2791(e)(1).

23 “(5) APPLICABLE STATE AUTHORITY.—The
24 term ‘applicable State authority’ means, with respect
25 to a health insurance issuer in a State, the State in-

1 insurance commissioner or official or officials des-
2 ignated by the State to enforce the requirements of
3 this title for the State with respect to the issuer.

4 “(6) HAZARDOUS FINANCIAL CONDITION.—The
5 term ‘hazardous financial condition’ means that,
6 based on its present or reasonably anticipated finan-
7 cial condition, a health insurance issuer is unlikely
8 to be able—

9 “(A) to meet obligations to policyholders
10 with respect to known claims and reasonably
11 anticipated claims; or

12 “(B) to pay other obligations in the normal
13 course of business.

14 “(7) COVERED LAWS.—

15 “(A) IN GENERAL.—The term ‘covered
16 laws’ means the laws, rules, regulations, agree-
17 ments, and orders governing the insurance busi-
18 ness pertaining to—

19 “(i) individual health insurance cov-
20 erage issued by a health insurance issuer;

21 “(ii) the offer, sale, rating (including
22 medical underwriting), renewal, and
23 issuance of individual health insurance cov-
24 erage to an individual;

1 “(iii) the provision to an individual in
2 relation to individual health insurance cov-
3 erage of health care and insurance related
4 services;

5 “(iv) the provision to an individual in
6 relation to individual health insurance cov-
7 erage of management, operations, and in-
8 vestment activities of a health insurance
9 issuer; and

10 “(v) the provision to an individual in
11 relation to individual health insurance cov-
12 erage of loss control and claims adminis-
13 tration for a health insurance issuer with
14 respect to liability for which the issuer pro-
15 vides insurance.

16 “(B) EXCEPTION.—Such term does not in-
17 clude any law, rule, regulation, agreement, or
18 order governing the use of care or cost manage-
19 ment techniques, including any requirement re-
20 lated to provider contracting, network access or
21 adequacy, health care data collection, or quality
22 assurance.

23 “(8) STATE.—The term ‘State’ means the 50
24 States and includes the District of Columbia, Puerto

1 Rico, the Virgin Islands, Guam, American Samoa,
2 and the Northern Mariana Islands.

3 “(9) UNFAIR CLAIMS SETTLEMENT PRAC-
4 TICES.—The term ‘unfair claims settlement prac-
5 tices’ means only the following practices:

6 “(A) Knowingly misrepresenting to claim-
7 ants and insured individuals relevant facts or
8 policy provisions relating to coverage at issue.

9 “(B) Failing to acknowledge with reason-
10 able promptness pertinent communications with
11 respect to claims arising under policies.

12 “(C) Failing to adopt and implement rea-
13 sonable standards for the prompt investigation
14 and settlement of claims arising under policies.

15 “(D) Failing to effectuate prompt, fair,
16 and equitable settlement of claims submitted in
17 which liability has become reasonably clear.

18 “(E) Refusing to pay claims without con-
19 ducting a reasonable investigation.

20 “(F) Failing to affirm or deny coverage of
21 claims within a reasonable period of time after
22 having completed an investigation related to
23 those claims.

24 “(G) A pattern or practice of compelling
25 insured individuals or their beneficiaries to in-

1 stitute suits to recover amounts due under its
2 policies by offering substantially less than the
3 amounts ultimately recovered in suits brought
4 by them.

5 “(H) A pattern or practice of attempting
6 to settle or settling claims for less than the
7 amount that a reasonable person would believe
8 the insured individual or his or her beneficiary
9 was entitled by reference to written or printed
10 advertising material accompanying or made
11 part of an application.

12 “(I) Attempting to settle or settling claims
13 on the basis of an application that was materi-
14 ally altered without notice to, or knowledge or
15 consent of, the insured.

16 “(J) Failing to provide forms necessary to
17 present claims within 15 calendar days of a re-
18 quests with reasonable explanations regarding
19 their use.

20 “(K) Attempting to cancel a policy in less
21 time than that prescribed in the policy or by the
22 law of the primary State.

23 “(10) FRAUD AND ABUSE.—The term ‘fraud
24 and abuse’ means an act or omission committed by
25 a person who, knowingly and with intent to defraud,

1 commits, or conceals any material information con-
2 cerning, one or more of the following:

3 “(A) Presenting, causing to be presented
4 or preparing with knowledge or belief that it
5 will be presented to or by an insurer, a rein-
6 surer, broker or its agent, false information as
7 part of, in support of or concerning a fact ma-
8 terial to one or more of the following:

9 “(i) An application for the issuance or
10 renewal of an insurance policy or reinsur-
11 ance contract.

12 “(ii) The rating of an insurance policy
13 or reinsurance contract.

14 “(iii) A claim for payment or benefit
15 pursuant to an insurance policy or reinsur-
16 ance contract.

17 “(iv) Premiums paid on an insurance
18 policy or reinsurance contract.

19 “(v) Payments made in accordance
20 with the terms of an insurance policy or
21 reinsurance contract.

22 “(vi) A document filed with the com-
23 missioner or the chief insurance regulatory
24 official of another jurisdiction.

1 “(vii) The financial condition of an in-
2 surer or reinsurer.

3 “(viii) The formation, acquisition,
4 merger, reconsolidation, dissolution or
5 withdrawal from one or more lines of in-
6 surance or reinsurance in all or part of a
7 State by an insurer or reinsurer.

8 “(ix) The issuance of written evidence
9 of insurance.

10 “(x) The reinstatement of an insur-
11 ance policy.

12 “(B) Solicitation or acceptance of new or
13 renewal insurance risks on behalf of an insurer
14 reinsurer or other person engaged in the busi-
15 ness of insurance by a person who knows or
16 should know that the insurer or other person
17 responsible for the risk is insolvent at the time
18 of the transaction.

19 “(C) Transaction of the business of insur-
20 ance in violation of laws requiring a license, cer-
21 tificate of authority or other legal authority for
22 the transaction of the business of insurance.

23 “(D) Attempt to commit, aiding or abet-
24 ting in the commission of, or conspiracy to com-

1 mit the acts or omissions specified in this para-
2 graph.

3 **“SEC. 2796. APPLICATION OF LAW.**

4 “(a) IN GENERAL.—The covered laws of the primary
5 State shall apply to individual health insurance coverage
6 offered by a health insurance issuer in the primary State
7 and in any secondary State, but only if the coverage and
8 issuer comply with the conditions of this section with re-
9 spect to the offering of coverage in any secondary State.

10 “(b) EXEMPTIONS FROM COVERED LAWS IN A SEC-
11 ONDARY STATE.—Except as provided in this section, a
12 health insurance issuer with respect to its offer, sale, rat-
13 ing (including medical underwriting), renewal, and
14 issuance of individual health insurance coverage in any
15 secondary State is exempt from any covered laws of the
16 secondary State (and any rules, regulations, agreements,
17 or orders sought or issued by such State under or related
18 to such covered laws) to the extent that such laws would—

19 “(1) make unlawful, or regulate, directly or in-
20 directly, the operation of the health insurance issuer
21 operating in the secondary State, except that any
22 secondary State may require such an issuer—

23 “(A) to pay, on a nondiscriminatory basis,
24 applicable premium and other taxes (including
25 high risk pool assessments) which are levied on

1 insurers and surplus lines insurers, brokers, or
2 policyholders under the laws of the State;

3 “(B) to register with and designate the
4 State insurance commissioner as its agent solely
5 for the purpose of receiving service of legal doc-
6 uments or process;

7 “(C) to submit to an examination of its fi-
8 nancial condition by the State insurance com-
9 missioner in any State in which the issuer is
10 doing business to determine the issuer’s finan-
11 cial condition, if—

12 “(i) the State insurance commissioner
13 of the primary State has not done an ex-
14 amination within the period recommended
15 by the National Association of Insurance
16 Commissioners; and

17 “(ii) any such examination is con-
18 ducted in accordance with the examiners’
19 handbook of the National Association of
20 Insurance Commissioners and is coordi-
21 nated to avoid unjustified duplication and
22 unjustified repetition;

23 “(D) to comply with a lawful order
24 issued—

1 “(i) in a delinquency proceeding com-
2 menced by the State insurance commis-
3 sioner if there has been a finding of finan-
4 cial impairment under subparagraph (C);
5 or

6 “(ii) in a voluntary dissolution pro-
7 ceeding;

8 “(E) to comply with an injunction issued
9 by a court of competent jurisdiction, upon a pe-
10 tition by the State insurance commissioner al-
11 leging that the issuer is in hazardous financial
12 condition;

13 “(F) to participate, on a nondiscriminatory
14 basis, in any insurance insolvency guaranty as-
15 sociation or similar association to which a
16 health insurance issuer in the State is required
17 to belong;

18 “(G) to comply with any State law regard-
19 ing fraud and abuse (as defined in section
20 2795(10)), except that if the State seeks an in-
21 junction regarding the conduct described in this
22 subparagraph, such injunction must be obtained
23 from a court of competent jurisdiction;

1 “(H) to comply with any State law regard-
2 ing unfair claims settlement practices (as de-
3 fined in section 2795(9)); or

4 “(I) to comply with the applicable require-
5 ments for independent review under section
6 2798 with respect to coverage offered in the
7 State;

8 “(2) require any individual health insurance
9 coverage issued by the issuer to be countersigned by
10 an insurance agent or broker residing in that Sec-
11 ondary State; or

12 “(3) otherwise discriminate against the issuer
13 issuing insurance in both the primary State and in
14 any secondary State.

15 “(c) CLEAR AND CONSPICUOUS DISCLOSURE.—A
16 health insurance issuer shall provide the following notice,
17 in 12-point bold type, in any insurance coverage offered
18 in a secondary State under this part by such a health in-
19 surance issuer and at renewal of the policy, with the 5
20 blank spaces therein being appropriately filled with the
21 name of the health insurance issuer, the name of primary
22 State, the name of the secondary State, the name of the
23 secondary State, and the name of the secondary State, re-
24 spectively, for the coverage concerned:

1 THIS POLICY IS ISSUED BY _____ AND IS GOV-
2 ERNED BY THE LAWS AND REGULATIONS
3 OF THE STATE OF _____, AND IT HAS
4 MET ALL THE LAWS OF THAT STATE AS DE-
5 TERMINED BY THAT STATE'S DEPART-
6 MENT OF INSURANCE. THIS POLICY MAY
7 BE LESS EXPENSIVE THAN OTHERS BE-
8 CAUSE IT IS NOT SUBJECT TO ALL OF THE
9 INSURANCE LAWS AND REGULATIONS OF
10 THE STATE OF _____, INCLUDING COV-
11 ERAGE OF SOME SERVICES OR BENEFITS
12 MANDATED BY THE LAW OF THE STATE OF
13 _____. ADDITIONALLY, THIS POLICY IS
14 NOT SUBJECT TO ALL OF THE CONSUMER
15 PROTECTION LAWS OR RESTRICTIONS ON
16 RATE CHANGES OF THE STATE OF
17 _____. AS WITH ALL INSURANCE PROD-
18 UCTS, BEFORE PURCHASING THIS POLICY,
19 YOU SHOULD CAREFULLY REVIEW THE
20 POLICY AND DETERMINE WHAT HEALTH
21 CARE SERVICES THE POLICY COVERS AND
22 WHAT BENEFITS IT PROVIDES, INCLUDING
23 ANY EXCLUSIONS, LIMITATIONS, OR CON-
24 DITIONS FOR SUCH SERVICES OR BENE-
25 FITS.”.

1 “(d) PROHIBITION ON CERTAIN RECLASSIFICATIONS
2 AND PREMIUM INCREASES.—

3 “(1) IN GENERAL.—For purposes of this sec-
4 tion, a health insurance issuer that provides indi-
5 vidual health insurance coverage to an individual
6 under this part in a primary or secondary State may
7 not upon renewal—

8 “(A) move or reclassify the individual in-
9 sured under the health insurance coverage from
10 the class such individual is in at the time of
11 issue of the contract based on the health-status
12 related factors of the individual; or

13 “(B) increase the premiums assessed the
14 individual for such coverage based on a health
15 status-related factor or change of a health sta-
16 tus-related factor or the past or prospective
17 claim experience of the insured individual.

18 “(2) CONSTRUCTION.—Nothing in paragraph
19 (1) shall be construed to prohibit a health insurance
20 issuer—

21 “(A) from terminating or discontinuing
22 coverage or a class of coverage in accordance
23 with subsections (b) and (c) of section 2742;

1 “(B) from raising premium rates for all
2 policy holders within a class based on claims ex-
3 perience;

4 “(C) from changing premiums or offering
5 discounted premiums to individuals who engage
6 in wellness activities at intervals prescribed by
7 the issuer, if such premium changes or incen-
8 tives—

9 “(i) are disclosed to the consumer in
10 the insurance contract;

11 “(ii) are based on specific wellness ac-
12 tivities that are not applicable to all indi-
13 viduals; and

14 “(iii) are not obtainable by all individ-
15 uals to whom coverage is offered;

16 “(D) from reinstating lapsed coverage; or

17 “(E) from retroactively adjusting the rates
18 charged an insured individual if the initial rates
19 were set based on material misrepresentation by
20 the individual at the time of issue.

21 “(e) PRIOR OFFERING OF POLICY IN PRIMARY
22 STATE.—A health insurance issuer may not offer for sale
23 individual health insurance coverage in a secondary State
24 unless that coverage is currently offered for sale in the
25 primary State.

1 “(f) LICENSING OF AGENTS OR BROKERS FOR
2 HEALTH INSURANCE ISSUERS.—Any State may require
3 that a person acting, or offering to act, as an agent or
4 broker for a health insurance issuer with respect to the
5 offering of individual health insurance coverage obtain a
6 license from that State, with commissions or other com-
7 pensation subject to the provisions of the laws of that
8 State, except that a State may not impose any qualifica-
9 tion or requirement which discriminates against a non-
10 resident agent or broker.

11 “(g) DOCUMENTS FOR SUBMISSION TO STATE IN-
12 SURANCE COMMISSIONER.—Each health insurance issuer
13 issuing individual health insurance coverage in both pri-
14 mary and secondary States shall submit—

15 “(1) to the insurance commissioner of each
16 State in which it intends to offer such coverage, be-
17 fore it may offer individual health insurance cov-
18 erage in such State—

19 “(A) a copy of the plan of operation or fea-
20 sibility study or any similar statement of the
21 policy being offered and its coverage (which
22 shall include the name of its primary State and
23 its principal place of business);

24 “(B) written notice of any change in its
25 designation of its primary State; and

1 “(C) written notice from the issuer of the
2 issuer’s compliance with all the laws of the pri-
3 mary State; and

4 “(2) to the insurance commissioner of each sec-
5 ondary State in which it offers individual health in-
6 surance coverage, a copy of the issuer’s quarterly fi-
7 nancial statement submitted to the primary State,
8 which statement shall be certified by an independent
9 public accountant and contain a statement of opin-
10 ion on loss and loss adjustment expense reserves
11 made by—

12 “(A) a member of the American Academy
13 of Actuaries; or

14 “(B) a qualified loss reserve specialist.

15 “(h) POWER OF COURTS TO ENJOIN CONDUCT.—
16 Nothing in this section shall be construed to affect the
17 authority of any Federal or State court to enjoin—

18 “(1) the solicitation or sale of individual health
19 insurance coverage by a health insurance issuer to
20 any person or group who is not eligible for such in-
21 surance; or

22 “(2) the solicitation or sale of individual health
23 insurance coverage that violates the requirements of
24 the law of a secondary State which are described in

1 subparagraphs (A) through (H) of section
2 2796(b)(1).

3 “(i) POWER OF SECONDARY STATES TO TAKE AD-
4 MINISTRATIVE ACTION.—Nothing in this section shall be
5 construed to affect the authority of any State to enjoin
6 conduct in violation of that State’s laws described in sec-
7 tion 2796(b)(1).

8 “(j) STATE POWERS TO ENFORCE STATE LAWS.—

9 “(1) IN GENERAL.—Subject to the provisions of
10 subsection (b)(1)(G) (relating to injunctions) and
11 paragraph (2), nothing in this section shall be con-
12 strued to affect the authority of any State to make
13 use of any of its powers to enforce the laws of such
14 State with respect to which a health insurance issuer
15 is not exempt under subsection (b).

16 “(2) COURTS OF COMPETENT JURISDICTION.—

17 If a State seeks an injunction regarding the conduct
18 described in paragraphs (1) and (2) of subsection
19 (h), such injunction must be obtained from a Fed-
20 eral or State court of competent jurisdiction.

21 “(k) STATES’ AUTHORITY TO SUE.—Nothing in this
22 section shall affect the authority of any State to bring ac-
23 tion in any Federal or State court.

24 “(l) GENERALLY APPLICABLE LAWS.—Nothing in
25 this section shall be construed to affect the applicability

1 of State laws generally applicable to persons or corpora-
2 tions.

3 “(m) GUARANTEED AVAILABILITY OF COVERAGE TO
4 HIPAA ELIGIBLE INDIVIDUALS.—To the extent that a
5 health insurance issuer is offering coverage in a primary
6 State that does not accommodate residents of secondary
7 States or does not provide a working mechanism for resi-
8 dents of a secondary State, and the issuer is offering cov-
9 erage under this part in such secondary State which has
10 not adopted a qualified high risk pool as its acceptable
11 alternative mechanism (as defined in section 2744(c)(2)),
12 the issuer shall, with respect to any individual health in-
13 surance coverage offered in a secondary State under this
14 part, comply with the guaranteed availability requirements
15 for eligible individuals in section 2741.

16 **“SEC. 2797. PRIMARY STATE MUST MEET FEDERAL FLOOR**
17 **BEFORE ISSUER MAY SELL INTO SECONDARY**
18 **STATES.**

19 “A health insurance issuer may not offer, sell, or
20 issue individual health insurance coverage in a secondary
21 State if the State insurance commissioner does not use
22 a risk-based capital formula for the determination of cap-
23 ital and surplus requirements for all health insurance
24 issuers.

1 **“SEC. 2798. INDEPENDENT EXTERNAL APPEALS PROCE-**
2 **DURES.**

3 “(a) **RIGHT TO EXTERNAL APPEAL.**—A health insur-
4 ance issuer may not offer, sell, or issue individual health
5 insurance coverage in a secondary State under the provi-
6 sions of this title unless—

7 “(1) both the secondary State and the primary
8 State have legislation or regulations in place estab-
9 lishing an independent review process for individuals
10 who are covered by individual health insurance cov-
11 erage, or

12 “(2) in any case in which the requirements of
13 subparagraph (A) are not met with respect to the ei-
14 ther of such States, the issuer provides an inde-
15 pendent review mechanism substantially identical (as
16 determined by the applicable State authority of such
17 State) to that prescribed in the ‘Health Carrier Ex-
18 ternal Review Model Act’ of the National Association
19 of Insurance Commissioners for all individuals who
20 purchase insurance coverage under the terms of this
21 part, except that, under such mechanism, the review
22 is conducted by an independent medical reviewer, or
23 a panel of such reviewers, with respect to whom the
24 requirements of subsection (b) are met.

1 “(b) QUALIFICATIONS OF INDEPENDENT MEDICAL
2 REVIEWERS.—In the case of any independent review
3 mechanism referred to in subsection (a)(2)—

4 “(1) IN GENERAL.—In referring a denial of a
5 claim to an independent medical reviewer, or to any
6 panel of such reviewers, to conduct independent
7 medical review, the issuer shall ensure that—

8 “(A) each independent medical reviewer
9 meets the qualifications described in paragraphs
10 (2) and (3);

11 “(B) with respect to each review, each re-
12 viewer meets the requirements of paragraph (4)
13 and the reviewer, or at least 1 reviewer on the
14 panel, meets the requirements described in
15 paragraph (5); and

16 “(C) compensation provided by the issuer
17 to each reviewer is consistent with paragraph
18 (6).

19 “(2) LICENSURE AND EXPERTISE.—Each inde-
20 pendent medical reviewer shall be a physician
21 (allopathic or osteopathic) or health care profes-
22 sional who—

23 “(A) is appropriately credentialed or li-
24 censed in 1 or more States to deliver health
25 care services; and

1 “(B) typically treats the condition, makes
2 the diagnosis, or provides the type of treatment
3 under review.

4 “(3) INDEPENDENCE.—

5 “(A) IN GENERAL.—Subject to subpara-
6 graph (B), each independent medical reviewer
7 in a case shall—

8 “(i) not be a related party (as defined
9 in paragraph (7));

10 “(ii) not have a material familial, fi-
11 nancial, or professional relationship with
12 such a party; and

13 “(iii) not otherwise have a conflict of
14 interest with such a party (as determined
15 under regulations).

16 “(B) EXCEPTION.—Nothing in subpara-
17 graph (A) shall be construed to—

18 “(i) prohibit an individual, solely on
19 the basis of affiliation with the issuer,
20 from serving as an independent medical re-
21 viewer if—

22 “(I) a non-affiliated individual is
23 not reasonably available;

1 “(II) the affiliated individual is
2 not involved in the provision of items
3 or services in the case under review;

4 “(III) the fact of such an affili-
5 ation is disclosed to the issuer and the
6 enrollee (or authorized representative)
7 and neither party objects; and

8 “(IV) the affiliated individual is
9 not an employee of the issuer and
10 does not provide services exclusively or
11 primarily to or on behalf of the issuer;

12 “(ii) prohibit an individual who has
13 staff privileges at the institution where the
14 treatment involved takes place from serv-
15 ing as an independent medical reviewer
16 merely on the basis of such affiliation if
17 the affiliation is disclosed to the issuer and
18 the enrollee (or authorized representative),
19 and neither party objects; or

20 “(iii) prohibit receipt of compensation
21 by an independent medical reviewer from
22 an entity if the compensation is provided
23 consistent with paragraph (6).

24 “(4) PRACTICING HEALTH CARE PROFESSIONAL
25 IN SAME FIELD.—

1 “(A) IN GENERAL.—In a case involving
2 treatment, or the provision of items or serv-
3 ices—

4 “(i) by a physician, a reviewer shall be
5 a practicing physician (allopathic or osteo-
6 pathic) of the same or similar specialty, as
7 a physician who, acting within the appro-
8 priate scope of practice within the State in
9 which the service is provided or rendered,
10 typically treats the condition, makes the
11 diagnosis, or provides the type of treat-
12 ment under review; or

13 “(ii) by a non-physician health care
14 professional, the reviewer, or at least 1
15 member of the review panel, shall be a
16 practicing non-physician health care pro-
17 fessional of the same or similar specialty
18 as the non-physician health care profes-
19 sional who, acting within the appropriate
20 scope of practice within the State in which
21 the service is provided or rendered, typi-
22 cally treats the condition, makes the diag-
23 nosis, or provides the type of treatment
24 under review.

1 “(B) PRACTICING DEFINED.—For pur-
2 poses of this paragraph, the term ‘practicing’
3 means, with respect to an individual who is a
4 physician or other health care professional, that
5 the individual provides health care services to
6 individual patients on average at least 2 days
7 per week.

8 “(5) PEDIATRIC EXPERTISE.—In the case of an
9 external review relating to a child, a reviewer shall
10 have expertise under paragraph (2) in pediatrics.

11 “(6) LIMITATIONS ON REVIEWER COMPENSA-
12 TION.—Compensation provided by the issuer to an
13 independent medical reviewer in connection with a
14 review under this section shall—

15 “(A) not exceed a reasonable level; and

16 “(B) not be contingent on the decision ren-
17 dered by the reviewer.

18 “(7) RELATED PARTY DEFINED.—For purposes
19 of this section, the term ‘related party’ means, with
20 respect to a denial of a claim under a coverage relat-
21 ing to an enrollee, any of the following:

22 “(A) The issuer involved, or any fiduciary,
23 officer, director, or employee of the issuer.

24 “(B) The enrollee (or authorized represent-
25 ative).

1 “(C) The health care professional that pro-
2 vides the items or services involved in the de-
3 nial.

4 “(D) The institution at which the items or
5 services (or treatment) involved in the denial
6 are provided.

7 “(E) The manufacturer of any drug or
8 other item that is included in the items or serv-
9 ices involved in the denial.

10 “(F) Any other party determined under
11 any regulations to have a substantial interest in
12 the denial involved.

13 “(8) DEFINITIONS.—For purposes of this sub-
14 section:

15 “(A) ENROLLEE.—The term ‘enrollee’
16 means, with respect to health insurance cov-
17 erage offered by a health insurance issuer, an
18 individual enrolled with the issuer to receive
19 such coverage.

20 “(B) HEALTH CARE PROFESSIONAL.—The
21 term ‘health care professional’ means an indi-
22 vidual who is licensed, accredited, or certified
23 under State law to provide specified health care
24 services and who is operating within the scope
25 of such licensure, accreditation, or certification.

1 **“SEC. 2799. ENFORCEMENT.**

2 “(a) IN GENERAL.—Subject to subsection (b), with
3 respect to specific individual health insurance coverage the
4 primary State for such coverage has sole jurisdiction to
5 enforce the primary State’s covered laws in the primary
6 State and any secondary State.

7 “(b) SECONDARY STATE’S AUTHORITY.—Nothing in
8 subsection (a) shall be construed to affect the authority
9 of a secondary State to enforce its laws as set forth in
10 the exception specified in section 2796(b)(1).

11 “(c) COURT INTERPRETATION.—In reviewing action
12 initiated by the applicable secondary State authority, the
13 court of competent jurisdiction shall apply the covered
14 laws of the primary State.

15 “(d) NOTICE OF COMPLIANCE FAILURE.—In the case
16 of individual health insurance coverage offered in a sec-
17 ondary State that fails to comply with the covered laws
18 of the primary State, the applicable State authority of the
19 secondary State may notify the applicable State authority
20 of the primary State.”.

21 (b) EFFECTIVE DATE.—The amendment made by
22 subsection (a) shall apply to individual health insurance
23 coverage offered, issued, or sold after the date that is one
24 year after the date of the enactment of this Act.

25 (c) GAO ONGOING STUDY AND REPORTS.—

1 (1) STUDY.—The Comptroller General of the
2 United States shall conduct an ongoing study con-
3 cerning the effect of the amendment made by sub-
4 section (a) on—

5 (A) the number of uninsured and under-in-
6 sured;

7 (B) the availability and cost of health in-
8 surance policies for individuals with preexisting
9 medical conditions;

10 (C) the availability and cost of health in-
11 surance policies generally;

12 (D) the elimination or reduction of dif-
13 ferent types of benefits under health insurance
14 policies offered in different States; and

15 (E) cases of fraud or abuse relating to
16 health insurance coverage offered under such
17 amendment and the resolution of such cases.

18 (2) ANNUAL REPORTS.—The Comptroller Gen-
19 eral shall submit to Congress an annual report, after
20 the end of each of the 5 years following the effective
21 date of the amendment made by subsection (a), on
22 the ongoing study conducted under paragraph (1).

1 **TITLE IV—IMPROVING HEALTH**
2 **SAVINGS ACCOUNTS**

3 **SEC. 231. SAVER'S CREDIT FOR CONTRIBUTIONS TO**
4 **HEALTH SAVINGS ACCOUNTS.**

5 (a) ALLOWANCE OF CREDIT.—Subsection (a) of sec-
6 tion 25B of the Internal Revenue Code of 1986 is amend-
7 ed by inserting “aggregate qualified HSA contributions
8 and” after “so much of the”.

9 (b) QUALIFIED HSA CONTRIBUTIONS.—Subsection
10 (d) of section 25B of such Code is amended by redesignig-
11 nating paragraph (2) as paragraph (3) and by inserting
12 after paragraph (1) the following new paragraph:

13 “(2) QUALIFIED HSA CONTRIBUTIONS.—The
14 term ‘qualified HSA contribution’ means, with re-
15 spect to any taxable year, a contribution of the eligi-
16 ble individual to a health savings account (as defined
17 in section 223(d)(1)) for which a deduction is allow-
18 able under section 223(a) for such taxable year.”.

19 (c) CONFORMING AMENDMENT.—The first sentence
20 of section 25B(d)(3)(A) of such Code (as redesignated by
21 subsection (b)) is amended to read as follows: “The aggre-
22 gate qualified retirement savings contributions determined
23 under paragraph (1) and qualified HSA contributions de-
24 termined under paragraph (2) shall be reduced (but not
25 below zero) by the aggregate distributions received by the

1 individual during the testing period from any entity of a
2 type to which contributions under paragraph (1) or para-
3 graph (2) (as the case may be) may be made.”.

4 (d) EFFECTIVE DATE.—The amendments made by
5 this section shall apply to contributions made after De-
6 cember 31, 2009.

7 **SEC. 232. HSA FUNDS FOR PREMIUMS FOR HIGH DEDUCT-**
8 **IBLE HEALTH PLANS.**

9 (a) IN GENERAL.—Subparagraph (C) of section
10 223(d)(2) of the Internal Revenue Code of 1986 is amend-
11 ed by striking “or” at the end of clause (iii), by striking
12 the period at the end of clause (iv) and inserting “, or”,
13 and by adding at the end the following:

14 “(v) a high deductible health plan if—

15 “(I) such plan is not offered in
16 connection with a group health plan,

17 “(II) no portion of any premium
18 (within the meaning of applicable pre-
19 mium under section 4980B(f)(4)) for
20 such plan is excludable from gross in-
21 come under section 106, and

22 “(III) the account beneficiary
23 demonstrates, using procedures
24 deemed appropriate by the Secretary,
25 that after payment of the premium

1 for such insurance the balance in the
2 health savings account is at least
3 twice the minimum deductible in ef-
4 fect under subsection (c)(2)(A)(i)
5 which is applicable to such plan.”.

6 (b) EFFECTIVE DATE.—The amendment made by
7 subsection (a) shall apply to premiums for a high deduct-
8 ible health plan for periods beginning after December 31,
9 2009.

10 **SEC. 233. REQUIRING GREATER COORDINATION BETWEEN**
11 **HDHP ADMINISTRATORS AND HSA ACCOUNT**
12 **ADMINISTRATORS SO THAT ENROLLEES CAN**
13 **ENROLL IN BOTH AT THE SAME TIME.**

14 The Secretary of the Treasury, through the issuance
15 of regulations or other guidance, shall encourage adminis-
16 trators of health plans and trustees of health savings ac-
17 counts to provide for simultaneous enrollment in high de-
18 ductible health plans and setup of health savings accounts.

19 **SEC. 234. SPECIAL RULE FOR CERTAIN MEDICAL EXPENSES**
20 **INCURRED BEFORE ESTABLISHMENT OF AC-**
21 **COUNT.**

22 (a) IN GENERAL.—Subsection (d) of section 223 of
23 the Internal Revenue Code of 1986 is amended by redesign-
24 ating paragraph (4) as paragraph (5) and by inserting
25 after paragraph (3) the following new paragraph:

1 “(4) CERTAIN MEDICAL EXPENSES INCURRED
2 BEFORE ESTABLISHMENT OF ACCOUNT TREATED AS
3 QUALIFIED.—

4 “(A) IN GENERAL.—For purposes of para-
5 graph (2), an expense shall not fail to be treat-
6 ed as a qualified medical expense solely because
7 such expense was incurred before the establish-
8 ment of the health savings account if such ex-
9 pense was incurred during the 60-day period
10 beginning on the date on which the high de-
11 ductible health plan is first effective.

12 “(B) SPECIAL RULES.—For purposes of
13 subparagraph (A)—

14 “(i) an individual shall be treated as
15 an eligible individual for any portion of a
16 month for which the individual is described
17 in subsection (c)(1), determined without
18 regard to whether the individual is covered
19 under a high deductible health plan on the
20 1st day of such month, and

21 “(ii) the effective date of the health
22 savings account is deemed to be the date
23 on which the high deductible health plan is
24 first effective after the date of the enact-
25 ment of this paragraph.”.

1 (b) EFFECTIVE DATE.—The amendment made by
2 this section shall apply with respect to insurance pur-
3 chased after the date of the enactment of this Act in tax-
4 able years beginning after such date.

5 **DIVISION C—ENACTING REAL**
6 **MEDICAL LIABILITY REFORM**

7 **SEC. 301. ENCOURAGING SPEEDY RESOLUTION OF CLAIMS.**

8 The time for the commencement of a health care law-
9 suit shall be 3 years after the date of manifestation of
10 injury or 1 year after the claimant discovers, or through
11 the use of reasonable diligence should have discovered, the
12 injury, whichever occurs first. In no event shall the time
13 for commencement of a health care lawsuit exceed 3 years
14 after the date of manifestation of injury unless tolled for
15 any of the following—

16 (1) upon proof of fraud;

17 (2) intentional concealment; or

18 (3) the presence of a foreign body, which has no
19 therapeutic or diagnostic purpose or effect, in the
20 person of the injured person.

21 Actions by a minor shall be commenced within 3 years
22 from the date of the alleged manifestation of injury except
23 that actions by a minor under the full age of 6 years shall
24 be commenced within 3 years of manifestation of injury
25 or prior to the minor's 8th birthday, whichever provides

1 a longer period. Such time limitation shall be tolled for
2 minors for any period during which a parent or guardian
3 and a health care provider or health care organization
4 have committed fraud or collusion in the failure to bring
5 an action on behalf of the injured minor.

6 **SEC. 302. COMPENSATING PATIENT INJURY.**

7 (a) UNLIMITED AMOUNT OF DAMAGES FOR ACTUAL
8 ECONOMIC LOSSES IN HEALTH CARE LAWSUITS.—In any
9 health care lawsuit, nothing in this title shall limit a claim-
10 ant's recovery of the full amount of the available economic
11 damages, notwithstanding the limitation in subsection (b).

12 (b) ADDITIONAL NONECONOMIC DAMAGES.—In any
13 health care lawsuit, the amount of noneconomic damages,
14 if available, may be as much as \$250,000, regardless of
15 the number of parties against whom the action is brought
16 or the number of separate claims or actions brought with
17 respect to the same injury.

18 (c) NO DISCOUNT OF AWARD FOR NONECONOMIC
19 DAMAGES.—For purposes of applying the limitation in
20 subsection (b), future noneconomic damages shall not be
21 discounted to present value. The jury shall not be in-
22 formed about the maximum award for noneconomic dam-
23 ages. An award for noneconomic damages in excess of
24 \$250,000 shall be reduced either before the entry of judg-
25 ment, or by amendment of the judgment after entry of

1 judgment, and such reduction shall be made before ac-
2 counting for any other reduction in damages required by
3 law. If separate awards are rendered for past and future
4 noneconomic damages and the combined awards exceed
5 \$250,000, the future noneconomic damages shall be re-
6 duced first.

7 (d) FAIR SHARE RULE.—In any health care lawsuit,
8 each party shall be liable for that party's several share
9 of any damages only and not for the share of any other
10 person. Each party shall be liable only for the amount of
11 damages allocated to such party in direct proportion to
12 such party's percentage of responsibility. Whenever a
13 judgment of liability is rendered as to any party, a sepa-
14 rate judgment shall be rendered against each such party
15 for the amount allocated to such party. For purposes of
16 this section, the trier of fact shall determine the propor-
17 tion of responsibility of each party for the claimant's
18 harm.

19 **SEC. 303. MAXIMIZING PATIENT RECOVERY.**

20 (a) COURT SUPERVISION OF SHARE OF DAMAGES
21 ACTUALLY PAID TO CLAIMANTS.—In any health care law-
22 suit, the court shall supervise the arrangements for pay-
23 ment of damages to protect against conflicts of interest
24 that may have the effect of reducing the amount of dam-
25 ages awarded that are actually paid to claimants. In par-

1 ticular, in any health care lawsuit in which the attorney
2 for a party claims a financial stake in the outcome by vir-
3 tue of a contingent fee, the court shall have the power
4 to restrict the payment of a claimant's damage recovery
5 to such attorney, and to redirect such damages to the
6 claimant based upon the interests of justice and principles
7 of equity. In no event shall the total of all contingent fees
8 for representing all claimants in a health care lawsuit ex-
9 ceed the following limits:

10 (1) 40 percent of the first \$50,000 recovered by
11 the claimant(s).

12 (2) 33 $\frac{1}{3}$ percent of the next \$50,000 recovered
13 by the claimant(s).

14 (3) 25 percent of the next \$500,000 recovered
15 by the claimant(s).

16 (4) 15 percent of any amount by which the re-
17 covery by the claimant(s) is in excess of \$600,000.

18 (b) APPLICABILITY.—The limitations in this section
19 shall apply whether the recovery is by judgment, settle-
20 ment, mediation, arbitration, or any other form of alter-
21 native dispute resolution. In a health care lawsuit involv-
22 ing a minor or incompetent person, a court retains the
23 authority to authorize or approve a fee that is less than
24 the maximum permitted under this section. The require-

1 ment for court supervision in the first two sentences of
2 subsection (a) applies only in civil actions.

3 **SEC. 304. ADDITIONAL HEALTH BENEFITS.**

4 In any health care lawsuit involving injury or wrong-
5 ful death, any party may introduce evidence of collateral
6 source benefits. If a party elects to introduce such evi-
7 dence, any opposing party may introduce evidence of any
8 amount paid or contributed or reasonably likely to be paid
9 or contributed in the future by or on behalf of the oppos-
10 ing party to secure the right to such collateral source bene-
11 fits. No provider of collateral source benefits shall recover
12 any amount against the claimant or receive any lien or
13 credit against the claimant's recovery or be equitably or
14 legally subrogated to the right of the claimant in a health
15 care lawsuit involving injury or wrongful death. This sec-
16 tion shall apply to any health care lawsuit that is settled
17 as well as a health care lawsuit that is resolved by a fact
18 finder. This section shall not apply to section 1862(b) (42
19 U.S.C. 1395y(b)) or section 1902(a)(25) (42 U.S.C.
20 1396a(a)(25)) of the Social Security Act.

21 **SEC. 305. PUNITIVE DAMAGES.**

22 (a) IN GENERAL.—Punitive damages may, if other-
23 wise permitted by applicable State or Federal law, be
24 awarded against any person in a health care lawsuit only
25 if it is proven by clear and convincing evidence that such

1 person acted with malicious intent to injure the claimant,
2 or that such person deliberately failed to avoid unneces-
3 sary injury that such person knew the claimant was sub-
4 stantially certain to suffer. In any health care lawsuit
5 where no judgment for compensatory damages is rendered
6 against such person, no punitive damages may be awarded
7 with respect to the claim in such lawsuit. No demand for
8 punitive damages shall be included in a health care lawsuit
9 as initially filed. A court may allow a claimant to file an
10 amended pleading for punitive damages only upon a mo-
11 tion by the claimant and after a finding by the court, upon
12 review of supporting and opposing affidavits or after a
13 hearing, after weighing the evidence, that the claimant has
14 established by a substantial probability that the claimant
15 will prevail on the claim for punitive damages. At the re-
16 quest of any party in a health care lawsuit, the trier of
17 fact shall consider in a separate proceeding—

18 (1) whether punitive damages are to be award-
19 ed and the amount of such award; and

20 (2) the amount of punitive damages following a
21 determination of punitive liability.

22 If a separate proceeding is requested, evidence relevant
23 only to the claim for punitive damages, as determined by
24 applicable State law, shall be inadmissible in any pro-

1 ceeding to determine whether compensatory damages are
2 to be awarded.

3 (b) DETERMINING AMOUNT OF PUNITIVE DAM-
4 AGES.—

5 (1) FACTORS CONSIDERED.—In determining
6 the amount of punitive damages, if awarded, in a
7 health care lawsuit, the trier of fact shall consider
8 only the following—

9 (A) the severity of the harm caused by the
10 conduct of such party;

11 (B) the duration of the conduct or any
12 concealment of it by such party;

13 (C) the profitability of the conduct to such
14 party;

15 (D) the number of products sold or med-
16 ical procedures rendered for compensation, as
17 the case may be, by such party, of the kind
18 causing the harm complained of by the claim-
19 ant;

20 (E) any criminal penalties imposed on such
21 party, as a result of the conduct complained of
22 by the claimant; and

23 (F) the amount of any civil fines assessed
24 against such party as a result of the conduct
25 complained of by the claimant.

1 (2) **MAXIMUM AWARD.**—The amount of punitive
2 damages, if awarded, in a health care lawsuit may
3 be as much as \$250,000 or as much as two times
4 the amount of economic damages awarded, which-
5 ever is greater. The jury shall not be informed of
6 this limitation.

7 **SEC. 306. AUTHORIZATION OF PAYMENT OF FUTURE DAM-**
8 **AGES TO CLAIMANTS IN HEALTH CARE LAW-**
9 **SUITS.**

10 (a) **IN GENERAL.**—In any health care lawsuit, if an
11 award of future damages, without reduction to present
12 value, equaling or exceeding \$50,000 is made against a
13 party with sufficient insurance or other assets to fund a
14 periodic payment of such a judgment, the court shall, at
15 the request of any party, enter a judgment ordering that
16 the future damages be paid by periodic payments. In any
17 health care lawsuit, the court may be guided by the Uni-
18 form Periodic Payment of Judgments Act promulgated by
19 the National Conference of Commissioners on Uniform
20 State Laws.

21 (b) **APPLICABILITY.**—This section applies to all ac-
22 tions which have not been first set for trial or retrial be-
23 fore the effective date of this title.

24 **SEC. 307. DEFINITIONS.**

25 In this title:

1 (1) ALTERNATIVE DISPUTE RESOLUTION SYS-
2 TEM; ADR.—The term “alternative dispute resolution
3 system” or “ADR” means a system that provides
4 for the resolution of health care lawsuits in a man-
5 ner other than through a civil action brought in a
6 State or Federal court.

7 (2) CLAIMANT.—The term “claimant” means
8 any person who brings a health care lawsuit, includ-
9 ing a person who asserts or claims a right to legal
10 or equitable contribution, indemnity, or subrogation,
11 arising out of a health care liability claim or action,
12 and any person on whose behalf such a claim is as-
13 serted or such an action is brought, whether de-
14 ceased, incompetent, or a minor.

15 (3) COLLATERAL SOURCE BENEFITS.—The
16 term “collateral source benefits” means any amount
17 paid or reasonably likely to be paid in the future to
18 or on behalf of the claimant, or any service, product,
19 or other benefit provided or reasonably likely to be
20 provided in the future to or on behalf of the claim-
21 ant, as a result of the injury or wrongful death, pur-
22 suant to—

23 (A) any State or Federal health, sickness,
24 income-disability, accident, or workers’ com-
25 pensation law;

1 (B) any health, sickness, income-disability,
2 or accident insurance that provides health bene-
3 fits or income-disability coverage;

4 (C) any contract or agreement of any
5 group, organization, partnership, or corporation
6 to provide, pay for, or reimburse the cost of
7 medical, hospital, dental, or income-disability
8 benefits; and

9 (D) any other publicly or privately funded
10 program.

11 (4) COMPENSATORY DAMAGES.—The term
12 “compensatory damages” means objectively
13 verifiable monetary losses incurred as a result of the
14 provision of, use of, or payment for (or failure to
15 provide, use, or pay for) health care services or med-
16 ical products, such as past and future medical ex-
17 penses, loss of past and future earnings, cost of ob-
18 taining domestic services, loss of employment, and
19 loss of business or employment opportunities, dam-
20 ages for physical and emotional pain, suffering, in-
21 convenience, physical impairment, mental anguish,
22 disfigurement, loss of enjoyment of life, loss of soci-
23 ety and companionship, loss of consortium (other
24 than loss of domestic service), hedonic damages, in-
25 jury to reputation, and all other nonpecuniary losses

1 of any kind or nature. The term “compensatory
2 damages” includes economic damages and non-
3 economic damages, as such terms are defined in this
4 section.

5 (5) CONTINGENT FEE.—The term “contingent
6 fee” includes all compensation to any person or per-
7 sons which is payable only if a recovery is effected
8 on behalf of one or more claimants.

9 (6) ECONOMIC DAMAGES.—The term “economic
10 damages” means objectively verifiable monetary
11 losses incurred as a result of the provision of, use
12 of, or payment for (or failure to provide, use, or pay
13 for) health care services or medical products, such as
14 past and future medical expenses, loss of past and
15 future earnings, cost of obtaining domestic services,
16 loss of employment, and loss of business or employ-
17 ment opportunities.

18 (7) HEALTH CARE LAWSUIT.—The term
19 “health care lawsuit” means any health care liability
20 claim concerning the provision of health care goods
21 or services or any medical product affecting inter-
22 state commerce, or any health care liability action
23 concerning the provision of health care goods or
24 services or any medical product affecting interstate
25 commerce, brought in a State or Federal court or

1 pursuant to an alternative dispute resolution system,
2 against a health care provider, a health care organi-
3 zation, or the manufacturer, distributor, supplier,
4 marketer, promoter, or seller of a medical product,
5 regardless of the theory of liability on which the
6 claim is based, or the number of claimants, plain-
7 tiffs, defendants, or other parties, or the number of
8 claims or causes of action, in which the claimant al-
9 leges a health care liability claim. Such term does
10 not include a claim or action which is based on
11 criminal liability; which seeks civil fines or penalties
12 paid to Federal, State, or local government; or which
13 is grounded in antitrust.

14 (8) HEALTH CARE LIABILITY ACTION.—The
15 term “health care liability action” means a civil ac-
16 tion brought in a State or Federal court or pursuant
17 to an alternative dispute resolution system, against
18 a health care provider, a health care organization, or
19 the manufacturer, distributor, supplier, marketer,
20 promoter, or seller of a medical product, regardless
21 of the theory of liability on which the claim is based,
22 or the number of plaintiffs, defendants, or other par-
23 ties, or the number of causes of action, in which the
24 claimant alleges a health care liability claim.

1 (9) HEALTH CARE LIABILITY CLAIM.—The
2 term “health care liability claim” means a demand
3 by any person, whether or not pursuant to ADR,
4 against a health care provider, health care organiza-
5 tion, or the manufacturer, distributor, supplier, mar-
6 keter, promoter, or seller of a medical product, in-
7 cluding, but not limited to, third-party claims, cross-
8 claims, counter-claims, or contribution claims, which
9 are based upon the provision of, use of, or payment
10 for (or the failure to provide, use, or pay for) health
11 care services or medical products, regardless of the
12 theory of liability on which the claim is based, or the
13 number of plaintiffs, defendants, or other parties, or
14 the number of causes of action.

15 (10) HEALTH CARE ORGANIZATION.—The term
16 “health care organization” means any person or en-
17 tity which is obligated to provide or pay for health
18 benefits under any health plan, including any person
19 or entity acting under a contract or arrangement
20 with a health care organization to provide or admin-
21 ister any health benefit.

22 (11) HEALTH CARE PROVIDER.—The term
23 “health care provider” means any person or entity
24 required by State or Federal laws or regulations to
25 be licensed, registered, or certified to provide health

1 care services, and being either so licensed, reg-
2 istered, or certified, or exempted from such require-
3 ment by other statute or regulation.

4 (12) HEALTH CARE GOODS OR SERVICES.—The
5 term “health care goods or services” means any
6 goods or services provided by a health care organiza-
7 tion, provider, or by any individual working under
8 the supervision of a health care provider, that relates
9 to the diagnosis, prevention, or treatment of any
10 human disease or impairment, or the assessment or
11 care of the health of human beings.

12 (13) MALICIOUS INTENT TO INJURE.—The
13 term “malicious intent to injure” means inten-
14 tionally causing or attempting to cause physical in-
15 jury other than providing health care goods or serv-
16 ices.

17 (14) MEDICAL PRODUCT.—The term “medical
18 product” means a drug, device, or biological product
19 intended for humans, and the terms “drug”, “de-
20 vice”, and “biological product” have the meanings
21 given such terms in sections 201(g)(1) and 201(h)
22 of the Federal Food, Drug and Cosmetic Act (21
23 U.S.C. 321(g)(1) and (h)) and section 351(a) of the
24 Public Health Service Act (42 U.S.C. 262(a)), re-

1 spectively, including any component or raw material
2 used therein, but excluding health care services.

3 (15) NONECONOMIC DAMAGES.—The term
4 “noneconomic damages” means damages for phys-
5 ical and emotional pain, suffering, inconvenience,
6 physical impairment, mental anguish, disfigurement,
7 loss of enjoyment of life, loss of society and compan-
8 ionship, loss of consortium (other than loss of do-
9 mestic service), hedonic damages, injury to reputa-
10 tion, and all other nonpecuniary losses of any kind
11 or nature.

12 (16) PUNITIVE DAMAGES.—The term “punitive
13 damages” means damages awarded, for the purpose
14 of punishment or deterrence, and not solely for com-
15 pensatory purposes, against a health care provider,
16 health care organization, or a manufacturer, dis-
17 tributor, or supplier of a medical product. Punitive
18 damages are neither economic nor noneconomic
19 damages.

20 (17) RECOVERY.—The term “recovery” means
21 the net sum recovered after deducting any disburse-
22 ments or costs incurred in connection with prosecu-
23 tion or settlement of the claim, including all costs
24 paid or advanced by any person. Costs of health care
25 incurred by the plaintiff and the attorneys’ office

1 overhead costs or charges for legal services are not
2 deductible disbursements or costs for such purpose.

3 (18) STATE.—The term “State” means each of
4 the several States, the District of Columbia, the
5 Commonwealth of Puerto Rico, the Virgin Islands,
6 Guam, American Samoa, the Northern Mariana Is-
7 lands, the Trust Territory of the Pacific Islands, and
8 any other territory or possession of the United
9 States, or any political subdivision thereof.

10 **SEC. 308. EFFECT ON OTHER LAWS.**

11 (a) VACCINE INJURY.—

12 (1) To the extent that title XXI of the Public
13 Health Service Act establishes a Federal rule of law
14 applicable to a civil action brought for a vaccine-re-
15 lated injury or death—

16 (A) this title does not affect the application
17 of the rule of law to such an action; and

18 (B) any rule of law prescribed by this title
19 in conflict with a rule of law of such title XXI
20 shall not apply to such action.

21 (2) If there is an aspect of a civil action
22 brought for a vaccine-related injury or death to
23 which a Federal rule of law under title XXI of the
24 Public Health Service Act does not apply, then this
25 title or otherwise applicable law (as determined

1 under this title) will apply to such aspect of such ac-
2 tion.

3 (b) OTHER FEDERAL LAW.—Except as provided in
4 this section, nothing in this title shall be deemed to affect
5 any defense available to a defendant in a health care law-
6 suit or action under any other provision of Federal law.

7 **SEC. 309. STATE FLEXIBILITY AND PROTECTION OF**
8 **STATES' RIGHTS.**

9 (a) HEALTH CARE LAWSUITS.—The provisions gov-
10 erning health care lawsuits set forth in this title preempt,
11 subject to subsections (b) and (c), State law to the extent
12 that State law prevents the application of any provisions
13 of law established by or under this title. The provisions
14 governing health care lawsuits set forth in this title super-
15 sede chapter 171 of title 28, United States Code, to the
16 extent that such chapter—

17 (1) provides for a greater amount of damages
18 or contingent fees, a longer period in which a health
19 care lawsuit may be commenced, or a reduced appli-
20 cability or scope of periodic payment of future dam-
21 ages, than provided in this title; or

22 (2) prohibits the introduction of evidence re-
23 garding collateral source benefits, or mandates or
24 permits subrogation or a lien on collateral source
25 benefits.

1 (b) PROTECTION OF STATES' RIGHTS AND OTHER
2 LAWS.—(1) Any issue that is not governed by any provi-
3 sion of law established by or under this title (including
4 State standards of negligence) shall be governed by other-
5 wise applicable State or Federal law.

6 (2) This title shall not preempt or supersede any
7 State or Federal law that imposes greater procedural or
8 substantive protections for health care providers and
9 health care organizations from liability, loss, or damages
10 than those provided by this title or create a cause of ac-
11 tion.

12 (c) STATE FLEXIBILITY.—No provision of this title
13 shall be construed to preempt—

14 (1) any State law (whether effective before, on,
15 or after the date of the enactment of this Act) that
16 specifies a particular monetary amount of compen-
17 satory or punitive damages (or the total amount of
18 damages) that may be awarded in a health care law-
19 suit, regardless of whether such monetary amount is
20 greater or lesser than is provided for under this title,
21 notwithstanding section 302(a); or

22 (2) any defense available to a party in a health
23 care lawsuit under any other provision of State or
24 Federal law.

1 **SEC. 310. APPLICABILITY; EFFECTIVE DATE.**

2 This title shall apply to any health care lawsuit
3 brought in a Federal or State court, or subject to an alter-
4 native dispute resolution system, that is initiated on or
5 after the date of the enactment of this Act, except that
6 any health care lawsuit arising from an injury occurring
7 prior to the date of the enactment of this Act shall be
8 governed by the applicable statute of limitations provisions
9 in effect at the time the injury occurred.

10 **DIVISION D—PROTECTING THE**
11 **DOCTOR-PATIENT RELATION-**
12 **SHIP**

13 **SEC. 401. RULE OF CONSTRUCTION.**

14 Nothing in this Act shall be construed to interfere
15 with the doctor-patient relationship or the practice of med-
16 icine.

17 **SEC. 402. REPEAL OF FEDERAL COORDINATING COUNCIL**
18 **FOR COMPARATIVE EFFECTIVENESS RE-**
19 **SEARCH.**

20 Effective on the date of the enactment of this Act,
21 section 804 of the American Recovery and Reinvestment
22 Act of 2009 is repealed.

1 **DIVISION E—INCENTIVIZING**
2 **WELLNESS AND QUALITY IM-**
3 **PROVEMENTS**

4 **SEC. 501. INCENTIVES FOR PREVENTION AND WELLNESS**
5 **PROGRAMS.**

6 (a) ERISA LIMITATION ON EXCEPTION FOR
7 WELLNESS PROGRAMS UNDER HIPAA DISCRIMINATION
8 RULES.—

9 (1) IN GENERAL.—Section 702(b)(2) of the
10 Employee Retirement Income Security Act of 1974
11 (29 U.S.C. 1182(b)(2)) is amended by adding after
12 and below subparagraph (B) the following:

13 “In applying subparagraph (B), a group health plan
14 (or a health insurance issuer with respect to health
15 insurance coverage) may vary premiums and cost-
16 sharing by up to 50 percent of the value of the bene-
17 fits under the plan (or coverage) based on participa-
18 tion (or lack of participation) in a standards-based
19 wellness program.”.

20 (2) EFFECTIVE DATE.—The amendment made
21 by paragraph (1) shall apply to plan years beginning
22 more than 1 year after the date of the enactment of
23 this Act.

24 (b) CONFORMING AMENDMENTS TO PHSA.—

25 (1) GROUP MARKET RULES.—

1 (A) IN GENERAL.—Section 2702(b)(2) of
2 the Public Health Service Act (42 U.S.C.
3 300gg–1(b)(2)) is amended by adding after and
4 below subparagraph (B) the following:

5 “In applying subparagraph (B), a group health plan
6 (or a health insurance issuer with respect to health
7 insurance coverage) may vary premiums and cost-
8 sharing by up to 50 percent of the value of the bene-
9 fits under the plan (or coverage) based on participa-
10 tion (or lack of participation) in a standards-based
11 wellness program.”.

12 (B) EFFECTIVE DATE.—The amendment
13 made by subparagraph (A) shall apply to plan
14 years beginning more than 1 year after the date
15 of the enactment of this Act.

16 (2) INDIVIDUAL MARKET RULES RELATING TO
17 GUARANTEED AVAILABILITY.—

18 (A) IN GENERAL.—Section 2741(f) of the
19 Public Health Service Act (42 U.S.C. 300gg–
20 1(b)(2)) is amended by adding after and below
21 paragraph (1) the following:

22 “In applying paragraph (2), a health insurance issuer may
23 vary premiums and cost-sharing under health insurance
24 coverage by up to 50 percent of the value of the benefits

1 under the coverage based on participation (or lack of par-
2 ticipation) in a standards-based wellness program.”.

3 (B) EFFECTIVE DATE.—The amendment
4 made by paragraph (1) shall apply to health in-
5 surance coverage offered or renewed on and
6 after the date that is 1 year after the date of
7 the enactment of this Act.

8 (c) CONFORMING AMENDMENTS TO IRC.—

9 (1) IN GENERAL.—Section 9802(b)(2) of the
10 Internal Revenue Code of 1986 is amended by add-
11 ing after and below subparagraph (B) the following:
12 “In applying subparagraph (B), a group health plan
13 (or a health insurance issuer with respect to health
14 insurance coverage) may vary premiums and cost-
15 sharing by up to 50 percent of the value of the bene-
16 fits under the plan (or coverage) based on participa-
17 tion (or lack of participation) in a standards-based
18 wellness program.”.

19 (2) EFFECTIVE DATE.—The amendment made
20 by paragraph (1) shall apply to plan years beginning
21 more than 1 year after the date of the enactment of
22 this Act.

1 **DIVISION F—PROTECTING**
2 **TAXPAYERS**

3 **SEC. 601. PROVIDE FULL FUNDING TO HHS OIG AND**
4 **HCFAC.**

5 (a) HCFAC FUNDING.— Section 1817(k)(3)(A) of
6 the Social Security Act (42 U.S.C. 1395i(k)(3)(A)) is
7 amended—

8 (1) in clause (i)—

9 (A) in subclause (IV), by striking “2009,
10 and 2010” and inserting “and 2009”; and

11 (B) by amending subclause (V) to read as
12 follows:

13 “(V) for each fiscal year after fis-
14 cal year 2009, \$300,000,000.”; and

15 (2) in clause (ii)—

16 (A) in subclause (IX), by striking “2009,
17 and 2010” and inserting “and 2009”; and

18 (B) in subclause (X), by striking “2010”
19 and inserting “2009” and by inserting before
20 the period at the end the following: “, plus the
21 amount by which the amount made available
22 under clause (i)(V) for fiscal year 2010 exceeds
23 the amount made available under clause (i)(IV)
24 for 2009”.

1 (b) **OIG FUNDING.**—There are authorized to be ap-
2 propriated for each of fiscal years 2010 through 2019
3 \$100,000,000 for the Office of the Inspector General of
4 the Department of Health and Human Services for fraud
5 prevention activities under the Medicare and Medicaid
6 programs.

7 **SEC. 602. PROHIBITING TAXPAYER FUNDED ABORTIONS**
8 **AND CONSCIENCE PROTECTIONS.**

9 Title 1 of the United States Code is amended by add-
10 ing at the end the following new chapter:

11 **“CHAPTER 4—PROHIBITING TAXPAYER**
12 **FUNDED ABORTIONS AND CON-**
13 **SCIENCE PROTECTIONS**

14 **“SEC. 301. PROHIBITION ON FUNDING FOR ABORTIONS.**

15 “No funds authorized or appropriated by federal law,
16 and none of the funds in any trust fund to which funds
17 are authorized or appropriated by federal law, shall be ex-
18 pended for any abortion.

19 **“SEC. 302. PROHIBITION ON FUNDING FOR HEALTH BENE-**
20 **FITS PLANS THAT COVER ABORTION.**

21 “None of the funds authorized or appropriated by
22 federal law, and none of the funds in any trust fund to
23 which funds are authorized or appropriated by federal law,
24 shall be expended for a health benefits plan that includes
25 coverage of abortion.

1 **“SEC. 303. TREATMENT OF ABORTIONS RELATED TO RAPE,**
2 **INCEST, OR PRESERVING THE LIFE OF THE**
3 **MOTHER.**

4 “The limitations established in sections 301 and 302
5 shall not apply to an abortion—

6 “(1) if the pregnancy is the result of an act of
7 rape or incest; or

8 “(2) in the case where a woman suffers from a
9 physical disorder, physical injury, or physical illness
10 that would, as certified by a physician, place the
11 woman in danger of death unless an abortion is per-
12 formed, including a life-endangering physical condi-
13 tion caused by or arising from the pregnancy itself.

14 **“SEC. 304. CONSTRUCTION RELATING TO SUPPLEMENTAL**
15 **COVERAGE.**

16 “Nothing in this chapter shall be construed as pro-
17 hibiting any individual, entity, or State or locality from
18 purchasing separate supplemental abortion plan or cov-
19 erage that includes abortion so long as such plan or cov-
20 erage is paid for entirely using only funds not authorized
21 or appropriated by federal law and such plan or coverage
22 shall not be purchased using matching funds required for
23 a federally subsidized program, including a State’s or lo-
24 cality’s contribution of Medicaid matching funds.

1 **“SEC. 305. CONSTRUCTION RELATING TO THE USE OF NON-**
2 **FEDERAL FUNDS FOR HEALTH COVERAGE.**

3 “Nothing in this chapter shall be construed as re-
4 stricting the ability of any managed care provider or other
5 organization from offering abortion coverage or the ability
6 of a State to contract separately with such a provider or
7 organization for such coverage with funds not authorized
8 or appropriated by federal law and such plan or coverage
9 shall not be purchased using matching funds required for
10 a federally subsidized program, including a State’s or lo-
11 cality’s contribution of Medicaid matching funds.

12 **“SEC. 306. NO GOVERNMENT DISCRIMINATION AGAINST**
13 **CERTAIN HEALTH CARE ENTITIES.**

14 “(a) IN GENERAL.—No funds authorized or appro-
15 priated by federal law may be made available to a Federal
16 agency or program, or to a State or local government, if
17 such agency, program, or government subjects any institu-
18 tional or individual health care entity to discrimination on
19 the basis that the health care entity does not provide, pay
20 for, provide coverage of, or refer for abortions.

21 “(b) HEALTH CARE ENTITY DEFINED.—For pur-
22 poses of this section, the term ‘health care entity’ includes
23 an individual physician or other health care professional,
24 a hospital, a provider-sponsored organization, a health
25 maintenance organization, a health insurance plan, or any
26 other kind of health care facility, organization, or plan.”.

1 **SEC. 603. IMPROVED ENFORCEMENT OF THE MEDICARE**
2 **AND MEDICAID SECONDARY PAYER PROVI-**
3 **SIONS.**

4 (a) **MEDICARE.**—

5 (1) **IN GENERAL.**—The Secretary, in coordina-
6 tion with the Inspector General of the Department
7 of Health and Human Services, shall provide
8 through the Coordination of Benefits Contractor for
9 the identification of instances where the Medicare
10 program should be, but is not, acting as a secondary
11 payer to an individual's private health benefits cov-
12 erage under section 1862(b) of the Social Security
13 Act (42 U.S.C. 1395y(b)).

14 (2) **UPDATING PROCEDURES.**—The Secretary
15 shall update procedures for identifying and resolving
16 credit balance situations which occur under the
17 Medicare program when payment under such title
18 and from other health benefit plans exceed the pro-
19 viders' charges or the allowed amount.

20 (3) **REPORT ON IMPROVED ENFORCEMENT.**—
21 Not later than 1 year after the date of the enact-
22 ment of this Act, the Secretary shall submit a report
23 to Congress on progress made in improved enforce-
24 ment of the Medicare secondary payer provisions, in-
25 cluding recoupment of credit balances.

1 (b) MEDICAID.—Section 1903 of the Social Security
2 Act (42 U.S.C. 1396b) is amended by adding at the end
3 the following new subsection:

4 “(aa) ENFORCEMENT OF PAYER OF LAST RESORT
5 PROVISIONS.—

6 “(1) SUBMISSION OF STATE PLAN AMEND-
7 MENT.—Each State shall submit, not later than 1
8 year after the date of the enactment of this sub-
9 section, a State plan amendment that details how
10 the State will become fully compliant with the re-
11 quirements of section 1902(a)(25).

12 “(2) BONUS FOR COMPLIANCE.—If a State sub-
13 mits a timely State plan amendment under para-
14 graph (1) that the Secretary determines provides for
15 full compliance of the State with the requirements of
16 section 1902(a)(25), the Secretary shall provide for
17 an additional payment to the State of \$1,000,000. If
18 a State certifies, to the Secretary’s satisfaction, that
19 it is already fully compliant with such requirements,
20 such amount shall be increased to \$2,000,000.

21 “(3) REDUCTION FOR NONCOMPLIANCE.—If a
22 State does not submit such an amendment, the Sec-
23 retary shall reduce the Federal medical assistance
24 percentage otherwise applicable under this title by 1

1 percentage point until the State submits such an
2 amendment.

3 “(4) ONGOING REDUCTION.—If at any time the
4 Secretary determines that a State is not in compli-
5 ance with section 1902(a)(25), regardless of the sta-
6 tus of the State’s submission of a State plan amend-
7 ment under this subsection or previous determina-
8 tions of compliance such requirements, the Secretary
9 shall reduce the Federal medical assistance percent-
10 age otherwise applicable under this title for the
11 State by 1 percentage point during the period of
12 non-compliance as determined by the Secretary.”.

13 **SEC. 604. STRENGTHEN MEDICARE PROVIDER ENROLL-**
14 **MENT STANDARDS AND SAFEGUARDS.**

15 (a) PROTECTING AGAINST THE FRAUDULENT USE
16 OF MEDICARE PROVIDER NUMBERS.—Subject to sub-
17 section (c)(2)—

18 (1) SCREENING NEW PROVIDERS.—As a condi-
19 tion of a provider of services or a supplier, including
20 durable medical equipment suppliers and home
21 health agencies, applying for the first time for a pro-
22 vider number under the Medicare program and be-
23 fore granting billing privileges under such title, the
24 Secretary shall screen the provider or supplier for a
25 criminal background or other financial or oper-

1 ational irregularities through fingerprinting, licen-
2 sure checks, site-visits, other database checks.

3 (2) APPLICATION FEES.—The Secretary shall
4 impose an application charge on such a provider or
5 supplier in order to cover the Secretary's costs in
6 performing the screening required under paragraph
7 (1) and that is revenue neutral to the Federal gov-
8 ernment.

9 (3) PROVISIONAL APPROVAL.—During an ini-
10 tial, provisional period (specified by the Secretary)
11 In which such a provider or supplier has been issued
12 such a number, the Secretary shall provide enhanced
13 oversight of the activities of such provider or sup-
14 plier under the Medicare program, such as through
15 prepayment review and payment limitations.

16 (4) PENALTIES FOR FALSE STATEMENTS.—In
17 the case of a provider or supplier that makes a false
18 statement in an application for such a number, the
19 Secretary may exclude the provider or supplier from
20 participation under the Medicare program, or may
21 impose a civil money penalty (in the amount de-
22 scribed in section 1128A(a)(4) of the Social Security
23 Act), in the same manner as the Secretary may im-
24 pose such an exclusion or penalty under sections
25 1128 and 1128A, respectively, of such Act in the

1 case of knowing presentation of a false claim de-
2 scribed in section 1128A(a)(1)(A) of such Act.

3 (5) DISCLOSURE REQUIREMENTS.—With re-
4 spect to approval of such an application, the Sec-
5 retary—

6 (A) shall require applicants to disclose pre-
7 vious affiliation with enrolled entities that have
8 uncollected debt related to the Medicare or
9 Medicaid programs;

10 (B) may deny approval if the Secretary de-
11 termines that these affiliations pose undue risk
12 to the Medicare or Medicaid program, subject
13 to an appeals process for the applicant as deter-
14 mined by the Secretary; and

15 (C) may implement enhanced safeguards
16 (such as surety bonds).

17 (b) MORATORIA.—The Secretary may impose mora-
18 toria on approval of provider and supplier numbers under
19 the Medicare program for new providers of services and
20 suppliers as determined necessary to prevent or combat
21 fraud a period of delay for any one applicant cannot ex-
22 ceed 30 days unless cause is shown by the Secretary.

23 (c) FUNDING.—

1 (1) IN GENERAL.—There are authorized to be
2 appropriated to carry out this section such sums as
3 may be necessary.

4 (2) CONDITION.—The provisions of paragraphs
5 (1) and (2) of subsection (a) shall not apply unless
6 and until funds are appropriated to carry out such
7 provisions

8 **SEC. 605. TRACKING BANNED PROVIDERS ACROSS STATE**
9 **LINES.**

10 (a) GREATER COORDINATION.—The Secretary of
11 Health and Human Services shall provide for increased
12 coordination between the Administrator of the Centers for
13 Medicare & Medicaid Services (in this section referred to
14 as “CMS”) and its regional offices to ensure that pro-
15 viders of services and suppliers that have operated in one
16 State and are excluded from participation in the Medicare
17 program are unable to begin operation and participation
18 in the Medicare program in another State.

19 (b) IMPROVED INFORMATION SYSTEMS.—

20 (1) IN GENERAL.—The Secretary shall improve
21 information systems to allow greater integration be-
22 tween databases under the Medicare program so
23 that—

24 (A) medicare administrative contractors,
25 fiscal intermediaries, and carriers have imme-

1 diate access to information identifying providers
2 and suppliers excluded from participation in the
3 Medicare and Medicaid program and other Fed-
4 eral health care programs; and

5 (B) such information can be shared across
6 Federal health care programs and agencies, in-
7 cluding between the Departments of Health and
8 Human Services, the Social Security Adminis-
9 tration, the Department of Veterans Affairs,
10 the Department of Defense, the Department of
11 Justice, and the Office of Personnel Manage-
12 ment.

13 (c) MEDICARE/MEDICAID “ONE PI” DATABASE.—
14 The Secretary shall implement a database that includes
15 claims and payment data for all components of the Medi-
16 care program and the Medicaid program.

17 (d) AUTHORIZING EXPANDED DATA MATCHING.—
18 Notwithstanding any provision of the Computer Matching
19 and Privacy Protection Act of 1988 to the contrary—

20 (1) the Secretary and the Inspector General in
21 the Department of Health and Human Services may
22 perform data matching of data from the Medicare
23 program with data from the Medicaid program; and

24 (2) the Commissioner of Social Security and the
25 Secretary may perform data matching of data of the

1 Social Security Administration with data from the
2 Medicare and Medicaid programs.

3 (e) CONSOLIDATION OF DATA BASES.—The Sec-
4 retary shall consolidate and expand into a centralized data
5 base for individuals and entities that have been excluded
6 from Federal health care programs the Healthcare Integ-
7 rity and Protection Data Bank, the National Practitioner
8 Data Bank, the List of Excluded Individuals/Entities, and
9 a national patient abuse/neglect registry.

10 (f) COMPREHENSIVE PROVIDER DATABASE.—

11 (1) ESTABLISHMENT.—The Secretary shall es-
12 tablish a comprehensive database that includes infor-
13 mation on providers of services, suppliers, and re-
14 lated entities participating in the Medicare program,
15 the Medicaid program, or both. Such database shall
16 include, information on ownership and business rela-
17 tionships, history of adverse actions, results of site
18 visits or other monitoring by any program.

19 (2) USE.—Prior to issuing a provider or sup-
20 plier number for an entity under the Medicare pro-
21 gram, the Secretary shall obtain information on the
22 entity from such database to assure the entity quali-
23 fies for the issuance of such a number.

24 (g) COMPREHENSIVE SANCTIONS DATABASE.—The
25 Secretary shall establish a comprehensive sanctions data-

1 base on sanctions imposed on providers of services, sup-
2 pliers, and related entities. Such database shall be over-
3 seen by the Inspector General of the Department of
4 Health and Human Services and shall be linked to related
5 databases maintained by State licensure boards and by
6 Federal or State law enforcement agencies.

7 (h) ACCESS TO CLAIMS AND PAYMENT DATA-
8 BASES.—The Secretary shall ensure that the Inspector
9 General of the Department of Health and Human Services
10 and Federal law enforcement agencies have direct access
11 to all claims and payment databases of the Secretary
12 under the Medicare or Medicaid programs.

13 (i) CIVIL MONEY PENALTIES FOR SUBMISSION OF
14 ERRONEOUS INFORMATION.—In the case of a provider of
15 services, supplier, or other entity that submits erroneous
16 information that serves as a basis for payment of any enti-
17 ty under the Medicare or Medicaid program, the Secretary
18 may impose a civil money penalty of not to exceed \$50,000
19 for each such erroneous submission. A civil money penalty
20 under this subsection shall be imposed and collected in the
21 same manner as a civil money penalty under subsection
22 (a) of section 1128A of the Social Security Act is imposed
23 and collected under that section.

1 **DIVISION G—PATHWAY FOR BIO-**
2 **SIMILAR BIOLOGICAL PROD-**
3 **UCTS**

4 **SEC. 701. APPROVAL PATHWAY FOR BIOSIMILAR BIOLOGI-**
5 **CAL PRODUCTS.**

6 (a) LICENSURE OF BIOLOGICAL PRODUCTS AS BIO-
7 SIMILAR OR INTERCHANGEABLE.—Section 351 of the
8 Public Health Service Act (42 U.S.C. 262) is amended—

9 (1) in subsection (a)(1)(A), by inserting “under
10 this subsection or subsection (k)” after “biologics li-
11 cense”; and

12 (2) by adding at the end the following:

13 “(k) LICENSURE OF BIOLOGICAL PRODUCTS AS BIO-
14 SIMILAR OR INTERCHANGEABLE.—

15 “(1) IN GENERAL.—Any person may submit an
16 application for licensure of a biological product
17 under this subsection.

18 “(2) CONTENT.—

19 “(A) IN GENERAL.—

20 “(i) REQUIRED INFORMATION.—An
21 application submitted under this subsection
22 shall include information demonstrating
23 that—

1 “(I) the biological product is bio-
2 similar to a reference product based
3 upon data derived from—
4 “(aa) analytical studies that
5 demonstrate that the biological
6 product is highly similar to the
7 reference product notwith-
8 standing minor differences in
9 clinically inactive components;
10 “(bb) animal studies (includ-
11 ing the assessment of toxicity);
12 and
13 “(cc) a clinical study or
14 studies (including the assessment
15 of immunogenicity and phar-
16 macokinetics or
17 pharmacodynamics) that are suf-
18 ficient to demonstrate safety, pu-
19 rity, and potency in 1 or more
20 appropriate conditions of use for
21 which the reference product is li-
22 censed and intended to be used
23 and for which licensure is sought
24 for the biological product;

1 “(II) the biological product and
2 reference product utilize the same
3 mechanism or mechanisms of action
4 for the condition or conditions of use
5 prescribed, recommended, or sug-
6 gested in the proposed labeling, but
7 only to the extent the mechanism or
8 mechanisms of action are known for
9 the reference product;

10 “(III) the condition or conditions
11 of use prescribed, recommended, or
12 suggested in the labeling proposed for
13 the biological product have been pre-
14 viously approved for the reference
15 product;

16 “(IV) the route of administra-
17 tion, the dosage form, and the
18 strength of the biological product are
19 the same as those of the reference
20 product; and

21 “(V) the facility in which the bio-
22 logical product is manufactured, proc-
23 essed, packed, or held meets stand-
24 ards designed to assure that the bio-

1 logical product continues to be safe,
2 pure, and potent.

3 “(ii) DETERMINATION BY SEC-
4 RETARY.—The Secretary may determine,
5 in the Secretary’s discretion, that an ele-
6 ment described in clause (i)(I) is unneces-
7 sary in an application submitted under this
8 subsection.

9 “(iii) ADDITIONAL INFORMATION.—
10 An application submitted under this sub-
11 section—

12 “(I) shall include publicly-avail-
13 able information regarding the Sec-
14 retary’s previous determination that
15 the reference product is safe, pure,
16 and potent; and

17 “(II) may include any additional
18 information in support of the applica-
19 tion, including publicly-available infor-
20 mation with respect to the reference
21 product or another biological product.

22 “(B) INTERCHANGEABILITY.—An applica-
23 tion (or a supplement to an application) sub-
24 mitted under this subsection may include infor-
25 mation demonstrating that the biological prod-

1 uct meets the standards described in paragraph
2 (4).

3 “(3) EVALUATION BY SECRETARY.—Upon re-
4 view of an application (or a supplement to an appli-
5 cation) submitted under this subsection, the Sec-
6 retary shall license the biological product under this
7 subsection if—

8 “(A) the Secretary determines that the in-
9 formation submitted in the application (or the
10 supplement) is sufficient to show that the bio-
11 logical product—

12 “(i) is biosimilar to the reference
13 product; or

14 “(ii) meets the standards described in
15 paragraph (4), and therefore is inter-
16 changeable with the reference product; and

17 “(B) the applicant (or other appropriate
18 person) consents to the inspection of the facility
19 that is the subject of the application, in accord-
20 ance with subsection (c).

21 “(4) SAFETY STANDARDS FOR DETERMINING
22 INTERCHANGEABILITY.—Upon review of an applica-
23 tion submitted under this subsection or any supple-
24 ment to such application, the Secretary shall deter-
25 mine the biological product to be interchangeable

1 with the reference product if the Secretary deter-
2 mines that the information submitted in the applica-
3 tion (or a supplement to such application) is suffi-
4 cient to show that—

5 “(A) the biological product—

6 “(i) is biosimilar to the reference
7 product; and

8 “(ii) can be expected to produce the
9 same clinical result as the reference prod-
10 uct in any given patient; and

11 “(B) for a biological product that is ad-
12 ministered more than once to an individual, the
13 risk in terms of safety or diminished efficacy of
14 alternating or switching between use of the bio-
15 logical product and the reference product is not
16 greater than the risk of using the reference
17 product without such alternation or switch.

18 “(5) GENERAL RULES.—

19 “(A) ONE REFERENCE PRODUCT PER AP-
20 PPLICATION.—A biological product, in an appli-
21 cation submitted under this subsection, may not
22 be evaluated against more than 1 reference
23 product.

24 “(B) REVIEW.—An application submitted
25 under this subsection shall be reviewed by the

1 division within the Food and Drug Administra-
2 tion that is responsible for the review and ap-
3 proval of the application under which the ref-
4 erence product is licensed.

5 “(C) RISK EVALUATION AND MITIGATION
6 STRATEGIES.—The authority of the Secretary
7 with respect to risk evaluation and mitigation
8 strategies under the Federal Food, Drug, and
9 Cosmetic Act shall apply to biological products
10 licensed under this subsection in the same man-
11 ner as such authority applies to biological prod-
12 ucts licensed under subsection (a).

13 “(6) EXCLUSIVITY FOR FIRST INTERCHANGE-
14 ABLE BIOLOGICAL PRODUCT.—Upon review of an
15 application submitted under this subsection relying
16 on the same reference product for which a prior bio-
17 logical product has received a determination of inter-
18 changeability for any condition of use, the Secretary
19 shall not make a determination under paragraph (4)
20 that the second or subsequent biological product is
21 interchangeable for any condition of use until the
22 earlier of—

23 “(A) 1 year after the first commercial
24 marketing of the first interchangeable bio-

1 similar biological product to be approved as
2 interchangeable for that reference product;

3 “(B) 18 months after—

4 “(i) a final court decision on all pat-
5 ents in suit in an action instituted under
6 subsection (l)(6) against the applicant that
7 submitted the application for the first ap-
8 proved interchangeable biosimilar biological
9 product; or

10 “(ii) the dismissal with or without
11 prejudice of an action instituted under sub-
12 section (l)(6) against the applicant that
13 submitted the application for the first ap-
14 proved interchangeable biosimilar biological
15 product; or

16 “(C)(i) 42 months after approval of the
17 first interchangeable biosimilar biological prod-
18 uct if the applicant that submitted such appli-
19 cation has been sued under subsection (l)(6)
20 and such litigation is still ongoing within such
21 42-month period; or

22 “(ii) 18 months after approval of the first
23 interchangeable biosimilar biological product if
24 the applicant that submitted such application
25 has not been sued under subsection (l)(6).

1 For purposes of this paragraph, the term ‘final court
2 decision’ means a final decision of a court from
3 which no appeal (other than a petition to the United
4 States Supreme Court for a writ of certiorari) has
5 been or can be taken.

6 “(7) EXCLUSIVITY FOR REFERENCE PROD-
7 UCT.—

8 “(A) EFFECTIVE DATE OF BIOSIMILAR AP-
9 PPLICATION APPROVAL.—Approval of an applica-
10 tion under this subsection may not be made ef-
11 fective by the Secretary until the date that is
12 12 years after the date on which the reference
13 product was first licensed under subsection (a).

14 “(B) FILING PERIOD.—An application
15 under this subsection may not be submitted to
16 the Secretary until the date that is 4 years
17 after the date on which the reference product
18 was first licensed under subsection (a).

19 “(C) FIRST LICENSURE.—Subparagraphs
20 (A) and (B) shall not apply to a license for or
21 approval of—

22 “(i) a supplement for the biological
23 product that is the reference product; or

24 “(ii) a subsequent application filed by
25 the same sponsor or manufacturer of the

1 biological product that is the reference
2 product (or a licensor, predecessor in inter-
3 est, or other related entity) for—

4 “(I) a change (not including a
5 modification to the structure of the bi-
6 ological product) that results in a new
7 indication, route of administration,
8 dosing schedule, dosage form, delivery
9 system, delivery device, or strength; or

10 “(II) a modification to the struc-
11 ture of the biological product that
12 does not result in a change in safety,
13 purity, or potency.

14 “(8) GUIDANCE DOCUMENTS.—

15 “(A) IN GENERAL.—The Secretary may,
16 after opportunity for public comment, issue
17 guidance in accordance, except as provided in
18 subparagraph (B)(i), with section 701(h) of the
19 Federal Food, Drug, and Cosmetic Act with re-
20 spect to the licensure of a biological product
21 under this subsection. Any such guidance may
22 be general or specific.

23 “(B) PUBLIC COMMENT.—

24 “(i) IN GENERAL.—The Secretary
25 shall provide the public an opportunity to

1 comment on any proposed guidance issued
2 under subparagraph (A) before issuing
3 final guidance.

4 “(ii) INPUT REGARDING MOST VALU-
5 ABLE GUIDANCE.—The Secretary shall es-
6 tablish a process through which the public
7 may provide the Secretary with input re-
8 garding priorities for issuing guidance.

9 “(C) NO REQUIREMENT FOR APPLICATION
10 CONSIDERATION.—The issuance (or non-
11 issuance) of guidance under subparagraph (A)
12 shall not preclude the review of, or action on,
13 an application submitted under this subsection.

14 “(D) REQUIREMENT FOR PRODUCT CLASS-
15 SPECIFIC GUIDANCE.—If the Secretary issues
16 product class-specific guidance under subpara-
17 graph (A), such guidance shall include a de-
18 scription of—

19 “(i) the criteria that the Secretary will
20 use to determine whether a biological prod-
21 uct is highly similar to a reference product
22 in such product class; and

23 “(ii) the criteria, if available, that the
24 Secretary will use to determine whether a

1 biological product meets the standards de-
2 scribed in paragraph (4).

3 “(E) CERTAIN PRODUCT CLASSES.—

4 “(i) GUIDANCE.—The Secretary may
5 indicate in a guidance document that the
6 science and experience, as of the date of
7 such guidance, with respect to a product or
8 product class (not including any recom-
9 binant protein) does not allow approval of
10 an application for a license as provided
11 under this subsection for such product or
12 product class.

13 “(ii) MODIFICATION OR REVERSAL.—
14 The Secretary may issue a subsequent
15 guidance document under subparagraph
16 (A) to modify or reverse a guidance docu-
17 ment under clause (i).

18 “(iii) NO EFFECT ON ABILITY TO
19 DENY LICENSE.—Clause (i) shall not be
20 construed to require the Secretary to ap-
21 prove a product with respect to which the
22 Secretary has not indicated in a guidance
23 document that the science and experience,
24 as described in clause (i), does not allow
25 approval of such an application.

1 “(l) PATENTS.—

2 “(1) CONFIDENTIAL ACCESS TO SUBSECTION
3 (k) APPLICATION.—

4 “(A) APPLICATION OF PARAGRAPH.—Un-
5 less otherwise agreed to by a person that sub-
6 mits an application under subsection (k) (re-
7 ferred to in this subsection as the ‘subsection
8 (k) applicant’) and the sponsor of the applica-
9 tion for the reference product (referred to in
10 this subsection as the ‘reference product spon-
11 sor’), the provisions of this paragraph shall
12 apply to the exchange of information described
13 in this subsection.

14 “(B) IN GENERAL.—

15 “(i) PROVISION OF CONFIDENTIAL IN-
16 FORMATION.—When a subsection (k) ap-
17 plicant submits an application under sub-
18 section (k), such applicant shall provide to
19 the persons described in clause (ii), subject
20 to the terms of this paragraph, confidential
21 access to the information required to be
22 produced pursuant to paragraph (2) and
23 any other information that the subsection
24 (k) applicant determines, in its sole discre-
25 tion, to be appropriate (referred to in this

1 subsection as the ‘confidential informa-
2 tion’).

3 “(ii) RECIPIENTS OF INFORMATION.—
4 The persons described in this clause are
5 the following:

6 “(I) OUTSIDE COUNSEL.—One or
7 more attorneys designated by the ref-
8 erence product sponsor who are em-
9 ployees of an entity other than the
10 reference product sponsor (referred to
11 in this paragraph as the ‘outside
12 counsel’), provided that such attor-
13 neys do not engage, formally or infor-
14 mally, in patent prosecution relevant
15 or related to the reference product.

16 “(II) IN-HOUSE COUNSEL.—One
17 attorney that represents the reference
18 product sponsor who is an employee
19 of the reference product sponsor, pro-
20 vided that such attorney does not en-
21 gage, formally or informally, in patent
22 prosecution relevant or related to the
23 reference product.

24 “(iii) PATENT OWNER ACCESS.—A
25 representative of the owner of a patent ex-

1 clusively licensed to a reference product
2 sponsor with respect to the reference prod-
3 uct and who has retained a right to assert
4 the patent or participate in litigation con-
5 cerning the patent may be provided the
6 confidential information, provided that the
7 representative informs the reference prod-
8 uct sponsor and the subsection (k) appli-
9 cant of his or her agreement to be subject
10 to the confidentiality provisions set forth in
11 this paragraph, including those under
12 clause (ii).

13 “(C) LIMITATION ON DISCLOSURE.—No
14 person that receives confidential information
15 pursuant to subparagraph (B) shall disclose
16 any confidential information to any other per-
17 son or entity, including the reference product
18 sponsor employees, outside scientific consult-
19 ants, or other outside counsel retained by the
20 reference product sponsor, without the prior
21 written consent of the subsection (k) applicant,
22 which shall not be unreasonably withheld.

23 “(D) USE OF CONFIDENTIAL INFORMA-
24 TION.—Confidential information shall be used
25 for the sole and exclusive purpose of deter-

1 mining, with respect to each patent assigned to
2 or exclusively licensed by the reference product
3 sponsor, whether a claim of patent infringement
4 could reasonably be asserted if the subsection
5 (k) applicant engaged in the manufacture, use,
6 offering for sale, sale, or importation into the
7 United States of the biological product that is
8 the subject of the application under subsection
9 (k).

10 “(E) OWNERSHIP OF CONFIDENTIAL IN-
11 FORMATION.—The confidential information dis-
12 closed under this paragraph is, and shall re-
13 main, the property of the subsection (k) appli-
14 cant. By providing the confidential information
15 pursuant to this paragraph, the subsection (k)
16 applicant does not provide the reference product
17 sponsor or the outside counsel any interest in or
18 license to use the confidential information, for
19 purposes other than those specified in subpara-
20 graph (D).

21 “(F) EFFECT OF INFRINGEMENT AC-
22 TION.—In the event that the reference product
23 sponsor files a patent infringement suit, the use
24 of confidential information shall continue to be
25 governed by the terms of this paragraph until

1 such time as a court enters a protective order
2 regarding the information. Upon entry of such
3 order, the subsection (k) applicant may redesignate
4 confidential information in accordance
5 with the terms of that order. No confidential in-
6 formation shall be included in any publicly-
7 available complaint or other pleading. In the
8 event that the reference product sponsor does
9 not file an infringement action by the date spec-
10 ified in paragraph (6), the reference product
11 sponsor shall return or destroy all confidential
12 information received under this paragraph, pro-
13 vided that if the reference product sponsor opts
14 to destroy such information, it will confirm de-
15 struction in writing to the subsection (k) appli-
16 cant.

17 “(G) RULE OF CONSTRUCTION.—Nothing
18 in this paragraph shall be construed—

19 “(i) as an admission by the subsection
20 (k) applicant regarding the validity, en-
21 forceability, or infringement of any patent;
22 or

23 “(ii) as an agreement or admission by
24 the subsection (k) applicant with respect to

1 the competency, relevance, or materiality
2 of any confidential information.

3 “(H) EFFECT OF VIOLATION.—The disclo-
4 sure of any confidential information in violation
5 of this paragraph shall be deemed to cause the
6 subsection (k) applicant to suffer irreparable
7 harm for which there is no adequate legal rem-
8 edy and the court shall consider immediate in-
9 junctive relief to be an appropriate and nec-
10 essary remedy for any violation or threatened
11 violation of this paragraph.

12 “(2) SUBSECTION (k) APPLICATION INFORMA-
13 TION.—Not later than 20 days after the Secretary
14 notifies the subsection (k) applicant that the applica-
15 tion has been accepted for review, the subsection (k)
16 applicant—

17 “(A) shall provide to the reference product
18 sponsor a copy of the application submitted to
19 the Secretary under subsection (k), and such
20 other information that describes the process or
21 processes used to manufacture the biological
22 product that is the subject of such application;
23 and

1 “(B) may provide to the reference product
2 sponsor additional information requested by or
3 on behalf of the reference product sponsor.

4 “(3) LIST AND DESCRIPTION OF PATENTS.—

5 “(A) LIST BY REFERENCE PRODUCT SPON-
6 SOR.—Not later than 60 days after the receipt
7 of the application and information under para-
8 graph (2), the reference product sponsor shall
9 provide to the subsection (k) applicant—

10 “(i) a list of patents for which the ref-
11 erence product sponsor believes a claim of
12 patent infringement could reasonably be
13 asserted by the reference product sponsor,
14 or by a patent owner that has granted an
15 exclusive license to the reference product
16 sponsor with respect to the reference prod-
17 uct, if a person not licensed by the ref-
18 erence product sponsor engaged in the
19 making, using, offering to sell, selling, or
20 importing into the United States of the bi-
21 ological product that is the subject of the
22 subsection (k) application; and

23 “(ii) an identification of the patents
24 on such list that the reference product

1 sponsor would be prepared to license to the
2 subsection (k) applicant.

3 “(B) LIST AND DESCRIPTION BY SUB-
4 SECTION (k) APPLICANT.—Not later than 60
5 days after receipt of the list under subpara-
6 graph (A), the subsection (k) applicant—

7 “(i) may provide to the reference
8 product sponsor a list of patents to which
9 the subsection (k) applicant believes a
10 claim of patent infringement could reason-
11 ably be asserted by the reference product
12 sponsor if a person not licensed by the ref-
13 erence product sponsor engaged in the
14 making, using, offering to sell, selling, or
15 importing into the United States of the bi-
16 ological product that is the subject of the
17 subsection (k) application;

18 “(ii) shall provide to the reference
19 product sponsor, with respect to each pat-
20 ent listed by the reference product sponsor
21 under subparagraph (A) or listed by the
22 subsection (k) applicant under clause (i)—

23 “(I) a detailed statement that de-
24 scribes, on a claim by claim basis, the
25 factual and legal basis of the opinion

1 of the subsection (k) applicant that
2 such patent is invalid, unenforceable,
3 or will not be infringed by the com-
4 mercial marketing of the biological
5 product that is the subject of the sub-
6 section (k) application; or

7 “(II) a statement that the sub-
8 section (k) applicant does not intend
9 to begin commercial marketing of the
10 biological product before the date that
11 such patent expires; and

12 “(iii) shall provide to the reference
13 product sponsor a response regarding each
14 patent identified by the reference product
15 sponsor under subparagraph (A)(ii).

16 “(C) DESCRIPTION BY REFERENCE PROD-
17 UCT SPONSOR.—Not later than 60 days after
18 receipt of the list and statement under subpara-
19 graph (B), the reference product sponsor shall
20 provide to the subsection (k) applicant a de-
21 tailed statement that describes, with respect to
22 each patent described in subparagraph
23 (B)(ii)(I), on a claim by claim basis, the factual
24 and legal basis of the opinion of the reference
25 product sponsor that such patent will be in-

1 fringed by the commercial marketing of the bio-
2 logical product that is the subject of the sub-
3 section (k) application and a response to the
4 statement concerning validity and enforceability
5 provided under subparagraph (B)(ii)(I).

6 “(4) PATENT RESOLUTION NEGOTIATIONS.—

7 “(A) IN GENERAL.—After receipt by the
8 subsection (k) applicant of the statement under
9 paragraph (3)(C), the reference product spon-
10 sor and the subsection (k) applicant shall en-
11 gage in good faith negotiations to agree on
12 which, if any, patents listed under paragraph
13 (3) by the subsection (k) applicant or the ref-
14 erence product sponsor shall be the subject of
15 an action for patent infringement under para-
16 graph (6).

17 “(B) FAILURE TO REACH AGREEMENT.—
18 If, within 15 days of beginning negotiations
19 under subparagraph (A), the subsection (k) ap-
20 plicant and the reference product sponsor fail to
21 agree on a final and complete list of which, if
22 any, patents listed under paragraph (3) by the
23 subsection (k) applicant or the reference prod-
24 uct sponsor shall be the subject of an action for
25 patent infringement under paragraph (6), the

1 provisions of paragraph (5) shall apply to the
2 parties.

3 “(5) PATENT RESOLUTION IF NO AGREE-
4 MENT.—

5 “(A) NUMBER OF PATENTS.—The sub-
6 section (k) applicant shall notify the reference
7 product sponsor of the number of patents that
8 such applicant will provide to the reference
9 product sponsor under subparagraph (B)(i)(I).

10 “(B) EXCHANGE OF PATENT LISTS.—

11 “(i) IN GENERAL.—On a date agreed
12 to by the subsection (k) applicant and the
13 reference product sponsor, but in no case
14 later than 5 days after the subsection (k)
15 applicant notifies the reference product
16 sponsor under subparagraph (A), the sub-
17 section (k) applicant and the reference
18 product sponsor shall simultaneously ex-
19 change—

20 “(I) the list of patents that the
21 subsection (k) applicant believes
22 should be the subject of an action for
23 patent infringement under paragraph
24 (6); and

1 “(II) the list of patents, in ac-
2 cordance with clause (ii), that the ref-
3 erence product sponsor believes should
4 be the subject of an action for patent
5 infringement under paragraph (6).

6 “(ii) NUMBER OF PATENTS LISTED BY
7 REFERENCE PRODUCT SPONSOR.—

8 “(I) IN GENERAL.—Subject to
9 subclause (II), the number of patents
10 listed by the reference product spon-
11 sor under clause (i)(II) may not ex-
12 ceed the number of patents listed by
13 the subsection (k) applicant under
14 clause (i)(I).

15 “(II) EXCEPTION.—If a sub-
16 section (k) applicant does not list any
17 patent under clause (i)(I), the ref-
18 erence product sponsor may list 1 pat-
19 ent under clause (i)(II).

20 “(6) IMMEDIATE PATENT INFRINGEMENT AC-
21 TION.—

22 “(A) ACTION IF AGREEMENT ON PATENT
23 LIST.—If the subsection (k) applicant and the
24 reference product sponsor agree on patents as
25 described in paragraph (4), not later than 30

1 days after such agreement, the reference prod-
2 uct sponsor shall bring an action for patent in-
3 fringement with respect to each such patent.

4 “(B) ACTION IF NO AGREEMENT ON PAT-
5 ENT LIST.—If the provisions of paragraph (5)
6 apply to the parties as described in paragraph
7 (4)(B), not later than 30 days after the ex-
8 change of lists under paragraph (5)(B), the ref-
9 erence product sponsor shall bring an action for
10 patent infringement with respect to each patent
11 that is included on such lists.

12 “(C) NOTIFICATION AND PUBLICATION OF
13 COMPLAINT.—

14 “(i) NOTIFICATION TO SECRETARY.—
15 Not later than 30 days after a complaint
16 is served to a subsection (k) applicant in
17 an action for patent infringement described
18 under this paragraph, the subsection (k)
19 applicant shall provide the Secretary with
20 notice and a copy of such complaint.

21 “(ii) PUBLICATION BY SECRETARY.—
22 The Secretary shall publish in the Federal
23 Register notice of a complaint received
24 under clause (i).

1 “(7) NEWLY ISSUED OR LICENSED PATENTS.—

2 In the case of a patent that—

3 “(A) is issued to, or exclusively licensed by,
4 the reference product sponsor after the date
5 that the reference product sponsor provided the
6 list to the subsection (k) applicant under para-
7 graph (3)(A); and

8 “(B) the reference product sponsor reason-
9 ably believes that, due to the issuance of such
10 patent, a claim of patent infringement could
11 reasonably be asserted by the reference product
12 sponsor if a person not licensed by the ref-
13 erence product sponsor engaged in the making,
14 using, offering to sell, selling, or importing into
15 the United States of the biological product that
16 is the subject of the subsection (k) application,
17 not later than 30 days after such issuance or licens-
18 ing, the reference product sponsor shall provide to
19 the subsection (k) applicant a supplement to the list
20 provided by the reference product sponsor under
21 paragraph (3)(A) that includes such patent, not
22 later than 30 days after such supplement is pro-
23 vided, the subsection (k) applicant shall provide a
24 statement to the reference product sponsor in ac-

1 cordance with paragraph (3)(B), and such patent
2 shall be subject to paragraph (8).

3 “(8) NOTICE OF COMMERCIAL MARKETING AND
4 PRELIMINARY INJUNCTION.—

5 “(A) NOTICE OF COMMERCIAL MAR-
6 KETING.—The subsection (k) applicant shall
7 provide notice to the reference product sponsor
8 not later than 180 days before the date of the
9 first commercial marketing of the biological
10 product licensed under subsection (k).

11 “(B) PRELIMINARY INJUNCTION.—After
12 receiving the notice under subparagraph (A)
13 and before such date of the first commercial
14 marketing of such biological product, the ref-
15 erence product sponsor may seek a preliminary
16 injunction prohibiting the subsection (k) appli-
17 cant from engaging in the commercial manufac-
18 ture or sale of such biological product until the
19 court decides the issue of patent validity, en-
20 forcement, and infringement with respect to any
21 patent that is—

22 “(i) included in the list provided by
23 the reference product sponsor under para-
24 graph (3)(A) or in the list provided by the

1 subsection (k) applicant under paragraph
2 (3)(B); and

3 “(ii) not included, as applicable, on—

4 “(I) the list of patents described
5 in paragraph (4); or

6 “(II) the lists of patents de-
7 scribed in paragraph (5)(B).

8 “(C) REASONABLE COOPERATION.—If the
9 reference product sponsor has sought a prelimi-
10 nary injunction under subparagraph (B), the
11 reference product sponsor and the subsection
12 (k) applicant shall reasonably cooperate to ex-
13 pedite such further discovery as is needed in
14 connection with the preliminary injunction mo-
15 tion.

16 “(9) LIMITATION ON DECLARATORY JUDGMENT
17 ACTION.—

18 “(A) SUBSECTION (k) APPLICATION PRO-
19 VIDED.—If a subsection (k) applicant provides
20 the application and information required under
21 paragraph (2)(A), neither the reference product
22 sponsor nor the subsection (k) applicant may,
23 prior to the date notice is received under para-
24 graph (8)(A), bring any action under section
25 2201 of title 28, United States Code, for a dec-

1 laration of infringement, validity, or enforce-
2 ability of any patent that is described in clauses
3 (i) and (ii) of paragraph (8)(B).

4 “(B) SUBSEQUENT FAILURE TO ACT BY
5 SUBSECTION (k) APPLICANT.—If a subsection
6 (k) applicant fails to complete an action re-
7 quired of the subsection (k) applicant under
8 paragraph (3)(B)(ii), paragraph (5), paragraph
9 (6)(C)(i), paragraph (7), or paragraph (8)(A),
10 the reference product sponsor, but not the sub-
11 section (k) applicant, may bring an action
12 under section 2201 of title 28, United States
13 Code, for a declaration of infringement, validity,
14 or enforceability of any patent included in the
15 list described in paragraph (3)(A), including as
16 provided under paragraph (7).

17 “(C) SUBSECTION (k) APPLICATION NOT
18 PROVIDED.—If a subsection (k) applicant fails
19 to provide the application and information re-
20 quired under paragraph (2)(A), the reference
21 product sponsor, but not the subsection (k) ap-
22 plicant, may bring an action under section 2201
23 of title 28, United States Code, for a declara-
24 tion of infringement, validity, or enforceability

1 of any patent that claims the biological product
2 or a use of the biological product.”.

3 (b) DEFINITIONS.—Section 351(i) of the Public
4 Health Service Act (42 U.S.C. 262(i)) is amended—

5 (1) by striking “In this section, the term ‘bio-
6 logical product’ means” and inserting the following:

7 “In this section:

8 “(1) The term ‘biological product’ means”;

9 (2) in paragraph (1), as so designated, by in-
10 serting “protein (except any chemically synthesized
11 polypeptide),” after “allergenic product,”; and

12 (3) by adding at the end the following:

13 “(2) The term ‘biosimilar’ or ‘biosimilarity’, in
14 reference to a biological product that is the subject
15 of an application under subsection (k), means—

16 “(A) that the biological product is highly
17 similar to the reference product notwith-
18 standing minor differences in clinically inactive
19 components; and

20 “(B) there are no clinically meaningful dif-
21 ferences between the biological product and the
22 reference product in terms of the safety, purity,
23 and potency of the product.

24 “(3) The term ‘interchangeable’ or ‘inter-
25 changeability’, in reference to a biological product

1 that is shown to meet the standards described in
2 subsection (k)(4), means that the biological product
3 may be substituted for the reference product without
4 the intervention of the health care provider who pre-
5 scribed the reference product.

6 “(4) The term ‘reference product’ means the
7 single biological product licensed under subsection
8 (a) against which a biological product is evaluated in
9 an application submitted under subsection (k).”.

10 (c) CONFORMING AMENDMENTS RELATING TO PAT-
11 ENTS.—

12 (1) PATENTS.—Section 271(e) of title 35,
13 United States Code, is amended—

14 (A) in paragraph (2)—

15 (i) in subparagraph (A), by striking
16 “or” at the end;

17 (ii) in subparagraph (B), by adding
18 “or” at the end; and

19 (iii) by inserting after subparagraph
20 (B) the following:

21 “(C)(i) with respect to a patent that is identi-
22 fied in the list of patents described in section
23 351(l)(3) of the Public Health Service Act (including
24 as provided under section 351(l)(7) of such Act), an

1 application seeking approval of a biological product,
2 or

3 “(ii) if the applicant for the application fails to
4 provide the application and information required
5 under section 351(l)(2)(A) of such Act, an applica-
6 tion seeking approval of a biological product for a
7 patent that could be identified pursuant to section
8 351(l)(3)(A)(i) of such Act,”; and

9 (iv) in the matter following subpara-
10 graph (C) (as added by clause (iii)), by
11 striking “or veterinary biological product”
12 and inserting “, veterinary biological prod-
13 uct, or biological product”;

14 (B) in paragraph (4)—

15 (i) in subparagraph (B), by—

16 (I) striking “or veterinary bio-
17 logical product” and inserting “, vet-
18 erinary biological product, or biologi-
19 cal product”; and

20 (II) striking “and” at the end;

21 (ii) in subparagraph (C), by—

22 (I) striking “or veterinary bio-
23 logical product” and inserting “, vet-
24 erinary biological product, or biologi-
25 cal product”; and

1 (II) striking the period and in-
2 serting “, and”;

3 (iii) by inserting after subparagraph
4 (C) the following:

5 “(D) the court shall order a permanent injunc-
6 tion prohibiting any infringement of the patent by
7 the biological product involved in the infringement
8 until a date which is not earlier than the date of the
9 expiration of the patent that has been infringed
10 under paragraph (2)(C), provided the patent is the
11 subject of a final court decision, as defined in sec-
12 tion 351(k)(6) of the Public Health Service Act, in
13 an action for infringement of the patent under sec-
14 tion 351(l)(6) of such Act, and the biological prod-
15 uct has not yet been approved because of section
16 351(k)(7) of such Act.”; and

17 (iv) in the matter following subpara-
18 graph (D) (as added by clause (iii)), by
19 striking “and (C)” and inserting “(C), and
20 (D)”;

21 (C) by adding at the end the following:

22 “(6)(A) Subparagraph (B) applies, in lieu of para-
23 graph (4), in the case of a patent—

24 “(i) that is identified, as applicable, in the list
25 of patents described in section 351(l)(4) of the Pub-

1 lic Health Service Act or the lists of patents de-
2 scribed in section 351(l)(5)(B) of such Act with re-
3 spect to a biological product; and

4 “(ii) for which an action for infringement of the
5 patent with respect to the biological product—

6 “(I) was brought after the expiration of
7 the 30-day period described in subparagraph
8 (A) or (B), as applicable, of section 351(l)(6) of
9 such Act; or

10 “(II) was brought before the expiration of
11 the 30-day period described in subclause (I),
12 but which was dismissed without prejudice or
13 was not prosecuted to judgment in good faith.

14 “(B) In an action for infringement of a patent de-
15 scribed in subparagraph (A), the sole and exclusive remedy
16 that may be granted by a court, upon a finding that the
17 making, using, offering to sell, selling, or importation into
18 the United States of the biological product that is the sub-
19 ject of the action infringed the patent, shall be a reason-
20 able royalty.

21 “(C) The owner of a patent that should have been
22 included in the list described in section 351(l)(3)(A) of
23 the Public Health Service Act, including as provided under
24 section 351(l)(7) of such Act for a biological product, but
25 was not timely included in such list, may not bring an

1 action under this section for infringement of the patent
2 with respect to the biological product.”.

3 (2) CONFORMING AMENDMENT UNDER TITLE
4 28.—Section 2201(b) of title 28, United States
5 Code, is amended by inserting before the period the
6 following: “, or section 351 of the Public Health
7 Service Act”.

8 (d) CONFORMING AMENDMENTS UNDER THE FED-
9 ERAL FOOD, DRUG, AND COSMETIC ACT.—

10 (1) CONTENT AND REVIEW OF APPLICA-
11 TIONS.—Section 505(b)(5)(B) of the Federal Food,
12 Drug, and Cosmetic Act (21 U.S.C. 355(b)(5)(B)) is
13 amended by inserting before the period at the end
14 of the first sentence the following: “or, with respect
15 to an applicant for approval of a biological product
16 under section 351(k) of the Public Health Service
17 Act, any necessary clinical study or studies”.

18 (2) NEW ACTIVE INGREDIENT.—Section 505B
19 of the Federal Food, Drug, and Cosmetic Act (21
20 U.S.C. 355c) is amended by adding at the end the
21 following:

22 “(n) NEW ACTIVE INGREDIENT.—

23 “(1) NON-INTERCHANGEABLE BIOSIMILAR BIO-
24 LOGICAL PRODUCT.—A biological product that is
25 biosimilar to a reference product under section 351

1 of the Public Health Service Act, and that the Sec-
2 retary has not determined to meet the standards de-
3 scribed in subsection (k)(4) of such section for inter-
4 changeability with the reference product, shall be
5 considered to have a new active ingredient under
6 this section.

7 “(2) INTERCHANGEABLE BIOSIMILAR BIOLOGI-
8 CAL PRODUCT.—A biological product that is inter-
9 changeable with a reference product under section
10 351 of the Public Health Service Act shall not be
11 considered to have a new active ingredient under
12 this section.”.

13 (e) PRODUCTS PREVIOUSLY APPROVED UNDER SEC-
14 TION 505.—

15 (1) REQUIREMENT TO FOLLOW SECTION 351.—
16 Except as provided in paragraph (2), an application
17 for a biological product shall be submitted under
18 section 351 of the Public Health Service Act (42
19 U.S.C. 262) (as amended by this Act).

20 (2) EXCEPTION.—An application for a biologi-
21 cal product may be submitted under section 505 of
22 the Federal Food, Drug, and Cosmetic Act (21
23 U.S.C. 355) if—

24 (A) such biological product is in a product
25 class for which a biological product in such

1 product class is the subject of an application
2 approved under such section 505 not later than
3 the date of enactment of this Act; and

4 (B) such application—

5 (i) has been submitted to the Sec-
6 retary of Health and Human Services (re-
7 ferred to in this Act as the “Secretary”)
8 before the date of enactment of this Act;
9 or

10 (ii) is submitted to the Secretary not
11 later than the date that is 10 years after
12 the date of enactment of this Act.

13 (3) LIMITATION.—Notwithstanding paragraph
14 (2), an application for a biological product may not
15 be submitted under section 505 of the Federal Food,
16 Drug, and Cosmetic Act (21 U.S.C. 355) if there is
17 another biological product approved under sub-
18 section (a) of section 351 of the Public Health Serv-
19 ice Act that could be a reference product with re-
20 spect to such application (within the meaning of
21 such section 351) if such application were submitted
22 under subsection (k) of such section 351.

23 (4) DEEMED APPROVED UNDER SECTION
24 351.—An approved application for a biological prod-
25 uct under section 505 of the Federal Food, Drug,

1 and Cosmetic Act (21 U.S.C. 355) shall be deemed
2 to be a license for the biological product under such
3 section 351 on the date that is 10 years after the
4 date of enactment of this Act.

5 (5) DEFINITIONS.—For purposes of this sub-
6 section, the term “biological product” has the mean-
7 ing given such term under section 351 of the Public
8 Health Service Act (42 U.S.C. 262) (as amended by
9 this Act).

10 (f) FOLLOW-ON BIOLOGICS USER FEES.—

11 (1) DEVELOPMENT OF USER FEES FOR BIO-
12 SIMILAR BIOLOGICAL PRODUCTS.—

13 (A) IN GENERAL.—Beginning not later
14 than October 1, 2010, the Secretary shall de-
15 velop recommendations to present to Congress
16 with respect to the goals, and plans for meeting
17 the goals, for the process for the review of bio-
18 similar biological product applications sub-
19 mitted under section 351(k) of the Public
20 Health Service Act (as added by this Act) for
21 the first 5 fiscal years after fiscal year 2012. In
22 developing such recommendations, the Sec-
23 retary shall consult with—

24 (i) the Committee on Health, Edu-
25 cation, Labor, and Pensions of the Senate;

1 (ii) the Committee on Energy and
2 Commerce of the House of Representa-
3 tives;

4 (iii) scientific and academic experts;

5 (iv) health care professionals;

6 (v) representatives of patient and con-
7 sumer advocacy groups; and

8 (vi) the regulated industry.

9 (B) PUBLIC REVIEW OF RECOMMENDA-
10 TIONS.—After negotiations with the regulated
11 industry, the Secretary shall—

12 (i) present the recommendations de-
13 veloped under subparagraph (A) to the
14 Congressional committees specified in such
15 subparagraph;

16 (ii) publish such recommendations in
17 the Federal Register;

18 (iii) provide for a period of 30 days
19 for the public to provide written comments
20 on such recommendations;

21 (iv) hold a meeting at which the pub-
22 lic may present its views on such rec-
23 ommendations; and

1 (v) after consideration of such public
2 views and comments, revise such rec-
3 ommendations as necessary.

4 (C) TRANSMITTAL OF RECOMMENDA-
5 TIONS.—Not later than January 15, 2012, the
6 Secretary shall transmit to Congress the revised
7 recommendations under subparagraph (B), a
8 summary of the views and comments received
9 under such subparagraph, and any changes
10 made to the recommendations in response to
11 such views and comments.

12 (2) ESTABLISHMENT OF USER FEE PRO-
13 GRAM.—It is the sense of the Senate that, based on
14 the recommendations transmitted to Congress by the
15 Secretary pursuant to paragraph (1)(C), Congress
16 should authorize a program, effective on October 1,
17 2012, for the collection of user fees relating to the
18 submission of biosimilar biological product applica-
19 tions under section 351(k) of the Public Health
20 Service Act (as added by this Act).

21 (3) TRANSITIONAL PROVISIONS FOR USER FEES
22 FOR BIOSIMILAR BIOLOGICAL PRODUCTS.—

23 (A) APPLICATION OF THE PRESCRIPTION
24 DRUG USER FEE PROVISIONS.—Section
25 735(1)(B) of the Federal Food, Drug, and Cos-

1 metic Act (21 U.S.C. 379g(1)(B)) is amended
2 by striking “section 351” and inserting “sub-
3 section (a) or (k) of section 351”.

4 (B) EVALUATION OF COSTS OF REVIEWING
5 BIOSIMILAR BIOLOGICAL PRODUCT APPLICA-
6 TIONS.—During the period beginning on the
7 date of enactment of this Act and ending on
8 October 1, 2010, the Secretary shall collect and
9 evaluate data regarding the costs of reviewing
10 applications for biological products submitted
11 under section 351(k) of the Public Health Serv-
12 ice Act (as added by this Act) during such pe-
13 riod.

14 (C) AUDIT.—

15 (i) IN GENERAL.—On the date that is
16 2 years after first receiving a user fee ap-
17 plicable to an application for a biological
18 product under section 351(k) of the Public
19 Health Service Act (as added by this Act),
20 and on a biennial basis thereafter until Oc-
21 tober 1, 2013, the Secretary shall perform
22 an audit of the costs of reviewing such ap-
23 plications under such section 351(k). Such
24 an audit shall compare—

1 (I) the costs of reviewing such
2 applications under such section
3 351(k) to the amount of the user fee
4 applicable to such applications; and

5 (II)(aa) such ratio determined
6 under subclause (I); to

7 (bb) the ratio of the costs of re-
8 viewing applications for biological
9 products under section 351(a) of such
10 Act (as amended by this Act) to the
11 amount of the user fee applicable to
12 such applications under such section
13 351(a).

14 (ii) ALTERATION OF USER FEE.—If
15 the audit performed under clause (i) indi-
16 cates that the ratios compared under sub-
17 clause (II) of such clause differ by more
18 than 5 percent, then the Secretary shall
19 alter the user fee applicable to applications
20 submitted under such section 351(k) to
21 more appropriately account for the costs of
22 reviewing such applications.

23 (iii) ACCOUNTING STANDARDS.—The
24 Secretary shall perform an audit under
25 clause (i) in conformance with the account-

1 ing principles, standards, and requirements
2 prescribed by the Comptroller General of
3 the United States under section 3511 of
4 title 31, United State Code, to ensure the
5 validity of any potential variability.

6 (4) AUTHORIZATION OF APPROPRIATIONS.—

7 There is authorized to be appropriated to carry out
8 this subsection such sums as may be necessary for
9 each of fiscal years 2010 through 2012.

10 (g) ALLOCATION OF SAVINGS; SPECIAL RESERVE
11 FUND.—

12 (1) DETERMINATION OF SAVINGS.—The Sec-
13 retary of the Treasury, in consultation with the Sec-
14 retary, shall for each fiscal year determine the
15 amount of the savings to the Federal Government as
16 a result of the enactment of this Act and shall trans-
17 fer such amount to the Fund established under
18 paragraph (2) pursuant to a relevant appropriations
19 Act.

20 (2) SPECIAL RESERVE FUND.—

21 (A) IN GENERAL.—There is established in
22 the Treasury of the United States a fund to be
23 designated as the “Biological Product Savings
24 Fund” to be made available to the Secretary
25 without fiscal year limitation.

1 (B) USE OF FUND.—The amounts made
2 available to the Secretary through the Fund
3 under subparagraph (A) shall be expended on
4 activities authorized under the Public Health
5 Service Act.

6 (3) AUTHORIZATION OF APPROPRIATIONS.—
7 There is authorized to be appropriated for each fis-
8 cal year to the Fund established under paragraph
9 (2), the amount of the savings determined for such
10 fiscal year under paragraph (1).

11 (h) GOVERNMENT ACCOUNTABILITY OFFICE
12 STUDY.—

13 (1) IN GENERAL.—Not later than 3 years after
14 the date of enactment of this Act, the Comptroller
15 General of the United States shall study and report
16 to Congress regarding—

17 (A) the extent to which pediatric studies of
18 biological products are being required under the
19 Federal Food, Drug, and Cosmetic Act (21
20 U.S.C. 301 et seq.); and

21 (B) any pediatric needs not being met
22 under existing authority.

23 (2) CONTENT OF STUDY.—The study under
24 paragraph (1) shall review and assess—

1 (A) the extent to which pediatric studies of
2 biological products are required under sub-
3 sections (a) and (b) of section 505B of the Fed-
4 eral Food, Drug and Cosmetic Act (21 U.S.C.
5 355c);

6 (B) the extent to which pediatric studies of
7 biological products are required as part of risk
8 evaluation and mitigation strategies under such
9 Act;

10 (C) the number, importance, and
11 prioritization of any biological products that are
12 not being tested for pediatric use; and

13 (D) recommendations for ensuring pedi-
14 atric testing of products identified in subpara-
15 graph (C), including the consideration of any
16 incentives, such as those provided under the
17 Best Pharmaceuticals for Children Act.

18 (i) ORPHAN PRODUCTS.—If a reference product, as
19 defined in section 351 of the Public Health Service Act
20 (42 U.S.C. 262) (as amended by this Act) has been des-
21 ignated under section 526 of the Federal Food, Drug, and
22 Cosmetic Act (21 U.S.C. 360bb) for a rare disease or con-
23 dition, a biological product seeking approval for such dis-
24 ease or condition under subsection (k) of such section 351
25 as biosimilar to, or interchangeable with, such reference

1 product may be licensed by the Secretary only after the
2 expiration for such reference product of the later of—

3 (1) the 7-year period described in section
4 527(a) of the Federal Food, Drug, and Cosmetic Act
5 (21 U.S.C. 360cc(a)); and

6 (2) the 12-year period described in subsection
7 (k)(7) of such section 351.

8 **SEC. 702. AMENDMENTS TO CERTAIN PATENT PROVISIONS.**

9 Section 271(e)(2) of title 35, United States Code is
10 amended—

11 (1) in subparagraph (A), by striking “or” after
12 “patent”;

13 (2) in subparagraph (B), by adding “or” after
14 the comma at the end; and

15 (3) by inserting the following after subpara-
16 graph (B):

17 “(C) a statement under section
18 351(l)(4)(D)(ii) of the Public Health Service
19 Act,”.

