

AMENDMENT IN THE NATURE OF A SUBSTITUTE
TO H.R. _____
OFFERED BY MR. BOEHNER OF OHIO

(Amendment to text of H.R. 3962)

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 “Common Sense Health Care Reform and Affordability
4 Act”.

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

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

16 (c) TABLE OF CONTENTS.—The table of contents of
17 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. Licensure pathway for biosimilar biological products.
- Sec. 702. Fees relating to biosimilar biological products.
- Sec. 703. 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.—

13 (1) IN GENERAL.—Not later than January 1,
14 2010, each State shall—

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

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

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

20 (B) subject to paragraph (3), apply to the
21 operation of such a program from State funds
22 an amount equivalent to the portion of State
23 funds derived from State premium assessments
24 (as defined by the Secretary) that are not oth-
25 erwise used on State health care programs.

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

3 (A) STATES NOT OPERATING A QUALIFIED
4 HIGH RISK POOL.—In the case of a State that
5 is not operating a current section 2745 quali-
6 fied high risk pool as of the date of the enact-
7 ment of this Act—

8 (i) the State may only meet the re-
9 quirement of paragraph (1) through the
10 operation of a qualified State reinsurance
11 program described in subsection (b); and

12 (ii) the State's operation of such a re-
13 insurance program shall be treated, for
14 purposes of section 2745 of the Public
15 Health Service Act, as the operation of a
16 qualified high risk pool described in such
17 section.

18 (B) STATE OPERATING A QUALIFIED HIGH
19 RISK POOL.—In the case of a State that is op-
20 erating a current section 2745 qualified high
21 risk pool as of the date of the enactment of this
22 Act—

23 (i) as of January 1, 2010, such a pool
24 shall not be treated as a qualified high risk
25 pool under section 2745 of the Public

1 Health Service Act unless the pool is a
2 qualifying State high risk pool described in
3 subsection (c)(1); and

4 (ii) the State may use premium as-
5 sessment funds described in paragraph
6 (1)(B) to transition from operation of such
7 a pool to operation of a qualified State re-
8 insurance program described in subsection
9 (b).

10 (3) APPLICATION OF FUNDS.—If the program
11 or pool operated under paragraph (1)(A) is in strong
12 fiscal health, as determined in accordance with
13 standards established by the National Association of
14 Insurance Commissioners and as approved by the
15 State Insurance Commissioner involved, the require-
16 ment of paragraph (1)(B) shall be deemed to be
17 met.

18 (b) QUALIFIED STATE REINSURANCE PROGRAM.—

19 (1) IN GENERAL.—For purposes of this section,
20 a “qualified State reinsurance program” means a
21 program operated by a State program that provides
22 reinsurance for health insurance coverage offered in
23 the small group market in accordance with the
24 model for such a program established (as of the date
25 of the enactment of this Act).

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

3 (A) on a prospective or retrospective basis;
4 and

5 (B) on a basis that protects health insur-
6 ance issuers against the annual aggregate
7 spending of their enrollees as well as purchase
8 protection against individual catastrophic costs.

9 (3) SATISFACTION OF HIPAA REQUIREMENT.—
10 A qualified State reinsurance program shall be
11 deemed, for purposes of section 2745 of the Public
12 Health Service Act, to be a qualified high-risk pool
13 under such section.

14 (c) QUALIFYING STATE HIGH RISK POOL.—

15 (1) IN GENERAL.—A qualifying State high risk
16 pool described in this subsection means a current
17 section 2745 qualified high risk pool that meets the
18 following requirements:

19 (A) The pool must provide at least two
20 coverage options, one of which must be a high
21 deductible health plan coupled with a health
22 savings account.

23 (B) The pool must be funded with a stable
24 funding source.

1 (C) The pool must eliminate any waiting
2 lists so that all eligible residents who are seek-
3 ing coverage through the pool should be allowed
4 to receive coverage through the pool.

5 (D) The pool must allow for coverage of
6 individuals who, but for the 24-month disability
7 waiting period under section 226(b) of the So-
8 cial Security Act, would be eligible for Medicare
9 during the period of such waiting period.

10 (E) The pool must limit the pool premiums
11 to no more than 150 percent of the average
12 premium for applicable standard risk rates in
13 that State.

14 (F) The pool must conduct education and
15 outreach initiatives so that residents and bro-
16 kers understand that the pool is available to eli-
17 gible residents.

18 (G) The pool must provide coverage for
19 preventive services and disease management for
20 chronic diseases.

21 (2) VERIFICATION OF CITIZENSHIP OR ALIEN
22 QUALIFICATION.—

23 (A) IN GENERAL.—Notwithstanding any
24 other provision of law, only citizens and nation-
25 als of the United States shall be eligible to par-

1 ticipate in a qualifying State high risk pool that
2 receives funds under section 2745 of the Public
3 Health Service Act or this section.

4 (B) CONDITION OF PARTICIPATION.—As a
5 condition of a State receiving such funds, the
6 Secretary shall require the State to certify, to
7 the satisfaction of the Secretary, that such
8 State requires all applicants for coverage in the
9 qualifying State high risk pool to provide satis-
10 factory documentation of citizenship or nation-
11 ality in a manner consistent with section
12 1903(x) of the Social Security Act.

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

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

22 (d) WAIVERS.—In order to accommodate new and in-
23 novative programs, the Secretary may waive such require-
24 ments of this section for qualified State reinsurance pro-

1 grams and for qualifying State high risk pools as the Sec-
2 retary deems appropriate.

3 (e) FUNDING.—In addition to any other amounts ap-
4 propriated, there is appropriated to carry out section 2745
5 of the Public Health Service Act (including through a pro-
6 gram or pool described in subsection (a)(1))—

7 (1) \$15,000,000,000 for the period of fiscal
8 years 2010 through 2019; and

9 (2) an additional \$10,000,000,000 for the pe-
10 riod of fiscal years 2015 through 2019.

11 (f) DEFINITIONS.—In this section:

12 (1) HEALTH INSURANCE COVERAGE; HEALTH
13 INSURANCE ISSUER.—The terms “health insurance
14 coverage” and “health insurance issuer” have the
15 meanings given such terms in section 2791 of the
16 Public Health Service Act.

17 (2) CURRENT SECTION 2745 QUALIFIED HIGH
18 RISK POOL.—The term “current section 2745 quali-
19 fied high risk pool” has the meaning given the term
20 “qualified high risk pool” under section 2745(g) of
21 the Public Health Service Act as in effect as of the
22 date of the enactment of this Act.

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

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

3 (A) is determined under the State high
4 risk pool by considering the premium rates
5 charged by other health insurance issuers offer-
6 ing health insurance coverage to individuals in
7 the insurance market served;

8 (B) is established using reasonable actu-
9 arial techniques; and

10 (C) reflects anticipated claims experience
11 and expenses for the coverage involved.

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

14 **SEC. 102. ELIMINATION OF CERTAIN REQUIREMENTS FOR**
15 **GUARANTEED AVAILABILITY IN INDIVIDUAL**
16 **MARKET.**

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

20 (1) in paragraph (1)—

21 (A) by striking “(1)(A)” and inserting
22 “(1)”; and

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

1 (2) by adding “and” at the end of paragraph

2 (2);

3 (3) in paragraph (3)—

4 (A) by striking “(1)(A)” and inserting

5 “(1)”; and

6 (B) by striking the semicolon at the end

7 and inserting a period; and

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

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

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

13 Notwithstanding any other provision of law, a health
14 insurance issuer (including an entity licensed to sell insur-
15 ance with respect to a State or group health plan) may
16 not apply an annual or lifetime aggregate spending cap
17 on any health insurance coverage or plan offered by such
18 issuer.

19 **SEC. 104. PREVENTING UNJUST CANCELLATION OF INSUR-**
20 **ANCE COVERAGE.**

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

1 (1) in its heading, by inserting “, **CONTINU-**
2 **ATION IN FORCE, INCLUDING PROHIBITION OF**
3 **RESCISSION,”** after “**GUARANTEED RENEW-**
4 **ABILITY”**;

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

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

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

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

18 “(a) NOTICE AND REVIEW RIGHT.—If a health in-
19 surance issuer determines to nonrenew or not continue in
20 force, including rescind, health insurance coverage for an
21 individual in the individual market on the basis described
22 in section 2742(b)(2) before such nonrenewal, discontinu-
23 ation, or rescission, may take effect the issuer shall pro-
24 vide the individual with notice of such proposed non-
25 renewal, discontinuation, or rescission and an opportunity

1 for a review of such determination by an independent, ex-
2 ternal third party under procedures specified by the Sec-
3 retary.

4 “(b) INDEPENDENT DETERMINATION.—If the indi-
5 vidual requests such review by an independent, external
6 third party of a nonrenewal, discontinuation, or rescission
7 of health insurance coverage, the coverage shall remain in
8 effect until such third party determines that the coverage
9 may be nonrenewed, discontinued, or rescinded under sec-
10 tion 2742(b)(2).”.

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

15 **TITLE II—REDUCING HEALTH**
16 **CARE PREMIUMS AND THE**
17 **NUMBER OF UNINSURED**
18 **AMERICANS**

19 **SEC. 111. STATE INNOVATION PROGRAMS.**

20 (a) PROGRAMS THAT REDUCE THE COST OF
21 HEALTH INSURANCE PREMIUMS.—

22 (1) PAYMENTS TO STATES.—

23 (A) FOR PREMIUM REDUCTIONS IN THE
24 SMALL GROUP MARKET.—If the Secretary de-
25 termines that a State has reduced the average

1 per capita premium for health insurance cov-
2 erage in the small group market in year 3, in
3 year 6, or year 9 (as defined in subsection (c))
4 below the premium baseline for such year (as
5 defined paragraph (2)), the Secretary shall pay
6 the State an amount equal to the product of—

7 (i) bonus premium percentage (as de-
8 fined in paragraph (3)) for the State, mar-
9 ket, and year; and

10 (ii) the maximum State premium pay-
11 ment amount (as defined in paragraph (4))
12 for the State, market, and year

13 (B) FOR PREMIUM REDUCTIONS IN THE
14 INDIVIDUAL MARKET.—If the Secretary deter-
15 mines that a State has reduced the average per
16 capita premium for health insurance coverage
17 in the individual market in year 3, in year 6,
18 or in year 9 below the premium baseline for
19 such year, the Secretary shall pay the State an
20 amount equal to the product of—

21 (i) bonus premium percentage for the
22 State, market, and year; and

23 (ii) the maximum State premium pay-
24 ment amount for the State, market, and
25 year.

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

4 (A) for year 1, the average per capita pre-
5 miums for health insurance coverage in such
6 market in the State in such year; or

7 (B) for a subsequent year, the baseline for
8 the market in the State for the previous year
9 under this paragraph increased by a percentage
10 specified in accordance with a formula estab-
11 lished by the Secretary, in consultation with the
12 Congressional Budget Office and the Bureau of
13 the Census, that takes into account at least the
14 following:

15 (i) GROWTH FACTOR.—The inflation
16 in the costs of inputs to health care serv-
17 ices in the year.

18 (ii) HISTORIC PREMIUM GROWTH
19 RATES.—Historic growth rates, during the
20 10 years before year 1, of per capita pre-
21 miums for health insurance coverage.

22 (iii) DEMOGRAPHIC CONSIDER-
23 ATIONS.—Historic average changes in the
24 demographics of the population covered

1 that impact on the rate of growth of per
2 capita health care costs.

3 (3) BONUS PREMIUM PERCENTAGE DEFINED.—

4 (A) IN GENERAL.—For purposes of this
5 subsection, the term “bonus premium percent-
6 age” means, for the small group market or indi-
7 vidual market in a State for a year, such per-
8 centage as determined in accordance with the
9 following table based on the State’s premium
10 performance level (as defined in subparagraph
11 (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%
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%

12 (B) PREMIUM PERFORMANCE LEVEL.—For
13 purposes of this subsection, the term “premium
14 performance level” means, for a State, market,
15 and year, the percentage reduction in the aver-
16 age per capita premiums for health insurance
17 coverage for the State, market, and year, as

1 compared to the premium baseline for such
2 State, market, and year.

3 (4) MAXIMUM STATE PREMIUM PAYMENT
4 AMOUNT DEFINED.—For purposes of this sub-
5 section, the term “maximum State premium pay-
6 ment amount” means, for a State for the small
7 group market or the individual market for a year,
8 the product of—

9 (A) the proportion (as determined by the
10 Secretary), of the number of nonelderly individ-
11 uals lawfully residing in all the States who are
12 enrolled in health insurance coverage in the re-
13 spective market in the year, who are residents
14 of the State; and

15 (B) the amount available for obligation
16 from amounts appropriated under subsection
17 (d) for such market with respect to perform-
18 ance in such year.

19 (5) METHODOLOGY FOR CALCULATING AVER-
20 AGE PER CAPITA PREMIUMS.—

21 (A) ESTABLISHMENT.—The Secretary
22 shall establish, by rule and consistent with this
23 subsection, a methodology for computing the
24 average per capita premiums for health insur-
25 ance coverage for the small group market and

1 for the individual market in each State for each
2 year beginning with year 1.

3 (B) ADJUSTMENTS.—Under such method-
4 ology, the Secretary shall provide for the fol-
5 lowing adjustments (in a manner determined
6 appropriate by the Secretary):

7 (i) EXCLUSION OF ILLEGAL ALIENS.—
8 An adjustment so as not to take into ac-
9 count enrollees who are not lawfully
10 present in the United States and their pre-
11 mium costs.

12 (ii) TREATING STATE PREMIUM SUB-
13 SIDIES AS PREMIUM COSTS.—An adjust-
14 ment so as to increase per capita pre-
15 miums to remove the impact of premium
16 subsidies made directly by a State to re-
17 duce health insurance premiums.

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

1 (b) PROGRAMS THAT REDUCE THE NUMBER OF UN-
2 INSURED.—

3 (1) IN GENERAL.—If the Secretary determines
4 that a State has reduced the percentage of unin-
5 sured nonelderly residents in year 5, year 7, or year
6 9, below the uninsured baseline (as defined in para-
7 graph (2)) for the State for the year, the Secretary
8 shall pay the State an amount equal to the product
9 of—

10 (A) bonus uninsured percentage (as de-
11 fined in paragraph (3)) for the State and year;
12 and

13 (B) the maximum uninsured payment
14 amount (as defined in paragraph (4)) for the
15 State and year.

16 (2) UNINSURED BASELINE.—

17 (A) IN GENERAL.—For purposes of this
18 subsection, and subject to subparagraph (B),
19 the term “uninsured baseline” means, for a
20 State, the percentage of nonelderly residents in
21 the State who are uninsured in year 1.

22 (B) ADJUSTMENT.—The Secretary may, at
23 the written request of a State, adjust the unin-
24 sured baseline for States for a year to take into
25 account unanticipated and exceptional changes,

1 such as an unanticipated migration, of non-
 2 elderly individuals into, or out of, States in a
 3 manner that does not reflect substantially the
 4 proportion of uninsured nonelderly residents in
 5 the States involved in year 1. Any such adjust-
 6 ment shall only be done in a manner that does
 7 not result in the average of the uninsured base-
 8 lines for nonelderly residents for all States
 9 being changed.

10 (3) BONUS UNINSURED PERCENTAGE.—

11 (A) BONUS UNINSURED PERCENTAGE.—

12 For purposes of this subsection, the term
 13 “bonus uninsured percentage” means, for a
 14 State for a year, such percentage as determined
 15 in accordance with the following table, based on
 16 the uninsured performance level (as defined in
 17 subparagraph (B)) for such State and year:

The bonus un- insured per- centage for a State is—	For year 5 if the uninsured per- formance level of the State is—	For year 7 if the uninsured per- formance level of the State is—	For year 9 if the uninsured per- formance 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%

1 (B) UNINSURED PERFORMANCE LEVEL.—

2 For purposes of this subsection, the term “un-
3 insured performance level” means, for a State
4 for a year, the reduction (expressed as a per-
5 centage) in the percentage of uninsured non-
6 elderly residents in such State in the year as
7 compared to the uninsured baseline for such
8 State for such year.

9 (4) MAXIMUM STATE UNINSURED PAYMENT
10 AMOUNT DEFINED.—For purposes of this sub-
11 section, the term “maximum State uninsured pay-
12 ment amount” means, for a State for a year, the
13 product of—

14 (A) the proportion (as determined by the
15 Secretary), of the number of uninsured non-
16 elderly individuals lawfully residing in all the
17 States in the year, who are residents of the
18 State; and

19 (B) the amount available for obligation
20 under this subsection from amounts appro-
21 priated under subsection (d) with respect to
22 performance in such year.

23 (5) METHODOLOGY FOR COMPUTING THE PER-
24 CENTAGE OF UNINSURED NONELDERLY RESIDENTS
25 IN A STATE.—

1 (A) ESTABLISHMENT.—The Secretary
2 shall establish, by rule and consistent with this
3 subsection, a methodology for computing the
4 percentage of nonelderly residents in a State
5 who are uninsured in each year beginning with
6 year 1.

7 (B) RULES.—

8 (i) TREATMENT OF UNINSURED.—
9 Such methodology shall treat as uninsured
10 those residents who do not have health in-
11 surance coverage or other creditable cov-
12 erage (as defined in section 9801(c)(1) of
13 the Internal Revenue Code of 1986), ex-
14 cept that such methodology shall rely upon
15 data on the nonelderly and uninsured pop-
16 ulations within each State in such year
17 provided through population surveys con-
18 ducted by federal agencies.

19 (ii) LIMITATION TO NONELDERLY.—
20 Such methodology shall exclude individuals
21 who are 65 years of age or older.

22 (iii) EXCLUSION OF ILLEGAL
23 ALIENS.—Such methodology shall exclude
24 individuals not lawfully present in the
25 United States.

1 (6) CONDITIONS OF PAYMENT.—As a condition
2 of receiving a payment under paragraph (1), a State
3 must agree to submit aggregate, non-individually
4 identifiable data to the Secretary, in a form and
5 manner specified by the Secretary, for use by the
6 Secretary in determining the State’s uninsured base-
7 line and uninsured performance level for purposes of
8 this subsection.

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

10 (1) GROUP HEALTH PLAN.—The term “group
11 health plan” has the meaning given such term in
12 section 9832(a) of the Internal Revenue Code of
13 1986.

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

18 (3) INDIVIDUAL MARKET.—Except as the Sec-
19 retary may otherwise provide in the case of group
20 health plans that have fewer than 2 participants as
21 current employees on the first day of a plan year,
22 the term “individual market” means the market for
23 health insurance coverage offered to individuals
24 other than in connection with a group health plan.

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

3 (5) SMALL GROUP MARKET.—The term “small
4 group market” means the market for health insur-
5 ance coverage under which individuals obtain health
6 insurance coverage (directly or through any arrange-
7 ment) on behalf of themselves (and their depend-
8 ents) through a group health plan maintained by an
9 employer who employed on average at least 2 but
10 not more than 50 employees on business days during
11 a calendar year.

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

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

18 (d) APPROPRIATIONS; PAYMENTS.—

19 (1) PAYMENTS FOR REDUCTIONS IN COST OF
20 HEALTH INSURANCE COVERAGE.—

21 (A) SMALL GROUP MARKET.—

22 (i) IN GENERAL.—From any funds in
23 the Treasury not otherwise appropriated,
24 there is appropriated for payments under
25 subsection (a)(1)(A)—

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

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

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

7 (ii) AVAILABILITY OF APPROPRIATED
8 FUNDS.—Funds appropriated under clause
9 (i) shall remain available until expended.

10 (B) INDIVIDUAL MARKET.—

11 (i) IN GENERAL.—Subject to clause
12 (ii), from any funds in the Treasury not
13 otherwise appropriated, there is appro-
14 priated for payments under subsection
15 (a)(1)(B)—

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

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

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

22 (ii) AVAILABILITY OF APPROPRIATED
23 FUNDS.—Of the funds appropriated under
24 clause (i) that are not expended or obli-
25 gated by the end of the year following the

1 year for which the funds are appro-
2 priated—

3 (I) 75 percent shall remain avail-
4 able until expended for payments
5 under subsection (a)(1)(B); and

6 (II) 25 percent shall remain
7 available until expended for payments
8 under subsection (a)(1)(A).

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

11 (A) IN GENERAL.—From any funds in the
12 Treasury not otherwise appropriated, there is
13 appropriated for payments under subsection
14 (b)(1)—

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

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

19 (iii) \$2,000,000,000 with respect to
20 performance in year 9

21 (B) AVAILABILITY OF APPROPRIATED
22 FUNDS.—Funds appropriated under subpara-
23 graph (A) shall remain available until expended.

24 (3) PAYMENT TIMING.—Payments under this
25 section shall be made in a form and manner speci-

1 fied by the Secretary in the year after the perform-
2 ance year involved.

3 **SEC. 112. HEALTH PLAN FINDERS.**

4 (a) STATE PLAN FINDERS.—Not later than 12
5 months after the date of the enactment of this Act, each
6 State may contract with a private entity to develop and
7 operate a plan finder website (referred to in this section
8 as a “State plan finder”) which shall provide information
9 to individuals in such State on plans of health insurance
10 coverage that are available to individuals in such State (in
11 this section referred to as a “health insurance plan”) .
12 Such State may not operate a plan finder itself.

13 (b) MULTI-STATE PLAN FINDERS.—

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

18 (2) SHARING OF INFORMATION.—States shall
19 regulate the manner in which data is shared between
20 plan finders to ensure consistency and accuracy in
21 the information about health insurance plans con-
22 tained in such finders.

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

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

4 (2) The plan finder shall present complete in-
5 formation on the costs and benefits of health insur-
6 ance plans (including information on monthly pre-
7 mium, copayments, and deductibles) in a uniform
8 manner that—

9 (A) uses the standard definitions developed
10 under paragraph (3); and

11 (B) is designed to allow consumers to eas-
12 ily compare such plans.

13 (3) The plan finder shall be available on the
14 internet and accessible to all individuals in the State
15 or, in the case of a multi-State plan finder, in all
16 States covered by the multi-State plan finder.

17 (4) The plan finder shall allow consumers to
18 search and sort data on the health insurance plans
19 in the plan finder on criteria such as coverage of
20 specific benefits (such as coverage of disease man-
21 agement services or pediatric care services), as well
22 as data available on quality.

23 (5) The plan finder shall meet all relevant State
24 laws and regulations, including laws and regulations
25 related to the marketing of insurance products. In

1 the case of a multi-State plan finder, the finder shall
2 meet such laws and regulations for all of the States
3 involved.

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

8 (7) The plan finder and the employees of the
9 plan finder shall be appropriately licensed in the
10 State or States in which the plan finder operates, if
11 such licensure is required by such State or States.

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

19 (d) REQUIREMENTS FOR PLANS PARTICIPATING IN
20 A PLAN FINDER.—

21 (1) IN GENERAL.—Each State shall ensure that
22 health insurance plans participating in the State
23 plan finder or in a multi-State plan finder meet the
24 requirements of paragraph (2) (relating to adequacy

1 of insurance coverage, consumer protection, and fi-
2 nancial strength).

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

7 (A) The health insurance plan shall be ac-
8 tuarially sound.

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

11 (C) The health insurance plan shall meet
12 financial and solvency requirements.

13 (D) The health insurance plan shall dis-
14 close—

15 (i) all financial arrangements involv-
16 ing the sale and purchase of health insur-
17 ance, such as the payment of fees and
18 commissions; and

19 (ii) such arrangements may not be
20 abusive.

21 (E) The health insurance plan shall main-
22 tain electronic health records that comply with
23 the requirements of the American Recovery and
24 Reinvestment Act of 2009 (Public Law 111–5)
25 related to electronic health records.

1 (F) The health insurance plan shall make
2 available to plan enrollees via the finder, wheth-
3 er by information provided to the finder or by
4 a website link directing the enrollee from the
5 finder to the health insurance plan website,
6 data that includes the price and cost to the in-
7 dividual of services offered by a provider ac-
8 cording to the terms and conditions of the
9 health plan. Data described in this paragraph is
10 not made public by the finder, only made avail-
11 able to the individual once enrolled in the
12 health plan.

13 (e) PROHIBITIONS.—

14 (1) DIRECT ENROLLMENT.—The State plan
15 finder may not directly enroll individuals in health
16 insurance plans.

17 (2) CONFLICTS OF INTEREST.—

18 (A) COMPANIES.—A health insurance
19 issuer offering a health insurance plan through
20 a plan finder may not—

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

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

1 (B) INDIVIDUALS.—An individual em-
2 employed by a health insurance issuer offering a
3 health insurance plan through a plan finder
4 may not serve as a director or officer for—

5 (i) the private entity developing and
6 maintaining a plan finder under sub-
7 sections (a) and (b); or

8 (ii) the plan finder.

9 (f) CONSTRUCTION.—Nothing in this section shall be
10 construed to allow the Secretary authority to regulate ben-
11 efit packages or to prohibit health insurance brokers and
12 agents from—

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

14 (2) marketing or offering health insurance
15 products.

16 (g) PLAN FINDER DEFINED.—For purposes of this
17 section, the term “plan finder” means a State plan finder
18 under subsection (a) or a multi-State plan finder under
19 subsection (b).

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

23 **SEC. 113. ADMINISTRATIVE SIMPLIFICATION.**

24 (a) OPERATING RULES FOR HEALTH INFORMATION
25 TRANSACTIONS.—

1 (1) DEFINITION OF OPERATING RULES.—Sec-
2 tion 1171 of the Social Security Act (42 U.S.C.
3 1320d) is amended by adding at the end the fol-
4 lowing:

5 “(9) OPERATING RULES.—The term ‘operating
6 rules’ means the necessary business rules and guide-
7 lines for the electronic exchange of information that
8 are not defined by a standard or its implementation
9 specifications as adopted for purposes of this part.”.

10 (2) OPERATING RULES AND COMPLIANCE.—
11 Section 1173 of the Social Security Act (42 U.S.C.
12 1320d–2) is amended—

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

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

16 (B) by adding at the end the following new
17 subsections:

18 “(g) OPERATING RULES.—

19 “(1) IN GENERAL.—The Secretary shall adopt
20 a single set of operating rules for each transaction
21 described in subsection (a)(2) with the goal of cre-
22 ating as much uniformity in the implementation of
23 the electronic standards as possible. Such operating
24 rules shall be consensus-based and reflect the nec-
25 essary business rules affecting health plans and

1 health care providers and the manner in which they
2 operate pursuant to standards issued under Health
3 Insurance Portability and Accountability Act of
4 1996.

5 “(2) OPERATING RULES DEVELOPMENT.—In
6 adopting operating rules under this subsection, the
7 Secretary shall rely on recommendations for oper-
8 ating rules developed by a qualified nonprofit entity,
9 as selected by the Secretary, that meets the fol-
10 lowing requirements:

11 “(A) The entity focuses its mission on ad-
12 ministrative simplification.

13 “(B) The entity demonstrates an estab-
14 lished multi-stakeholder and consensus-based
15 process for development of operating rules, in-
16 cluding representation by or participation from
17 health plans, health care providers, vendors, rel-
18 evant Federal agencies, and other standard de-
19 velopment organizations.

20 “(C) The entity has established a public
21 set of guiding principles that ensure the oper-
22 ating rules and process are open and trans-
23 parent.

24 “(D) The entity coordinates its activities
25 with the HIT Policy Committee and the HIT

1 Standards Committee (as established under
2 title XXX of the Public Health Service Act)
3 and complements the efforts of the Office of the
4 National Healthcare Coordinator and its related
5 health information exchange goals.

6 “(E) The entity incorporates national
7 standards, including the transaction standards
8 issued under Health Insurance Portability and
9 Accountability Act of 1996.

10 “(F) The entity supports nondiscrimina-
11 tion and conflict of interest policies that dem-
12 onstrate a commitment to open, fair, and non-
13 discriminatory practices.

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

16 “(3) REVIEW AND RECOMMENDATIONS.—The
17 National Committee on Vital and Health Statistics
18 shall—

19 “(A) review the operating rules developed
20 by a nonprofit entity described under paragraph
21 (2);

22 “(B) determine whether such rules rep-
23 resent a consensus view of the health care in-
24 dustry and are consistent with and do not alter
25 current standards;

1 “(C) evaluate whether such rules are con-
2 sistent with electronic standards adopted for
3 health information technology; and

4 “(D) submit to the Secretary a rec-
5 ommendation as to whether the Secretary
6 should adopt such rules.

7 “(4) IMPLEMENTATION.—

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

17 “(B) ADOPTION REQUIREMENTS; EFFEC-
18 TIVE DATES.—

19 “(i) ELIGIBILITY FOR A HEALTH
20 PLAN AND HEALTH CLAIM STATUS.—The
21 set of operating rules for transactions for
22 eligibility for a health plan and health
23 claim status shall be adopted not later
24 than July 1, 2011, in a manner ensuring
25 that such rules are effective not later than

1 January 1, 2013, and may allow for the
2 use of a machine readable identification
3 card.

4 “(ii) ELECTRONIC FUNDS TRANSFERS
5 AND HEALTH CARE PAYMENT AND REMIT-
6 TANCE ADVICE.—The set of operating
7 rules for electronic funds transfers and
8 health care payment and remittance advice
9 shall be adopted not later than July 1,
10 2012, in a manner ensuring that such
11 rules are effective not later than January
12 1, 2014.

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

1 “(C) EXPEDITED RULEMAKING.—The Sec-
2 retary shall promulgate an interim final rule
3 applying any standard or operating rule rec-
4 ommended by the National Committee on Vital
5 and Health Statistics pursuant to paragraph
6 (3). The Secretary shall accept public comments
7 on any interim final rule published under this
8 subparagraph for 60 days after the date of such
9 publication.

10 “(h) COMPLIANCE.—

11 “(1) HEALTH PLAN CERTIFICATION.—

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

1 claim status, and health care payment and re-
2 mittance advice, respectively.

3 “(B) OTHER COMPLETED TRANS-
4 ACTIONS.—Not later than December 31, 2015,
5 a health plan shall file a statement with the
6 Secretary, in such form as the Secretary may
7 require, certifying that the data and informa-
8 tion systems for such plan are in compliance
9 with any applicable standards and operating
10 rules for the remainder of the completed trans-
11 actions described in subsection (a)(2), including
12 health claims or equivalent encounter informa-
13 tion, enrollment and disenrollment in a health
14 plan, health plan premium payments, and refer-
15 ral certification and authorization, respectively.
16 A health plan shall provide the same level of
17 documentation to certify compliance with such
18 transactions as is required to certify compliance
19 with the transactions specified in subparagraph
20 (A).

21 “(2) DOCUMENTATION OF COMPLIANCE.—A
22 health plan shall provide the Secretary, in such form
23 as the Secretary may require, with adequate docu-
24 mentation of compliance with the standards and op-
25 erating rules described under paragraph (1). A

1 health plan shall not be considered to have provided
2 adequate documentation and shall not be certified as
3 being in compliance with such standards, unless the
4 health plan—

5 “(A) demonstrates to the Secretary that
6 the plan conducts the electronic transactions
7 specified in paragraph (1) in a manner that
8 fully complies with the regulations of the Sec-
9 retary; and

10 “(B) provides documentation showing that
11 the plan has completed end-to-end testing for
12 such transactions with their partners, such as
13 hospitals and physicians.

14 “(3) SERVICE CONTRACTS.—A health plan shall
15 be required to comply with any applicable certifi-
16 cation and compliance requirements (and provide the
17 Secretary with adequate documentation of such com-
18 pliance) under this subsection for any entities that
19 provide services pursuant to a contract with such
20 health plan.

21 “(4) CERTIFICATION BY OUTSIDE ENTITY.—
22 The Secretary may contract with an independent,
23 outside entity to certify that a health plan has com-
24 plied with the requirements under this subsection,
25 provided that the certification standards employed

1 by such entities are in accordance with any stand-
2 ards or rules issued by the Secretary.

3 “(5) COMPLIANCE WITH REVISED STANDARDS
4 AND RULES.—A health plan (including entities de-
5 scribed under paragraph (3)) shall comply with the
6 certification and documentation requirements under
7 this subsection for any interim final rule promul-
8 gated by the Secretary under subsection (i) that
9 amends any standard or operating rule described
10 under paragraph (1) of this subsection. A health
11 plan shall comply with such requirements not later
12 than the effective date of the applicable interim final
13 rule.

14 “(6) AUDITS OF HEALTH PLANS.—The Sec-
15 retary shall conduct periodic audits to ensure that
16 health plans (including entities described under
17 paragraph (3)) are in compliance with any standards
18 and operating rules that are described under para-
19 graph (1).

20 “(i) REVIEW AND AMENDMENT OF STANDARDS AND
21 RULES.—

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

25 “(2) EVALUATIONS AND REPORTS.—

1 “(A) HEARINGS.—Not later than April 1,
2 2014, and not less than biennially thereafter,
3 the Secretary, acting through the review com-
4 mittee, shall conduct hearings to evaluate and
5 review the existing standards and operating
6 rules established under this section.

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

16 “(3) INTERIM FINAL RULEMAKING.—

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

25 “(B) PUBLIC COMMENT.—

1 “(i) PUBLIC COMMENT PERIOD.—The
2 Secretary shall accept public comments on
3 any interim final rule published under this
4 paragraph for 60 days after the date of
5 such publication.

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

13 “(4) REVIEW COMMITTEE.—

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

20 “(i) the National Committee on Vital
21 and Health Statistics; or

22 “(ii) any appropriate committee as de-
23 termined by the Secretary.

24 “(B) COORDINATION OF HIT STAND-
25 ARDS.—In developing recommendations under

1 this subsection, the review committee shall con-
2 sider the standards approved by the Office of
3 the National Coordinator for Health Informa-
4 tion Technology.

5 “(j) PENALTIES.—

6 “(1) PENALTY FEE.—

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

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

1 compliance with the requirements under sub-
2 section (h).

3 “(C) ADDITIONAL PENALTY FOR MIS-
4 REPRESENTATION.—A health plan that know-
5 ingly provides inaccurate or incomplete informa-
6 tion in a statement of certification or docu-
7 mentation of compliance under subsection (h)
8 shall be subject to a penalty fee that is double
9 the amount that would otherwise be imposed
10 under this subsection.

11 “(D) ANNUAL FEE INCREASE.—The
12 amount of the penalty fee imposed under this
13 subsection shall be increased on an annual basis
14 by the annual percentage increase in total na-
15 tional health care expenditures, as determined
16 by the Secretary.

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

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

22 “(ii) an amount equal to \$40 per cov-
23 ered life under the plan if such plan has
24 knowingly provided inaccurate or incom-

1 plete information (as described under sub-
2 paragraph (C)).

3 “(F) DETERMINATION OF COVERED INDI-
4 VIDUALS.—The Secretary shall determine the
5 number of covered lives under a health plan
6 based upon the most recent statements and fil-
7 ings that have been submitted by such plan to
8 the Securities and Exchange Commission.

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

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

21 “(4) COLLECTION OF PENALTY FEE.—

22 “(A) IN GENERAL.—The Secretary of the
23 Treasury, acting through the Financial Man-
24 agement Service, shall administer the collection
25 of penalty fees from health plans that have been

1 identified by the Secretary in the penalty fee re-
2 port provided under paragraph (3).

3 “(B) NOTICE.—Not later than August 1,
4 2014, and annually thereafter, the Secretary of
5 the Treasury shall provide notice to each health
6 plan that has been assessed a penalty fee by the
7 Secretary under this subsection. Such notice
8 shall include the amount of the penalty fee as-
9 sessed by the Secretary and the due date for
10 payment of such fee to the Secretary of the
11 Treasury (as described in subparagraph (C)).

12 “(C) PAYMENT DUE DATE.—Payment by a
13 health plan for a penalty fee assessed under
14 this subsection shall be made to the Secretary
15 of the Treasury not later than November 1,
16 2014, and annually thereafter.

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

22 “(i) increased by the interest accrued
23 on such amount, as determined pursuant
24 to the underpayment rate established

1 under section 6601 of the Internal Rev-
2 enue Code of 1986; and

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

7 “(E) ADMINISTRATIVE FEES.—Any fee
8 charged or allocated for collection activities con-
9 ducted by the Financial Management Service
10 will be passed on to a health plan on a pro-rata
11 basis and added to any penalty fee collected
12 from the plan.”.

13 (b) PROMULGATION OF RULES.—

14 (1) UNIQUE HEALTH PLAN IDENTIFIER.—The
15 Secretary shall promulgate a final rule to establish
16 a unique health plan identifier (as described in sec-
17 tion 1173(b) of the Social Security Act (42 U.S.C.
18 1320d-2(b))) based on the input of the National
19 Committee of Vital and Health Statistics. The Sec-
20 retary may do so on an interim final basis and such
21 rule shall be effective not later than October 1,
22 2012.

23 (2) ELECTRONIC FUNDS TRANSFER.—The Sec-
24 retary shall promulgate a final rule to establish a
25 standard for electronic funds transfers (as described

1 in section 1173(a)(2)(J) of the Social Security Act,
2 as added by subsection (a)(2)(A). The Secretary
3 may do so on an interim final basis and shall adopt
4 such standard not later than January 1, 2012, in a
5 manner ensuring that such standard is effective not
6 later than January 1, 2014.

7 (c) EXPANSION OF ELECTRONIC TRANSACTIONS IN
8 MEDICARE.—Section 1862(a) of the Social Security Act
9 (42 U.S.C. 1395y(a)) is amended—

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

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

14 (3) by inserting after paragraph (24) the fol-
15 lowing new paragraph:

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

21 (d) MEDICARE AND MEDICAID COMPLIANCE RE-
22 PORTS.—Not later than July 1, 2013, the Secretary of
23 Health and Human Services shall submit a report to the
24 Chairs and Ranking Members of the Committee on Ways
25 and Means and the Committee on Energy and Commerce

1 of the House of Representatives and the Chairs and Rank-
2 ing Members of the Committee on Health, Education,
3 Labor, and Pensions and the Committee on Finance of
4 the Senate on the extent to which the Medicare program
5 and providers that serve beneficiaries under that program,
6 and State Medicaid programs and providers that serve
7 beneficiaries under those programs, transact electronically
8 in accordance with transaction standards issued under the
9 Health Insurance Portability and Accountability Act of
10 1996, part C of title XI of the Social Security Act, and
11 regulations promulgated under such Acts.

12 **DIVISION B—IMPROVING**
13 **ACCESS TO HEALTH CARE**
14 **TITLE I—EXPANDING ACCESS**
15 **AND LOWERING COSTS FOR**
16 **SMALL BUSINESSES**

17 **SEC. 201. RULES GOVERNING ASSOCIATION HEALTH**
18 **PLANS.**

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

1 **“PART 8—RULES GOVERNING ASSOCIATION**

2 **HEALTH PLANS**

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

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

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

10 “(1) is organized and maintained in good faith,
11 with a constitution and bylaws specifically stating its
12 purpose and providing for periodic meetings on at
13 least an annual basis, as a bona fide trade associa-
14 tion, a bona fide industry association (including a
15 rural electric cooperative association or a rural tele-
16 phone cooperative association), a bona fide profes-
17 sional association, or a bona fide chamber of com-
18 merce (or similar bona fide business association, in-
19 cluding a corporation or similar organization that
20 operates on a cooperative basis (within the meaning
21 of section 1381 of the Internal Revenue Code of
22 1986)), for substantial purposes other than that of
23 obtaining or providing medical care;

24 “(2) is established as a permanent entity which
25 receives the active support of its members and re-
26 quires for membership payment on a periodic basis

1 of dues or payments necessary to maintain eligibility
2 for membership in the sponsor; and

3 “(3) does not condition membership, such dues
4 or payments, or coverage under the plan on the
5 basis of health status-related factors with respect to
6 the employees of its members (or affiliated mem-
7 bers), or the dependents of such employees, and does
8 not condition such dues or payments on the basis of
9 group health plan participation.

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

14 **“SEC. 802. CERTIFICATION OF ASSOCIATION HEALTH**
15 **PLANS.**

16 “(a) IN GENERAL.—The applicable authority shall
17 prescribe by regulation a procedure under which, subject
18 to subsection (b), the applicable authority shall certify as-
19 sociation health plans which apply for certification as
20 meeting the requirements of this part.

21 “(b) STANDARDS.—Under the procedure prescribed
22 pursuant to subsection (a), in the case of an association
23 health plan that provides at least one benefit option which
24 does not consist of health insurance coverage, the applica-
25 ble authority shall certify such plan as meeting the re-

1 requirements of this part only if the applicable authority is
2 satisfied that the applicable requirements of this part are
3 met (or, upon the date on which the plan is to commence
4 operations, will be met) with respect to the plan.

5 “(c) REQUIREMENTS APPLICABLE TO CERTIFIED
6 PLANS.—An association health plan with respect to which
7 certification under this part is in effect shall meet the ap-
8 plicable requirements of this part, effective on the date
9 of certification (or, if later, on the date on which the plan
10 is to commence operations).

11 “(d) REQUIREMENTS FOR CONTINUED CERTIFI-
12 CATION.—The applicable authority may provide by regula-
13 tion for continued certification of association health plans
14 under this part.

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

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

6 “(1) a plan which offered such coverage on the
7 date of the enactment of the Small Business Health
8 Fairness Act of 2009,

9 “(2) a plan under which the sponsor does not
10 restrict membership to one or more trades and busi-
11 nesses or industries and whose eligible participating
12 employers represent a broad cross-section of trades
13 and businesses or industries, or

14 “(3) a plan whose eligible participating employ-
15 ers represent one or more trades or businesses, or
16 one or more industries, consisting of any of the fol-
17 lowing: agriculture; equipment and automobile deal-
18 erships; barbering and cosmetology; certified public
19 accounting practices; child care; construction; dance,
20 theatrical and orchestra productions; disinfecting
21 and pest control; financial services; fishing; food
22 service establishments; hospitals; labor organiza-
23 tions; logging; manufacturing (metals); mining; med-
24 ical and dental practices; medical laboratories; pro-
25 fessional consulting services; sanitary services; trans-

1 portation (local and freight); warehousing; whole-
2 saling/distributing; or any other trade or business or
3 industry which has been indicated as having average
4 or above-average risk or health claims experience by
5 reason of State rate filings, denials of coverage, pro-
6 posed premium rate levels, or other means dem-
7 onstrated by such plan in accordance with regula-
8 tions.

9 **“SEC. 803. REQUIREMENTS RELATING TO SPONSORS AND**
10 **BOARDS OF TRUSTEES.**

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

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

20 “(1) FISCAL CONTROL.—The plan is operated,
21 pursuant to a trust agreement, by a board of trust-
22 ees which has complete fiscal control over the plan
23 and which is responsible for all operations of the
24 plan.

1 “(2) RULES OF OPERATION AND FINANCIAL
2 CONTROLS.—The board of trustees has in effect
3 rules of operation and financial controls, based on a
4 3-year plan of operation, adequate to carry out the
5 terms of the plan and to meet all requirements of
6 this title applicable to the plan.

7 “(3) RULES GOVERNING RELATIONSHIP TO
8 PARTICIPATING EMPLOYERS AND TO CONTRAC-
9 TORS.—

10 “(A) BOARD MEMBERSHIP.—

11 “(i) IN GENERAL.—Except as pro-
12 vided in clauses (ii) and (iii), the members
13 of the board of trustees are individuals se-
14 lected from individuals who are the owners,
15 officers, directors, or employees of the par-
16 ticipating employers or who are partners in
17 the participating employers and actively
18 participate in the business.

19 “(ii) LIMITATION.—

20 “(I) GENERAL RULE.—Except as
21 provided in subclauses (II) and (III),
22 no such member is an owner, officer,
23 director, or employee of, or partner in,
24 a contract administrator or other
25 service provider to the plan.

1 “(II) LIMITED EXCEPTION FOR
2 PROVIDERS OF SERVICES SOLELY ON
3 BEHALF OF THE SPONSOR.—Officers
4 or employees of a sponsor which is a
5 service provider (other than a contract
6 administrator) to the plan may be
7 members of the board if they con-
8 stitute not more than 25 percent of
9 the membership of the board and they
10 do not provide services to the plan
11 other than on behalf of the sponsor.

12 “(III) TREATMENT OF PRO-
13 VIDERS OF MEDICAL CARE.—In the
14 case of a sponsor which is an associa-
15 tion whose membership consists pri-
16 marily of providers of medical care,
17 subclause (I) shall not apply in the
18 case of any service provider described
19 in subclause (I) who is a provider of
20 medical care under the plan.

21 “(iii) CERTAIN PLANS EXCLUDED.—
22 Clause (i) shall not apply to an association
23 health plan which is in existence on the
24 date of the enactment of the Small Busi-
25 ness Health Fairness Act of 2009.

1 “(B) SOLE AUTHORITY.—The board has
2 sole authority under the plan to approve appli-
3 cations for participation in the plan and to con-
4 tract with a service provider to administer the
5 day-to-day affairs of the plan.

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

10 “(1) the requirements of subsection (a) and sec-
11 tion 801(a) shall be deemed met if such require-
12 ments would otherwise be met if the franchiser were
13 deemed to be the sponsor referred to in section
14 801(b), such network were deemed to be an associa-
15 tion described in section 801(b), and each franchisee
16 were deemed to be a member (of the association and
17 the sponsor) referred to in section 801(b); and

18 “(2) the requirements of section 804(a)(1) shall
19 be deemed met.

20 The Secretary may by regulation define for purposes of
21 this subsection the terms ‘franchiser’, ‘franchise network’,
22 and ‘franchisee’.

1 **“SEC. 804. PARTICIPATION AND COVERAGE REQUIRE-**
2 **MENTS.**

3 “(a) COVERED EMPLOYERS AND INDIVIDUALS.—The
4 requirements of this subsection are met with respect to
5 an association health plan if, under the terms of the
6 plan—

7 “(1) each participating employer must be—

8 “(A) a member of the sponsor,

9 “(B) the sponsor, or

10 “(C) an affiliated member of the sponsor
11 with respect to which the requirements of sub-
12 section (b) are met,

13 except that, in the case of a sponsor which is a pro-
14 fessional association or other individual-based asso-
15 ciation, if at least one of the officers, directors, or
16 employees of an employer, or at least one of the in-
17 dividuals who are partners in an employer and who
18 actively participates in the business, is a member or
19 such an affiliated member of the sponsor, partici-
20 pating employers may also include such employer;
21 and

22 “(2) all individuals commencing coverage under
23 the plan after certification under this part must
24 be—

25 “(A) active or retired owners (including
26 self-employed individuals), officers, directors, or

1 employees of, or partners in, participating em-
2 ployers; or

3 “(B) the beneficiaries of individuals de-
4 scribed in subparagraph (A).

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

11 “(1) the affiliated member was an affiliated
12 member on the date of certification under this part;
13 or

14 “(2) during the 12-month period preceding the
15 date of the offering of such coverage, the affiliated
16 member has not maintained or contributed to a
17 group health plan with respect to any of its employ-
18 ees who would otherwise be eligible to participate in
19 such association health plan.

20 “(c) INDIVIDUAL MARKET UNAFFECTED.—The re-
21 quirements of this subsection are met with respect to an
22 association health plan if, under the terms of the plan,
23 no participating employer may provide health insurance
24 coverage in the individual market for any employee not
25 covered under the plan which is similar to the coverage

1 contemporaneously provided to employees of the employer
2 under the plan, if such exclusion of the employee from cov-
3 erage under the plan is based on a health status-related
4 factor with respect to the employee and such employee
5 would, but for such exclusion on such basis, be eligible
6 for coverage under the plan.

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

11 “(1) under the terms of the plan, all employers
12 meeting the preceding requirements of this section
13 are eligible to qualify as participating employers for
14 all geographically available coverage options, unless,
15 in the case of any such employer, participation or
16 contribution requirements of the type referred to in
17 section 2711 of the Public Health Service Act are
18 not met;

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

22 “(3) the applicable requirements of sections
23 701, 702, and 703 are met with respect to the plan.

1 **“SEC. 805. OTHER REQUIREMENTS RELATING TO PLAN**
2 **DOCUMENTS, CONTRIBUTION RATES, AND**
3 **BENEFIT OPTIONS.**

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

7 “(1) CONTENTS OF GOVERNING INSTRU-
8 MENTS.—The instruments governing the plan in-
9 clude a written instrument, meeting the require-
10 ments of an instrument required under section
11 402(a)(1), which—

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

17 “(B) provides that the sponsor of the plan
18 is to serve as plan sponsor (referred to in sec-
19 tion 3(16)(B)); and

20 “(C) incorporates the requirements of sec-
21 tion 806.

22 “(2) CONTRIBUTION RATES MUST BE NON-
23 DISCRIMINATORY.—

24 “(A) The contribution rates for any par-
25 ticipating small employer do not vary on the
26 basis of any health status-related factor in rela-

1 tion to employees of such employer or their
2 beneficiaries and do not vary on the basis of the
3 type of business or industry in which such em-
4 ployer is engaged.

5 “(B) Nothing in this title or any other pro-
6 vision of law shall be construed to preclude an
7 association health plan, or a health insurance
8 issuer offering health insurance coverage in
9 connection with an association health plan,
10 from—

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

13 “(ii) varying contribution rates for
14 small employers in a State to the extent
15 that such rates could vary using the same
16 methodology employed in such State for
17 regulating premium rates in the small
18 group market with respect to health insur-
19 ance coverage offered in connection with
20 bona fide associations (within the meaning
21 of section 2791(d)(3) of the Public Health
22 Service Act),

23 subject to the requirements of section 702(b)
24 relating to contribution rates.

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

7 “(4) MARKETING REQUIREMENTS.—

8 “(A) IN GENERAL.—If a benefit option
9 which consists of health insurance coverage is
10 offered under the plan, State-licensed insurance
11 agents shall be used to distribute to small em-
12 ployers coverage which does not consist of
13 health insurance coverage in a manner com-
14 parable to the manner in which such agents are
15 used to distribute health insurance coverage.

16 “(B) STATE-LICENSED INSURANCE
17 AGENTS.—For purposes of subparagraph (A),
18 the term ‘State-licensed insurance agents’
19 means one or more agents who are licensed in
20 a State and are subject to the laws of such
21 State relating to licensure, qualification, test-
22 ing, examination, and continuing education of
23 persons authorized to offer, sell, or solicit
24 health insurance coverage in such State.

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

6 “(b) ABILITY OF ASSOCIATION HEALTH PLANS TO
7 DESIGN BENEFIT OPTIONS.—Subject to section 514(d),
8 nothing in this part or any provision of State law (as de-
9 fined in section 514(c)(1)) shall be construed to preclude
10 an association health plan, or a health insurance issuer
11 offering health insurance coverage in connection with an
12 association health plan, from exercising its sole discretion
13 in selecting the specific items and services consisting of
14 medical care to be included as benefits under such plan
15 or coverage, except (subject to section 514) in the case
16 of (1) any law to the extent that it is not preempted under
17 section 731(a)(1) with respect to matters governed by sec-
18 tion 711, 712, or 713, or (2) any law of the State with
19 which filing and approval of a policy type offered by the
20 plan was initially obtained to the extent that such law pro-
21 hibits an exclusion of a specific disease from such cov-
22 erage.

1 **“SEC. 806. MAINTENANCE OF RESERVES AND PROVISIONS**
2 **FOR SOLVENCY FOR PLANS PROVIDING**
3 **HEALTH BENEFITS IN ADDITION TO HEALTH**
4 **INSURANCE COVERAGE.**

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

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

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

12 “(A) establishes and maintains reserves
13 with respect to such additional benefit options,
14 in amounts recommended by the qualified actu-
15 ary, consisting of—

16 “(i) a reserve sufficient for unearned
17 contributions;

18 “(ii) a reserve sufficient for benefit li-
19 abilities which have been incurred, which
20 have not been satisfied, and for which risk
21 of loss has not yet been transferred, and
22 for expected administrative costs with re-
23 spect to such benefit liabilities;

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

1 “(iv) a reserve sufficient for a margin
2 of error and other fluctuations, taking into
3 account the specific circumstances of the
4 plan; and

5 “(B) establishes and maintains aggregate
6 and specific excess/stop loss insurance and sol-
7 vency indemnification, with respect to such ad-
8 ditional benefit options for which risk of loss
9 has not yet been transferred, as follows:

10 “(i) The plan shall secure aggregate
11 excess/stop loss insurance for the plan with
12 an attachment point which is not greater
13 than 125 percent of expected gross annual
14 claims. The applicable authority may by
15 regulation provide for upward adjustments
16 in the amount of such percentage in speci-
17 fied circumstances in which the plan spe-
18 cifically provides for and maintains re-
19 serves in excess of the amounts required
20 under subparagraph (A).

21 “(ii) The plan shall secure specific ex-
22 cess/stop loss insurance for the plan with
23 an attachment point which is at least equal
24 to an amount recommended by the plan’s
25 qualified actuary. The applicable authority

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

7 “(iii) The plan shall secure indem-
8 nification insurance for any claims which
9 the plan is unable to satisfy by reason of
10 a plan termination.

11 Any person issuing to a plan insurance described in clause
12 (i), (ii), or (iii) of subparagraph (B) shall notify the Sec-
13 retary of any failure of premium payment meriting can-
14 cellation of the policy prior to undertaking such a cancella-
15 tion. Any regulations prescribed by the applicable author-
16 ity pursuant to clause (i) or (ii) of subparagraph (B) may
17 allow for such adjustments in the required levels of excess/
18 stop loss insurance as the qualified actuary may rec-
19 ommend, taking into account the specific circumstances
20 of the plan.

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

1 “(1) \$500,000, or

2 “(2) such greater amount (but not greater than
3 \$2,000,000) as may be set forth in regulations pre-
4 scribed by the applicable authority, considering the
5 level of aggregate and specific excess/stop loss insur-
6 ance provided with respect to such plan and other
7 factors related to solvency risk, such as the plan’s
8 projected levels of participation or claims, the nature
9 of the plan’s liabilities, and the types of assets avail-
10 able to assure that such liabilities are met.

11 “(c) **ADDITIONAL REQUIREMENTS.**—In the case of
12 any association health plan described in subsection (a)(2),
13 the applicable authority may provide such additional re-
14 quirements relating to reserves, excess/stop loss insurance,
15 and indemnification insurance as the applicable authority
16 considers appropriate. Such requirements may be provided
17 by regulation with respect to any such plan or any class
18 of such plans.

19 “(d) **ADJUSTMENTS FOR EXCESS/STOP LOSS INSUR-**
20 **ANCE.**—The applicable authority may provide for adjust-
21 ments to the levels of reserves otherwise required under
22 subsections (a) and (b) with respect to any plan or class
23 of plans to take into account excess/stop loss insurance
24 provided with respect to such plan or plans.

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

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

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

24 “(A) IN GENERAL.—In the case of an as-
25 sociation health plan described in subsection

1 (a)(2), the requirements of this subsection are
2 met if the plan makes payments into the Asso-
3 ciation Health Plan Fund under this subpara-
4 graph when they are due. Such payments shall
5 consist of annual payments in the amount of
6 \$5,000, and, in addition to such annual pay-
7 ments, such supplemental payments as the Sec-
8 retary may determine to be necessary under
9 paragraph (2). Payments under this paragraph
10 are payable to the Fund at the time determined
11 by the Secretary. Initial payments are due in
12 advance of certification under this part. Pay-
13 ments shall continue to accrue until a plan's as-
14 sets are distributed pursuant to a termination
15 procedure.

16 “(B) PENALTIES FOR FAILURE TO MAKE
17 PAYMENTS.—If any payment is not made by a
18 plan when it is due, a late payment charge of
19 not more than 100 percent of the payment
20 which was not timely paid shall be payable by
21 the plan to the Fund.

22 “(C) CONTINUED DUTY OF THE SEC-
23 RETARY.—The Secretary shall not cease to
24 carry out the provisions of paragraph (2) on ac-

1 count of the failure of a plan to pay any pay-
2 ment when due.

3 “(2) PAYMENTS BY SECRETARY TO CONTINUE
4 EXCESS/STOP LOSS INSURANCE COVERAGE AND IN-
5 DEMNIFICATION INSURANCE COVERAGE FOR CER-
6 TAIN PLANS.—In any case in which the applicable
7 authority determines that there is, or that there is
8 reason to believe that there will be: (A) a failure to
9 take necessary corrective actions under section
10 809(a) with respect to an association health plan de-
11 scribed in subsection (a)(2); or (B) a termination of
12 such a plan under section 809(b) or 810(b)(8) (and,
13 if the applicable authority is not the Secretary, cer-
14 tifies such determination to the Secretary), the Sec-
15 retary shall determine the amounts necessary to
16 make payments to an insurer (designated by the
17 Secretary) to maintain in force excess/stop loss in-
18 surance coverage or indemnification insurance cov-
19 erage for such plan, if the Secretary determines that
20 there is a reasonable expectation that, without such
21 payments, claims would not be satisfied by reason of
22 termination of such coverage. The Secretary shall, to
23 the extent provided in advance in appropriation
24 Acts, pay such amounts so determined to the insurer
25 designated by the Secretary.

1 “(3) ASSOCIATION HEALTH PLAN FUND.—

2 “(A) IN GENERAL.—There is established
3 on the books of the Treasury a fund to be
4 known as the ‘Association Health Plan Fund’.
5 The Fund shall be available for making pay-
6 ments pursuant to paragraph (2). The Fund
7 shall be credited with payments received pursu-
8 ant to paragraph (1)(A), penalties received pur-
9 suant to paragraph (1)(B); and earnings on in-
10 vestments of amounts of the Fund under sub-
11 paragraph (B).

12 “(B) INVESTMENT.—Whenever the Sec-
13 retary determines that the moneys of the fund
14 are in excess of current needs, the Secretary
15 may request the investment of such amounts as
16 the Secretary determines advisable by the Sec-
17 retary of the Treasury in obligations issued or
18 guaranteed by the United States.

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

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

1 “(A) under which an insurer (meeting such
2 minimum standards as the applicable authority
3 may prescribe by regulation) provides for pay-
4 ment to the plan with respect to aggregate
5 claims under the plan in excess of an amount
6 or amounts specified in such contract;

7 “(B) which is guaranteed renewable; and

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

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

15 “(A) under which an insurer (meeting such
16 minimum standards as the applicable authority
17 may prescribe by regulation) provides for pay-
18 ment to the plan with respect to claims under
19 the plan in connection with a covered individual
20 in excess of an amount or amounts specified in
21 such contract in connection with such covered
22 individual;

23 “(B) which is guaranteed renewable; and

1 “(C) which allows for payment of pre-
2 miums by any third party on behalf of the in-
3 sured plan.

4 “(h) INDEMNIFICATION INSURANCE.—For purposes
5 of this section, the term ‘indemnification insurance’
6 means, in connection with an association health plan, a
7 contract—

8 “(1) under which an insurer (meeting such min-
9 imum standards as the applicable authority may pre-
10 scribe by regulation) provides for payment to the
11 plan with respect to claims under the plan which the
12 plan is unable to satisfy by reason of a termination
13 pursuant to section 809(b) (relating to mandatory
14 termination);

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

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

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

1 “(j) SOLVENCY STANDARDS WORKING GROUP.—

2 “(1) IN GENERAL.—Within 90 days after the
3 date of the enactment of the Small Business Health
4 Fairness Act of 2009, the applicable authority shall
5 establish a Solvency Standards Working Group. In
6 prescribing the initial regulations under this section,
7 the applicable authority shall take into account the
8 recommendations of such Working Group.

9 “(2) MEMBERSHIP.—The Working Group shall
10 consist of not more than 15 members appointed by
11 the applicable authority. The applicable authority
12 shall include among persons invited to membership
13 on the Working Group at least one of each of the
14 following:

15 “(A) a representative of the National Asso-
16 ciation of Insurance Commissioners;

17 “(B) a representative of the American
18 Academy of Actuaries;

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

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

23 “(E) a representative of associations of the
24 type referred to in section 801(b)(1), or their
25 interests; and

1 “(F) a representative of multiemployer
2 plans that are group health plans, or their in-
3 terests.

4 **“SEC. 807. REQUIREMENTS FOR APPLICATION AND RE-**
5 **LATED REQUIREMENTS.**

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

15 “(b) INFORMATION TO BE INCLUDED IN APPLICA-
16 TION FOR CERTIFICATION.—An application for certifi-
17 cation under this part meets the requirements of this sec-
18 tion only if it includes, in a manner and form which shall
19 be prescribed by the applicable authority by regulation, at
20 least the following information:

21 “(1) IDENTIFYING INFORMATION.—The names
22 and addresses of—

23 “(A) the sponsor; and

24 “(B) the members of the board of trustees
25 of the plan.

1 “(2) STATES IN WHICH PLAN INTENDS TO DO
2 BUSINESS.—The States in which participants and
3 beneficiaries under the plan are to be located and
4 the number of them expected to be located in each
5 such State.

6 “(3) BONDING REQUIREMENTS.—Evidence pro-
7 vided by the board of trustees that the bonding re-
8 quirements of section 412 will be met as of the date
9 of the application or (if later) commencement of op-
10 erations.

11 “(4) PLAN DOCUMENTS.—A copy of the docu-
12 ments governing the plan (including any bylaws and
13 trust agreements), the summary plan description,
14 and other material describing the benefits that will
15 be provided to participants and beneficiaries under
16 the plan.

17 “(5) AGREEMENTS WITH SERVICE PRO-
18 VIDERS.—A copy of any agreements between the
19 plan and contract administrators and other service
20 providers.

21 “(6) FUNDING REPORT.—In the case of asso-
22 ciation health plans providing benefits options in ad-
23 dition to health insurance coverage, a report setting
24 forth information with respect to such additional
25 benefit options determined as of a date within the

1 120-day period ending with the date of the applica-
2 tion, including the following:

3 “(A) RESERVES.—A statement, certified
4 by the board of trustees of the plan, and a
5 statement of actuarial opinion, signed by a
6 qualified actuary, that all applicable require-
7 ments of section 806 are or will be met in ac-
8 cordance with regulations which the applicable
9 authority shall prescribe.

10 “(B) ADEQUACY OF CONTRIBUTION
11 RATES.—A statement of actuarial opinion,
12 signed by a qualified actuary, which sets forth
13 a description of the extent to which contribution
14 rates are adequate to provide for the payment
15 of all obligations and the maintenance of re-
16 quired reserves under the plan for the 12-
17 month period beginning with such date within
18 such 120-day period, taking into account the
19 expected coverage and experience of the plan. If
20 the contribution rates are not fully adequate,
21 the statement of actuarial opinion shall indicate
22 the extent to which the rates are inadequate
23 and the changes needed to ensure adequacy.

24 “(C) CURRENT AND PROJECTED VALUE OF
25 ASSETS AND LIABILITIES.—A statement of ac-

1 tuarial opinion signed by a qualified actuary,
2 which sets forth the current value of the assets
3 and liabilities accumulated under the plan and
4 a projection of the assets, liabilities, income,
5 and expenses of the plan for the 12-month pe-
6 riod referred to in subparagraph (B). The in-
7 come statement shall identify separately the
8 plan’s administrative expenses and claims.

9 “(D) COSTS OF COVERAGE TO BE
10 CHARGED AND OTHER EXPENSES.—A state-
11 ment of the costs of coverage to be charged, in-
12 cluding an itemization of amounts for adminis-
13 tration, reserves, and other expenses associated
14 with the operation of the plan.

15 “(E) OTHER INFORMATION.—Any other
16 information as may be determined by the appli-
17 cable authority, by regulation, as necessary to
18 carry out the purposes of this part.

19 “(c) FILING NOTICE OF CERTIFICATION WITH
20 STATES.—A certification granted under this part to an
21 association health plan shall not be effective unless written
22 notice of such certification is filed with the applicable
23 State authority of each State in which at least 25 percent
24 of the participants and beneficiaries under the plan are
25 located. For purposes of this subsection, an individual

1 shall be considered to be located in the State in which a
2 known address of such individual is located or in which
3 such individual is employed.

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

14 “(e) REPORTING REQUIREMENTS FOR CERTAIN AS-
15 SOCIATION HEALTH PLANS.—An association health plan
16 certified under this part which provides benefit options in
17 addition to health insurance coverage for such plan year
18 shall meet the requirements of section 103 by filing an
19 annual report under such section which shall include infor-
20 mation described in subsection (b)(6) with respect to the
21 plan year and, notwithstanding section 104(a)(1)(A), shall
22 be filed with the applicable authority not later than 90
23 days after the close of the plan year (or on such later date
24 as may be prescribed by the applicable authority). The ap-

1 plicable authority may require by regulation such interim
2 reports as it considers appropriate.

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

16 “(1) are in the aggregate reasonably related to
17 the experience of the plan and to reasonable expecta-
18 tions; and

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

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

1 **“SEC. 808. NOTICE REQUIREMENTS FOR VOLUNTARY TER-**
2 **MINATION.**

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

9 “(1) provides to the participants and bene-
10 ficiaries a written notice of intent to terminate stat-
11 ing that such termination is intended and the pro-
12 posed termination date;

13 “(2) develops a plan for winding up the affairs
14 of the plan in connection with such termination in
15 a manner which will result in timely payment of all
16 benefits for which the plan is obligated; and

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

19 Actions required under this section shall be taken in such
20 form and manner as may be prescribed by the applicable
21 authority by regulation.

22 **“SEC. 809. CORRECTIVE ACTIONS AND MANDATORY TERMI-**
23 **NATION.**

24 “(a) ACTIONS TO AVOID DEPLETION OF RE-
25 SERVES.—An association health plan which is certified
26 under this part and which provides benefits other than

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

1 “(b) MANDATORY TERMINATION.—In any case in
2 which—

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

13 “(2) the applicable authority determines that
14 there is a reasonable expectation that the plan will
15 continue to fail to meet the requirements of section
16 806,

17 the board of trustees of the plan shall, at the direction
18 of the applicable authority, terminate the plan and, in the
19 course of the termination, take such actions as the appli-
20 cable authority may require, including satisfying any
21 claims referred to in section 806(a)(2)(B)(iii) and recov-
22 ering for the plan any liability under subsection
23 (a)(2)(B)(iii) or (e) of section 806, as necessary to ensure
24 that the affairs of the plan will be, to the maximum extent

1 possible, wound up in a manner which will result in timely
2 provision of all benefits for which the plan is obligated.

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

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

1 tence of this subsection are remedied or the plan is termi-
2 nated.

3 “(b) POWERS AS TRUSTEE.—The Secretary, upon
4 appointment as trustee under subsection (a), shall have
5 the power—

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

9 “(2) to require the transfer of all (or any part)
10 of the assets and records of the plan to the Sec-
11 retary as trustee;

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

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

22 “(5) to collect for the plan any amounts due the
23 plan and to recover reasonable expenses of the trust-
24 eeship;

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

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

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

13 “(9) to provide for the enrollment of plan par-
14 ticipants and beneficiaries under appropriate cov-
15 erage options; and

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

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

24 “(1) the sponsor and plan administrator;

25 “(2) each participant;

1 “(3) each participating employer; and

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

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

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

19 “(f) JURISDICTION OF COURT.—

20 “(1) IN GENERAL.—Upon the filing of an appli-
21 cation for the appointment as trustee or the issuance
22 of a decree under this section, the court to which the
23 application is made shall have exclusive jurisdiction
24 of the plan involved and its property wherever lo-
25 cated with the powers, to the extent consistent with

1 the purposes of this section, of a court of the United
2 States having jurisdiction over cases under chapter
3 11 of title 11, United States Code. Pending an adju-
4 dication under this section such court shall stay, and
5 upon appointment by it of the Secretary as trustee,
6 such court shall continue the stay of, any pending
7 mortgage foreclosure, equity receivership, or other
8 proceeding to reorganize, conserve, or liquidate the
9 plan, the sponsor, or property of such plan or spon-
10 sor, and any other suit against any receiver, conser-
11 vator, or trustee of the plan, the sponsor, or prop-
12 erty of the plan or sponsor. Pending such adjudica-
13 tion and upon the appointment by it of the Sec-
14 retary as trustee, the court may stay any proceeding
15 to enforce a lien against property of the plan or the
16 sponsor or any other suit against the plan or the
17 sponsor.

18 “(2) VENUE.—An action under this section
19 may be brought in the judicial district where the
20 sponsor or the plan administrator resides or does
21 business or where any asset of the plan is situated.
22 A district court in which such action is brought may
23 issue process with respect to such action in any
24 other judicial district.

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

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

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

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

18 “(1) such tax is computed by applying a rate to
19 the amount of premiums or contributions, with re-
20 spect to individuals covered under the plan who are
21 residents of such State, which are received by the
22 plan from participating employers located in such
23 State or from such individuals;

24 “(2) the rate of such tax does not exceed the
25 rate of any tax imposed by such State on premiums

1 or contributions received by insurers or health main-
2 tenance organizations for health insurance coverage
3 offered in such State in connection with a group
4 health plan;

5 “(3) such tax is otherwise nondiscriminatory;
6 and

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

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

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

21 “(1) GROUP HEALTH PLAN.—The term ‘group
22 health plan’ has the meaning provided in section
23 733(a)(1) (after applying subsection (b) of this sec-
24 tion).

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

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

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

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

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

19 “(7) INDIVIDUAL MARKET.—

20 “(A) IN GENERAL.—The term ‘individual
21 market’ means the market for health insurance
22 coverage offered to individuals other than in
23 connection with a group health plan.

24 “(B) TREATMENT OF VERY SMALL
25 GROUPS.—

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

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

17 “(8) PARTICIPATING EMPLOYER.—The term
18 ‘participating employer’ means, in connection with
19 an association health plan, any employer, if any indi-
20 vidual who is an employee of such employer, a part-
21 ner in such employer, or a self-employed individual
22 who is such employer (or any dependent, as defined
23 under the terms of the plan, of such individual) is
24 or was covered under such plan in connection with
25 the status of such individual as such an employee,

1 partner, or self-employed individual in relation to the
2 plan.

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

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

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

15 “(A) a person who is otherwise eligible to
16 be a member of the sponsor but who elects an
17 affiliated status with the sponsor,

18 “(B) in the case of a sponsor with mem-
19 bers which consist of associations, a person who
20 is a member of any such association and elects
21 an affiliated status with the sponsor, or

22 “(C) in the case of an association health
23 plan in existence on the date of the enactment
24 of the Small Business Health Fairness Act of

1 2009, a person eligible to be a member of the
2 sponsor or one of its member associations.

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

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

14 “(b) RULES OF CONSTRUCTION.—

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

22 “(A) in the case of a partnership, the term
23 ‘employer’ (as defined in section 3(5)) includes
24 the partnership in relation to the partners, and
25 the term ‘employee’ (as defined in section 3(6))

1 includes any partner in relation to the partner-
2 ship; and

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

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

21 (b) CONFORMING AMENDMENTS TO PREEMPTION
22 RULES.—

23 (1) Section 514(b)(6) of such Act (29 U.S.C.
24 1144(b)(6)) is amended by adding at the end the
25 following new subparagraph:

1 “(E) The preceding subparagraphs of this paragraph
2 do not apply with respect to any State law in the case
3 of an association health plan which is certified under part
4 8.”.

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

7 (A) in subsection (b)(4), by striking “Sub-
8 section (a)” and inserting “Subsections (a) and
9 (d)”;

10 (B) in subsection (b)(5), by striking “sub-
11 section (a)” in subparagraph (A) and inserting
12 “subsection (a) of this section and subsections
13 (a)(2)(B) and (b) of section 805”, and by strik-
14 ing “subsection (a)” in subparagraph (B) and
15 inserting “subsection (a) of this section or sub-
16 section (a)(2)(B) or (b) of section 805”;

17 (C) by redesignating subsections (d) and
18 (e) as subsections (e) and (f), respectively; and

19 (D) by inserting after subsection (c) the
20 following new subsection:

21 “(d)(1) Except as provided in subsection (b)(4), the
22 provisions of this title shall supersede any and all State
23 laws insofar as they may now or hereafter preclude, or
24 have the effect of precluding, a health insurance issuer
25 from offering health insurance coverage in connection with

1 an association health plan which is certified under part
2 8.

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

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

17 “(B) In any case in which health insurance cov-
18 erage of any policy type is offered in a State under
19 an association health plan certified under part 8 and
20 the filing, with the applicable State authority (as de-
21 fined in section 812(a)(9)), of the policy form in
22 connection with such policy type is approved by such
23 State authority, the provisions of this title shall su-
24 persede any and all laws of any other State in which
25 health insurance coverage of such type is offered, in-

1 sofar as they may preclude, upon the filing in the
2 same form and manner of such policy form with the
3 applicable State authority in such other State, the
4 approval of the filing in such other State.

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

9 “(A) providing solvency standards or similar
10 standards regarding the adequacy of insurer capital,
11 surplus, reserves, or contributions, or

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

13 “(4) For additional provisions relating to association
14 health plans, see subsections (a)(2)(B) and (b) of section
15 805.

16 “(5) For purposes of this subsection, the term ‘asso-
17 ciation health plan’ has the meaning provided in section
18 801(a), and the terms ‘health insurance coverage’, ‘par-
19 ticipating employer’, and ‘health insurance issuer’ have
20 the meanings provided such terms in section 812, respec-
21 tively.”.

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

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

1 (B) in clause (ii), by inserting “and which
2 does not provide medical care (within the mean-
3 ing of section 733(a)(2)),” after “arrange-
4 ment,”, and by striking “title.” and inserting
5 “title, and”; and

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

8 “(iii) subject to subparagraph (E), in the case
9 of any other employee welfare benefit plan which is
10 a multiple employer welfare arrangement and which
11 provides medical care (within the meaning of section
12 733(a)(2)), any law of any State which regulates in-
13 surance may apply.”.

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

16 (A) by striking “Nothing” and inserting
17 “(1) Except as provided in paragraph (2), noth-
18 ing”; and

19 (B) by adding at the end the following new
20 paragraph:

21 “(2) Nothing in any other provision of law enacted
22 on or after the date of the enactment of the Small Busi-
23 ness Health Fairness Act of 2009 shall be construed to
24 alter, amend, modify, invalidate, impair, or supersede any

1 provision of this title, except by specific cross-reference to
2 the affected section.”.

3 (c) PLAN SPONSOR.—Section 3(16)(B) of such Act
4 (29 U.S.C. 102(16)(B)) is amended by adding at the end
5 the following new sentence: “Such term also includes a
6 person serving as the sponsor of an association health plan
7 under part 8.”.

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

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

19 (f) REPORT TO THE CONGRESS REGARDING CERTIFI-
20 CATION OF SELF-INSURED ASSOCIATION HEALTH
21 PLANS.—Not later than January 1, 2012, the Secretary
22 of Labor shall report to the Committee on Education and
23 the Workforce of the House of Representatives and the
24 Committee on Health, Education, Labor, and Pensions of

1 the Senate the effect association health plans have had,
2 if any, on reducing the number of uninsured individuals.

3 (g) CLERICAL AMENDMENT.—The table of contents
4 in section 1 of the Employee Retirement Income Security
5 Act of 1974 is amended by inserting after the item relat-
6 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.”.

7 **SEC. 202. CLARIFICATION OF TREATMENT OF SINGLE EM-**
8 **PLOYER ARRANGEMENTS.**

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

12 (1) in clause (i), by inserting after “control
13 group,” the following: “except that, in any case in
14 which the benefit referred to in subparagraph (A)
15 consists of medical care (as defined in section
16 812(a)(2)), two or more trades or businesses, wheth-
17 er or not incorporated, shall be deemed a single em-

1 ployer for any plan year of such plan, or any fiscal
2 year of such other arrangement, if such trades or
3 businesses are within the same control group during
4 such year or at any time during the preceding 1-year
5 period,”;

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

8 “(iii)(I) in any case in which the benefit re-
9 ferred to in subparagraph (A) consists of medical
10 care (as defined in section 812(a)(2)), the deter-
11 mination of whether a trade or business is under
12 ‘common control’ with another trade or business
13 shall be determined under regulations of the Sec-
14 retary applying principles consistent and coextensive
15 with the principles applied in determining whether
16 employees of two or more trades or businesses are
17 treated as employed by a single employer under sec-
18 tion 4001(b), except that, for purposes of this para-
19 graph, an interest of greater than 25 percent may
20 not be required as the minimum interest necessary
21 for common control, or

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

23 (3) by redesignating clauses (iv) and (v) as
24 clauses (v) and (vi), respectively; and

1 (4) by inserting after clause (iii) the following
2 new clause:

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

17 **SEC. 203. ENFORCEMENT PROVISIONS RELATING TO ASSO-**
18 **CIATION HEALTH PLANS.**

19 (a) **CRIMINAL PENALTIES FOR CERTAIN WILLFUL**
20 **MISREPRESENTATIONS.**—Section 501 of the Employee
21 Retirement Income Security Act of 1974 (29 U.S.C. 1131)
22 is amended—

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

24 (2) by adding at the end the following new sub-
25 section:

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

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

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

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

21 shall, upon conviction, be imprisoned not more than 5
22 years, be fined under title 18, United States Code, or
23 both.”.

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

4 “(n) ASSOCIATION HEALTH PLAN CEASE AND DE-
5 SIST ORDERS.—

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

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

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

22 a district court of the United States shall enter an
23 order requiring that the plan or arrangement cease
24 activities.

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

5 “(A) all benefits under it referred to in
6 paragraph (1) consist of health insurance cov-
7 erage; and

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

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

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

23 “(b) ASSOCIATION HEALTH PLANS.—The terms of
24 each association health plan which is or has been certified
25 under part 8 shall require the board of trustees or the

1 named fiduciary (as applicable) to ensure that the require-
2 ments of this section are met in connection with claims
3 filed under the plan.”.

4 **SEC. 204. COOPERATION BETWEEN FEDERAL AND STATE**
5 **AUTHORITIES.**

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

9 “(d) CONSULTATION WITH STATES WITH RESPECT
10 TO ASSOCIATION HEALTH PLANS.—

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

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

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

22 “(2) RECOGNITION OF PRIMARY DOMICILE
23 STATE.—In carrying out paragraph (1), the Sec-
24 retary shall ensure that only one State will be recog-
25 nized, with respect to any particular association

1 health plan, as the State with which consultation is
2 required. In carrying out this paragraph—

3 “(A) in the case of a plan which provides
4 health insurance coverage (as defined in section
5 812(a)(3)), such State shall be the State with
6 which filing and approval of a policy type of-
7 fered by the plan was initially obtained, and

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

13 **SEC. 205. EFFECTIVE DATE AND TRANSITIONAL AND**
14 **OTHER RULES.**

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

21 (b) **TREATMENT OF CERTAIN EXISTING HEALTH**
22 **BENEFITS PROGRAMS.**—

23 (1) **IN GENERAL.**—In any case in which, as of
24 the date of the enactment of this Act, an arrange-
25 ment is maintained in a State for the purpose of

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

15 (A) such arrangement shall be deemed to
16 be a group health plan for purposes of title I
17 of such Act;

18 (B) the requirements of sections 801(a)
19 and 803(a) of the Employee Retirement Income
20 Security Act of 1974 shall be deemed met with
21 respect to such arrangement;

22 (C) the requirements of section 803(b) of
23 such Act shall be deemed met, if the arrange-
24 ment is operated by a board of directors
25 which—

1 (i) is elected by the participating em-
2 ployers, with each employer having one
3 vote; and

4 (ii) has complete fiscal control over
5 the arrangement and which is responsible
6 for all operations of the arrangement;

7 (D) the requirements of section 804(a) of
8 such Act shall be deemed met with respect to
9 such arrangement; and

10 (E) the arrangement may be certified by
11 any applicable authority with respect to its op-
12 erations in any State only if it operates in such
13 State on the date of certification.

14 The provisions of this subsection shall cease to apply
15 with respect to any such arrangement at such time
16 after the date of the enactment of this Act as the
17 applicable requirements of this subsection are not
18 met with respect to such arrangement.

19 (2) DEFINITIONS.—For purposes of this sub-
20 section, the terms “group health plan”, “medical
21 care”, and “participating employer” shall have the
22 meanings provided in section 812 of the Employee
23 Retirement Income Security Act of 1974, except
24 that the reference in paragraph (7) of such section
25 to an “association health plan” shall be deemed a

1 reference to an arrangement referred to in this sub-
2 section.

3 **TITLE II—TARGETED EFFORTS**
4 **TO EXPAND ACCESS**

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

6 (a) EMPLOYEE RETIREMENT INCOME SECUR-
7 RITY ACT OF 1974.—

8 (1) IN GENERAL.—Part 7 of subtitle B of title
9 I of the Employee Retirement Income Security Act
10 of 1974 is amended by inserting after section 2714
11 the following new section:

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

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

23 “(b) CONSTRUCTION.—Nothing in this section shall
24 be construed as requiring a group health plan to provide
25 benefits for dependent children as beneficiaries under the

1 plan or to require a participant to elect coverage of de-
2 pendent children.”.

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

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

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

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

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

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

1 (c) IRC.—

2 (1) IN GENERAL.—Subchapter B of chapter
3 100 of the Internal Revenue Code of 1986 is amend-
4 ed by adding at the end the following new section:

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

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

14 “(b) CONSTRUCTION.—Nothing in this section shall
15 be construed as requiring a group health plan to provide
16 coverage for dependent children as beneficiaries under the
17 plan or to require a participant to elect coverage of de-
18 pendent children.”.

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

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

22 (d) EFFECTIVE DATE.—The amendments made by
23 this section shall apply to group health plans for plan
24 years beginning more than 3 months after the date of the

1 enactment of this Act and shall apply to individuals who
2 are dependent children under a group health plan, or
3 health insurance coverage offered in connection with such
4 a plan, on or after such date.

5 **SEC. 212. ALLOWING AUTO-ENROLLMENT FOR EMPLOYER**
6 **SPONSORED COVERAGE.**

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

14 (b) AUTOENROLLMENT.—

15 (1) NOTICE REQUIRED.—Employers with auto-
16 enrollment under a group health plan or health in-
17 surance coverage shall provide annual notification,
18 within a reasonable period before the beginning of
19 each plan year, to each employee eligible to partici-
20 pate in the plan. The notice shall explain the em-
21 ployee contribution to such plan and the employee's
22 right to decline coverage.

23 (2) TREATMENT OF NON-ACTION.—After a rea-
24 sonable period of time after receipt of the notice, if
25 an employee fails to make an affirmative declaration

1 declining coverage, then such an employee may be
2 enrolled in the group health plan or health insurance
3 coverage offered in connection with such a plan.”

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

12 **TITLE III—EXPANDING CHOICES**
13 **BY ALLOWING AMERICANS TO**
14 **BUY HEALTH CARE COV-**
15 **ERAGE ACROSS STATE LINES**

16 **SEC. 221. INTERSTATE PURCHASING OF HEALTH INSUR-**
17 **ANCE.**

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

21 **“PART D—COOPERATIVE GOVERNING OF**
22 **INDIVIDUAL HEALTH INSURANCE COVERAGE**

23 **“SEC. 2795. DEFINITIONS.**

24 “In this part:

1 “(1) PRIMARY STATE.—The term ‘primary
2 State’ means, with respect to individual health insur-
3 ance coverage offered by a health insurance issuer,
4 the State designated by the issuer as the State
5 whose covered laws shall govern the health insurance
6 issuer in the sale of such coverage under this part.
7 An issuer, with respect to a particular policy, may
8 only designate one such State as its primary State
9 with respect to all such coverage it offers. Such an
10 issuer may not change the designated primary State
11 with respect to individual health insurance coverage
12 once the policy is issued, except that such a change
13 may be made upon renewal of the policy. With re-
14 spect to such designated State, the issuer is deemed
15 to be doing business in that State.

16 “(2) SECONDARY STATE.—The term ‘secondary
17 State’ means, with respect to individual health insur-
18 ance coverage offered by a health insurance issuer,
19 any State that is not the primary State. In the case
20 of a health insurance issuer that is selling a policy
21 in, or to a resident of, a secondary State, the issuer
22 is deemed to be doing business in that secondary
23 State.

24 “(3) HEALTH INSURANCE ISSUER.—The term
25 ‘health insurance issuer’ has the meaning given such

1 term in section 2791(b)(2), except that such an
2 issuer must be licensed in the primary State and be
3 qualified to sell individual health insurance coverage
4 in that State.

5 “(4) INDIVIDUAL HEALTH INSURANCE COV-
6 ERAGE.—The term ‘individual health insurance cov-
7 erage’ means health insurance coverage offered in
8 the individual market, as defined in section
9 2791(e)(1).

10 “(5) APPLICABLE STATE AUTHORITY.—The
11 term ‘applicable State authority’ means, with respect
12 to a health insurance issuer in a State, the State in-
13 surance commissioner or official or officials des-
14 ignated by the State to enforce the requirements of
15 this title for the State with respect to the issuer.

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

21 “(A) to meet obligations to policyholders
22 with respect to known claims and reasonably
23 anticipated claims; or

24 “(B) to pay other obligations in the normal
25 course of business.

1 “(7) COVERED LAWS.—

2 “(A) IN GENERAL.—The term ‘covered
3 laws’ means the laws, rules, regulations, agree-
4 ments, and orders governing the insurance busi-
5 ness pertaining to—

6 “(i) individual health insurance cov-
7 erage issued by a health insurance issuer;

8 “(ii) the offer, sale, rating (including
9 medical underwriting), renewal, and
10 issuance of individual health insurance cov-
11 erage to an individual;

12 “(iii) the provision to an individual in
13 relation to individual health insurance cov-
14 erage of health care and insurance related
15 services;

16 “(iv) the provision to an individual in
17 relation to individual health insurance cov-
18 erage of management, operations, and in-
19 vestment activities of a health insurance
20 issuer; and

21 “(v) the provision to an individual in
22 relation to individual health insurance cov-
23 erage of loss control and claims adminis-
24 tration for a health insurance issuer with

1 respect to liability for which the issuer pro-
2 vides insurance.

3 “(B) EXCEPTION.—Such term does not in-
4 clude any law, rule, regulation, agreement, or
5 order governing the use of care or cost manage-
6 ment techniques, including any requirement re-
7 lated to provider contracting, network access or
8 adequacy, health care data collection, or quality
9 assurance.

10 “(8) STATE.—The term ‘State’ means the 50
11 States and includes the District of Columbia, Puerto
12 Rico, the Virgin Islands, Guam, American Samoa,
13 and the Northern Mariana Islands.

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

17 “(A) Knowingly misrepresenting to claim-
18 ants and insured individuals relevant facts or
19 policy provisions relating to coverage at issue.

20 “(B) Failing to acknowledge with reason-
21 able promptness pertinent communications with
22 respect to claims arising under policies.

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

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

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

6 “(F) Failing to affirm or deny coverage of
7 claims within a reasonable period of time after
8 having completed an investigation related to
9 those claims.

10 “(G) A pattern or practice of compelling
11 insured individuals or their beneficiaries to in-
12 stitute suits to recover amounts due under its
13 policies by offering substantially less than the
14 amounts ultimately recovered in suits brought
15 by them.

16 “(H) A pattern or practice of attempting
17 to settle or settling claims for less than the
18 amount that a reasonable person would believe
19 the insured individual or his or her beneficiary
20 was entitled by reference to written or printed
21 advertising material accompanying or made
22 part of an application.

23 “(I) Attempting to settle or settling claims
24 on the basis of an application that was materi-

1 ally altered without notice to, or knowledge or
2 consent of, the insured.

3 “(J) Failing to provide forms necessary to
4 present claims within 15 calendar days of a re-
5 quests with reasonable explanations regarding
6 their use.

7 “(K) Attempting to cancel a policy in less
8 time than that prescribed in the policy or by the
9 law of the primary State.

10 “(10) FRAUD AND ABUSE.—The term ‘fraud
11 and abuse’ means an act or omission committed by
12 a person who, knowingly and with intent to defraud,
13 commits, or conceals any material information con-
14 cerning, one or more of the following:

15 “(A) Presenting, causing to be presented
16 or preparing with knowledge or belief that it
17 will be presented to or by an insurer, a rein-
18 surer, broker or its agent, false information as
19 part of, in support of or concerning a fact ma-
20 terial to one or more of the following:

21 “(i) An application for the issuance or
22 renewal of an insurance policy or reinsur-
23 ance contract.

24 “(ii) The rating of an insurance policy
25 or reinsurance contract.

1 “(iii) A claim for payment or benefit
2 pursuant to an insurance policy or reinsur-
3 ance contract.

4 “(iv) Premiums paid on an insurance
5 policy or reinsurance contract.

6 “(v) Payments made in accordance
7 with the terms of an insurance policy or
8 reinsurance contract.

9 “(vi) A document filed with the com-
10 missioner or the chief insurance regulatory
11 official of another jurisdiction.

12 “(vii) The financial condition of an in-
13 surer or reinsurer.

14 “(viii) The formation, acquisition,
15 merger, reconsolidation, dissolution or
16 withdrawal from one or more lines of in-
17 surance or reinsurance in all or part of a
18 State by an insurer or reinsurer.

19 “(ix) The issuance of written evidence
20 of insurance.

21 “(x) The reinstatement of an insur-
22 ance policy.

23 “(B) Solicitation or acceptance of new or
24 renewal insurance risks on behalf of an insurer
25 reinsurer or other person engaged in the busi-

1 ness of insurance by a person who knows or
2 should know that the insurer or other person
3 responsible for the risk is insolvent at the time
4 of the transaction.

5 “(C) Transaction of the business of insur-
6 ance in violation of laws requiring a license, cer-
7 tificate of authority or other legal authority for
8 the transaction of the business of insurance.

9 “(D) Attempt to commit, aiding or abet-
10 ting in the commission of, or conspiracy to com-
11 mit the acts or omissions specified in this para-
12 graph.

13 **“SEC. 2796. APPLICATION OF LAW.**

14 “(a) IN GENERAL.—The covered laws of the primary
15 State shall apply to individual health insurance coverage
16 offered by a health insurance issuer in the primary State
17 and in any secondary State, but only if the coverage and
18 issuer comply with the conditions of this section with re-
19 spect to the offering of coverage in any secondary State.

20 “(b) EXEMPTIONS FROM COVERED LAWS IN A SEC-
21 ONDARY STATE.—Except as provided in this section, a
22 health insurance issuer with respect to its offer, sale, rat-
23 ing (including medical underwriting), renewal, and
24 issuance of individual health insurance coverage in any
25 secondary State is exempt from any covered laws of the

1 secondary State (and any rules, regulations, agreements,
2 or orders sought or issued by such State under or related
3 to such covered laws) to the extent that such laws would—

4 “(1) make unlawful, or regulate, directly or in-
5 directly, the operation of the health insurance issuer
6 operating in the secondary State, except that any
7 secondary State may require such an issuer—

8 “(A) to pay, on a nondiscriminatory basis,
9 applicable premium and other taxes (including
10 high risk pool assessments) which are levied on
11 insurers and surplus lines insurers, brokers, or
12 policyholders under the laws of the State;

13 “(B) to register with and designate the
14 State insurance commissioner as its agent solely
15 for the purpose of receiving service of legal doc-
16 uments or process;

17 “(C) to submit to an examination of its fi-
18 nancial condition by the State insurance com-
19 missioner in any State in which the issuer is
20 doing business to determine the issuer’s finan-
21 cial condition, if—

22 “(i) the State insurance commissioner
23 of the primary State has not done an ex-
24 amination within the period recommended

1 by the National Association of Insurance
2 Commissioners; and

3 “(ii) any such examination is con-
4 ducted in accordance with the examiners’
5 handbook of the National Association of
6 Insurance Commissioners and is coordi-
7 nated to avoid unjustified duplication and
8 unjustified repetition;

9 “(D) to comply with a lawful order
10 issued—

11 “(i) in a delinquency proceeding com-
12 menced by the State insurance commis-
13 sioner if there has been a finding of finan-
14 cial impairment under subparagraph (C);
15 or

16 “(ii) in a voluntary dissolution pro-
17 ceeding;

18 “(E) to comply with an injunction issued
19 by a court of competent jurisdiction, upon a pe-
20 tition by the State insurance commissioner al-
21 leging that the issuer is in hazardous financial
22 condition;

23 “(F) to participate, on a nondiscriminatory
24 basis, in any insurance insolvency guaranty as-
25 sociation or similar association to which a

1 health insurance issuer in the State is required
2 to belong;

3 “(G) to comply with any State law regard-
4 ing fraud and abuse (as defined in section
5 2795(10)), except that if the State seeks an in-
6 junction regarding the conduct described in this
7 subparagraph, such injunction must be obtained
8 from a court of competent jurisdiction;

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

12 “(I) to comply with the applicable require-
13 ments for independent review under section
14 2798 with respect to coverage offered in the
15 State;

16 “(2) require any individual health insurance
17 coverage issued by the issuer to be countersigned by
18 an insurance agent or broker residing in that Sec-
19 ondary State; or

20 “(3) otherwise discriminate against the issuer
21 issuing insurance in both the primary State and in
22 any secondary State.

23 “(c) CLEAR AND CONSPICUOUS DISCLOSURE.—A
24 health insurance issuer shall provide the following notice,
25 in 12-point bold type, in any insurance coverage offered

1 in a secondary State under this part by such a health in-
2 surance issuer and at renewal of the policy, with the 5
3 blank spaces therein being appropriately filled with the
4 name of the health insurance issuer, the name of primary
5 State, the name of the secondary State, the name of the
6 secondary State, and the name of the secondary State, re-
7 spectively, for the coverage concerned:

8 THIS POLICY IS ISSUED BY _____ **AND IS GOV-**
9 **ERNED BY THE LAWS AND REGULATIONS**
10 **OF THE STATE OF _____, AND IT HAS**
11 **MET ALL THE LAWS OF THAT STATE AS DE-**
12 **TERMINED BY THAT STATE'S DEPART-**
13 **MENT OF INSURANCE. THIS POLICY MAY**
14 **BE LESS EXPENSIVE THAN OTHERS BE-**
15 **CAUSE IT IS NOT SUBJECT TO ALL OF THE**
16 **INSURANCE LAWS AND REGULATIONS OF**
17 **THE STATE OF _____, INCLUDING COV-**
18 **ERAGE OF SOME SERVICES OR BENEFITS**
19 **MANDATED BY THE LAW OF THE STATE OF**
20 **_____ . ADDITIONALLY, THIS POLICY IS**
21 **NOT SUBJECT TO ALL OF THE CONSUMER**
22 **PROTECTION LAWS OR RESTRICTIONS ON**
23 **RATE CHANGES OF THE STATE OF**
24 **_____ . AS WITH ALL INSURANCE PROD-**
25 **UCTS, BEFORE PURCHASING THIS POLICY,**

1 **YOU SHOULD CAREFULLY REVIEW THE**
2 **POLICY AND DETERMINE WHAT HEALTH**
3 **CARE SERVICES THE POLICY COVERS AND**
4 **WHAT BENEFITS IT PROVIDES, INCLUDING**
5 **ANY EXCLUSIONS, LIMITATIONS, OR CON-**
6 **DITIONS FOR SUCH SERVICES OR BENE-**
7 **FITS.”.**

8 “(d) PROHIBITION ON CERTAIN RECLASSIFICATIONS
9 AND PREMIUM INCREASES.—

10 “(1) IN GENERAL.—For purposes of this sec-
11 tion, a health insurance issuer that provides indi-
12 vidual health insurance coverage to an individual
13 under this part in a primary or secondary State may
14 not upon renewal—

15 “(A) move or reclassify the individual in-
16 sured under the health insurance coverage from
17 the class such individual is in at the time of
18 issue of the contract based on the health-status
19 related factors of the individual; or

20 “(B) increase the premiums assessed the
21 individual for such coverage based on a health
22 status-related factor or change of a health sta-
23 tus-related factor or the past or prospective
24 claim experience of the insured individual.

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

4 “(A) from terminating or discontinuing
5 coverage or a class of coverage in accordance
6 with subsections (b) and (c) of section 2742;

7 “(B) from raising premium rates for all
8 policy holders within a class based on claims ex-
9 perience;

10 “(C) from changing premiums or offering
11 discounted premiums to individuals who engage
12 in wellness activities at intervals prescribed by
13 the issuer, if such premium changes or incen-
14 tives—

15 “(i) are disclosed to the consumer in
16 the insurance contract;

17 “(ii) are based on specific wellness ac-
18 tivities that are not applicable to all indi-
19 viduals; and

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

22 “(D) from reinstating lapsed coverage; or

23 “(E) from retroactively adjusting the rates
24 charged an insured individual if the initial rates

1 were set based on material misrepresentation by
2 the individual at the time of issue.

3 “(e) PRIOR OFFERING OF POLICY IN PRIMARY
4 STATE.—A health insurance issuer may not offer for sale
5 individual health insurance coverage in a secondary State
6 unless that coverage is currently offered for sale in the
7 primary State.

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

18 “(g) DOCUMENTS FOR SUBMISSION TO STATE IN-
19 SURANCE COMMISSIONER.—Each health insurance issuer
20 issuing individual health insurance coverage in both pri-
21 mary and secondary States shall submit—

22 “(1) to the insurance commissioner of each
23 State in which it intends to offer such coverage, be-
24 fore it may offer individual health insurance cov-
25 erage in such State—

1 “(A) a copy of the plan of operation or fea-
2 sibility study or any similar statement of the
3 policy being offered and its coverage (which
4 shall include the name of its primary State and
5 its principal place of business);

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

8 “(C) written notice from the issuer of the
9 issuer’s compliance with all the laws of the pri-
10 mary State; and

11 “(2) to the insurance commissioner of each sec-
12 ondary State in which it offers individual health in-
13 surance coverage, a copy of the issuer’s quarterly fi-
14 nancial statement submitted to the primary State,
15 which statement shall be certified by an independent
16 public accountant and contain a statement of opin-
17 ion on loss and loss adjustment expense reserves
18 made by—

19 “(A) a member of the American Academy
20 of Actuaries; or

21 “(B) a qualified loss reserve specialist.

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

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

5 “(2) the solicitation or sale of individual health
6 insurance coverage that violates the requirements of
7 the law of a secondary State which are described in
8 subparagraphs (A) through (H) of section
9 2796(b)(1).

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

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

16 “(1) IN GENERAL.—Subject to the provisions of
17 subsection (b)(1)(G) (relating to injunctions) and
18 paragraph (2), nothing in this section shall be con-
19 strued to affect the authority of any State to make
20 use of any of its powers to enforce the laws of such
21 State with respect to which a health insurance issuer
22 is not exempt under subsection (b).

23 “(2) COURTS OF COMPETENT JURISDICTION.—

24 If a State seeks an injunction regarding the conduct
25 described in paragraphs (1) and (2) of subsection

1 (h), such injunction must be obtained from a Fed-
2 eral or State court of competent jurisdiction.

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

6 “(l) GENERALLY APPLICABLE LAWS.—Nothing in
7 this section shall be construed to affect the applicability
8 of State laws generally applicable to persons or corpora-
9 tions.

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

1 **“SEC. 2797. PRIMARY STATE MUST MEET FEDERAL FLOOR**
2 **BEFORE ISSUER MAY SELL INTO SECONDARY**
3 **STATES.**

4 “A health insurance issuer may not offer, sell, or
5 issue individual health insurance coverage in a secondary
6 State if the State insurance commissioner does not use
7 a risk-based capital formula for the determination of cap-
8 ital and surplus requirements for all health insurance
9 issuers.

10 **“SEC. 2798. INDEPENDENT EXTERNAL APPEALS PROCE-**
11 **DURES.**

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

16 “(1) both the secondary State and the primary
17 State have legislation or regulations in place estab-
18 lishing an independent review process for individuals
19 who are covered by individual health insurance cov-
20 erage, or

21 “(2) in any case in which the requirements of
22 subparagraph (A) are not met with respect to the ei-
23 ther of such States, the issuer provides an inde-
24 pendent review mechanism substantially identical (as
25 determined by the applicable State authority of such
26 State) to that prescribed in the ‘Health Carrier Ex-

1 ternal Review Model Act’ of the National Association
2 of Insurance Commissioners for all individuals who
3 purchase insurance coverage under the terms of this
4 part, except that, under such mechanism, the review
5 is conducted by an independent medical reviewer, or
6 a panel of such reviewers, with respect to whom the
7 requirements of subsection (b) are met.

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

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

15 “(A) each independent medical reviewer
16 meets the qualifications described in paragraphs
17 (2) and (3);

18 “(B) with respect to each review, each re-
19 viewer meets the requirements of paragraph (4)
20 and the reviewer, or at least 1 reviewer on the
21 panel, meets the requirements described in
22 paragraph (5); and

23 “(C) compensation provided by the issuer
24 to each reviewer is consistent with paragraph
25 (6).

1 “(2) LICENSURE AND EXPERTISE.—Each inde-
2 pendent medical reviewer shall be a physician
3 (allopathic or osteopathic) or health care profes-
4 sional who—

5 “(A) is appropriately credentialed or li-
6 censed in 1 or more States to deliver health
7 care services; and

8 “(B) typically treats the condition, makes
9 the diagnosis, or provides the type of treatment
10 under review.

11 “(3) INDEPENDENCE.—

12 “(A) IN GENERAL.—Subject to subpara-
13 graph (B), each independent medical reviewer
14 in a case shall—

15 “(i) not be a related party (as defined
16 in paragraph (7));

17 “(ii) not have a material familial, fi-
18 nancial, or professional relationship with
19 such a party; and

20 “(iii) not otherwise have a conflict of
21 interest with such a party (as determined
22 under regulations).

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

1 “(i) prohibit an individual, solely on
2 the basis of affiliation with the issuer,
3 from serving as an independent medical re-
4 viewer if—

5 “(I) a non-affiliated individual is
6 not reasonably available;

7 “(II) the affiliated individual is
8 not involved in the provision of items
9 or services in the case under review;

10 “(III) the fact of such an affili-
11 ation is disclosed to the issuer and the
12 enrollee (or authorized representative)
13 and neither party objects; and

14 “(IV) the affiliated individual is
15 not an employee of the issuer and
16 does not provide services exclusively or
17 primarily to or on behalf of the issuer;

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

1 “(iii) prohibit receipt of compensation
2 by an independent medical reviewer from
3 an entity if the compensation is provided
4 consistent with paragraph (6).

5 “(4) PRACTICING HEALTH CARE PROFESSIONAL
6 IN SAME FIELD.—

7 “(A) IN GENERAL.—In a case involving
8 treatment, or the provision of items or serv-
9 ices—

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

19 “(ii) by a non-physician health care
20 professional, the reviewer, or at least 1
21 member of the review panel, shall be a
22 practicing non-physician health care pro-
23 fessional of the same or similar specialty
24 as the non-physician health care profes-
25 sional who, acting within the appropriate

1 scope of practice within the State in which
2 the service is provided or rendered, typi-
3 cally treats the condition, makes the diag-
4 nosis, or provides the type of treatment
5 under review.

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

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

16 “(6) LIMITATIONS ON REVIEWER COMPENSA-
17 TION.—Compensation provided by the issuer to an
18 independent medical reviewer in connection with a
19 review under this section shall—

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

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

23 “(7) RELATED PARTY DEFINED.—For purposes
24 of this section, the term ‘related party’ means, with

1 respect to a denial of a claim under a coverage relat-
2 ing to an enrollee, any of the following:

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

5 “(B) The enrollee (or authorized represent-
6 ative).

7 “(C) The health care professional that pro-
8 vides the items or services involved in the de-
9 nial.

10 “(D) The institution at which the items or
11 services (or treatment) involved in the denial
12 are provided.

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

16 “(F) Any other party determined under
17 any regulations to have a substantial interest in
18 the denial involved.

19 “(8) DEFINITIONS.—For purposes of this sub-
20 section:

21 “(A) ENROLLEE.—The term ‘enrollee’
22 means, with respect to health insurance cov-
23 erage offered by a health insurance issuer, an
24 individual enrolled with the issuer to receive
25 such coverage.

1 “(B) HEALTH CARE PROFESSIONAL.—The
2 term ‘health care professional’ means an indi-
3 vidual who is licensed, accredited, or certified
4 under State law to provide specified health care
5 services and who is operating within the scope
6 of such licensure, accreditation, or certification.

7 **“SEC. 2799. ENFORCEMENT.**

8 “(a) IN GENERAL.—Subject to subsection (b), with
9 respect to specific individual health insurance coverage the
10 primary State for such coverage has sole jurisdiction to
11 enforce the primary State’s covered laws in the primary
12 State and any secondary State.

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

17 “(c) COURT INTERPRETATION.—In reviewing action
18 initiated by the applicable secondary State authority, the
19 court of competent jurisdiction shall apply the covered
20 laws of the primary State.

21 “(d) NOTICE OF COMPLIANCE FAILURE.—In the case
22 of individual health insurance coverage offered in a sec-
23 ondary State that fails to comply with the covered laws
24 of the primary State, the applicable State authority of the

1 secondary State may notify the applicable State authority
2 of the primary State.”.

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

7 (c) GAO ONGOING STUDY AND REPORTS.—

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

12 (A) the number of uninsured and under-in-
13 sured;

14 (B) the availability and cost of health in-
15 surance policies for individuals with preexisting
16 medical conditions;

17 (C) the availability and cost of health in-
18 surance policies generally;

19 (D) the elimination or reduction of dif-
20 ferent types of benefits under health insurance
21 policies offered in different States; and

22 (E) cases of fraud or abuse relating to
23 health insurance coverage offered under such
24 amendment and the resolution of such cases.

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

6 **TITLE IV—IMPROVING HEALTH**
7 **SAVINGS ACCOUNTS**

8 **SEC. 231. SAVER'S CREDIT FOR CONTRIBUTIONS TO**
9 **HEALTH SAVINGS ACCOUNTS.**

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

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

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

24 (c) CONFORMING AMENDMENT.—The first sentence
25 of section 25B(d)(3)(A) of such Code (as redesignated by

1 subsection (b)) is amended to read as follows: “The aggregate
2 qualified retirement savings contributions determined
3 under paragraph (1) and qualified HSA contributions determined
4 under paragraph (2) shall be reduced (but not
5 below zero) by the aggregate distributions received by the
6 individual during the testing period from any entity of a
7 type to which contributions under paragraph (1) or paragraph
8 (2) (as the case may be) may be made.”.

9 (d) EFFECTIVE DATE.—The amendments made by
10 this section shall apply to contributions made after December
11 31, 2009.

12 **SEC. 232. HSA FUNDS FOR PREMIUMS FOR HIGH DEDUCTIBLE HEALTH PLANS.**

13
14 (a) IN GENERAL.—Subparagraph (C) of section
15 223(d)(2) of the Internal Revenue Code of 1986 is amended
16 by striking “or” at the end of clause (iii), by striking
17 the period at the end of clause (iv) and inserting “, or”,
18 and by adding at the end the following:

19 “(v) a high deductible health plan if—
20 “(I) such plan is not offered in
21 connection with a group health plan,
22 “(II) no portion of any premium
23 (within the meaning of applicable premium
24 under section 4980B(f)(4)) for

1 such plan is excludable from gross in-
2 come under section 106, and

3 “(III) the account beneficiary
4 demonstrates, using procedures
5 deemed appropriate by the Secretary,
6 that after payment of the premium
7 for such insurance the balance in the
8 health savings account is at least
9 twice the minimum deductible in ef-
10 fect under subsection (c)(2)(A)(i)
11 which is applicable to such plan.”.

12 (b) EFFECTIVE DATE.—The amendment made by
13 subsection (a) shall apply to premiums for a high deduct-
14 ible health plan for periods beginning after December 31,
15 2009.

16 **SEC. 233. REQUIRING GREATER COORDINATION BETWEEN**
17 **HDHP ADMINISTRATORS AND HSA ACCOUNT**
18 **ADMINISTRATORS SO THAT ENROLLEES CAN**
19 **ENROLL IN BOTH AT THE SAME TIME.**

20 The Secretary of the Treasury, through the issuance
21 of regulations or other guidance, shall encourage adminis-
22 trators of health plans and trustees of health savings ac-
23 counts to provide for simultaneous enrollment in high de-
24 ductible health plans and setup of health savings accounts.

1 **SEC. 234. SPECIAL RULE FOR CERTAIN MEDICAL EXPENSES**
2 **INCURRED BEFORE ESTABLISHMENT OF AC-**
3 **COUNT.**

4 (a) IN GENERAL.—Subsection (d) of section 223 of
5 the Internal Revenue Code of 1986 is amended by redesi-
6 gnating paragraph (4) as paragraph (5) and by inserting
7 after paragraph (3) the following new paragraph:

8 “(4) CERTAIN MEDICAL EXPENSES INCURRED
9 BEFORE ESTABLISHMENT OF ACCOUNT TREATED AS
10 QUALIFIED.—

11 “(A) IN GENERAL.—For purposes of para-
12 graph (2), an expense shall not fail to be treat-
13 ed as a qualified medical expense solely because
14 such expense was incurred before the establish-
15 ment of the health savings account if such ex-
16 pense was incurred during the 60-day period
17 beginning on the date on which the high de-
18 ductible health plan is first effective.

19 “(B) SPECIAL RULES.—For purposes of
20 subparagraph (A)—

21 “(i) an individual shall be treated as
22 an eligible individual for any portion of a
23 month for which the individual is described
24 in subsection (c)(1), determined without
25 regard to whether the individual is covered

1 under a high deductible health plan on the
2 1st day of such month, and

3 “(ii) the effective date of the health
4 savings account is deemed to be the date
5 on which the high deductible health plan is
6 first effective after the date of the enact-
7 ment of this paragraph.”.

8 (b) EFFECTIVE DATE.—The amendment made by
9 this section shall apply with respect to insurance pur-
10 chased after the date of the enactment of this Act in tax-
11 able years beginning after such date.

12 **DIVISION C—ENACTING REAL**
13 **MEDICAL LIABILITY REFORM**

14 **SEC. 301. ENCOURAGING SPEEDY RESOLUTION OF CLAIMS.**

15 The time for the commencement of a health care law-
16 suit shall be 3 years after the date of manifestation of
17 injury or 1 year after the claimant discovers, or through
18 the use of reasonable diligence should have discovered, the
19 injury, whichever occurs first. In no event shall the time
20 for commencement of a health care lawsuit exceed 3 years
21 after the date of manifestation of injury unless tolled for
22 any of the following—

- 23 (1) upon proof of fraud;
24 (2) intentional concealment; or

1 (3) the presence of a foreign body, which has no
2 therapeutic or diagnostic purpose or effect, in the
3 person of the injured person.

4 Actions by a minor shall be commenced within 3 years
5 from the date of the alleged manifestation of injury except
6 that actions by a minor under the full age of 6 years shall
7 be commenced within 3 years of manifestation of injury
8 or prior to the minor's 8th birthday, whichever provides
9 a longer period. Such time limitation shall be tolled for
10 minors for any period during which a parent or guardian
11 and a health care provider or health care organization
12 have committed fraud or collusion in the failure to bring
13 an action on behalf of the injured minor.

14 **SEC. 302. COMPENSATING PATIENT INJURY.**

15 (a) UNLIMITED AMOUNT OF DAMAGES FOR ACTUAL
16 ECONOMIC LOSSES IN HEALTH CARE LAWSUITS.—In any
17 health care lawsuit, nothing in this title shall limit a claim-
18 ant's recovery of the full amount of the available economic
19 damages, notwithstanding the limitation in subsection (b).

20 (b) ADDITIONAL NONECONOMIC DAMAGES.—In any
21 health care lawsuit, the amount of noneconomic damages,
22 if available, may be as much as \$250,000, regardless of
23 the number of parties against whom the action is brought
24 or the number of separate claims or actions brought with
25 respect to the same injury.

1 (c) NO DISCOUNT OF AWARD FOR NONECONOMIC
2 DAMAGES.—For purposes of applying the limitation in
3 subsection (b), future noneconomic damages shall not be
4 discounted to present value. The jury shall not be in-
5 formed about the maximum award for noneconomic dam-
6 ages. An award for noneconomic damages in excess of
7 \$250,000 shall be reduced either before the entry of judg-
8 ment, or by amendment of the judgment after entry of
9 judgment, and such reduction shall be made before ac-
10 counting for any other reduction in damages required by
11 law. If separate awards are rendered for past and future
12 noneconomic damages and the combined awards exceed
13 \$250,000, the future noneconomic damages shall be re-
14 duced first.

15 (d) FAIR SHARE RULE.—In any health care lawsuit,
16 each party shall be liable for that party's several share
17 of any damages only and not for the share of any other
18 person. Each party shall be liable only for the amount of
19 damages allocated to such party in direct proportion to
20 such party's percentage of responsibility. Whenever a
21 judgment of liability is rendered as to any party, a sepa-
22 rate judgment shall be rendered against each such party
23 for the amount allocated to such party. For purposes of
24 this section, the trier of fact shall determine the propor-

1 tion of responsibility of each party for the claimant's
2 harm.

3 **SEC. 303. MAXIMIZING PATIENT RECOVERY.**

4 (a) COURT SUPERVISION OF SHARE OF DAMAGES
5 ACTUALLY PAID TO CLAIMANTS.—In any health care law-
6 suit, the court shall supervise the arrangements for pay-
7 ment of damages to protect against conflicts of interest
8 that may have the effect of reducing the amount of dam-
9 ages awarded that are actually paid to claimants. In par-
10 ticular, in any health care lawsuit in which the attorney
11 for a party claims a financial stake in the outcome by vir-
12 tue of a contingent fee, the court shall have the power
13 to restrict the payment of a claimant's damage recovery
14 to such attorney, and to redirect such damages to the
15 claimant based upon the interests of justice and principles
16 of equity. In no event shall the total of all contingent fees
17 for representing all claimants in a health care lawsuit ex-
18 ceed the following limits:

19 (1) 40 percent of the first \$50,000 recovered by
20 the claimant(s).

21 (2) $33\frac{1}{3}$ percent of the next \$50,000 recovered
22 by the claimant(s).

23 (3) 25 percent of the next \$500,000 recovered
24 by the claimant(s).

1 (4) 15 percent of any amount by which the re-
2 covery by the claimant(s) is in excess of \$600,000.

3 (b) APPLICABILITY.—The limitations in this section
4 shall apply whether the recovery is by judgment, settle-
5 ment, mediation, arbitration, or any other form of alter-
6 native dispute resolution. In a health care lawsuit involv-
7 ing a minor or incompetent person, a court retains the
8 authority to authorize or approve a fee that is less than
9 the maximum permitted under this section. The require-
10 ment for court supervision in the first two sentences of
11 subsection (a) applies only in civil actions.

12 **SEC. 304. ADDITIONAL HEALTH BENEFITS.**

13 In any health care lawsuit involving injury or wrong-
14 ful death, any party may introduce evidence of collateral
15 source benefits. If a party elects to introduce such evi-
16 dence, any opposing party may introduce evidence of any
17 amount paid or contributed or reasonably likely to be paid
18 or contributed in the future by or on behalf of the oppos-
19 ing party to secure the right to such collateral source bene-
20 fits. No provider of collateral source benefits shall recover
21 any amount against the claimant or receive any lien or
22 credit against the claimant's recovery or be equitably or
23 legally subrogated to the right of the claimant in a health
24 care lawsuit involving injury or wrongful death. This sec-
25 tion shall apply to any health care lawsuit that is settled

1 as well as a health care lawsuit that is resolved by a fact
2 finder. This section shall not apply to section 1862(b) (42
3 U.S.C. 1395y(b)) or section 1902(a)(25) (42 U.S.C.
4 1396a(a)(25)) of the Social Security Act.

5 **SEC. 305. PUNITIVE DAMAGES.**

6 (a) IN GENERAL.—Punitive damages may, if other-
7 wise permitted by applicable State or Federal law, be
8 awarded against any person in a health care lawsuit only
9 if it is proven by clear and convincing evidence that such
10 person acted with malicious intent to injure the claimant,
11 or that such person deliberately failed to avoid unneces-
12 sary injury that such person knew the claimant was sub-
13 stantially certain to suffer. In any health care lawsuit
14 where no judgment for compensatory damages is rendered
15 against such person, no punitive damages may be awarded
16 with respect to the claim in such lawsuit. No demand for
17 punitive damages shall be included in a health care lawsuit
18 as initially filed. A court may allow a claimant to file an
19 amended pleading for punitive damages only upon a mo-
20 tion by the claimant and after a finding by the court, upon
21 review of supporting and opposing affidavits or after a
22 hearing, after weighing the evidence, that the claimant has
23 established by a substantial probability that the claimant
24 will prevail on the claim for punitive damages. At the re-

1 quest of any party in a health care lawsuit, the trier of
2 fact shall consider in a separate proceeding—

3 (1) whether punitive damages are to be award-
4 ed and the amount of such award; and

5 (2) the amount of punitive damages following a
6 determination of punitive liability.

7 If a separate proceeding is requested, evidence relevant
8 only to the claim for punitive damages, as determined by
9 applicable State law, shall be inadmissible in any pro-
10 ceeding to determine whether compensatory damages are
11 to be awarded.

12 (b) DETERMINING AMOUNT OF PUNITIVE DAM-
13 AGES.—

14 (1) FACTORS CONSIDERED.—In determining
15 the amount of punitive damages, if awarded, in a
16 health care lawsuit, the trier of fact shall consider
17 only the following—

18 (A) the severity of the harm caused by the
19 conduct of such party;

20 (B) the duration of the conduct or any
21 concealment of it by such party;

22 (C) the profitability of the conduct to such
23 party;

24 (D) the number of products sold or med-
25 ical procedures rendered for compensation, as

1 the case may be, by such party, of the kind
2 causing the harm complained of by the claim-
3 ant;

4 (E) any criminal penalties imposed on such
5 party, as a result of the conduct complained of
6 by the claimant; and

7 (F) the amount of any civil fines assessed
8 against such party as a result of the conduct
9 complained of by the claimant.

10 (2) MAXIMUM AWARD.—The amount of punitive
11 damages, if awarded, in a health care lawsuit may
12 be as much as \$250,000 or as much as two times
13 the amount of economic damages awarded, which-
14 ever is greater. The jury shall not be informed of
15 this limitation.

16 **SEC. 306. AUTHORIZATION OF PAYMENT OF FUTURE DAM-**
17 **AGES TO CLAIMANTS IN HEALTH CARE LAW-**
18 **SUITS.**

19 (a) IN GENERAL.—In any health care lawsuit, if an
20 award of future damages, without reduction to present
21 value, equaling or exceeding \$50,000 is made against a
22 party with sufficient insurance or other assets to fund a
23 periodic payment of such a judgment, the court shall, at
24 the request of any party, enter a judgment ordering that
25 the future damages be paid by periodic payments. In any

1 health care lawsuit, the court may be guided by the Uni-
2 form Periodic Payment of Judgments Act promulgated by
3 the National Conference of Commissioners on Uniform
4 State Laws.

5 (b) APPLICABILITY.—This section applies to all ac-
6 tions which have not been first set for trial or retrial be-
7 fore the effective date of this title.

8 **SEC. 307. DEFINITIONS.**

9 In this title:

10 (1) ALTERNATIVE DISPUTE RESOLUTION SYS-
11 TEM; ADR.—The term “alternative dispute resolution
12 system” or “ADR” means a system that provides
13 for the resolution of health care lawsuits in a man-
14 ner other than through a civil action brought in a
15 State or Federal court.

16 (2) CLAIMANT.—The term “claimant” means
17 any person who brings a health care lawsuit, includ-
18 ing a person who asserts or claims a right to legal
19 or equitable contribution, indemnity, or subrogation,
20 arising out of a health care liability claim or action,
21 and any person on whose behalf such a claim is as-
22 serted or such an action is brought, whether de-
23 ceased, incompetent, or a minor.

24 (3) COLLATERAL SOURCE BENEFITS.—The
25 term “collateral source benefits” means any amount

1 paid or reasonably likely to be paid in the future to
2 or on behalf of the claimant, or any service, product,
3 or other benefit provided or reasonably likely to be
4 provided in the future to or on behalf of the claim-
5 ant, as a result of the injury or wrongful death, pur-
6 suant to—

7 (A) any State or Federal health, sickness,
8 income-disability, accident, or workers’ com-
9 pensation law;

10 (B) any health, sickness, income-disability,
11 or accident insurance that provides health bene-
12 fits or income-disability coverage;

13 (C) any contract or agreement of any
14 group, organization, partnership, or corporation
15 to provide, pay for, or reimburse the cost of
16 medical, hospital, dental, or income-disability
17 benefits; and

18 (D) any other publicly or privately funded
19 program.

20 (4) COMPENSATORY DAMAGES.—The term
21 “compensatory damages” means objectively
22 verifiable monetary losses incurred as a result of the
23 provision of, use of, or payment for (or failure to
24 provide, use, or pay for) health care services or med-
25 ical products, such as past and future medical ex-

1 penses, loss of past and future earnings, cost of ob-
2 taining domestic services, loss of employment, and
3 loss of business or employment opportunities, dam-
4 ages for physical and emotional pain, suffering, in-
5 convenience, physical impairment, mental anguish,
6 disfigurement, loss of enjoyment of life, loss of soci-
7 ety and companionship, loss of consortium (other
8 than loss of domestic service), hedonic damages, in-
9 jury to reputation, and all other nonpecuniary losses
10 of any kind or nature. The term “compensatory
11 damages” includes economic damages and non-
12 economic damages, as such terms are defined in this
13 section.

14 (5) CONTINGENT FEE.—The term “contingent
15 fee” includes all compensation to any person or per-
16 sons which is payable only if a recovery is effected
17 on behalf of one or more claimants.

18 (6) ECONOMIC DAMAGES.—The term “economic
19 damages” means objectively verifiable monetary
20 losses incurred as a result of the provision of, use
21 of, or payment for (or failure to provide, use, or pay
22 for) health care services or medical products, such as
23 past and future medical expenses, loss of past and
24 future earnings, cost of obtaining domestic services,

1 loss of employment, and loss of business or employ-
2 ment opportunities.

3 (7) HEALTH CARE LAWSUIT.—The term
4 “health care lawsuit” means any health care liability
5 claim concerning the provision of health care goods
6 or services or any medical product affecting inter-
7 state commerce, or any health care liability action
8 concerning the provision of health care goods or
9 services or any medical product affecting interstate
10 commerce, brought in a State or Federal court or
11 pursuant to an alternative dispute resolution system,
12 against a health care provider, a health care organi-
13 zation, or the manufacturer, distributor, supplier,
14 marketer, promoter, or seller of a medical product,
15 regardless of the theory of liability on which the
16 claim is based, or the number of claimants, plain-
17 tiffs, defendants, or other parties, or the number of
18 claims or causes of action, in which the claimant al-
19 leges a health care liability claim. Such term does
20 not include a claim or action which is based on
21 criminal liability; which seeks civil fines or penalties
22 paid to Federal, State, or local government; or which
23 is grounded in antitrust.

24 (8) HEALTH CARE LIABILITY ACTION.—The
25 term “health care liability action” means a civil ac-

1 tion brought in a State or Federal court or pursuant
2 to an alternative dispute resolution system, against
3 a health care provider, a health care organization, or
4 the manufacturer, distributor, supplier, marketer,
5 promoter, or seller of a medical product, regardless
6 of the theory of liability on which the claim is based,
7 or the number of plaintiffs, defendants, or other par-
8 ties, or the number of causes of action, in which the
9 claimant alleges a health care liability claim.

10 (9) HEALTH CARE LIABILITY CLAIM.—The
11 term “health care liability claim” means a demand
12 by any person, whether or not pursuant to ADR,
13 against a health care provider, health care organiza-
14 tion, or the manufacturer, distributor, supplier, mar-
15 keter, promoter, or seller of a medical product, in-
16 cluding, but not limited to, third-party claims, cross-
17 claims, counter-claims, or contribution claims, which
18 are based upon the provision of, use of, or payment
19 for (or the failure to provide, use, or pay for) health
20 care services or medical products, regardless of the
21 theory of liability on which the claim is based, or the
22 number of plaintiffs, defendants, or other parties, or
23 the number of causes of action.

24 (10) HEALTH CARE ORGANIZATION.—The term
25 “health care organization” means any person or en-

1 tity which is obligated to provide or pay for health
2 benefits under any health plan, including any person
3 or entity acting under a contract or arrangement
4 with a health care organization to provide or admin-
5 ister any health benefit.

6 (11) HEALTH CARE PROVIDER.—The term
7 “health care provider” means any person or entity
8 required by State or Federal laws or regulations to
9 be licensed, registered, or certified to provide health
10 care services, and being either so licensed, reg-
11 istered, or certified, or exempted from such require-
12 ment by other statute or regulation.

13 (12) HEALTH CARE GOODS OR SERVICES.—The
14 term “health care goods or services” means any
15 goods or services provided by a health care organiza-
16 tion, provider, or by any individual working under
17 the supervision of a health care provider, that relates
18 to the diagnosis, prevention, or treatment of any
19 human disease or impairment, or the assessment or
20 care of the health of human beings.

21 (13) MALICIOUS INTENT TO INJURE.—The
22 term “malicious intent to injure” means inten-
23 tionally causing or attempting to cause physical in-
24 jury other than providing health care goods or serv-
25 ices.

1 (14) MEDICAL PRODUCT.—The term “medical
2 product” means a drug, device, or biological product
3 intended for humans, and the terms “drug”, “de-
4 vice”, and “biological product” have the meanings
5 given such terms in sections 201(g)(1) and 201(h)
6 of the Federal Food, Drug and Cosmetic Act (21
7 U.S.C. 321(g)(1) and (h)) and section 351(a) of the
8 Public Health Service Act (42 U.S.C. 262(a)), re-
9 spectively, including any component or raw material
10 used therein, but excluding health care services.

11 (15) NONECONOMIC DAMAGES.—The term
12 “noneconomic damages” means damages for phys-
13 ical and emotional pain, suffering, inconvenience,
14 physical impairment, mental anguish, disfigurement,
15 loss of enjoyment of life, loss of society and compan-
16 ionship, loss of consortium (other than loss of do-
17 mestic service), hedonic damages, injury to reputa-
18 tion, and all other nonpecuniary losses of any kind
19 or nature.

20 (16) PUNITIVE DAMAGES.—The term “punitive
21 damages” means damages awarded, for the purpose
22 of punishment or deterrence, and not solely for com-
23 pensatory purposes, against a health care provider,
24 health care organization, or a manufacturer, dis-
25 tributor, or supplier of a medical product. Punitive

1 damages are neither economic nor noneconomic
2 damages.

3 (17) RECOVERY.—The term “recovery” means
4 the net sum recovered after deducting any disburse-
5 ments or costs incurred in connection with prosecu-
6 tion or settlement of the claim, including all costs
7 paid or advanced by any person. Costs of health care
8 incurred by the plaintiff and the attorneys’ office
9 overhead costs or charges for legal services are not
10 deductible disbursements or costs for such purpose.

11 (18) STATE.—The term “State” means each of
12 the several States, the District of Columbia, the
13 Commonwealth of Puerto Rico, the Virgin Islands,
14 Guam, American Samoa, the Northern Mariana Is-
15 lands, the Trust Territory of the Pacific Islands, and
16 any other territory or possession of the United
17 States, or any political subdivision thereof.

18 **SEC. 308. EFFECT ON OTHER LAWS.**

19 (a) VACCINE INJURY.—

20 (1) To the extent that title XXI of the Public
21 Health Service Act establishes a Federal rule of law
22 applicable to a civil action brought for a vaccine-re-
23 lated injury or death—

24 (A) this title does not affect the application
25 of the rule of law to such an action; and

1 (B) any rule of law prescribed by this title
2 in conflict with a rule of law of such title XXI
3 shall not apply to such action.

4 (2) If there is an aspect of a civil action
5 brought for a vaccine-related injury or death to
6 which a Federal rule of law under title XXI of the
7 Public Health Service Act does not apply, then this
8 title or otherwise applicable law (as determined
9 under this title) will apply to such aspect of such ac-
10 tion.

11 (b) OTHER FEDERAL LAW.—Except as provided in
12 this section, nothing in this title shall be deemed to affect
13 any defense available to a defendant in a health care law-
14 suit or action under any other provision of Federal law.

15 **SEC. 309. STATE FLEXIBILITY AND PROTECTION OF**
16 **STATES' RIGHTS.**

17 (a) HEALTH CARE LAWSUITS.—The provisions gov-
18 erning health care lawsuits set forth in this title preempt,
19 subject to subsections (b) and (c), State law to the extent
20 that State law prevents the application of any provisions
21 of law established by or under this title. The provisions
22 governing health care lawsuits set forth in this title super-
23 sede chapter 171 of title 28, United States Code, to the
24 extent that such chapter—

1 (1) provides for a greater amount of damages
2 or contingent fees, a longer period in which a health
3 care lawsuit may be commenced, or a reduced appli-
4 cability or scope of periodic payment of future dam-
5 ages, than provided in this title; or

6 (2) prohibits the introduction of evidence re-
7 garding collateral source benefits, or mandates or
8 permits subrogation or a lien on collateral source
9 benefits.

10 (b) PROTECTION OF STATES' RIGHTS AND OTHER
11 LAWS.—(1) Any issue that is not governed by any provi-
12 sion of law established by or under this title (including
13 State standards of negligence) shall be governed by other-
14 wise applicable State or Federal law.

15 (2) This title shall not preempt or supersede any
16 State or Federal law that imposes greater procedural or
17 substantive protections for health care providers and
18 health care organizations from liability, loss, or damages
19 than those provided by this title or create a cause of ac-
20 tion.

21 (c) STATE FLEXIBILITY.—No provision of this title
22 shall be construed to preempt—

23 (1) any State law (whether effective before, on,
24 or after the date of the enactment of this Act) that
25 specifies a particular monetary amount of compen-

1 satory or punitive damages (or the total amount of
2 damages) that may be awarded in a health care law-
3 suit, regardless of whether such monetary amount is
4 greater or lesser than is provided for under this title,
5 notwithstanding section 302(a); or

6 (2) any defense available to a party in a health
7 care lawsuit under any other provision of State or
8 Federal law.

9 **SEC. 310. APPLICABILITY; EFFECTIVE DATE.**

10 This title shall apply to any health care lawsuit
11 brought in a Federal or State court, or subject to an alter-
12 native dispute resolution system, that is initiated on or
13 after the date of the enactment of this Act, except that
14 any health care lawsuit arising from an injury occurring
15 prior to the date of the enactment of this Act shall be
16 governed by the applicable statute of limitations provisions
17 in effect at the time the injury occurred.

18 **DIVISION D—PROTECTING THE**
19 **DOCTOR-PATIENT RELATION-**
20 **SHIP**

21 **SEC. 401. RULE OF CONSTRUCTION.**

22 Nothing in this Act shall be construed to interfere
23 with the doctor-patient relationship or the practice of med-
24 icine.

1 **SEC. 402. REPEAL OF FEDERAL COORDINATING COUNCIL**
2 **FOR COMPARATIVE EFFECTIVENESS RE-**
3 **SEARCH.**

4 Effective on the date of the enactment of this Act,
5 section 804 of the American Recovery and Reinvestment
6 Act of 2009 is repealed.

7 **DIVISION E—INCENTIVIZING**
8 **WELLNESS AND QUALITY IM-**
9 **PROVEMENTS**

10 **SEC. 501. INCENTIVES FOR PREVENTION AND WELLNESS**
11 **PROGRAMS.**

12 (a) EMPLOYEE RETIREMENT INCOME SECU-
13 RITY ACT OF 1974 LIMITATION ON EXCEPTION FOR
14 WELLNESS PROGRAMS UNDER HIPAA DISCRIMINATION
15 RULES.—

16 (1) IN GENERAL.—Section 702(b)(2) of the
17 Employee Retirement Income Security Act of 1974
18 (29 U.S.C. 1182(b)(2)) is amended by adding after
19 and below subparagraph (B) the following:

20 “In applying subparagraph (B), a group health plan
21 (or a health insurance issuer with respect to health
22 insurance coverage) may vary premiums and cost-
23 sharing by up to 50 percent of the value of the bene-
24 fits under the plan (or coverage) based on participa-
25 tion in a standards-based wellness program.”.

1 (2) EFFECTIVE DATE.—The amendment made
2 by paragraph (1) shall apply to plan years beginning
3 more than 1 year after the date of the enactment of
4 this Act.

5 (b) CONFORMING AMENDMENTS TO PHSA.—

6 (1) GROUP MARKET RULES.—

7 (A) IN GENERAL.—Section 2702(b)(2) of
8 the Public Health Service Act (42 U.S.C.
9 300gg–1(b)(2)) is amended by adding after and
10 below subparagraph (B) the following:

11 “In applying subparagraph (B), a group health plan
12 (or a health insurance issuer with respect to health
13 insurance coverage) may vary premiums and cost-
14 sharing by up to 50 percent of the value of the bene-
15 fits under the plan (or coverage) based on participa-
16 tion in a standards-based wellness program.”.

17 (B) EFFECTIVE DATE.—The amendment
18 made by subparagraph (A) shall apply to plan
19 years beginning more than 1 year after the date
20 of the enactment of this Act.

21 (2) INDIVIDUAL MARKET RULES RELATING TO
22 GUARANTEED AVAILABILITY.—

23 (A) IN GENERAL.—Section 2741(f) of the
24 Public Health Service Act (42 U.S.C. 300gg–

1 1(b)(2)) is amended by adding after and below
2 paragraph (1) the following:

3 “In applying paragraph (2), a health insurance issuer may
4 vary premiums and cost-sharing under health insurance
5 coverage by up to 50 percent of the value of the benefits
6 under the coverage based on participation in a standards-
7 based wellness program.”.

8 (B) EFFECTIVE DATE.—The amendment
9 made by paragraph (1) shall apply to health in-
10 surance coverage offered or renewed on and
11 after the date that is 1 year after the date of
12 the enactment of this Act.

13 (c) CONFORMING AMENDMENTS TO IRC.—

14 (1) IN GENERAL.—Section 9802(b)(2) of the
15 Internal Revenue Code of 1986 is amended by add-
16 ing after and below subparagraph (B) the following:
17 “In applying subparagraph (B), a group health plan
18 (or a health insurance issuer with respect to health
19 insurance coverage) may vary premiums and cost-
20 sharing by up to 50 percent of the value of the bene-
21 fits under the plan (or coverage) based on partici-
22 pation in a standards-based wellness program.”.

23 (2) EFFECTIVE DATE.—The amendment made
24 by paragraph (1) shall apply to plan years beginning

1 more than 1 year after the date of the enactment of
2 this Act.

3 **DIVISION F—PROTECTING**
4 **TAXPAYERS**

5 **SEC. 601. PROVIDE FULL FUNDING TO HHS OIG AND**
6 **HCFAC.**

7 (a) HCFAC FUNDING.— Section 1817(k)(3)(A) of
8 the Social Security Act (42 U.S.C. 1395i(k)(3)(A)) is
9 amended—

10 (1) in clause (i)—

11 (A) in subclause (IV), by striking “2009,
12 and 2010” and inserting “and 2009”; and

13 (B) by amending subclause (V) to read as
14 follows:

15 “(V) for each fiscal year after fis-
16 cal year 2009, \$300,000,000.”; and

17 (2) in clause (ii)—

18 (A) in subclause (IX), by striking “2009,
19 and 2010” and inserting “and 2009”; and

20 (B) in subclause (X), by striking “2010”
21 and inserting “2009” and by inserting before
22 the period at the end the following: “, plus the
23 amount by which the amount made available
24 under clause (i)(V) for fiscal year 2010 exceeds

1 shall be expended for a health benefits plan that includes
2 coverage of abortion.

3 **“SEC. 303. TREATMENT OF ABORTIONS RELATED TO RAPE,**
4 **INCEST, OR PRESERVING THE LIFE OF THE**
5 **MOTHER.**

6 “The limitations established in sections 301 and 302
7 shall not apply to an abortion—

8 “(1) if the pregnancy is the result of an act of
9 rape or incest; or

10 “(2) in the case where a woman suffers from a
11 physical disorder, physical injury, or physical illness
12 that would, as certified by a physician, place the
13 woman in danger of death unless an abortion is per-
14 formed, including a life-endangering physical condi-
15 tion caused by or arising from the pregnancy itself.

16 **“SEC. 304. CONSTRUCTION RELATING TO SUPPLEMENTAL**
17 **COVERAGE.**

18 “Nothing in this chapter shall be construed as pro-
19 hibiting any individual, entity, or State or locality from
20 purchasing separate supplemental abortion plan or cov-
21 erage that includes abortion so long as such plan or cov-
22 erage is paid for entirely using only funds not authorized
23 or appropriated by federal law and such plan or coverage
24 shall not be purchased using matching funds required for

1 a federally subsidized program, including a State's or lo-
2 cality's contribution of Medicaid matching funds.

3 **“SEC. 305. CONSTRUCTION RELATING TO THE USE OF NON-
4 FEDERAL FUNDS FOR HEALTH COVERAGE.**

5 “Nothing in this chapter shall be construed as re-
6 stricting the ability of any managed care provider or other
7 organization from offering abortion coverage or the ability
8 of a State to contract separately with such a provider or
9 organization for such coverage with funds not authorized
10 or appropriated by federal law and such plan or coverage
11 shall not be purchased using matching funds required for
12 a federally subsidized program, including a State's or lo-
13 cality's contribution of Medicaid matching funds.

14 **“SEC. 306. NO GOVERNMENT DISCRIMINATION AGAINST
15 CERTAIN HEALTH CARE ENTITIES.**

16 “(a) IN GENERAL.—No funds authorized or appro-
17 priated by federal law may be made available to a Federal
18 agency or program, or to a State or local government, if
19 such agency, program, or government subjects any institu-
20 tional or individual health care entity to discrimination on
21 the basis that the health care entity does not provide, pay
22 for, provide coverage of, or refer for abortions.

23 “(b) HEALTH CARE ENTITY DEFINED.—For pur-
24 poses of this section, the term ‘health care entity’ includes
25 an individual physician or other health care professional,

1 a hospital, a provider-sponsored organization, a health
2 maintenance organization, a health insurance plan, or any
3 other kind of health care facility, organization, or plan.”.

4 **SEC. 603. IMPROVED ENFORCEMENT OF THE MEDICARE**
5 **AND MEDICAID SECONDARY PAYER PROVI-**
6 **SIONS.**

7 (a) MEDICARE.—

8 (1) IN GENERAL.—The Secretary, in coordina-
9 tion with the Inspector General of the Department
10 of Health and Human Services, shall provide
11 through the Coordination of Benefits Contractor for
12 the identification of instances where the Medicare
13 program should be, but is not, acting as a secondary
14 payer to an individual’s private health benefits cov-
15 erage under section 1862(b) of the Social Security
16 Act (42 U.S.C. 1395y(b)).

17 (2) UPDATING PROCEDURES.—The Secretary
18 shall update procedures for identifying and resolving
19 credit balance situations which occur under the
20 Medicare program when payment under such title
21 and from other health benefit plans exceed the pro-
22 viders’ charges or the allowed amount.

23 (3) REPORT ON IMPROVED ENFORCEMENT.—
24 Not later than 1 year after the date of the enact-
25 ment of this Act, the Secretary shall submit a report

1 to Congress on progress made in improved enforce-
2 ment of the Medicare secondary payer provisions, in-
3 cluding recoupment of credit balances.

4 (b) MEDICAID.—Section 1903 of the Social Security
5 Act (42 U.S.C. 1396b) is amended by adding at the end
6 the following new subsection:

7 “(aa) ENFORCEMENT OF PAYER OF LAST RESORT
8 PROVISIONS.—

9 “(1) SUBMISSION OF STATE PLAN AMEND-
10 MENT.—Each State shall submit, not later than 1
11 year after the date of the enactment of this sub-
12 section, a State plan amendment that details how
13 the State will become fully compliant with the re-
14 quirements of section 1902(a)(25).

15 “(2) BONUS FOR COMPLIANCE.—If a State sub-
16 mits a timely State plan amendment under para-
17 graph (1) that the Secretary determines provides for
18 full compliance of the State with the requirements of
19 section 1902(a)(25), the Secretary shall provide for
20 an additional payment to the State of \$1,000,000. If
21 a State certifies, to the Secretary’s satisfaction, that
22 it is already fully compliant with such requirements,
23 such amount shall be increased to \$2,000,000.

24 “(3) REDUCTION FOR NONCOMPLIANCE.—If a
25 State does not submit such an amendment, the Sec-

1 retary shall reduce the Federal medical assistance
2 percentage otherwise applicable under this title by 1
3 percentage point until the State submits such an
4 amendment.

5 “(4) ONGOING REDUCTION.—If at any time the
6 Secretary determines that a State is not in compli-
7 ance with section 1902(a)(25), regardless of the sta-
8 tus of the State’s submission of a State plan amend-
9 ment under this subsection or previous determina-
10 tions of compliance such requirements, the Secretary
11 shall reduce the Federal medical assistance percent-
12 age otherwise applicable under this title for the
13 State by 1 percentage point during the period of
14 non-compliance as determined by the Secretary.”.

15 **SEC. 604. STRENGTHEN MEDICARE PROVIDER ENROLL-**
16 **MENT STANDARDS AND SAFEGUARDS.**

17 (a) PROTECTING AGAINST THE FRAUDULENT USE
18 OF MEDICARE PROVIDER NUMBERS.—Subject to sub-
19 section (c)(2)—

20 (1) SCREENING NEW PROVIDERS.—As a condi-
21 tion of a provider of services or a supplier, including
22 durable medical equipment suppliers and home
23 health agencies, applying for the first time for a pro-
24 vider number under the Medicare program and be-
25 fore granting billing privileges under such title, the

1 Secretary shall screen the provider or supplier for a
2 criminal background or other financial or oper-
3 ational irregularities through fingerprinting, licen-
4 sure checks, site-visits, other database checks.

5 (2) APPLICATION FEES.—The Secretary shall
6 impose an application charge on such a provider or
7 supplier in order to cover the Secretary's costs in
8 performing the screening required under paragraph
9 (1) and that is revenue neutral to the Federal gov-
10 ernment.

11 (3) PROVISIONAL APPROVAL.—During an ini-
12 tial, provisional period (specified by the Secretary)
13 In which such a provider or supplier has been issued
14 such a number, the Secretary shall provide enhanced
15 oversight of the activities of such provider or sup-
16 plier under the Medicare program, such as through
17 prepayment review and payment limitations.

18 (4) PENALTIES FOR FALSE STATEMENTS.—In
19 the case of a provider or supplier that makes a false
20 statement in an application for such a number, the
21 Secretary may exclude the provider or supplier from
22 participation under the Medicare program, or may
23 impose a civil money penalty (in the amount de-
24 scribed in section 1128A(a)(4) of the Social Security
25 Act), in the same manner as the Secretary may im-

1 pose such an exclusion or penalty under sections
2 1128 and 1128A, respectively, of such Act in the
3 case of knowing presentation of a false claim de-
4 scribed in section 1128A(a)(1)(A) of such Act.

5 (5) DISCLOSURE REQUIREMENTS.—With re-
6 spect to approval of such an application, the Sec-
7 retary—

8 (A) shall require applicants to disclose pre-
9 vious affiliation with enrolled entities that have
10 uncollected debt related to the Medicare or
11 Medicaid programs;

12 (B) may deny approval if the Secretary de-
13 termines that these affiliations pose undue risk
14 to the Medicare or Medicaid program, subject
15 to an appeals process for the applicant as deter-
16 mined by the Secretary; and

17 (C) may implement enhanced safeguards
18 (such as surety bonds).

19 (b) MORATORIA.—The Secretary may impose mora-
20 toria on approval of provider and supplier numbers under
21 the Medicare program for new providers of services and
22 suppliers as determined necessary to prevent or combat
23 fraud a period of delay for any one applicant cannot ex-
24 ceed 30 days unless cause is shown by the Secretary.

25 (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. LICENSURE 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 “(D) RESTRICTIONS ON BIOLOGICAL PROD-
14 UCTS CONTAINING DANGEROUS INGREDI-
15 ENTS.—If information in an application sub-
16 mitted under this subsection, in a supplement
17 to such an application, or otherwise available to
18 the Secretary shows that a biological product—

19 “(i) is, bears, or contains a select
20 agent or toxin listed in section 73.3 or
21 73.4 of title 42, section 121.3 or 121.4 of
22 title 9, or section 331.3 of title 7, Code of
23 Federal Regulations (or any successor reg-
24 ulations); or

1 “(ii) is, bears, or contains a controlled
2 substance in schedule I or II of section
3 202 of the Controlled Substances Act, as
4 listed in part 1308 of title 21, Code of
5 Federal Regulations (or any successor reg-
6 ulations);

7 the Secretary shall not license the biological
8 product under this subsection unless the Sec-
9 retary determines, after consultation with ap-
10 propriate national security and drug enforce-
11 ment agencies, that there would be no increased
12 risk to the security or health of the public from
13 licensing such biological product under this sub-
14 section.

15 “(6) EXCLUSIVITY FOR FIRST INTERCHANGE-
16 ABLE BIOLOGICAL PRODUCT.—Upon review of an
17 application submitted under this subsection relying
18 on the same reference product for which a prior bio-
19 logical product has received a determination of inter-
20 changeability for any condition of use, the Secretary
21 shall not make a determination under paragraph (4)
22 that the second or subsequent biological product is
23 interchangeable for any condition of use until the
24 earlier of—

1 “(A) 1 year after the first commercial
2 marketing of the first interchangeable bio-
3 similar biological product to be approved as
4 interchangeable for that reference product;

5 “(B) 18 months after—

6 “(i) a final court decision on all pat-
7 ents in suit in an action instituted under
8 subsection (l)(5) against the applicant that
9 submitted the application for the first ap-
10 proved interchangeable biosimilar biological
11 product; or

12 “(ii) the dismissal with or without
13 prejudice of an action instituted under sub-
14 section (l)(5) against the applicant that
15 submitted the application for the first ap-
16 proved interchangeable biosimilar biological
17 product; or

18 “(C)(i) 42 months after approval of the
19 first interchangeable biosimilar biological prod-
20 uct if the applicant that submitted such appli-
21 cation has been sued under subsection (l)(5)
22 and such litigation is still ongoing within such
23 42-month period; or

24 “(ii) 18 months after approval of the first
25 interchangeable biosimilar biological product if

1 the applicant that submitted such application
2 has not been sued under subsection (1)(5).

3 For purposes of this paragraph, the term ‘final court
4 decision’ means a final decision of a court from
5 which no appeal (other than a petition to the United
6 States Supreme Court for a writ of certiorari) has
7 been or can be taken.

8 “(7) EXCLUSIVITY FOR REFERENCE PROD-
9 UCT.—

10 “(A) EFFECTIVE DATE OF BIOSIMILAR AP-
11 PLICATION APPROVAL.—Approval of an applica-
12 tion under this subsection may not be made ef-
13 fective by the Secretary until the date that is
14 12 years after the date on which the reference
15 product was first licensed under subsection (a).

16 “(B) FILING PERIOD.—An application
17 under this subsection may not be submitted to
18 the Secretary until the date that is 4 years
19 after the date on which the reference product
20 was first licensed under subsection (a).

21 “(C) FIRST LICENSURE.—Subparagraphs
22 (A) and (B) shall not apply to a license for or
23 approval of—

24 “(i) a supplement for the biological
25 product that is the reference product; or

1 “(ii) a subsequent application filed by
2 the same sponsor or manufacturer of the
3 biological product that is the reference
4 product (or a licensor, predecessor in inter-
5 est, or other related entity) for—

6 “(I) a change (not including a
7 modification to the structure of the bi-
8 ological product) that results in a new
9 indication, route of administration,
10 dosing schedule, dosage form, delivery
11 system, delivery device, or strength; or

12 “(II) a modification to the struc-
13 ture of the biological product that
14 does not result in a change in safety,
15 purity, or potency.

16 “(8) PEDIATRIC STUDIES.—

17 “(A) EXCLUSIVITY.—If, before or after li-
18 censure of the reference product under sub-
19 section (a) of this section, the Secretary deter-
20 mines that information relating to the use of
21 such product in the pediatric population may
22 produce health benefits in that population, the
23 Secretary makes a written request for pediatric
24 studies (which shall include a timeframe for
25 completing such studies), the applicant or hold-

1 er of the approved application agrees to the re-
2 quest, such studies are completed using appro-
3 priate formulations for each age group for
4 which the study is requested within any such
5 timeframe, and the reports thereof are sub-
6 mitted and accepted in accordance with section
7 505A(d)(3) of the Federal Food, Drug, and
8 Cosmetic Act the period referred to in para-
9 graph (7)(A) of this subsection is deemed to be
10 12 years and 6 months rather than 12 years.

11 “(B) EXCEPTION.—The Secretary shall
12 not extend the period referred to in subpara-
13 graph (A) of this paragraph if the determina-
14 tion under section 505A(d)(3) of the Federal
15 Food, Drug, and Cosmetic Act is made later
16 than 9 months prior to the expiration of such
17 period.

18 “(C) APPLICATION OF CERTAIN PROVI-
19 SIONS.—The provisions of subsections (a), (d),
20 (e), (f), (h), (j), (k), and (l) of section 505A of
21 the Federal Food, Drug, and Cosmetic Act
22 shall apply with respect to the extension of a
23 period under subparagraph (A) of this para-
24 graph to the same extent and in the same man-
25 ner as such provisions apply with respect to the

1 extension of a period under subsection (b) or
2 (c) of section 505A of the Federal Food, Drug,
3 and Cosmetic Act.

4 “(9) GUIDANCE DOCUMENTS.—

5 “(A) IN GENERAL.—The Secretary may,
6 after opportunity for public comment, issue
7 guidance in accordance, except as provided in
8 subparagraph (B)(i), with section 701(h) of the
9 Federal Food, Drug, and Cosmetic Act with re-
10 spect to the licensure of a biological product
11 under this subsection. Any such guidance may
12 be general or specific.

13 “(B) PUBLIC COMMENT.—

14 “(i) IN GENERAL.—The Secretary
15 shall provide the public an opportunity to
16 comment on any proposed guidance issued
17 under subparagraph (A) before issuing
18 final guidance.

19 “(ii) INPUT REGARDING MOST VALU-
20 ABLE GUIDANCE.—The Secretary shall es-
21 tablish a process through which the public
22 may provide the Secretary with input re-
23 garding priorities for issuing guidance.

24 “(C) NO REQUIREMENT FOR APPLICATION
25 CONSIDERATION.—The issuance (or non-

1 issuance) of guidance under subparagraph (A)
2 shall not preclude the review of, or action on,
3 an application submitted under this subsection.

4 “(D) REQUIREMENT FOR PRODUCT CLASS-
5 SPECIFIC GUIDANCE.—If the Secretary issues
6 product class-specific guidance under subpara-
7 graph (A), such guidance shall include a de-
8 scription of—

9 “(i) the criteria that the Secretary will
10 use to determine whether a biological prod-
11 uct is highly similar to a reference product
12 in such product class; and

13 “(ii) the criteria, if available, that the
14 Secretary will use to determine whether a
15 biological product meets the standards de-
16 scribed in paragraph (4).

17 “(E) CERTAIN PRODUCT CLASSES.—

18 “(i) GUIDANCE.—The Secretary may
19 indicate in a guidance document that the
20 science and experience, as of the date of
21 such guidance, with respect to a product or
22 product class (not including any recom-
23 binant protein) does not allow approval of
24 an application for a license as provided

1 under this subsection for such product or
2 product class.

3 “(ii) MODIFICATION OR REVERSAL.—
4 The Secretary may issue a subsequent
5 guidance document under subparagraph
6 (A) to modify or reverse a guidance docu-
7 ment under clause (i).

8 “(iii) NO EFFECT ON ABILITY TO
9 DENY LICENSE.—Clause (i) shall not be
10 construed to require the Secretary to ap-
11 prove a product with respect to which the
12 Secretary has not indicated in a guidance
13 document that the science and experience,
14 as described in clause (i), does not allow
15 approval of such an application.

16 “(10) NAMING.—The Secretary shall ensure
17 that the labeling and packaging of each biological
18 product licensed under this subsection bears a name
19 that uniquely identifies the biological product and
20 distinguishes it from the reference product and any
21 other biological products licensed under this sub-
22 section following evaluation against such reference
23 product.

24 “(l) PATENT NOTICES; RELATIONSHIP TO FINAL AP-
25 PROVAL.—

1 “(1) DEFINITIONS.—For the purposes of this
2 subsection, the term—

3 “(A) ‘biosimilar product’ means the bio-
4 logical product that is the subject of the appli-
5 cation under subsection (k);

6 “(B) ‘relevant patent’ means a patent
7 that—

8 “(i) expires after the date specified in
9 subsection (k)(7)(A) that applies to the
10 reference product; and

11 “(ii) could reasonably be asserted
12 against the applicant due to the unauthor-
13 ized making, use, sale, or offer for sale
14 within the United States, or the importa-
15 tion into the United States of the bio-
16 similar product, or materials used in the
17 manufacture of the biosimilar product, or
18 due to a use of the biosimilar product in
19 a method of treatment that is indicated in
20 the application;

21 “(C) ‘reference product sponsor’ means the
22 holder of an approved application or license for
23 the reference product; and

24 “(D) ‘interested third party’ means a per-
25 son other than the reference product sponsor

1 that owns a relevant patent, or has the right to
2 commence or participate in an action for in-
3 fringement of a relevant patent.

4 “(2) HANDLING OF CONFIDENTIAL INFORMA-
5 TION.—Any entity receiving confidential information
6 pursuant to this subsection shall designate one or
7 more individuals to receive such information. Each
8 individual so designated shall execute an agreement
9 in accordance with regulations promulgated by the
10 Secretary. The regulations shall require each such
11 individual to take reasonable steps to maintain the
12 confidentiality of information received pursuant to
13 this subsection and use the information solely for
14 purposes authorized by this subsection. The obliga-
15 tions imposed on an individual who has received con-
16 fidential information pursuant to this subsection
17 shall continue until the individual returns or de-
18 stroys the confidential information, a court imposes
19 a protective order that governs the use or handling
20 of the confidential information, or the party pro-
21 viding the confidential information agrees to other
22 terms or conditions regarding the handling or use of
23 the confidential information.

24 “(3) PUBLIC NOTICE BY SECRETARY.—Within
25 30 days of acceptance by the Secretary of an appli-

1 cation filed under subsection (k), the Secretary shall
2 publish a notice identifying—

3 “(A) the reference product identified in the
4 application; and

5 “(B) the name and address of an agent
6 designated by the applicant to receive notices
7 pursuant to paragraph (4)(B).

8 “(4) EXCHANGES CONCERNING PATENTS.—

9 “(A) EXCHANGES WITH REFERENCE
10 PRODUCT SPONSOR.—

11 “(i) Within 30 days of the date of ac-
12 ceptance of the application by the Sec-
13 retary, the applicant shall provide the ref-
14 erence product sponsor with a copy of the
15 application and information concerning the
16 biosimilar product and its production. This
17 information shall include a detailed de-
18 scription of the biosimilar product, its
19 method of manufacture, and the materials
20 used in the manufacture of the product.

21 “(ii) Within 60 days of the date of re-
22 ceipt of the information required to be pro-
23 vided under clause (i), the reference prod-
24 uct sponsor shall provide to the applicant
25 a list of relevant patents owned by the ref-

1 erence product sponsor, or in respect of
2 which the reference product sponsor has
3 the right to commence an action of in-
4 fringement or otherwise has an interest in
5 the patent as such patent concerns the bio-
6 similar product.

7 “(iii) If the reference product sponsor
8 is issued or acquires an interest in a rel-
9 evant patent after the date on which the
10 reference product sponsor provides the list
11 required by clause (ii) to the applicant, the
12 reference product sponsor shall identify
13 that patent to the applicant within 30 days
14 of the date of issue of the patent, or the
15 date of acquisition of the interest in the
16 patent, as applicable.

17 “(B) EXCHANGES WITH INTERESTED
18 THIRD PARTIES.—

19 “(i) At any time after the date on
20 which the Secretary publishes a notice for
21 an application under paragraph (3), any
22 interested third party may provide notice
23 to the designated agent of the applicant
24 that the interested third party owns or has
25 rights under 1 or more patents that may

1 be relevant patents. The notice shall iden-
2 tify at least 1 patent and shall designate
3 an individual who has executed an agree-
4 ment in accordance with paragraph (2) to
5 receive confidential information from the
6 applicant.

7 “(ii) Within 30 days of the date of re-
8 ceiving notice pursuant to clause (i), the
9 applicant shall send to the individual des-
10 ignated by the interested third party the
11 information specified in subparagraph
12 (A)(i), unless the applicant and interested
13 third party otherwise agree.

14 “(iii) Within 90 days of the date of
15 receiving information pursuant to clause
16 (ii), the interested third party shall provide
17 to the applicant a list of relevant patents
18 which the interested third party owns, or
19 in respect of which the interested third
20 party has the right to commence or partici-
21 pate in an action for infringement.

22 “(iv) If the interested third party is
23 issued or acquires an interest in a relevant
24 patent after the date on which the inter-
25 ested third party provides the list required

1 by clause (iii), the interested third party
2 shall identify that patent within 30 days of
3 the date of issue of the patent, or the date
4 of acquisition of the interest in the patent,
5 as applicable.

6 “(C) IDENTIFICATION OF BASIS FOR IN-
7 FRINGEMENT.—For any patent identified under
8 clause (ii) or (iii) of subparagraph (A) or under
9 clause (iii) or (iv) of subparagraph (B), the ref-
10 erence product sponsor or the interested third
11 party, as applicable—

12 “(i) shall explain in writing why the
13 sponsor or the interested third party be-
14 lieves the relevant patent would be in-
15 fringed by the making, use, sale, or offer
16 for sale within the United States, or im-
17 portation into the United States, of the
18 biosimilar product or by a use of the bio-
19 similar product in treatment that is indi-
20 cated in the application;

21 “(ii) may specify whether the relevant
22 patent is available for licensing; and

23 “(iii) shall specify the number and
24 date of expiration of the relevant patent.

1 “(D) CERTIFICATION BY APPLICANT CON-
2 CERNING IDENTIFIED RELEVANT PATENTS.—
3 Not later than 45 days after the date on which
4 a patent is identified under clause (ii) or (iii) of
5 subparagraph (A) or under clause (iii) or (iv) of
6 subparagraph (B), the applicant shall send a
7 written statement regarding each identified pat-
8 ent to the party that identified the patent. Such
9 statement shall either—

10 “(i) state that the applicant will not
11 commence marketing of the biosimilar
12 product and has requested the Secretary to
13 not grant final approval of the application
14 before the date of expiration of the noticed
15 patent; or

16 “(ii) provide a detailed written expla-
17 nation setting forth the reasons why the
18 applicant believes—

19 “(I) the making, use, sale, or
20 offer for sale within the United
21 States, or the importation into the
22 United States, of the biosimilar prod-
23 uct, or the use of the biosimilar prod-
24 uct in a treatment indicated in the ap-

1 plication, would not infringe the pat-
2 ent; or

3 “**(II)** the patent is invalid or un-
4 enforceable.

5 “**(5) ACTION FOR INFRINGEMENT INVOLVING**
6 **REFERENCE PRODUCT SPONSOR.**—If an action for
7 infringement concerning a relevant patent identified
8 by the reference product sponsor under clause (ii) or
9 (iii) of paragraph (4)(A), or by an interested third
10 party under clause (iii) or (iv) of paragraph (4)(B),
11 is brought within 60 days of the date of receipt of
12 a statement under paragraph (4)(D)(ii), and the
13 court in which such action has been commenced de-
14 termines the patent is infringed prior to the date ap-
15 plicable under subsection (k)(7)(A) or (k)(8), the
16 Secretary shall make approval of the application ef-
17 fective on the day after the date of expiration of the
18 patent that has been found to be infringed. If more
19 than one such patent is found to be infringed by the
20 court, the approval of the application shall be made
21 effective on the day after the date that the last such
22 patent expires.

23 “**(6) NOTIFICATION OF AGREEMENTS.**—

24 “**(A) REQUIREMENTS.**—

1 “(i) AGREEMENT BETWEEN BIO-
2 SIMILAR PRODUCT APPLICANT AND REF-
3 ERENCE PRODUCT SPONSOR.—If a bio-
4 similar product applicant under subsection
5 (k) and the reference product sponsor
6 enter into an agreement described in sub-
7 paragraph (B), the applicant and sponsor
8 shall each file the agreement in accordance
9 with subparagraph (C).

10 “(ii) AGREEMENT BETWEEN BIO-
11 SIMILAR PRODUCT APPLICANTS.—If 2 or
12 more biosimilar product applicants submit
13 an application under subsection (k) for bio-
14 similar products with the same reference
15 product and enter into an agreement de-
16 scribed in subparagraph (B), the appli-
17 cants shall each file the agreement in ac-
18 cordance with subparagraph (C).

19 “(B) SUBJECT MATTER OF AGREEMENT.—
20 An agreement described in this subparagraph—

21 “(i) is an agreement between the bio-
22 similar product applicant under subsection
23 (k) and the reference product sponsor or
24 between 2 or more biosimilar product ap-

1 plicants under subsection (k) regarding the
2 manufacture, marketing, or sale of—

3 “(I) the biosimilar product (or
4 biosimilar products) for which an ap-
5 plication was submitted; or

6 “(II) the reference product;

7 “(ii) includes any agreement between
8 the biosimilar product applicant under sub-
9 section (k) and the reference product spon-
10 sor or between 2 or more biosimilar prod-
11 uct applicants under subsection (k) that is
12 contingent upon, provides a contingent
13 condition for, or otherwise relates to an
14 agreement described in clause (i); and

15 “(iii) excludes any agreement that
16 solely concerns—

17 “(I) purchase orders for raw ma-
18 terial supplies;

19 “(II) equipment and facility con-
20 tracts;

21 “(III) employment or consulting
22 contracts; or

23 “(IV) packaging and labeling
24 contracts.

25 “(C) FILING.—

1 “(i) IN GENERAL.—The text of an
2 agreement required to be filed by subpara-
3 graph (A) shall be filed with the Assistant
4 Attorney General and the Federal Trade
5 Commission not later than—

6 “(I) 10 business days after the
7 date on which the agreement is exe-
8 cuted; and

9 “(II) prior to the date of the first
10 commercial marketing of, for agree-
11 ments described in subparagraph
12 (A)(i), the biosimilar product that is
13 the subject of the application or, for
14 agreements described in subparagraph
15 (A)(ii), any biosimilar product that is
16 the subject of an application described
17 in such subparagraph.

18 “(ii) IF AGREEMENT NOT REDUCED
19 TO TEXT.—If an agreement required to be
20 filed by subparagraph (A) has not been re-
21 duced to text, the persons required to file
22 the agreement shall each file written de-
23 scriptions of the agreement that are suffi-
24 cient to disclose all the terms and condi-
25 tions of the agreement.

1 “(iii) CERTIFICATION.—The chief ex-
2 ecutive officer or the company official re-
3 sponsible for negotiating any agreement re-
4 quired to be filed by subparagraph (A)
5 shall include in any filing under this para-
6 graph a certification as follows: ‘I declare
7 under penalty of perjury that the following
8 is true and correct: The materials filed
9 with the Federal Trade Commission and
10 the Department of Justice under section
11 351(l)(6) of the Public Health Service Act,
12 with respect to the agreement referenced in
13 this certification: (1) represent the com-
14 plete, final, and exclusive agreement be-
15 tween the parties; (2) include any ancillary
16 agreements that are contingent upon, pro-
17 vide a contingent condition for, or are oth-
18 erwise related to, the referenced agree-
19 ment; and (3) include written descriptions
20 of any oral agreements, representations,
21 commitments, or promises between the
22 parties that are responsive to such section
23 and have not been reduced to writing.’.

24 “(D) DISCLOSURE EXEMPTION.—Any in-
25 formation or documentary material filed with

1 the Assistant Attorney General or the Federal
2 Trade Commission pursuant to this paragraph
3 shall be exempt from disclosure under section
4 552 of title 5, United States Code, and no such
5 information or documentary material may be
6 made public, except as may be relevant to any
7 administrative or judicial action or proceeding.
8 Nothing in this subparagraph prevents disclo-
9 sure of information or documentary material to
10 either body of the Congress or to any duly au-
11 thorized committee or subcommittee of the Con-
12 gress.

13 “(E) ENFORCEMENT.—

14 “(i) CIVIL PENALTY.—Any person
15 that violates a provision of this paragraph
16 shall be liable for a civil penalty of not
17 more than \$11,000 for each day on which
18 the violation occurs. Such penalty may be
19 recovered in a civil action—

20 “(I) brought by the United
21 States; or

22 “(II) brought by the Federal
23 Trade Commission in accordance with
24 the procedures established in section

1 16(a)(1) of the Federal Trade Com-
2 mission Act.

3 “(ii) COMPLIANCE AND EQUITABLE
4 RELIEF.—If any person violates any provi-
5 sion of this paragraph, the United States
6 district court may order compliance, and
7 may grant such other equitable relief as
8 the court in its discretion determines nec-
9 essary or appropriate, upon application of
10 the Assistant Attorney General or the Fed-
11 eral Trade Commission.

12 “(F) RULEMAKING.—The Federal Trade
13 Commission, with the concurrence of the Assist-
14 ant Attorney General and by rule in accordance
15 with section 553 of title 5, United States Code,
16 consistent with the purposes of this para-
17 graph—

18 “(i) may define the terms used in this
19 paragraph;

20 “(ii) may exempt classes of persons or
21 agreements from the requirements of this
22 paragraph; and

23 “(iii) may prescribe such other rules
24 as may be necessary and appropriate to
25 carry out the purposes of this paragraph.

1 “(G) SAVINGS CLAUSE.—Any action taken
2 by the Assistant Attorney General or the Fed-
3 eral Trade Commission, or any failure of the
4 Assistant Attorney General or the Commission
5 to take action, under this paragraph shall not
6 at any time bar any proceeding or any action
7 with respect to any agreement between a bio-
8 similar product applicant under subsection (k)
9 and the reference product sponsor, or any
10 agreement between biosimilar product appli-
11 cants under subsection (k), under any other
12 provision of law, nor shall any filing under this
13 paragraph constitute or create a presumption of
14 any violation of any competition laws.”.

15 (b) DEFINITIONS.—Section 351(i) of the Public
16 Health Service Act (42 U.S.C. 262(i)) is amended—

17 (1) by striking “In this section, the term ‘bio-
18 logical product’ means” and inserting the following:

19 “In this section:

20 “(1) The term ‘biological product’ means”;

21 (2) in paragraph (1), as so designated, by in-
22 serting “protein (except any chemically synthesized
23 polypeptide),” after “allergenic product,”; and

24 (3) by adding at the end the following:

1 “(2) The term ‘biosimilar’ or ‘biosimilarity’, in
2 reference to a biological product that is the subject
3 of an application under subsection (k), means—

4 “(A) that the biological product is highly
5 similar to the reference product notwith-
6 standing minor differences in clinically inactive
7 components; and

8 “(B) there are no clinically meaningful dif-
9 ferences between the biological product and the
10 reference product in terms of the safety, purity,
11 and potency of the product.

12 “(3) The term ‘interchangeable’ or ‘inter-
13 changeability’, in reference to a biological product
14 that is shown to meet the standards described in
15 subsection (k)(4), means that the biological product
16 may be substituted for the reference product without
17 the intervention of the health care provider who pre-
18 scribed the reference product.

19 “(4) The term ‘reference product’ means the
20 single biological product licensed under subsection
21 (a) against which a biological product is evaluated in
22 an application submitted under subsection (k).”.

23 (c) PRODUCTS PREVIOUSLY APPROVED UNDER SEC-
24 TION 505.—

1 (1) REQUIREMENT TO FOLLOW SECTION 351.—
2 Except as provided in paragraph (2), an application
3 for a biological product shall be submitted under
4 section 351 of the Public Health Service Act (42
5 U.S.C. 262) (as amended by this Act).

6 (2) EXCEPTION.—An application for a biologi-
7 cal product may be submitted under section 505 of
8 the Federal Food, Drug, and Cosmetic Act (21
9 U.S.C. 355) if—

10 (A) such biological product is in a product
11 class for which a biological product in such
12 product class is the subject of an application
13 approved under such section 505 not later than
14 the date of enactment of this Act; and

15 (B) such application—

16 (i) has been submitted to the Sec-
17 retary of Health and Human Services (re-
18 ferred to in this Act as the “Secretary”)
19 before the date of enactment of this Act;
20 or

21 (ii) is submitted to the Secretary not
22 later than the date that is 10 years after
23 the date of enactment of this Act.

24 (3) LIMITATION.—Notwithstanding paragraph
25 (2), an application for a biological product may not

1 be submitted under section 505 of the Federal Food,
2 Drug, and Cosmetic Act (21 U.S.C. 355) if there is
3 another biological product approved under sub-
4 section (a) of section 351 of the Public Health Serv-
5 ice Act that could be a reference product with re-
6 spect to such application (within the meaning of
7 such section 351) if such application were submitted
8 under subsection (k) of such section 351.

9 (4) DEEMED APPROVED UNDER SECTION 351.—
10 An approved application for a biological product
11 under section 505 of the Federal Food, Drug, and
12 Cosmetic Act (21 U.S.C. 355) shall be deemed to be
13 a license for the biological product under such sec-
14 tion 351 on the date that is 10 years after the date
15 of enactment of this Act.

16 (5) DEFINITIONS.—For purposes of this sub-
17 section, the term “biological product” has the mean-
18 ing given such term under section 351 of the Public
19 Health Service Act (42 U.S.C. 262) (as amended by
20 this Act).

21 **SEC. 702. FEES RELATING TO BIOSIMILAR BIOLOGICAL**
22 **PRODUCTS.**

23 Subparagraph (B) of section 735(1) of the Federal
24 Food, Drug, and Cosmetic Act (21 U.S.C. 379g(1)) is
25 amended by inserting “, including licensure of a biological

1 product under section 351(k) of such Act” before the pe-
2 riod at the end.

3 **SEC. 703. AMENDMENTS TO CERTAIN PATENT PROVISIONS.**

4 (a) Section 271(e)(2) of title 35, United States Code
5 is amended—

6 (1) in subparagraph (A), by striking “or” after
7 “patent,”;

8 (2) in subparagraph (B), by adding “or” after
9 the comma at the end;

10 (3) by inserting the following after subpara-
11 graph (B):

12 “(C) a statement under section
13 351(l)(4)(D)(ii) of the Public Health Service
14 Act,”; and

15 (4) in the matter following subparagraph (C)
16 (as added by paragraph (3)), by inserting before the
17 period the following: “, or if the statement described
18 in subparagraph (C) is provided in connection with
19 an application to obtain a license to engage in the
20 commercial manufacture, use, or sale of a biological
21 product claimed in a patent or the use of which is
22 claimed in a patent before the expiration of such
23 patent”.

1 (b) Section 271(e)(4) of title 35, United States Code,
2 is amended by striking “in paragraph (2)” in both places
3 it appears and inserting “in paragraph (2)(A) or (2)(B)”.

