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

Base text: HR 3962 as posted for Rules

Strike all after the enacting clause and insert the following:

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

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

(b) PURPOSE.—The purpose of this Act is to take meaningful steps to lower health care costs and increase access to health insurance coverage (especially for individuals with preexisting conditions) without—

(1) raising taxes;

(2) cutting Medicare benefits for seniors;

(3) adding to the national deficit;

(4) intervening in the doctor-patient relationship; or

(5) instituting a government takeover of health care.

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

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.

(a) STATE REQUIREMENT.—

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

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

(i) a qualified State reinsurance program described in subsection (b); or

(ii) qualifying State high risk pool described in subsection (c)(1); and

(B) subject to paragraph (4), apply to the operation of such a program from State funds an amount equivalent to the portion of State funds derived from State premium assessments (as defined by the Secretary) that are not otherwise used on State health care programs.

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

(A) STATES NOT OPERATING A QUALIFIED HIGH RISK POOL.—In the case of a State that is not operating a current section 2745 qualified high risk pool as of the date of the enactment of this Act—

(i) the State may only meet the requirement of paragraph (1) through the operation of a qualified State reinsurance program described in subsection (b); and

(ii) the State's operation of such a reinsurance program shall be treated, for purposes of section 2745 of the Public Health Service Act, as the operation of a qualified high risk pool described in such section.

(B) STATE OPERATING A QUALIFIED HIGH RISK POOL.—In the case of a State that is operating a current section 2745 qualified high risk pool as of the date of the enactment of this Act—

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

(ii) the State may use premium assessment funds described in paragraph (1)(B) to transition from operation of such a pool to operation of a qualified State reinsurance program described in subsection (b).

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

fiscal health, as determined in accordance with standards established by the National Association of Insurance Commissioners and as approved by the State Insurance Commissioner involved, the requirement of paragraph (1)(B) shall be deemed to be met.

(b) QUALIFIED STATE REINSURANCE PROGRAM.—

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

(2) FORM OF PROGRAM.—A qualified State reinsurance program may provide reinsurance—

(A) on a prospective or retrospective basis; and

(B) on a basis that protects health insurance issuers against the annual aggregate spending of their enrollees as well as purchase protection against individual catastrophic costs.

(3) SATISFACTION OF HIPAA REQUIREMENT.—A qualified State reinsurance program shall be deemed, for purposes of section 2745 of the Public

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

(c) QUALIFYING STATE HIGH RISK POOL.—

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

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

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

(C) The pool must eliminate any waiting lists so that all eligible residents who are seeking coverage through the pool should be allowed to receive coverage through the pool.

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

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

premium for applicable standard risk rates in that State.

(F) The pool must conduct education and outreach initiatives so that residents and brokers understand that the pool is available to eligible residents.

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

(2) VERIFICATION OF CITIZENSHIP OR ALIEN QUALIFICATION.—

(A) IN GENERAL.—Notwithstanding any other provision of law, only citizens and nationals of the United States shall be eligible to participate in a qualifying State high risk pool that receives funds under section 2745 of the Public Health Service Act or this section.

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

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

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

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

(d) WAIVERS.—In order to accommodate new and innovative programs, the Secretary may waive such requirements of this section for qualified State reinsurance programs and for qualifying State high risk pools as the Secretary deems appropriate.

(e) FUNDING.—In addition to any other amounts appropriated, there is appropriated to carry out section 2745 of the Public Health Service Act (including through a program or pool described in subsection (a)(1)), $15,000,000,000 for the period of fiscal years 2010 through 2019.

(f) DEFINITIONS.—In this section:

(1) HEALTH INSURANCE COVERAGE; HEALTH INSURANCE ISSUER.—The terms ''health insurance

coverage'' and ''health insurance issuer'' have the meanings given such terms in section 2791 of the Public Health Service Act.

(2) CURRENT SECTION 2745 QUALIFIED HIGH RISK POOL.—The term ''current section 2745 qualified high risk pool'' has the meaning given the term ''qualified high risk pool'' under section 2745(g) of the Public Health Service Act as in effect as of the date of the enactment of this Act.

(3) SECRETARY.—The term ''Secretary'' means Secretary of Health and Human Services.

(4) STANDARD RISK RATE.—The term ''standard risk rate'' means a rate that—

(A) is determined under the State high risk pool by considering the premium rates charged by other health insurance issuers offering health insurance coverage to individuals in the insurance market served;

(B) is established using reasonable actuarial techniques; and

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

(5) STATE.—The term ''State'' means any of the 50 States or the District of Columbia.

SEC. 102. ELIMINATION OF CERTAIN REQUIREMENTS FOR GUARANTEED AVAILABILITY IN INDIVIDUAL MARKET.

(a) IN GENERAL.—Section 2741(b) of the Public Health Service Act (42 U.S.C. 300gg–41(b)) is amended——

(1) in paragraph (1)—

(A) by striking ''(1)(A)'' and inserting ''(1)''; and

(B) by striking ''and (B)'' and all that follows up to the semicolon at the end;

(2) by adding ''and'' at the end of paragraph (2);

(3) in paragraph (3)—

(A) by striking ''(1)(A)'' and inserting ''(1)''; and

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

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

(b) EFFECTIVE DATE.—The amendments made by subsection (a) shall take effect on the date of the enactment of this Act.

SEC. 103. NO ANNUAL OR LIFETIME SPENDING CAPS.

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

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

SEC. 104. PREVENTING UNJUST CANCELLATION OF INSURANCE COVERAGE.

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

(1) in its heading, by inserting ''**, CONTINUATION IN FORCE, INCLUDING PROHIBITION OF RESCISSION,**'' after ''**GUARANTEED RENEWABILITY**'';

(2) in subsection (a), by inserting '', including without rescission,'' after ''continue in force''; and

(3) in subsection (b)(2), by inserting before the period at the end the following: '', including intentional concealment of material facts regarding a health condition related to the condition for which coverage is being claimed''.

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

"SEC. 2746. OPPORTUNITY FOR INDEPENDENT, EXTERNAL THIRD PARTY REVIEW IN CERTAIN CASES.

"(a) NOTICE AND REVIEW RIGHT.—If a health insurance issuer determines to nonrenew or not continue in force, including rescind, health insurance coverage for an individual in the individual market on the basis described in section 2742(b)(2) before such nonrenewal, discontinuation, or rescission, may take effect the issuer shall provide the individual with notice of such proposed nonrenewal, discontinuation, or rescission and an opportunity for a review of such determination by an independent, external third party under procedures specified by the Secretary.

"(b) INDEPENDENT DETERMINATION.—If the individual requests such review by an independent, external third party of a nonrenewal, discontinuation, or rescission of health insurance coverage, the coverage shall remain in effect until such third party determines that the coverage may be nonrenewed, discontinued, or rescinded under section 2742(b)(2).".

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

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

SEC. 111. STATE INNOVATION PROGRAMS.

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

(1) PAYMENTS TO STATES.—

(A) FOR PREMIUM REDUCTIONS IN THE SMALL GROUP MARKET.—If the Secretary determines that a State has reduced the average per capita premium for health insurance coverage in the small group market in year 3, in year 6, or year 9 (as defined in subsection (c)) below the premium baseline for such year (as defined paragraph (2)), the Secretary shall pay the State an amount equal to the product of—

(i) bonus premium percentage (as defined in paragraph (3)) for the State, market, and year; and

(ii) the maximum State premium payment amount (as defined in paragraph (4)) for the State, market, and year

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

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

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

(ii) the maximum State premium payment amount for the State, market, and year.

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

(A) for year 1, the average per capita premiums for health insurance coverage in such market in the State in such year; or

(B) for a subsequent year, the baseline for the market in the State for the previous year under this paragraph increased by a percentage specified in accordance with a formula established by the Secretary, in consultation with the Congressional Budget Office and the Bureau of the Census, that takes into account at least the following:

(i) GROWTH FACTOR.—The inflation in the costs of inputs to health care services in the year.

(ii) HISTORIC PREMIUM GROWTH RATES.—Historic growth rates, during the 10 years before year 1, of per capita premiums for health insurance coverage.

(iii) DEMOGRAPHIC CONSIDERATIONS.—Historic average changes in the demographics of the population covered that impact on the rate of growth of per capita health care costs.

(3) BONUS PREMIUM PERCENTAGE DEFINED.—

(A) IN GENERAL.—For purposes of this subsection, the term ''bonus premium percentage'' means, for the small group market or individual market in a State for a year, such percentage as determined in accordance with the following table based on the State's premium performance level (as defined in subparagraph (B)) for such market and year:

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

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

(B) PREMIUM PERFORMANCE LEVEL.—For purposes of this subsection, the term ''premium performance level'' means, for a State, market, and year, the percentage reduction in the average per capita premiums for health insurance coverage for the State, market, and year, as compared to the premium baseline for such State, market, and year.

(4) MAXIMUM STATE PREMIUM PAYMENT AMOUNT DEFINED.—For purposes of this subsection, the term ''maximum State premium payment amount'' means, for a State for the small group market or the individual market for a year, the product of—

(A) the proportion (as determined by the Secretary), of the number of nonelderly individuals lawfully residing in all the States who are enrolled in health insurance coverage in the re-

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

(B) the amount available for obligation from amounts appropriated under subsection (d) for such market with respect to performance in such year.

(5) METHODOLOGY FOR CALCULATING AVERAGE PER CAPITA PREMIUMS.—

(A) ESTABLISHMENT.—The Secretary shall establish, by rule and consistent with this subsection, a methodology for computing the average per capita premiums for health insurance coverage for the small group market and for the individual market in each State for each year beginning with year 1.

(B) ADJUSTMENTS.—Under such methodology, the Secretary shall provide for the following adjustments (in a manner determined appropriate by the Secretary):

(i) EXCLUSION OF ILLEGAL ALIENS.—An adjustment so as not to take into account enrollees who are not lawfully present in the United States and their premium costs.

(ii) TREATING STATE PREMIUM SUBSIDIES AS PREMIUM COSTS.—An adjustment so as to increase per capita premiums to remove the impact of premium subsidies made directly by a State to reduce health insurance premiums.

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

(b) PROGRAMS THAT REDUCE THE NUMBER OF UNINSURED.—

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

(A) bonus uninsured percentage (as defined in paragraph (3)) for the State and year; and

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

(2) UNINSURED BASELINE.—

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

(B) ADJUSTMENT.—The Secretary may, at the written request of a State, adjust the uninsured baseline for States for a year to take into account unanticipated and exceptional changes, such as an unanticipated migration, of nonelderly individuals into, or out of, States in a manner that does not reflect substantially the proportion of uninsured nonelderly residents in the States involved in year 1. Any such adjustment shall only be done in a manner that does not result in the average of the uninsured baselines for nonelderly residents for all States being changed.

(3) BONUS UNINSURED PERCENTAGE.—

(A) BONUS UNINSURED PERCENTAGE.—For purposes of this subsection, the term ''bonus uninsured percentage'' means, for a State for a year, such percentage as determined in accordance with the following table, based on the uninsured performance level (as defined in subparagraph (B)) for such State and year:

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

(B) UNINSURED PERFORMANCE LEVEL.—For purposes of this subsection, the term ''uninsured performance level'' means, for a State for a year, the reduction (expressed as a percentage) in the percentage of uninsured nonelderly residents in such State in the year as compared to the uninsured baseline for such State for such year.

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

section, the term ''maximum State uninsured payment amount'' means, for a State for a year, the product of—

(A) the proportion (as determined by the Secretary), of the number of uninsured nonelderly individuals lawfully residing in all the States in the year, who are residents of the State; and

(B) the amount available for obligation under this subsection from amounts appropriated under subsection (d) with respect to performance in such year.

(5) METHODOLOGY FOR COMPUTING THE PERCENTAGE OF UNINSURED NONELDERLY RESIDENTS IN A STATE.—

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

(B) RULES.—

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

surance coverage or other creditable coverage (as defined in section 9801(c)(1) of the Internal Revenue Code of 1986), except that such methodology shall rely upon data on the nonelderly and uninsured populations within each State in such year provided through population surveys conducted by federal agencies.

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

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

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

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

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

(2) HEALTH INSURANCE COVERAGE.—The term ''health insurance coverage'' has the meaning given such term in section 9832(b)(1) of the Internal Revenue Code of 1986.

(3) INDIVIDUAL MARKET.—Except as the Secretary may otherwise provide in the case of group health plans that have fewer than 2 participants as current employees on the first day of a plan year, the term ''individual market'' means the market for health insurance coverage offered to individuals other than in connection with a group health plan.

(4) SECRETARY.—The term ''Secretary'' means the Secretary of Health and Human Services.

(5) SMALL GROUP MARKET.—The term ''small group market'' means the market for health insurance coverage under which individuals obtain health insurance coverage (directly or through any arrangement) on behalf of themselves (and their dependents) through a group health plan maintained by an employer who employed on average at least 2 but

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

(6) STATE.—The term ''State'' means any of the 50 States and the District of Columbia.

(7) YEARS.—The terms ''year 1'', ''year 2'', ''year 3'', and similar subsequently numbered years mean 2010, 2011, 2012, and subsequent sequentially numbered years.

(d) APPROPRIATIONS; PAYMENTS.—

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

(A) SMALL GROUP MARKET.—

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

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

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

(III) $2,000,000,000 with respect to performance in year 9.

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

(B) INDIVIDUAL MARKET.—

(i) IN GENERAL.—Subject to clause (ii), from any funds in the Treasury not otherwise appropriated, there is appropriated for payments under subsection (a)(1)(B)—

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

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

(III) $1,000,000,000 with respect to performance in year 9.

(ii) AVAILABILITY OF APPROPRIATED FUNDS.—Of the funds appropriated under clause (i) that are not expended or obligated by the end of the year following the year for which the funds are appropriated—

(I) 75 percent shall remain available until expended for payments under subsection (a)(1)(B); and

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

(2) PAYMENTS FOR REDUCTIONS IN THE PERCENTAGE OF UNINSURED.—

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

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

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

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

(B) AVAILABILITY OF APPROPRIATED FUNDS.—Funds appropriated under subparagraph (A) shall remain available until expended.

(3) PAYMENT TIMING.—Payments under this section shall be made in a form and manner specified by the Secretary in the year after the performance year involved.

SEC. 112. HEALTH PLAN FINDERS.

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

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

(b) MULTI-STATE PLAN FINDERS.—

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

(2) SHARING OF INFORMATION.—States shall regulate the manner in which data is shared between plan finders to ensure consistency and accuracy in the information about health insurance plans contained in such finders.

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

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

(2) The plan finder shall present complete information on the costs and benefits of health insurance plans (including information on monthly premium, copayments, and deductibles) in a uniform manner that—

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

(B) is designed to allow consumers to easily compare such plans.

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

(4) The plan finder shall allow consumers to search and sort data on the health insurance plans in the plan finder on criteria such as coverage of specific benefits (such as coverage of disease management services or pediatric care services), as well as data available on quality.

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

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

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

(8) Notwithstanding subsection (f)(1), the plan finder shall assist individuals who are eligible for the Medicaid program under title XIX of the Social Security Act or State Children's Health Insurance Program under title XXI of such Act by including information on Medicaid options, eligibility, and how to enroll.

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

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

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

(A) The health insurance plan shall be actuarially sound.

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

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

(D) The health insurance plan shall disclose—

(i) all financial arrangements involving the sale and purchase of health insurance, such as the payment of fees and commissions; and

(ii) such arrangements may not be abusive.

(E) The health insurance plan shall maintain electronic health records that comply with the requirements of the American Recovery and Reinvestment Act of 2009 (Public Law 111–5) related to electronic health records.

(F) The health insurance plan shall make available to plan enrollees via the finder, whether by information provided to the finder or by a website link directing the enrollee from the finder to the health insurance plan website, data that includes the price and cost to the individual of services offered by a provider according to the terms and conditions of the

health plan. Data described in this paragraph is not made public by the finder, only made available to the individual once enrolled in the health plan.

(e) PROHIBITIONS.—

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

(2 CONFLICTS OF INTEREST.—

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

(i) be the private entity developing and maintaining a plan finder under subsections (a) and (b); or

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

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

(i) the private entity developing and maintaining a plan finder under subsections (a) and (b); or

(ii) the plan finder.

(f) CONSTRUCTION.—Nothing in this section shall be construed to allow the Secretary authority to regulate benefit packages or to prohibit health insurance brokers and agents from—

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

(2) marketing or offering health insurance products.

(g) PLAN FINDER DEFINED.—For purposes of this section, the term ''plan finder'' means a State plan finder under subsection (a) or a multi-State plan finder under subsection (b).

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

SEC. 113. ADMINISTRATIVE SIMPLIFICATION.

(a) OPERATING RULES FOR HEALTH INFORMATION TRANSACTIONS.—

(1) DEFINITION OF OPERATING RULES.—Section 1171 of the Social Security Act (42 U.S.C. 1320d) is amended by adding at the end the following:

''(9) OPERATING RULES.—The term 'operating rules' means the necessary business rules and guidelines for the electronic exchange of information that

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

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

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

''(J) Electronic funds transfers.''; and

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

''(g) OPERATING RULES.—

''(1) IN GENERAL.—The Secretary shall adopt a single set of operating rules for each transaction described in subsection (a)(2) with the goal of creating as much uniformity in the implementation of the electronic standards as possible. Such operating rules shall be consensus-based and reflect the necessary business rules affecting health plans and health care providers and the manner in which they operate pursuant to standards issued under Health Insurance Portability and Accountability Act of 1996.

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

ating rules developed by a qualified nonprofit entity, as selected by the Secretary, that meets the following requirements:

''(A) The entity focuses its mission on administrative simplification.

''(B) The entity demonstrates an established multi-stakeholder and consensus-based process for development of operating rules, including representation by or participation from health plans, health care providers, vendors, relevant Federal agencies, and other standard development organizations.

''(C) The entity has established a public set of guiding principles that ensure the operating rules and process are open and transparent.

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

''(E) The entity incorporates national standards, including the transaction standards

issued under Health Insurance Portability and Accountability Act of 1996.

''(F) The entity supports nondiscrimination and conflict of interest policies that demonstrate a commitment to open, fair, and nondiscriminatory practices.

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

''(3) REVIEW AND RECOMMENDATIONS.—The National Committee on Vital and Health Statistics shall—

''(A) review the operating rules developed by a nonprofit entity described under paragraph (2);

''(B) determine whether such rules represent a consensus view of the health care industry and are consistent with and do not alter current standards;

''(C) evaluate whether such rules are consistent with electronic standards adopted for health information technology; and

''(D) submit to the Secretary a recommendation as to whether the Secretary should adopt such rules.

''(4) IMPLEMENTATION.—

"(A) IN GENERAL.—The Secretary shall adopt operating rules under this subsection, by regulation in accordance with subparagraph (C), following consideration of the rules developed by the non-profit entity described in paragraph (2) and the recommendation submitted by the National Committee on Vital and Health Statistics under paragraph (3)(D) and having ensured consultation with providers.

"(B) ADOPTION REQUIREMENTS; EFFECTIVE DATES.—

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

"(ii) ELECTRONIC FUNDS TRANSFERS AND HEALTH CARE PAYMENT AND REMITTANCE ADVICE.—The set of operating rules for electronic funds transfers and

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

''(iii) OTHER COMPLETED TRANSACTIONS.—The set of operating rules for the remainder of the completed transactions described in subsection (a)(2), including health claims or equivalent encounter information, enrollment and disenrollment in a health plan, health plan premium payments, and referral certification and authorization, shall be adopted not later than July 1, 2014, in a manner ensuring that such rules are effective not later than January 1, 2016.

''(C) EXPEDITED RULEMAKING.—The Secretary shall promulgate an interim final rule applying any standard or operating rule recommended by the National Committee on Vital and Health Statistics pursuant to paragraph (3). The Secretary shall accept public comments on any interim final rule published under this

subparagraph for 60 days after the date of such publication.

''(h) COMPLIANCE.—

''(1) HEALTH PLAN CERTIFICATION.—

''(A) ELIGIBILITY FOR A HEALTH PLAN, HEALTH CLAIM STATUS, ELECTRONIC FUNDS TRANSFERS, HEALTH CARE PAYMENT AND REMITTANCE ADVICE.—Not later than December 31, 2013, a health plan shall file a statement with the Secretary, in such form as the Secretary may require, certifying that the data and information systems for such plan are in compliance with any applicable standards (as described under paragraph (7) of section 1171) and operating rules (as described under paragraph (9) of such section) for electronic funds transfers, eligibility for a health plan, health claim status, and health care payment and remittance advice, respectively.

''(B) OTHER COMPLETED TRANSACTIONS.—Not later than December 31, 2015, a health plan shall file a statement with the Secretary, in such form as the Secretary may require, certifying that the data and information systems for such plan are in compliance

with any applicable standards and operating rules for the remainder of the completed transactions described in subsection (a)(2), including health claims or equivalent encounter information, enrollment and disenrollment in a health plan, health plan premium payments, and referral certification and authorization, respectively. A health plan shall provide the same level of documentation to certify compliance with such transactions as is required to certify compliance with the transactions specified in subparagraph (A).

''(2) DOCUMENTATION OF COMPLIANCE.—A health plan shall provide the Secretary, in such form as the Secretary may require, with adequate documentation of compliance with the standards and operating rules described under paragraph (1). A health plan shall not be considered to have provided adequate documentation and shall not be certified as being in compliance with such standards, unless the health plan—

''(A) demonstrates to the Secretary that the plan conducts the electronic transactions specified in paragraph (1) in a manner that

fully complies with the regulations of the Secretary; and

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

''(3) SERVICE CONTRACTS.—A health plan shall be required to comply with any applicable certification and compliance requirements (and provide the Secretary with adequate documentation of such compliance) under this subsection for any entities that provide services pursuant to a contract with such health plan.

''(4) CERTIFICATION BY OUTSIDE ENTITY.—The Secretary may contract with an independent, outside entity to certify that a health plan has complied with the requirements under this subsection, provided that the certification standards employed by such entities are in accordance with any standards or rules issued by the Secretary.

''(5) COMPLIANCE WITH REVISED STANDARDS AND RULES.—A health plan (including entities described under paragraph (3)) shall comply with the certification and documentation requirements under this subsection for any interim final rule promul-

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

''(6) AUDITS OF HEALTH PLANS.—The Secretary shall conduct periodic audits to ensure that health plans (including entities described under paragraph (3)) are in compliance with any standards and operating rules that are described under paragraph (1).

''(i) REVIEW AND AMENDMENT OF STANDARDS AND RULES.—

''(1) ESTABLISHMENT.—Not later than January 1, 2014, the Secretary shall establish a review committee (as described under paragraph (4)).

''(2) EVALUATIONS AND REPORTS.—

''(A) HEARINGS.—Not later than April 1, 2014, and not less than biennially thereafter, the Secretary, acting through the review committee, shall conduct hearings to evaluate and review the existing standards and operating rules established under this section.

''(B) REPORT.—Not later than July 1, 2014, and not less than biennially thereafter, the review committee shall provide recommendations for updating and improving such standards and rules. The review committee shall recommend a single set of operating rules per transaction standard and maintain the goal of creating as much uniformity as possible in the implementation of the electronic standards.

''(3) INTERIM FINAL RULEMAKING.—

''(A) IN GENERAL.—Any recommendations to amend existing standards and operating rules that have been approved by the review committee and reported to the Secretary under paragraph (2)(B) shall be adopted by the Secretary through promulgation of an interim final rule not later than 90 days after receipt of the committee's report.

''(B) PUBLIC COMMENT.—

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

''(ii) EFFECTIVE DATE.—The effective date of any amendment to existing standards or operating rules that is adopted through an interim final rule published under this paragraph shall be 25 months following the close of such public comment period.

''(4) REVIEW COMMITTEE.—

''(A) DEFINITION.—For the purposes of this subsection, the term 'review committee' means a committee within the Department of Health and Human services that has been designated by the Secretary to carry out this subsection, including—

''(i) the National Committee on Vital and Health Statistics; or

''(ii) any appropriate committee as determined by the Secretary.

''(B) COORDINATION OF HIT STANDARDS.—In developing recommendations under this subsection, the review committee shall consider the standards approved by the Office of the National Coordinator for Health Information Technology.

''(j) PENALTIES.—

''(1) PENALTY FEE.—

''(A) IN GENERAL.—Not later than April 1, 2014, and annually thereafter, the Secretary shall assess a penalty fee (as determined under subparagraph (B)) against a health plan that has failed to meet the requirements under subsection (h) with respect to certification and documentation of compliance with the standards (and their operating rules) as described under paragraph (1) of such subsection.

''(B) FEE AMOUNT.—Subject to subparagraphs (C), (D), and (E), the Secretary shall assess a penalty fee against a health plan in the amount of $1 per covered life until certification is complete. The penalty shall be assessed per person covered by the plan for which its data systems for major medical policies are not in compliance and shall be imposed against the health plan for each day that the plan is not in compliance with the requirements under subsection (h).

''(C) ADDITIONAL PENALTY FOR MISREPRESENTATION.—A health plan that knowingly provides inaccurate or incomplete information in a statement of certification or docu-

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

''(D) ANNUAL FEE INCREASE.—The amount of the penalty fee imposed under this subsection shall be increased on an annual basis by the annual percentage increase in total national health care expenditures, as determined by the Secretary.

''(E) PENALTY LIMIT.—A penalty fee assessed against a health plan under this subsection shall not exceed, on an annual basis—

''(i) an amount equal to $20 per covered life under such plan; or

''(ii) an amount equal to $40 per covered life under the plan if such plan has knowingly provided inaccurate or incomplete information (as described under subparagraph (C)).

''(F) DETERMINATION OF COVERED INDIVIDUALS.—The Secretary shall determine the number of covered lives under a health plan based upon the most recent statements and fil-

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

''(2) NOTICE AND DISPUTE PROCEDURE.—The Secretary shall establish a procedure for assessment of penalty fees under this subsection that provides a health plan with reasonable notice and a dispute resolution procedure prior to provision of a notice of assessment by the Secretary of the Treasury (as described under paragraph (4)(B)).

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

''(4) COLLECTION OF PENALTY FEE.—

''(A) IN GENERAL.—The Secretary of the Treasury, acting through the Financial Management Service, shall administer the collection of penalty fees from health plans that have been identified by the Secretary in the penalty fee report provided under paragraph (3).

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

Secretary under this subsection. Such notice shall include the amount of the penalty fee assessed by the Secretary and the due date for payment of such fee to the Secretary of the Treasury (as described in subparagraph (C)).

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

''(D) UNPAID PENALTY FEES.—Any amount of a penalty fee assessed against a health plan under this subsection for which payment has not been made by the due date provided under subparagraph (C) shall be—

''(i) increased by the interest accrued on such amount, as determined pursuant to the underpayment rate established under section 6601 of the Internal Revenue Code of 1986; and

''(ii) treated as a past-due, legally enforceable debt owed to a Federal agency for purposes of section 6402(d) of the Internal Revenue Code of 1986.

''(E) ADMINISTRATIVE FEES.—Any fee charged or allocated for collection activities conducted by the Financial Management Service will be passed on to a health plan on a pro-rata basis and added to any penalty fee collected from the plan.''.

(b) PROMULGATION OF RULES.—

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

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

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

(1) in paragraph (23), by striking the ''or'' at the end;

(2) in paragraph (24), by striking the period and inserting ''; or''; and

(3) by inserting after paragraph (24) the following new paragraph:

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

(d) MEDICARE AND MEDICAID COMPLIANCE REPORTS.—Not later than July 1, 2013, the Secretary of Health and Human Services shall submit a report to the Chairs and Ranking Members of the Committee on Ways and Means and the Committee on Energy and Commerce of the House of Representatives and the Chairs and Ranking Members of the Committee on Health, Education, Labor, and Pensions and the Committee on Finance of the Senate on the extent to which the Medicare program and providers that serve beneficiaries under that program, and State Medicaid programs and providers that serve

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

DIVISION B—IMPROVING ACCESS TO HEALTH CARE

TITLE I—EXPANDING ACCESS AND LOWERING COSTS FOR SMALL BUSINESSES

SEC. 201. RULES GOVERNING ASSOCIATION HEALTH PLANS.

(a) IN GENERAL.—Subtitle B of title I of the Employee Retirement Income Security Act of 1974 is amended by adding after part 7 the following new part:

"PART 8—RULES GOVERNING ASSOCIATION HEALTH PLANS

"SEC. 801. ASSOCIATION HEALTH PLANS.

"(a) IN GENERAL.—For purposes of this part, the term 'association health plan' means a group health plan whose sponsor is (or is deemed under this part to be) described in subsection (b).

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

''(1) is organized and maintained in good faith, with a constitution and bylaws specifically stating its purpose and providing for periodic meetings on at least an annual basis, as a bona fide trade association, a bona fide industry association (including a rural electric cooperative association or a rural telephone cooperative association), a bona fide professional association, or a bona fide chamber of commerce (or similar bona fide business association, including a corporation or similar organization that operates on a cooperative basis (within the meaning of section 1381 of the Internal Revenue Code of 1986)), for substantial purposes other than that of obtaining or providing medical care;

''(2) is established as a permanent entity which receives the active support of its members and requires for membership payment on a periodic basis of dues or payments necessary to maintain eligibility for membership in the sponsor; and

''(3) does not condition membership, such dues or payments, or coverage under the plan on the basis of health status-related factors with respect to the employees of its members (or affiliated members), or the dependents of such employees, and does

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

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

"SEC. 802. CERTIFICATION OF ASSOCIATION HEALTH PLANS.

''(a) IN GENERAL.—The applicable authority shall prescribe by regulation a procedure under which, subject to subsection (b), the applicable authority shall certify association health plans which apply for certification as meeting the requirements of this part.

''(b) STANDARDS.—Under the procedure prescribed pursuant to subsection (a), in the case of an association health plan that provides at least one benefit option which does not consist of health insurance coverage, the applicable authority shall certify such plan as meeting the requirements of this part only if the applicable authority is satisfied that the applicable requirements of this part are met (or, upon the date on which the plan is to commence operations, will be met) with respect to the plan.

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

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

''(d) REQUIREMENTS FOR CONTINUED CERTIFICATION.—The applicable authority may provide by regulation for continued certification of association health plans under this part.

''(e) CLASS CERTIFICATION FOR FULLY INSURED PLANS.—The applicable authority shall establish a class certification procedure for association health plans under which all benefits consist of health insurance coverage. Under such procedure, the applicable authority shall provide for the granting of certification under this part to the plans in each class of such association health plans upon appropriate filing under such procedure in connection with plans in such class and payment of the prescribed fee under section 807(a).

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

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

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

''(3) a plan whose eligible participating employers represent one or more trades or businesses, or one or more industries, consisting of any of the following: agriculture; equipment and automobile dealerships; barbering and cosmetology; certified public accounting practices; child care; construction; dance, theatrical and orchestra productions; disinfecting and pest control; financial services; fishing; food service establishments; hospitals; labor organizations; logging; manufacturing (metals); mining; medical and dental practices; medical laboratories; professional consulting services; sanitary services; transportation (local and freight); warehousing; wholesaling/distributing; or any other trade or business or industry which has been indicated as having average or above-average risk or health claims experience by reason of State rate filings, denials of coverage, proposed premium rate levels, or other means demonstrated by such plan in accordance with regulations.

"SEC. 803. REQUIREMENTS RELATING TO SPONSORS AND BOARDS OF TRUSTEES.

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

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

''(1) FISCAL CONTROL.—The plan is operated, pursuant to a trust agreement, by a board of trustees which has complete fiscal control over the plan and which is responsible for all operations of the plan.

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

''(3) RULES GOVERNING RELATIONSHIP TO PARTICIPATING EMPLOYERS AND TO CONTRACTORS.—

''(A) BOARD MEMBERSHIP.—

''(i) IN GENERAL.—Except as provided in clauses (ii) and (iii), the members of the board of trustees are individuals selected from individuals who are the owners, officers, directors, or employees of the participating employers or who are partners in the participating employers and actively participate in the business.

''(ii) LIMITATION.—

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

''(II) LIMITED EXCEPTION FOR PROVIDERS OF SERVICES SOLELY ON BEHALF OF THE SPONSOR.—Officers or employees of a sponsor which is a service provider (other than a contract administrator) to the plan may be members of the board if they constitute not more than 25 percent of the membership of the board and they

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

''(III) TREATMENT OF PROVIDERS OF MEDICAL CARE.—In the case of a sponsor which is an association whose membership consists primarily of providers of medical care, subclause (I) shall not apply in the case of any service provider described in subclause (I) who is a provider of medical care under the plan.

''(iii) CERTAIN PLANS EXCLUDED.—Clause (i) shall not apply to an association health plan which is in existence on the date of the enactment of the Small Business Health Fairness Act of 2009.

''(B) SOLE AUTHORITY.—The board has sole authority under the plan to approve applications for participation in the plan and to contract with a service provider to administer the day-to-day affairs of the plan.

''(c) TREATMENT OF FRANCHISE NETWORKS.—In the case of a group health plan which is established and maintained by a franchiser for a franchise network consisting of its franchisees—

''(1) the requirements of subsection (a) and section 801(a) shall be deemed met if such requirements would otherwise be met if the franchiser were deemed to be the sponsor referred to in section 801(b), such network were deemed to be an association described in section 801(b), and each franchisee were deemed to be a member (of the association and the sponsor) referred to in section 801(b); and

''(2) the requirements of section 804(a)(1) shall be deemed met.

The Secretary may by regulation define for purposes of this subsection the terms 'franchiser', 'franchise network', and 'franchisee'.

"SEC. 804. PARTICIPATION AND COVERAGE REQUIREMENTS.

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

''(1) each participating employer must be—

''(A) a member of the sponsor,

''(B) the sponsor, or

''(C) an affiliated member of the sponsor with respect to which the requirements of subsection (b) are met,

except that, in the case of a sponsor which is a professional association or other individual-based association, if at least one of the officers, directors, or employees of an employer, or at least one of the individuals who are partners in an employer and who actively participates in the business, is a member or such an affiliated member of the sponsor, participating employers may also include such employer; and

''(2) all individuals commencing coverage under the plan after certification under this part must be—

''(A) active or retired owners (including self-employed individuals), officers, directors, or employees of, or partners in, participating employers; or

''(B) the beneficiaries of individuals described in subparagraph (A).

''(b) COVERAGE OF PREVIOUSLY UNINSURED EMPLOYEES.—In the case of an association health plan in existence on the date of the enactment of the Small Business Health Fairness Act of 2009, an affiliated member of the sponsor of the plan may be offered coverage under the plan as a participating employer only if—

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

''(2) during the 12-month period preceding the date of the offering of such coverage, the affiliated member has not maintained or contributed to a group health plan with respect to any of its employees who would otherwise be eligible to participate in such association health plan.

''(c) INDIVIDUAL MARKET UNAFFECTED.—The requirements of this subsection are met with respect to an association health plan if, under the terms of the plan, no participating employer may provide health insurance coverage in the individual market for any employee not covered under the plan which is similar to the coverage contemporaneously provided to employees of the employer under the plan, if such exclusion of the employee from coverage under the plan is based on a health status-related factor with respect to the employee and such employee would, but for such exclusion on such basis, be eligible for coverage under the plan.

''(d) PROHIBITION OF DISCRIMINATION AGAINST EMPLOYERS AND EMPLOYEES ELIGIBLE TO PARTICIPATE.—The requirements of this subsection are met with respect to an association health plan if—

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

''(2) upon request, any employer eligible to participate is furnished information regarding all coverage options available under the plan; and

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

''SEC. 805. OTHER REQUIREMENTS RELATING TO PLAN DOCUMENTS, CONTRIBUTION RATES, AND BENEFIT OPTIONS.

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

''(1) CONTENTS OF GOVERNING INSTRUMENTS.—The instruments governing the plan include a written instrument, meeting the requirements of an instrument required under section 402(a)(1), which—

''(A) provides that the board of trustees serves as the named fiduciary required for plans under section 402(a)(1) and serves in the capacity of a plan administrator (referred to in section 3(16)(A));

''(B) provides that the sponsor of the plan is to serve as plan sponsor (referred to in section 3(16)(B)); and

''(C) incorporates the requirements of section 806.

''(2) CONTRIBUTION RATES MUST BE NONDISCRIMINATORY.—

''(A) The contribution rates for any participating small employer do not vary on the basis of any health status-related factor in relation to employees of such employer or their beneficiaries and do not vary on the basis of the type of business or industry in which such employer is engaged.

''(B) Nothing in this title or any other provision of law shall be construed to preclude an association health plan, or a health insurance issuer offering health insurance coverage in connection with an association health plan, from—

''(i) setting contribution rates based on the claims experience of the plan; or

''(ii) varying contribution rates for small employers in a State to the extent that such rates could vary using the same methodology employed in such State for regulating premium rates in the small group market with respect to health insurance coverage offered in connection with bona fide associations (within the meaning of section 2791(d)(3) of the Public Health Service Act),

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

''(3) FLOOR FOR NUMBER OF COVERED INDIVIDUALS WITH RESPECT TO CERTAIN PLANS.—If any benefit option under the plan does not consist of health insurance coverage, the plan has as of the beginning of the plan year not fewer than 1,000 participants and beneficiaries.

''(4) MARKETING REQUIREMENTS.—

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

ployers coverage which does not consist of health insurance coverage in a manner comparable to the manner in which such agents are used to distribute health insurance coverage.

''(B) STATE-LICENSED INSURANCE AGENTS.—For purposes of subparagraph (A), the term 'State-licensed insurance agents' means one or more agents who are licensed in a State and are subject to the laws of such State relating to licensure, qualification, testing, examination, and continuing education of persons authorized to offer, sell, or solicit health insurance coverage in such State.

''(5) REGULATORY REQUIREMENTS.—Such other requirements as the applicable authority determines are necessary to carry out the purposes of this part, which shall be prescribed by the applicable authority by regulation.

''(b) ABILITY OF ASSOCIATION HEALTH PLANS TO DESIGN BENEFIT OPTIONS.—Subject to section 514(d), nothing in this part or any provision of State law (as defined in section 514(c)(1)) shall be construed to preclude an association health plan, or a health insurance issuer offering health insurance coverage in connection with an association health plan, from exercising its sole discretion

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

"SEC. 806. MAINTENANCE OF RESERVES AND PROVISIONS FOR SOLVENCY FOR PLANS PROVIDING HEALTH BENEFITS IN ADDITION TO HEALTH INSURANCE COVERAGE.

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

''(1) the benefits under the plan consist solely of health insurance coverage; or

''(2) if the plan provides any additional benefit options which do not consist of health insurance coverage, the plan—

''(A) establishes and maintains reserves with respect to such additional benefit options, in amounts recommended by the qualified actuary, consisting of—

''(i) a reserve sufficient for unearned contributions;

''(ii) a reserve sufficient for benefit liabilities which have been incurred, which have not been satisfied, and for which risk of loss has not yet been transferred, and for expected administrative costs with respect to such benefit liabilities;

''(iii) a reserve sufficient for any other obligations of the plan; and

''(iv) a reserve sufficient for a margin of error and other fluctuations, taking into account the specific circumstances of the plan; and

''(B) establishes and maintains aggregate and specific excess/stop loss insurance and solvency indemnification, with respect to such additional benefit options for which risk of loss has not yet been transferred, as follows:

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

in the amount of such percentage in specified circumstances in which the plan specifically provides for and maintains reserves in excess of the amounts required under subparagraph (A).

''(ii) The plan shall secure specific excess/stop loss insurance for the plan with an attachment point which is at least equal to an amount recommended by the plan's qualified actuary. The applicable authority may by regulation provide for adjustments in the amount of such insurance in specified circumstances in which the plan specifically provides for and maintains reserves in excess of the amounts required under subparagraph (A).

''(iii) The plan shall secure indemnification insurance for any claims which the plan is unable to satisfy by reason of a plan termination.

Any person issuing to a plan insurance described in clause (i), (ii), or (iii) of subparagraph (B) shall notify the Secretary of any failure of premium payment meriting cancellation of the policy prior to undertaking such a cancellation. Any regulations prescribed by the applicable author-

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

''(b) MINIMUM SURPLUS IN ADDITION TO CLAIMS RESERVES.—In the case of any association health plan described in subsection (a)(2), the requirements of this subsection are met if the plan establishes and maintains surplus in an amount at least equal to—

''(1) $500,000, or

''(2) such greater amount (but not greater than $2,000,000) as may be set forth in regulations prescribed by the applicable authority, considering the level of aggregate and specific excess/stop loss insurance provided with respect to such plan and other factors related to solvency risk, such as the plan's projected levels of participation or claims, the nature of the plan's liabilities, and the types of assets available to assure that such liabilities are met.

''(c) ADDITIONAL REQUIREMENTS.—In the case of any association health plan described in subsection (a)(2), the applicable authority may provide such additional requirements relating to reserves, excess/stop loss insurance, and indemnification insurance as the applicable authority

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

''(d) ADJUSTMENTS FOR EXCESS/STOP LOSS INSURANCE.—The applicable authority may provide for adjustments to the levels of reserves otherwise required under subsections (a) and (b) with respect to any plan or class of plans to take into account excess/stop loss insurance provided with respect to such plan or plans.

''(e) ALTERNATIVE MEANS OF COMPLIANCE.—The applicable authority may permit an association health plan described in subsection (a)(2) to substitute, for all or part of the requirements of this section (except subsection (a)(2)(B)(iii)), such security, guarantee, hold-harmless arrangement, or other financial arrangement as the applicable authority determines to be adequate to enable the plan to fully meet all its financial obligations on a timely basis and is otherwise no less protective of the interests of participants and beneficiaries than the requirements for which it is substituted. The applicable authority may take into account, for purposes of this subsection, evidence provided by the plan or sponsor which demonstrates an assumption of liability with respect to the plan. Such evidence may be in the form of a contract of indemnification, lien, bonding, insurance, letter of credit, recourse under

applicable terms of the plan in the form of assessments of participating employers, security, or other financial arrangement.

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

''(1) PAYMENTS BY CERTAIN PLANS TO ASSOCIATION HEALTH PLAN FUND.—

''(A) IN GENERAL.—In the case of an association health plan described in subsection (a)(2), the requirements of this subsection are met if the plan makes payments into the Association Health Plan Fund under this subparagraph when they are due. Such payments shall consist of annual payments in the amount of $5,000, and, in addition to such annual payments, such supplemental payments as the Secretary may determine to be necessary under paragraph (2). Payments under this paragraph are payable to the Fund at the time determined by the Secretary. Initial payments are due in advance of certification under this part. Payments shall continue to accrue until a plan's assets are distributed pursuant to a termination procedure.

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

''(C) CONTINUED DUTY OF THE SECRETARY.—The Secretary shall not cease to carry out the provisions of paragraph (2) on account of the failure of a plan to pay any payment when due.

''(2) PAYMENTS BY SECRETARY TO CONTINUE EXCESS/STOP LOSS INSURANCE COVERAGE AND INDEMNIFICATION INSURANCE COVERAGE FOR CERTAIN PLANS.—In any case in which the applicable authority determines that there is, or that there is reason to believe that there will be: (A) a failure to take necessary corrective actions under section 809(a) with respect to an association health plan described in subsection (a)(2); or (B) a termination of such a plan under section 809(b) or 810(b)(8) (and, if the applicable authority is not the Secretary, certifies such determination to the Secretary), the Secretary shall determine the amounts necessary to make payments to an insurer (designated by the

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

''(3) ASSOCIATION HEALTH PLAN FUND.—

''(A) IN GENERAL.—There is established on the books of the Treasury a fund to be known as the 'Association Health Plan Fund'. The Fund shall be available for making payments pursuant to paragraph (2). The Fund shall be credited with payments received pursuant to paragraph (1)(A), penalties received pursuant to paragraph (1)(B); and earnings on investments of amounts of the Fund under subparagraph (B).

''(B) INVESTMENT.—Whenever the Secretary determines that the moneys of the fund are in excess of current needs, the Secretary may request the investment of such amounts as the Secretary determines advisable by the Sec-

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

''(g) EXCESS/STOP LOSS INSURANCE.—For purposes of this section—

''(1) AGGREGATE EXCESS/STOP LOSS INSURANCE.—The term 'aggregate excess/stop loss insurance' means, in connection with an association health plan, a contract—

''(A) under which an insurer (meeting such minimum standards as the applicable authority may prescribe by regulation) provides for payment to the plan with respect to aggregate claims under the plan in excess of an amount or amounts specified in such contract;

''(B) which is guaranteed renewable; and

''(C) which allows for payment of premiums by any third party on behalf of the insured plan.

''(2) SPECIFIC EXCESS/STOP LOSS INSURANCE.—The term 'specific excess/stop loss insurance' means, in connection with an association health plan, a contract—

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

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

''(B) which is guaranteed renewable; and

''(C) which allows for payment of premiums by any third party on behalf of the insured plan.

''(h) INDEMNIFICATION INSURANCE.—For purposes of this section, the term 'indemnification insurance' means, in connection with an association health plan, a contract—

''(1) under which an insurer (meeting such minimum standards as the applicable authority may prescribe by regulation) provides for payment to the plan with respect to claims under the plan which the plan is unable to satisfy by reason of a termination pursuant to section 809(b) (relating to mandatory termination);

''(2) which is guaranteed renewable and noncancellable for any reason (except as the applicable authority may prescribe by regulation); and

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

''(i) RESERVES.—For purposes of this section, the term 'reserves' means, in connection with an association health plan, plan assets which meet the fiduciary standards under part 4 and such additional requirements regarding liquidity as the applicable authority may prescribe by regulation.

''(j) SOLVENCY STANDARDS WORKING GROUP.—

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

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

''(A) a representative of the National Association of Insurance Commissioners;

''(B) a representative of the American Academy of Actuaries;

''(C) a representative of the State governments, or their interests;

''(D) a representative of existing self-insured arrangements, or their interests;

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

''(F) a representative of multiemployer plans that are group health plans, or their interests.

''SEC. 807. REQUIREMENTS FOR APPLICATION AND RELATED REQUIREMENTS.

''(a) FILING FEE.—Under the procedure prescribed pursuant to section 802(a), an association health plan shall pay to the applicable authority at the time of filing an application for certification under this part a filing fee in the amount of $5,000, which shall be available in the case of the Secretary, to the extent provided in appropriation Acts, for the sole purpose of administering the certification procedures applicable with respect to association health plans.

''(b) INFORMATION TO BE INCLUDED IN APPLICATION FOR CERTIFICATION.—An application for certification under this part meets the requirements of this section only if it includes, in a manner and form which shall

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

''(1) IDENTIFYING INFORMATION.—The names and addresses of—

''(A) the sponsor; and

''(B) the members of the board of trustees of the plan.

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

''(3) BONDING REQUIREMENTS.—Evidence provided by the board of trustees that the bonding requirements of section 412 will be met as of the date of the application or (if later) commencement of operations.

''(4) PLAN DOCUMENTS.—A copy of the documents governing the plan (including any bylaws and trust agreements), the summary plan description, and other material describing the benefits that will be provided to participants and beneficiaries under the plan.

''(5) AGREEMENTS WITH SERVICE PROVIDERS.—A copy of any agreements between the

plan and contract administrators and other service providers.

''(6) FUNDING REPORT.—In the case of association health plans providing benefits options in addition to health insurance coverage, a report setting forth information with respect to such additional benefit options determined as of a date within the 120-day period ending with the date of the application, including the following:

''(A) RESERVES.—A statement, certified by the board of trustees of the plan, and a statement of actuarial opinion, signed by a qualified actuary, that all applicable requirements of section 806 are or will be met in accordance with regulations which the applicable authority shall prescribe.

''(B) ADEQUACY OF CONTRIBUTION RATES.—A statement of actuarial opinion, signed by a qualified actuary, which sets forth a description of the extent to which contribution rates are adequate to provide for the payment of all obligations and the maintenance of required reserves under the plan for the 12-month period beginning with such date within such 120-day period, taking into account the

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

''(C) CURRENT AND PROJECTED VALUE OF ASSETS AND LIABILITIES.—A statement of actuarial opinion signed by a qualified actuary, which sets forth the current value of the assets and liabilities accumulated under the plan and a projection of the assets, liabilities, income, and expenses of the plan for the 12-month period referred to in subparagraph (B). The income statement shall identify separately the plan's administrative expenses and claims.

''(D) COSTS OF COVERAGE TO BE CHARGED AND OTHER EXPENSES.—A statement of the costs of coverage to be charged, including an itemization of amounts for administration, reserves, and other expenses associated with the operation of the plan.

''(E) OTHER INFORMATION.—Any other information as may be determined by the applicable authority, by regulation, as necessary to carry out the purposes of this part.

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

''(d) NOTICE OF MATERIAL CHANGES.—In the case of any association health plan certified under this part, descriptions of material changes in any information which was required to be submitted with the application for the certification under this part shall be filed in such form and manner as shall be prescribed by the applicable authority by regulation. The applicable authority may require by regulation prior notice of material changes with respect to specified matters which might serve as the basis for suspension or revocation of the certification.

''(e) REPORTING REQUIREMENTS FOR CERTAIN ASSOCIATION HEALTH PLANS.—An association health plan certified under this part which provides benefit options in addition to health insurance coverage for such plan year shall meet the requirements of section 103 by filing an

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

''(f) ENGAGEMENT OF QUALIFIED ACTUARY.—The board of trustees of each association health plan which provides benefits options in addition to health insurance coverage and which is applying for certification under this part or is certified under this part shall engage, on behalf of all participants and beneficiaries, a qualified actuary who shall be responsible for the preparation of the materials comprising information necessary to be submitted by a qualified actuary under this part. The qualified actuary shall utilize such assumptions and techniques as are necessary to enable such actuary to form an opinion as to whether the contents of the matters reported under this part—

''(1) are in the aggregate reasonably related to the experience of the plan and to reasonable expectations; and

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

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

"SEC. 808. NOTICE REQUIREMENTS FOR VOLUNTARY TERMINATION.

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

''(1) provides to the participants and beneficiaries a written notice of intent to terminate stating that such termination is intended and the proposed termination date;

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

''(3) submits such plan in writing to the applicable authority.

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

"SEC. 809. CORRECTIVE ACTIONS AND MANDATORY TERMINATION.

"(a) ACTIONS TO AVOID DEPLETION OF RESERVES.—An association health plan which is certified under this part and which provides benefits other than health insurance coverage shall continue to meet the requirements of section 806, irrespective of whether such certification continues in effect. The board of trustees of such plan shall determine quarterly whether the requirements of section 806 are met. In any case in which the board determines that there is reason to believe that there is or will be a failure to meet such requirements, or the applicable authority makes such a determination and so notifies the board, the board shall immediately notify the qualified actuary engaged by the plan, and such actuary shall, not later than the end of the next following month, make such recommendations to the board for corrective action as the actuary determines necessary to ensure compliance with section 806. Not later than 30 days after receiving from the actuary recommendations for corrective actions, the board shall notify the applicable authority (in such form and manner as the applicable authority may prescribe by regulation) of such recommendations of the actuary for corrective action, together with a description of the actions (if any) that the board has taken or plans to take in response to such recommendations. The board

shall thereafter report to the applicable authority, in such form and frequency as the applicable authority may specify to the board, regarding corrective action taken by the board until the requirements of section 806 are met.

''(b) MANDATORY TERMINATION.—In any case in which—

''(1) the applicable authority has been notified under subsection (a) (or by an issuer of excess/stop loss insurance or indemnity insurance pursuant to section 806(a)) of a failure of an association health plan which is or has been certified under this part and is described in section 806(a)(2) to meet the requirements of section 806 and has not been notified by the board of trustees of the plan that corrective action has restored compliance with such requirements; and

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

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

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

"SEC. 810. TRUSTEESHIP BY THE SECRETARY OF INSOLVENT ASSOCIATION HEALTH PLANS PROVIDING HEALTH BENEFITS IN ADDITION TO HEALTH INSURANCE COVERAGE.

''(a) APPOINTMENT OF SECRETARY AS TRUSTEE FOR INSOLVENT PLANS.—Whenever the Secretary determines that an association health plan which is or has been certified under this part and which is described in section 806(a)(2) will be unable to provide benefits when due or is otherwise in a financially hazardous condition, as shall be defined by the Secretary by regulation, the Secretary shall, upon notice to the plan, apply to the appropriate United States district court for appointment of the Secretary as trustee to administer the plan for the duration of the insolvency. The plan may appear as a party and other interested persons may intervene in the proceedings at the discretion of the court. The court shall appoint such Secretary trustee if the court determines that the trusteeship is necessary to protect the interests of the participants and beneficiaries or providers of medical care or to

avoid any unreasonable deterioration of the financial condition of the plan. The trusteeship of such Secretary shall continue until the conditions described in the first sentence of this subsection are remedied or the plan is terminated.

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

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

''(2) to require the transfer of all (or any part) of the assets and records of the plan to the Secretary as trustee;

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

''(4) to require the sponsor, the plan administrator, any participating employer, and any employee organization representing plan participants to furnish any information with respect to the plan which the Secretary as trustee may reasonably need in order to administer the plan;

''(5) to collect for the plan any amounts due the plan and to recover reasonable expenses of the trusteeship;

''(6) to commence, prosecute, or defend on behalf of the plan any suit or proceeding involving the plan;

''(7) to issue, publish, or file such notices, statements, and reports as may be required by the Secretary by regulation or required by any order of the court;

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

''(9) to provide for the enrollment of plan participants and beneficiaries under appropriate coverage options; and

''(10) to do such other acts as may be necessary to comply with this title or any order of the court and to protect the interests of plan participants and beneficiaries and providers of medical care.

''(c) NOTICE OF APPOINTMENT.—As soon as practicable after the Secretary's appointment as trustee, the Secretary shall give notice of such appointment to—

''(1) the sponsor and plan administrator;

''(2) each participant;

''(3) each participating employer; and

''(4) if applicable, each employee organization which, for purposes of collective bargaining, represents plan participants.

''(d) ADDITIONAL DUTIES.—Except to the extent inconsistent with the provisions of this title, or as may be otherwise ordered by the court, the Secretary, upon appointment as trustee under this section, shall be subject to the same duties as those of a trustee under section 704 of title 11, United States Code, and shall have the duties of a fiduciary for purposes of this title.

''(e) OTHER PROCEEDINGS.—An application by the Secretary under this subsection may be filed notwithstanding the pendency in the same or any other court of any bankruptcy, mortgage foreclosure, or equity receivership proceeding, or any proceeding to reorganize, conserve, or liquidate such plan or its property, or any proceeding to enforce a lien against property of the plan.

''(f) JURISDICTION OF COURT.—

''(1) IN GENERAL.—Upon the filing of an application for the appointment as trustee or the issuance of a decree under this section, the court to which the application is made shall have exclusive jurisdiction of the plan involved and its property wherever located with the powers, to the extent consistent with the purposes of this section, of a court of the United States having jurisdiction over cases under chapter 11 of title 11, United States Code. Pending an adjudication under this section such court shall stay, and upon appointment by it of the Secretary as trustee, such court shall continue the stay of, any pending mortgage foreclosure, equity receivership, or other proceeding to reorganize, conserve, or liquidate the plan, the sponsor, or property of such plan or sponsor, and any other suit against any receiver, conservator, or trustee of the plan, the sponsor, or property of the plan or sponsor. Pending such adjudication and upon the appointment by it of the Secretary as trustee, the court may stay any proceeding to enforce a lien against property of the plan or the sponsor or any other suit against the plan or the sponsor.

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

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

''(g) PERSONNEL.—In accordance with regulations which shall be prescribed by the Secretary, the Secretary shall appoint, retain, and compensate accountants, actuaries, and other professional service personnel as may be necessary in connection with the Secretary's service as trustee under this section.

''SEC. 811. STATE ASSESSMENT AUTHORITY.

''(a) IN GENERAL.—Notwithstanding section 514, a State may impose by law a contribution tax on an association health plan described in section 806(a)(2), if the plan commenced operations in such State after the date of the enactment of the Small Business Health Fairness Act of 2009.

''(b) CONTRIBUTION TAX.—For purposes of this section, the term 'contribution tax' imposed by a State on an association health plan means any tax imposed by such State if—

''(1) such tax is computed by applying a rate to the amount of premiums or contributions, with respect to individuals covered under the plan who are

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

''(2) the rate of such tax does not exceed the rate of any tax imposed by such State on premiums or contributions received by insurers or health maintenance organizations for health insurance coverage offered in such State in connection with a group health plan;

''(3) such tax is otherwise nondiscriminatory; and

''(4) the amount of any such tax assessed on the plan is reduced by the amount of any tax or assessment otherwise imposed by the State on premiums, contributions, or both received by insurers or health maintenance organizations for health insurance coverage, aggregate excess/stop loss insurance (as defined in section 806(g)(1)), specific excess/stop loss insurance (as defined in section 806(g)(2)), other insurance related to the provision of medical care under the plan, or any combination thereof provided by such insurers or health maintenance organizations in such State in connection with such plan.

''SEC. 812. DEFINITIONS AND RULES OF CONSTRUCTION.

''(a) DEFINITIONS.—For purposes of this part—

''(1) GROUP HEALTH PLAN.—The term 'group health plan' has the meaning provided in section 733(a)(1) (after applying subsection (b) of this section).

''(2) MEDICAL CARE.—The term 'medical care' has the meaning provided in section 733(a)(2).

''(3) HEALTH INSURANCE COVERAGE.—The term 'health insurance coverage' has the meaning provided in section 733(b)(1).

''(4) HEALTH INSURANCE ISSUER.—The term 'health insurance issuer' has the meaning provided in section 733(b)(2).

''(5) APPLICABLE AUTHORITY.—The term 'applicable authority' means the Secretary, except that, in connection with any exercise of the Secretary's authority regarding which the Secretary is required under section 506(d) to consult with a State, such term means the Secretary, in consultation with such State.

''(6) HEALTH STATUS-RELATED FACTOR.—The term 'health status-related factor' has the meaning provided in section 733(d)(2).

''(7) INDIVIDUAL MARKET.—

''(A) IN GENERAL.—The term 'individual market' means the market for health insurance

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

''(B) TREATMENT OF VERY SMALL GROUPS.—

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

''(ii) STATE EXCEPTION.—Clause (i) shall not apply in the case of health insurance coverage offered in a State if such State regulates the coverage described in such clause in the same manner and to the same extent as coverage in the small group market (as defined in section 2791(e)(5) of the Public Health Service Act) is regulated by such State.

''(8) PARTICIPATING EMPLOYER.—The term 'participating employer' means, in connection with an association health plan, any employer, if any individual who is an employee of such employer, a partner in such employer, or a self-employed individual

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

''(9) APPLICABLE STATE AUTHORITY.—The term 'applicable State authority' means, with respect to a health insurance issuer in a State, the State insurance commissioner or official or officials designated by the State to enforce the requirements of title XXVII of the Public Health Service Act for the State involved with respect to such issuer.

''(10) QUALIFIED ACTUARY.—The term 'qualified actuary' means an individual who is a member of the American Academy of Actuaries.

''(11) AFFILIATED MEMBER.—The term 'affiliated member' means, in connection with a sponsor—

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

''(B) in the case of a sponsor with members which consist of associations, a person who is a member of any such association and elects an affiliated status with the sponsor, or

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

"(12) LARGE EMPLOYER.—The term 'large employer' means, in connection with a group health plan with respect to a plan year, an employer who employed an average of at least 51 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year.

"(13) SMALL EMPLOYER.—The term 'small employer' means, in connection with a group health plan with respect to a plan year, an employer who is not a large employer.

"(b) RULES OF CONSTRUCTION.—

"(1) EMPLOYERS AND EMPLOYEES.—For purposes of determining whether a plan, fund, or program is an employee welfare benefit plan which is an association health plan, and for purposes of applying this title in connection with such plan, fund, or program so determined to be such an employee welfare benefit plan—

''(A) in the case of a partnership, the term 'employer' (as defined in section 3(5)) includes the partnership in relation to the partners, and the term 'employee' (as defined in section 3(6)) includes any partner in relation to the partnership; and

''(B) in the case of a self-employed individual, the term 'employer' (as defined in section 3(5)) and the term 'employee' (as defined in section 3(6)) shall include such individual.

''(2) PLANS, FUNDS, AND PROGRAMS TREATED AS EMPLOYEE WELFARE BENEFIT PLANS.—In the case of any plan, fund, or program which was established or is maintained for the purpose of providing medical care (through the purchase of insurance or otherwise) for employees (or their dependents) covered thereunder and which demonstrates to the Secretary that all requirements for certification under this part would be met with respect to such plan, fund, or program if such plan, fund, or program were a group health plan, such plan, fund, or program shall be treated for purposes of this title as an employee welfare benefit plan on and after the date of such demonstration.''.

(b) CONFORMING AMENDMENTS TO PREEMPTION RULES.—

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

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

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

(A) in subsection (b)(4), by striking ''Subsection (a)'' and inserting ''Subsections (a) and (d)'';

(B) in subsection (b)(5), by striking ''subsection (a)'' in subparagraph (A) and inserting ''subsection (a) of this section and subsections (a)(2)(B) and (b) of section 805'', and by striking ''subsection (a)'' in subparagraph (B) and inserting ''subsection (a) of this section or subsection (a)(2)(B) or (b) of section 805'';

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

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

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

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

''(A) In any case in which health insurance coverage of any policy type is offered under an association health plan certified under part 8 to a participating employer operating in such State, the provisions of this title shall supersede any and all laws of such State insofar as they may preclude a health insurance issuer from offering health insurance coverage of the same policy type to other employers operating in the State which are eligible for coverage under such association health plan, whether or not such other employers are participating employers in such plan.

''(B) In any case in which health insurance coverage of any policy type is offered in a State under an association health plan certified under part 8 and the filing, with the applicable State authority (as de-

fined in section 812(a)(9)), of the policy form in connection with such policy type is approved by such State authority, the provisions of this title shall supersede any and all laws of any other State in which health insurance coverage of such type is offered, insofar as they may preclude, upon the filing in the same form and manner of such policy form with the applicable State authority in such other State, the approval of the filing in such other State.

''(3) Nothing in subsection (b)(6)(E) or the preceding provisions of this subsection shall be construed, with respect to health insurance issuers or health insurance coverage, to supersede or impair the law of any State—

''(A) providing solvency standards or similar standards regarding the adequacy of insurer capital, surplus, reserves, or contributions, or

''(B) relating to prompt payment of claims.

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

''(5) For purposes of this subsection, the term 'association health plan' has the meaning provided in section 801(a), and the terms 'health insurance coverage', 'participating employer', and 'health insurance issuer' have

the meanings provided such terms in section 812, respectively.''.

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

(A) in clause (i)(II), by striking ''and'' at the end;

(B) in clause (ii), by inserting ''and which does not provide medical care (within the meaning of section 733(a)(2)),'' after ''arrangement,'', and by striking ''title.'' and inserting ''title, and''; and

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

''(iii) subject to subparagraph (E), in the case of any other employee welfare benefit plan which is a multiple employer welfare arrangement and which provides medical care (within the meaning of section 733(a)(2)), any law of any State which regulates insurance may apply.''.

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

(A) by striking ''Nothing'' and inserting ''(1) Except as provided in paragraph (2), nothing''; and

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

''(2) Nothing in any other provision of law enacted on or after the date of the enactment of the Small Business Health Fairness Act of 2009 shall be construed to alter, amend, modify, invalidate, impair, or supersede any provision of this title, except by specific cross-reference to the affected section.''.

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

(d) DISCLOSURE OF SOLVENCY PROTECTIONS RELATED TO SELF-INSURED AND FULLY INSURED OPTIONS UNDER ASSOCIATION HEALTH PLANS.—Section 102(b) of such Act (29 U.S.C. 102(b)) is amended by adding at the end the following: ''An association health plan shall include in its summary plan description, in connection with each benefit option, a description of the form of solvency or guarantee fund protection secured pursuant to this Act or applicable State law, if any.''.

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

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

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

SEC. 202. CLARIFICATION OF TREATMENT OF SINGLE EMPLOYER ARRANGEMENTS.

Section 3(40)(B) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1002(40)(B)) is amended—

(1) in clause (i), by inserting after ''control group,'' the following: ''except that, in any case in which the benefit referred to in subparagraph (A) consists of medical care (as defined in section 812(a)(2)), two or more trades or businesses, whether or not incorporated, shall be deemed a single employer for any plan year of such plan, or any fiscal year of such other arrangement, if such trades or businesses are within the same control group during such year or at any time during the preceding 1-year period,'';

(2) in clause (iii), by striking ''(iii) the determination'' and inserting the following:

''(iii)(I) in any case in which the benefit referred to in subparagraph (A) consists of medical care (as defined in section 812(a)(2)), the determination of whether a trade or business is under 'common control' with another trade or business shall be determined under regulations of the Secretary applying principles consistent and coextensive with the principles applied in determining whether employees of two or more trades or businesses are treated as employed by a single employer under section 4001(b), except that, for purposes of this paragraph, an interest of greater than 25 percent may

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

''(II) in any other case, the determination'';

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

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

''(iv) in any case in which the benefit referred to in subparagraph (A) consists of medical care (as defined in section 812(a)(2)), in determining, after the application of clause (i), whether benefits are provided to employees of two or more employers, the arrangement shall be treated as having only one participating employer if, after the application of clause (i), the number of individuals who are employees and former employees of any one participating employer and who are covered under the arrangement is greater than 75 percent of the aggregate number of all individuals who are employees or former employees of participating employers and who are covered under the arrangement,''.

SEC. 203. ENFORCEMENT PROVISIONS RELATING TO ASSOCIATION HEALTH PLANS.

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

Retirement Income Security Act of 1974 (29 U.S.C. 1131) is amended—

(1) by inserting ''(a)'' after ''Sec. 501.''; and

(2) by adding at the end the following new subsection:

''(b) Any person who willfully falsely represents, to any employee, any employee's beneficiary, any employer, the Secretary, or any State, a plan or other arrangement established or maintained for the purpose of offering or providing any benefit described in section 3(1) to employees or their beneficiaries as—

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

''(2) having been established or maintained under or pursuant to one or more collective bargaining agreements which are reached pursuant to collective bargaining described in section 8(d) of the National Labor Relations Act (29 U.S.C. 158(d)) or paragraph Fourth of section 2 of the Railway Labor Act (45 U.S.C. 152, paragraph Fourth) or which are reached pursuant to labor-management negotiations under similar provisions of State public employee relations laws; or

''(3) being a plan or arrangement described in section 3(40)(A)(i),

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

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

''(n) ASSOCIATION HEALTH PLAN CEASE AND DESIST ORDERS.—

''(1) IN GENERAL.—Subject to paragraph (2), upon application by the Secretary showing the operation, promotion, or marketing of an association health plan (or similar arrangement providing benefits consisting of medical care (as defined in section 733(a)(2))) that—

''(A) is not certified under part 8, is subject under section 514(b)(6) to the insurance laws of any State in which the plan or arrangement offers or provides benefits, and is not licensed, registered, or otherwise approved under the insurance laws of such State; or

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

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

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

''(A) all benefits under it referred to in paragraph (1) consist of health insurance coverage; and

''(B) with respect to each State in which the plan or arrangement offers or provides benefits, the plan or arrangement is operating in accordance with applicable State laws that are not superseded under section 514.

''(3) ADDITIONAL EQUITABLE RELIEF.—The court may grant such additional equitable relief, including any relief available under this title, as it deems necessary to protect the interests of the public and of persons having claims for benefits against the plan.''.

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

''(b) ASSOCIATION HEALTH PLANS.—The terms of each association health plan which is or has been certified under part 8 shall require the board of trustees or the named fiduciary (as applicable) to ensure that the requirements of this section are met in connection with claims filed under the plan.''.

SEC. 204. COOPERATION BETWEEN FEDERAL AND STATE AUTHORITIES.

Section 506 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1136) is amended by adding at the end the following new subsection:

''(d) CONSULTATION WITH STATES WITH RESPECT TO ASSOCIATION HEALTH PLANS.—

''(1) AGREEMENTS WITH STATES.—The Secretary shall consult with the State recognized under paragraph (2) with respect to an association health plan regarding the exercise of—

''(A) the Secretary's authority under sections 502 and 504 to enforce the requirements for certification under part 8; and

''(B) the Secretary's authority to certify association health plans under part 8 in accordance with regulations of the Secretary applicable to certification under part 8.

''(2) RECOGNITION OF PRIMARY DOMICILE STATE.—In carrying out paragraph (1), the Secretary shall ensure that only one State will be recognized, with respect to any particular association health plan, as the State with which consultation is required. In carrying out this paragraph—

''(A) in the case of a plan which provides health insurance coverage (as defined in section 812(a)(3)), such State shall be the State with which filing and approval of a policy type offered by the plan was initially obtained, and

''(B) in any other case, the Secretary shall take into account the places of residence of the participants and beneficiaries under the plan and the State in which the trust is maintained.''.

SEC. 205. EFFECTIVE DATE AND TRANSITIONAL AND OTHER RULES.

(a) EFFECTIVE DATE.—The amendments made by this title shall take effect 1 year after the date of the enactment of this Act. The Secretary of Labor shall first issue all regulations necessary to carry out the amendments made by this title within 1 year after the date of the enactment of this Act.

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

(1) IN GENERAL.—In any case in which, as of the date of the enactment of this Act, an arrangement is maintained in a State for the purpose of providing benefits consisting of medical care for the employees and beneficiaries of its participating employers, at least 200 participating employers make contributions to such arrangement, such arrangement has been in existence for at least 10 years, and such arrangement is licensed under the laws of one or more States to provide such benefits to its participating employers, upon the filing with the applicable authority (as defined in section 812(a)(5) of the Employee Retirement Income Security Act of 1974 (as amended by this subtitle)) by the arrangement of an application for certification of the arrangement under part 8 of subtitle B of title I of such Act—

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

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

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

(C) the requirements of section 803(b) of such Act shall be deemed met, if the arrangement is operated by a board of directors which—

(i) is elected by the participating employers, with each employer having one vote; and

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

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

(E) the arrangement may be certified by any applicable authority with respect to its operations in any State only if it operates in such State on the date of certification.

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

(2) DEFINITIONS.—For purposes of this subsection, the terms ''group health plan'', ''medical care'', and ''participating employer'' shall have the meanings provided in section 812 of the Employee Retirement Income Security Act of 1974, except that the reference in paragraph (7) of such section to an ''association health plan'' shall be deemed a reference to an arrangement referred to in this subsection.

TITLE II—TARGETED EFFORTS TO EXPAND ACCESS

SEC. 211. EXTENDING COVERAGE OF DEPENDENTS.

(a) ERISA.—

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

''SEC. 715. EXTENDING COVERAGE OF DEPENDENTS.

''(a) IN GENERAL.—In the case of a group health plan, or health insurance coverage offered in connection with a group health plan, that treats as a beneficiary under the plan an individual who is a dependent child of a participant or beneficiary under the plan, the plan or coverage shall continue to treat the individual as a dependent child without regard to the individual's age through

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

''(b) CONSTRUCTION.—Nothing in this section shall be construed as requiring a group health plan to provide benefits for dependent children as beneficiaries under the plan or to require a participant to elect coverage of dependent children.''.

(2) CLERICAL AMENDMENT.—The table of contents of such Act is amended by inserting after the item relating to section 714 the following new item:

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

(b) PHSA.—Title XXVII of the Public Health Service Act is amended by inserting after section 2707 the following new section:

''SEC. 2708. EXTENDING COVERAGE OF DEPENDENTS.

''(a) IN GENERAL.—In the case of a group health plan, or health insurance coverage offered in connection with a group health plan, that treats as a beneficiary under the plan an individual who is a dependent child of a participant or beneficiary under the plan, the plan or coverage shall continue to treat the individual as a dependent child without regard to the individual's age through at least the end of the plan year in which the individual

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

''(b) CONSTRUCTION.—Nothing in this section shall be construed as requiring a group health plan to provide benefits for dependent children as beneficiaries under the plan or to require a participant to elect coverage of dependent children.''.

(c) IRC.—

(1) IN GENERAL.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended by adding at the end the following new section:

''SEC. 9814. EXTENDING COVERAGE OF DEPENDENTS.

''(a) IN GENERAL.—In the case of a group health plan that treats as a beneficiary under the plan an individual who is a dependent child of a participant or beneficiary under the plan, the plan shall continue to treat the individual as a dependent child without regard to the individual's age through at least the end of the plan year in which the individual turns an age specified in the plan, but not less than 25 years of age.

''(b) CONSTRUCTION.—Nothing in this section shall be construed as requiring a group health plan to provide coverage for dependent children as beneficiaries under the plan or to require a participant to elect coverage of dependent children.''.

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

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

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

SEC. 212. ALLOWING AUTO-ENROLLMENT FOR EMPLOYER SPONSORED COVERAGE.

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

(b) AUTOENROLLMENT.—

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

each plan year, to each employee eligible to participate in the plan. The notice shall explain the employee contribution to such plan and the employee's right to decline coverage.

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

(c) CONSTRUCTION.—Nothing in this section shall be construed to supersede State law which establishes, implements, or continues in effect any standard or requirement relating to employers in connection with payroll or the sponsoring of employer sponsored health insurance coverage except to the extent that such standard or requirement prevents an employer from instituting the auto-enrollment described in subsection (a).

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

SEC. 221. INTERSTATE PURCHASING OF HEALTH INSURANCE.

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

"PART D—COOPERATIVE GOVERNING OF INDIVIDUAL HEALTH INSURANCE COVERAGE

"SEC. 2795. DEFINITIONS.

''In this part:

''(1) PRIMARY STATE.—The term 'primary State' means, with respect to individual health insurance coverage offered by a health insurance issuer, the State designated by the issuer as the State whose covered laws shall govern the health insurance issuer in the sale of such coverage under this part. An issuer, with respect to a particular policy, may only designate one such State as its primary State with respect to all such coverage it offers. Such an issuer may not change the designated primary State with respect to individual health insurance coverage once the policy is issued, except that such a change

may be made upon renewal of the policy. With respect to such designated State, the issuer is deemed to be doing business in that State.

''(2) SECONDARY STATE.—The term 'secondary State' means, with respect to individual health insurance coverage offered by a health insurance issuer, any State that is not the primary State. In the case of a health insurance issuer that is selling a policy in, or to a resident of, a secondary State, the issuer is deemed to be doing business in that secondary State.

''(3) HEALTH INSURANCE ISSUER.—The term 'health insurance issuer' has the meaning given such term in section 2791(b)(2), except that such an issuer must be licensed in the primary State and be qualified to sell individual health insurance coverage in that State.

''(4) INDIVIDUAL HEALTH INSURANCE COVERAGE.—The term 'individual health insurance coverage' means health insurance coverage offered in the individual market, as defined in section 2791(e)(1).

''(5) APPLICABLE STATE AUTHORITY.—The term 'applicable State authority' means, with respect to a health insurance issuer in a State, the State in-

surance commissioner or official or officials designated by the State to enforce the requirements of this title for the State with respect to the issuer.

''(6) HAZARDOUS FINANCIAL CONDITION.—The term 'hazardous financial condition' means that, based on its present or reasonably anticipated financial condition, a health insurance issuer is unlikely to be able—

''(A) to meet obligations to policyholders with respect to known claims and reasonably anticipated claims; or

''(B) to pay other obligations in the normal course of business.

''(7) COVERED LAWS.—

''(A) IN GENERAL.—The term 'covered laws' means the laws, rules, regulations, agreements, and orders governing the insurance business pertaining to—

''(i) individual health insurance coverage issued by a health insurance issuer;

''(ii) the offer, sale, rating (including medical underwriting), renewal, and issuance of individual health insurance coverage to an individual;

''(iii) the provision to an individual in relation to individual health insurance coverage of health care and insurance related services;

''(iv) the provision to an individual in relation to individual health insurance coverage of management, operations, and investment activities of a health insurance issuer; and

''(v) the provision to an individual in relation to individual health insurance coverage of loss control and claims administration for a health insurance issuer with respect to liability for which the issuer provides insurance.

''(B) EXCEPTION.—Such term does not include any law, rule, regulation, agreement, or order governing the use of care or cost management techniques, including any requirement related to provider contracting, network access or adequacy, health care data collection, or quality assurance.

''(8) STATE.—The term 'State' means the 50 States and includes the District of Columbia, Puerto

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

''(9) UNFAIR CLAIMS SETTLEMENT PRACTICES.—The term 'unfair claims settlement practices' means only the following practices:

''(A) Knowingly misrepresenting to claimants and insured individuals relevant facts or policy provisions relating to coverage at issue.

''(B) Failing to acknowledge with reasonable promptness pertinent communications with respect to claims arising under policies.

''(C) Failing to adopt and implement reasonable standards for the prompt investigation and settlement of claims arising under policies.

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

''(E) Refusing to pay claims without conducting a reasonable investigation.

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

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

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

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

''(I) Attempting to settle or settling claims on the basis of an application that was materially altered without notice to, or knowledge or consent of, the insured.

''(J) Failing to provide forms necessary to present claims within 15 calendar days of a requests with reasonable explanations regarding their use.

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

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

commits, or conceals any material information concerning, one or more of the following:

''(A) Presenting, causing to be presented or preparing with knowledge or belief that it will be presented to or by an insurer, a reinsurer, broker or its agent, false information as part of, in support of or concerning a fact material to one or more of the following:

''(i) An application for the issuance or renewal of an insurance policy or reinsurance contract.

''(ii) The rating of an insurance policy or reinsurance contract.

''(iii) A claim for payment or benefit pursuant to an insurance policy or reinsurance contract.

''(iv) Premiums paid on an insurance policy or reinsurance contract.

''(v) Payments made in accordance with the terms of an insurance policy or reinsurance contract.

''(vi) A document filed with the commissioner or the chief insurance regulatory official of another jurisdiction.

''(vii) The financial condition of an insurer or reinsurer.

''(viii) The formation, acquisition, merger, reconsolidation, dissolution or withdrawal from one or more lines of insurance or reinsurance in all or part of a State by an insurer or reinsurer.

''(ix) The issuance of written evidence of insurance.

''(x) The reinstatement of an insurance policy.

''(B) Solicitation or acceptance of new or renewal insurance risks on behalf of an insurer reinsurer or other person engaged in the business of insurance by a person who knows or should know that the insurer or other person responsible for the risk is insolvent at the time of the transaction.

''(C) Transaction of the business of insurance in violation of laws requiring a license, certificate of authority or other legal authority for the transaction of the business of insurance.

''(D) Attempt to commit, aiding or abetting in the commission of, or conspiracy to com-

mit the acts or omissions specified in this paragraph.

"SEC. 2796. APPLICATION OF LAW.

"(a) IN GENERAL.—The covered laws of the primary State shall apply to individual health insurance coverage offered by a health insurance issuer in the primary State and in any secondary State, but only if the coverage and issuer comply with the conditions of this section with respect to the offering of coverage in any secondary State.

"(b) EXEMPTIONS FROM COVERED LAWS IN A SECONDARY STATE.—Except as provided in this section, a health insurance issuer with respect to its offer, sale, rating (including medical underwriting), renewal, and issuance of individual health insurance coverage in any secondary State is exempt from any covered laws of the secondary State (and any rules, regulations, agreements, or orders sought or issued by such State under or related to such covered laws) to the extent that such laws would—

"(1) make unlawful, or regulate, directly or indirectly, the operation of the health insurance issuer operating in the secondary State, except that any secondary State may require such an issuer—

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

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

''(B) to register with and designate the State insurance commissioner as its agent solely for the purpose of receiving service of legal documents or process;

''(C) to submit to an examination of its financial condition by the State insurance commissioner in any State in which the issuer is doing business to determine the issuer's financial condition, if—

''(i) the State insurance commissioner of the primary State has not done an examination within the period recommended by the National Association of Insurance Commissioners; and

''(ii) any such examination is conducted in accordance with the examiners' handbook of the National Association of Insurance Commissioners and is coordinated to avoid unjustified duplication and unjustified repetition;

''(D) to comply with a lawful order issued—

''(i) in a delinquency proceeding commenced by the State insurance commissioner if there has been a finding of financial impairment under subparagraph (C); or

''(ii) in a voluntary dissolution proceeding;

''(E) to comply with an injunction issued by a court of competent jurisdiction, upon a petition by the State insurance commissioner alleging that the issuer is in hazardous financial condition;

''(F) to participate, on a nondiscriminatory basis, in any insurance insolvency guaranty association or similar association to which a health insurance issuer in the State is required to belong;

''(G) to comply with any State law regarding fraud and abuse (as defined in section 2795(10)), except that if the State seeks an injunction regarding the conduct described in this subparagraph, such injunction must be obtained from a court of competent jurisdiction;

''(H) to comply with any State law regarding unfair claims settlement practices (as defined in section 2795(9)); or

''(I) to comply with the applicable requirements for independent review under section 2798 with respect to coverage offered in the State;

''(2) require any individual health insurance coverage issued by the issuer to be countersigned by an insurance agent or broker residing in that Secondary State; or

''(3) otherwise discriminate against the issuer issuing insurance in both the primary State and in any secondary State.

''(c) CLEAR AND CONSPICUOUS DISCLOSURE.—A health insurance issuer shall provide the following notice, in 12-point bold type, in any insurance coverage offered in a secondary State under this part by such a health insurance issuer and at renewal of the policy, with the 5 blank spaces therein being appropriately filled with the name of the health insurance issuer, the name of primary State, the name of the secondary State, the name of the secondary State, and the name of the secondary State, respectively, for the coverage concerned:

THIS POLICY IS ISSUED BY _____ **AND IS GOVERNED BY THE LAWS AND REGULATIONS OF THE STATE OF _____, AND IT HAS MET ALL THE LAWS OF THAT STATE AS DETERMINED BY THAT STATE'S DEPARTMENT OF INSURANCE. THIS POLICY MAY BE LESS EXPENSIVE THAN OTHERS BECAUSE IT IS NOT SUBJECT TO ALL OF THE INSURANCE LAWS AND REGULATIONS OF THE STATE OF _____, INCLUDING COVERAGE OF SOME SERVICES OR BENEFITS MANDATED BY THE LAW OF THE STATE OF _____. ADDITIONALLY, THIS POLICY IS NOT SUBJECT TO ALL OF THE CONSUMER PROTECTION LAWS OR RESTRICTIONS ON RATE CHANGES OF THE STATE OF _____. AS WITH ALL INSURANCE PRODUCTS, BEFORE PURCHASING THIS POLICY, YOU SHOULD CAREFULLY REVIEW THE POLICY AND DETERMINE WHAT HEALTH CARE SERVICES THE POLICY COVERS AND WHAT BENEFITS IT PROVIDES, INCLUDING ANY EXCLUSIONS, LIMITATIONS, OR CONDITIONS FOR SUCH SERVICES OR BENEFITS.**''.

''(d) PROHIBITION ON CERTAIN RECLASSIFICATIONS AND PREMIUM INCREASES.—

''(1) IN GENERAL.—For purposes of this section, a health insurance issuer that provides individual health insurance coverage to an individual under this part in a primary or secondary State may not upon renewal—

''(A) move or reclassify the individual insured under the health insurance coverage from the class such individual is in at the time of issue of the contract based on the health-status related factors of the individual; or

''(B) increase the premiums assessed the individual for such coverage based on a health status-related factor or change of a health status-related factor or the past or prospective claim experience of the insured individual.

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

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

''(B) from raising premium rates for all policy holders within a class based on claims experience;

''(C) from changing premiums or offering discounted premiums to individuals who engage in wellness activities at intervals prescribed by the issuer, if such premium changes or incentives—

''(i) are disclosed to the consumer in the insurance contract;

''(ii) are based on specific wellness activities that are not applicable to all individuals; and

''(iii) are not obtainable by all individuals to whom coverage is offered;

''(D) from reinstating lapsed coverage; or

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

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

''(f) LICENSING OF AGENTS OR BROKERS FOR HEALTH INSURANCE ISSUERS.—Any State may require that a person acting, or offering to act, as an agent or broker for a health insurance issuer with respect to the offering of individual health insurance coverage obtain a license from that State, with commissions or other compensation subject to the provisions of the laws of that State, except that a State may not impose any qualification or requirement which discriminates against a nonresident agent or broker.

''(g) DOCUMENTS FOR SUBMISSION TO STATE INSURANCE COMMISSIONER.—Each health insurance issuer issuing individual health insurance coverage in both primary and secondary States shall submit—

''(1) to the insurance commissioner of each State in which it intends to offer such coverage, before it may offer individual health insurance coverage in such State—

''(A) a copy of the plan of operation or feasibility study or any similar statement of the policy being offered and its coverage (which shall include the name of its primary State and its principal place of business);

''(B) written notice of any change in its designation of its primary State; and

''(C) written notice from the issuer of the issuer's compliance with all the laws of the primary State; and

''(2) to the insurance commissioner of each secondary State in which it offers individual health insurance coverage, a copy of the issuer's quarterly financial statement submitted to the primary State, which statement shall be certified by an independent public accountant and contain a statement of opinion on loss and loss adjustment expense reserves made by—

''(A) a member of the American Academy of Actuaries; or

''(B) a qualified loss reserve specialist.

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

''(1) the solicitation or sale of individual health insurance coverage by a health insurance issuer to any person or group who is not eligible for such insurance; or

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

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

''(i) POWER OF SECONDARY STATES TO TAKE ADMINISTRATIVE ACTION.—Nothing in this section shall be construed to affect the authority of any State to enjoin conduct in violation of that State's laws described in section 2796(b)(1).

''(j) STATE POWERS TO ENFORCE STATE LAWS.—

''(1) IN GENERAL.—Subject to the provisions of subsection (b)(1)(G) (relating to injunctions) and paragraph (2), nothing in this section shall be construed to affect the authority of any State to make use of any of its powers to enforce the laws of such State with respect to which a health insurance issuer is not exempt under subsection (b).

''(2) COURTS OF COMPETENT JURISDICTION.—If a State seeks an injunction regarding the conduct described in paragraphs (1) and (2) of subsection (h), such injunction must be obtained from a Federal or State court of competent jurisdiction.

''(k) STATES' AUTHORITY TO SUE.—Nothing in this section shall affect the authority of any State to bring action in any Federal or State court.

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

of State laws generally applicable to persons or corporations.

''(m) GUARANTEED AVAILABILITY OF COVERAGE TO HIPAA ELIGIBLE INDIVIDUALS.—To the extent that a health insurance issuer is offering coverage in a primary State that does not accommodate residents of secondary States or does not provide a working mechanism for residents of a secondary State, and the issuer is offering coverage under this part in such secondary State which has not adopted a qualified high risk pool as its acceptable alternative mechanism (as defined in section 2744(c)(2)), the issuer shall, with respect to any individual health insurance coverage offered in a secondary State under this part, comply with the guaranteed availability requirements for eligible individuals in section 2741.

"SEC. 2797. PRIMARY STATE MUST MEET FEDERAL FLOOR BEFORE ISSUER MAY SELL INTO SECONDARY STATES.

''A health insurance issuer may not offer, sell, or issue individual health insurance coverage in a secondary State if the State insurance commissioner does not use a risk-based capital formula for the determination of capital and surplus requirements for all health insurance issuers.

"SEC. 2798. INDEPENDENT EXTERNAL APPEALS PROCEDURES.

"(a) RIGHT TO EXTERNAL APPEAL.—A health insurance issuer may not offer, sell, or issue individual health insurance coverage in a secondary State under the provisions of this title unless—

"(1) both the secondary State and the primary State have legislation or regulations in place establishing an independent review process for individuals who are covered by individual health insurance coverage, or

"(2) in any case in which the requirements of subparagraph (A) are not met with respect to the either of such States, the issuer provides an independent review mechanism substantially identical (as determined by the applicable State authority of such State) to that prescribed in the 'Health Carrier External Review Model Act' of the National Association of Insurance Commissioners for all individuals who purchase insurance coverage under the terms of this part, except that, under such mechanism, the review is conducted by an independent medical reviewer, or a panel of such reviewers, with respect to whom the requirements of subsection (b) are met.

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

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

''(A) each independent medical reviewer meets the qualifications described in paragraphs (2) and (3);

''(B) with respect to each review, each reviewer meets the requirements of paragraph (4) and the reviewer, or at least 1 reviewer on the panel, meets the requirements described in paragraph (5); and

''(C) compensation provided by the issuer to each reviewer is consistent with paragraph (6).

''(2) LICENSURE AND EXPERTISE.—Each independent medical reviewer shall be a physician (allopathic or osteopathic) or health care professional who—

''(A) is appropriately credentialed or licensed in 1 or more States to deliver health care services; and

''(B) typically treats the condition, makes the diagnosis, or provides the type of treatment under review.

''(3) INDEPENDENCE.—

''(A) IN GENERAL.—Subject to subparagraph (B), each independent medical reviewer in a case shall—

''(i) not be a related party (as defined in paragraph (7));

''(ii) not have a material familial, financial, or professional relationship with such a party; and

''(iii) not otherwise have a conflict of interest with such a party (as determined under regulations).

''(B) EXCEPTION.—Nothing in subparagraph (A) shall be construed to—

''(i) prohibit an individual, solely on the basis of affiliation with the issuer, from serving as an independent medical reviewer if—

''(I) a non-affiliated individual is not reasonably available;

''(II) the affiliated individual is not involved in the provision of items or services in the case under review;

''(III) the fact of such an affiliation is disclosed to the issuer and the enrollee (or authorized representative) and neither party objects; and

''(IV) the affiliated individual is not an employee of the issuer and does not provide services exclusively or primarily to or on behalf of the issuer;

''(ii) prohibit an individual who has staff privileges at the institution where the treatment involved takes place from serving as an independent medical reviewer merely on the basis of such affiliation if the affiliation is disclosed to the issuer and the enrollee (or authorized representative), and neither party objects; or

''(iii) prohibit receipt of compensation by an independent medical reviewer from an entity if the compensation is provided consistent with paragraph (6).

''(4) PRACTICING HEALTH CARE PROFESSIONAL IN SAME FIELD.—

''(A) IN GENERAL.—In a case involving treatment, or the provision of items or services—

''(i) by a physician, a reviewer shall be a practicing physician (allopathic or osteopathic) of the same or similar specialty, as a physician who, acting within the appropriate scope of practice within the State in which the service is provided or rendered, typically treats the condition, makes the diagnosis, or provides the type of treatment under review; or

''(ii) by a non-physician health care professional, the reviewer, or at least 1 member of the review panel, shall be a practicing non-physician health care professional of the same or similar specialty as the non-physician health care professional who, acting within the appropriate scope of practice within the State in which the service is provided or rendered, typically treats the condition, makes the diagnosis, or provides the type of treatment under review.

''(B) PRACTICING DEFINED.—For purposes of this paragraph, the term 'practicing' means, with respect to an individual who is a physician or other health care professional, that the individual provides health care services to individual patients on average at least 2 days per week.

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

''(6) LIMITATIONS ON REVIEWER COMPENSATION.—Compensation provided by the issuer to an independent medical reviewer in connection with a review under this section shall—

''(A) not exceed a reasonable level; and

''(B) not be contingent on the decision rendered by the reviewer.

''(7) RELATED PARTY DEFINED.—For purposes of this section, the term 'related party' means, with respect to a denial of a claim under a coverage relating to an enrollee, any of the following:

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

''(B) The enrollee (or authorized representative).

''(C) The health care professional that provides the items or services involved in the denial.

''(D) The institution at which the items or services (or treatment) involved in the denial are provided.

''(E) The manufacturer of any drug or other item that is included in the items or services involved in the denial.

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

''(8) DEFINITIONS.—For purposes of this subsection:

''(A) ENROLLEE.—The term 'enrollee' means, with respect to health insurance coverage offered by a health insurance issuer, an individual enrolled with the issuer to receive such coverage.

''(B) HEALTH CARE PROFESSIONAL.—The term 'health care professional' means an individual who is licensed, accredited, or certified under State law to provide specified health care services and who is operating within the scope of such licensure, accreditation, or certification.

"SEC. 2799. ENFORCEMENT.

"(a) IN GENERAL.—Subject to subsection (b), with respect to specific individual health insurance coverage the primary State for such coverage has sole jurisdiction to enforce the primary State's covered laws in the primary State and any secondary State.

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

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

"(d) NOTICE OF COMPLIANCE FAILURE.—In the case of individual health insurance coverage offered in a secondary State that fails to comply with the covered laws of the primary State, the applicable State authority of the secondary State may notify the applicable State authority of the primary State.".

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

(c) GAO ONGOING STUDY AND REPORTS.—

(1) STUDY.—The Comptroller General of the United States shall conduct an ongoing study concerning the effect of the amendment made by subsection (a) on—

(A) the number of uninsured and under-insured;

(B) the availability and cost of health insurance policies for individuals with preexisting medical conditions;

(C) the availability and cost of health insurance policies generally;

(D) the elimination or reduction of different types of benefits under health insurance policies offered in different States; and

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

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

TITLE IV—IMPROVING HEALTH SAVINGS ACCOUNTS

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

(a) ALLOWANCE OF CREDIT.—Subsection (a) of section 25B of the Internal Revenue Code of 1986 is amended by inserting ''aggregate qualified HSA contributions and'' after ''so much of the''.

(b) QUALIFIED HSA CONTRIBUTIONS.—Subsection (d) of section 25B of such Code is amended by redesignating paragraph (2) as paragraph (3) and by inserting after paragraph (1) the following new paragraph:

''(2) QUALIFIED HSA CONTRIBUTIONS.—The term 'qualified HSA contribution' means, with respect to any taxable year, a contribution of the eligible individual to a health savings account (as defined in section 223(d)(1)) for which a deduction is allowable under section 223(a) for such taxable year.''.

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

individual during the testing period from any entity of a type to which contributions under paragraph (1) or paragraph (2) (as the case may be) may be made.''.

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

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

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

''(v) a high deductible health plan if—

''(I) such plan is not offered in connection with a group health plan,

''(II) no portion of any premium (within the meaning of applicable premium under section 4980B(f)(4)) for such plan is excludable from gross income under section 106, and

''(III) the account beneficiary demonstrates, using procedures deemed appropriate by the Secretary, that after payment of the premium

for such insurance the balance in the health savings account is at least twice the minimum deductible in effect under subsection (c)(2)(A)(i) which is applicable to such plan.''.

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to premiums for a high deductible health plan for periods beginning after December 31, 2009.

SEC. 233. REQUIRING GREATER COORDINATION BETWEEN HDHP ADMINISTRATORS AND HSA ACCOUNT ADMINISTRATORS SO THAT ENROLLEES CAN ENROLL IN BOTH AT THE SAME TIME.

The Secretary of the Treasury, through the issuance of regulations or other guidance, shall encourage administrators of health plans and trustees of health savings accounts to provide for simultaneous enrollment in high deductible health plans and setup of health savings accounts.

SEC. 234. SPECIAL RULE FOR CERTAIN MEDICAL EXPENSES INCURRED BEFORE ESTABLISHMENT OF ACCOUNT.

(a) IN GENERAL.—Subsection (d) of section 223 of the Internal Revenue Code of 1986 is amended by redesignating paragraph (4) as paragraph (5) and by inserting after paragraph (3) the following new paragraph:

''(4) CERTAIN MEDICAL EXPENSES INCURRED BEFORE ESTABLISHMENT OF ACCOUNT TREATED AS QUALIFIED.—

''(A) IN GENERAL.—For purposes of paragraph (2), an expense shall not fail to be treated as a qualified medical expense solely because such expense was incurred before the establishment of the health savings account if such expense was incurred during the 60-day period beginning on the date on which the high deductible health plan is first effective.

''(B) SPECIAL RULES.—For purposes of subparagraph (A)—

''(i) an individual shall be treated as an eligible individual for any portion of a month for which the individual is described in subsection (c)(1), determined without regard to whether the individual is covered under a high deductible health plan on the 1st day of such month, and

''(ii) the effective date of the health savings account is deemed to be the date on which the high deductible health plan is first effective after the date of the enactment of this paragraph.''.

(b) EFFECTIVE DATE.—The amendment made by this section shall apply with respect to insurance purchased after the date of the enactment of this Act in taxable years beginning after such date.

DIVISION C—ENACTING REAL MEDICAL LIABILITY REFORM

SEC. 301. ENCOURAGING SPEEDY RESOLUTION OF CLAIMS.

The time for the commencement of a health care lawsuit shall be 3 years after the date of manifestation of injury or 1 year after the claimant discovers, or through the use of reasonable diligence should have discovered, the injury, whichever occurs first. In no event shall the time for commencement of a health care lawsuit exceed 3 years after the date of manifestation of injury unless tolled for any of the following—

(1) upon proof of fraud;

(2) intentional concealment; or

(3) the presence of a foreign body, which has no therapeutic or diagnostic purpose or effect, in the person of the injured person.

Actions by a minor shall be commenced within 3 years from the date of the alleged manifestation of injury except that actions by a minor under the full age of 6 years shall be commenced within 3 years of manifestation of injury or prior to the minor's 8th birthday, whichever provides

a longer period. Such time limitation shall be tolled for minors for any period during which a parent or guardian and a health care provider or health care organization have committed fraud or collusion in the failure to bring an action on behalf of the injured minor.

SEC. 302. COMPENSATING PATIENT INJURY.

(a) UNLIMITED AMOUNT OF DAMAGES FOR ACTUAL ECONOMIC LOSSES IN HEALTH CARE LAWSUITS.—In any health care lawsuit, nothing in this title shall limit a claimant's recovery of the full amount of the available economic damages, notwithstanding the limitation in subsection (b).

(b) ADDITIONAL NONECONOMIC DAMAGES.—In any health care lawsuit, the amount of noneconomic damages, if available, may be as much as $250,000, regardless of the number of parties against whom the action is brought or the number of separate claims or actions brought with respect to the same injury.

(c) NO DISCOUNT OF AWARD FOR NONECONOMIC DAMAGES.—For purposes of applying the limitation in subsection (b), future noneconomic damages shall not be discounted to present value. The jury shall not be informed about the maximum award for noneconomic damages. An award for noneconomic damages in excess of $250,000 shall be reduced either before the entry of judgment, or by amendment of the judgment after entry of

judgment, and such reduction shall be made before accounting for any other reduction in damages required by law. If separate awards are rendered for past and future noneconomic damages and the combined awards exceed $250,000, the future noneconomic damages shall be reduced first.

(d) FAIR SHARE RULE.—In any health care lawsuit, each party shall be liable for that party's several share of any damages only and not for the share of any other person. Each party shall be liable only for the amount of damages allocated to such party in direct proportion to such party's percentage of responsibility. Whenever a judgment of liability is rendered as to any party, a separate judgment shall be rendered against each such party for the amount allocated to such party. For purposes of this section, the trier of fact shall determine the proportion of responsibility of each party for the claimant's harm.

SEC. 303. MAXIMIZING PATIENT RECOVERY.

(a) COURT SUPERVISION OF SHARE OF DAMAGES ACTUALLY PAID TO CLAIMANTS.—In any health care lawsuit, the court shall supervise the arrangements for payment of damages to protect against conflicts of interest that may have the effect of reducing the amount of damages awarded that are actually paid to claimants. In par-

ticular, in any health care lawsuit in which the attorney for a party claims a financial stake in the outcome by virtue of a contingent fee, the court shall have the power to restrict the payment of a claimant's damage recovery to such attorney, and to redirect such damages to the claimant based upon the interests of justice and principles of equity. In no event shall the total of all contingent fees for representing all claimants in a health care lawsuit exceed the following limits:

(1) 40 percent of the first $50,000 recovered by the claimant(s).

(2) 33⅓ percent of the next $50,000 recovered by the claimant(s).

(3) 25 percent of the next $500,000 recovered by the claimant(s).

(4) 15 percent of any amount by which the recovery by the claimant(s) is in excess of $600,000.

(b) APPLICABILITY.—The limitations in this section shall apply whether the recovery is by judgment, settlement, mediation, arbitration, or any other form of alternative dispute resolution. In a health care lawsuit involving a minor or incompetent person, a court retains the authority to authorize or approve a fee that is less than the maximum permitted under this section. The require-

ment for court supervision in the first two sentences of subsection (a) applies only in civil actions.

SEC. 304. ADDITIONAL HEALTH BENEFITS.

In any health care lawsuit involving injury or wrongful death, any party may introduce evidence of collateral source benefits. If a party elects to introduce such evidence, any opposing party may introduce evidence of any amount paid or contributed or reasonably likely to be paid or contributed in the future by or on behalf of the opposing party to secure the right to such collateral source benefits. No provider of collateral source benefits shall recover any amount against the claimant or receive any lien or credit against the claimant's recovery or be equitably or legally subrogated to the right of the claimant in a health care lawsuit involving injury or wrongful death. This section shall apply to any health care lawsuit that is settled as well as a health care lawsuit that is resolved by a fact finder. This section shall not apply to section 1862(b) (42 U.S.C. 1395y(b)) or section 1902(a)(25) (42 U.S.C. 1396a(a)(25)) of the Social Security Act.

SEC. 305. PUNITIVE DAMAGES.

(a) IN GENERAL.—Punitive damages may, if otherwise permitted by applicable State or Federal law, be awarded against any person in a health care lawsuit only if it is proven by clear and convincing evidence that such

person acted with malicious intent to injure the claimant, or that such person deliberately failed to avoid unnecessary injury that such person knew the claimant was substantially certain to suffer. In any health care lawsuit where no judgment for compensatory damages is rendered against such person, no punitive damages may be awarded with respect to the claim in such lawsuit. No demand for punitive damages shall be included in a health care lawsuit as initially filed. A court may allow a claimant to file an amended pleading for punitive damages only upon a motion by the claimant and after a finding by the court, upon review of supporting and opposing affidavits or after a hearing, after weighing the evidence, that the claimant has established by a substantial probability that the claimant will prevail on the claim for punitive damages. At the request of any party in a health care lawsuit, the trier of fact shall consider in a separate proceeding—

(1) whether punitive damages are to be awarded and the amount of such award; and

(2) the amount of punitive damages following a determination of punitive liability.

If a separate proceeding is requested, evidence relevant only to the claim for punitive damages, as determined by applicable State law, shall be inadmissible in any pro-

ceeding to determine whether compensatory damages are to be awarded.

(b) DETERMINING AMOUNT OF PUNITIVE DAMAGES.—

(1) FACTORS CONSIDERED.—In determining the amount of punitive damages, if awarded, in a health care lawsuit, the trier of fact shall consider only the following—

(A) the severity of the harm caused by the conduct of such party;

(B) the duration of the conduct or any concealment of it by such party;

(C) the profitability of the conduct to such party;

(D) the number of products sold or medical procedures rendered for compensation, as the case may be, by such party, of the kind causing the harm complained of by the claimant;

(E) any criminal penalties imposed on such party, as a result of the conduct complained of by the claimant; and

(F) the amount of any civil fines assessed against such party as a result of the conduct complained of by the claimant.

(2) MAXIMUM AWARD.—The amount of punitive damages, if awarded, in a health care lawsuit may be as much as $250,000 or as much as two times the amount of economic damages awarded, whichever is greater. The jury shall not be informed of this limitation.

SEC. 306. AUTHORIZATION OF PAYMENT OF FUTURE DAMAGES TO CLAIMANTS IN HEALTH CARE LAWSUITS.

(a) IN GENERAL.—In any health care lawsuit, if an award of future damages, without reduction to present value, equaling or exceeding $50,000 is made against a party with sufficient insurance or other assets to fund a periodic payment of such a judgment, the court shall, at the request of any party, enter a judgment ordering that the future damages be paid by periodic payments. In any health care lawsuit, the court may be guided by the Uniform Periodic Payment of Judgments Act promulgated by the National Conference of Commissioners on Uniform State Laws.

(b) APPLICABILITY.—This section applies to all actions which have not been first set for trial or retrial before the effective date of this title.

SEC. 307. DEFINITIONS.

In this title:

(1) ALTERNATIVE DISPUTE RESOLUTION SYSTEM; ADR.—The term ''alternative dispute resolution system'' or ''ADR'' means a system that provides for the resolution of health care lawsuits in a manner other than through a civil action brought in a State or Federal court.

(2) CLAIMANT.—The term ''claimant'' means any person who brings a health care lawsuit, including a person who asserts or claims a right to legal or equitable contribution, indemnity, or subrogation, arising out of a health care liability claim or action, and any person on whose behalf such a claim is asserted or such an action is brought, whether deceased, incompetent, or a minor.

(3) COLLATERAL SOURCE BENEFITS.—The term ''collateral source benefits'' means any amount paid or reasonably likely to be paid in the future to or on behalf of the claimant, or any service, product, or other benefit provided or reasonably likely to be provided in the future to or on behalf of the claimant, as a result of the injury or wrongful death, pursuant to—

(A) any State or Federal health, sickness, income-disability, accident, or workers' compensation law;

(B) any health, sickness, income-disability, or accident insurance that provides health benefits or income-disability coverage;

(C) any contract or agreement of any group, organization, partnership, or corporation to provide, pay for, or reimburse the cost of medical, hospital, dental, or income-disability benefits; and

(D) any other publicly or privately funded program.

(4) COMPENSATORY DAMAGES.—The term ''compensatory damages'' means objectively verifiable monetary losses incurred as a result of the provision of, use of, or payment for (or failure to provide, use, or pay for) health care services or medical products, such as past and future medical expenses, loss of past and future earnings, cost of obtaining domestic services, loss of employment, and loss of business or employment opportunities, damages for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium (other than loss of domestic service), hedonic damages, injury to reputation, and all other nonpecuniary losses

of any kind or nature. The term ''compensatory damages'' includes economic damages and non-economic damages, as such terms are defined in this section.

(5) CONTINGENT FEE.—The term ''contingent fee'' includes all compensation to any person or persons which is payable only if a recovery is effected on behalf of one or more claimants.

(6) ECONOMIC DAMAGES.—The term ''economic damages'' means objectively verifiable monetary losses incurred as a result of the provision of, use of, or payment for (or failure to provide, use, or pay for) health care services or medical products, such as past and future medical expenses, loss of past and future earnings, cost of obtaining domestic services, loss of employment, and loss of business or employment opportunities.

(7) HEALTH CARE LAWSUIT.—The term ''health care lawsuit'' means any health care liability claim concerning the provision of health care goods or services or any medical product affecting interstate commerce, or any health care liability action concerning the provision of health care goods or services or any medical product affecting interstate commerce, brought in a State or Federal court or

pursuant to an alternative dispute resolution system, against a health care provider, a health care organization, or the manufacturer, distributor, supplier, marketer, promoter, or seller of a medical product, regardless of the theory of liability on which the claim is based, or the number of claimants, plaintiffs, defendants, or other parties, or the number of claims or causes of action, in which the claimant alleges a health care liability claim. Such term does not include a claim or action which is based on criminal liability; which seeks civil fines or penalties paid to Federal, State, or local government; or which is grounded in antitrust.

(8) HEALTH CARE LIABILITY ACTION.—The term ''health care liability action'' means a civil action brought in a State or Federal court or pursuant to an alternative dispute resolution system, against a health care provider, a health care organization, or the manufacturer, distributor, supplier, marketer, promoter, or seller of a medical product, regardless of the theory of liability on which the claim is based, or the number of plaintiffs, defendants, or other parties, or the number of causes of action, in which the claimant alleges a health care liability claim.

(9) HEALTH CARE LIABILITY CLAIM.—The term ''health care liability claim'' means a demand by any person, whether or not pursuant to ADR, against a health care provider, health care organization, or the manufacturer, distributor, supplier, marketer, promoter, or seller of a medical product, including, but not limited to, third-party claims, cross-claims, counter-claims, or contribution claims, which are based upon the provision of, use of, or payment for (or the failure to provide, use, or pay for) health care services or medical products, regardless of the theory of liability on which the claim is based, or the number of plaintiffs, defendants, or other parties, or the number of causes of action.

(10) HEALTH CARE ORGANIZATION.—The term ''health care organization'' means any person or entity which is obligated to provide or pay for health benefits under any health plan, including any person or entity acting under a contract or arrangement with a health care organization to provide or administer any health benefit.

(11) HEALTH CARE PROVIDER.—The term ''health care provider'' means any person or entity required by State or Federal laws or regulations to be licensed, registered, or certified to provide health

care services, and being either so licensed, registered, or certified, or exempted from such requirement by other statute or regulation.

(12) HEALTH CARE GOODS OR SERVICES.—The term ''health care goods or services'' means any goods or services provided by a health care organization, provider, or by any individual working under the supervision of a health care provider, that relates to the diagnosis, prevention, or treatment of any human disease or impairment, or the assessment or care of the health of human beings.

(13) MALICIOUS INTENT TO INJURE.—The term ''malicious intent to injure'' means intentionally causing or attempting to cause physical injury other than providing health care goods or services.

(14) MEDICAL PRODUCT.—The term ''medical product'' means a drug, device, or biological product intended for humans, and the terms ''drug'', ''device'', and ''biological product'' have the meanings given such terms in sections 201(g)(1) and 201(h) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 321(g)(1) and (h)) and section 351(a) of the Public Health Service Act (42 U.S.C. 262(a)), re-

spectively, including any component or raw material used therein, but excluding health care services.

(15) NONECONOMIC DAMAGES.—The term ''noneconomic damages'' means damages for physical and emotional pain, suffering, inconvenience, physical impairment, mental anguish, disfigurement, loss of enjoyment of life, loss of society and companionship, loss of consortium (other than loss of domestic service), hedonic damages, injury to reputation, and all other nonpecuniary losses of any kind or nature.

(16) PUNITIVE DAMAGES.—The term ''punitive damages'' means damages awarded, for the purpose of punishment or deterrence, and not solely for compensatory purposes, against a health care provider, health care organization, or a manufacturer, distributor, or supplier of a medical product. Punitive damages are neither economic nor noneconomic damages.

(17) RECOVERY.—The term ''recovery'' means the net sum recovered after deducting any disbursements or costs incurred in connection with prosecution or settlement of the claim, including all costs paid or advanced by any person. Costs of health care incurred by the plaintiff and the attorneys' office

overhead costs or charges for legal services are not deductible disbursements or costs for such purpose.

(18) STATE.—The term ''State'' means each of the several States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, the Trust Territory of the Pacific Islands, and any other territory or possession of the United States, or any political subdivision thereof.

SEC. 308. EFFECT ON OTHER LAWS.

(a) VACCINE INJURY.—

(1) To the extent that title XXI of the Public Health Service Act establishes a Federal rule of law applicable to a civil action brought for a vaccine-related injury or death—

(A) this title does not affect the application of the rule of law to such an action; and

(B) any rule of law prescribed by this title in conflict with a rule of law of such title XXI shall not apply to such action.

(2) If there is an aspect of a civil action brought for a vaccine-related injury or death to which a Federal rule of law under title XXI of the Public Health Service Act does not apply, then this title or otherwise applicable law (as determined

under this title) will apply to such aspect of such action.

(b) OTHER FEDERAL LAW.—Except as provided in this section, nothing in this title shall be deemed to affect any defense available to a defendant in a health care lawsuit or action under any other provision of Federal law.

SEC. 309. STATE FLEXIBILITY AND PROTECTION OF STATES' RIGHTS.

(a) HEALTH CARE LAWSUITS.—The provisions governing health care lawsuits set forth in this title preempt, subject to subsections (b) and (c), State law to the extent that State law prevents the application of any provisions of law established by or under this title. The provisions governing health care lawsuits set forth in this title supersede chapter 171 of title 28, United States Code, to the extent that such chapter—

(1) provides for a greater amount of damages or contingent fees, a longer period in which a health care lawsuit may be commenced, or a reduced applicability or scope of periodic payment of future damages, than provided in this title; or

(2) prohibits the introduction of evidence regarding collateral source benefits, or mandates or permits subrogation or a lien on collateral source benefits.

(b) PROTECTION OF STATES' RIGHTS AND OTHER LAWS.—(1) Any issue that is not governed by any provision of law established by or under this title (including State standards of negligence) shall be governed by otherwise applicable State or Federal law.

(2) This title shall not preempt or supersede any State or Federal law that imposes greater procedural or substantive protections for health care providers and health care organizations from liability, loss, or damages than those provided by this title or create a cause of action.

(c) STATE FLEXIBILITY.—No provision of this title shall be construed to preempt—

(1) any State law (whether effective before, on, or after the date of the enactment of this Act) that specifies a particular monetary amount of compensatory or punitive damages (or the total amount of damages) that may be awarded in a health care lawsuit, regardless of whether such monetary amount is greater or lesser than is provided for under this title, notwithstanding section 302(a); or

(2) any defense available to a party in a health care lawsuit under any other provision of State or Federal law.

SEC. 310. APPLICABILITY; EFFECTIVE DATE.

This title shall apply to any health care lawsuit brought in a Federal or State court, or subject to an alternative dispute resolution system, that is initiated on or after the date of the enactment of this Act, except that any health care lawsuit arising from an injury occurring prior to the date of the enactment of this Act shall be governed by the applicable statute of limitations provisions in effect at the time the injury occurred.

DIVISION D—PROTECTING THE DOCTOR-PATIENT RELATIONSHIP

SEC. 401. RULE OF CONSTRUCTION.

Nothing in this Act shall be construed to interfere with the doctor-patient relationship or the practice of medicine.

SEC. 402. REPEAL OF FEDERAL COORDINATING COUNCIL FOR COMPARATIVE EFFECTIVENESS RESEARCH.

Effective on the date of the enactment of this Act, section 804 of the American Recovery and Reinvestment Act of 2009 is repealed.

DIVISION E—INCENTIVIZING WELLNESS AND QUALITY IMPROVEMENTS

SEC. 501. INCENTIVES FOR PREVENTION AND WELLNESS PROGRAMS.

(a) ERISA LIMITATION ON EXCEPTION FOR WELLNESS PROGRAMS UNDER HIPAA DISCRIMINATION RULES.—

(1) IN GENERAL.—Section 702(b)(2) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1182(b)(2)) is amended by adding after and below subparagraph (B) the following:

''In applying subparagraph (B), a group health plan (or a health insurance issuer with respect to health insurance coverage) may vary premiums and cost-sharing by up to 50 percent of the value of the benefits under the plan (or coverage) based on participation (or lack of participation) in a standards-based wellness program.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to plan years beginning more than 1 year after the date of the enactment of this Act.

(b) CONFORMING AMENDMENTS TO PHSA.—

(1) GROUP MARKET RULES.—

(A) IN GENERAL.—Section 2702(b)(2) of the Public Health Service Act (42 U.S.C. 300gg–1(b)(2)) is amended by adding after and below subparagraph (B) the following:

''In applying subparagraph (B), a group health plan (or a health insurance issuer with respect to health insurance coverage) may vary premiums and cost-sharing by up to 50 percent of the value of the benefits under the plan (or coverage) based on participation (or lack of participation) in a standards-based wellness program.''.

(B) EFFECTIVE DATE.—The amendment made by subparagraph (A) shall apply to plan years beginning more than 1 year after the date of the enactment of this Act.

(2) INDIVIDUAL MARKET RULES RELATING TO GUARANTEED AVAILABILITY.—

(A) IN GENERAL.—Section 2741(f) of the Public Health Service Act (42 U.S.C. 300gg–1(b)(2)) is amended by adding after and below paragraph (1) the following:

''In applying paragraph (2), a health insurance issuer may vary premiums and cost-sharing under health insurance coverage by up to 50 percent of the value of the benefits

under the coverage based on participation (or lack of participation) in a standards-based wellness program.''.

(B) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to health insurance coverage offered or renewed on and after the date that is 1 year after the date of the enactment of this Act.

(c) CONFORMING AMENDMENTS TO IRC.—

(1) IN GENERAL.—Section 9802(b)(2) of the Internal Revenue Code of 1986 is amended by adding after and below subparagraph (B) the following: ''In applying subparagraph (B), a group health plan (or a health insurance issuer with respect to health insurance coverage) may vary premiums and cost-sharing by up to 50 percent of the value of the benefits under the plan (or coverage) based on participation (or lack of participation) in a standards-based wellness program.''.

(2) EFFECTIVE DATE.—The amendment made by paragraph (1) shall apply to plan years beginning more than 1 year after the date of the enactment of this Act.

DIVISION F—PROTECTING TAXPAYERS

SEC. 601. PROVIDE FULL FUNDING TO HHS OIG AND HCFAC.

(a) HCFAC FUNDING.— Section 1817(k)(3)(A) of the Social Security Act (42 U.S.C. 1395i(k)(3)(A)) is amended—

(1) in clause (i)—

(A) in subclause (IV), by striking ''2009, and 2010'' and inserting ''and 2009''; and

(B) by amending subclause (V) to read as follows:

''(V) for each fiscal year after fiscal year 2009, $300,000,000.''; and

(2) in clause (ii)—

(A) in subclause (IX), by striking ''2009, and 2010'' and inserting ''and 2009''; and

(B) in subclause (X), by striking ''2010'' and inserting ''2009'' and by inserting before the period at the end the following: '', plus the amount by which the amount made available under clause (i)(V) for fiscal year 2010 exceeds the amount made available under clause (i)(IV) for 2009''.

(b) OIG FUNDING.—There are authorized to be appropriated for each of fiscal years 2010 through 2019 $100,000,000 for the Office of the Inspector General of the Department of Health and Human Services for fraud prevention activities under the Medicare and Medicaid programs.

SEC. 602. PROHIBITING TAXPAYER FUNDED ABORTIONS AND CONSCIENCE PROTECTIONS.

Title 1 of the United States Code is amended by adding at the end the following new chapter:

"CHAPTER 4—PROHIBITING TAXPAYER FUNDED ABORTIONS AND CONSCIENCE PROTECTIONS

"SEC. 301. PROHIBITION ON FUNDING FOR ABORTIONS.

''No funds authorized or appropriated by federal law, and none of the funds in any trust fund to which funds are authorized or appropriated by federal law, shall be expended for any abortion.

"SEC. 302. PROHIBITION ON FUNDING FOR HEALTH BENEFITS PLANS THAT COVER ABORTION.

''None of the funds authorized or appropriated by federal law, and none of the funds in any trust fund to which funds are authorized or appropriated by federal law, shall be expended for a health benefits plan that includes coverage of abortion.

''SEC. 303. TREATMENT OF ABORTIONS RELATED TO RAPE, INCEST, OR PRESERVING THE LIFE OF THE MOTHER.

''The limitations established in sections 301 and 302 shall not apply to an abortion—

''(1) if the pregnancy is the result of an act of rape or incest; or

''(2) in the case where a woman suffers from a physical disorder, physical injury, or physical illness that would, as certified by a physician, place the woman in danger of death unless an abortion is performed, including a life-endangering physical condition caused by or arising from the pregnancy itself.

''SEC. 304. CONSTRUCTION RELATING TO SUPPLEMENTAL COVERAGE.

''Nothing in this chapter shall be construed as prohibiting any individual, entity, or State or locality from purchasing separate supplemental abortion plan or coverage that includes abortion so long as such plan or coverage is paid for entirely using only funds not authorized or appropriated by federal law and such plan or coverage shall not be purchased using matching funds required for a federally subsidized program, including a State's or locality's contribution of Medicaid matching funds.

"SEC. 305. CONSTRUCTION RELATING TO THE USE OF NON-FEDERAL FUNDS FOR HEALTH COVERAGE.

''Nothing in this chapter shall be construed as restricting the ability of any managed care provider or other organization from offering abortion coverage or the ability of a State to contract separately with such a provider or organization for such coverage with funds not authorized or appropriated by federal law and such plan or coverage shall not be purchased using matching funds required for a federally subsidized program, including a State's or locality's contribution of Medicaid matching funds.

"SEC. 306. NO GOVERNMENT DISCRIMINATION AGAINST CERTAIN HEALTH CARE ENTITIES.

''(a) IN GENERAL.—No funds authorized or appropriated by federal law may be made available to a Federal agency or program, or to a State or local government, if such agency, program, or government subjects any institutional or individual health care entity to discrimination on the basis that the health care entity does not provide, pay for, provide coverage of, or refer for abortions.

''(b) HEALTH CARE ENTITY DEFINED.—For purposes of this section, the term 'health care entity' includes an individual physician or other health care professional, a hospital, a provider-sponsored organization, a health maintenance organization, a health insurance plan, or any other kind of health care facility, organization, or plan.''.

SEC. 603. IMPROVED ENFORCEMENT OF THE MEDICARE AND MEDICAID SECONDARY PAYER PROVISIONS.

(a) MEDICARE.—

(1) IN GENERAL.—The Secretary, in coordination with the Inspector General of the Department of Health and Human Services, shall provide through the Coordination of Benefits Contractor for the identification of instances where the Medicare program should be, but is not, acting as a secondary payer to an individual's private health benefits coverage under section 1862(b) of the Social Security Act (42 U.S.C. 1395y(b)).

(2) UPDATING PROCEDURES.—The Secretary shall update procedures for identifying and resolving credit balance situations which occur under the Medicare program when payment under such title and from other health benefit plans exceed the providers' charges or the allowed amount.

(3) REPORT ON IMPROVED ENFORCEMENT.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall submit a report to Congress on progress made in improved enforcement of the Medicare secondary payer provisions, including recoupment of credit balances.

(b) MEDICAID.—Section 1903 of the Social Security Act (42 U.S.C. 1396b) is amended by adding at the end the following new subsection:

''(aa) ENFORCEMENT OF PAYER OF LAST RESORT PROVISIONS.—

''(1) SUBMISSION OF STATE PLAN AMENDMENT.—Each State shall submit, not later than 1 year after the date of the enactment of this subsection, a State plan amendment that details how the State will become fully compliant with the requirements of section 1902(a)(25).

''(2) BONUS FOR COMPLIANCE.—If a State submits a timely State plan amendment under paragraph (1) that the Secretary determines provides for full compliance of the State with the requirements of section 1902(a)(25), the Secretary shall provide for an additional payment to the State of $1,000,000. If a State certifies, to the Secretary's satisfaction, that it is already fully compliant with such requirements, such amount shall be increased to $2,000,000.

''(3) REDUCTION FOR NONCOMPLIANCE.—If a State does not submit such an amendment, the Secretary shall reduce the Federal medical assistance percentage otherwise applicable under this title by 1

percentage point until the State submits such an amendment.

''(4) ONGOING REDUCTION.—If at any time the Secretary determines that a State is not in compliance with section 1902(a)(25), regardless of the status of the State's submission of a State plan amendment under this subsection or previous determinations of compliance such requirements, the Secretary shall reduce the Federal medical assistance percentage otherwise applicable under this title for the State by 1 percentage point during the period of non-compliance as determined by the Secretary.''.

SEC. 604. STRENGTHEN MEDICARE PROVIDER ENROLLMENT STANDARDS AND SAFEGUARDS.

(a) PROTECTING AGAINST THE FRAUDULENT USE OF MEDICARE PROVIDER NUMBERS.—Subject to subsection (c)(2)—

(1) SCREENING NEW PROVIDERS.—As a condition of a provider of services or a supplier, including durable medical equipment suppliers and home health agencies, applying for the first time for a provider number under the Medicare program and before granting billing privileges under such title, the Secretary shall screen the provider or supplier for a criminal background or other financial or oper-

ational irregularities through fingerprinting, licensure checks, site-visits, other database checks.

(2) APPLICATION FEES.—The Secretary shall impose an application charge on such a provider or supplier in order to cover the Secretary's costs in performing the screening required under paragraph (1) and that is revenue neutral to the Federal government.

(3) PROVISIONAL APPROVAL.—During an initial, provisional period (specified by the Secretary) In which such a provider or supplier has been issued such a number, the Secretary shall provide enhanced oversight of the activities of such provider or supplier under the Medicare program, such as through prepayment review and payment limitations.

(4) PENALTIES FOR FALSE STATEMENTS.—In the case of a provider or supplier that makes a false statement in an application for such a number, the Secretary may exclude the provider or supplier from participation under the Medicare program, or may impose a civil money penalty (in the amount described in section 1128A(a)(4) of the Social Security Act), in the same manner as the Secretary may impose such an exclusion or penalty under sections 1128 and 1128A, respectively, of such Act in the

case of knowing presentation of a false claim described in section 1128A(a)(1)(A) of such Act.

(5) DISCLOSURE REQUIREMENTS.—With respect to approval of such an application, the Secretary—

(A) shall require applicants to disclose previous affiliation with enrolled entities that have uncollected debt related to the Medicare or Medicaid programs;

(B) may deny approval if the Secretary determines that these affiliations pose undue risk to the Medicare or Medicaid program, subject to an appeals process for the applicant as determined by the Secretary; and

(C) may implement enhanced safeguards (such as surety bonds).

(b) MORATORIA.—The Secretary may impose moratoria on approval of provider and supplier numbers under the Medicare program for new providers of services and suppliers as determined necessary to prevent or combat fraud a period of delay for any one applicant cannot exceed 30 days unless cause is shown by the Secretary.

(c) FUNDING.—

(1) IN GENERAL.—There are authorized to be appropriated to carry out this section such sums as may be necessary.

(2) CONDITION.—The provisions of paragraphs (1) and (2) of subsection (a) shall not apply unless and until funds are appropriated to carry out such provisions

SEC. 605. TRACKING BANNED PROVIDERS ACROSS STATE LINES.

(a) GREATER COORDINATION.—The Secretary of Health and Human Services shall provide for increased coordination between the Administrator of the Centers for Medicare & Medicaid Services (in this section referred to as ''CMS'') and its regional offices to ensure that providers of services and suppliers that have operated in one State and are excluded from participation in the Medicare program are unable to begin operation and participation in the Medicare program in another State.

(b) IMPROVED INFORMATION SYSTEMS.—

(1) IN GENERAL.—The Secretary shall improve information systems to allow greater integration between databases under the Medicare program so that—

(A) medicare administrative contractors, fiscal intermediaries, and carriers have imme-

diate access to information identifying providers and suppliers excluded from participation in the Medicare and Medicaid program and other Federal health care programs; and

(B) such information can be shared across Federal health care programs and agencies, including between the Departments of Health and Human Services, the Social Security Administration, the Department of Veterans Affairs, the Department of Defense, the Department of Justice, and the Office of Personnel Management.

(c) MEDICARE/MEDICAID ''ONE PI'' DATABASE.—The Secretary shall implement a database that includes claims and payment data for all components of the Medicare program and the Medicaid program.

(d) AUTHORIZING EXPANDED DATA MATCHING.—Notwithstanding any provision of the Computer Matching and Privacy Protection Act of 1988 to the contrary—

(1) the Secretary and the Inspector General in the Department of Health and Human Services may perform data matching of data from the Medicare program with data from the Medicaid program; and

(2) the Commissioner of Social Security and the Secretary may perform data matching of data of the

Social Security Administration with data from the Medicare and Medicaid programs.

(e) CONSOLIDATION OF DATA BASES.—The Secretary shall consolidate and expand into a centralized data base for individuals and entities that have been excluded from Federal health care programs the Healthcare Integrity and Protection Data Bank, the National Practitioner Data Bank, the List of Excluded Individuals/Entities, and a national patient abuse/neglect registry.

(f) COMPREHENSIVE PROVIDER DATABASE.—

(1) ESTABLISHMENT.—The Secretary shall establish a comprehensive database that includes information on providers of services, suppliers, and related entities participating in the Medicare program, the Medicaid program, or both. Such database shall include, information on ownership and business relationships, history of adverse actions, results of site visits or other monitoring by any program.

(2) USE.—Prior to issuing a provider or supplier number for an entity under the Medicare program, the Secretary shall obtain information on the entity from such database to assure the entity qualifies for the issuance of such a number.

(g) COMPREHENSIVE SANCTIONS DATABASE.—The Secretary shall establish a comprehensive sanctions data-

base on sanctions imposed on providers of services, suppliers, and related entities. Such database shall be overseen by the Inspector General of the Department of Health and Human Services and shall be linked to related databases maintained by State licensure boards and by Federal or State law enforcement agencies.

(h) ACCESS TO CLAIMS AND PAYMENT DATABASES.—The Secretary shall ensure that the Inspector General of the Department of Health and Human Services and Federal law enforcement agencies have direct access to all claims and payment databases of the Secretary under the Medicare or Medicaid programs.

(i) CIVIL MONEY PENALTIES FOR SUBMISSION OF ERRONEOUS INFORMATION.—In the case of a provider of services, supplier, or other entity that submits erroneous information that serves as a basis for payment of any entity under the Medicare or Medicaid program, the Secretary may impose a civil money penalty of not to exceed $50,000 for each such erroneous submission. A civil money penalty under this subsection shall be imposed and collected in the same manner as a civil money penalty under subsection (a) of section 1128A of the Social Security Act is imposed and collected under that section.

DIVISION G—PATHWAY FOR BIOSIMILAR BIOLOGICAL PRODUCTS

SEC. 701. APPROVAL PATHWAY FOR BIOSIMILAR BIOLOGICAL PRODUCTS.

(a) LICENSURE OF BIOLOGICAL PRODUCTS AS BIOSIMILAR OR INTERCHANGEABLE.—Section 351 of the Public Health Service Act (42 U.S.C. 262) is amended—

(1) in subsection (a)(1)(A), by inserting ''under this subsection or subsection (k)'' after ''biologics license''; and

(2) by adding at the end the following:

''(k) LICENSURE OF BIOLOGICAL PRODUCTS AS BIOSIMILAR OR INTERCHANGEABLE.—

''(1) IN GENERAL.—Any person may submit an application for licensure of a biological product under this subsection.

''(2) CONTENT.—

''(A) IN GENERAL.—

''(i) REQUIRED INFORMATION.—An application submitted under this subsection shall include information demonstrating that—

"(I) the biological product is biosimilar to a reference product based upon data derived from—

"(aa) analytical studies that demonstrate that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components;

"(bb) animal studies (including the assessment of toxicity); and

"(cc) a clinical study or studies (including the assessment of immunogenicity and pharmacokinetics or pharmacodynamics) that are sufficient to demonstrate safety, purity, and potency in 1 or more appropriate conditions of use for which the reference product is licensed and intended to be used and for which licensure is sought for the biological product;

''(II) the biological product and reference product utilize the same mechanism or mechanisms of action for the condition or conditions of use prescribed, recommended, or suggested in the proposed labeling, but only to the extent the mechanism or mechanisms of action are known for the reference product;

''(III) the condition or conditions of use prescribed, recommended, or suggested in the labeling proposed for the biological product have been previously approved for the reference product;

''(IV) the route of administration, the dosage form, and the strength of the biological product are the same as those of the reference product; and

''(V) the facility in which the biological product is manufactured, processed, packed, or held meets standards designed to assure that the bio-

logical product continues to be safe, pure, and potent.

''(ii) DETERMINATION BY SECRETARY.—The Secretary may determine, in the Secretary's discretion, that an element described in clause (i)(I) is unnecessary in an application submitted under this subsection.

''(iii) ADDITIONAL INFORMATION.—An application submitted under this subsection—

''(I) shall include publicly-available information regarding the Secretary's previous determination that the reference product is safe, pure, and potent; and

''(II) may include any additional information in support of the application, including publicly-available information with respect to the reference product or another biological product.

''(B) INTERCHANGEABILITY.—An application (or a supplement to an application) submitted under this subsection may include information demonstrating that the biological prod-

uct meets the standards described in paragraph (4).

''(3) EVALUATION BY SECRETARY.—Upon review of an application (or a supplement to an application) submitted under this subsection, the Secretary shall license the biological product under this subsection if—

''(A) the Secretary determines that the information submitted in the application (or the supplement) is sufficient to show that the biological product—

''(i) is biosimilar to the reference product; or

''(ii) meets the standards described in paragraph (4), and therefore is interchangeable with the reference product; and

''(B) the applicant (or other appropriate person) consents to the inspection of the facility that is the subject of the application, in accordance with subsection (c).

''(4) SAFETY STANDARDS FOR DETERMINING INTERCHANGEABILITY.—Upon review of an application submitted under this subsection or any supplement to such application, the Secretary shall determine the biological product to be interchangeable

with the reference product if the Secretary determines that the information submitted in the application (or a supplement to such application) is sufficient to show that—

''(A) the biological product—

''(i) is biosimilar to the reference product; and

''(ii) can be expected to produce the same clinical result as the reference product in any given patient; and

''(B) for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

''(5) GENERAL RULES.—

''(A) ONE REFERENCE PRODUCT PER APPLICATION.—A biological product, in an application submitted under this subsection, may not be evaluated against more than 1 reference product.

''(B) REVIEW.—An application submitted under this subsection shall be reviewed by the

division within the Food and Drug Administration that is responsible for the review and approval of the application under which the reference product is licensed.

''(C) RISK EVALUATION AND MITIGATION STRATEGIES.—The authority of the Secretary with respect to risk evaluation and mitigation strategies under the Federal Food, Drug, and Cosmetic Act shall apply to biological products licensed under this subsection in the same manner as such authority applies to biological products licensed under subsection (a).

''(6) EXCLUSIVITY FOR FIRST INTERCHANGEABLE BIOLOGICAL PRODUCT.—Upon review of an application submitted under this subsection relying on the same reference product for which a prior biological product has received a determination of interchangeability for any condition of use, the Secretary shall not make a determination under paragraph (4) that the second or subsequent biological product is interchangeable for any condition of use until the earlier of—

''(A) 1 year after the first commercial marketing of the first interchangeable bio-

similar biological product to be approved as interchangeable for that reference product;

''(B) 18 months after—

''(i) a final court decision on all patents in suit in an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

''(ii) the dismissal with or without prejudice of an action instituted under subsection (l)(6) against the applicant that submitted the application for the first approved interchangeable biosimilar biological product; or

''(C)(i) 42 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has been sued under subsection (l)(6) and such litigation is still ongoing within such 42-month period; or

''(ii) 18 months after approval of the first interchangeable biosimilar biological product if the applicant that submitted such application has not been sued under subsection (l)(6).

For purposes of this paragraph, the term 'final court decision' means a final decision of a court from which no appeal (other than a petition to the United States Supreme Court for a writ of certiorari) has been or can be taken.

"(7) EXCLUSIVITY FOR REFERENCE PRODUCT.—

"(A) EFFECTIVE DATE OF BIOSIMILAR APPLICATION APPROVAL.—Approval of an application under this subsection may not be made effective by the Secretary until the date that is 12 years after the date on which the reference product was first licensed under subsection (a).

"(B) FILING PERIOD.—An application under this subsection may not be submitted to the Secretary until the date that is 4 years after the date on which the reference product was first licensed under subsection (a).

"(C) FIRST LICENSURE.—Subparagraphs (A) and (B) shall not apply to a license for or approval of—

"(i) a supplement for the biological product that is the reference product; or

"(ii) a subsequent application filed by the same sponsor or manufacturer of the

biological product that is the reference product (or a licensor, predecessor in interest, or other related entity) for—

"(I) a change (not including a modification to the structure of the biological product) that results in a new indication, route of administration, dosing schedule, dosage form, delivery system, delivery device, or strength; or

"(II) a modification to the structure of the biological product that does not result in a change in safety, purity, or potency.

"(8) GUIDANCE DOCUMENTS.—

"(A) IN GENERAL.—The Secretary may, after opportunity for public comment, issue guidance in accordance, except as provided in subparagraph (B)(i), with section 701(h) of the Federal Food, Drug, and Cosmetic Act with respect to the licensure of a biological product under this subsection. Any such guidance may be general or specific.

"(B) PUBLIC COMMENT.—

"(i) IN GENERAL.—The Secretary shall provide the public an opportunity to

comment on any proposed guidance issued under subparagraph (A) before issuing final guidance.

''(ii) INPUT REGARDING MOST VALUABLE GUIDANCE.—The Secretary shall establish a process through which the public may provide the Secretary with input regarding priorities for issuing guidance.

''(C) NO REQUIREMENT FOR APPLICATION CONSIDERATION.—The issuance (or non-issuance) of guidance under subparagraph (A) shall not preclude the review of, or action on, an application submitted under this subsection.

''(D) REQUIREMENT FOR PRODUCT CLASS-SPECIFIC GUIDANCE.—If the Secretary issues product class-specific guidance under subparagraph (A), such guidance shall include a description of—

''(i) the criteria that the Secretary will use to determine whether a biological product is highly similar to a reference product in such product class; and

''(ii) the criteria, if available, that the Secretary will use to determine whether a

biological product meets the standards described in paragraph (4).

''(E) CERTAIN PRODUCT CLASSES.—

''(i) GUIDANCE.—The Secretary may indicate in a guidance document that the science and experience, as of the date of such guidance, with respect to a product or product class (not including any recombinant protein) does not allow approval of an application for a license as provided under this subsection for such product or product class.

''(ii) MODIFICATION OR REVERSAL.—The Secretary may issue a subsequent guidance document under subparagraph (A) to modify or reverse a guidance document under clause (i).

''(iii) NO EFFECT ON ABILITY TO DENY LICENSE.—Clause (i) shall not be construed to require the Secretary to approve a product with respect to which the Secretary has not indicated in a guidance document that the science and experience, as described in clause (i), does not allow approval of such an application.

''(l) PATENTS.—

''(1) CONFIDENTIAL ACCESS TO SUBSECTION (k) APPLICATION.—

''(A) APPLICATION OF PARAGRAPH.—Unless otherwise agreed to by a person that submits an application under subsection (k) (referred to in this subsection as the 'subsection (k) applicant') and the sponsor of the application for the reference product (referred to in this subsection as the 'reference product sponsor'), the provisions of this paragraph shall apply to the exchange of information described in this subsection.

''(B) IN GENERAL.—

''(i) PROVISION OF CONFIDENTIAL INFORMATION.—When a subsection (k) applicant submits an application under subsection (k), such applicant shall provide to the persons described in clause (ii), subject to the terms of this paragraph, confidential access to the information required to be produced pursuant to paragraph (2) and any other information that the subsection (k) applicant determines, in its sole discretion, to be appropriate (referred to in this

subsection as the 'confidential information').

''(ii) RECIPIENTS OF INFORMATION.—The persons described in this clause are the following:

''(I) OUTSIDE COUNSEL.—One or more attorneys designated by the reference product sponsor who are employees of an entity other than the reference product sponsor (referred to in this paragraph as the 'outside counsel'), provided that such attorneys do not engage, formally or informally, in patent prosecution relevant or related to the reference product.

''(II) IN-HOUSE COUNSEL.—One attorney that represents the reference product sponsor who is an employee of the reference product sponsor, provided that such attorney does not engage, formally or informally, in patent prosecution relevant or related to the reference product.

''(iii) PATENT OWNER ACCESS.—A representative of the owner of a patent ex-

clusively licensed to a reference product sponsor with respect to the reference product and who has retained a right to assert the patent or participate in litigation concerning the patent may be provided the confidential information, provided that the representative informs the reference product sponsor and the subsection (k) applicant of his or her agreement to be subject to the confidentiality provisions set forth in this paragraph, including those under clause (ii).

''(C) LIMITATION ON DISCLOSURE.—No person that receives confidential information pursuant to subparagraph (B) shall disclose any confidential information to any other person or entity, including the reference product sponsor employees, outside scientific consultants, or other outside counsel retained by the reference product sponsor, without the prior written consent of the subsection (k) applicant, which shall not be unreasonably withheld.

''(D) USE OF CONFIDENTIAL INFORMATION.—Confidential information shall be used for the sole and exclusive purpose of deter-

mining, with respect to each patent assigned to or exclusively licensed by the reference product sponsor, whether a claim of patent infringement could reasonably be asserted if the subsection (k) applicant engaged in the manufacture, use, offering for sale, sale, or importation into the United States of the biological product that is the subject of the application under subsection (k).

''(E) OWNERSHIP OF CONFIDENTIAL INFORMATION.—The confidential information disclosed under this paragraph is, and shall remain, the property of the subsection (k) applicant. By providing the confidential information pursuant to this paragraph, the subsection (k) applicant does not provide the reference product sponsor or the outside counsel any interest in or license to use the confidential information, for purposes other than those specified in subparagraph (D).

''(F) EFFECT OF INFRINGEMENT ACTION.—In the event that the reference product sponsor files a patent infringement suit, the use of confidential information shall continue to be governed by the terms of this paragraph until

such time as a court enters a protective order regarding the information. Upon entry of such order, the subsection (k) applicant may redesignate confidential information in accordance with the terms of that order. No confidential information shall be included in any publicly-available complaint or other pleading. In the event that the reference product sponsor does not file an infringement action by the date specified in paragraph (6), the reference product sponsor shall return or destroy all confidential information received under this paragraph, provided that if the reference product sponsor opts to destroy such information, it will confirm destruction in writing to the subsection (k) applicant.

''(G) RULE OF CONSTRUCTION.—Nothing in this paragraph shall be construed—

''(i) as an admission by the subsection (k) applicant regarding the validity, enforceability, or infringement of any patent; or

''(ii) as an agreement or admission by the subsection (k) applicant with respect to

the competency, relevance, or materiality of any confidential information.

''(H) EFFECT OF VIOLATION.—The disclosure of any confidential information in violation of this paragraph shall be deemed to cause the subsection (k) applicant to suffer irreparable harm for which there is no adequate legal remedy and the court shall consider immediate injunctive relief to be an appropriate and necessary remedy for any violation or threatened violation of this paragraph.

''(2) SUBSECTION (k) APPLICATION INFORMATION.—Not later than 20 days after the Secretary notifies the subsection (k) applicant that the application has been accepted for review, the subsection (k) applicant—

''(A) shall provide to the reference product sponsor a copy of the application submitted to the Secretary under subsection (k), and such other information that describes the process or processes used to manufacture the biological product that is the subject of such application; and

''(B) may provide to the reference product sponsor additional information requested by or on behalf of the reference product sponsor.

''(3) LIST AND DESCRIPTION OF PATENTS.—

''(A) LIST BY REFERENCE PRODUCT SPONSOR.—Not later than 60 days after the receipt of the application and information under paragraph (2), the reference product sponsor shall provide to the subsection (k) applicant—

''(i) a list of patents for which the reference product sponsor believes a claim of patent infringement could reasonably be asserted by the reference product sponsor, or by a patent owner that has granted an exclusive license to the reference product sponsor with respect to the reference product, if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application; and

''(ii) an identification of the patents on such list that the reference product

sponsor would be prepared to license to the subsection (k) applicant.

''(B) LIST AND DESCRIPTION BY SUBSECTION (k) APPLICANT.—Not later than 60 days after receipt of the list under subparagraph (A), the subsection (k) applicant—

''(i) may provide to the reference product sponsor a list of patents to which the subsection (k) applicant believes a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application;

''(ii) shall provide to the reference product sponsor, with respect to each patent listed by the reference product sponsor under subparagraph (A) or listed by the subsection (k) applicant under clause (i)—

''(I) a detailed statement that describes, on a claim by claim basis, the factual and legal basis of the opinion

of the subsection (k) applicant that such patent is invalid, unenforceable, or will not be infringed by the commercial marketing of the biological product that is the subject of the subsection (k) application; or

''(II) a statement that the subsection (k) applicant does not intend to begin commercial marketing of the biological product before the date that such patent expires; and

''(iii) shall provide to the reference product sponsor a response regarding each patent identified by the reference product sponsor under subparagraph (A)(ii).

''(C) DESCRIPTION BY REFERENCE PRODUCT SPONSOR.—Not later than 60 days after receipt of the list and statement under subparagraph (B), the reference product sponsor shall provide to the subsection (k) applicant a detailed statement that describes, with respect to each patent described in subparagraph (B)(ii)(I), on a claim by claim basis, the factual and legal basis of the opinion of the reference product sponsor that such patent will be in-

fringed by the commercial marketing of the biological product that is the subject of the subsection (k) application and a response to the statement concerning validity and enforceability provided under subparagraph (B)(ii)(I).

''(4) PATENT RESOLUTION NEGOTIATIONS.—

''(A) IN GENERAL.—After receipt by the subsection (k) applicant of the statement under paragraph (3)(C), the reference product sponsor and the subsection (k) applicant shall engage in good faith negotiations to agree on which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6).

''(B) FAILURE TO REACH AGREEMENT.—If, within 15 days of beginning negotiations under subparagraph (A), the subsection (k) applicant and the reference product sponsor fail to agree on a final and complete list of which, if any, patents listed under paragraph (3) by the subsection (k) applicant or the reference product sponsor shall be the subject of an action for patent infringement under paragraph (6), the

provisions of paragraph (5) shall apply to the parties.

''(5) PATENT RESOLUTION IF NO AGREEMENT.—

''(A) NUMBER OF PATENTS.—The subsection (k) applicant shall notify the reference product sponsor of the number of patents that such applicant will provide to the reference product sponsor under subparagraph (B)(i)(I).

''(B) EXCHANGE OF PATENT LISTS.—

''(i) IN GENERAL.—On a date agreed to by the subsection (k) applicant and the reference product sponsor, but in no case later than 5 days after the subsection (k) applicant notifies the reference product sponsor under subparagraph (A), the subsection (k) applicant and the reference product sponsor shall simultaneously exchange—

''(I) the list of patents that the subsection (k) applicant believes should be the subject of an action for patent infringement under paragraph (6); and

''(II) the list of patents, in accordance with clause (ii), that the reference product sponsor believes should be the subject of an action for patent infringement under paragraph (6).

''(ii) NUMBER OF PATENTS LISTED BY REFERENCE PRODUCT SPONSOR.—

''(I) IN GENERAL.—Subject to subclause (II), the number of patents listed by the reference product sponsor under clause (i)(II) may not exceed the number of patents listed by the subsection (k) applicant under clause (i)(I).

''(II) EXCEPTION.—If a subsection (k) applicant does not list any patent under clause (i)(I), the reference product sponsor may list 1 patent under clause (i)(II).

''(6) IMMEDIATE PATENT INFRINGEMENT ACTION.—

''(A) ACTION IF AGREEMENT ON PATENT LIST.—If the subsection (k) applicant and the reference product sponsor agree on patents as described in paragraph (4), not later than 30

days after such agreement, the reference product sponsor shall bring an action for patent infringement with respect to each such patent.

''(B) ACTION IF NO AGREEMENT ON PATENT LIST.—If the provisions of paragraph (5) apply to the parties as described in paragraph (4)(B), not later than 30 days after the exchange of lists under paragraph (5)(B), the reference product sponsor shall bring an action for patent infringement with respect to each patent that is included on such lists.

''(C) NOTIFICATION AND PUBLICATION OF COMPLAINT.—

''(i) NOTIFICATION TO SECRETARY.—Not later than 30 days after a complaint is served to a subsection (k) applicant in an action for patent infringement described under this paragraph, the subsection (k) applicant shall provide the Secretary with notice and a copy of such complaint.

''(ii) PUBLICATION BY SECRETARY.—The Secretary shall publish in the Federal Register notice of a complaint received under clause (i).

''(7) NEWLY ISSUED OR LICENSED PATENTS.—In the case of a patent that—

''(A) is issued to, or exclusively licensed by, the reference product sponsor after the date that the reference product sponsor provided the list to the subsection (k) applicant under paragraph (3)(A); and

''(B) the reference product sponsor reasonably believes that, due to the issuance of such patent, a claim of patent infringement could reasonably be asserted by the reference product sponsor if a person not licensed by the reference product sponsor engaged in the making, using, offering to sell, selling, or importing into the United States of the biological product that is the subject of the subsection (k) application,

not later than 30 days after such issuance or licensing, the reference product sponsor shall provide to the subsection (k) applicant a supplement to the list provided by the reference product sponsor under paragraph (3)(A) that includes such patent, not later than 30 days after such supplement is provided, the subsection (k) applicant shall provide a statement to the reference product sponsor in ac-

cordance with paragraph (3)(B), and such patent shall be subject to paragraph (8).

''(8) NOTICE OF COMMERCIAL MARKETING AND PRELIMINARY INJUNCTION.—

''(A) NOTICE OF COMMERCIAL MARKETING.—The subsection (k) applicant shall provide notice to the reference product sponsor not later than 180 days before the date of the first commercial marketing of the biological product licensed under subsection (k).

''(B) PRELIMINARY INJUNCTION.—After receiving the notice under subparagraph (A) and before such date of the first commercial marketing of such biological product, the reference product sponsor may seek a preliminary injunction prohibiting the subsection (k) applicant from engaging in the commercial manufacture or sale of such biological product until the court decides the issue of patent validity, enforcement, and infringement with respect to any patent that is—

''(i) included in the list provided by the reference product sponsor under paragraph (3)(A) or in the list provided by the

subsection (k) applicant under paragraph (3)(B); and

''(ii) not included, as applicable, on—

''(I) the list of patents described in paragraph (4); or

''(II) the lists of patents described in paragraph (5)(B).

''(C) REASONABLE COOPERATION.—If the reference product sponsor has sought a preliminary injunction under subparagraph (B), the reference product sponsor and the subsection (k) applicant shall reasonably cooperate to expedite such further discovery as is needed in connection with the preliminary injunction motion.

''(9) LIMITATION ON DECLARATORY JUDGMENT ACTION.—

''(A) SUBSECTION (k) APPLICATION PROVIDED.—If a subsection (k) applicant provides the application and information required under paragraph (2)(A), neither the reference product sponsor nor the subsection (k) applicant may, prior to the date notice is received under paragraph (8)(A), bring any action under section 2201 of title 28, United States Code, for a dec-

laration of infringement, validity, or enforceability of any patent that is described in clauses (i) and (ii) of paragraph (8)(B).

''(B) SUBSEQUENT FAILURE TO ACT BY SUBSECTION (k) APPLICANT.—If a subsection (k) applicant fails to complete an action required of the subsection (k) applicant under paragraph (3)(B)(ii), paragraph (5), paragraph (6)(C)(i), paragraph (7), or paragraph (8)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability of any patent included in the list described in paragraph (3)(A), including as provided under paragraph (7).

''(C) SUBSECTION (k) APPLICATION NOT PROVIDED.—If a subsection (k) applicant fails to provide the application and information required under paragraph (2)(A), the reference product sponsor, but not the subsection (k) applicant, may bring an action under section 2201 of title 28, United States Code, for a declaration of infringement, validity, or enforceability

of any patent that claims the biological product or a use of the biological product.''.

(b) DEFINITIONS.—Section 351(i) of the Public Health Service Act (42 U.S.C. 262(i)) is amended—

(1) by striking ''In this section, the term 'biological product' means'' and inserting the following: ''In this section:

''(1) The term 'biological product' means'';

(2) in paragraph (1), as so designated, by inserting ''protein (except any chemically synthesized polypeptide),'' after ''allergenic product,''; and

(3) by adding at the end the following:

''(2) The term 'biosimilar' or 'biosimilarity', in reference to a biological product that is the subject of an application under subsection (k), means—

''(A) that the biological product is highly similar to the reference product notwithstanding minor differences in clinically inactive components; and

''(B) there are no clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product.

''(3) The term 'interchangeable' or 'interchangeability', in reference to a biological product

that is shown to meet the standards described in subsection (k)(4), means that the biological product may be substituted for the reference product without the intervention of the health care provider who prescribed the reference product.

''(4) The term 'reference product' means the single biological product licensed under subsection (a) against which a biological product is evaluated in an application submitted under subsection (k).''.

(c) CONFORMING AMENDMENTS RELATING TO PATENTS.—

(1) PATENTS.—Section 271(e) of title 35, United States Code, is amended—

(A) in paragraph (2)—

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

(ii) in subparagraph (B), by adding ''or'' at the end; and

(iii) by inserting after subparagraph (B) the following:

''(C)(i) with respect to a patent that is identified in the list of patents described in section 351(l)(3) of the Public Health Service Act (including as provided under section 351(l)(7) of such Act), an

application seeking approval of a biological product, or

''(ii) if the applicant for the application fails to provide the application and information required under section 351(l)(2)(A) of such Act, an application seeking approval of a biological product for a patent that could be identified pursuant to section 351(l)(3)(A)(i) of such Act,''; and

(iv) in the matter following subparagraph (C) (as added by clause (iii)), by striking ''or veterinary biological product'' and inserting '', veterinary biological product, or biological product'';

(B) in paragraph (4)—

(i) in subparagraph (B), by—

(I) striking ''or veterinary biological product'' and inserting '', veterinary biological product, or biological product''; and

(II) striking ''and'' at the end;

(ii) in subparagraph (C), by—

(I) striking ''or veterinary biological product'' and inserting '', veterinary biological product, or biological product''; and

(II) striking the period and inserting ", and";

(iii) by inserting after subparagraph (C) the following:

"(D) the court shall order a permanent injunction prohibiting any infringement of the patent by the biological product involved in the infringement until a date which is not earlier than the date of the expiration of the patent that has been infringed under paragraph (2)(C), provided the patent is the subject of a final court decision, as defined in section 351(k)(6) of the Public Health Service Act, in an action for infringement of the patent under section 351(l)(6) of such Act, and the biological product has not yet been approved because of section 351(k)(7) of such Act."; and

(iv) in the matter following subparagraph (D) (as added by clause (iii)), by striking "and (C)" and inserting "(C), and (D)"; and

(C) by adding at the end the following:

"(6)(A) Subparagraph (B) applies, in lieu of paragraph (4), in the case of a patent—

"(i) that is identified, as applicable, in the list of patents described in section 351(l)(4) of the Pub-

lic Health Service Act or the lists of patents described in section 351(l)(5)(B) of such Act with respect to a biological product; and

''(ii) for which an action for infringement of the patent with respect to the biological product—

''(I) was brought after the expiration of the 30-day period described in subparagraph (A) or (B), as applicable, of section 351(l)(6) of such Act; or

''(II) was brought before the expiration of the 30-day period described in subclause (I), but which was dismissed without prejudice or was not prosecuted to judgment in good faith.

''(B) In an action for infringement of a patent described in subparagraph (A), the sole and exclusive remedy that may be granted by a court, upon a finding that the making, using, offering to sell, selling, or importation into the United States of the biological product that is the subject of the action infringed the patent, shall be a reasonable royalty.

''(C) The owner of a patent that should have been included in the list described in section 351(l)(3)(A) of the Public Health Service Act, including as provided under section 351(l)(7) of such Act for a biological product, but was not timely included in such list, may not bring an

action under this section for infringement of the patent with respect to the biological product.''.

(2) CONFORMING AMENDMENT UNDER TITLE 28.—Section 2201(b) of title 28, United States Code, is amended by inserting before the period the following: '', or section 351 of the Public Health Service Act''.

(d) CONFORMING AMENDMENTS UNDER THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.—

(1) CONTENT AND REVIEW OF APPLICATIONS.—Section 505(b)(5)(B) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355(b)(5)(B)) is amended by inserting before the period at the end of the first sentence the following: ''or, with respect to an applicant for approval of a biological product under section 351(k) of the Public Health Service Act, any necessary clinical study or studies''.

(2) NEW ACTIVE INGREDIENT.—Section 505B of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355c) is amended by adding at the end the following:

''(n) NEW ACTIVE INGREDIENT.—

''(1) NON-INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT.—A biological product that is biosimilar to a reference product under section 351

of the Public Health Service Act, and that the Secretary has not determined to meet the standards described in subsection (k)(4) of such section for interchangeability with the reference product, shall be considered to have a new active ingredient under this section.

''(2) INTERCHANGEABLE BIOSIMILAR BIOLOGICAL PRODUCT.—A biological product that is interchangeable with a reference product under section 351 of the Public Health Service Act shall not be considered to have a new active ingredient under this section.''.

(e) PRODUCTS PREVIOUSLY APPROVED UNDER SECTION 505.—

(1) REQUIREMENT TO FOLLOW SECTION 351.—Except as provided in paragraph (2), an application for a biological product shall be submitted under section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act).

(2) EXCEPTION.—An application for a biological product may be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) if—

(A) such biological product is in a product class for which a biological product in such

product class is the subject of an application approved under such section 505 not later than the date of enactment of this Act; and

(B) such application—

(i) has been submitted to the Secretary of Health and Human Services (referred to in this Act as the ''Secretary'') before the date of enactment of this Act; or

(ii) is submitted to the Secretary not later than the date that is 10 years after the date of enactment of this Act.

(3) LIMITATION.—Notwithstanding paragraph (2), an application for a biological product may not be submitted under section 505 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) if there is another biological product approved under subsection (a) of section 351 of the Public Health Service Act that could be a reference product with respect to such application (within the meaning of such section 351) if such application were submitted under subsection (k) of such section 351.

(4) DEEMED APPROVED UNDER SECTION 351.—An approved application for a biological product under section 505 of the Federal Food, Drug,

and Cosmetic Act (21 U.S.C. 355) shall be deemed to be a license for the biological product under such section 351 on the date that is 10 years after the date of enactment of this Act.

(5) DEFINITIONS.—For purposes of this subsection, the term ''biological product'' has the meaning given such term under section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act).

(f) FOLLOW-ON BIOLOGICS USER FEES.—

(1) DEVELOPMENT OF USER FEES FOR BIOSIMILAR BIOLOGICAL PRODUCTS.—

(A) IN GENERAL.—Beginning not later than October 1, 2010, the Secretary shall develop recommendations to present to Congress with respect to the goals, and plans for meeting the goals, for the process for the review of biosimilar biological product applications submitted under section 351(k) of the Public Health Service Act (as added by this Act) for the first 5 fiscal years after fiscal year 2012. In developing such recommendations, the Secretary shall consult with—

(i) the Committee on Health, Education, Labor, and Pensions of the Senate;

(ii) the Committee on Energy and Commerce of the House of Representatives;

(iii) scientific and academic experts;

(iv) health care professionals;

(v) representatives of patient and consumer advocacy groups; and

(vi) the regulated industry.

(B) PUBLIC REVIEW OF RECOMMENDATIONS.—After negotiations with the regulated industry, the Secretary shall—

(i) present the recommendations developed under subparagraph (A) to the Congressional committees specified in such subparagraph;

(ii) publish such recommendations in the Federal Register;

(iii) provide for a period of 30 days for the public to provide written comments on such recommendations;

(iv) hold a meeting at which the public may present its views on such recommendations; and

(v) after consideration of such public views and comments, revise such recommendations as necessary.

(C) TRANSMITTAL OF RECOMMENDATIONS.—Not later than January 15, 2012, the Secretary shall transmit to Congress the revised recommendations under subparagraph (B), a summary of the views and comments received under such subparagraph, and any changes made to the recommendations in response to such views and comments.

(2) ESTABLISHMENT OF USER FEE PROGRAM.—It is the sense of the Senate that, based on the recommendations transmitted to Congress by the Secretary pursuant to paragraph (1)(C), Congress should authorize a program, effective on October 1, 2012, for the collection of user fees relating to the submission of biosimilar biological product applications under section 351(k) of the Public Health Service Act (as added by this Act).

(3) TRANSITIONAL PROVISIONS FOR USER FEES FOR BIOSIMILAR BIOLOGICAL PRODUCTS.—

(A) APPLICATION OF THE PRESCRIPTION DRUG USER FEE PROVISIONS.—Section 735(1)(B) of the Federal Food, Drug, and Cos-

metic Act (21 U.S.C. 379g(1)(B)) is amended by striking ''section 351'' and inserting ''subsection (a) or (k) of section 351''.

(B) EVALUATION OF COSTS OF REVIEWING BIOSIMILAR BIOLOGICAL PRODUCT APPLICATIONS.—During the period beginning on the date of enactment of this Act and ending on October 1, 2010, the Secretary shall collect and evaluate data regarding the costs of reviewing applications for biological products submitted under section 351(k) of the Public Health Service Act (as added by this Act) during such period.

(C) AUDIT.—

(i) IN GENERAL.—On the date that is 2 years after first receiving a user fee applicable to an application for a biological product under section 351(k) of the Public Health Service Act (as added by this Act), and on a biennial basis thereafter until October 1, 2013, the Secretary shall perform an audit of the costs of reviewing such applications under such section 351(k). Such an audit shall compare—

(I) the costs of reviewing such applications under such section 351(k) to the amount of the user fee applicable to such applications; and

(II)(aa) such ratio determined under subclause (I); to

(bb) the ratio of the costs of reviewing applications for biological products under section 351(a) of such Act (as amended by this Act) to the amount of the user fee applicable to such applications under such section 351(a).

(ii) ALTERATION OF USER FEE.—If the audit performed under clause (i) indicates that the ratios compared under subclause (II) of such clause differ by more than 5 percent, then the Secretary shall alter the user fee applicable to applications submitted under such section 351(k) to more appropriately account for the costs of reviewing such applications.

(iii) ACCOUNTING STANDARDS.—The Secretary shall perform an audit under clause (i) in conformance with the account-

ing principles, standards, and requirements prescribed by the Comptroller General of the United States under section 3511 of title 31, United State Code, to ensure the validity of any potential variability.

(4) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this subsection such sums as may be necessary for each of fiscal years 2010 through 2012.

(g) ALLOCATION OF SAVINGS; SPECIAL RESERVE FUND.—

(1) DETERMINATION OF SAVINGS.—The Secretary of the Treasury, in consultation with the Secretary, shall for each fiscal year determine the amount of the savings to the Federal Government as a result of the enactment of this Act and shall transfer such amount to the Fund established under paragraph (2) pursuant to a relevant appropriations Act.

(2) SPECIAL RESERVE FUND.—

(A) IN GENERAL.—There is established in the Treasury of the United States a fund to be designated as the ''Biological Product Savings Fund'' to be made available to the Secretary without fiscal year limitation.

(B) USE OF FUND.—The amounts made available to the Secretary through the Fund under subparagraph (A) shall be expended on activities authorized under the Public Health Service Act.

(3) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated for each fiscal year to the Fund established under paragraph (2), the amount of the savings determined for such fiscal year under paragraph (1).

(h) GOVERNMENT ACCOUNTABILITY OFFICE STUDY.—

(1) IN GENERAL.—Not later than 3 years after the date of enactment of this Act, the Comptroller General of the United States shall study and report to Congress regarding—

(A) the extent to which pediatric studies of biological products are being required under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.); and

(B) any pediatric needs not being met under existing authority.

(2) CONTENT OF STUDY.—The study under paragraph (1) shall review and assess—

(A) the extent to which pediatric studies of biological products are required under subsections (a) and (b) of section 505B of the Federal Food, Drug and Cosmetic Act (21 U.S.C. 355c);

(B) the extent to which pediatric studies of biological products are required as part of risk evaluation and mitigation strategies under such Act;

(C) the number, importance, and prioritization of any biological products that are not being tested for pediatric use; and

(D) recommendations for ensuring pediatric testing of products identified in subparagraph (C), including the consideration of any incentives, such as those provided under the Best Pharmaceuticals for Children Act.

(i) ORPHAN PRODUCTS.—If a reference product, as defined in section 351 of the Public Health Service Act (42 U.S.C. 262) (as amended by this Act) has been designated under section 526 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360bb) for a rare disease or condition, a biological product seeking approval for such disease or condition under subsection (k) of such section 351 as biosimilar to, or interchangeable with, such reference

product may be licensed by the Secretary only after the expiration for such reference product of the later of—

(1) the 7-year period described in section 527(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360cc(a)); and

(2) the 12-year period described in subsection (k)(7) of such section 351.

SEC. 702. AMENDMENTS TO CERTAIN PATENT PROVISIONS.

Section 271(e)(2) of title 35, United States Code is amended—

(1) in subparagraph (A), by striking ''or'' after ''patent'';

(2) in subparagraph (B), by adding ''or'' after the comma at the end; and

(3) by inserting the following after subparagraph (B):

''(C) a statement under section 351(l)(4)(D)(ii) of the Public Health Service Act,''.

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